USER:	**GRAY, ILKA K (ixg)**
FOLDER:	**K063530 - 251 pages (FOI:08007474)**
COMPANY:	**I-FLOW CORP. (IFLOW)**
PRODUCT:	**PUMP, INFUSION, ELASTOMERIC (MEB)**
SUMMARY:	**Product: ON-Q, PAINBUSTER, C-BLOC, SELECT-A-FLOW, ONDEMAND, HOMEPUMP, ECLIPSE,**

DATE REQUESTED:	**Fri Nov 05 24:00:00 2010**
DATE PRINTED:	**Thu Feb 03 09:34:07 2011**
Note:	**Releasable Version**

Table of Contents

510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	I-Flow Corporation 20202 Windrow Drive Lake Forest, CA. 962630
Contact:	Shane Noehre Director, Regulatory Affairs I-Flow Corporation
Trade Names:	ON-Q Pump, ON-Q Pump with Select-A-Flow, ON-Q Pump with OnDemand
Common Name:	Elastomeric Infusion Pump
Existing Device:	I-Flow Elastomeric Pump (K052117)
Design Change:	This Special 510(k) submission proposes an increase in the maximum fill volume from 500 to 770 ml.
Device Description:	The *ON-Q Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 770 ml. Flow rates range from 0.5 to 250 ml/hr. The administration line typically consists of fixed flow rate control tubing or orifice but may contain any of the following optional features: • Select-A-Flow component that provides a range of flow rates that may be dialed depending on the needs of the healthcare professional. • Bolus component (e.g. OnDemand) that provides basal and/or bolus delivery. • Y-adapter component that may split the administration line into two or more delivery sites. The Y-adapter component may also be used to provide a combination of options (such as both the Select-A-Flow and OnDemand components) for one delivery site. • Air and particulate eliminating filter. The pump may be sold as a kit with additional medical devices or accessories such as the following: • Catheter, introducer needle, Tunneler, syringe, dressing, filling extension set, carry case, E-clip, nerve block accessories, etc.
Indications for Use	1. The *ON-Q Pump* is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. 2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.
Technology Comparison:	There is no change in fundamental scientific technology. The design remains the same as previously cleared devices.
Conclusion:	The *ON-Q Pump* with fill volumes up to 770 ml are substantially equivalent to the existing I-Flow elastomeric pumps currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2007

Mr. Shane Noehre
Director of Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K063530
Trade/Device Name: ON-Q-Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: I-Flow Corporation

510(k) Number (if known): K063530

Device Name: *ON-Q Pump*

Indications For Use:

1. The *ON-Q Pump* is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.
2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]
Anesthesiology, General Hospital,
Infection Control, Dental Devices

K063530

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2007

Mr. Shane Noehre
Director of Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K063530
Trade/Device Name: ON-Q-Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: I-Flow Corporation

510(k) Number (if known): K063530

Device Name: *ON-Q Pump*

Indications For Use:

1. The *ON-Q Pump* is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.
2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]
...Anesthesiology, General Hospital,
...Control, Dental Devices

K063530

8

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 28, 2006

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: JAMES J. DAL PORTO

510(k) Number: K063530
Product: ON-Q,
PAINBUSTER,
C-BLOC,
SELECT-A-FLOW,

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 30, 2006

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: JAMES J. DAL PORTO

510(k) Number: K063530
Received: 29-NOV-2006
Product: ON-Q, PAINBUSTER, C-BLOC, SELECT-A-FLOW, ONDEMAND, HOMEPUMP,

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA

resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 24, 2006

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: JAMES J. DAL PORTO

510(k) Number: K063530
Received: 22-NOV-2006
Product: ON-Q, PAINBUSTER, SELECT-A-FLOW, HOMEPUMP,
User Fee ID Number: 6028640

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K063530

FDA ORIGINAL

Table of Contents

TAB 1

Section 1 – Medical Device User Fee Cover Sheet

<go to next page>

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

I FLOW CORP
20202 WINDROW DRIVE
LAKE FOREST CA 92630
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Shane Noehre

2.1 E-MAIL ADDRESS
(b)(4)

2.2 TELEPHONE NUMBER (include Area code)
(b)(4)

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
(b)(4)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)
17-Nov-2006

Form FDA 3601 (08/2003)

"Close Window" Print Cover sheet (b)(6) (b)(6) 11/17/2006

TAB 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
November 21, 2006	(b)(3) (b)(3)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ **Original Submission:**	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ **Special**	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ **Yes** ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
I-Flow Corporation	(b)(4) (b)(4)		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	((b)(4) (b)(4)		
Street Address	**FAX Number** *(including area code)*		
20202 Windrow Drive	((b)(4) (b)(4)		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Lake Forest	CA	92630	USA
Contact Name			
(b)(4) (b)(4) (b)(6) (b)(6)			
Contact Title	**Contact E-mail Address**		
(b)(4) (b)(4)	(b)(4) (b)(4)		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
I-Flow Corporation			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	((b)(4) (b)(4)		
Street Address	**FAX Number** *(including area code)*		
20202 Windrow Drive	((b)(4) (b)(4)		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Lake Forest	CA	92630	USA
Contact Name			
Shane Noehre			
Contact Title	**Contact E-mail Address**		
Director of Regulatory Affairs	(b)(4) (b)(4)		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ **Other Reason *(specify)*:**

Minor design change to increase the maximum fill volume from 550 ml to 770 ml.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MEB	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ **510 (k) summary attached**
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K052117	1	I-Flow Elastomeric Pump	1	I-Flow
2		2		2	
3		4		4	
4		5		5	
5					
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Elastomeric Infusion Pump

	Trade or Proprietary or Model Name for This Device		Model Number
1	ON-Q, PainBuster, C-bloc, Select-A-Flow, OnDemand, Homepump, Eclipse, C-Series, One-Step KVO, Easypump	1	various
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MEB	880.5725	☐ Class I ☒ **Class II** ☐ Class III ☐ Unclassified

Classification Panel

General Hospital

Indications *(from labeling)*

See ***section 4*** of this 510(k).

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ **Original** ☐ Add ☐ Delete

FDA Establishment Registration Number: (b)(4)

☒ **Manufacturer** ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name: I-Flow Corporation

Establishment Registration Number: (b)(4)

Division Name *(if applicable)*

Phone Number *(including area code)*: ((b)(4)

Street Address: 20202 Windrow Drive

FAX Number *(including area code)*: ((b)(4)

City: Lake Forest | State / Province: CA | ZIP/Postal Code: 92630 | Country: USA

Contact Name: Shane Noehre | Contact Title: Director of Regulatory Affairs | Contact E-mail Address: (b)(4)

☒ **Original** ☐ Add ☐ Delete

FDA Establishment Registration Number: (b)(4)

☒ **Manufacturer** ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name: Block Medical de Mexico

Establishment Registration Number: (b)(4)

Division Name *(if applicable)*

Phone Number *(including area code)*: ((b)(4)

Street Address: Ave. Noruega Edificio D-1B, Fracc. Rubio, La Mesa

FAX Number *(including area code)*: ((b)(4)

City: Tijuana | State / Province: B.C. | ZIP/Postal Code: 22650 | Country: Mexico

Contact Name: Shane Noehre | Contact Title: Director of Regulatory Affairs | Contact E-mail Address: (b)(4)

☒ **Original** ☐ Add ☐ Delete

FDA Establishment Registration Number: (b)(4)

☐ Manufacturer ☐ Contract Manufacturer ☒ **Contract Sterilizer** ☐ Repackager / Relabeler

Company / Institution Name: (b)(4)

Establishment Registration Number: (b)(4)

Division Name *(if applicable)*

Phone Number *(including area code)*: ((b)(4)

Street Address: (b)(4)

FAX Number *(including area code)*: ((b)(4)

City: (b)(4) | State / Province: (b)(4) | ZIP/Postal Code: (b)(4) | Country: (b)(4)

Contact Name: (b)(4) | Contact Title: Customer Service | Contact E-mail Address: (b)(4)

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

☒ **Original** ☐ Add ☐ Delete	FDA Establishment Registration Number (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ **Contract Sterilizer** ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)	
Division Name *(if applicable)*		Phone Number *(including area code)* ((b)(4)	
Street Address (b)(4)		FAX Number *(including area code)* ((b)(4)	
City (b)(4)	State / Province (b)(4)	ZIP/Postal Code (b)(4)	Country (b)(4)
Contact Name (b)(4)	Contact Title Customer Service	Contact E-mail Address (b)(4)	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 594-1	ISO	Conical Fittings with 6% (Luer) Taper – Part 1: General Requirements	1986	1986
2	ISO 594-2	ISO	Conical Fittings with 6% (Luer) Taper – Part 2: Lock Fitting	1998	1998
3	ISO 10993-1	ISO	Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing	2003	2003
4	ISO 10993-3	ISO	Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	2003	2003
5	ISO 10993-4	ISO	Part 4: Selection of tests for Interactions with Blood	2002	2002
6	ISO 10993-5	ISO	Part 5: Tests for *in vitro* Cytotoxicity	1999	1999
7	ISO 10993-7	ISO	Part 7: Ethylene Oxide Sterilization Residuals	1996	1996
8	ISO 10993-10	ISO	Part 10: Tests for Irritation / Delayed Hypersensitivity	2002	2002
9	ISO 10993-11	ISO	Part 11: Tests for Systemic Toxicity	1993	1993
10	ISO 11135	ISO	Validation and Routine Control of EO Sterilization	1994	1994
11	ISO 11137	ISO	Validation and Routine Control of Radiation Sterilization	1995	1995
12	ISO 11607	ISO	Packaging for Terminally Sterilized Medical Devices	2003	2003
13	ISO 14971	ISO	Application of Risk Management to Medical Devices	2000	2000

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

TAB 3

510(k) Notification – Type: Special

November 21, 2006

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *I-Flow Elastomeric Pumps* prior to introduction into interstate commerce for commercial distribution. The enclosed documents are submitted to support this notification.

I-Flow currently markets *I-Flow* (b)(4) (b)(4) This Special 510(k) proposes a new model with a (b)(4) nominal fill volume and a maximum fill volume of (b)(4) The 600 ml model has the exact same design as the (b)(4) model as described in (b)(4) and its preceding 510(k) clearances.

All other aspects of the pump will remain the same including its performance and intended use.

All questions and/or comments concerning this document should be made to:

Shane Noehre
Director, Regulatory Affairs

Sincerely,

(b)(6)

Shane Noehre, R.A.C.
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel:
Fax:
Email: (b)(4)

NO Class II

Tabular Information

Administrative Information	
Type of 510(k)	Special
Device Type	Elastomeric Infusion Pump
510(k) Submitter	I-Flow Corporation
Contact Person	Shane Noehre, R.A.C. Director, Regulatory Affairs I-Flow Corporation 20202 Windrow Drive Lake Forest, CA. 92630 Tel: (b)(4) Fax: (b)(4) E-mail
Preference for Continued Confidentiality	Pursuant of 21 CFR 807.95(c)(3), I-Flow considers our intent to market the device to be confidential information and request that FDA not disclose the content of this 510(k) notification until the device is cleared to market and I-Flow's intent to market has been disclosed to the public.
Classification Regulation	880.5725
Class	Class II
Panel	General Hospital
Product code	MEB
FDA Document Numbers	no prior correspondence

Basis for the Submission: Design Change

Design and Use of Device		
Question	**Yes**	**No**
1. Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
2. Is the device intended for over-the-counter use (21 CFR 207 Subpart C)?		√
3. Does the device contain components derived from tissue / biologic source?		√
4. Is the device provided sterile?	√	
5. Is the device intended for single use?	√	
6. Is the device a reprocessed single use device?		√
a. If yes, does this device type require reprocessed validation data?		
7. Does the device contain a drug?		√
8. Does the device contain a biologic?		√
9. Does the device use software?		√
10. Does the submission include clinical information?		√
11. Is the device implanted?		√

TAB 4

Applicant: I-Flow Corporation

510(k) Number (if known): _____

Device Name: *I-Flow Elastomeric Pumps*

Indications For Use:

1. The *I-Flow Elastomeric Pump* is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The *I-Flow Elastomeric Pump* is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.
3. The *I-Flow Elastomeric Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

TAB 5

510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	I-Flow Corporation 20202 Windrow Drive Lake Forest, CA. 962630
Contact:	Shane Noehre Director, Regulatory Affairs I-Flow Corporation
Trade Names:	ON-Q, Painbuster, C-Bloc, Select-A-Flow, OnDemand, Easypump, Homepump, Eclipse, C-Series, One•Step KVO
Common Name:	Elastomeric Infusion Pump
Existing Device:	I-Flow Elastomeric Pump (K052117)
Design Change:	This Special 510(k) submission proposes an increase in the maximum fill volume from 550 to 770 ml.
Device Description:	The *I-Flow Elastomeric Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 770 ml. Flow rates range from 0.5 to 250 ml/hr. The administration line typically consists of fixed flow rate control tubing or orifice but may contain any of the following optional features: • Select-A-Flow component that provides a range of flow rates that may be dialed depending on the needs of the healthcare professional. • Bolus component (e.g. OnDemand) that provides basal and/or bolus delivery. • Y-adapter component that may split the administration line into two or more delivery sites. The Y-adapter component may also be used to provide a combination of options (such as both the Select-A-Flow and OnDemand components) for one delivery site. • Y-site component to allow piggyback infusions. • Air and particulate eliminating filter. • Pressure regulator, check valve, or flow view indicator. The pump may be sold as a kit with additional medical devices or accessories such as the following: • Catheter, introducer needle, Tunneler, syringe, dressing, filling extension set, carry case, E-clip, nerve block accessories, etc.
Technology Comparison:	There is no change in fundamental scientific technology. The design remains the same as previously cleared devices.
Conclusion:	The *I-Flow Elastomeric Pump* with fill volumes up to 770 ml are substantially equivalent to the existing I-Flow pumps currently marketed.

TAB 6

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Executive Vice President and C.O.O. of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the *I-Flow Elastomeric Pumps* are truthful and accurate and that no material fact has been omitted.

(b)(6)

(b)(6)

(b)(4) (b)(4)

Name

Executive Vice President and C.O.O.

Title

I-Flow Corporation

Company

11/21/06

Date

Premarket Notification (510(k) Number)

TAB 7

Section 7 - Class III Summary and Certification

This 510(k) submission is for a Class II device therefore this section does not apply.

<Go to next section>

TAB 8

Section 8 - Disclosure Statement

This 510(k) submission does not utilize clinical studies for establishing substantial equivalence therefore this section does not apply.

<Go to next section>

TAB 9

DECLARATION OF CONFORMITY

As required by the risk analysis, all verification and validation activities will be performed by designated individuals and the results shall demonstrate that the predetermined acceptance criteria are met prior to introduction into interstate commerce for commercial distribution for the *I-Flow Elastomeric Pump.*

The I-Flow Corporation manufacturing facilities are in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

(b)(6) (b)(6)

(b)(6) (b)(6)

(b)(4) (b)(4)

I-Flow Corporation I-Flow Corporation

Verification and Validation activity will ensure that the proposed design change will not change the device performance specifications or acceptance criteria identified below per the risk assessment. See **section 18** for a detailed design control summary.

1. Flow Rate Accuracy:
   - Fixed Flow Rate Component: (b)(4) (b)(4)
   - Select-A-Flow (variable flow rate) Component: (b)(4) (b)(4)
   - OnDemand (bolus) Component:
     - (b)(4) (b)(4)
     -
     -
2. Residual Volume: from (b)(4) (b)(4) (depending on fill volume).
3. Leak Testing: no leaks or bladder rupture wher (b)(4) (b)(4)
4. Filling Pressure: (b)(4) (b)(4)
5. Shelf Life: performance specification met throughout labeled shelf life.
6. Overfill Flow Rate: Directions for Use shall include delivery times for labeled fill volumes.

Reference Documents:

Risk Assessment for the I-Flow Elastomeric Pump (DCD1129K). See ***Appendix A.***

TAB 10

Section 10 - Executive Summary

Background

10.1 I-Flow currently markets *I-Flow Elastomeric Pumps* with a nominal fill volume of 400 ml and a maximum fill volume of 550 ml. This Special 510(k) proposes a new model with a 600 ml nominal fill volume and a maximum fill volume of 770 ml.

10.2 This new model will be identical in design as the currently marketed 400 ml pump. The only change will be in the pump pressure. The 600 ml pump will have a slightly lower pump pressure therefore the flow control components will be characterized to meet specification at the lower pump pressure. The new model does not raise any new issues of safety or effectiveness.

10.3 No changes will be made to the indications for use, packaging, sterilization methods, fundamental technology or labeling (except for clarification of safer and more effective use).

Device Description

10.4 The *I-Flow Elastomeric Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 550 ml with a proposed increase to maximum 770 ml. Flow rates can range from 0.5 to 250 ml/hr. The administration line may typically incorporates fixed diameter flow control tubing or glass orifice to control the flow rate; however, the administration line may contain any of the of following optional components (variable flow rate control, bolus capability, Y-adapter, Y-site, filter, regulator, flow view indicator or check valve). See ***section 11*** for a more detailed description.

10.5 Indications for Use

Note: There is no change to the indications for use.

10.5.1 The *I-Flow Elastomeric Pump* is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.

10.5.2 The *I-Flow Elastomeric Pump* is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

10.5.3 The *I-Flow Elastomeric Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

10.6 Technology

10.6.1 There is no change in the design or technology of the pump. Minor dimensional changes will be made to the flow control components to match the lower pump pressure of a 600 ml fill volume in order to achieve the same performance specifications.

10.7 Device Comparison Table

10.7.1 See ***section 12*** of this 510(k) for a comparison table of the subject device vs. the predicate devices.

10.8 Summary of Performance Testing

10.8.1 The *I-Flow Elastomeric Pumps* shall be tested per the risk assessment to demonstrate that the performance remains within the device design specification.

10.8.2 See ***section 18*** of this 510(k) for detailed information on the design control activities performed based upon the results of the risk assessment.

TAB 11

Section 11 - Device Description

11.1 Existing (Unmodified) Device

11.1.1 The *I-Flow Elastomeric Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 550 ml. Flow rates can range from 0.5 to 250 ml/hr.

11.1.2 The elastomeric membranes function as the fluid reservoir and the pressure source. The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled.

11.1.3 The incorporation of a fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate. The administration line may incorporate any of the following optional components as described in preceding 510(k) clearances noted in ***section 12.2***:

11.1.3.1 Variable flow rate control (Selec-A-Flow), bolus capability (OnDemand), Y-adapter, Y-site, filter, regulator, flow view indicator or check valve.

11.1.4 The *I-Flow Elastomeric Pump* is suitable for use as an ambulatory device and is intended for use in hospitals, home environments or alternate care sites.

11.1.5 **Flow Control**: The flow restricting mechanism consists of fixed diameter flow control tubing or glass orifice. This is cut to a specific length. When the pump is filled and pressurized, the flow rates are approximated by Poiseulle's equation:

(b)(4)
(b)(4)

Where the (b)(4) (b)(4) across the orifice, (b)(4) (b)(4) (b)(4) (b)(4) orifice, (b)(4) (b)(4) of the fluid and (b)(4) (b)(4) of the orifice. The equation provides an approximation of the actual delivery time.

11.1.6 **Power Requirements**: The *I-Flow Elastomeric Pump* is a mechanical device that utilizes the strain energy of the elastomeric membranes which are forced to expand when the pump is filled. No additional external power source is required to operate.

11.1.7 **Safety/ Alarm Functions**: The *I-Flow Elastomeric Pump* provides fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps. Administration sets contain a pinch clamp to stop the infusion if necessary. This device contains no alarms or indicators for flow other than visual. The device contains no alarms or indicators to detect air in line; however, each set may include an integrated air and particulate eliminating filter.

11.2 Proposed Design Change

11.2.1 This Special 510(k) submission proposes a new model with a 600 ml nominal fill volume and a maximum fill volume of 770 ml.

11.2.2 This new model will be identical in design as the 400 ml pump. The only change will be in the pump pressure. The 600 ml pump will have a lower pump pressure therefore the flow control components will be characterized to meet specification at the lower pump pressure. The new model does not raise any new issues of safety or effectiveness.

11.2.3 No changes will be made to the indications for use, packaging, sterilization methods, fundamental technology or labeling (except for clarification of safer and more effective use).

11.3 Models

Table 11.3.1 below shows the parameters available for *I-Flow Elastomeric Pumps*. The only change to the existing parameters will be the availability of the higher fill volume (600 to 770 ml).

Table 11.3.1

	(b)(4)
Fill Volume	
Flow Control Component	
Flow Rate	
Bolus Volume	
Bolus Refill Time	
Delivery Sites	

Tables 11.3.2 and 11.3.3 below show the basic types of models currently sold.

Table 11.3.2

Model	**Type 1**	**Type 2**	**Type 3**	**Type 4**
Trade Name	Homepump Eclipse, C-Series, Easypump	Homepump CP-Series, Easypump PCA LT	One-Step KVO	Bolus Accessory Set
Fill Volume	50 to 550 ml	100 to 125 ml	60 to 125 ml	n/a
Routes of Administration	intravenous, epidural, intramuscular, intra-arterial, subcutaneous	intravenous, epidural, intramuscular, intra-arterial, subcutaneous	intravenous	intravenous, intra-arterial, intramuscular, epidural, subcutaneous
Flow Control Component	(b)(4)			
Basal Flow Rate	0.5 to 250 ml/hr	0.5 to 2 ml/hr	0.5 ml/hr	n/a
Bolus Delivery	n/a	0.5 ml / 6 to 15 min.	n/a	0.5 ml / 3.6 to 70 min.
Filter	yes	yes	yes	n/a
Y-site	no	no	yes	no
Check Valve	no	no	yes	no
Delivery Sites	1	1	1	1

Table 11.3.3

Model	**Type 5**	**Type 6**	**Type 7**	**Type 8**
Trade Name	ON-Q PainBuster, ON-Q C-bloc	Select-A-Flow	OnDemand	ON-Q Rawal Bolus
Fill Volume	65 to 550 ml	270 to 550 ml	270 to 550 ml	100 ml
Routes of Administration	to or around surgical sites or near nerves, epidural	to or around surgical sites or near nerves, epidural	to or around surgical sites or near nerves, epidural	to or around surgical sites or near nerves
Flow Control Component	(b)(4)			
Basal Flow Rate	0.5 to 10 ml/hr	1 to 7 ml/hr, 2 – 14 ml/hr	2 to 5 ml/hr	n/a
Bolus Delivery	n/a	optional	5 ml / 30 to 60 min.	10 ml / 45 sec.
Filter	yes	yes	yes	yes
Y-adapter [1]	optional	optional	optional	n/a

[1] The optional Y-adapter can split the administration line for multi-site delivery and/or to provide a combination of administration set options such as the Select-A-Flow component for basal flow rate delivery and the OnDemand component for bolus delivery.

11.4 Drawings

11.4.1 Example drawings for each model type currently sold can be found in ***Appendix B***. These models could be available as 600 ml models with maximum fill volume of 770 ml upon clearance of this 510(k).

11.5 Accessories

11.5.1 The *I-Flow Elastomeric Pump* may be sold individually or as part of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market by FDA or class I exempt devices).

Examples of kit components include catheters, syringes, dressings, introducer needles, Tunnelers and nerve block accessories. The accessories may be purchased from suppliers either bulk non-sterile or packaged sterile.

11.5.2 The following carry aids and filling aids are available as currently available accessories for *I-Flow Elastomeric Pumps*. See ***Appendix B*** for drawings.

- Filling Extension set: used to help fill 400 ml or greater volume pumps.
- E-Clip: used to secure the elastomeric pump to an arm sling or clothing, etc.
- Carry Case: used to hold the elastomeric pump while delivering medication.
- PowerFiller: fits over a syringe to ease filling.
- HandiFiller and EasyFiller: accessories that facilitate filling multiple pumps.
- Cable Tie: used to secure Select-A-Flow device for tamper evidence.

11.6 Materials

There are no changes in the materials currently used.

TAB 12

Section 12 - Substantial Equivalence Description

12.1 The proposed design change is very minor. The pump design is identical to currently marketed 400 ml I-Flow Elastomeric pumps with a maximum volume of 550 ml. This 510(k) submission simply proposes a new model with a 600 ml nominal fill volume and maximum fill volume of 770 ml. The pump remains substantially equivalent to the existing *I-Flow Elastomeric Pump*.

12.2 The existing (unmodified) *I-Flow Elastomeric Pump* has been cleared under the following 510(k)s:

12.2.1 K932740: the initial *I-Flow Elastomeric Pump* premarket notification.

12.2.2 K944692: added low flow rates for chemotherapy and pain management.

12.2.3 K984502: added intraoperative and nerve block (perineural) routes of administration including Y-adapter for dual site delivery.

12.2.4 K991513: added KVO indications and the optional regulator, flow view and Y-site components.

12.2.5 K992072: added bolus accessory set.

Letter to File (February 5, 2001): added new model with a different design. Bolus component consists of an in-line operator activating push valve. Pushing the valve button allows fluid to pass through the valve. Letting go of the button instantly restores the button to its original position and shuts off fluid flow. The catheter supplied with the pump acts as the flow restrictor. Device labeled for 10 ml delivery in 45 seconds. (b)(4) (b)(4)

Letter to File: added new model with bolus component integrated with administration line. Same design but with a basal flow rate in addition to the bolus. Basal flow rate (b)(4) (b)(4) (b)(4)

12.2.6 K020862: added optional polyisoprene bladder instead of latex.

12.2.7 K023318: added optional bolus capability (i.e. OnDemand).

Letter to File (June 22, 2004): established the bolus volume (b)(4) (b)(4) (b)(4) (b)(4) The is the same range increment but (b)(4) (b)(4) Added additional models to include 0.5 ml/hr basal rate with 60 minute refill rate and 2 ml/hr basal rate with 60 minute refill. Both models are within the 510(k) parameters.

12.2.8 K023883: added optional variable flow rate mechanism (i.e. Select-A-Flow).

12.2.9 K040337: added the potential benefits of using the *I-Flow Elastomeric Pump*.

Letter to File (June 23, 2004): minor design change moved the internal check valve to the center of the mandrel to ease filling.

Letter to File (August 11, 2004): introduced the bolus + variable flow rate model. The Y-adapter splits the administration line to allow the bolus component and variable flow rate component to be in parallel with each other. An additional Y-adapter reestablishes a single administration line. The variable flow rate component serves as a continuous basal flow rate (chosen by the healthcare provider) while the bolus component provides bolus capability for the patient. The

flow rate and bolus parameters conform with the parameters established for their respective 510(k)s cited above.

12.2.10 K052117: added multiple Y-adapters to provide 3 or more integrated administration lines for multi-site delivery.

12.3 Device Comparison Table

#	Information	Existing I-Flow Elastomeric Pumps (predicate device: K052117)	New (modified) I-Flow Elastomeric Pumps (subject device)
A.	**Device Description**		
		1. The I-Flow Elastomeric Pump consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 550 ml. Flow rates range from 0.5 to 250 ml/hr. 2. The elastomeric membranes function as the fluid reservoir and the pressure source. 3. The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled. 4. The incorporation of a fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate. 5. Optional administration line components include the following: ▪ Select-A-Flow (variable flow rate delivery) ▪ OnDemand (bolus delivery) ▪ Y-Adapter (multi-site delivery or combination of administration line components) ▪ Y-Site (piggyback infusions) ▪ Air and particulate eliminating filter ▪ Pressure regulator, check valve or flow view indicator	1. Same except fill volumes up to 770 ml. 2. Same 3. Same 4. Same 5. Same
B	**Indications for Use**		
		1. The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural. 2. The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous. 3. The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.	1. Same 2. Same 3. Same
C	**Product Classification**		
C1	Product Code	MEB	Same
C2	Device Classification	Class 2	Same
C3	Device Regulation	880.5725	Same
D	**Materials**		
D1	Biocompatibility	per ISO 10993-1	Same
E	**Technology**	elastomeric pressure source with integrated administration set	Same

#	Information	Existing I-Flow Elastomeric Pumps (predicate device: K052117)	New (modified) I-Flow Elastomeric Pumps (subject device)
F	**Sterilization**		
F1	Methods	(b)(4)	Same
F2	Residual Limits	per ISO 10993-7	Same
F3	Sterility Assurance Level	(b)(4)	Same
G	**Packaging**		
G1	Type	(b)(4)	Same
G2	Requirements	per ISO 11607	Same
G3	Shelf Life	(b)(4)	Same

Conclusion

12.4 The only change this 510(k) submission proposes is the increase in maximum fill volume of the pump from 550 ml to 770 ml. Based upon the results of the risk analysis and design verification and validation activities, this change does not raise any new issues of safety or efficacy. All other aspects of the device remain the same.

TAB 13

Section 13 - Labeling

13.1 I-Flow Corporation believes the proposed labeling, where appropriate, meet the requirements of ***21 CFR Part 801*** as it relates to a determination of intended use and adequate directions for use. Labeling makes use of symbols, where appropriate, in compliance with ***EN 980***.

13.2 The *I-Flow Elastomeric Pumps'* package labels include the following (see ***section 13.4***):

13.2.1 Model and part number.

13.2.2 Name, quantity and description of the devices.

13.2.3 Specifications.

13.2.4 Symbols compliant with ***EN 980*** and defined in the directions for use:
- Rx only (required under 801.109 (b)(1))
- Single use only (if applicable)
- Do not use if package has been opened or is damaged
- Sterile (if applicable)
- Expiration date
- Lot number
- Manufacturer

13.2.5 Manufacturer name and address.

13.2.6 EU Representative and CE mark (if applicable)

13.3 The *I-Flow Elastomeric Pumps'* directions for use include the following (see ***section 13.6***):

13.3.1 Name and description of the devices.

13.3.2 Indications for use.

13.3.3 Cautions, warnings, and contraindications information.

13.3.4 Comprehensive directions for use, including illustrations.

13.3.5 Specifications (unless already included on the package label).

13.3.6 The prescription statement required under 801.109 (b)(1) or the equivalent symbol (Rx only).

13.3.7 Customer service contact information.

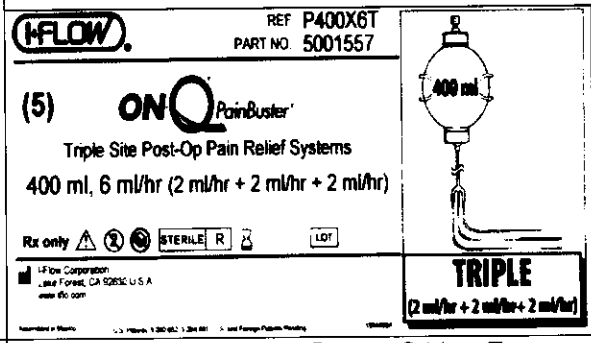
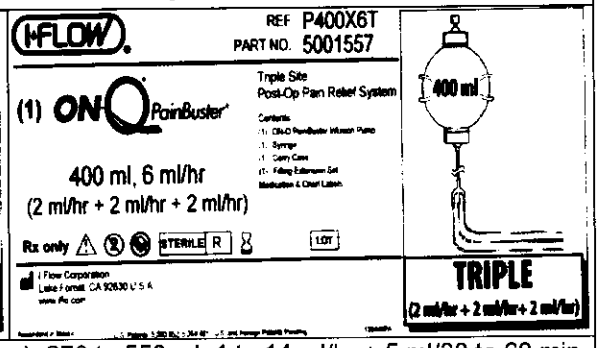
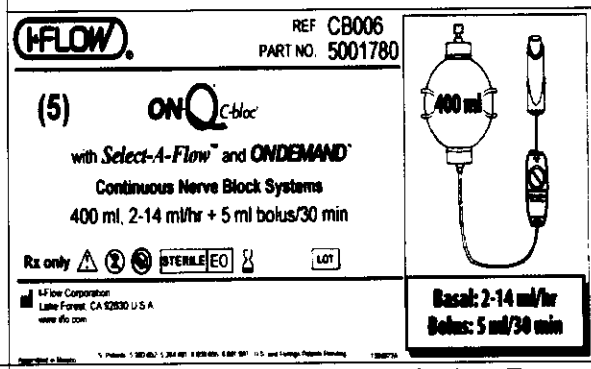
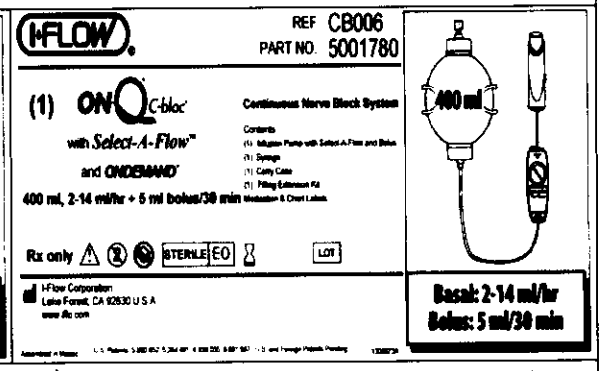
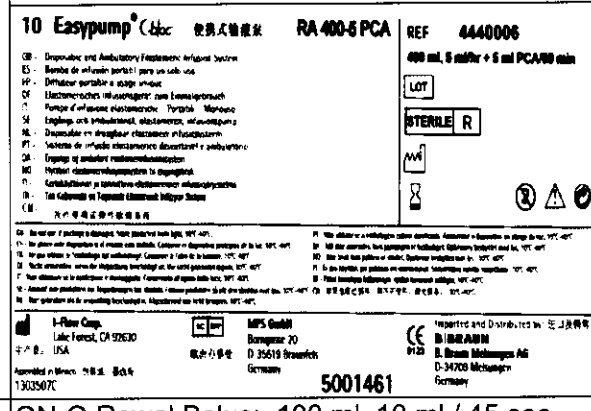
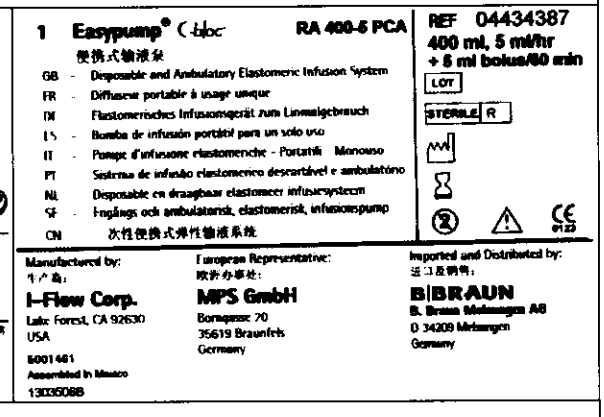
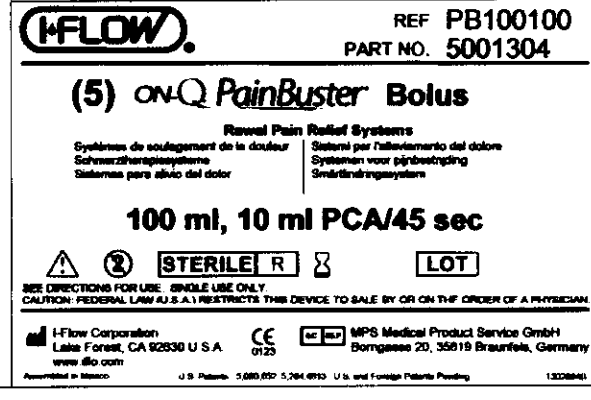
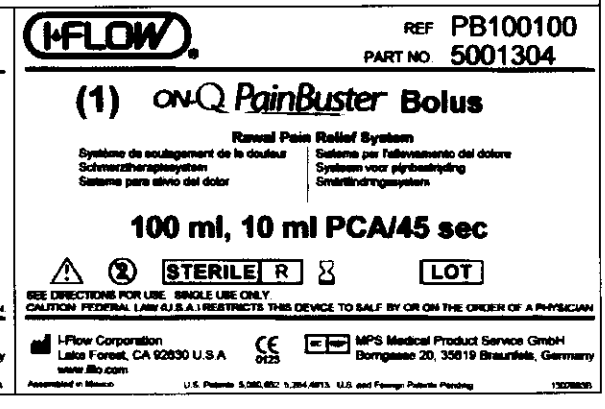
13.3.8 Manufacturer name and address.

13.3.9 Revision date of labeling.

13.4 Example Box Labels and Sterile Pouch Labels

Note: Below are representative box and sterile pouch labels for each type of model currently sold. Upon clearance of this 510(k), some models may be sold at the higher 600 ml nominal fill volume (maximum 770 ml). The labels will remain the same except for the designation of the higher fill volume on the label.

Model	Box Label	Sterile Pouch Label
Type 1	Homepump Eclipse, C-Series, Easypump: 50 to 550 ml, 0.5 to 250 ml/hr	
	10 Easypump® ST 500-2 REF 04434364 500 ml, 250 ml/hr LOT STERILE R I-Flow Corp. Lake Forest, CA 92630 USA Production Site: 27650 Pasco Ref. S/N Frace. Rubio, Mexico MPS GmbH Borngasse 20 35619 Braunfels Germany Imported and Distributed by B BRAUN B. Braun Medical 204 avenue du Marechal Juin 92107 Boulogne Cedex France Rx only 5001123	1 Easypump® ST 500-2 REF 04434364 500 ml, 250 ml/hr LOT STERILE R I-Flow Corp. Lake Forest CA 92630, USA Production Site: 27650 Pasco Ref. S/N Frace. Rubio, Mexico MPS GmbH Borngasse 20 35619 Braunfels Germany Imported and Distributed by B BRAUN B. Braun Medical 204 avenue du Marechal Juin 92107 Boulogne Cedex France Rx only 5001123
Type 2	Homepump CP-Series, Easypump PCA LT: 100 - 125 ml, 0.5 - 2 ml/hr + 0.5 ml / 6 - 15 min.	
	A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE UN PRODUCTO DE / UN PRODOTTO I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE 24 REF CP100020-6 PART NO. 5001240 **Homepump Eclipse® CP-Series** Basal with Bolus 2 ml/hr Basal Rate, 0.5 ml Bolus Vol 6 min Refill Rate STERILE R LOT SEE DIRECTIONS FOR USE. SINGLE PATIENT USE ONLY. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. European Representative: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany CE 0123 Manufactured by: I-Flow Corporation Lake Forest, CA 92630 U.S.A. www.i-flowcorp.com	A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE UN PRODUCTO DE / UN PRODOTTO I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE 1 REF CP100020-6 PART NO. 5001240 **Homepump Eclipse® CP-Series** Basal with Bolus 2 ml/hr Basal Rate, 0.5 ml Bolus Vol 6 min Refill Rate STERILE R LOT SEE DIRECTIONS FOR USE. SINGLE PATIENT USE ONLY. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. European Representative: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany CE 0123 Manufactured by: I-Flow Corporation Lake Forest, CA 92630 U.S.A. www.i-flowcorp.com
Type 3	One-Step KVO: 60 to 125 ml, 0.5 ml/hr	
	A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE UN PRODUCTO DE / UN PRODOTTO I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE 24 REF EY110005 PART NO. 5001210 **ONE • STEP KVO™** (LP) 110 ml Vol x 0.5 ml/hr STERILE LOT SEE DIRECTIONS FOR USE. SINGLE PATIENT USE ONLY. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. European Representative / Europäische Vertretung / Représentant pour l'Europe / Representante Europeo / Rappresentante Europeo: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany CE 0123 Manufactured by / Hersteller von / Fabriqué par / Fabricado por / Prodotto Da: I-Flow Corporation Lake Forest, CA 92630 U.S.A.	A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE UN PRODUCTO DE / UN PRODOTTO I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE 1 REF EY110005 PART NO. 5001210 **ONE • STEP KVO™** (LP) 110 ml Vol x 0.5 ml/hr STERILE LOT SEE DIRECTIONS FOR USE. SINGLE PATIENT USE ONLY. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. European Representative / Europäische Vertretung / Représentant pour l'Europe / Representante Europeo / Rappresentante Europeo: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany CE 0123 Manufactured by / Hersteller von / Fabriqué par / Fabricado por / Prodotto Da: I-Flow Corporation Lake Forest, CA 92630 U.S.A.
Type 4	Bolus Accessory Set: 0.5 ml / 3.6 to 70 min.	
	I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE 12 REF 5001150 **Bolus Accessory Set** **0.5 ml Bolus Vol** STERILE R LOT SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. Manufactured by / Hersteller von / Fabriqué par / Fabricado por / Prodotto Da: I-Flow Corporation Lake Forest, CA 92630 U.S.A. CE 0123 European Representative / Europäische Vertretung / Représentant pour l'Europe / Representante Europeo / Rappresentante Europeo: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany	I-FLOW I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. REF 5001150 **Bolus Accessory Set** **0.5 ml Bolus Vol** STERILE R LOT SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. European Representative / Europäische Vertretung / Représentant pour l'Europe / Representante Europeo / Rappresentante Europeo: MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany CE 0123 Manufactured by / Hersteller von / Fabriqué par / Fabricado por / Prodotto Da: I-Flow Corporation Lake Forest, CA 92630 U.S.A.

Model	Box Label	Sterile Pouch Label
Type 5	ON-Q PainBuster, C-bloc: 65 to 550 ml, 0.5 to 10 ml/hr, single, dual or triple site	
		
Type 6	Select-A-Flow (ON-Q PainBuster, C-bloc, Easypump): 270 to 550 ml, 1 to 14 ml/hr + 5 ml/30 to 60 min.	
		
Type 7	OnDemand (ON-Q PainBuster, C-bloc, Easypump): 270 to 550 ml, 2 to 5 ml/hr + 5 ml/30 to 60 min.	
		
Type 8	ON-Q Rawal Bolus: 100 ml, 10 ml / 45 sec.	
		

13.5 Directions for Use (DFU)

Directions for use for *I-Flow Elastomeric Pumps* that are currently sold are located in ***Appendix C***. The only changes the 600 ml model would have is a different maximum fill volume, expected delivery time and residual volume.

13.6 Marketing Literature

Example marketing literature currently used is located in ***Appendix D***.

TAB 14

Section 14 - Sterilization and Shelf Life

14.1 Sterilization

Note: There is no change in the sterilization methods. Below is a summary of the current sterilization methods used for the existing models.

14.1.1 The methods of sterilization are either (b)(4) (b)(4) (b)(4) (b)(4)

14.1.2 (b)(4) (b)(4) sterilization validation conforms with ***ISO 11137*** (Method 1).

14.1.2.1 The (b)(4) (b)(4) dose validated for this (b)(4) (b)(4)

14.1.3 (b)(4) (b)(4) validation conforms with ***ISO 11135***.

14.1.3.1 (b)(4) (b)(4)

14.1.3.2 Exposure category is "prolonged exposure", less than 30 days contact.

14.1.4 The Sterility Assuarance Level (SAL) is at (b)(4)

14.1.4.1 For (b)(4) sterilization, sterility testing is confirmed by routine biological indicators containing a spore strip.

14.1.4.2 For (b)(4) (b)(4) (Method 1), no sterility test is required. Sterilization is process controlled with a minimum of (b)(4) (b)(4) required to assure an SAL of (b)(4)

14.2 Packaging

14.2.1 There is no change in the type of packaging currently used. Packaging consists of either (b)(4) (b)(4) (b)(4) (b)(4)

14.2.2 Packaging is in conformance with the standard ***ISO 11607*** (Packaging for Terminally Sterilized Medical Devices).

14.2.3 Packaging is suitable for (b)(4) (b)(4)

14.3 Pyrogenicity

14.3.1 Every lot of I-Flow product is tested for pyrogenicity using the USP limulus amebocyte lysate (LAL) method.

14.4 Shelf Life

14.4.1 There is no change in shelf life specification. Shelf life testing will be performed on real time or accelerated aged product (prior to market distribution) to establish the minimum shelf life where product still meets the requirements stated in ***section 9 – Declaration of Conformity.***

TAB 15

Section 15 - Biocompatibility

15.1 Biocompatibility is not affected by the proposed design change. There are no changes to the currently used materials. A summary of existing biocompatibility follows.

15.2 The *I-Flow Elastomeric Pumps* are compliant with ***ISO 10993-1*** for biocompatibility. Per this standard, the pumps are categorized as indicated below:

Category: External Communicating

Contact: Tissue/bone/dentin or Blood path, indirect (depending on indications)

Duration: Prolonged (24 hours to 30 days)

15.3 Biocompatibility tests recommended the above categorizations include the following:

15.3.1 Cytotoxicity

15.3.2 Sensitization

15.3.3 Irritation / Intracutaneous Reactivity

15.3.4 Systemic Toxicity (acute)

15.3.5 Subacute and Subchronic Toxicity

15.3.6 Genotoxicity

15.3.7 Haemocompatibility

Note: None of the pump components are in direct body contact and therefore implantation is not required. Pyrogenicity is tested on each lot of I-Flow product built.

15.4 Test Results: All patient contacting materials have documentation to support biocompatibility for the tests indicated in section 15.2 above.

Test	Method*	Result
Cytotoxicity	***ISO 10993-5***	non-cytotoxic
Sensitization	***ISO 10993-10***	non-sensitizing
Irritation / Intracutaneous Reactivity	***ISO 10993-10***	intracutaneously non-irritating
System Toxicity (acute)	***ISO 10993-11***	systemically non-toxic (acute)
Subacute and Subchronic Toxicity	***ISO 10993-11***	systemically non-toxic (subchronic)
Genotoxicity	***ISO 10993-3***	non-mutagenic
Haemocompatibility	***ISO 10993-4***	non-hemolytic
Pyrogenicity	USP limulus amebocyte lysate (LAL)	non-pyrogenic

*Method refers to testing sponsored by I-Flow. Some documentation is based upon supplier information or justification based upon existing material usage.

TAB 16

Section 16 - Software

The *I-Flow Elastomeric Pumps* are non-electronic and do not contain software therefore this section does not apply.

<Go to next section>

TAB 17

Section 17 - Electromagnetic Compatibility and Electrical Safety

The *I-Flow Elastomeric Pumps* are non-electronic therefore this section does not apply.

<Go to next section>

TAB 18

Section 18 – Design Control Activities Summary

18.1 A risk analysis was performed per ISO 14971 in order to assess the impact of the modification on the device and its components. The results of the risk analysis are documented in ***Appendix A.*** Below is a summary of verification and validation activity that will be performed prior to market and the corresponding acceptance criteria.

Test methodology is per established I-Flow procedures with identical acceptance criteria with the exception of residual volume. The residual volume will increase for the larger pump volume.

18.2 Flow Accuracy Testing

Testing occurs at nominal fill volume using normal saline as the diluent at the labeled temperature and back pressure. Acceptance criteria is for the sample size mean at (b)(4) confidence interval.

18.2.1 Fixed Flow Rate Component: (b)(4)

18.2.2 Select-A-Flow (variable flow rate) Component: (b)(4)

18.2.3 OnDemand (bolus) Component:

Basal flow rate: (b)(4)

Bolus volume accuracy: (b)(4)

Bolus refill accuracy: (b)(4)

18.3 Residual Volume

Testing occurs at the same conditions as specified in the Flow Accuracy Testing. Residual volume acceptance criteria is based upon nominal fill volume.

Nominal Fill Volume (ml)	(b)(4)
Maximum Fill Volume (ml)	
Residual Volume (ml)	

18.4 Leak and Bladder Rupture Testing

Testing shall ensure that the pump will not leak at (b)(4) Testing will continue beyond (b)(4) to determine at what fill volume the pump begins to (b)(4) (b)(4)

18.5 Filling Pressure

Testing shall ensure that the initial filling pressure and average filling pressure from the beginning to the end (b)(4)

18.6 Shelf Life

Testing shall ensure that the pump performance specifications are met throughout is labeled shelf life.

18.7 Overfill Flow Rate Testing

Testing shall measure the impact of filling the pump greater than nominal. The results of overfill will be documented in the product's Directions for Use.

18.8 Conclusion

The design of the 600 ml pump is identical to the currently marketed 400 ml pumps with the exception of minor dimensional changes to the flow control components. Testing will ensure that the new model does not raise any new issues of safety or effectiveness.

TAB 19

Section 19 - Performance Testing (Animal)

This 510(k) submission does not utilize animal testing for establishing substantial equivalence therefore this section does not apply.

<Go to next section>

TAB 20

Section 20 - Performance Testing (Clinical)

This 510(k) submission does not utilize clinical studies for establishing substantial equivalence therefore this section does not apply.

<Go to next section>

TAB 21

Appendix A - Risk Assessment

This section contains the risk assessment per ISO 14971 for the *I-Flow Elastomeric Pumps*.

Title: Risk Assessment for Elastomeric Pumps

Doc. No.: (b)(4) (b)(4) Rev.:

DCN: Effectivity:

Owner:

1.0 PURPOSE

(b)(4)

(b)(4)

2.0 SCOPE

(b)(4)

(b)(4)

3.0 REFERENCES

(b)(4)

(b)(4)

4.0 RISK ANALYSIS

(b)(4)

(b)(4)

(b)(4)

(b)(4)

5.0 RISK EVALUATION

(b)(4)

(b)(4)

6.0 RISK CONTROL

(b)(4)

(b)(4)

(b)(4)

(b)(4)

7.0 NATURAL RUBBER (LATEX) SENSITIVITY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

8.0 POST MARKET SURVEILLANCE

(b)(4)

(b)(4)

9.0 RISK MANAGEMENT REPORT

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 1 - Failure Mode and Effect Analysis (FMEA)

Note: For sake of space, "bad" can mean broken, cracked, mismolded, or otherwise out of specification

POTENTIAL FAILURES/CAUSES	POTENTIAL EFFECTS	POTENTIAL HAZARDS	Probability	Severity	Risk Estimation	Counter Measure
(b)(4)						

Table 1 - Failure Mode and Effect Analysis (FMEA)

Note: For sake of space, "bad" can mean broken, cracked, mismolded, or otherwise out of specification

POTENTIAL FAILURES/CAUSES	POTENTIAL EFFECTS	POTENTIAL HAZARDS	Probability	Severity	Risk Estimation	Counter Measure
(b)(4)						

(b)(4)

Table 1 - Failure Mode and Effect Analysis (FMEA)

Note: For sake of space, "bad" can mean broken, cracked, mismolded, or otherwise out of specification

POTENTIAL FAILURES/CAUSES	POTENTIAL EFFECTS	POTENTIAL HAZARDS	Probability	Severity	Risk Estimation	Counter Measure
(b)(4)						

(b)(4)

TAB 22

Appendix B – Drawings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Pages 88 through 113 redacted for the following reasons:
- -
Technicial drawings, b4

TAB 23

Appendix C – Directions for Use (DFUs) and Marketing Literature

This section contains updated Directions for Use and example marketing literature for the *I-Flow Elastomeric Pumps* that are currently sold.

I-Flow Elastomeric Pumps

Model	Part Number	Description
Type 1	111092e, 111111f	Homepump Eclipse, Homepump C-Series
Type 2	1302890c	Easypump Basal with Bolus
Type 3	1302298b	One Step KVO
Type 4	1302889c	Easypump Bolus Accessory Set
Type 5	1304265c, 1304267d	ON-Q Pump, ON-Q Pump Fixed Flow Rate Insert
Type 6	1304513c	ON-Q Pump Select-A-Flow Insert
Type 7	1304514c	ON-Q Pump OnDemand Insert
Type 8	1302887b	ON-Q Rawal Bolus

Accessories

Model	Part Number	Description
ACC05	1303396c	Filling Extension Set
ACC11	1304208a	Reusable PowerFiller
H000004	1304313a	Easy Filler

E050500	E100500	E101000	E102000	
E251750	E252500	E401000	E402000	E502500
SE050500	SE100500	SE101000	SE102000	

Homepump® ECLIPSE

Disposable and Ambulatory Elastomeric Infusion System

Sistema de infusión elastomérico desechable y ambulatorio

Système de perfusion en élastomère jetable à usage ambulatoire

Elastomeres Einweg-Infusionssystem für ambulante Behandlung

Ambulatoriskt elastinfusionssystem för engångsbruk

ディスポーザブル携帯式エラストメリック注入システム

일회용 휴대가능 탄성체 주입 장치

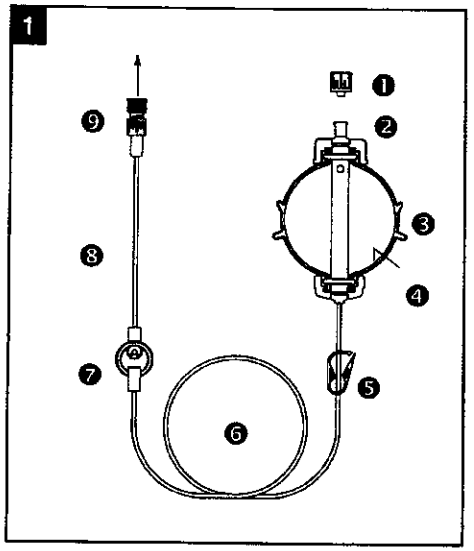
Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

ENGLISH

1



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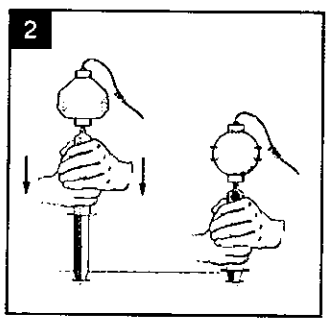


ENGLISH

Homepump® Eclipse: Disposable and Ambulatory Elastomeric Infusion System, see figure 1:

- ❶ Fill Port Cap
- ❷ Fill Port
- ❸ Outer Shell
- ❹ Elastomeric Membrane
- ❺ Clamp
- ❻ Tubing
- ❼ Air Eliminating Filter
- ❽ Flow Restricting Tubing
- ❾ Distal End Cap

INDICATIONS FOR USE

- Homepump Eclipse is indicated for continuous delivery of medications through intravenous routes.

CAUTIONS

- The Homepump Eclipse is sterile and nonpyrogenic. Do not use if sterile pouch has been opened, damaged, or if either protector cap is not in place.
- Single use only. Do not reuse, resterilize or refill.
- Do not remove from package until ready for use.
- This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Store protected from light at room temperature: 10°-40°C, 10-90% relative humidity.
- For drug stability, please contact your local representative.

CONTRAINDICATIONS

- Homepump Eclipse is not intended for the delivery of blood, blood products, lipids or fat emulsions.

DIRECTIONS FOR FILLING – Use Aseptic Technique

1. Remove the cap from the fill port and retain for later use.
2. The Homepump Eclipse can be filled with a syringe or similar device. Remove all air from the filling device and attach it securely to the fill port. See Figure 2 for proper technique.
3. Attach the fill port to the filled syringe and invert pump as shown. Firmly grasp the syringe with both hands and push down on the plunger continuously until the volume is dispensed. Do not push down on the pump while filling, as the syringe tip may break. Repeat as necessary.
4. Close the clamp on the tubing and fill the Homepump Eclipse with no more than the recommended maximum fill volume (refer to Table 1: Delivery Time Information)
5. Remove filling device from the fill port.
6. Securely replace fill port cap. Ensure that the distal end cap on the tubing is tight.
7. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING – Use Aseptic Technique

1. Remove the cap from the distal end of the tubing.
2. Open tubing clamp. Fluid will begin to flow, filling the tubing set. When all air has been expelled from the tubing set, close the tubing clamp and replace end cap.

STARTING INFUSION – Use Aseptic Technique

- Patient must be educated on proper use of product by healthcare provider.
- Do not use while showering, bathing or swimming.
- Do not microwave or submerge in water.

1. Allow Homepump Eclipse to warm to room temperature before using (See Table 1).
2. Verify that the clamp on the tubing is closed.
3. Cleanse injection site of IV access port as directed by healthcare provider.
4. Attach the Homepump Eclipse tubing to access site, as instructed by healthcare provider.
5. Begin infusion by opening the clamp; fluid delivery will start immediately. If tubing is kinked, roll kinked portion of the tubing between fingers to restore shape of tubing and promote fluid flow.
6. Infusion is complete when the elastomeric membrane is no longer expanded. Close clamp, disconnect and dispose of the Homepump Eclipse as instructed by healthcare provider.

147

ENGLISH

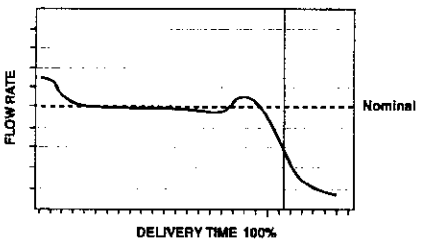
CAUTIONS

Actual infusion times may vary due to the following:

- Filling the pump less than nominal results in faster flow rate.
- Filling the pump more than nominal results in slower flow rate.
- Temperature will affect solution viscosity, resulting in shorter or longer delivery time. The Homepump Eclipse is designed to be used at room temperature (20°C/68°F). If the Homepump Eclipse or its tubing is at 25°C/78°F, the flow rate will increase approximately 14% above its nominal rate; at 15°C/60°F, the flow rate will decrease approximately 12% below its nominal rate.
- The Homepump Eclipse and tubing should be worn outside the clothing.
- The Homepump Eclipse must be filled 4 hours prior to administration to infuse at the labeled flow rate.
  - If the Homepump Eclipse is used immediately after filling, flow rate may increase by up to 50%.
- If the Homepump Eclipse unit needs to be stored in the refrigerator or freezer, allow the unit to warm to room temperature before using. Refer to Table 1: Delivery Time Information, for the required information to meet room temperature.
  Note: Delivery time can increase significantly as a result of extended storage time.
- The Homepump Eclipse nominal flow rates are based on the use of normal saline as the diluent. Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate. Use of 5% dextrose will result in 10% longer delivery time.
- When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 mm (or other restrictive devices) will decrease flow rate.
- Avoid getting alcohol or detergents (like soap) on the filter which may cause leakage from the air eliminating vent.
- Roll tubing between fingers to promote flow if clamped for extended time.

NOTE: Length of tubing is approximately 96±20cm (38±8").

Typical Flow Curve



ENGLISH

Table 1: Delivery Time Information

Models	E050500	E100500	E101000	E102000	E251750	E252500	E401000	E402000	E502500
	SE050500	SE100500	SE101000	SE102000	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Nominal Flow Rate (ml/hr)	50	50	100	200	175	250	100	200	250
Nominal Fill Volume (ml)	50	100	100	100	250	250	400	400	500
Maximum Fill Volume (ml)	85	125	125	125	335	335	500	500	550
Retained Volume (ml)	≤3	≤3	≤3	≤3	≤8	≤8	≤10	≤10	≤10
Refrigerator to room temp (hrs)	6	6	8	6	10	10	12	12	18
Freezer to room temp (hrs)	12	12	12	12	18	18	24	24	30
Approximate Delivery	Fill Volume								
00 : 15 h			40	60					
00 : 30 h	25	35	65	100					
00 : 40 h				125				200	
01 : 00 h	50	60	100		200	250		250	300
01 : 15 h	65		125						
01 : 25 h					250	335		300	
01 : 30 h		80					200		400
01 : 45 h					300			350	
02 : 00 h		100			335		250	400	500
02 : 15 h								450	550
02 : 30 h		120					300		
02 : 40 h		125						500	
03 : 00 h							350		
04 : 00 h							400		
04 : 45 h							450		
05 : 15 h							500		

When filled to nominal volume, the Homepump Eclipse flow rate accuracy is ±15% (at 95% confidence interval) of the labeled flow rate when infusion is started 4 hours after fill and delivering normal saline as the diluent at (20°C/68°F).

For Customer Service please call:
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C060020	C065005	C100005	C100020	C125050
C270010	C270020	C270050	C270100	C300060

Homepump® ECLIPSE C-Series

Disposable and Ambulatory Elastomeric Infusion System

Sistema de infusión elastomérico desechable y ambulatorio

Système de perfusion en élastomère jetable à usage ambulatoire

Elastomeres Einweg-Infusionssystem für ambulante Behandlung

Ambulatoriskt elastinfusionssystem för engångsbruk

ディスポーザブル携帯式エラストメリック注入システム

일회용 휴대가능 탄성체 주입 장치

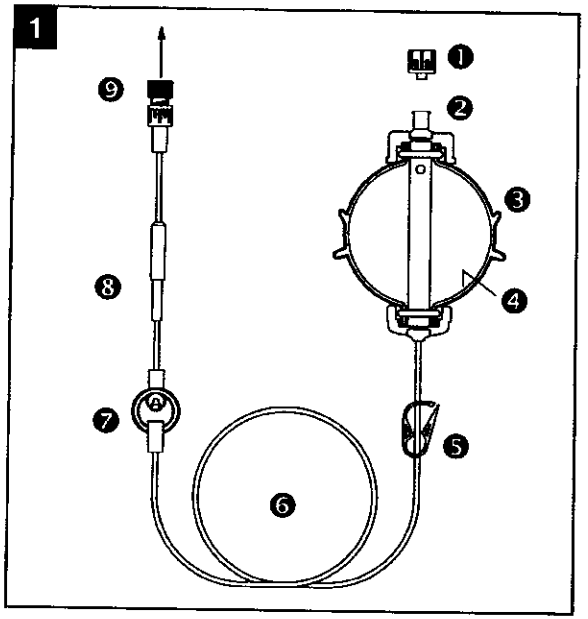
Manufactured by:
i-Flow Corporation
Lake Forest, CA 92630
U.S.A.

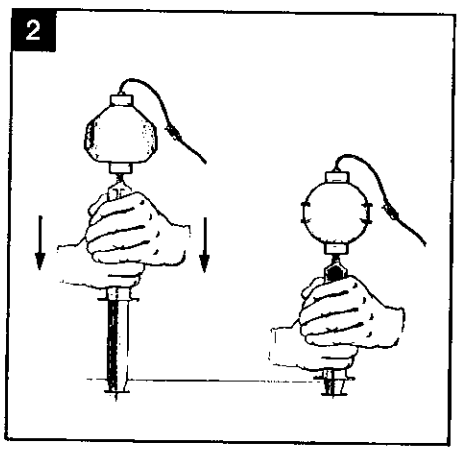
CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

ENGLISH | ESPAÑOL | FRANÇAIS | DEUTSCH | SVENSKA | 日本語 | 한국어

ENGLISH





151

ENGLISH

Homepump Eclipse C-Series: Disposable and Ambulatory Elastomeric Infusion System, see figure 1:

1. Fill Port Cap
2. Fill Port
3. Outer Shell
4. Elastomeric Membrane
5. Clamp
6. Tubing
7. Air Eliminating Filter
8. Flow Restrictor
9. Distal End Cap

INDICATIONS FOR USE

- Homepump C-Series is indicated for continuous delivery of medications through intravenous, intra-arterial, intramuscular, subcutaneous or epidural routes.

CAUTIONS

- The Homepump C-Series is sterile and nonpyrogenic. Do not use if sterile pouch has been opened, damaged, or if either protector cap is not in place.
- Single use only. Do not reuse, resterilize or refill.
- Do not remove from package until ready for use.
- This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Store protected from light at room temperature: 10°-40°C, 10-90% relative humidity.
- For drug stability, please contact your local representative.

WARNING

- Epidural infusion of analgesics is limited to use of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.

CONTRAINDICATIONS

- Homepump C-Series is not intended for the delivery of blood, blood products, lipids or fat emulsions.

DIRECTIONS FOR FILLING – Use Aseptic Technique

1. Remove the cap from the fill port and retain for later use.
2. The Homepump C-Series can be filled with a syringe or similar device. Remove all air from the filling device and attach it securely to the fill port. See Figure 2 for proper technique.
3. Close the clamp on the tubing and fill the Homepump C-Series with no more than the recommended maximum fill volume (refer to Table 1: Delivery Time Information).
4. Attach the fill port to the filled syringe and invert pump as shown. Firmly grasp the syringe with both hands and push down on the plunger continuously until the volume is dispensed. Do not push down on the pump while filling, as the syringe tip may break. Repeat as necessary.
5. Remove filling device from the fill port.
6. Securely replace fill port cap. Ensure that the distal end cap on the tubing is snug.
7. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING – Use Aseptic Technique

1. Remove the cap from the distal end of the tubing.
2. Open tubing clamp. Fluid will begin to flow, filling the tubing set. When all air has been expelled from the tubing set (may take up to 15 minutes), close the tubing clamp and replace end cap.

STARTING INFUSION – Use Aseptic Technique

- Patient must be educated on proper use of product by healthcare provider.
- Do not use while showering, bathing or swimming.
- Do not microwave or submerge in water.

1. Allow Homepump C-Series to warm to room temperature before using.
2. Homepump C-Series delivery should be started 0-8 hours after filling. Storage of a filled Homepump unit for more than 8 hours prior to starting infusion may result in a longer delivery time.
3. If a filled Homepump C-Series unit needs to be stored in the refrigerator or freezer, for any reason, allow the unit to warm to room temperature before using.
4. Verify that the clamp on the tubing is closed.
5. Cleanse patient access site as directed by healthcare provider.
6. Attach the Homepump C-Series tubing to injection site, as instructed by healthcare provider.
7. **Tape the flow restrictor (not the filter) to the patient's skin.**

ENGLISH

8. Begin infusion by opening the clamp; fluid delivery will start immediately. If tubing is kinked, roll kinked portion of the tubing between fingers to restore shape of tubing and promote fluid flow.
9. Infusion is complete when the elastomeric membrane is no longer expanded. Close clamp, disconnect and dispose of the Homepump C-Series as instructed by healthcare provider.

CAUTIONS

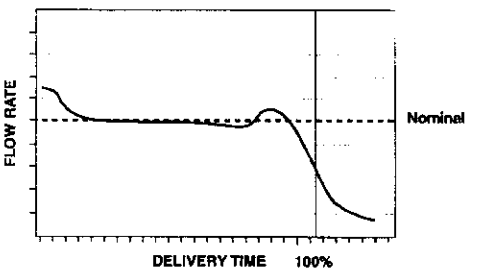
Actual infusion times may vary due to the following:

- Filling the pump less than nominal results in faster flow rate.
- Filling the pump more than nominal results in slower flow rate.
- Temperature will affect solution viscosity, resulting in shorter or longer delivery time. The Homepump C-Series flow restrictor (located distal to the filter) should be close to, or in direct contact with the skin (31°C/88°F) and the tubing should be under the patient's clothing. If the Homepump C-Series is used with the flow restrictor at room temperature (20°C/68°F), delivery time will increase approximately by 25%.
- The Homepump C-Series delivery should be started within 8 hours of filling. Storage of a filled Homepump C-Series unit for more than 8 hours prior to starting infusion may result in a 10% longer delivery time.
- If the Homepump C-Series unit needs to be stored in the refrigerator or freezer, allow the unit to warm to room temperature before using. Refer to Table 1: Delivery Time Information, for the required information to meet room temperature.
  Note: Delivery time can increase significantly as a result of extended storage time.
- The Homepump C-Series nominal flow rates are based on the use of normal saline as the diluent. Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate. Use of 5% dextrose will result in 10% longer delivery time.
- When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 mm (or other restrictive devices) will decrease flow rate.
- Avoid getting alcohol or detergents (like soap) on the filter which may cause leakage from the air eliminating vent.
- Roll tubing between fingers to promote flow if clamped for extended time.

NOTE: Length of tubing is approximately 115±15cm (40±5").

152

Typical Flow Curve



ENGLISH

Table 1: Delivery Time Information

Models		C060020	C060005	C100005	C100020	C125050	C270018	C270020	C270050	C270100	C300060
Nominal Flow Rate (ml/hr)		2	0.5	0.5	2	5	1	2	5	10	6
Nominal Volume (ml)		60	65	100	100	125	270	270	270	270	300
Maximum Volume (ml)		65	65	125	125	125	335	335	335	335	335
Retained Volume (ml)		≤ 2	≤ 2	≤ 4	< 3	≤ 3	≤ 8	≤ 8	≤ 8	≤ 8	≤ 8
Refrigerator to Room Temp (hrs)		6	6	6	6	6	10	10	10	10	10
Freezer to Room Temp (hrs)		12	12	12	12	12	18	18	18	18	18
Approx. Delivery Time		Volume (ml)									
6 hr											
12 hr		38			35	75				160	
18 hr		42				100				200	
24 hr	1 d	52			65	125			150	250	170
30 hr		60									
36 hr											235
48 hr	2 d		35		100				265		285
60 hr					125				290		335
72 hr	3 d		45					175	330		
96 hr	4 d		55					215			
120 hr	5 d		65		70		155	250			
	6 d				80		175	290			
	7 d				89		196	325			
	8 d				98		216				
	9 d				106		230				
	10 d				113		245				
	11 d				120		255				
	12 d						265				

When filled to nominal volume, Homepump C-Series flow rate accuracy is ±15% (at 95% confidence interval) of the labeled flow rate when infusion is started 0-8 h after fill and delivering normal saline as the diluent at (31°C/88°F) against a back pressure of 40 cm of water.

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PCA LT100-0.5-15 PCA LT100-2-6

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Basal with Bolus

Easypump®
Pompe de base à bolus

Easypump®
Laufende Infusion mit Bolusmöglichkeit

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Basal con inyección en embolada

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Basal ve Bolus

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Manufactured by:
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Lake Forest, CA 92630
U.S.A.

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

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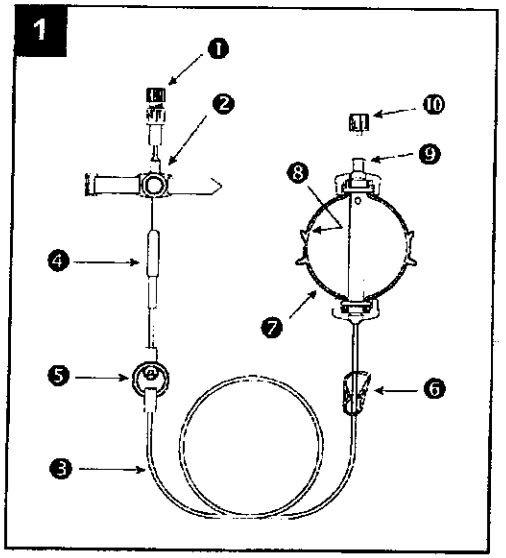

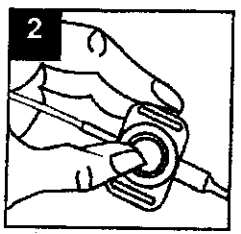

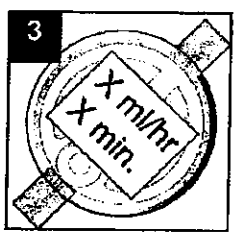

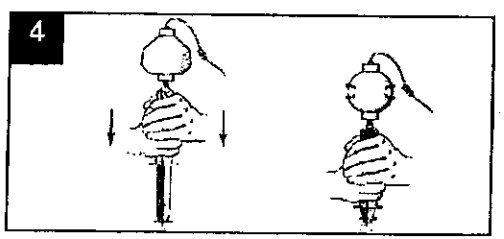

ENGLISH

DIRECTIONS FOR USE
Easypump Basal with Bolus

NOMENCLATURE AND ILLUSTRATION

FIGURE 1: Easypump Infusor (see page 4)

1. Luer Lock ❶
2. Patient-Controlled Bolus Module ❷
3. Tubing ❸
4. Flow Restrictor ❹
5. Air-Eliminating Filter ❺
6. Tubing Clamp ❻
7. Protective PVC Cover ❼
8. Elastomeric Membrane ❽
9. Fill Port ❾
10. Fill Port Cap ❿

FIGURE 2 : BOLUS BUTTON (see page 4)

FIGURE 3: FLOW RATE AND REFILL TIME LABEL (see page 4)

INDICATIONS FOR USE
Easypump with Patient-Controlled Bolus Module is intended to provide a continuous basal level infusion of medication and to allow patient-controlled bolus delivery. The bolus component of the PCA module enables fixed boluses to be delivered upon demand by the patient or healthcare provider. Routes of administration include intravenous, epidural, intramuscular and subcutaneous.

CAUTIONS

- Easypump is sterile and nonpyrogenic. Do not use if the sterile pouch is opened, damaged or if either protective cap is not in place.
- Single use only. Do not reuse, resterilize, or refill.
- Do not remove from package until ready for use.
- The Easypump should be filled a minimum of one hour prior to administration. If the Easypump is used immediately after filling, the flow rate may increase.
- Store protected from light at room temperature; 10°-40°C, 10-90% relative humidity.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- For drug stability, please contact your local representative.

WARNING

- Epidural infusion of analgesics is limited to use of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.

CONTRAINDICATION

- Easypump is not intended for the delivery of blood, blood products, lipids, fat emulsions or TPN.

PATIENT-CONTROLLED BOLUS MODULE (FIGURE 2, see page 4)

The Patient-Controlled Bolus Module incorporates a reservoir containing the medication that can be released with the push of the delivery button. When the button is pushed, a 0.5 ml dose of solution is infused. Upon release of the button, the reservoir begins to fill with medication. The refill time for the bolus is specified on the Product Label. The Bolus Module incorporates a safety feature that allows the patient to deliver a maximum of 0.5 ml bolus of medication only after a specified time. Pressing the bolus button before the specified refill time will result in a partial bolus dose.

FLOW RATE AND REFILL TIME TABLE (FIGURE 3, see page 4)

Flow rates and bolus refill times for each system are printed on the label located on the air-eliminating filter.

DIRECTIONS FOR FILLING – Use Aseptic Technique (FIGURE 1, see page 4)

1. Remove the cap from the fill port and retain for later use.
2. The Easypump can be filled with a syringe or similar device. Remove all air from the filling device and attach it securely to the fill port. See Figure 4 on page 4 for proper technique.
3. Close the clamp on the tubing and fill the Easypump with no more than the recommended maximum fill volume (refer to Table 2: Delivery Time Information)
4. Remove filling device from the fill port.
5. Securely replace fill port cap. Ensure that the distal end cap on the tubing is tight.
6. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING – Use Aseptic Technique

1. Remove the cap from the distal end of tubing and open the tubing clamp. The medication will flow, filling the tubing set.
2. When the bolus button has filled (the button rises to the top of the housing), press the bolus button to prime. Repeat until air is removed from the tubing and connector. This may take up to four pushes of the bolus button.
3. Pinch the clamp closed and replace the cap.

STARTING THE INFUSION – Use Aseptic Technique

- Patient must be educated on proper use of product by healthcare provider.
- Do not use while showering, bathing or swimming.
- Do not microwave or submerge in water.

1. Allow Easypump to warm to room temperature before using.
2. Verify that the clamp on tubing is closed.
3. Cleanse access site and attach the luer connector on the administration set to patient's access site.
4. Secure the Bolus Module with bolus button against the skin using either the strap provided or tape.
5. **Tape the flow restrictor to the patient's skin. Do not tape the filter.**

6. Start the infusion by opening the clamp on the administration tubing. The infusion will begin immediately. If the tubing is kinked, roll kinked portion between fingers to restore shape and promote fluid flow.

BOLUS ACTIVATION

1. To receive a bolus of medication, press down on the bolus button until it stops.
2. At any time during the infusion, the bolus button can be pushed to deliver a bolus of medication.
3. The next full bolus will be available after the stated refill time. (See Table 1)
4. Pressing the bolus button prior to the end of the refill time will result in a partial bolus dose.

END OF INFUSION

1. When the elastomeric membrane is no longer extended, infusion is complete. Close clamp, disconnect and dispose of the Easypump.

CAUTIONS

Actual infusion times may vary due to:

- Filling the pump more than nominal results in slower flow.
- Filling the pump less than nominal results in faster flow.
- Temperature will affect solution viscosity, resulting in shorter or longer delivery time. The Easypump flow restrictor (located distal to the filter) should be taped to the skin (88°F/31°C). If the Easypump is used with the flow restrictor at room temperature (68°F/20°C), e.g., not taped to the skin, delivery time may increase by approximately 25%.
- The Easypump nominal flow rates are based on the use of normal saline as the diluent. Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate. Use of 5% dextrose will result in 10% longer delivery time.
- The Easypump delivery should be started no less than one hour after filling to avoid risk of excessive dosage.
- Storage of a filled Easypump unit for more than 8 hours prior to starting infusion may result in a 10% longer delivery time.
- If the Easypump unit needs to be stored in the refrigerator, allow the unit to warm to room temperature before using (about 6 hours).
  Note: Delivery time can increase significantly as a result of extended storage time.
- When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 mm (or other restrictive devices) will decrease flow rate.

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159

Delivery Times and Fill Volumes

One • Step KVO				
	EV060005		EV110005	
	EY060005		EY110005	
Flow Rate (ml / hr)	0.5		0.5	
Nominal Fill Volume (ml)	60		110	
Maximum Fill Volume (ml)	65		125	
Retained Volume (ml)	10		10	
Accuracy	± 15%		± 15%	
Time to Reach Room Temperature				
From Refrigerator:	6 hours		6 hours	
From Freezer:	12 hours		12 hours	
Nominal Fill Volumes (ml)				
	Temperatures			
	Skin	Room	Skin	Room
Approximate Delivery Times	31°C	20°C	31°C	20°C
2 days	35	28		
3 days	47	36		
4 days	60	44		
5 days			90	75
6 days			100	86
7 days			110	95
8 days			120	104
9 days				113
10 days				12

Fill Volumes account for device accuracy to ensure device will run for minimum stated time. Excess volume may remain at the end of the stated delivery time.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.i-flowcorp.com

CE 0123 European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; 5,284,481; and Foreign Pat. Pend.
Assembled in Mexico

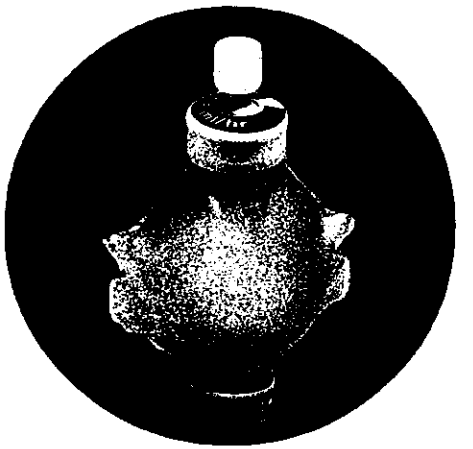
A PRODUCT OF
I-FLOW
I-FLOW CORPORATION
LAKE FOREST, CA 92630
USA

13022998
07/2001

One·Step KVO™

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

DIRECTIONS FOR USE
EY060005, EY110005, EV060005 & EV110005



INDICATIONS FOR USE:
The One-Step KVO is indicated for continuous delivery (keep vein open) through intravenous access devices.

Single Patient Use.
The One-Step KVO is sterile and non-pyrogenic. Do not resterilize.
Do not refill.
CAUTION

- Do not use if package has been opened or is damaged or if either protector cap is not in place.
- Do not use while showering, bathing or swimming.
- Do not microwave or submerge in water.
- The One-Step KVO tubing is made of DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the IV administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- It is the responsibility of the healthcare professional to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert. It is the responsibility of the healthcare provider to assure that the patient is educated on the proper use of this product.
- Refer to the Center of Disease Control Guideline for Prevention of Intravenous Therapy Related Infections for specific recommendations regarding the usage of IV administration sets.

CONTRAINDICATION

- This product is not indicated for the delivery of blood, blood products or TPN.
- This device is not intended for the infusion of epidural or chemotherapy medications.

DIRECTIONS FOR USE

DESCRIPTION

The One•Step KVO may be used as an alternative to flushing before and after an intermittent medication is administered.

The device is an elastomeric pump with a flow rate of 0.5 ml/hr and a Y-Site for medication administration. Models EV060005 and EV110005 contain a check valve in the Y-Site

FILLING INSTRUCTIONS

1. Remove the cap from the fill port.
2. The One•Step KVO can be filled with a syringe or similar device. After all air has been removed from the filling device, attach securely to the fill port.
3. During the filling process, the tubing clamp on the One•Step KVO may be opened or closed. To expedite the priming of the tubing and filter of the One•Step KVO, leave the clamp open during filling and loosen the distal end cap.
4. Fill the One•Step KVO with no more than the maximum fill volume (refer to table on back page).
5. Remove the filling device from the fill port and securely replace the fill port cap.
6. To prime the distal end of the tubing and Y-Site during the filling process, open the tubing clamp and loosen the distal end cap. Fluid will slowly begin to fill the Y-Site. Invert and tap to remove any trapped air.

   or

   To expedite the priming process, remove the Y-Site cap, attach a filling device (or saline filled syringe) to the end of the Y-Site, loosen or remove the distal end cap, then flush the Y-Site, invert and tap the Y-Site to remove any trapped air. This may expedite priming of EV060005 and EV110005 with the check valve.
7. Close the tubing clamp and tighten the distal end caps before transporting or storing the device.

NOTE

The following needleless devices have been tested with the One•Step KVO with Y-Site; Baxter Interlink®, ICU Medical Inc. Clave™ and the B. Braun Medical, Inc. SafeSite®. Follow the manufacturer's recommendations for their use.

Do not fill this device with fluids that are incompatible with the intermittent (piggyback) line medication.

Use Aseptic Technique

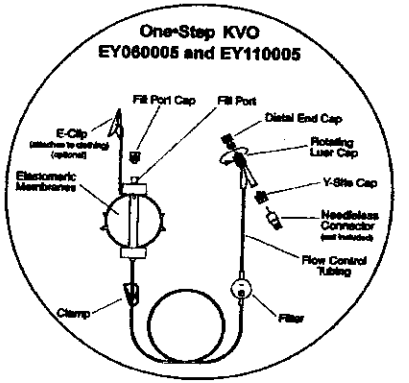
Do not remove from package until ready to use.

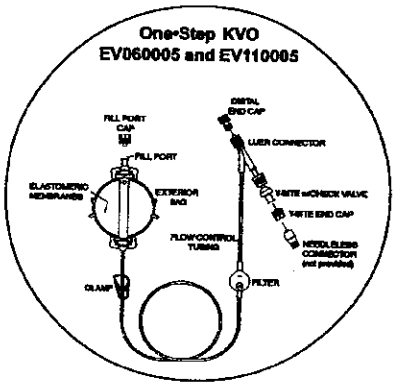
INFUSION INSTRUCTIONS

1. Allow the One•Step KVO to reach room temperature before using. For guidelines refer to the table on the back page.
2. Verify that the tubing clamp is closed.
3. If the tubing and Y-Site need to be primed, open the clamp and loosen the distal end cap of the Y-Site to allow air to escape.
   Note: The device will prime slowly.
4. To expedite priming the Y-Site, remove the Y-Site cap, then flush the Y-Site with a saline filled syringe or other filling device.
5. Replace the Y-Site cap, or attach a needleless connector or an injection port to the Y-Site.
6. Following your institutional protocol, check the patency of the IV access device. Do NOT attach the One•Step KVO if the IV catheter is NOT patent.
7. Connect the rotating distal Luer connector to the patient's IV access device. Position the Y-Site connector as necessary, then tighten the rotating Luer connector until it is secure.
   Note: The rotating Luer connector must be securely tightened to prevent leakage or disconnection from the IV access device.
8. Begin the infusion by opening the clamp — fluid delivery will start immediately. If the tubing is partially kinked, massage the tubing to promote flow.
   Note: The One•Step KVO can be attached to the patient's clothing using an E-Clip (optional) or carried in the Carrying Pouch (optional) to assist in patient mobility.
9. When the elastomeric membrane is no longer extended, the infusion is complete. Approximately 10 ml of fluid may remain in the membrane. Disconnect and dispose of the One•Step KVO according to your institution's protocol.

Medication Administration through the Y-Site of the One•Step KVO

1. To infuse medication, cleanse the injection site according to your institution's protocol.
2. Connect the intermittent ("piggyback") medication line to the Y-Site connector using aseptic technique. Begin the intermittent infusion.
   Note: Do not close the tubing clamp on the One•Step KVO.
3. When the medication infusion is complete, close the clamp on the intermittent medication line and disconnect from the Y-Site following your institution's protocol.
4. The One•Step KVO should remain connected to the IV access device until the One•Step KVO infusion is complete, or the IV therapy is discontinued.





Infusion delivery times for the One•Step KVO elastomeric infusion device are influenced by environmental conditions. The information below is provided to assist the healthcare provider in understanding these factors.

1. The One•Step KVO can be filled with normal saline and stored for up to 8 weeks. However, storage of a filled One•Step KVO unit for more than 8 hours prior to starting infusion may result in a longer delivery time. Storage conditions other than the specified usage condition may affect delivery time.
2. Each One•Step KVO is designed for the infusion tubing to be worn under the clothing, while the fluid reservoir can be worn in the manner most comfortable for the patient. The tubing below the filter should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect the solution viscosity, resulting in a shorter or longer delivery time. If the One•Step KVO is used with the flow control tubing at room temperature (20°C/68°F), delivery time will be approximately 25% longer.
3. The flow rate of 0.5 ml/hr may be decreased by infusion of more viscous fluids. Use of D5W will decrease the flow rate by approximately 8%.
4. If the One•Step KVO is filled with more than the nominal volume it will infuse at a lower than nominal flow rate. A One•Step KVO filled with less than the nominal volume will infuse at a higher than nominal flow rate. Refer to the fill table on the back page for appropriate fill volumes.
5. After priming the tubing set of the One•Step KVO, ensure that the distal end cap and Y-Site cap are tightened securely to prevent fluid evaporation and occlusion of the flow control tubing.
6. Check for any tubing occlusion at the clamp site. After opening the clamp, if the tubing is partially kinked, squeeze the tubing to facilitate flow.
7. Use extra care when handling frozen units.

161

Easypump®
BOLUS ACCESSORY SET

Easypump®
SYSTÈME DE TUBULURE DE BOLUS ACCESSOIRE

Easypump®
BOLUS-ZUBEHÖRSET

Easypump®
EQUIPO ACCESORIO PARA INYECCIÓN EN EMBOLADA

Easypump®
SET ACCESSORIO PER LA SOMMINISTRAZIONE DI BOLO

Easypump®
SET VOOR BOLUSTOEDIENING

Easypump®
CONJUNTO DE ACESSÓRIOS PARA BÓLUS

Easypump®
BOLUSTILLBEHÖRSSET

Easypump®
BOLUS AKSESUAR SETİ

便携式输液泵
大剂量输液附件套装

Imported and Distributed by:

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B. Braun Medical
204 avenue du Maréchal Juin
92107 Boulogne Cedex - France

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE 0123

European Representative:
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Borngasse 20, 35619 Braunfels
Germany

182

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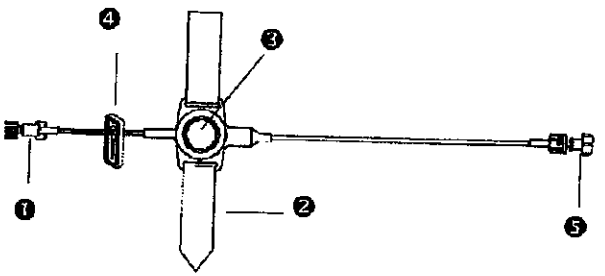

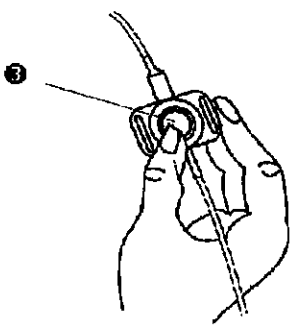

ENGLISH

DIRECTIONS FOR USE
Easypump Bolus Accessory Set

NOMENCLATURE AND ILLUSTRATION (see page 4):

1. Female Luer (connects to infusion pump) ❶
2. Wrist Strap ❷
3. Bolus Button ❸
4. Clamp ❹
5. Distal End Cap ❺

INDICATIONS FOR USE

The Easypump Bolus Accessory Set, in combination with a positive pressure, continuous flow infusion pump, is intended to allow the patient or healthcare provider controlled bolus delivery on demand. Refer to the infusion pump Directions for Use for additional instructions.

The Easypump Bolus Accessory Set is sterile and non-pyrogenic. Do not reuse, resterilize, or refill.

CAUTIONS

- Do not use if package has been opened or is damaged or if either protector cap is not in place.
- If the device is to be used for epidural analgesic drug administration, it should be labeled to differentiate from other routes of administration.
- The Bolus Accessory Set does not provide basal flow rate. It should be used in conjunction with another infusion line providing a continuous delivery when required to keep the IV line patent.
- It is recommended that the Easypump Bolus Accessory Set be changed in accordance with established guidelines.
- Do not remove from package until ready for use.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Store protected from light at room temperature: 10°-40°C, 10-90% relative humidity.
- This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the Easypump Bolus Accessory Set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

CONTRAINDICATIONS

1. Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic drug delivery. Do not use Y adapter with epidural delivery.
2. This product is not intended for the delivery of blood, blood products, lipids, fat emulsions, or TPN.

THE EASYPUMP BOLUS ACCESSORY SET

The Easypump Bolus Accessory Set is designed to allow the patient or healthcare provider to administer a 0.5 ml bolus on demand. The refill time for the bolus depends on the flow rate of the infusion pump to which the Easypump Bolus Accessory Set is attached. See Table 1 for specific refill times.

Table 1

Flow Rate	Bolus Refill Time
0.5 ml/hr	70.0 min.
1.0 ml/hr	35.0 min.
2.0 ml/hr	18.0 min.
5.0 ml/hr	7.2 min.
10.0 ml/hr	3.6 min.

NOTES

1. Actual refill times may vary from the specified range due to:
   - viscosity and/or drug concentration.
   - temperatures above or below the operating conditions.
   - the positioning of the attached infusion pump above or below the infusion site.
   - delivery pressure of the attached pump.
2. Designed for use with positive pressure continuous flow infusion pumps with delivery pressures in the range of 8-18 psi.

PRIMING THE EASYPUMP BOLUS ACCESSORY SET

Method 1:

1. Prime the infusion pump first.
2. Attach the Easypump Bolus Accessory Set to the infusion pump. Slide clamp to open position.
3. Using aseptic technique, remove the distal end cap from the Easypump Bolus Accessory Set. Do not discard cap. Open the clamp on the infusion pump tubing. The medication will flow into the bolus chamber on the Easypump Bolus Accessory Set.
4. When the Bolus button has filled (button rises to top of housing), press the Bolus button to prime. Repeat until air is purged downstream from the bolus housing, which may take several pushes.
5. Close the infusion pump clamp and replace distal end cap.

Method 2:

1. Prime infusion pump first.
2. Using aseptic technique, remove distal end cap from the Easypump Bolus Accessory Set. Do not discard cap.
3. Remove cap from female Luer and attach syringe with a minimum of 2 ml of solution or diluent.
4. Slide clamp to open position.
5. Inject solution until button rises to the top of the housing.

ENGLISH

6. Slide clamp to closed position and depress bolus button to expel air from line.
7. Repeat Steps 4 - 6 until air is purged.
8. Slide clamp to open position and refill bolus reservoir from syringe.
9. Slide clamp to closed position, remove syringe and attach to the infusion pump. Slide clamp back to open position.
10. If diluent is used to prime the Easypump Bolus Accessory Set, be sure to expel the first bolus and allow to refill from infusion pump.
11. Replace distal end cap.

CHANGING INFUSION PUMP

1. If changing the infusion pump, first prime the new infusion pump.
2. Slide clamp to closed position on Easypump Bolus Accessory Set.
3. Detach old infusion pump and connect new infusion pump.
4. Slide clamp to open position on Easypump Bolus Accessory Set.

STARTING THE INFUSION

1. Attach the Easypump Bolus Accessory Set to the infusion site. Secure the bolus housing against the skin, using either the strap provided or tape.
2. Open the clamp on the infusion pump. A bolus can be delivered immediately.

BOLUS ACTIVATION

1. To receive a bolus of medication, press firmly down on the bolus button until it stops.
2. At any time during the infusion, the bolus button can be pushed to deliver a bolus of medication.
3. The next full bolus will be available after the refill time noted in Table 1.
4. Pressing the bolus button prior to the end of the refill time will result in a partial bolus dose.

The Easypump Bolus Accessory Set Specifications

Bolus Volume: 0.5 ml

Refill Time: 3.6 min. - 70 min., depending on the rate of the attached infusion pump.

Accuracy: Bolus Volume: ±10% at 95% confidence interval at the identified refill time.

Priming volume: Allow 1.5 ml for drug loss during priming.

Residual volume: Approximately 0.5 ml (accessory only; does not include infusion pump).

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

U.S. Patent # 5,900,597

ON-Q PainBuster® Redefining Recovery™

ON-Q C-bloc® Redefining Recovery™

For Customer Service please call:

(800) 448-3569

(949) 206-2700

Visit www.iflo.com for the latest product information and Technical Bulletins.

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167

Rx only

DO NOT USE IF PACKAGE HAS BEEN OPENED, IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.

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3/2006

ON-Q Pump Directions for Use

READ FIRST

ON-Q PainBuster® Redefining Recovery™

ON-Q C-bloc® Redefining Recovery™

Refer to ON-Q Pump Insert for Model Specific Information

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U.S.A.

I-FLOW®

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Germany

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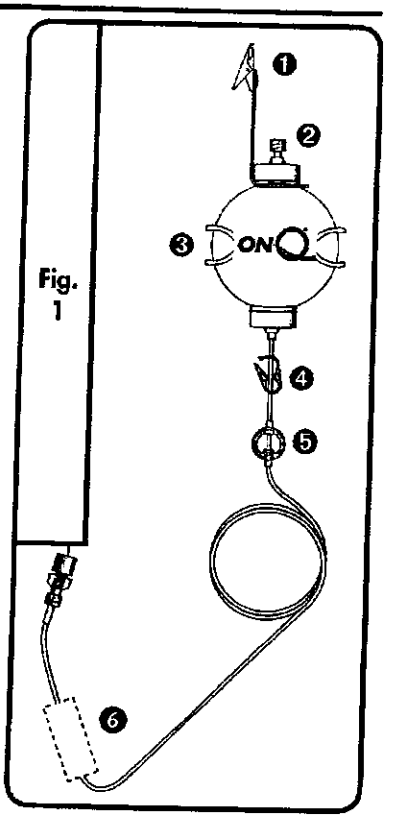
ON-Q Pump Directions for Use

ILLUSTRATION AND NOMENCLATURE

Figure 1

1. E-Clip
2. Fill Port
3. ON-Q Pump
4. Clamp
5. Filter
6. Flow Controller (see Pump Insert)



INDICATIONS FOR USE

- The ON-Q pump is indicated to provide delivery of medication (such as local anesthesics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative & postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, perineural, percutaneous and epidural.
- ON-Q is indicated to significantly decrease pain and narcotic use when compared to narcotic only pain management.
- ON-Q is sterile, non-pyrogenic and single use only.
- Storage conditions: protect from sunlight, 10°– 40° C, 10–90% relative humidity.

CAUTIONS

- Do not use if package is open, damaged or a protector cap is missing.
- Do not resterilize, refill, reuse or exceed maximum fill volume of pump.

WARNINGS

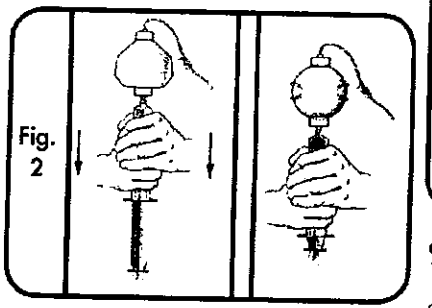
- Vasoconstrictors such as Epinephrine are not recommended for continuous infusions.
- Medications must be administered per instructions provided by drug manufacturer.
- Limit volumes, flow rates and tight dressings, particularly with hand or foot surgery, to avoid fluid build up in restricted spaces that may lead to wound complications (e.g. necrosis).
- Epidural infusion of analgesics is limited to uses of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.

CONTRAINDICATIONS

- ON-Q is not intended for blood, blood products, lipids, fat emulsion or intravascular delivery.

DIRECTIONS FOR USE

Use Aseptic Technique



FILLING THE ON-Q PAINBUSTER PUMP

Figure 2

- Close clamp.
- Un-cap the fill port.
- Attach filled syringe to fill port. Invert pump as shown. Grasp syringe with both hands. Push down on plunger continuously until volume is dispensed. Do not handle pump while filling, as the syringe tip may break. Repeat as necessary.
  Note: Filling Extension Sets are provided with 400 ml pumps (see product insert).
- Do not fill less than minimum or exceed maximum fill volume. See ON-Q Pump Insert for model specific information on fill volumes.
- Replace fill port cap. Label with the appropriate pharmaceutical and patient information.
  Note: The ON-Q contains either an E-Clip or Carry Case for holding the pump. If using the E-Clip, attach to top of pump.

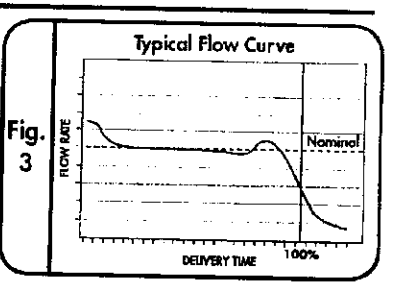
PRIMING THE ADMINISTRATION SET

Refer to ON-Q Pump Insert for model specific information for priming the administration set, starting the infusion, and Flow Controller information.

END OF INFUSION

Figure 3

- Infusion is complete when pump is no longer inflated. Dispose of pump according to your institution's protocol.



CAUTIONS

1. The nominal infusion rate and fill volume for each pump is labeled on the fill port.
2. Actual infusion times may vary due to:
   - Filling the pump less than nominal results in faster flow rate.
   - Filling the pump greater than nominal results in slower flow rate.
   - Viscosity and/or drug concentration.
   - Positioning the pump above (increases flow rate) or below (decreases flow rate) the catheter site.
   - Temperature: Refer to ON-Q Pump Insert for model specific information on temperature.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
4. If refrigerated, allow pump to warm to room temperature before using.
5. Start delivery within 8 hours of filling. Storage of a filled ON-Q pump for more than 8 hours prior to starting infusion may result in a slower flow rate.
6. Avoid contact of cleansing agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
7. Roll tubing between fingers to promote flow if clamped for extended time.

NOTE

Latex is not in fluid pathway or in contact with human. Technical Bulletin available upon request.

ON-Q Pump Insert (model specific information)

ON-Q PainBuster® Redefining Recovery™ ON-Q C-bloc® Redefining Recovery™ www.iflo.com

IMPORTANT Start by reading the ON-Q Pump Instructions For Use, then continue with this document

ILLUSTRATION AND NOMENCLATURE
Figure 1

1. E-Clip
2. Fill Port
3. ON-Q Pump
4. Clamp
5. Filter
6. Flow Controller (tape to skin)

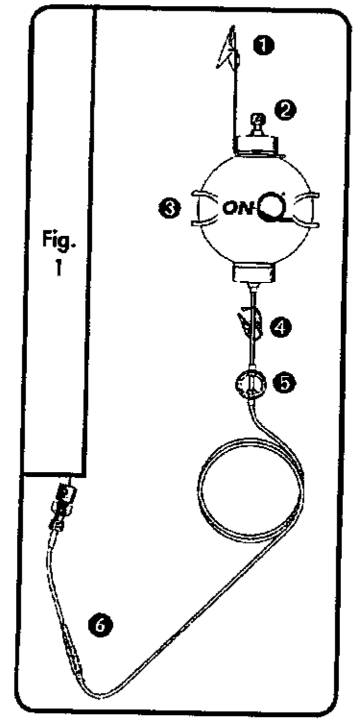


Fig. 1

PRIMING THE ADMINISTRATION SET

- Open clamp.
- Remove tubing cap to prime pump (up to 15 minutes). When tubing is fully primed, close clamp and replace tubing cap until ready for use.

STARTING THE INFUSION

- Connect catheter to pump tubing. Open clamp to begin infusion.
- Tape Flow Controller to skin to ensure flow rate accuracy. Avoid contact with cold therapy. Do not tape over filter.

CAUTION

- Temperature: The ON-Q Flow Controller should be in direct contact with the skin (88°F/31°C). Temperature will affect solution viscosity, resulting in faster or slower flow rate. If ON-Q is used with the Flow Controller at room temperature (68°F/20°C), flow rate may decrease by approximately 25%.

See Table 1 on back for Flow Rate Accuracy and Delivery Time information.

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Borngasse 20, 35619 Braunfels
Germany

CAUTION: Do not fill less than minimum or exceed maximum fill volume (see below).

TABLE 1 *– Delivery Time Information*

PRODUCT INFORMATION											
ml x ml/hr		65 x 0.5	100 x 1	100 x 2	100 x 2D	270 x 2	270 x 5	270 x 4D	400 x 5	400 x 10	400 x 4D	400 x 6T
Nominal Flow Rate (ml/hr)		0.5	1	2	2 (1 per site)	2	5	4 (2 per site)	5	10	4 (2 per site)	6 (2 per site)
Nominal Fill Vol. (ml)		65	100	100	100	270	270	270	400	400	400	400
Maximum Fill Vol. (ml)		65	125	125	125	335	335	335	550	550	550	550
Retained Vol. (ml)		≤ 3	≤ 4	≤ 4	≤ 4	≤ 9	≤ 9	≤ 9	≤ 15	≤ 15	≤ 15	≤ 15
Refrigerator to Room Temp (hr)		6	6	6	6	10	10	10	12	12	12	12
APPROXIMATE DELIVERY TIME		FILL VOLUME (ml)										
24 hrs	1 day			65	65							
36 hrs	1.5 days			80	80					370		
48 hrs	2 days		60	100	100		255	215		460		
60 hrs	2.5 days		70	125	125		290	250				
72 hrs	3 days	45	80			175	330	290				430
84 hrs	3.5 days	50	90			195		325	420		340	
96 hrs	4 days	55	100			215			475		380	540
120 hrs	5 days	65	120			250					450	

When filled to nominal volume, flow rate accuracy is ±15% of the labeled infusion rate when infusion is started 0-8 hrs after fill and delivering nominal saline as the diluent at 88°F (31°C) against a back pressure of 40 cm of water.

CAUTION: Filling the pump less than nominal, increases flow rate. Filling the pump greater than nominal, decreases flow rate.

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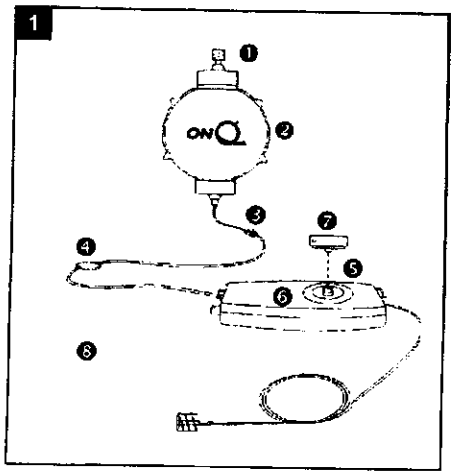
ON-Q PUMP INSERT (MODEL SPECIFIC INFORMATION)

ON-Q

with

Select-A-Flow®



ON-Q WITH *Select-A-Flow*

1. Fill Port
2. Elastomeric Infusion Pump
3. Clamp
4. Air-Eliminating Filter
5. *Select-A-Flow* Variable Rate Controller
6. Flow Rate Dial
7. Rate-Changing Key
8. Lockable Cover

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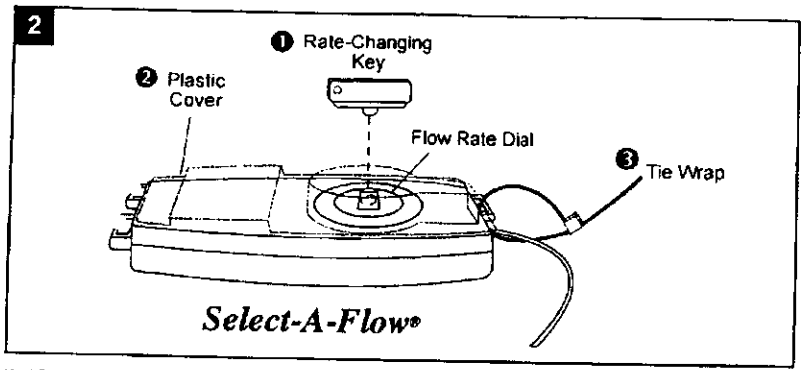

IMPORTANT. Start by reading the ON-Q Pump Directions For Use, then continue with this document.

Select-A-Flow DESCRIPTION

ON-Q with *Select-A-Flow* incorporates a controller that allows the user to adjust the infusion rate by turning the rate-changing key on the device. The flow rate is within a predetermined range and is designated on each device.

NOTE: For models including bolus delivery, see important information in the **ONDEMAND** product insert for bolus delivery.

TO DISCOURAGE TAMPERING: See Figure 2

1. To discourage tampering, remove the rate-changing key from the dial by pulling the key straight out. Put the key in a safe place for later use, e.g., attached to a key ring.
2. Close the cover over the *Select-A-Flow* Variable Rate Controller.
3. For increased tamper resistance, the cover may be locked to the *Select-A-Flow* Variable Rate Controller using the tie wrap.

   NOTE: If desired, the cover may also be removed from the *Select-A-Flow* by fully opening the cover and then pulling straight up on the plastic feet at the bottom of the cover.

CAUTIONS

The amount of medication over the therapeutic period and delivery time can vary by as much as 20% due to the flow rate variation. Please take this variance into consideration when determining medication delivery to reduce potential adverse effects.

1. Do not underfill. Underfilling the pump may significantly increase the flow rate
2. Do not exceed maximum fill volume of the pump (see Table 1).
3. The *Select-A-Flow* should be worn outside clothing and kept at room temperature

WARNING
Flow rate is adjustable. To reduce potential adverse effects, medication dosing should be based on this maximum flow rate. Flow rate may vary +/- 20%

PRIMING THE *Select-A-Flow* ADMINISTRATION SET

Use Aseptic Technique

NOTE: For models including bolus delivery, follow the priming instructions in the **ONDEMAND** product insert instead of this section.

1. Verify clamp is closed.
2. Open plastic cover. Ensure dial on face of device is at highest flow rate setting to minimize priming time. Make sure you feel or hear the dial "click" into place and selected flow rate is aligned below the ml/hr mark on the *Select-A-Flow*.
3. Open clamp and remove the tubing cap.
4. When air has been removed from the tubing and fluid is observed at the end of the luer lock, turn the dial to the Ø, off position, and replace the cap on the end of the tubing until ready for use. **CAUTION:** Make sure the dial is in the Ø, off position, or the clamp is closed.

STARTING THE INFUSION

1. Connect tubing to patient's catheter. Make sure the connection is secure
2. Select the appropriate flow rate by turning the dial on the *Select-A-Flow* until the dial clicks into place, and the flow rate setting is aligned with the ml/hr mark on the face of the *Select-A-Flow*. Open clamp.
   CAUTION: Dial must "click" into place to ensure accurate flow rate. Flow rate is unpredictable if it is dialed between rate settings.

CHANGING THE FLOW RATE DURING AN INFUSION

1. Insert the rate-changing key into the dial.
2. Turn the dial until the new flow rate is selected. Make sure you hear the dial "click" into place and the selected flow rate is aligned below the ml/hr mark on the *Select-A-Flow*.
3. Remove the key from the dial and put in a safe place for later use.

CAUTIONS:

1. Do not underfill pump. Underfilling the pump may significantly increase the flow rate
   - Filling the pump less than nominal results in faster flow rate.
   - Filling the pump greater than nominal results in slower flow rate.
   - Temperature will affect solution viscosity, resulting in faster or slower flow rate. The ON-Q *Select-A-Flow* has been calibrated using Normal Saline (NS) as the diluent and room temperature (22°C, 72°F) as the operating environment. The *Select-A-Flow* should be worn outside clothing and kept at room temperature.

Table 1

Nominal Fill Volume (ml)	270	400	600
Maximum Fill Volume (ml)	335	550	750
Retained Volume (ml)	≤8	≤15	≤22
Refrigerator to Room Temp (hr)	10	12	15

Select-A-Flow models are color-coded.

GREEN:
1, 2, 3, 4, 5, 6, 7 ml/hr

WHITE:
2, 4, 6, 8, 10, 12, 14 ml/hr

Delivery Accuracy: When filled to nominal volume, flow accuracy is ± 20% of the labeled flow rate when infusion is started 0-8 hours after fill and delivering normal saline as the diluent at 22°C, 72°F.

NOTE: For models including bolus delivery, see **ONDEMAND** product insert for bolus information.

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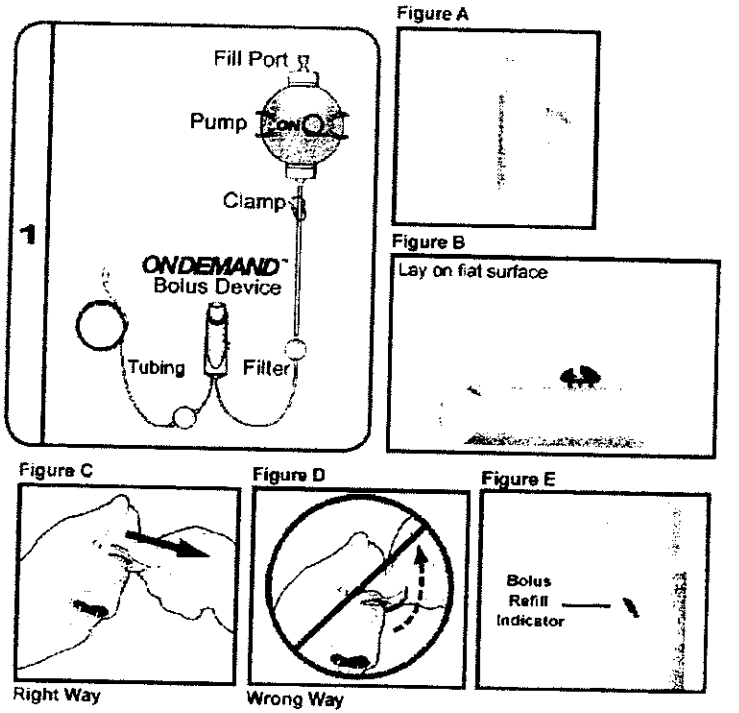
ON-Q PUMP INSERT (MODEL SPECIFIC INFORMATION)

ON-Q with ONDEMAND™



I-Flow Corporation
Lake Forest, CA 92630
U.S.A

I·FLOW

CE 0123

MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

IMPORTANT: Start by reading the ON-Q Pump Directions For Use, then continue with this document.

ONDEMAND DESCRIPTION

ON-Q with ONDEMAND incorporates a bolus device. The ONDEMAND delivers a continuous infusion (basal) and allows fixed boluses to be delivered on demand by the patient or health care provider.

NOTE: For models including Select-A-Flow, see important information in the Select-A-Flow product insert for setting the basal flow rate.

CAUTIONS:

- Do not underfill the pump. Underfilling the pump may significantly increase the flow rate.
- Do not remove the red holding tab until the tubing is completely primed. Up to a 5 ml bolus of air may be delivered if not primed correctly.

WARNING: To reduce potential adverse effects, medication dosing should be based on the maximum flow rate, bolus + basal (see Table 2 below).
1. Red tab must be removed before use. If red tab is not removed before use or breaks while removing, bolus button will not work resulting in maximum flow rate.
2. If the bolus button does not pop back up within 30 minutes after delivering a bolus, then something may be impeding the flow or the button may be stuck which could result in maximum flow rate.

Delivery Time Information for the ON-Q with ONDEMAND

Table 1

Nominal Fill Vol	Maximum Fill Vol	Retained Vol
270 ml	335 ml	< 9 ml
400 ml	550 ml	< 15 ml
600 ml	750 ml	< 22 ml

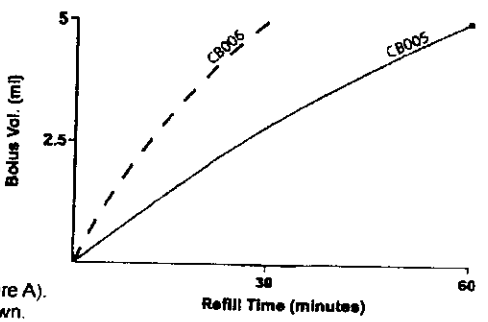
Table 2

Bolus Dose	Refill Time	Maximum Flow Rate
5 ml	30 min	10 ml/hr + Basal Rate
5 ml	60 min	5 ml/hr + Basal Rate

When filled to nominal volume, accuracy is ±15% (except bolus dose +10/-20%) of the labeled rates when infusion is started 0-8 hours after fill when delivering normal saline at 72°F (22°C).
NOTE: For models including Select-A-Flow, see Select-A-Flow product insert for basal flow rate accuracy information.

ONDEMAND™ Refill Chart

Refill time is approximately linear.



PRIMING ONDEMAND DEVICE

Use Aseptic Technique

1. Depress ONDEMAND button until it latches in the down position (Figure A). Button will click and stay locked down.
   NOTE: For models including Select-A-Flow, there are two channels to prime. The ONDEMAND is primed first followed by the Select-A-Flow. To begin priming ONDEMAND channel, set Select-A-Flow dial to Ø, off position. Be sure dial "clicks" into place.
2. Lay ONDEMAND device on flat surface with red tab label side up. (Figure B).
3. Open clamp and remove tubing cap to begin priming. Do not discard tubing cap.
   NOTE: For models including Select-A-Flow, when all air is removed from the ONDEMAND and fluid is observed at the luer lock (approximately 4 minutes), the ONDEMAND channel is primed. To begin priming the Select-A-Flow, set dial to highest flow rate setting.
4. When all air has been removed from the entire tubing and fluid is observed at end of luer lock, replace tubing cap until ready for use.
   NOTE: For models including Select-A-Flow, set the Select-A-Flow dial back to Ø, off position until ready for use.
5. Remove the red holding tab by pulling straight out. (Figure C) It is important to remove red tab completely and ensure it does not break. (Figure D inset) The ONDEMAND button will return to its upper most position allowing the bolus device to fill.
   WARNING: Do not pull the red tab upwards as breakage could occcur (Figure D). Do not use if red tab breaks inside unit as maximum flow rate (basal + bolus) can occur.
6. The pump is now ready to use, however a complete bolus dose won't be available until the labeled refill time has elapsed. The orange bolus refill indicator will be at the top level. (Figure E)

STARTING INFUSION

1. Connect tubing to patient's catheter. Make sure connection is secure and clamp is open.
   NOTE: For models including Select-A-Flow, see Select-A-Flow Product Insert for starting infusion and changing the flow rate.
2. The patient or clinician should give a bolus as soon as possible after the infusion has started to ensure the bolus device is working properly. The bolus button should pop up within a few minutes and the orange indicator should be at the bottom level.

BOLUS ACTIVATION

1. Press down on button until it locks into place. (Figure A).
2. Bolus will be delivered and ONDEMAND will begin to refill.
3. The orange indicator shows how much medication is in the bolus device. (Figure E).
4. The next full bolus will be available when orange indicator is at the top level.
5. Pressing the bolus button prior to the end of the refill time will result in a partial bolus dose.
   WARNING: If the button does not pop back up within 30 minutes, then:
   1. Something may be impeding the flow. Check for tubing kinks, closed clamp or patency of connected devices such as catheter or unvented filter (verify patency) according to your standard protocol.
   or
   2. The button may be stuck which could result in maximum delivery (bolus + basal) to the patient. Instruct patient to close the clamp. Pump should be replaced if appropriate.

CAUTIONS:

Do not underfill pump. Underfilling the pump may significantly increase flow rate.

- Filling the pump less than nominal results in faster flow rate.
- Filling the pump greater than nominal results in slower flow rate.
- Temperature will affect solution viscosity, resulting in faster or slower flow rate. ONDEMAND has been calibrated using Normal Saline (NS) as the diluent and room temperature (22° C, 72° F) as the operating environment. The ONDEMAND should be worn outside clothing and kept at room temperature.

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U.S Patents: 6,936,035; 6,981,987.
U.S and Foreign Patents Pending.

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PB100100 PB100100-S

ON-Q PainBuster® Redefining Recovery™ Bolus

Rawal Pain Relief System
Rawal-smärtbehandlingssystem

I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

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Germany

ENGLISH SVENSKA

ON-Q PainBuster Redefining Recovery™ Bolus

Rawal Pain Relief System

Rawal-smärtbehandlingssystem

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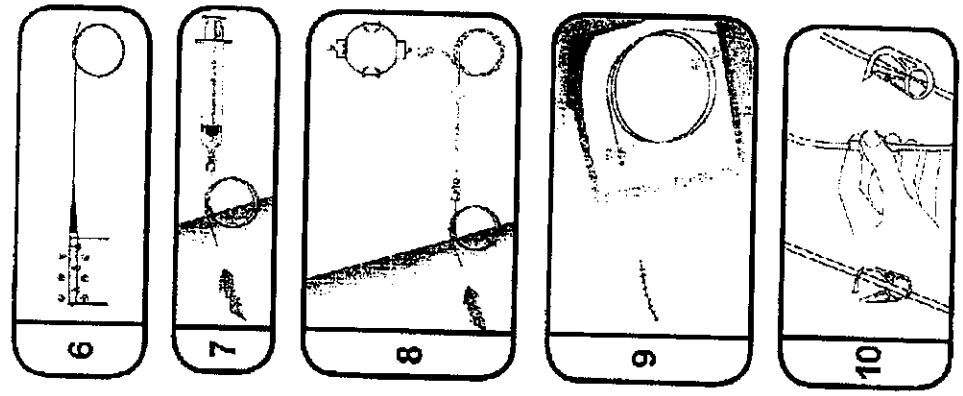

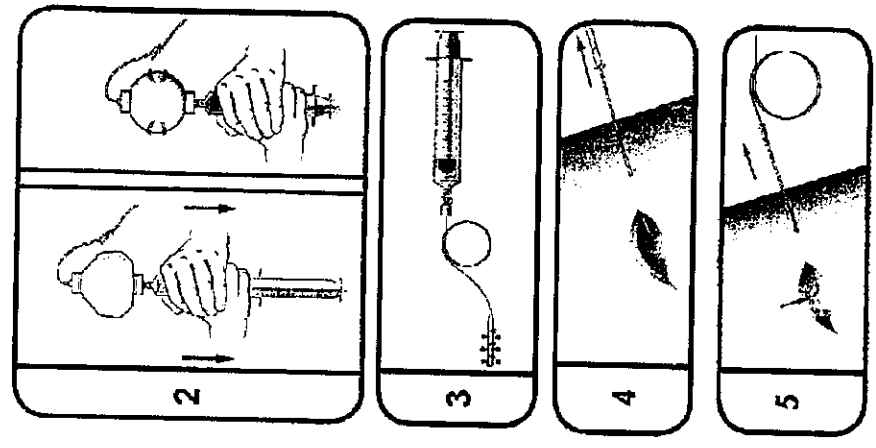

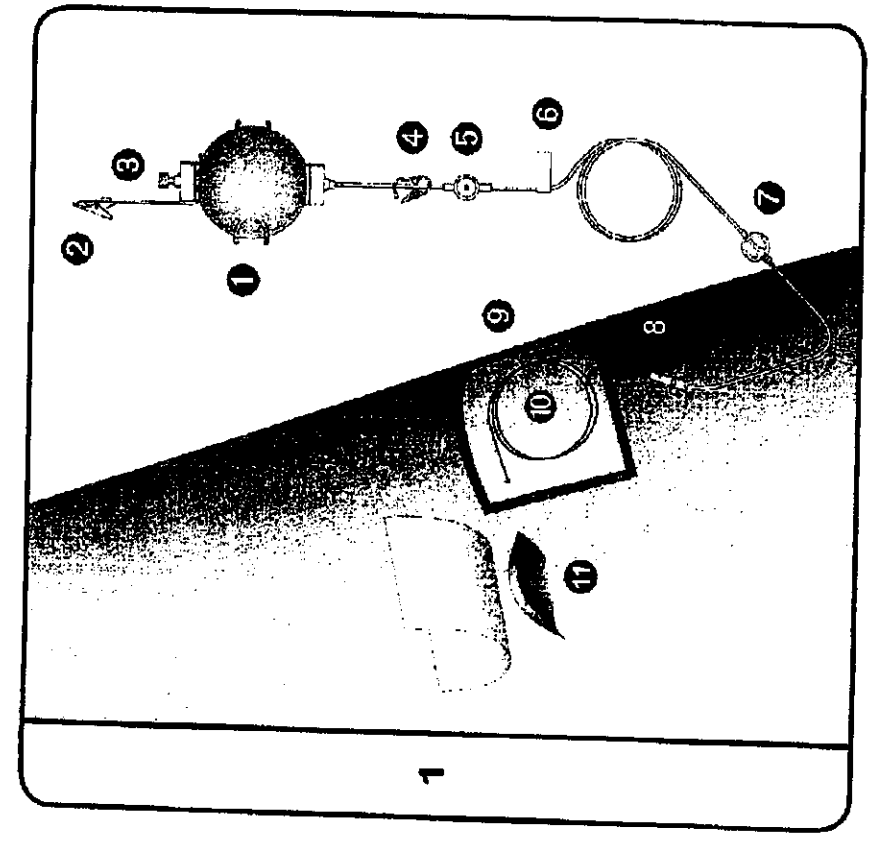

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ILLUSTRATION AND NOMENCLATURE

Figure 1 on page 4:

❶	Pump	❼	Filter
❷	E-Clip	❽	Connector
❸	Fill Port	❾	Dressing (not included)
❹	Clamp	❿	Catheter
❺	Bolus Button	⓫	Surgical Wound Site
❻	Bolus Label		

INDICATIONS FOR USE

The ON-Q PainBuster Bolus Rawal Pain Relief System is intended for providing boluses of medication upon demand by the patient or healthcare provider to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, perineural or percutaneous.

PainBuster is indicated to significantly decrease pain and narcotic use when compared to narcotic-only pain management.

⚠ **THE ONLY FLOW RESTRICTOR IS THE CATHETER PROVIDED. DO NOT USE ANY OTHER CATHETER OR BOLUS VOLUME MAY VARY SIGNIFICANTLY.**

DO NOT USE IF PACKAGE HAS BEEN OPENED, IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.

THE ON-Q PAINBUSTER BOLUS SYSTEM IS STERILE, NON-PYROGENIC, AND SINGLE USE ONLY. DO NOT RESTERILIZE, REUSE OR REFILL. THERE IS NO LATEX IN THE FLUID PATHWAY OR IN CONTACT WITH HUMANS. Technical Bulletin available upon request.

CAUTIONS

- Underfilling the pump is not recommended. Underfilling the pump can significantly increase the flow rate.
- Do not exceed maximum fill volume of pump.
- Vasoconstrictors, such as epinephrine or adrenaline are not necessary and may not be recommended for continuous infusions.
- Use only smooth-edged atraumatic clamps or forceps.
- Do not withdraw catheter through needle because of the possible danger of shearing.
- Medications used with system should be administered in accordance with instructions provided by the drug manufacturer.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.
- Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- The PainBuster pump should be stored at 10-40°C, 10-90% relative humidity and out of sunlight.

ENGLISH

WARNINGS

- The only flow restrictor is the catheter provided. Do not use any other catheter or bolus volume may vary significantly.
- Caution should be used when selecting appropriate bolus dosing keeping in mind potential fluid build up in a restricted space that may lead to complications, particularly with hand and/or foot surgery. We do not recommend incision site catheter placement near distal extremeties such as fingers or toes.
- Do not trim catheter as this will increase the volume of the bolus delivered.
- Do not suture catheter. Check distal end of the catheter for black marking to assure the entire catheter was removed.
- It is recommended that the catheter be placed under direct visualization to ensure proper placement.
- Do not use if any part of the product leaks.
- Assure that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended. Refer to the drug manufacturer's package insert.
- The device does not contain a bolus limit. Maximum bolus volume equals the pump volume. (e.g., if filled to 100 ml, entire amount will infuse in approximately 8 minutes if the button is depressed for that time).

  NOTE: It is normal for some fluid to exit the catheter insertion site.

CONTRAINDICATIONS

- The PainBuster Bolus system is not intended for intravenous, intra-arterial or epidural drug delivery.
- The PainBuster Bolus system is not intended for the delivery of blood, blood products, lipids, fat emulsions or TPN.

SUGGESTED CATHETER MAINTENANCE

The catheter should be maintained in accordance with standard hospital protocols.

DIRECTIONS FOR USE - USE ASEPTIC TECHNIQUE

Figure 2 on page 5 - FILLING THE PUMP

- Close clamp on tubing.
- Remove protective cap from fill port.
- Do not discard cap.
- Attach the fill port to the filled syringe and invert pump as shown. Firmly grasp the syringe with both hands and push down on the plunger continuously until the volume is dispensed. Do not push down on the pump while filling, as the syringe tip may break. Repeat as necessary.
- Do not exceed maximum fill volume (See Table 1).

- To prime, open the clamp, remove the distal end cap and depress bolus button until priming is complete.
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.
- Open the clamp and remove the distal end cap to prime the pump (up to 15 minutes). Allow the medication to fill the entire tubing and luer connector. When all air has been removed from the tubing and connector close the clamp until ready to use.

Figure 3 on page 5 - PRIMING THE CATHETER

1. Proper priming of the catheter and pump tubing is important.
2. Attach a syringe filled with medication to the catheter connector. Slowly prime the catheter until medication infuses out along the length of the catheter. Make sure no air is trapped in the catheter.

PLACING THE CATHETER

1. Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site. **Note:** There is no needle included in the PB100100-S kit.
2. Remove the needle from the introducer.

Figure 5 on page 6

3. Insert the marked end of the catheter through the hub of the introducer into the wound site.
4. Place the catheter within wound site to desired position. Ensure that entire infusion segment is within wound site.

Figure 4 on page 5

5. While holding catheter tip withdraw T-handle from puncture site and split the introducer sheath and peel it away from the catheter.

CAUTION: Completely remove the T-handle sheath from the body before peeling away from the catheter.

WARNINGS:

- Assure that the catheter tip is not in a vein or artery. Do not suture catheter.
- Assure that the catheter is not in a vein or artery.

WARNING: Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended - refer to the drug manufacturer's package insert.

NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement to ensure that occlusion will not occur during use and that catheter removal will not be impeded.

Figure 6 on page 5

6. Drug infusion occurs between catheter marking and marked tip (see Table 2).

Figure 7 on page 5

7. Attach syringe to catheter connector and prime catheter.

Figure 8 on page 5

8. Attach the catheter connector to the pump tubing. Open the pump clamp to begin infusion.

Figure 9 on page 5

9. Secure catheter by coiling close to the insertion site and apply adhesive skin closure strips (not included).
10. Apply occlusive dressing (not included) over insertion site and coiled catheter, keeping separate from wound site. Do not cover filter.

Figure 10 on page 5 - BOLUS ACTIVATION

1. Open clamp.
2. Fully depress bolus button for time required for desired bolus volume (see Table 1).
3. Release button.
4. Close clamp
5. When pump is empty (no longer inflated) boluses are no longer available.

REMOVING THE CATHETER

- Infusion is complete when the PainBuster Pump is no longer inflated.
- Dispose of system in an appropriate manner according to your institution's protocol.

WARNING:

The device does not contain a bolus limit. Maximum bolus volume equals the pump volume (e.g., if filled to 100 ml, entire amount will infuse in approximately 8 minutes if the button is depressed for that time).

Notes: The system may contain an E-Clip. If using the E-Clip, attach to top of pump. Secure the pump with the E-Clip.

INFUSION COMPLETE

WARNING: If the patient is removing the catheter, it is the responsibility of the healthcare provider to inform the patient of the following catheter removal instructions:

1. Remove the dressing covering and loosen adhesive closure strips at the catheter site.
2. Grasp the catheter close to the skin and gently pull catheter to remove. The catheter should be easy to remove. Do not tug or quickly pull on the catheter during removal.

CAUTIONS

- If resistance is encountered or the catheter stretches, STOP. It is advisable to wait 30–60 minutes and try again. The patient's body movements may relieve the catheter to allow easier removal.
- If catheter is still difficult to remove, an X-ray is recommended.
- Do not cut or forcefully remove the catheter.
- Do not apply additional tension if the catheter begins to stretch.
- After removal, check the distal end of the catheter for both black markings to ensure the entire catheter was removed.

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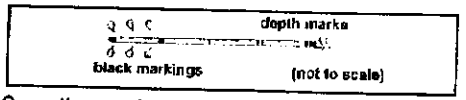

3. Cover the puncture site with an appropiate dressing.

PATIENT EDUCATION

It is the responsibility of the physician to educate the patient to immediately report any of the following symptoms to his/her healthcare provider:*(close clamp on pump tubing to stop infusion)*

- Increase in pain
- Redness, swelling, pain and/or discharge at the catheter site
- Dizziness, light-headedness
- Blurred vision
- Ringing, buzzing in ears
- Metal taste in mouth
- Numbness and/or tingling of the mouth and lips
- Other side effects such as drowniness, confusion

NUMBNESS

- Be aware that you may experience loss of feeling at and around the surgical area. If numbness occurs, take proper measures to avoid injury.

PRECAUTIONS

- Do not reuse.
- Protect pump and catheter site from water according to your doctor's instructions.

CALL YOUR DOCTOR IF YOU HAVE:

- Redness, warmth or excessive bleeding from the catheter site.
- Pain, swelling or a large bruise around the catheter site.

CAUTIONS:

1. Underfilling the pump is not recommended. Underfilling the pump can significantly increase the flow rate.
2. The nominal fill volume is labeled on the fill port.
3. Nominal bolus time and volume (10 ml/45 seconds) are labeled on pump tubing.
4. Actual bolus volume may vary due to:

- Filling the pump less than nominal results in faster flow rate.
- Filling the pump greater than nominal results in slower flow rate.
- The pump should be filled a minimum of 2 hours prior to administration or the flow rate may increase significantly.
- Viscosity and/or drug concentration; increased viscosity will reduce bolus volume.
- Temperature will affect solution viscosity, resulting in increased or reduced bolus volumes.

- Positioning the pump above (bolus volume increases) or below (bolus volume decreases) the catheter site.

5. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

Table 1

Normal Volume	100 ml
Maximum Volume	125 ml
Retained Volume	≤ 4 ml

Bolus Time	Bolus Volume	Number of doses in pump
22.5 seconds	5 ml	20
45 seconds	10 ml	10
90 seconds	20 ml	5

[1]When filled to nominal volume, delivery accuracy is ±15% of the labeled bolus volume two hours after fill when delivering normal saline at 88°F (31°C).

Table 2

Catheter	Dimensions
Total Length	59 cm (24 inches)
Infusion Segment	3.3 cm (1.3 inch)
Gauge	19/20 GA

Measurements are approximate. Catheter is radiopaque.

For more information please call: +1(949) 206-2700, English only.
Visit iflo.com for the latest product information & technical bulletins.

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Germany
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EC REP
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12/2005

MODEL: ACC11

ON-Q REUSABLE POWERFILLER

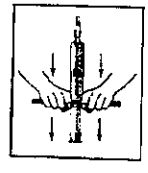
Intended Use

The PowerFiller is intended to be used with ON-Q pumps to allow for easier filling.

CAUTIONS: DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED.

ON-Q POWERFILLER IS NONSTERILE AND REUSABLE.

- Clean, decontaminate and sterilize prior to use per standard hospital protocol.*

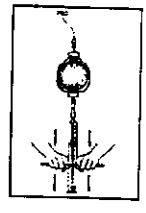


Directions For Use

Use Aseptic Technique

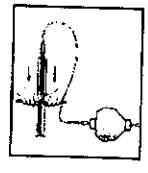
Connecting PowerFiller to Syringe

1. Secure PowerFiller to 60 ml syringe barrel and slide the ring down to the bottom of the syringe until it is secure.
2. Fill the 60 ml syringe with medication.
3. Hold PowerFiller during refilling syringe to prevent PowerFiller from sliding off syringe.



To Fill the Pump:

1. Close clamp on pump.
2. Open the cap on the pump fill port and connect the syringe to the pump fill port. Verify connection is secure.
3. Hold syringe upright with plunger resting on a flat surface.
4. Grasp each side of the PowerFiller and push down as the fluid is injected into the pump.
5. Repeat as necessary.



To Fill Pump using Filling Extension Set

1. Refer to Directions For Use for Priming the Extension Set.
2. Attach filled syringe to Extension Set.
3. Connect primed Extension Set to the pump.
4. Follow directions above for filling the pump.

Note: Extension Set should remain securely attached to pump fill port until filling is complete.
** Reference current ANSI/AAMI standard for further information on the safe handling, biological decontamination and sterilization of medical devices.*

Sterilization Recommendations

Using a validated gravity displacement steam sterilizer, the minimum exposure time and temperature is 10 minutes at 132° C (270° F).

Sterility of the product is the responsibility of the healthcare facility.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service Please Call:
1.800.448.3569

I-FLOW®

www.iflo.com

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

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EASY FILLER™

FOR USE WITH ELASTOMERIC PUMPS

PARA USAR CON BOMBAS ELASTOMÉRICAS

POUR UTILISATION AVEC DES POMPES ÉLASTOMÉRIQUES

ZUR VERWENDUNG MIT ELASTOMERPUMPEN

PER POMPE ELASTOMERICHE

PARA UTILIZAÇÃO COM BOMBAS ELASTOMÉRICAS

FÖR ANVÄNDNING MED ELASTOMERISKA PUMPAR

VOOR GEBRUIK BIJ ELASTOMEERPOMPEN

ELASTOMERİK POMPALARLA KULLANILMAK İÇİN

탄성 중합체 재질의 펌프와 같이 사용

エラストマーポンプ用

使用说明

Easy 填充器

I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE

EC REP MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

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EASY FILER™

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Figure 1 / Figura 1 / Figure 1 / Abbildung 1
Figura 1 / Figura 1 / Bild 1 / Afbeelding 1
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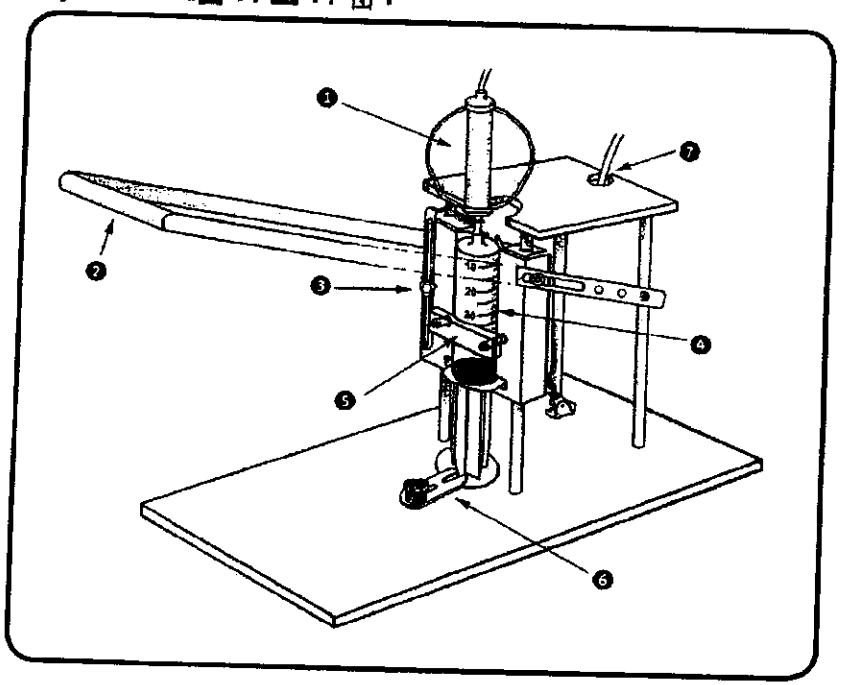

ILLUSTRATION AND NOMENCLATURE

Figure 1 on Page 4

1. Elastomeric Infusion Pump
2. Handle
3. Volume Adjustment Knob
4. Syringe
5. Syringe Holder
6. Syringe Plunger Holder
7. Guide Hole

INSTRUCTIONS FOR USE

1. Attach a check valve tubing set to a 50 - 60 ml syringe (not included).
2. With handle up, pull out syringe holder and slide the closed syringe into place so the flanges on the syringe fit into the slots on the front panel.
3. Feed set through the guide hole on top of Easy Filler.
4. Press handle down and hold. Slide syringe plunger holder over the plunger flange and tighten knob.
5. Attach a fluid transfer set (not included) to the fluid container, open clamp, and allow handle to rise. To set the volume dispensed, loosen the volume adjustment knob, adjust height for desired syringe volume, and tighten knob.
6. Attach pump fill port to the fluid transfer set by turning clockwise. Close pump set clamp and bring the infusion set forward so as not to entangle tubing.
7. Using both hands, press handle down slowly to fill the pump no faster than 10 ml per second. Allow handle to rise to refill syringe. Press handle down to add additional fluid. When filled to desired volume, detach pump.
8. Once filling has been completed, hold handle down, detach tubing, and unload syringe.
9. Clean any spilled filling solution from the Easy Filler after use.

CAUTION: Keep hands free of all moving parts when using this device.
For best results use a 50 - 60 ml syringe.

For more information please call: +1(949) 206-2700, English only.
Visit iflo.com for the latest product information & technical bulletins.

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TAB 24

Appendix D – Marketing Literature

This section contains example marketing literature currently in use for the *I-Flow Elastomeric Pumps.* The new 600 ml models have minimal impact on existing marketing literature. The only updates necessary would be references to nominal fill volume (600 ml), maximum fill volume (770 ml) and delivery time.

Add

"CONTINUOUS"

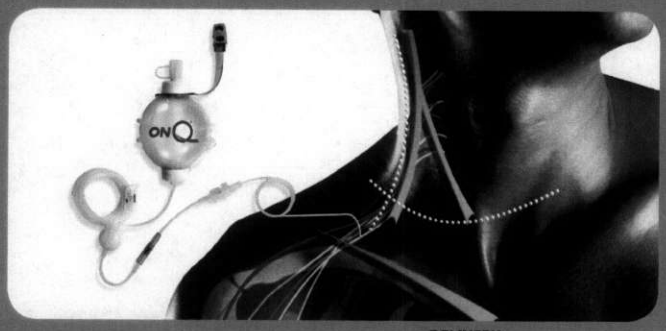
To Your Nerve Blocks

and get your patients back
to normal faster

ON-Q® C-bloc®
Redefining Recovery™

→ *Relieves pain narcotic-free while allowing patients to have both continuous and on demand pain relief.*

ON-Q® C-bloc®—*A New Best Practice For Post-Operative Pain Relief.*



ON-Q C-bloc slowly infuses local anesthetic near a nerve for regional anesthesia and post-operative pain relief.

A simple and reliable system for effective continuous nerve blocks, ON-Q C-bloc is an optimal alternative to electronic pumps. It requires less clinical intervention and helps your patients leave the hospital sooner.

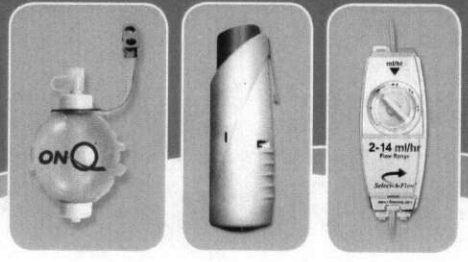
ON-Q C-bloc with ONDEMAND™ has an added feature that allows patients to give a 5 ml bolus in addition to the continuous 5 ml/hr rate.

ON-Q C-bloc with Select-A-Flow® allows you to adjust the flow rate according to your patients' needs.

ADVANTAGES*

- Provides significantly better pain relief than narcotics
- Lasts up to ten times longer than single injection
- Provides consistent pain relief compared to intermittent injection
- No complicated electronics
- Reduced length-of-stay and overall costs
- Patients return to normal quicker
- Select-A-Flow offers titration for dosing flexibility
- A unique and ergonomic "mini-pump" for patient-controlled bolus

	DELIVERY TIME	MODEL
ON-Q C-bloc		
400 ml vol x 5 ml/hr	3 days	CB001
400 ml vol x 10 ml/hr	2 days	CB002
ON-Q C-bloc with ONDEMAND		
400 ml vol x 5 ml/hr with 5 ml bolus *(60 minute refill)*	≤ 3 days	CB003
ON-Q C-bloc with Select-A-Flow		
400 ml vol x 2-14 ml/hr		CB004
ON-Q C-bloc with Select-A-Flow & ONDEMAND		
400 ml vol x 1-7 ml/hr with 5 ml bolus *(60 minute refill)*		CB005



REIMBURSEMENT HOTLINE

CPT CODE	DESCRIPTION
64446	Continuous Sciatic
64448	Continuous Femoral
64416	Continuous Brachial Plexus
64449	Continuous Lumbar Plexus

If reimbursement issues arise, please call our toll-free hotline:

1.866.745.2455

Reimbursement specialists for ON-Q C-bloc are able to:

- Clarify coding and reimbursement issues
- Answer questions regarding general billing policies and procedures

Introducing *NEW* ON-Q C-bloc with Select-A-Flow and ONDEMAND allows you to adjust the flow rate between 1-7 ml/hr while providing patients with an optional 5 ml bolus/60 minute refill – all in one product – to return patients to normal quicker.

NOW LABELED FOR ENHANCED INDICATIONS

ON-Q IS INDICATED FOR:

- *Significantly better pain relief than narcotics*
- *Significantly less need for narcotics*

Confidential

ON-Q C-bloc® Redefining Recovery™

FOR MORE PRODUCT RELATED OR ORDERING INFORMATION CALL

800.448.3569 *or* **949.206.2700**

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I-Flow Corporation

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* FOR A LIST OF SUPPORTING STUDIES VISIT

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1303367E 03/2006

193

ON-Q C-bloc®
Redefining Recovery™

ON-Q IS INDICATED FOR:
- Significantly better pain relief than narcotics
- Significantly less need for narcotics

FREQUENTLY ASKED QUESTIONS

→ **Will ON-Q C-bloc provide better pain relief than traditional therapies?**
By adding ON-Q to a patient's post-surgical pain treatment, patients will get significantly better pain relief than with narcotics alone. When ON-Q is used with narcotics, it significantly reduces the amount of narcotics needed to relieve pain following surgery. Key studies from various surgical specialties were submitted as clinical evidence validating these new indications. With these key studies the data also demonstrated reduced length of stay, decreased cost, increased patient satisfaction and a quicker return to normal function.

→ **What medication should be used in the ON-Q C-bloc pump?**
A local anesthetic preferred by the anesthesiologist. The most common local anesthetic used for continuous regional analgesia is ropivacaine. Drug manufacturer dosage guidelines should be followed.

→ **Is the C-bloc indicated for epidural use?**
Yes. The C-bloc may also be used for epidural applications. Refer to the *Directions For Use* for specific information on epidural use.

→ **How does the pump work?**
The pump consists of a multi-layer membrane with a protective PVC cover. The strain of the elastomeric membrane provides a positive pressure of approximately 10 PSI. A capillary orifice controls the flow rate.

→ **What is the material in the elastomeric membranes?**
The pump consists of three layers:
- The inner layers are a synthetic thermoplastic elastomer which contains the drug and is non-latex.
- The middle layer is composed of natural rubber latex. *(Technical Bulletin available upon request)*
- The outer protective layer is PVC.

The fluid contact materials are biocompatible.

→ **Can the ON-Q C-bloc pump be used on patients with latex sensitivity?**
The pump does not contain latex in the fluid pathway. The PVC bag that surrounds the pump membranes eliminates the risk of contact dermatitis that can occur when latex comes in contact with the skin. *(Technical Bulletin available upon request)*

→ **How can I tell if the pump is infusing?**
The medication infuses at a slow rate. A change in the size of the pump will not be noticed on an hourly basis. It may take longer than 24 hours to notice a change in the appearance of the pump. Over time the outside bag will become loose and creases will form in the bag. If the patient is getting good pain relief, the pump should be infusing as expected.

→ **What is the accuracy of the flow delivery?**
Delivery accuracy is ±15% (±20% for C-bloc with Select-A-Flow™) of the labeled infusion rate when filled to nominal volume.

→ **What is the size of the in-line filter?**
The filter is 1.2 micron particulate and 0.02 micron air-eliminating filter.

→ **Are there any factors that affect the flow rate?**
The ON-Q C-bloc pump is calibrated for the flow restrictor to be in contact with the patient's skin. Care should be taken to ensure that this portion of the tubing is secured to the patient's skin and that it is not near any cold therapy. If the restrictor is away from the body, the medication will infuse at a slower than expected flow rate. Also, do not tape over the filter vent. Underfilling or overfilling will also affect the flow rate. See *Directions For Use* for other factors.

→ **What is the difference between ON-Q C-bloc and ON-Q C-bloc with *ONDEMAND*™?**
The ON-Q C-bloc with *ONDEMAND* has an added feature that allows patients to give a 5 ml bolus every hour in addition to the continuous 5 ml/hr rate.

→ **How does temperature affect the *ONDEMAND*?**
The restrictors are inside the bolus device. ON-Q C-bloc with *ONDEMAND* should not be in skin contact, as it is calibrated to room temperature. The *ONDEMAND* bolus should be worn outside the patient's clothing and may be clipped to the carrying case for convenient access.

→ **Does *ONDEMAND* have a lockout feature?**
The ONDEMAND has a one hour refill. If the patient presses the bolus button before one hour they will receive a partial bolus dose. Medication doses should be calculated at the total average rate of 10 ml/hr (5 ml/hr basal + 5 ml bolus).

→ **What is the ON-Q C-bloc with Select-A-Flow™?**
ON-Q C-bloc with Select-A-Flow incorporates a controller that allows the infusion rate to be adjusted by turning the rate changing key on the device.

→ **What flow rate ranges are available with the Select-A-Flow?**
2 ml to 14 ml/hr at 2 ml increments.

→ **What happens if the flow rate is dialed between settings such as 2-3 ml/hr?**
To ensure accurate flow rates, the dial on the Select-A-Flow must be "clicked" into place under the specified rate. Placing the dial between settings will result in unknown flow rates.

→ **How does temperature affect the Select-A-Flow?**
The Select-A-Flow should not be in skin contact, as it is calibrated to room temperature. Avoid ice or cold therapy near the controller. The Select-A-Flow should be worn outside the patient's clothing.

→ **What about tamper resistance with the Select-A-Flow?**
To discourage tampering, the rate-changing key may be removed from the dial and put in a place for safe keeping. The plastic cover over the dial may be secured with a standard tie wrap.

→ **Can patients shower with ON-Q C-bloc?**
Physician's instructions should be followed. Precautions should be taken to protect catheter site and pump from water.

→ **Can ON-Q C-bloc be refilled?**
No. The device is single use and disposable.

→ **Is there reimbursement for ON-Q C-bloc?**
New CPT codes for Continuous Nerve Blocks include the following:

64446 Continuous Sciatic	64448 Continuous Femoral
64416 Continuous Brachial Plexus	64449 Continuous Lumbar Plexus

Refer to the Reimbursement Hotline for any questions on coding and billing policies and issues (866) 745-2455 (toll free)

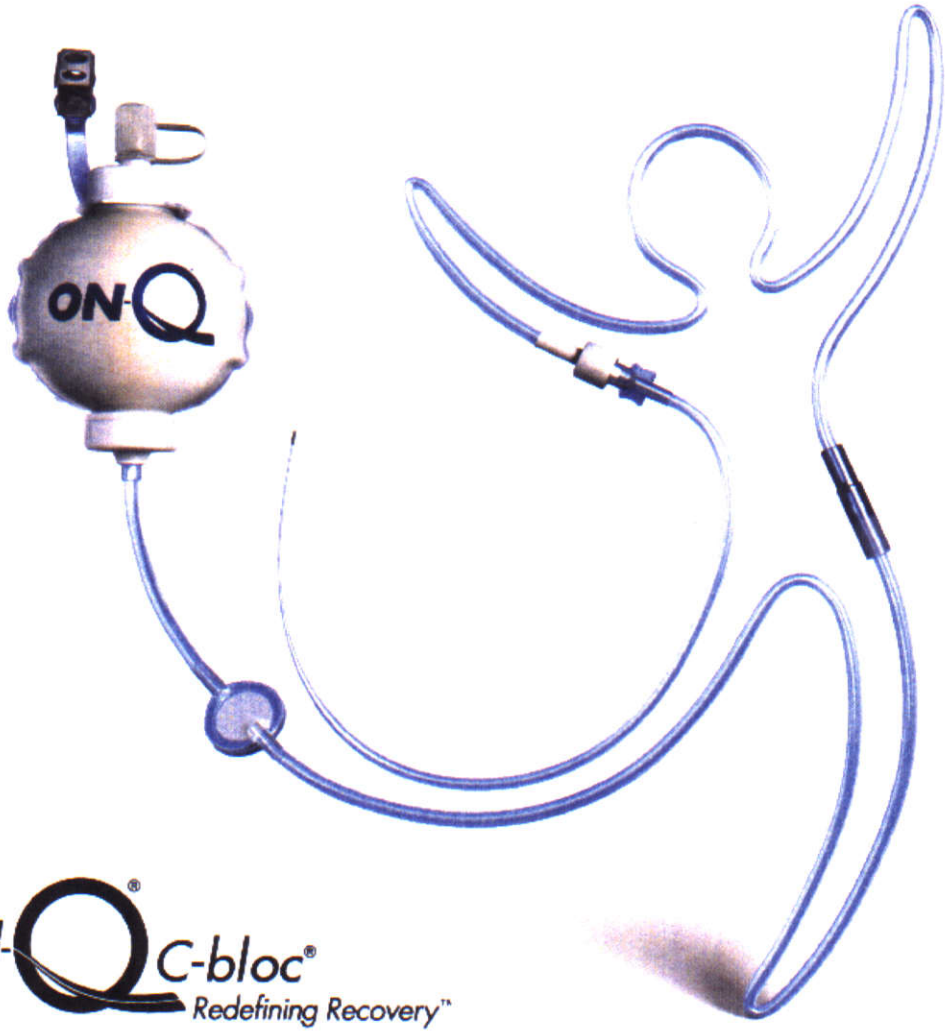
REFER TO THE PRODUCT'S *DIRECTIONS FOR USE* FOR MORE INFORMATION.

195

PATIENT INFORMATION

Your Recovery is Redefined with ON-Q® C-bloc®

PAIN RELIEVED AFTER SURGERY SO YOU CAN GET BACK TO NORMAL FASTER



ON-Q® C-bloc®
Redefining Recovery™

24-Hour Patient Hotline 800.444.2728 www.AskYourSurgeon.com

196

Pain Relief after Surgery

Pain relief after surgery is an important part of the recovery process. When you're not in pain, you move around sooner, have a better appetite and ultimately return to normal quicker.

There are two primary methods of relieving pain after surgery. The most familiar is the use of narcotics like morphine. These drugs can cause unpleasant side effects such as nausea, drowsiness, constipation and difficulty breathing. They may also be habit forming. Medical science has developed a new way of relieving pain that can cut down or even stop the need for these drugs. This important new type of pain relief is called ON-Q C-bloc.

The Better Choice for Post-Surgical Pain Relief

Narcotic Pain Relief

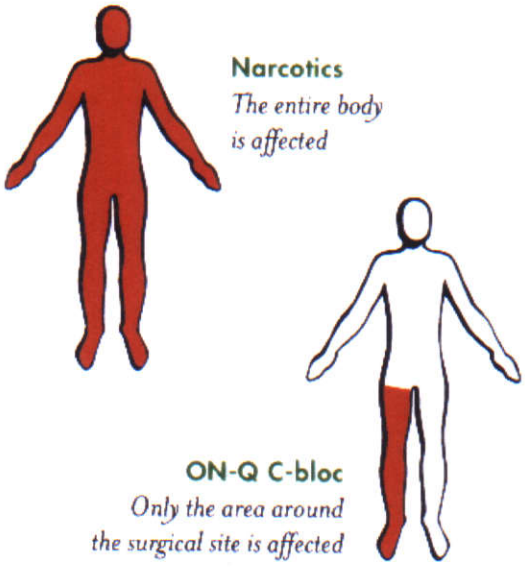
Common narcotics are morphine, codeine and Demerol. They may be taken in pill form or given through an IV. Narcotics affect the entire body and may slow the recovery process. They can make you sleepy or groggy. Narcotics may also cause nausea, vomiting, constipation and possible breathing problems.

Local Anesthetic Pain Relief

Local anesthetics are numbing medicines like Novocain® that work right where the pain is. They don't affect the whole body, so they won't make you sleepy or groggy and don't numb other body parts. Other local anesthetics that are commonly used are ropivacaine and bupivacaine.

Continuous Nerve Block Pain Relief

Doctors have used local anesthetics during different types of surgeries for years. Now these medicines are used to relieve pain after surgery. The local anesthetic is put directly where key nerves are to block the pain in and around the surgical area. This method of pain relief is called a Continuous Nerve Block.



Narcotics
The entire body is affected

ON-Q C-bloc
Only the area around the surgical site is affected

It's Time You Know About ON-Q C-bloc

ON-Q C-bloc is a system many doctors use to deliver a Continuous Nerve Block. It includes a balloon-type pump filled with a local anesthetic medicine. The pump is automatic and completely portable and may be clipped to your clothing or placed in a small carrying case.

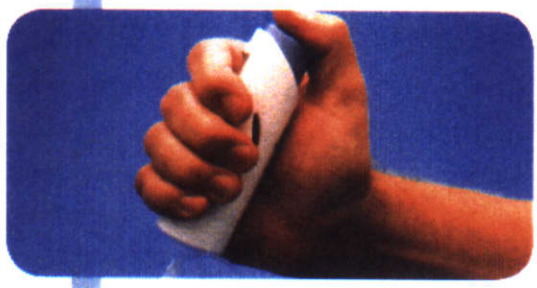
The pump is attached to a very thin tube (catheter) that is placed by an anesthesiologist. It is placed under the skin next to a nerve near the surgical area. The ON-Q C-bloc pump automatically delivers the medicine at a very slow flow rate, blocking the pain in the area of your surgery. ON-Q C-bloc gives you better pain relief than taking only a narcotic medicine. With ON-Q C-bloc, you may need to take less traditional pain medicine.

You may wear your pump while you're in the hospital or even take it home for a few days.

There are different models of the **ON-Q C-bloc** pump. Your healthcare team will decide which product is right for you.

ON-Q C-bloc Pump

ON-Q infusion pump automatically delivers numbing medicine for pain relief.

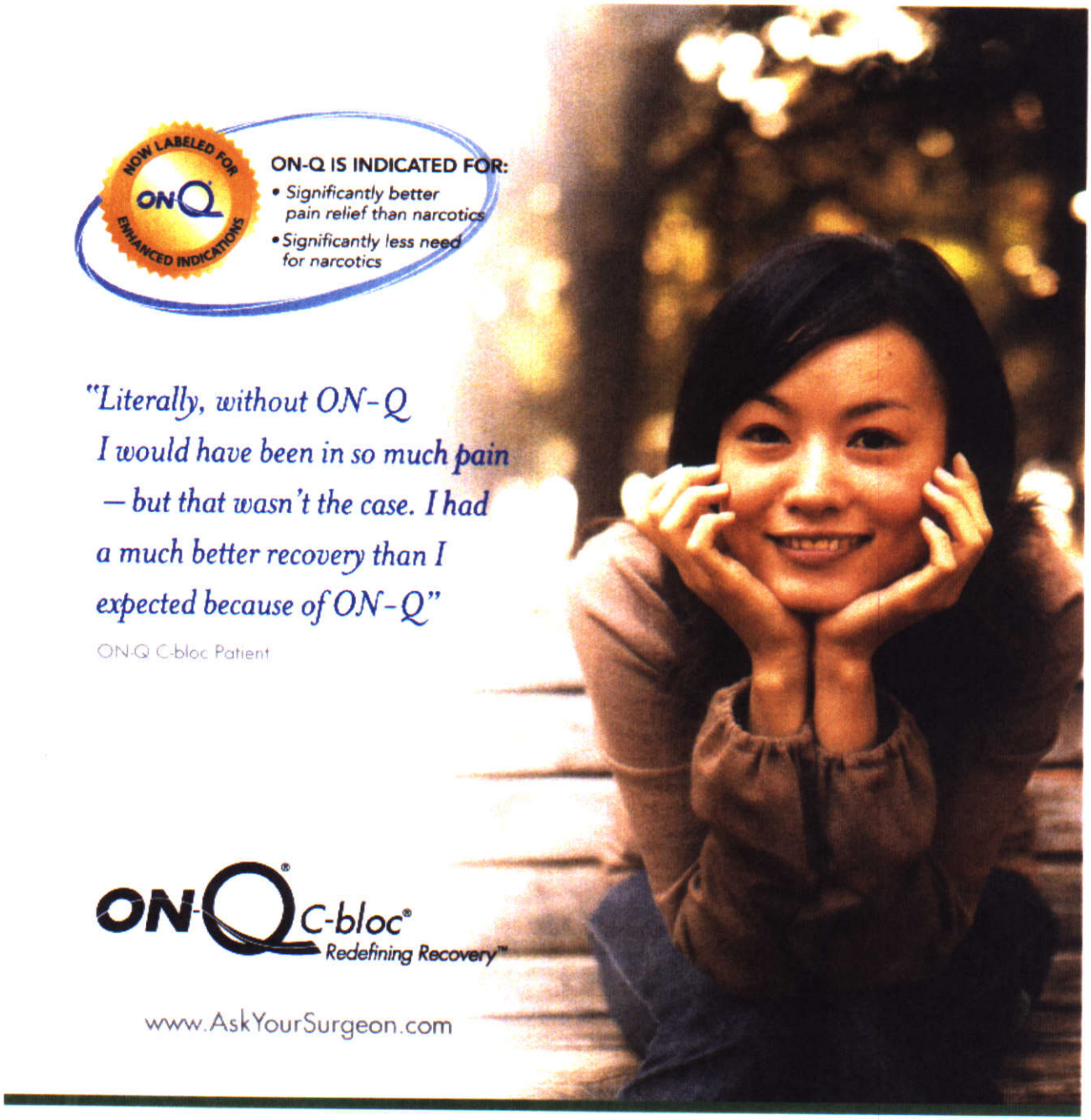


ON-Q C-bloc with ONDemand

ONDemand bolus button allows an extra dose of numbing medicine if needed.

ON-Q C-bloc with Select-A-Flow

Variable Rate Controller lets your doctor adjust the amount of numbing medicine you receive to best meet your needs.



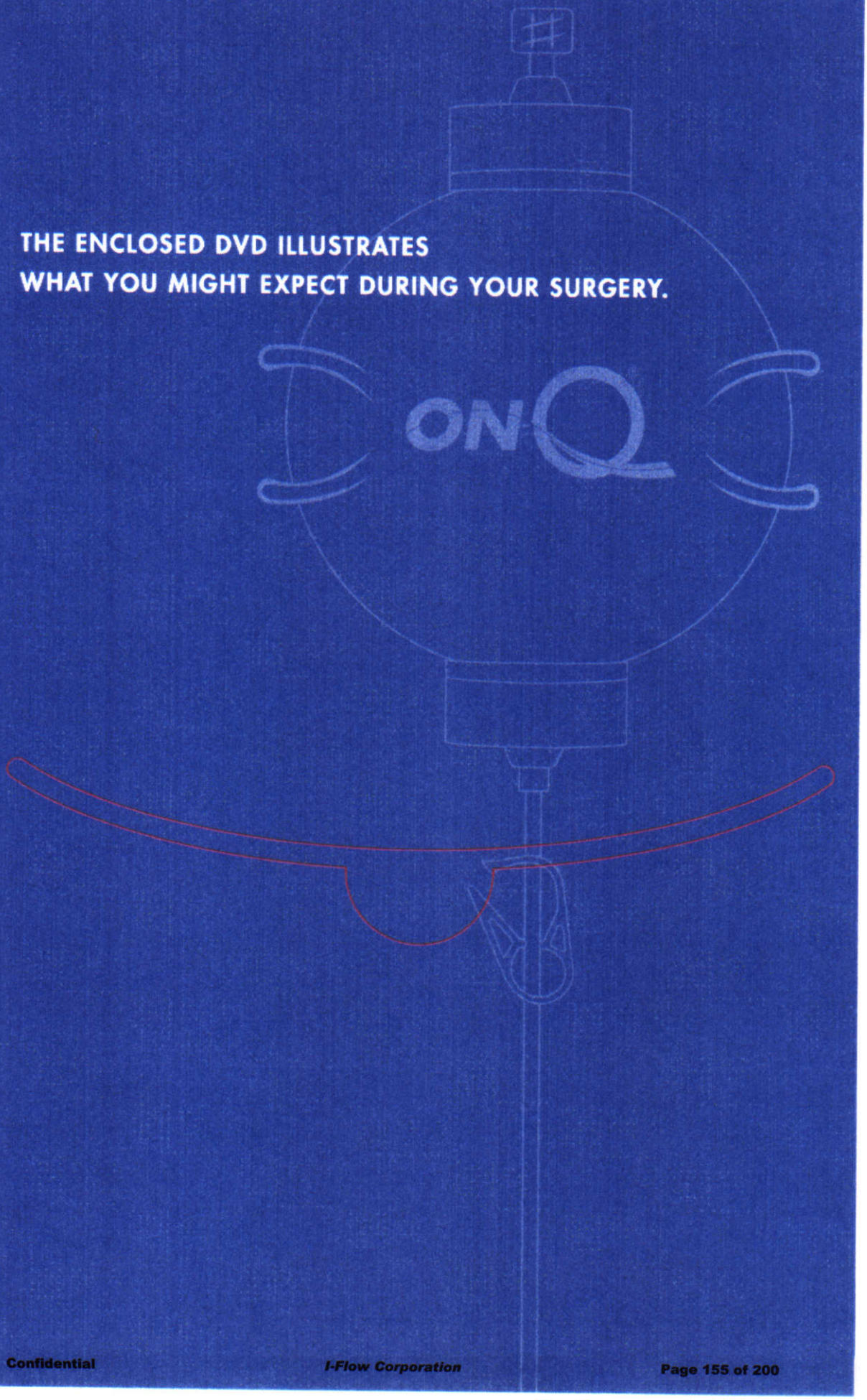
Benefits of ON-Q C-bloc

ON-Q C-bloc may provide:

- More comfortable pain relief and recovery
- Pain relief without the side effects of narcotics
- Constant pain relief, so pain doesn't "break through" as it sometimes does with narcotics
- Quicker return to normal
- Earlier release from the hospital

Your surgeon and anesthesiology pain management team will tell you if a continuous nerve block with ON-Q C-bloc is right for you.

THE ENCLOSED DVD ILLUSTRATES
WHAT YOU MIGHT EXPECT DURING YOUR SURGERY.



POTENTIAL RESULTS*	ON-Q	NARCOTICS
Faster return to normal activities	•	
Quicker return to normal body function	•	
Clear and groggy-free head	•	
Greater mobility	•	
More comfortable recovery	•	
Earlier hospital release	•	
Nausea		•
Vomiting		•
Potential for addiction		•
Possible breathing problems		•
Constipation		•
Groggy, knocked-out, 'hangover' feeling		•
Overall slower recovery		•

YOUR DOCTOR'S INFORMATION

Call your doctor for any questions or concerns about your nerve block and all other medical questions:

Doctor: _____

Phone: _____

After Hours/Weekends: _____

I-FLOW®

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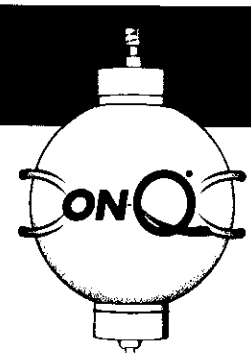
Lake Forest, CA 92630 | www.AskYourSurgeon.com

Finally, you can start

Redefining Recovery

ON-Q IS INDICATED FOR:
- *Significantly better pain relief than narcotics*
- *Significantly less need for narcotics*

The ON-Q® PainBuster® Triple Site Pump
Post-Op Pain Relief for Multiple Site Surgeries



*Customers asked for it, and ON-Q has provided it – the **NEW** Triple Site Pump for large incisions or surgeries with multiple surgical sites. Count on the ON-Q Triple Site Pump for reliable continuous pain relief to get patients back to normal faster.*

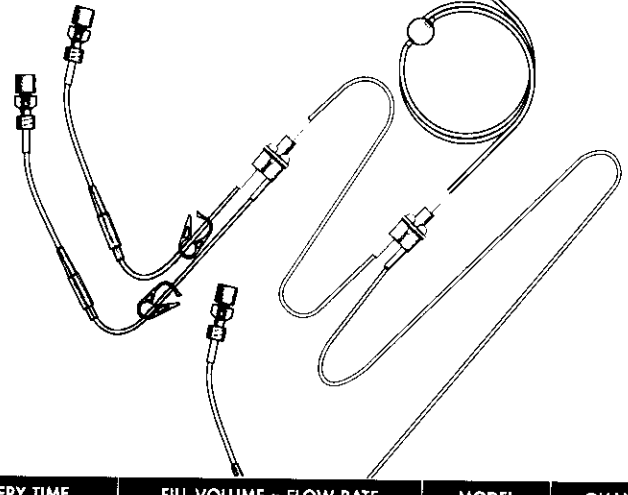
The ON-Q PainBuster Triple Site Pump may be used in several procedures, such as large oncology incisions and trauma surgeries. It is also effective across many specialties, including the following procedures:

CV-CT
CABG + Chest Tube
CABG + Saphenous Vein Harvesting
Thoracotomy + Chest Tube
Thoracoabdominal Aortic Aneurysm

PLASTIC
Breast Augmentation + Abdominoplasty
TRAM + Reconstruction

ORTHOPEDIC
Total Knee Replacement

GENERAL
Laparotomy
Bilateral Mastectomy
Nephrectomy



DELIVERY TIME	FILL VOLUME x FLOW RATE	MODEL	QUANTITY
Up to 4 Days	400 ml x 6 ml/hr (2 ml/site)	P400X6T	5 per case

The Triple Site Pumps are conveniently packaged as pump-only models. This allows for USP compliance and also versatility when selecting Soaker® Catheters. Please see the ON-Q Expansion Kits below for corresponding catheters and needles.

ON-Q SOAKER® EXPANSION KITS

DESCRIPTION	MODEL	QTY.
Expansion Kit – 2.5 in (6.5 cm) T-Peel Needle 3.25 in	PM010	5 per package
Expansion Kit – 5 in (12.5 cm) T-Peel Needle 6 in	PM020	5 per package
Expansion Kit – 1 in (2.5 cm) T-Peel Needle 3.25 in	PM030	5 per package
Expansion Kit – 10 in (25 cm) T-Peel Needle 8 in	PM040	5 per package

Also available – the new ON-Q Antimicrobial SilverSoaker™ for an added layer of protection (PM010-A, PM020-A, PM030-A, PM040-A).

I-FLOW®

20202 Windrow Drive
Lake Forest, CA 92630
Phone: 800-448-3569
949-206-2700

For a list of supporting studies, please visit *www.iflo.com*

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202

ON-Q PainBuster Triple Site Pump
Drug Dosing Information P400X6T

ON-Q PainBuster® Redefining Recovery™

This chart should be used as a reference only; it does not replace specific instructions from clinicians with experience and additional information about administering these drugs. Drug doses are approximate and based on nominal specifications.

CAUTIONS

- Chart is based on nominal (labeled) flow rate of 6 ml/hr (2 ml/hr each site).
- At nominal flow rate, as indicated in the chart below, there is no clinical experience to support the use of bupivacaine at concentrations greater than 0.25%.
- Flow rate may vary by ± 15%. See ON-Q Pump Directions for Use for additional factors that may affect flow rate.
- It is up to the physician to determine which patients are most appropriate for this device and ensure that patients are properly instructed on its use.
- 24 hour dose (mg) is calculated by filling ON-Q PainBuster pump to the nominal (labeled) volume. Filling the pump less than nominal increases the flow rate and increases the dose delivered in 24 hours.
- Additional bolus or loading dose should be added to the calculation.
- Refer to the drug manufacturer's package insert for complete prescribing information. Physician is responsible for prescribing drug based on each patient's clinical status (such as age, body weight, and disease state of patient).
- All local anesthetics are guidelines for use in adults.
- Referenced local anesthetics are without Epinephrine. Vasoconstrictors such as Epinephrine are not recommended for continuous infusions.

ON-Q PainBuster Triple Site Pump 24 hour dosing (mg) Cross Reference Chart

Chart is based on nominal (labeled) flow rate of 6 ml/hr.

Drug Concentration	0.2%	0.25%	0.5%
P400X6T	288 mg	360 mg	720 mg (BU, LE)

Calculations based on nominal flow rate. Flow rate may vary by ± 15%. See ON-Q Pump Directions for Use for additional factors that may affect flow rate.
Formula: ml/hr x % drug concentration x 10 x 24 hr = 24 hour dose (mg)

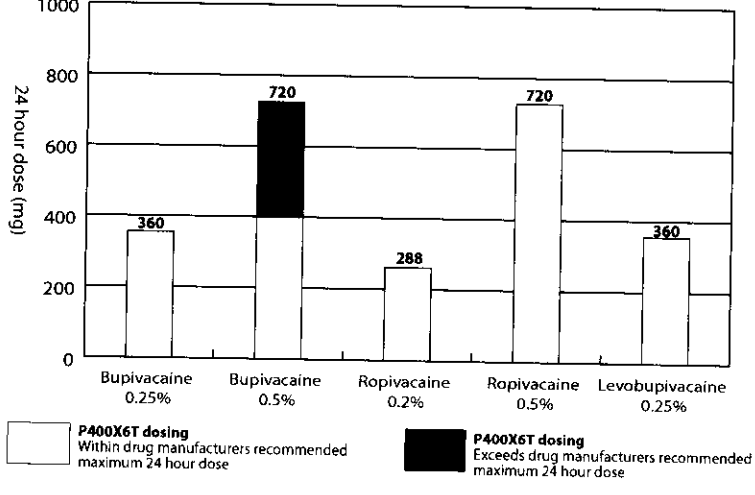
CAUTION

Toxic Level Indicator: Drug symbols that appear in chart above indicate that the cross referenced drug concentration exceeds the drug manufacturer's recommended maximum 24 hour dose.

Drug Manufacturers Recommended Maximum 24-hour dose (intraoperative)

Drug	Maximum	Toxic Level Indicator
Bupivacaine	400 mg	BU
Levobupivacaine	695 mg	LE
Ropivacaine	770 mg	RO

ON-Q PainBuster Triple Site Pump



Reference:

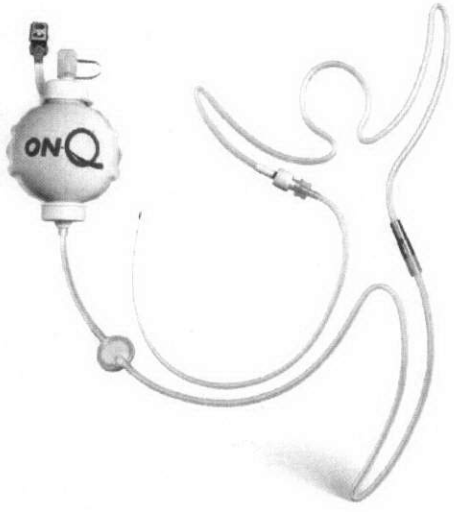
Gottschalk A et al. Continuous wound infiltration with ropivacaine reduces pain and analgesic requirement after shoulder surgery. *Anesthesia Analgesia.* 2003;97:1086-91.

White P et al. Use of a continuous local anesthetic infusion for pain management after median sternotomy. *Anesthesiology.* 2003; 99:918-923.

Finally, you can start

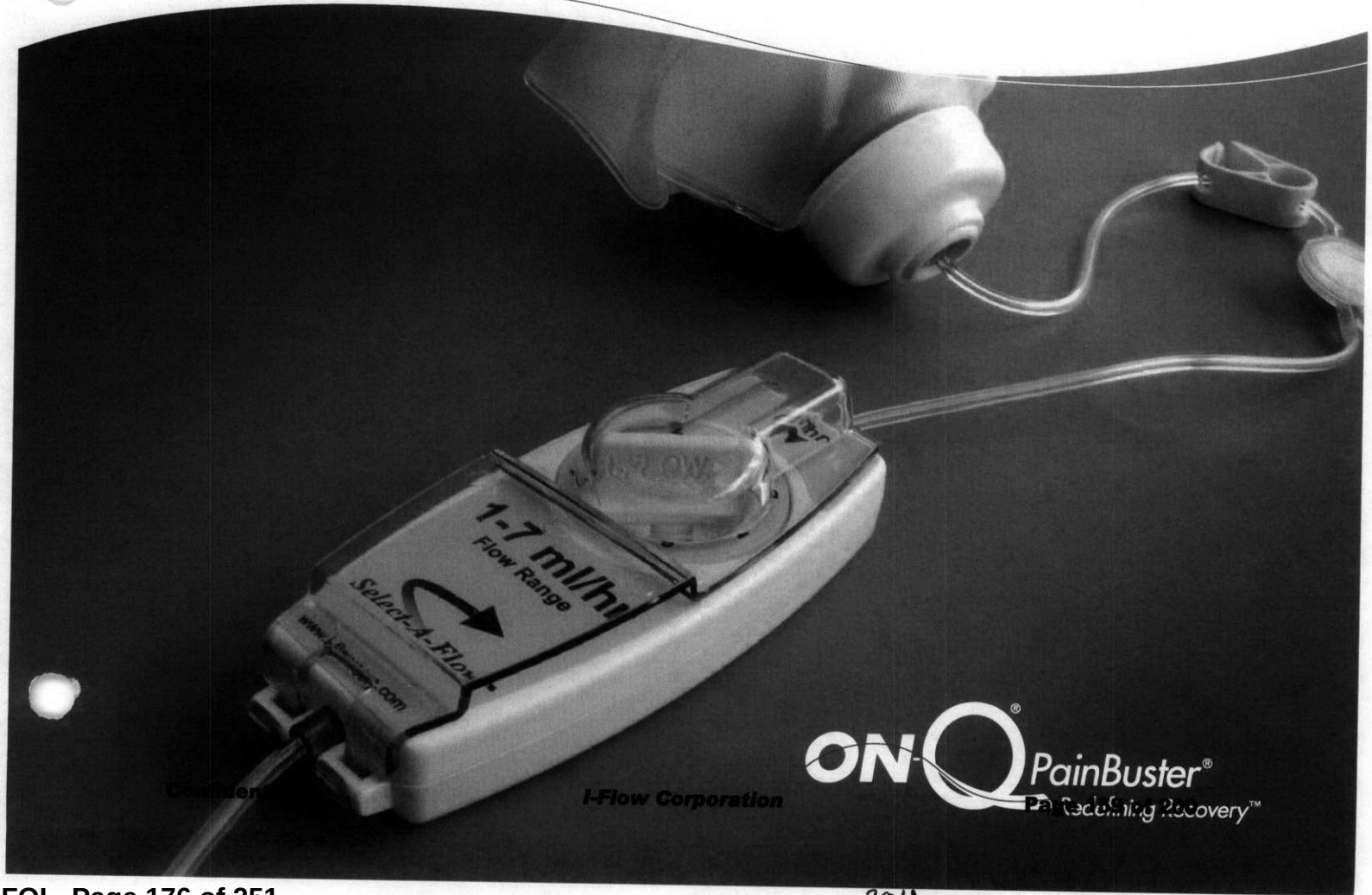
Redefining Recovery™

The ON-Q® Select-A-Flow System—Increasing Control and Flexibility in Post-Op Pain Relief

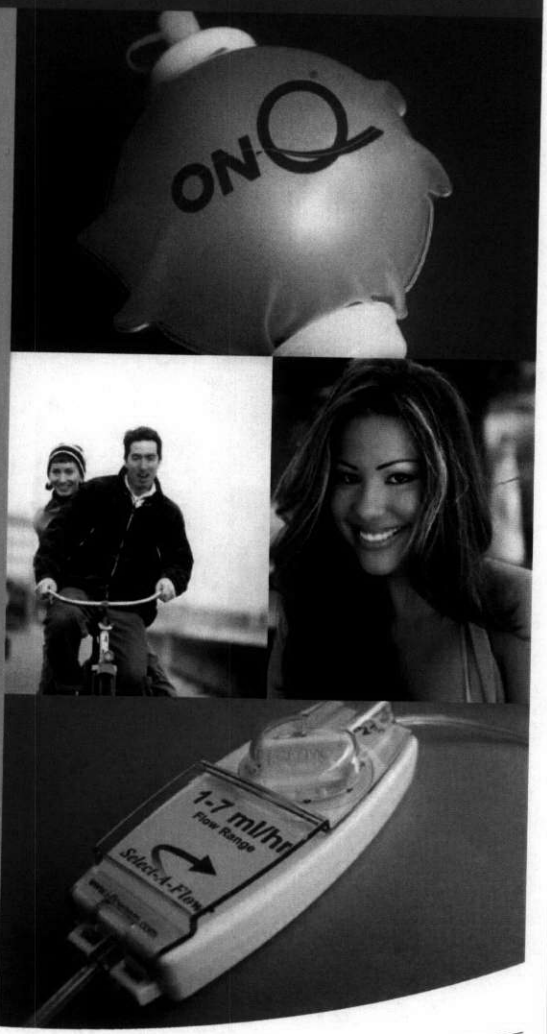


The ON-Q Select-A-Flow:

- *1–7 ml variable rate allows you to set the optimal rate for your patients' individual pain relief requirements*
- *The same simple and reliable continuous pain relief you know and trust with ON-Q*
- *Provides flexibility to change flow rates to effectively manage your patients' post-op pain*
- *Gets patients back to normal faster*
- *Designed with patient safety in mind*



ON-Q Select-A-Flow allows you to adjust the flow rate according to your patients' needs.

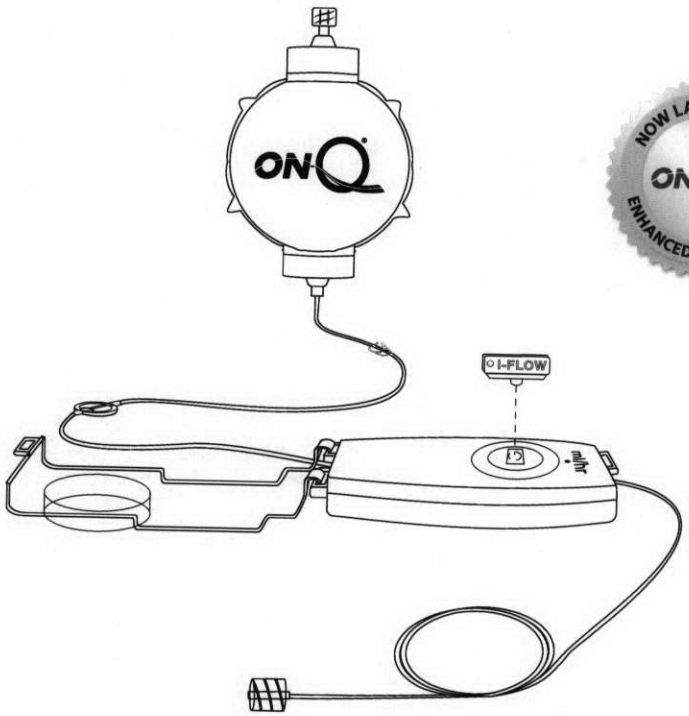


BENEFITS*

- Select-A-Flow offers titration for dosing flexibility
- Provides significantly better pain relief than narcotics
- Patients return to normal quicker
- Rate-changing key clicks into place and may be removed for tamper resistance
- Easy viewing of rate setting
- Cover can be secured for tamper evidence
- Requires less clinical intervention and helps patients leave the hospital sooner so your hospital saves money

DELIVERY TIME	FILL VOLUME x FLOW RATE	MODEL	QUANTITY
2–5 days	Select-A-Flow 270 ml x 1–7 ml/hr	SAF01	5 per package*

*Catheter sold separately



NOW LABELED FOR ON-Q ENHANCED INDICATIONS

Soaker Catheter Expansion Kits

DESCRIPTION	MODEL	QTY.
Expansion Kit 6.5 2.5 in (6.5 cm) T-Peel Needle 6 in	PM010	5 per package
Expansion Kit 12.5 5 in (12.5 cm) T-Peel Needle 6 in	PM020	5 per package
Expansion Kit 2.5 1in (2.5 cm) T-Peel Needle 3.25 in	PM030	5 per package
Expansion Kit 25 10 in (25 cm) T-Peel Needle 8 in	PM040	5 per package

ON-Q® PainBuster® Redefining Recovery™

CONTACT YOUR ON-Q REPRESENTATIVE FOR ORDERING INFORMATION

I-FLOW®

FOR MORE PRODUCT RELATED OR ORDERING INFORMATION CALL 800.448.3569 or 949.206.2700

*FOR A LIST OF SUPPORTING STUDIES VISIT AskYourSurgeon.com

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M1304340 12/05

205

ON-Q® PainBuster®
Redefining Recovery™

ON-Q IS INDICATED FOR:
- Significantly better pain relief than narcotics
- Significantly less need for narcotics

Frequently Asked Questions

1. *Will ON-Q PainBuster provide better pain relief than traditional therapies?*
By adding ON-Q to a patient's post-surgical pain treatment, patients will get significantly better pain relief than with narcotics alone. When ON-Q is used with narcotics, it significantly reduces the amount of narcotics needed to relieve pain following surgery.

2. *What medication should be used in the ON-Q PainBuster pump?*
A local anesthetic of the Physician's choice. Drug manufacturer dosage guidelines should be followed. I-Flow Corporation has performed stability testing on Bupivicaine HCl, Lidocaine HCl and Ropivacaine HCl. Technical Bulletins available upon request.

3. *How does the pump work?*
The pump consists of a multi-layer membrane with a protective PVC cover. The strain of the elastomeric membrane provides a positive pressure of approximately 10 PSI. A capillary orifice controls the flow rate.

4. *What is the material in the elastomeric membranes?*
The pump consists of three layers:
- *The inner layer is a synthetic thermoplastic elastomer which contains the drug and is non-latex.*
- *The middle layer is composed of natural rubber latex.*
- *The outer protective layer is PVC.*

The fluid contact materials are biocompatible.

5. *Can the ON-Q PainBuster Pump be used on patients with latex sensitivity?*
The pump does not contain latex in the fluid pathway. The PVC bag that surrounds the pump membranes eliminates the risk of contact dermatitis that can occur when latex comes in contact with the skin. (Technical Bulletin available upon request)

6. *How much medication does the device hold?*
A variety of sizes and flow rates are available, providing dosing flexibility. Depending on the model selected, the device may hold from 35 ml up to 550 ml of medication. Infusion times range from 12 hours to 5 days depending on the model and fill volume selected. (Refer to ON-Q PainBuster Directions for Use for delivery time information)

7. *What happens if the pump does not fill evenly?*
The pump may fill unevenly; this is normal and should not cause concern. One side of the pump may completely fill and then the other side begins to expand; you may experience increased resistance during filling.

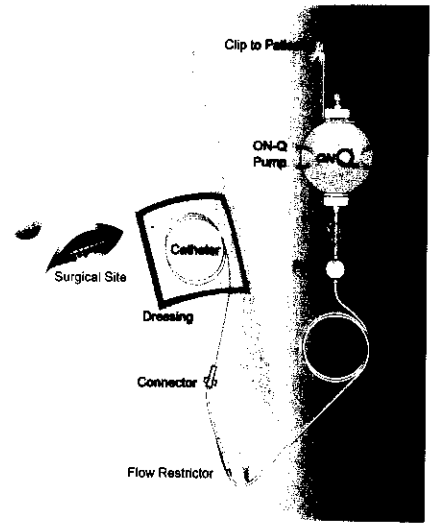
8. *How can I tell if the pump is infusing?*
Because the medication is infusing at a slow rate, you will not see a change in the size of the pump on an hourly basis. It may take longer than 24 hours to notice a change in the appearance of the pump. Over time the outside bag will become loose and creases will form in the bag. The pump ball will gradually decrease in size. If the patient is getting good pain relief the pump should be infusing as expected.

9. *How much pressure does the pump exert?*
Approximately 10 PSI (500mm Hg) pressure.

10. *What is the accuracy of flow delivery?*
Delivery accuracy is ±15% of the labeled infusion rate.

11. *What is the size of the in-line filter?*
The filter is 1.2 micron particulate and 0.02 micron air-eliminating filter.

12. *What effect does temperature have on the pump?*
The ON-Q PainBuster pump is calibrated for the flow restrictor to be in contact with the patient's skin. Care should be taken to ensure that this portion of the tubing is secured to the patient's skin and that it is not near any cold therapy. If the restrictor is away from the body, the medication will infuse at a slower than expected flow rate.



13. *What is the difference between ON-Q PainBuster and ON-Q PainBuster with ONDEMAND™?*
The ON-Q PainBuster with ONDEMAND has an added feature that allows patients to give a 5 ml bolus every hour in addition to the continuous 2 ml/hr rate.

14. *How does temperature affect the ONDEMAND?*
The restrictors are inside the bolus device. ON-Q PainBuster with ONDEMAND should not be in skin contact, as it is calibrated to room temperature. The ONDEMAND bolus should be worn outside the patient's clothing and may be clipped to the carrying case for convenient access.

15. *Does ONDEMAND have a lockout feature?*
The ONDEMAND has a one hour refill. If the patient presses the bolus button before one hour they will receive a partial bolus dose. Medication doses should be calculated at the total average rate of 7 ml/hr (2 ml/hr basal + 5 ml bolus).

16. *Is there a greater risk of infection with a catheter in the wound?*
An internal audit was conducted that compared reported cases of infection in patients using the ON-Q PainBuster pump to data available from the CDC which surveyed the incidence of surgical site infections. When compared to this CDC data, the ON-Q PainBuster system did not appear to increase the risk of surgical site infections. A detailed report is available upon request.

17. *What measures can I take to prevent infection in patients?*
- *Insert the catheter 3-5 cm away from the wound site.*
- *Cover the catheter site with an occlusive dressing keeping the catheter separate from surgical site.*
- *Protect catheter site from water.*
- *Perform routine assessment and monitoring of the catheter site.*
- *Remove the catheter as soon as the infusion is complete.*
- *Follow instructions for proper catheter removal.*
- *The catheter should remain in place no longer than 5 days.*
- *Do not refill the pump.*

18. *What type of catheter configurations are available?*
The ON-Q PainBuster system is available with either a standard 20 GA infusion catheter or a Soaker Catheter™. The Soaker Catheter has multiple ports along the distal portion of the catheter to provide better drug distribution at the incision site. This catheter is available with a 2.5 cm (1 inch), 6.5 cm (2.5 inch), or 12.5 cm (5 inch) soaker segment. The ON-Q PainBuster with ONDEMAND is available with a 1" multi-hole catheter.

19. *Can patients shower with ON-Q PainBuster?*
Physician instructions should be followed. Protect pump and catheter site from water.

20. *Who should remove the catheter?*
Physician's choice. The surgeon, nurse, or patient may remove the catheter.

21. *Can ON-Q PainBuster be refilled?*
No. The device is single use and disposable.

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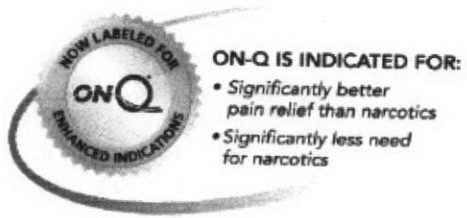
For a list of supporting studies, please visit www.iflo.com

Things to be Aware of When Using ON-Q PainBuster

Some patients may have adverse reactions to local anesthesia. Call your doctor immediately if you experience any of the following:

- Redness, warmth or excessive bleeding around the area where the tube enters your skin
- Pain, swelling or a large bruise around this area
- Dizziness, light headedness
- Blurred vision
- Ringing, buzzing in your ears
- Metal taste in your mouth
- Numbness and/or tingling around your mouth, fingers or toes
- Drowsiness



ON-Q IS INDICATED FOR:

- *Significantly better pain relief than narcotics*
- *Significantly less need for narcotics*

I-FLOW®

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Relieve Pain after Your Surgery

ON-Q PainBuster® Redefining Recovery™

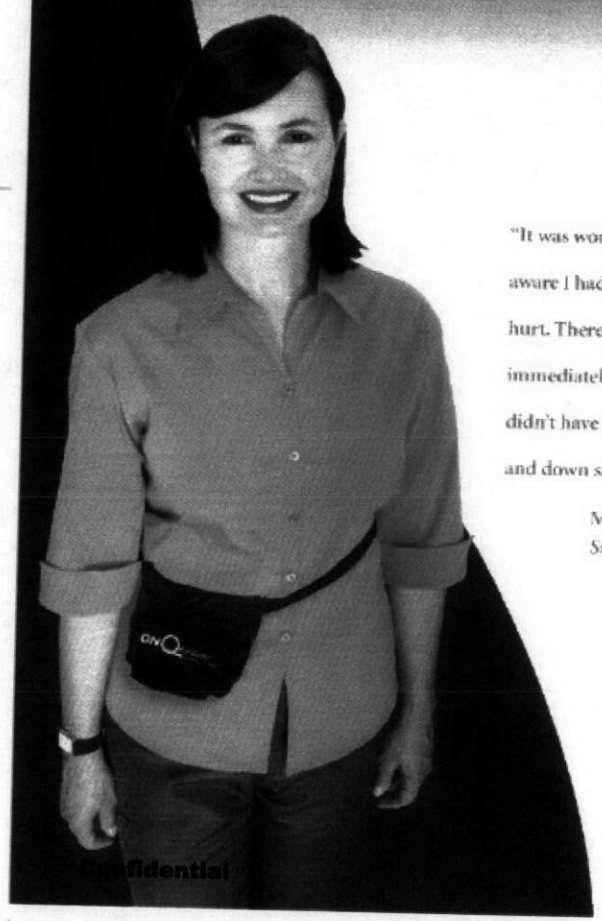
Feel Better Faster

AskYourSurgeon.com

ON-Q® PainBuster® is widely recommended for general surgery procedures such as:

- hernia
- liver
- hemorrhoid
- colon and other procedures

Visit AskYourSurgeon.com for more detailed information.



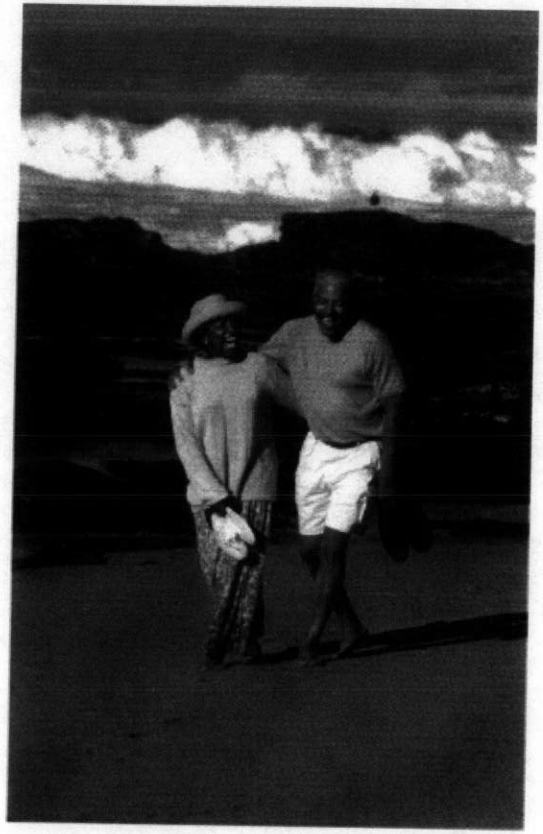
"It was wonderful. I really wasn't even aware I had an incision because it didn't hurt. There was just no pain. Almost immediately I was on my feet and really didn't have any problems at home going up and down stairs."

Mozelle D.
Surgery patient

Relieve Your Pain after Surgery

After your surgery, it's important that your pain is relieved. When you're not in pain, you may sleep better, move around sooner and may get back to your normal appetite quicker so you feel better faster.

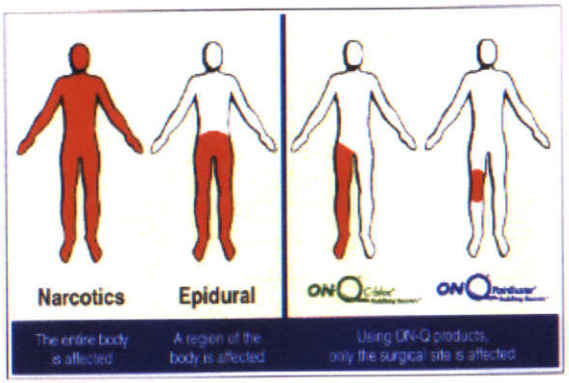
There are two major ways that pain is relieved after surgery. The most familiar is the use of narcotics like morphine. These drugs can cause unpleasant side effects such as nausea, drowsiness, constipation and difficulty breathing. They may also be habit forming. Medical science has developed a new way of relieving pain that can cut down or even stop the need for these drugs. This important new type of pain relief is called ON-Q PainBuster.



The New Choice for Post-Surgical Pain Relief

Narcotic Pain Relief

Most people know about common drugs called narcotics such as morphine, Demerol and codeine. These are often given after surgery in pill form, in a shot or through a tube placed directly in the vein (intravenous or IV).



Pros and Cons of Narcotic Pain Relief

Drugs like morphine affect the entire body. They're good for relieving really bad pain in a large area. But narcotics can make it harder to walk, eat and go to the bathroom. For these reasons, when pain is only in a small area, it may be better to choose pain relief that affects only that area.

Local Anesthetic Pain Relief

Local "anesthetics" are medicines, like Novocain®, that work right where the pain is. They don't affect the whole body, so they won't make you sleepy or groggy and don't numb other body parts. Other local anesthetics you may have heard about are lidocaine and bupivacaine.

Potential Results*	ON-Q System	Narcotics
Less pain	✘	✘
Continuous pain relief	✘	✘
Faster return to normal activities	✘	
Quicker return to normal body function	✘	
Clear and groggy-free head	✘	
Greater mobility	✘	
More comfortable recovery	✘	
Earlier hospital release	✘	
Nausea		✘
Vomiting		✘
Potential for addiction		✘
Possible breathing problems		✘
Constipation		✘
Groggy, knocked-out, 'hangover' feeling		✘
Overall slower recovery		✘
Higher risk for intense pain spikes		✘

Continuous Pain Relief at the Surgical Site

Doctors have used local anesthetics during all kinds of surgeries for years. But now, these medicines are used to control pain after surgery. The medicine can be put right where the surgical cut is and it relieves the pain even while you're *up and moving around.*

*For a list of published clinical studies, visit AskYourSurgeon.com.

It's Time You Know ON-Q PainBuster

For local pain relief many surgeons use a system called ON-Q PainBuster. ON-Q PainBuster uses a little pump shaped like a rubber ball to put medicine right on the spot of your incision. The pump connects to a very thin tube (catheter), which is put in place by your surgeon. You may wear your ON-Q PainBuster while you're in the hospital or even take it home for a few days.

It easily clips to your clothing or it can be carried in a small case. After you're finished using it, you simply throw it away.

ON-Q PainBuster May Provide*:

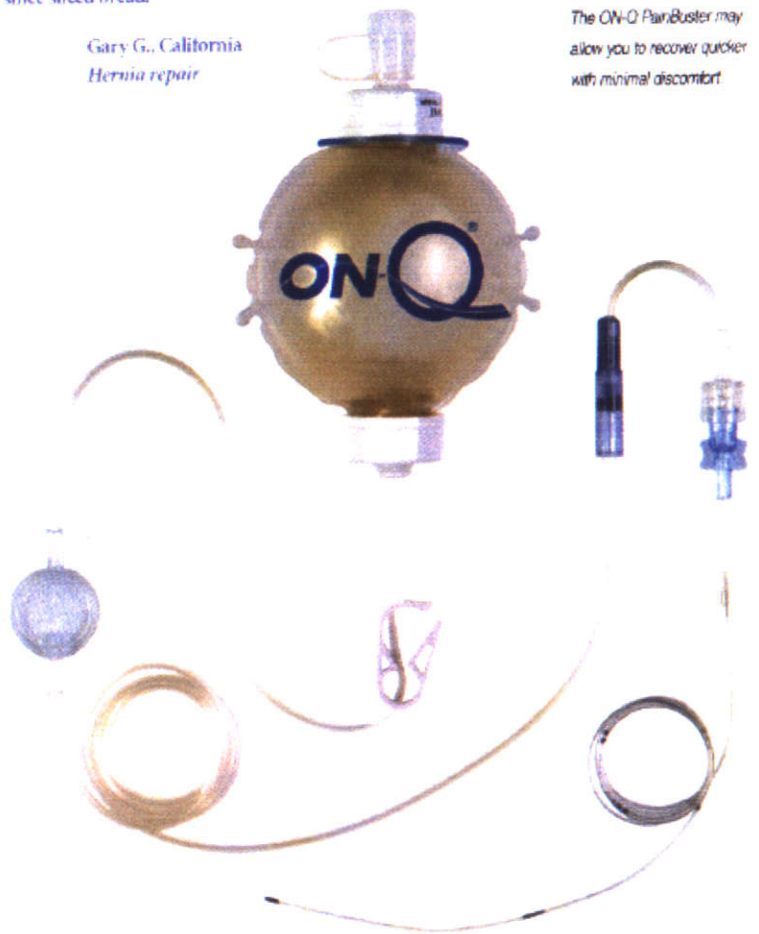
- More comfortable pain relief and recovery
- Pain relief without the side effects of narcotics
- Constant pain relief — so pain doesn't "break through" as it sometimes does with narcotics
- Quicker return to normal activities like walking, eating and generally moving around
- Earlier release from the hospital

Your surgeon will tell you if ON-Q PainBuster is right for you, either alone or with a small amount of pain pills. If your surgeon gives you pain pills, you should take them according to your surgeon's directions. You may be one of the many people who get better faster with ON-Q PainBuster. Ask your surgeon about ON-Q PainBuster today.

*For a list of published clinical studies, visit AskYourSurgeon.com.

"I'm a healthcare consultant by day and a judo instructor by night. The ON-Q System helped keep the pain of my hernia operation to a minimum and it got me back on my feet fast! It's the best thing since sliced bread."

Gary G., California
Hernia repair



The ON-Q PainBuster may allow you to recover quicker with minimal discomfort

Guidelines for Pain Relief Using

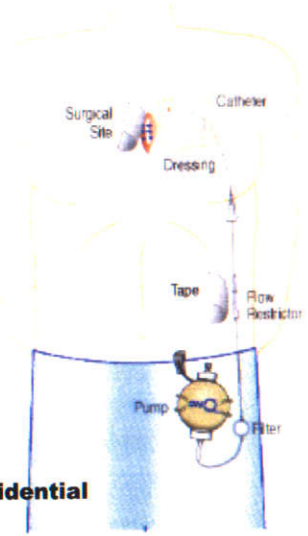
ON-Q PainBuster®
Redefining Recovery™

During Use:

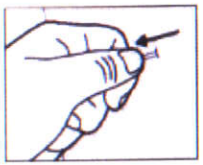
The ON-Q PainBuster pump is filled with medicine. It is completely portable and can be attached to your clothing or carried in a small pouch. A tiny tube or catheter connects to the pump. The flow restrictor is taped to the skin.

The medicine is automatically delivered to your incision from the pump — there is no need to squeeze or adjust it. As the medicine is released, the pump will get smaller. This is a very slow process — barely noticeable in the first 24 hours.

When the time is up and the medicine is gone, the pump will be flat and you'll be able to feel a hard, thick tube in the middle of it.



ON-Q PainBuster Removal (Catheter):



If your doctor has instructed you to remove the catheter, then follow his or her instructions keeping in mind these key steps — simply remove the small bandage covering your catheter, hold the tube close to the skin, and gently pull. Generally, it will come out easily. There should be no pain. If there is any resistance at all, you can call the doctor and arrange to have it removed. Don't ever pull hard or cut the catheter. Just call the doctor if you have trouble removing it.

At the tip of the tube you'll see a small black mark. If you can't see the black mark

when you remove the catheter, let your doctor know. Your doctor or nurse should give you a Patient Guidelines pamphlet to take home with you for more information on using your ON-Q PainBuster.

Your doctor's information:

Doctor: _____

Phone _____

Special Instructions: _____

_____

For more information about ON-Q PainBuster:

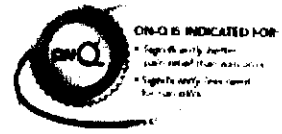
24-Hour Product Support Hotline

800-444-2728

AskYourSurgeon.com

Your doctor may want to use this drawing to explain your specific surgery and how ON-Q PainBuster may be used

ON-Q PainBuster® Redefining Recovery®



Local Anesthetic Dosing by Drug Concentration and ON-Q PainBuster Model

This chart should be used as a reference only; it does not replace specific instructions from clinicians with experience and additional information about administering these drugs. Drug doses are approximate and based on nominal specifications.

CAUTIONS

- Toxic Level Indicator: Drug symbols that appear in chart below indicate that the cross referenced drug concentration and ON-Q PainBuster model exceeds the drug manufacturer's recommended maximum 24 hour dose.
- 24 hour dose (mg) is calculated by filling the ON-Q PainBuster pump to the labeled NOMINAL volume. Filling the pump less than NOMINAL will increase the flow rate and thus increase the dose delivered in 24 hours.
- Bolus or loading dose should be added to dose calculation. See Bolus Dose Cross Reference Chart on reverse side.
- Refer to drug manufacturers' package insert for complete prescribing information. Surgeon is responsible for prescribing drug based on each patient's clinical status (such as age, body weight and disease state of patient).
- All local anesthetics should be regarded as guidelines for use in adults.
- Referenced local anesthetics are without Epinephrine. Vasoconstrictors such as Epinephrine or adrenaline are not necessary and may not be recommended for continuous infusions.

Drug Manufacturers' Recommended Maximum Dose* (intraoperative)

Drug	Maximum 24-Hour Dose	Toxic Level Indicator
Bupivacaine (Marcaine®, Sensorcaine®)	400 mg	BU
Levobupivacaine (Chirocaine®)	695 mg	LE
Ropivacaine (Naropin®)	770 mg	RO

Drug	Maximum 24-Hour Dose	Toxic Level Indicator
	(24-hour dosing not specified)	
Lidocaine (Xylocaine®)	300 mg	—

ON-Q PainBuster 24 Hour Dose (mg) Cross Reference Chart

PM001, PM011	**24 mg**	**30 mg**	**60 mg**
PM002, PM012, PM022	**96 mg**	**120 mg**	**240 mg**
PM003, PM013, PM023	**96 mg**	**120 mg**	**240 mg**
PM004, PM014, PM024	**240 mg**	**300 mg**	**BU 600 mg**
PM005, PM015, PM025 dvo 2 ml per site	**192 mg**	**240 mg**	**BU 480 mg**
PM026	**240 mg**	**300 mg**	**BU 600 mg**
PM027	**BU 480 mg**	**BU 600 mg**	**BU LE RO 1200 mg**
PM018, PM028 dvo 2 ml per site	**192 mg**	**240 mg**	**BU 480 mg**

Calculations based on nominal flow rate. Flow rate may vary by ±15%. See ON-Q PainBuster Directions For Use for additional factors that may affect flow rate. Formula: ml/hr x % drug concentration x 10 x 24 hr = 24 hour dose (mg).

Local Anesthetic Dose

Drug Manufacturers' Maximum Recommended Dose* (intraoperative)

Drug	Maximum 24-Hour Dose	Toxic Level Indicator
Bupivacaine (Marcaine®, Sensorcaine®)	400 mg	BU
Levobupivacaine (Chirocaine®)	695 mg	LE
Ropivacaine (Naropin®)	770 mg	RO

Drug	Maximum 24-Hour Dose	Toxic Level Indicator
	(24-hour dosing not specified)	
Lidocaine (Xylocaine®)	300 mg	—

Bolus Dose (mg) Cross Reference Chart

Volume Bolus			
10 ml	20 mg	25 mg	50 mg
20 ml	40 mg	50 mg	100 mg
30 ml	60 mg	75 mg	150 mg
40 ml	80 mg	100 mg	200 mg

Formula: Bolus Volume (ml) x % drug concentration x 10 = dose (mg)

* For complete prescribing information refer to drug manufacturer's instructions for use.
See CAUTIONS on front side.

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For a list of supporting studies, please visit www.dfio.com

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Abdominoplasty

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This material is provided for educational purposes and represents the technique used by the above surgeon. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Pump Used: PM046: 400 ml x 5 ml/hr, 10" Soaker Catheter™

Drugs in Pump: 330 ml of 0.25% Marcaine

Pre-Incision Infiltration: Subfascial block, peripherally and adjacent to the midline repair.

30 ml 1.0% Lidocaine with epinephrine
30 ml 0.25% Marcaine with epinephrine

Catheter Placement: Fascial repair in 2 layers. A 4 mm curved suction cannula is passed from the suprapubic drain site into the repair and brought out in the epigastric area of the repair. The catheter is threaded down the cannula. The cannula is slowly withdrawn to the hypogastric area of the repair and the tip poked up through the repair. The catheter is visible as the cannula is withdrawn from the drain site. The catheter is pulled until it goes into the repair itself and are under the fascia.

Postoperative Bolus: None

Catheter Securement Technique: The catheter is taped to the central drain with a Steri-Strip.

Additional Post-Op Pain Medication: Hydrocodone or ibuprofen as needed.

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

CAUTIONS

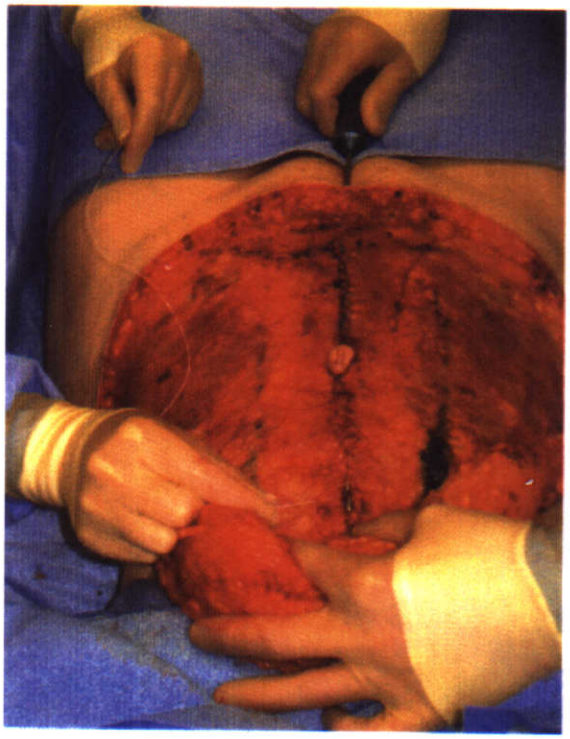
- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or Adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q Directions for Use for full instructions on using the ON-Q System.*

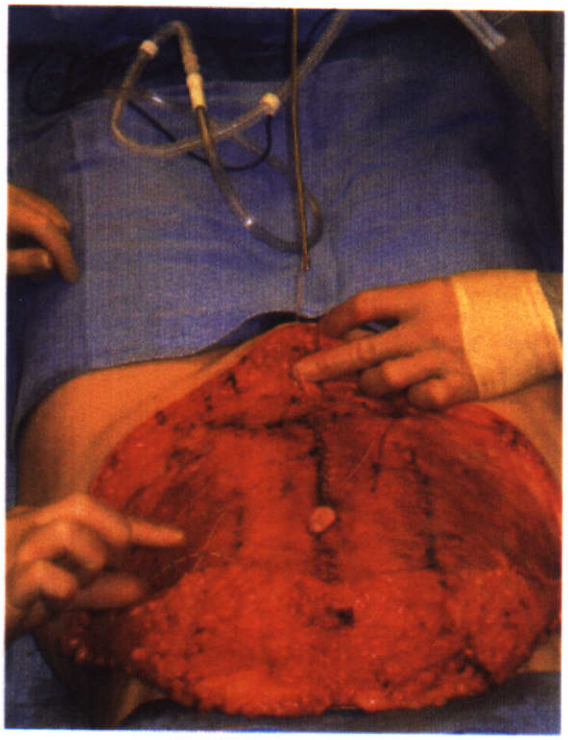
NOW LABELED FOR ON-Q ENHANCED INDICATIONS

ON-Q PainBuster® Redefining Recovery™

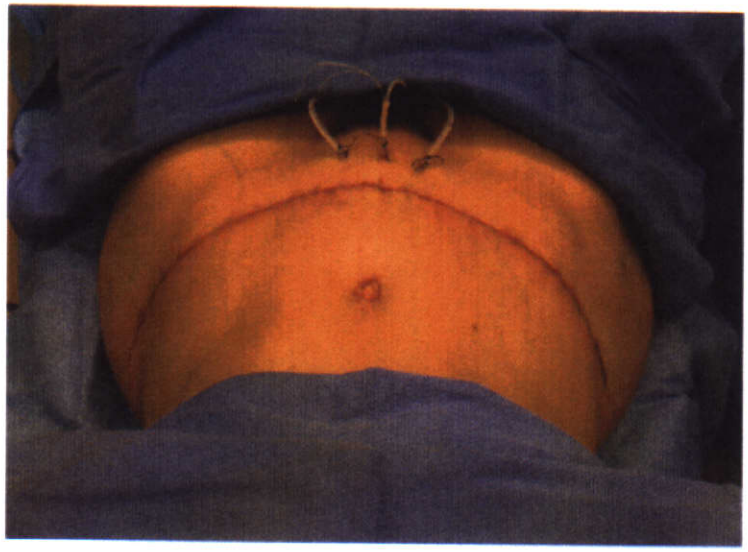
These images are for general guidance only and not intended to be construed as I-Flow's specific recommendation.

PLACEMENT





SECUREMENT



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Femoropopliteal Artery Bypass Using Reverse Saphenous Vein

This material is provided for educational purposes and represents the technique used by the above surgeon. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Pump Used: PM025: 270 ml x 4 ml/hr (2 ml/hr +2 ml/hr) or
PM028: 400 ml x 4 ml/hr (2 ml/hr +2 ml/hr)

Drugs in Pump: 270 ml or 400 ml of 0.5% Marcaine plain, depending on pump used. In addition, an optional dose of Ancef, one gram, may be added to the Marcaine to be infused via the pain pump. Marcaine and Ancef are compatible.

Catheter Placement: The first catheter is inserted approximately three inches laterally from the superior aspect of the proximal incision and tunneled into the incision. (See Figure 1) The catheter is then placed alongside the femoral artery (See Figure 2). The wound is closed in layers on top of the catheter, followed by a subcutaneous closure. The second catheter is inserted approximately three inches proximal to the superior aspect of the distal incision and tunneled into the incision (See Figure 3). The catheter is then placed alongside the saphenous nerve (See Figure 4), and the wound is closed in layers on top of the catheter, followed by subcutaneous closure.

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

Catheter Securement: Both ON-Q catheters should be secured first with Steri-Strips at the insertion sites, followed by placement of a clear occlusive dressing over both insertion sites. (See Figure 5). To prevent catching or pulling of the pump tubing, additional Steri-Strips can be applied to the tubing along the patient's thigh (See Figure 6). The pump should then be placed into the carrying bag.

Additional Post-Op Pain Medications: Vicodin or the physician's medication of choice should be available for postoperative breakthrough pain.

CAUTIONS

- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q Directions for Use for full instructions on using the ON-Q System.*

Femoropopliteal Artery Bypass Using Reverse Saphenous Vein

These images are for general guidance only and not intended to be construed as I-Flow's specific recommendation.

PUNCTURE SITE

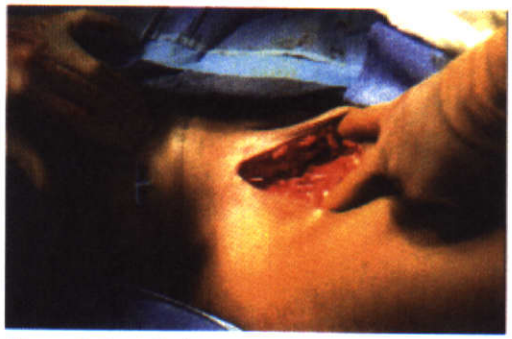

Figure 1 First Catheter

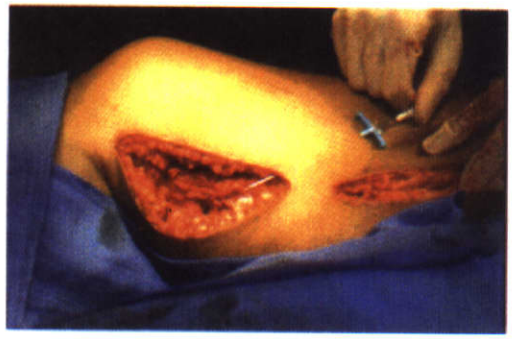

Figure 3 Second Catheter

PLACEMENT

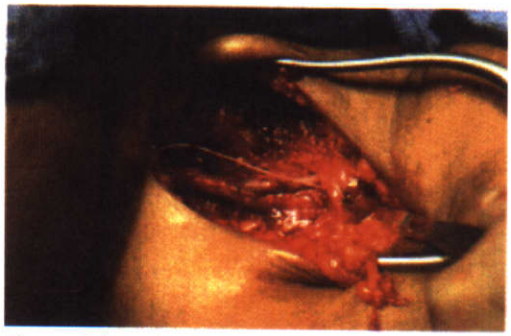

Figure 2 First Catheter

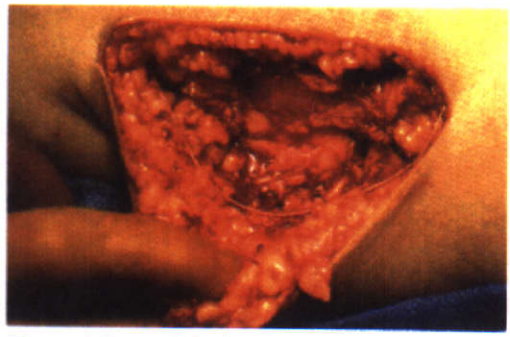

Figure 4 Second Catheter

SECUREMENT

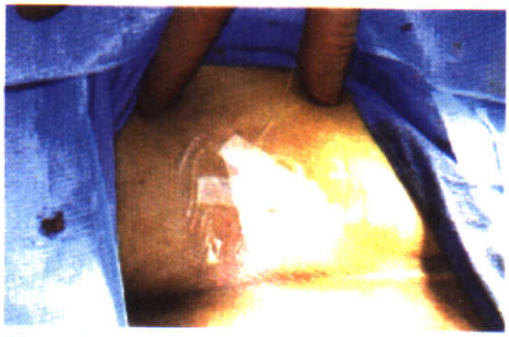

Figure 5

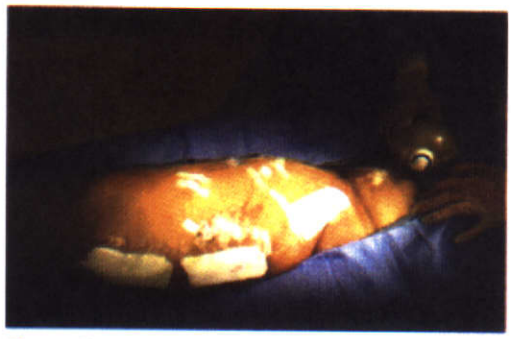

Figure 6

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(b)(4)

Above Knee Amputation

(b)(4)

This material is provided for educational purposes and represents the technique used by the above surgeon. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Pump Used: PM028: 400 ml x 4 ml/hr (2 ml/hr + 2 ml/hr)

Drugs in Pump: 500 ml 0.5% bupivacaine

Pre-Incision Infiltration: None

Catheter Placement: Once amputation has been completed, a tear-away introducer is inserted through the skin and into the wound from the lateral side of the thigh. A second tear-away introducer is inserted adjacent to the first. Once both catheters are in place, the catheters are adjusted so that the perforated infusion portion of the catheter is centered in the wound and no perforations are outside the skin. The fascia is closed over one of the catheters using interrupted absorbable suture. The skin is closed over the second catheter using interrupted monofilament suture or staples. Thus, infusion from one catheter will be in the tissue below the fascia. The infusion from the second catheter will be in the subcutaneous tissue.

Postoperative Bolus Technique: Once closure is completed, the catheters are hand injected with a few ml of bupivacaine or other appropriate local anesthetic.

Catheter Securement Technique: The catheters are secured by creating a loop near the skin entry site and then an adhesive polyurethane dressing is placed to secure the catheters.

Additional Post-Op Pain Medications: Oral Vicodin PRN.

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

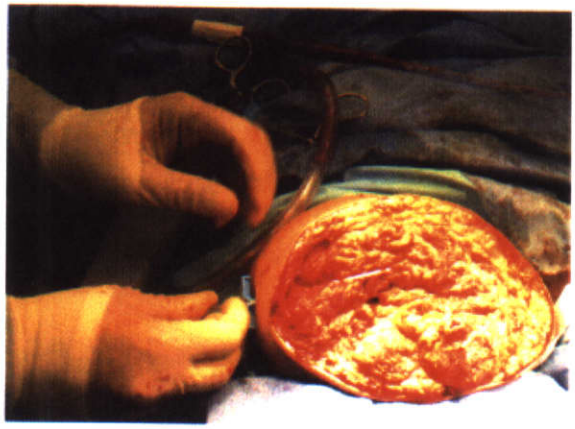
CAUTIONS

- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q Directions for Use for full instructions on using the ON-Q System.*

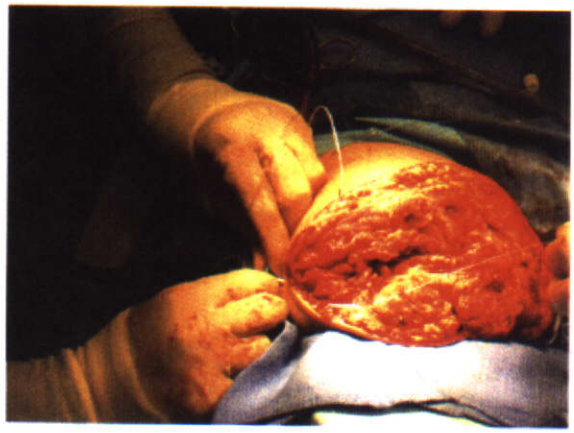
Above Knee Amputation

These images are for general guidance only and not intended to be construed as I-Flow's specific recommendation.

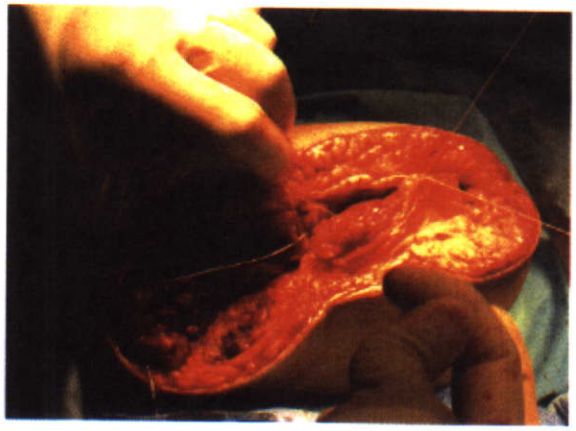
SUBFASCIAL INTRODUCTION



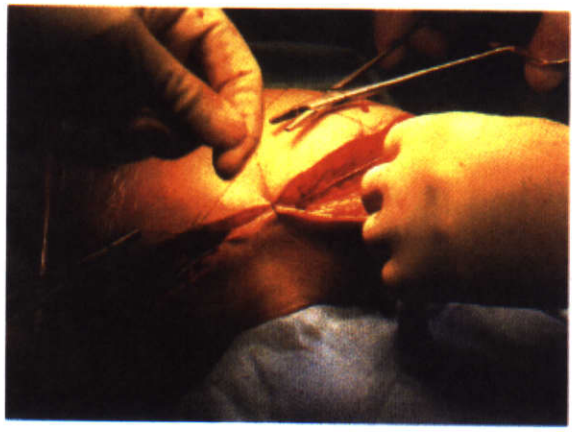
SUBCUTANEOUS INTRODUCTION



FASCIA CLOSURE OVER 1ST CATHETER



SKIN CLOSURE OVER 2ND CATHETER



CATHETER SECUREMENT

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(b)(4)

Single & Bilateral Breast Reconstruction with Tissue Expander and Latissimus Dorsi Flap

(b)(4)

This material is provided for educational purposes and represents the technique used by the above surgeons. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Pump Used: **Single:** PM025 (270 ml x 4 ml/hr) *1 pump procedure*
Bilateral: PM025 (270 ml x 4 ml/hr) *2 pump procedure*

Drugs in Pump: **Single:** 270 ml of 0.25% bupivacaine plain
Bilateral: Fill two pumps with 270 ml of a 50:50 mixture of 0.5% lidocaine and 0.25% bupivacaine plain

Catheter Placement: Insertion of catheters is done through the axilla prior to inserting tissue expanders as not to damage the implant with the insertion needle.

For the incision, the catheter is placed superiorly in the sub pectoral space. Drains are placed anteriorly in the pocket(s) and axilla.

Bolus Technique: **Single:** 10 ml of 0.25% bupivacaine into submuscular space per catheter
Bilateral: 10 ml of 50:50 mixture lidocaine 0.5% and 0.25% bupivacaine into submuscular space per catheter

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

Wound Closure and Catheter Securement Technique: Catheter secured with Steri-Strips and bio-occlusive dressing. Wound(s) closed with subcuticular suture.

Additional Postoperative Pain Medications: PCA if additional treatment of post-operative pain is needed.

Other Notes: Remove ON-Q on Post-op day 2.

CAUTIONS

- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or Adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q PainBuster Directions for Use for full instructions on using the ON-Q PainBuster System.*

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ON-Q PainBuster® Redefining Recovery™

221

Single & Bilateral Breast Reconstruction with Tissue Expander and Latissimus Dorsi Flap

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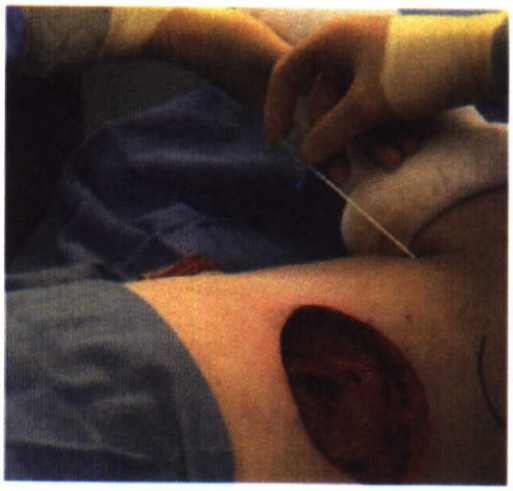
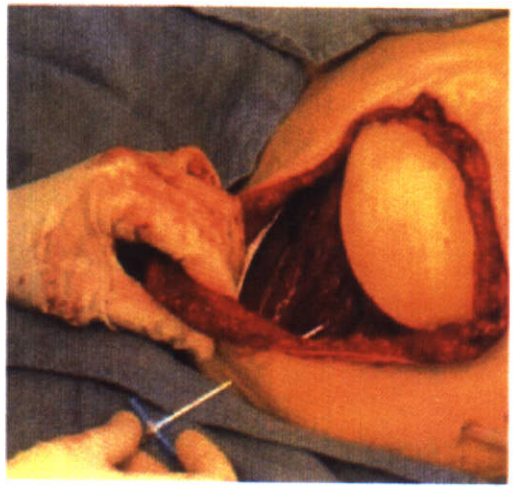
PUNCTURE SITE



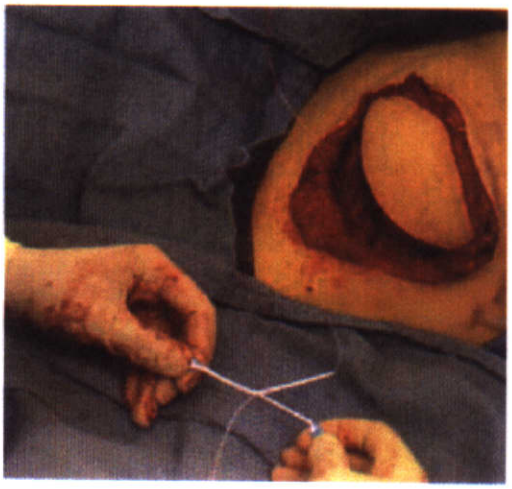
Placement of catheter in back along the muscle donor site

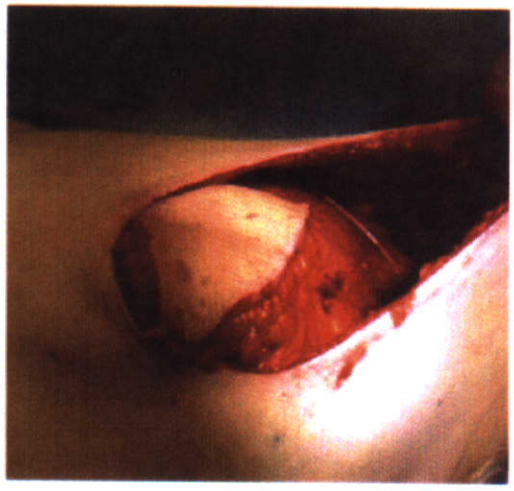
NOTE: Insertion of catheters is done through the axilla prior to inserting tissue expanders as not to damage the implant with the insertion needle



Placement of catheter in the mastectomy site in the superior sub-pectoral plane

PLACEMENT





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Hand Surgery (Cubital Tunnel Release)

(b)(4)

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This material is provided for educational purposes and represents the technique used by the above surgeon. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Surgical Procedures: Cubital tunnel release, radial tunnel release, CMC arthroplasties, epicondylectomy, hand/wrist fractures/fusions, ligament reconstruction.

Pump Used: PM012: 100 ml x 2 ml/hr

Drugs in Pump: 100 ml of 0.25% bupivacaine plain

Catheter Placement: The catheter is inserted through the introducer away from the surgical site and placed along the base of the wound on top of the fascia.

Catheter Securement Technique: When the catheter is properly placed, apply one steri-strip at the insertion site. Also, apply a small sterile Tegaderm® to hold down approximately 2-3 inches of the catheter. Then apply normal dressing and/or a splint. Avoid kinking of the tubing throughout its course.

Postoperative Bolus Technique: 0.25% bupivacaine plain (injected)

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

CAUTIONS

- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q Directions for Use for full instructions on using the ON-Q System.*
- *Caution should be used when selecting appropriate volumes and flow rates keeping in mind potential fluid build-up in a restricted space that may lead to a complication, particularly with hand and /or foot surgery. complications may include: blisters, dehiscence, seromas, sloughing tissue and subsequent necrosis when too much fluid is delivered near the distal end of extremities. It's not recommended for incisional site delivery near the distal end of extremities; instead, a nerve block approach is preferred. The above protocol is an example. Avoid flow rates in excess of 2 ml/hr and total volumes greater than 100 ml. Technical Bulletin available upon request.*

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Hand Surgery (Cubital Tunnel Release)

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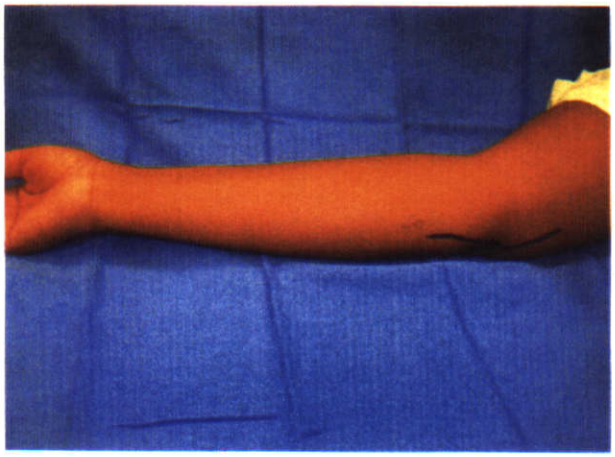
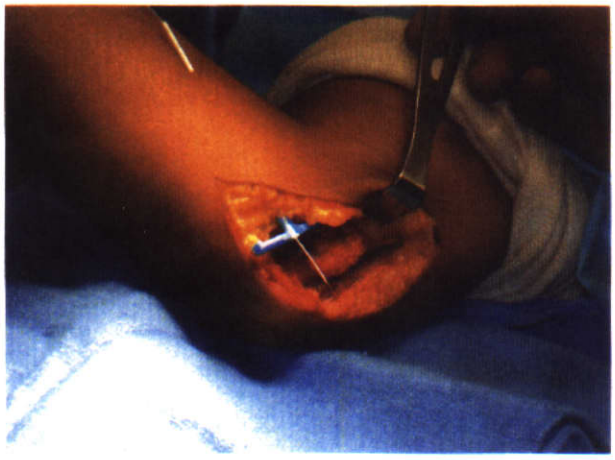
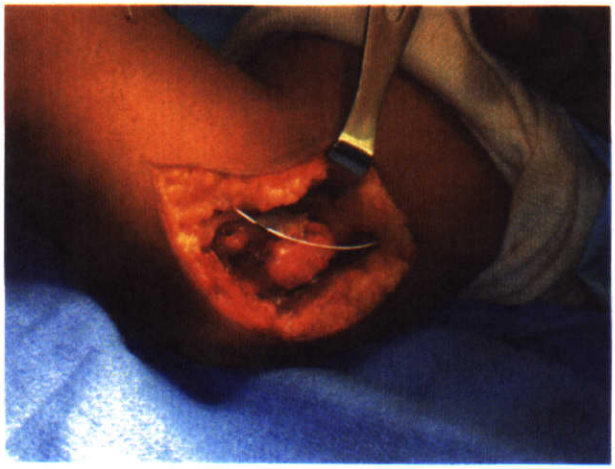
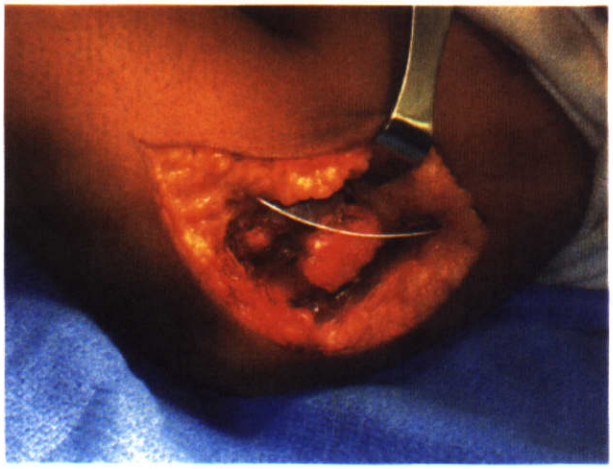
PUNCTURE SITE





PLACEMENT





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(b)(4)

Rotator Cuff Repair

(b)(4)

This material is provided for educational purposes and represents the technique used by the above surgeon. Catheter placement is provided for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. This protocol is not to be construed as I-Flow's specific recommendation.

SAMPLE PROTOCOL

Pump Used: PM012: 100 ml x 2 ml/hr

Drugs in Pump: 100 ml of 1% lidocaine plain

Pre-Incision Infiltration: 10 ml of 0.25% bupivacaine plain. Aspirate before injection to avoid intravenous or intra-arterial injection.

Catheter Placement: Placed anteriorly in the subacromial space. Arthoscopically confirm the position of the catheter. Tighten all connections and then inject 1-3 ml of 1% lidocaine plain to ensure patency of the catheter.

Bolus Technique: A 25 ml bolus of 0.25% bupivacaine plain is injected into the subacromial space through the arthroscopic portals.

Catheter Securement Technique: Catheter is secured with 3 wound closure strips and is coiled under an occlusive dressing.

Additional Post-Op Pain Medications: Vicodin

Other Notes: The catheter is removed either in physical therapy or at home by a family member - as instructed during the pre-operative teaching program. Tape flow restrictor to skin, away from ice packs.

Drug Manufacturers' Recommended Dose

DRUG	MAXIMUM
Maximum 24 Hour Dose	
Bupivacaine *(Marcaine®, Sensorcaine®)*	400 mg
Levobupivacaine *(Chirocaine®)*	695 mg
Ropivacaine *(Naropin®)*	770 mg
Maximum Total Dose *(24 hour dose not specified)*	
Lidocaine *(Xylocaine)*	300 mg

All local anesthetics are without epinephrine and manufacturer recommendations should be regarded as guidelines for use in adults.

CAUTIONS

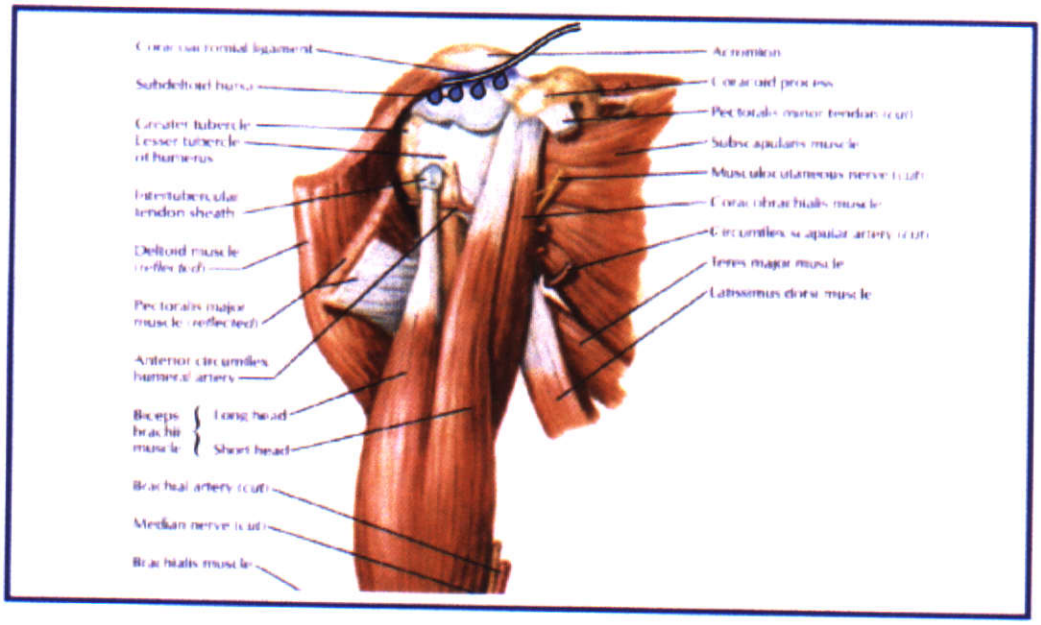
- *Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer (see guidelines above). Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient).*
- *Vasoconstrictors such as Epinephrine or Adrenaline are not necessary and may not be recommended for continuous infusions.*
- *Refer to ON-Q PainBuster Directions for Use for full instructions on using the ON-Q PainBuster System.*

NOW LABELED FOR ON-Q ENHANCED INDICATIONS

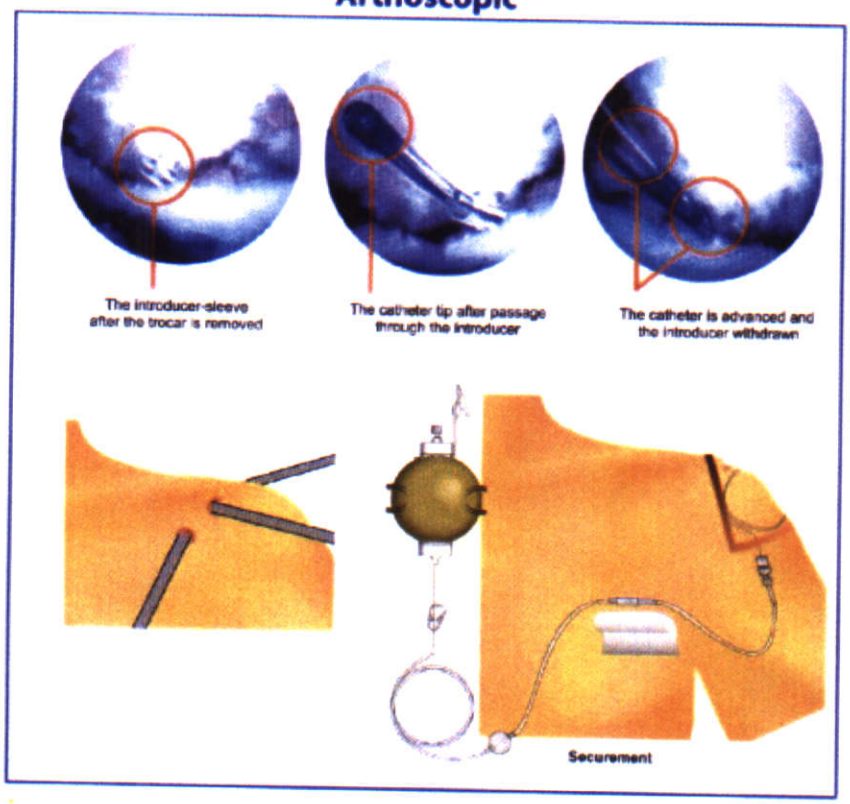
Rotator Cuff Repair

These illustrations are for general guidance only and not intended to be interpreted as precise anatomical illustrations.

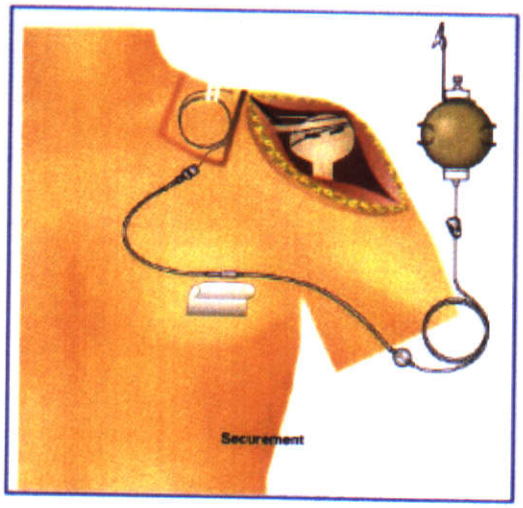
Placement



Arthoscopic



Anterolateral Stab Incision



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Create your ON-Q Procedure Kit that's right for you. You can now choose from selected components to create a unique kit for your procedures. From the list of ON-Q products, choose a pump, catheter(s), needle(s) and tunneler to design a custom kit to return patients to normal faster.

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Doctor or

Facility Name: _____
(MAX 32 CHARACTERS)

or None: ☐

and/or

CHOICE II ***(Pick one)***

☐ OB/GYN Kit ☐ Urology Kit ☐ Cardiovascular Kit ☐ Orthopedic Kit ☐ None

☐ General Surgery Kit ☐ CV/CT Kit ☐ Thoracic Kit ☐ Custom Procedure Kit

Each Custom Order includes 5 kits per case

Estimated Quantity of Cases/Month:_____ (Minimum Volume 5 cases/month)

Price Quote

Each: $_____ **Case: $**_____

Hospital Name _____ **Acct. No.** _____

Hospital Representative Name _____ **Acknowledgement Signature** _____

Products currently ordering (e.g. PM025, ACC02, ACC08S, etc)

Models	Price per case	Models	Price per case
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

I-Flow Rep _____

I-Flow Approval _____
NAME SIGNATURE DATE

FAX FORM TO:
949-206-2663

ON-Q INFUSION PUMPS *(Select desired pump)*
Limit 1 Pump

- ☐ P65X0.5 (65 ml x 0.5 ml/hr)
- ☐ P100X1 (100 ml x 1 ml/hr)
- ☐ P100X2 (100 ml x 2 ml/hr)
- ☐ P270X2 (270 ml x 2 ml/hr)
- ☐ P270X4 (270 ml x 4 ml/hr)
- ☐ P270X5 (270 ml x 5 ml/hr)
- ☐ P400X4 (400 ml x 4 ml/hr)
- ☐ P400X5 (400 ml x 5 ml/hr)
- ☐ SAF01 (270 ml x 1-7 ml/hr)

(Choose 1 catheter below)

- ☐ P100X2D (100 ml x 2 ml/hr; 1 ml/site)
- ☐ P270X4D (270 ml x 4 ml/hr; 2 ml/site)
- ☐ P400X4D (400 ml x 4 ml/hr; 2 ml/site)

(Choose 2 catheters below)

- ☐ P400X6T (400 ml x 2 ml/site)

(Choose 3 catheters below)

☐ **NONE. Pump ordered separately.**

ON-Q SOAKER CATHETERS *(Select desired catheters)*
Limit 4 Catheters

- QTY: ___ CT010 (2.5 inch Soaker catheter)
- QTY: ___ CT020 (5 inch Soaker catheter)
- QTY: ___ CT030 (1 inch Soaker catheter)
- QTY: ___ CT040 (10 inch Soaker catheter)
- QTY: ___ CT010-A (2.5 inch SilverSoaker catheter)
- QTY: ___ CT020-A (5 inch SilverSoaker catheter)
- QTY: ___ CT030-A (1 inch SilverSoaker catheter)
- QTY: ___ CT040-A (10 inch SilverSoaker catheter)

ON-Q INTRODUCER NEEDLES *(Select desired needles)*
Limit 3 Needles

- QTY: ___ ACC01-05 (3.25 inch Introducer needle)
- QTY: ___ ACC02-05 (6 inch Introducer needle)
- QTY: ___ ACC03-05 (8 inch Introducer needle)

ON-Q TUNNELING SYSTEM *(Choose Disposable Tunneler with Sheaths OR Reusable Tunneler)*

ON-Q TUNNELERS & SHEATHS *(Select desired tunneler & sheaths)*
Limit 1

- QTY: ___ T17X3.25 (17 gauge x 3.25 inch)
- QTY: ___ T17X5 (17 gauge x 5 inch)
- QTY: ___ T17X8 (17 gauge x 8 inch)
- QTY: ___ T16X12 (16 gauge x 12 inch)
- QTY: ___ T11X8 (11 gauge x 8 inch)
- QTY: ___ T11X12 (11 gauge x 12 inch)

**Each disposable tunneler is packaged with two introducer sheaths.*

OR

ON-Q TUNNELER (REUSABLE)
Limit 1 Tunneler

- ☐ ACC07 (11 gauge x 8 inch)
- ☐ ACC08 (17 gauge x 8 inch)
- ☐ ACC09 (11 gauge x 12 inch)
- ☐ ACC010 (16 gauge x 12 inch)
- ☐ ACC12 (17 gauge x 3.25 inch)
- ☐ ACC13 (17 gauge x 5 inch)

ON-Q TUNNELER SHEATHS
Limit 3

- ☐ ACC07S (11 gauge x 8 inch)
- ☐ ACC08S (17 gauge x 8 inch)
- ☐ ACC09S (11 gauge x 12 inch)
- ☐ ACC10S (16 gauge x 12 inch)
- ☐ ACC12S (17 gauge x 3.25 inch)
- ☐ ACC13S (17 gauge x 5 inch)

TECHNICAL BULLETIN

ON-Q® Pain Relief System®
Redefining Recovery™

Pediatric Application with ON-Q

The use of continuous incision infusions of local anesthetics for postoperative pain management has been used in children for various procedures because of the benefits for the patient. Although the general indications for continuous infusions of local anesthetics for postoperative pain management in pediatric patients are similar to adults, optimal dosing of these agents may differ. **Practitioners who choose to administer local anesthetics to pediatric patients with the ON-Q must be familiar with the safety profile of the drug they choose and refer to relevant published information on this therapy in this population.**

Distribution and systemic absorption of the local anesthetic agents may be greater in young children due to increased cardiac output and regional blood flow. Also, in infants, plasma levels of local anesthetics may be higher due to the lower levels of albumin and α1-acid glycoprotein, which binds the molecules of these agents to plasma proteins.[1]

Dosing in children is primarily based on weight, age, and clinical status of the patient. Due to the potential for toxicity, these dosages should not be extrapolated from adult experiences, which often use a generalized dosage regimen. In order to maintain infusion amounts (mg/kg/hr) within referenced dosage guidelines, it is strongly recommended that concentrations of local anesthetics (bupivacaine and ropivacaine) do **not** exceed 0.25%. The patient's weight and age must be carefully considered when determining the dosage. When continuous infusions are utilized, care must be taken not to exceed toxic doses. For example, **a bupivacaine infusion should not exceed 0.2 mg/kg/hr in neonates and 0.4 mg/kg/hr in older infants, toddlers and children.**[2]

Because these patients need to be monitored by a clinician, it is recommended that if this therapy is used for outpatient procedures, that the caregivers receive technical training on the early signs and symptoms of local anesthetic toxicity.

I-Flow is in the process of studying the use of ON-Q on pediatric patients at this time but cannot give dosing recommendations. **The drug concentration and daily dosage is the responsibility of the surgeon and anesthesiologist attending to the patient.**

Dosing for pediatrics is calculated on a mg/kg/hr basis. Please refer to the calculation method below to determine the amount being delivered to the patient.

Mg dosage — Concentration of local anesthetic x 10 x flow rate (ml/hr) delivered by the pump

Example — For a 2 ml/hr pump with 0.25% bupivacaine
0.25% x 10 x 2 = 5 mg/hr
Patient's weight 15 kg
Dose given = $\frac{5\text{mg/hr}}{15\text{ kg}}$ = 0.33 mg/kg/hr

Continuous infusions of local anesthetics have been used for many pediatric surgical procedures and may expand the capability for providing safe and effective pain relief. Dosing of local anesthetic, with limits set for maximum doses, may provide a consistent level of prolonged pain relief that may allow for easier discharge of the patient, a reduction in side effects such as nausea and vomiting, drowsiness or ventilatory depression.

As a reference, signs and symptoms of local anesthetic toxicity are listed in Table 1.
Suggested references for dosing information are summarized in Table 2. A bibliography of these references is attached.

Please contact the Clinical Services Department at 800-448-3569 or 949-206-2700 if you have any questions regarding this information.

Table 1

Signs and Symptoms of local anesthetic toxicity
Drowsiness, Confusion
Dizziness, Light-headedness
Metallic taste
Numbness/Tingling of mouth and lips
Buzzing/ringing in the ears (or other auditory hallucinations)
Muscle spasms
Seizures
Coma
Respiratory arrest
Cardiac arrest

Table 2

Author	Catheter Placement	Drug*	Weight Range (kg)	Dose range mg/kg/hr	Duration of infusion (hr)	Plasma levels µg ml-1	Toxicity y/n
Scherhag[3]	Peridural	B	Unknown	Max 0.4	na	Max 2.2	N
Tobias[4]	Interpleural	B	Unknown; Age 2 mos - 17 yrs.	0.75 - 1.0	72	na	N
Downs[5]	Intercostal	B	12 - 66	Mean 0.28	72	na	N
Cheung[8]	Paravertebral	B	2.5 - 4.2	0.2	48	Mean 1.6 @ 48 hr 3 subjects >3.0	N
Shah[9]	Paravertebral	B	Unknown	0.25	120	na	N
Eng[10]	Paravertebral	-	Unknown, age 7-16 yrs	1.0	120	na	N
Semsroth[11]	Thoracotomy/Intrapleural	B	6.8 - 43.5	Max 1.25 Min 0.73	24	na	N
Gibson[12]	Thoracotomy/retropleural	B	26 - 72	0.625-1.25	91.2	na	N
Peutrell[13]	Extradural	B	5.6 - 9.3	0.375	40	Mean <2.0 One subject peaked at 2.02 @ 32 hr	N
Karmakar[14]	Extrapleural/Paravertebral	B	2.5 - 6.2	0.5	24	Max 2.0	N
Wolf[15]	Lumbar or thoracic extradural	B	Mean 10.4	0.25-0.375	24	Two subjects had max levels of 2.5 and 3.7 @ 24 hr	N
Rothstein[16]	Intercostal NB	B	5.2 - 60	2-4mg/kg	Single shot	0.77-1.87	N
Desparmet[17]	Epidural	B	10 - 43	0.25 Day 1 0.2 thereafter	48	Mean 0.58	N
McCloskey[18]	Caudal epidural	B	3.89 45 12	Pt.1) 2.5 and 1.87 mg/kg Pt 2) 0.8, 0.55, 1 mg/kg Pt 3) 2.5 and 1.7 (x3)	2 doses 3 doses 4 doses	Max 5.6 Max 6.6 Max 10.2	Y
Agarwal[20]	Intrapleural/epidural	B	9.4 26	Pt. 1: 0.25 first 5 hrs 0.5 after Pt. 2: 1.25	5 16 56	5.6 5.4	Y
Larsson[19]	Epidural	B	2.4 - 4.2	0.2	48	Max 3.06	Y
Dadure[21]	Popliteal/axillary NB	R**	15-75	0.2	50 max	na	N

* B= bupivacaine ** R= Ropivacaine

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TECHNICAL BULLETIN

ON-Q Pain Relief System®
Redefining Recovery™

The Use of ON-Q with Perioperative Autologous Blood Transfusion Systems

Background

"Autologous" transfusion, or "autotransfusion" refers to those transfusions in which the blood donor and the transfusion recipient are the same. "Allogenic" transfusions refer to blood transfused to someone other than the donor.[1] While autologous blood transfusion is most commonly performed in the weeks prior to an elective surgical procedure, it also may be utilized during a surgical procedure in which the patient has significant blood loss. Although once used almost exclusively for open heart and vascular procedures, it is now commonly used for orthopedic, liver transplants, trauma and complex spinal surgeries. The advantages of autologous blood transfusion are many and include reduction of the risk of transmission of viruses, avoidance of allogenic transfusion reactions and supplementation of the sometimes-sparse supply of allogenic blood. [2]

In perioperative autologous blood transfusions, shed blood is collected from the patient during surgery and reinfused intravenously during surgery, or immediately postoperatively.

Autotransfusion can be accomplished either with a device that collects the whole blood and washes it to separate its components (Cell-Saver®, OrthoPAT™, CATS, or Medtronic Autolog or Sequestra 1000), or by a device that simply collects whole blood and filters it before reinfusion (ConstaVac™, Autovac™, Solcotrans®, or AT200™).[3]

The advantage of the former process is that the blood is separated into its components (RBCs, platelets, and plasma) and the patient can be given only the component needed.[4] It also theoretically removes toxic by-products, but may remove clotting factors in the process.[3] The washing devices may require operation by a specially trained operator. While the hemofiltration systems are limited in function, they are easy to use and cost effective.[2]

Caution When Using Pain Pumps with Autotransfusion

Questions frequently arise in the surgical setting regarding the use of the ON-Q Pain Management system in conjunction with an autotransfusion system, like the Cell Saver®. The safety concern involves the potential for intravascular infusion of the local anesthetics used in the ON-Q pump, and the risk of toxic effects as a result. While the risk may be small, given that the pump is at a slow infusion rate, precaution should be practiced to avoid any such hazard to the patient.
Recommendations when using an autotransfusion system:

DON'T:

- Use ON-Q when blood is still being salvaged for autotransfusion

DO:

- Place the primed catheter(s) into the wound and connect to the ON-Q with the clamp closed until the autotransfusion system is discontinued,
- Or, place the primed catheter(s) into the wound leaving the ends of the catheters capped until autotransfusion is discontinued; then connect the pump using aseptic technique.

Please contact the Clinical Services Department at 800-444-2728 or 949-206-2700 if you have any questions regarding this information.

References

1. American Association of Blood Banks web site: http://www/aabb/org/All_About_Blood/FAQs/aabb_faqs
2. The National Heart, Lung, and Blood Institute web site: http://www.nhlbi.nih.gov/health/prof/blood/transfusion
3. Fleischlag JA. Intraoperative blood salvage in vascular surgery – worth the effort? Available online at http://ccforum.com/content/8/S2/S53.
4. http://www.haemonetics.com/site/content/products/cellsaver.asp?section=hospitals&subSection=hospitals.

ON-Q Pain Relief System®
Redefining Recovery™

Hand and Foot Surgery Continuous Infusion – Volume and Flow Rate Selection

A potential complication may occur if too much fluid is infused into the incision site near the fingers or toes.

Caution should be used when selecting appropriate volumes and flow rates keeping in mind potential fluid build up in a restricted space that may lead to complications. Complications may include: edema, seroma, blisters, dehiscence, tissue sloughing and subsequent necrosis when too much fluid is delivered into the incisional site near the distal end of extremities (such as fingers and toes). The nerve block approach instead of incisional site catheter placement may be preferred for these procedures. Sprinkle and Watkins (1, 2) describe a nerve block procedure for bunionectomies where the catheter is placed away from the incision site. This approach appears to provide good pain relief while minimizing complications that may occur with incisional site placement.

In general, the total volume of fluid delivered should decrease as the catheter placement gets closer to the distal end of extremities. White (3) selected 270 ml at 5 ml/hr for delivery into the leg. Sprinkle (1) and Watkins (2) selected 100 ml at 2 ml/hr for delivery into the foot. All three used the nerve block approach.

In summary, when using the ON-Q after these procedures the following should be considered:

- Avoid incisional site catheter placement near the distal end of extremities (such as fingers and toes)
- Avoid flow rates in excess of 2 ml/hr in the hand or foot
- Avoid total volumes greater than 100 ml in the hand or foot.

The references below are not to be construed as I-Flow's specific recommendations. As with any surgical procedure, it is the responsibility of the physician to determine the appropriate catheter placement, medication, pump volume and flow rate for each individual patient.

Reference:

1. ON-Q Catheter Placement Technique, Bunionectomy – Dr. Ralph Sprinkle, Podiatrist.
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3. White P et al. The use of a continuous popliteal sciatic nerve block after surgery involving the foot and ankle: Does it improve the quality of recovery? Anesth Analg 2003;97:1303-1309.
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Please contact the Clinical Services Department at 800-444-2728 or 949-206-2700 if you have any questions regarding this information.

I-Flow Corporation

Technical Bulletin

Relationship between the ON-Q® Pain Relief System and the USP-NF 27 <797> Pharmaceutical Compounding – Sterile Preparations

Introduction

The ON-Q PainBuster® and C-bloc® systems are intended to provide continuous infusions of a local anesthetic directly into an intra-operative site or near a nerve for postoperative pain relief. ON-Q helps to break the circle of pain by providing non-narcotic pain relief for up to five days. The system requires little management by either the caregiver or the patient and encourages the patient's return to normal function. The ON-Q Pain Relief System is provided as a sterile, non-pyrogenic, single use medical device intended for filling in either the pharmacy or surgical suite. When the ON-Q elastomeric pump is filled at the healthcare facility, by USP-NF definition, it becomes a Compounded Sterile Preparation (CSP). Recent changes to the United States Pharmacopoeia (USP-NF 27, effective January 1, 2004) have altered the scope for producing CSPs and now require healthcare facilities to follow certain guidelines when filling, storing and dispensing CSPs.

This technical bulletin provided to you by I-Flow Corporation, is intended to provide the reader with a summary of the technical information regarding the microbial contamination risk level of the ON-Q pump, storage and beyond use dating of the pump and filling/media fill qualification studies.

Microbial Contamination Risk Levels/Compounding Conditions

The USP-NF classification into low-, medium- and high-risk CSPs is based upon the probability of microbial and chemical contamination and the potential risk to the patient. These risk classifications are based upon the environment in which the CSP is filled. Depending upon the location where the ON-Q Pump is filled, the device is classified as either a medium-risk or a high-risk CSP.

- When the ON-Q pump is aseptically filled in the pharmacy in an ISO Class 5 or better (formerly classification known as Class 100) laminar flow bench, USP-NF 27 <797> classifies the device as a medium-risk CSP.

- When the ON-Q pump is aseptically filled in the surgical suite, USP classifies the device as a high-risk CSP.

Storage and Beyond Use Dating

I-Flow Corporation has generated numerous chemical and microbiological stability studies to support storage conditions prior to and during administration. I-Flow's recommendations for storage and beyond use dating comply fully with the requirements of USP-NF 27 <797>. Pumps filled in the surgical suite (high-risk classification) should be stored at room temperature for no longer than 24 hours prior to the pump being connected to the patient. Pumps filled in the pharmacy (medium-risk classification) should be stored at room temperature for no longer than 30 hours or refrigerated at 2-8°C for no longer than 7 days prior to use. These recommendations are supported by microbiological stability studies.

Chemical stability of the pump has been verified with the following drugs:

Drug Description	Concentration	Storage Time at RT
Bupivacaine	0.25 – 0.5%	30 days
Lidocaine	1%	30 days
Ropivacaine	0.2%	30 days
Ropivacaine	0.2 – 0.75%	14 days

The chemical stability studies performed by I-Flow Corporation exceed the USP storage requirements and support the storage conditions and beyond use dating recommendations of I-Flow Corporation.

Filling/Media Fill Qualification

USP-NF 27 <797> contains extensive information on processing CSPs and performance evaluation of personnel preparing CSPs. The USP requires "Each person assigned to the aseptic area in the preparation of sterile products must successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs." To assist the healthcare facility with this requirement, I-Flow Corporation has developed specific training and performance evaluation programs for healthcare facilities to use. These programs provide the facility with instructions for filling the ON-Q pump and protocols for performing the required media fill qualification studies.

When these protocols are used as part of the established training program of the healthcare facility they provide an effective method of complying with the requirements of USP-NF 27 <797> as it pertains to filling and use of the ON-Q Pain Relief System.

Summary

I-Flow Corporation is committed providing information and training to ensure compliance with these regulations as they apply to the use of the ON-Q Pain Relief System. When the system is used as recommended in the labeled instructions and with support of the other available technical documents, the device can be used in a manner that fully complies with the specific requirements of USP 27 <797>.

For additional information contact your I-Flow representative.

I-Flow Corporation

Technical Bulletin

Prior to Use Storage and Patient Administration Periods for CSPs

The subject of "beyond use dating" for compounded sterile preparations published in USP-NF 27 <797> has been a continuing source of questions and concern for pharmacies. Questions regarding storage times, sterility test requirements and administration times are commonplace in the industry. <797> has specific requirements that must be met:

- Appropriateness of containers to preserve sterility and strength
- Before-administration storage periods
- Patient administration times

This technical bulletin seeks to clarify the USP issues and provide the pharmacist with a clear understanding of and a rationale for I-Flow's position on the subject as well as a list of available I-Flow references for chemical and microbiological studies performed in support of this position.

USP-NF 27 <797> is concerned with two issues, risk of microbiological contamination and chemical stability. In the section titled RESPONSIBILITY OF COMPOUNDING PERSONNEL, item number 8, the USP states "Packaging selected for CSPs is appropriate to preserve the sterility and strength until the beyond-use date". To satisfy this requirement I-Flow has performed Protocol Number PSI-04073 entitled *Microbial Ingress Testing of the I-Flow On-Q Device*. In this study, ON-Q pumps were filled with a microbial growth supporting medium and then immersed for 24 hours in a circulating bath containing *Brevundimonas diminuta*. *Brevundimonas* is the bacteria of choice for filter bacteria retention studies and packaging ingress studies due to its extremely small size and motility. Following the exposure to the bacterial challenge solution, the filled devices were incubated at 20-25 °C for 7 days. At the end of the seven days the pumps were emptied and the growth medium inspected for bacterial contamination. No bacterial contamination was present. This study clearly demonstrates that the ON-Q pump meets the USP requirements for an appropriate container to maintain product integrity and content sterility. Item number 11 of the same USP section states, "Beyond-use dates are assigned based on direct testing or extrapolation from reliable literature sources and other documentation". The referenced testing performed by I-Flow, at an independent contract laboratory, meets the requirement of "other documentation" as stated in <797>.

The ON-Q Soaker Post-Op Pain Relief System is intended to provide continuous infusion of a local anesthetic directly into the intra-operative site for postoperative pain relief. In USP-NF 27 <797> under Examples of Medium-Risk Compounding, item number 3 provides for a description of a medium risk device such as the ON-Q pump, and states "Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25° and 40°. The same statement can be

applied to devices filled in high-risk situations in the surgical suite. The only reason the I-Flow pump is re-classified as high-risk is because the air quality in the surgical suite does not meet the standard of ISO Class 5. USP <797> specifically states that if a device is filled in an area with an environmental classification of greater than ISO Class 5, that the device must be classified as a high risk device. Surgical suites are typically operated with a controlled environment greater than ISO Class 5. The USP has provided for classification of CSPs that will be administered over several days. I-Flow recommends a maximum patient administration period of 5 days.

Since USP has chosen to include devices such as the ON-Q pump as medium-risk the storage conditions before administration must meet the USP guidelines: "For a medium-risk preparation, in absence of passing a sterility test, the storage periods cannot exceed the following time periods: Before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see General Notices and Requirements) for not more than 7 days at cold temperatures (see General Notices and Requirements), and for 45 days in solid frozen state at -20° or colder." The General Notices Section of USP lists requirements for temperature monitoring, etc. Cold temperatures are defined by the USP as 2-8°C. For a high-risk CSP the room temperature storage period drops to $\leq$ 24 hours and the cold temperature time to $\leq$ 3 days.

These sections of the USP are clearly discussing the risk of microbial contamination and the ability of the CSP to remain sterile for both the storage period and the administration period. To this end, I-Flow has performed protocol number PSI-04063 entitled *Microbial Storage Stability of the I-Flow On-Q Device*. In this study, 10 ON-Q pumps were filled with a microbial growth supporting medium and then stored at 2-8 °C for seven days. At the completion of the seven days the pumps were transferred to room temperature storage (20-25 °C) for an additional 14 days. Another group of 10 pumps was stored at room temperature only for 14 days. Appropriate media growth promotion studies and bacteriostasis/fungistasis studies were performed with this stability study. At the completion of the prescribed storage periods the pumps were examined for microbial growth. In all cases all pumps were sterile. This study demonstrates that the ON-Q pump, when filled under aseptic conditions, by appropriately trained personnel, maintains its contents sterile for time periods that exceed the USP pre-administration storage periods and also exceeds the manufacturers recommendations of a maximum 5 day administration period. The USP states in the section on DETERMINING BEYOND-USE DATES that "compounding personnel may consult the manufacturer of particular products for advice on assigning beyond-use dates based on chemical and physical stability y parameters."
I-Flow has also performed protocols PSI-04062 entitled *Medium Risk Media Fill Protocol of the I-Flow ON-Q Device using the BAXA Repeater Pump,* protocol PSI-04059 entitled *Medium Risk Media Fill Protocol of the I-Flow On-Q Device* and PSI-04061 entitled *High Risk Media Fill Protocol of the I-Flow On-Q Device.* In these three studies the media fill qualifications recommendations of USP-NF 27 <797> were followed. The final container filled and incubated for 14 days was the ON-Q pump. These three studies provide even more documentation as to the suitability of the ON-Q pump as a final container for CSPs in both medium-risk and high-risk conditions.

I-Flow has also performed appropriate chemical stability studies for the most commonly used local anesthetics. These studies demonstrate that the anesthetics are stable for periods that exceed the USP prior to administration storage periods and the I-Flow's recommended patient administration period. Chemical stability of the pump has been verified with the following drugs:

Drug Description	Concentration	Storage Time at RT
Bupivacaine	0.25 – 0.5%	30 days
Lidocaine	1%	30 days
Ropivacaine	0.2%	30 days
Ropivacaine	0.2 – 0.75%	14 days

Summary

- Microbial ingress studies and media fill challenges performed by I-Flow have demonstrated the ON-Q pump is an appropriate container for CSP storage.
- The USP makes a clear difference between "before-administration" storage periods and patient administration periods.
- Studies performed by I-Flow have demonstrated both microbiological and chemical stability of the filled ON-Q pump for time periods that exceed the USP requirements for before-administration storage and I-Flows recommended patient administration times.

For copies of the referenced protocols and final reports, please contact I-Flow Technical Service.

TECHNICAL BULLETIN

ON-Q Pain Relief System®
Redefining Recovery™

USP <797> Position Paper
Classification of Ambulatory Pain Pumps as Compounded Sterile Preparations

Some manufacturers of ambulatory pain pumps have recently taken the position that their products are not considered compounded sterile preparations as defined in USP 28/NF 23 <797> "Pharmaceutical Compounding—Sterile Preparations" when filled with drug products in accordance with a licensed practitioner's prescription. These manufacturers have attempted to use examples provided in USP 28 <1075> "Good Compounding Practices" to defend their position that these devices need not be handled in accordance with <797>. According to <1075>, four examples of compounding include: (1) pharmaceuticals that are prepared in anticipation of a prescription order, (2) prescription orders that require the reconstitution of two or more ingredients, (3) manipulated commercial products that may require the addition of one or more ingredients, and (4) drugs and devices prepared for the purposes of, or as an incident to, research, teaching, or chemical analysis. The manufacturers assert that if a device is not included on this list, then it is not compounded. This position is short-sighted and does not meet either the content of USP <1075> or the spirit.

The four examples of compounding listed above and in <1075> are not all inclusive. USP <1075> defines compounding as "the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription...." The preparation of an ambulatory pain pump involves: preparation of the pump; adding or mixing of multiple small-volume parenteral vials of drug to fill the pump; potential packaging of the pump for transport to the surgical area; and proper labeling of the pump. These processes are clearly defined in USP <1075> as "compounding." Support for this position is found in the section of <1075> entitled *Levels of Compounding*. In this section, an example is listed under level 4 that describes the preparation of simple sterile injections reconstituted for immediate use. This section does not require that only products reconstituted with more than one ingredient qualify as compounded products. Additionally, when defining the requirements of compounded sterile devices (CSPs), USP <1075> refers the reader to USP <797>. USP <797> provides detailed instructions for the preparation of CSPs and presents examples of CSPs that undoubtedly describe ambulatory pain pumps.

At the heart of USP <797> and <1075> is the importance of evaluating and controlling the risk of microbial contamination. The reconstitution of several vials of different drug products is no higher risk than the combination of multiple vials of the same drug product. The underlying principle is that multiple vials have to be accessed with sterile transfer equipment and that the risk of contamination increases the more times this occurs. USP <797> classifies the following examples of compounding as a medium risk for contamination: "Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25°C and 40°C" and "Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product." Both of these examples clearly apply to pain pumps, which provide continuous infusion of a local anesthetic directly into an intra-operative site at ambient temperature over several days for postoperative pain relief. Multiple vials of drug product are combined to achieve a sufficient volume to meet the needs of several days of infusion.

There are two key factors in the microbial risk assessment: First, multiple vials have been accessed, thereby increasing the risk of a break in aseptic transfer. Second, the drug products will be maintained at 25° and 40° for several days. If a break in sterility did occur during the transfer process, bacteria would have a chance to multiply since the drug container is at a growth supporting temperature. These examples in USP <797> are very specific and apply directly to the use of pain infusion devices.

Supporting this is a document that predates USP <797>: the ASHP guideline on Quality Assurance for Pharmacy Prepared Sterile Products. This document provided much of the content for the USP chapter. In the ASHP guideline, a microbial risk level 2 is assigned to "preparing portable pump reservoirs for multi-day (i.e. ambient temperature) administration."

USP <1075> and <797> are in complete agreement that ambulatory pain pumps, when filled with multiple vials of drug product, are classified as compounded sterile preparations. Guidelines from the pharmacy industry are also in agreement with this assessment. Manufacturers of these devices must manufacture in accordance with the applicable rules and regulations of the U.S. Food and Drug Administration. However, once the device is delivered to a healthcare facility and a licensed practitioner prescribes the use of the device filled with a drug product, the requirements of USP <1075> and <797> apply. USP <797> states that the contents of the chapter apply to CSPs that include "preparations prepared according to the manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination." Manufacturers have a duty to provide healthcare facilities with proper information on the use of their products and methods for reducing the risk of microbial contamination when manipulating the product.

More information on policies and procedures concerning proper filling techniques, protocols, sterility testing and training is available by contacting I-Flow at (800) 448-3569. For questions concerning this document or other materials concerning USP <797>, please contact Julie Schneider at (949) 206-2678.

TECHNICAL BULLETIN

Homepump Eclipse®, C-Series, One Step KVO™, Easypump®

I-Flow Elastomeric Pumps

Latex Sensitivity

The FDA has issued a Latex Labeling requirement, 21 CFR 801.437, that states: "A labeling statement is required for devices that contain natural rubber when the rubber contacts humans". The European Union has a similar requirement.

The I-Flow Elastomeric Pump is manufactured with multiple layers. The outer layer of the pumping chamber is composed of natural rubber latex. This natural rubber layer is prevented from contacting humans by two other layers.

The inner layer of the pumping chamber is a synthetic thermoplastic elastomer. The inner layer contacts the fluid pathway and prevents contact with the natural rubber layer.

The outer cover of the pump is made of PVC. This outer cover surrounds the pumping chamber which eliminates direct human skin contact with the natural rubber layer.

Independent laboratory testing has been conducted on the I-Flow Elastomeric Pump fluid pathway and the actual natural rubber latex component itself to measure the potential amount of natural rubber proteins extracted. Two methods were used:

The Modified Lowery Assay to measure the *total* extractable proteins associated with the natural rubber; and

The ELISA Inhibition Assay to measure the amount of *antigenic* protein in the natural rubber.

Based on current tests methods available today, no natural rubber proteins were detected for either test method for both the fluid pathway of the I-Flow Elastomeric Pump and the latex component itself.

All remaining system components are latex free.

Conclusion: The natural rubber layer of the pump does not come into human contact. In addition, laboratory testing could not detect any extractable proteins from either the pump fluid pathway or the natural rubber component itself.

Please contact the Product Support Hotline at 800.444.2728 or 949.206.2700 if you have any questions regarding this information.

TAB 25

Appendix E – Predicate Information

This section contains the latest 510(k) clearance letter for the *I-Flow Elastomeric Pumps*. See ***section 12*** for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

Mr. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K052117
Trade/Device Name: I-Flow Elastomeric Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: August 3, 2005
Received: August 11, 2005

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

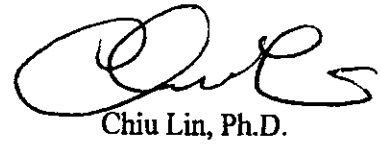
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052117

Device Name: I-Flow Elastomeric Pump

Indications For Use:

1. The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.
3. The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark W Milhoan, MD for A Watson, GHDB 9/8/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052117

SEP 9 2005

SPECIAL 510(k) - SUMMARY OF SAFETY AND EFFECTIVENESS

K052117

August 3, 2005

Submitter: I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Contact: Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation

Trade Name: I-Flow Elastomeric Pump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: I-Flow Elastomeric Pump (K040337)

Device Description: The *I-Flow Elastomeric Pump* consists of an elastomeric pressure source with an integrated administration line. The current device has an optional Y-adapter that splits the administration line into two delivery sites. This special 510(k) proposes a multi-Y adapter that can provide 3 or more integrated administration lines for multi-site delivery.

Technology Comparison: The multi-Y adapter utilizes the same technology for splitting the administration line as the existing unmodified design.

Conclusion: The new *I-Flow Elastomeric Pump* with a multi-Y adaptor model is simply an extension of the existing *I-Flow Elastomeric Pump* product line.

I-Flow Corporation believes that the new *I-Flow Elastomeric Pump* with a mulit-Y adaptor model is substantially equivalent to the existing (unmodified) *I-Flow Elastomeric Pump* and no new issues of safety or effectiveness arise from this design change.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Chip Zunkel

Subject: 510(k) Number K063530/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices. KISE
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

MEB, Pump, Infusion, Elastomeric, 880.5725, Class II

Review: [signature], Branch Chief (Branch Code) 1/16/07 (Date)

Final Review: [signature], Division Director 1/16/07 (Date)

Revised:4/2/03

4

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K D63530

Reviewer: Chip Zimlki

Division/Branch: DAGID / GHDB

Device Name: ON-Q Pump

Product To Which Compared (510(K) Number If Known): K052117

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop (SE)
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K063530/S1

Date: January 25, 2007

From: Charles Zimliki, Ph.D., Biomedical Engineer (HFZ-480) CZ **Division:** DAGID/GHDB

Device Name: I-Flow ON-Q Pumps

Classification: **MEB**, Pump, Infusion, Elastomeric, 21 CFR 880.5725, Class II

Company: I Flow Corporation
20202 Windrow Drive
Lake Forest CA 92630

Contact: Shane Noehre, Director of Regulatory Affairs
(Phone: (b)(4) (b)(4) Fax : (b)(4) (b)(4) Email: (b)(4) (b)(4)

Dated: December 28, 2006
Received: December 29, 2006

Recommendation: I recommend that device is Substantially Equivalent to the predicate device (below).

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   - I-Flow Elastomeric Pumps (K052117, K023883, K023318)

*Discussion (**Acceptable**):* (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

   - Subject Device (K063530/S1)
     - The ON-Q Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) **to or around surgical wound sites** and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous, epidural.
     - The ON-Q Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics **to or around surgical wound sites** or close proximity to nerves when compared with narcotic only pain management.

8

- Predicate Device (K052117)
  - The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular, and epidural
  - The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) **to surgical wound sites** and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous
  - The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to delivery local anesthetics **to surgical wound sites** or close proximity to nerves when compared with narcotic only pain management.

*Discussion (**Acceptable**):* (b)(4) (b)(4)
(b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
   - The following modifications were made to the subject device when compared to the predicate device (K052117) (Tab 12, p. 36). Engineering diagrams were provided in Tab 22.
     - Increase in maximum fill volume size from 550 mL (K052117) to 770mL (subject device) and an increase in nominal fill volume from 400mL (K052117) to 600mL (subject device)
       - Note, since the subject device is bigger and the device uses an elastomeric pumping mechanism, the pump pressure will be lower in the subject device.

*Discussion (**Acceptable**):* (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.

   - Labeling (K063530/S1, Attachment 2)
     - Indications on labeling match indication page

- *Discussion (Acceptable):* (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

- Intended Use Subject device is identical to the predicate device.
- Physical Characteristics The subject device is identical to the predicate device in regards to device components. The sponsor has only increased the volume of the chamber size from a maximum of 550mL to 700mL.

5. A **Design Control Activities Summary** which includes:

A Design Control Activities Summary (DCAS) was provided by the sponsor.

a) Risk Analysis
   - Risk analysis (K063530, Tab 21) used the Failure Mode and Effects Analysis (FMEA).

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   - Information provided in Tabs 21 & 18 (K063530)

c) Declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
      - Tab 9, p. 26 (K063530)

   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
      - Tab 9, p. 26 (K063530)

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**
   - Truthful and Accuracy Statement –Tab 6 (K063530)
   - 510(k) Summary – Attachment 3 (K063530/S1)
   - Indication for Use page – Attachment 1 (K063530/S1)

Contact History/Requests for More Information:

12-27-06 Informed sponsor via email & phone that their application has been put on hold. There was some concern about the date stamp being 11-22-06, but CTS having the due date registered as 12-29-06. I brought this to the attention of Tony Watson who informed me that CTS is correct.

K063530 Deficiencies

The sponsor must provide additional information for me to determine if the subject device is substantially equivalent to the predicate device.

1. You have indicated that you intend to increase the maximum fill volume of your device to 770mL. In your submission, you have identified various models (i.e., ON-Q, Painbuster, C-Bloc, Select-A-Flow, OnDemand, Easypump, Homepump, Eclipse, C-Series, One●Step KVO), but it is unclear which model will be modified. Please provide the following information on the models that will be modified.

Sponsor's Response

In an effort to expedite the 510(k) review process, I-Flow will limit the proposed volume change to just the ON-Q models identified as Type 5 – 7 in Table 11.3.3 on page 32 of *K063530*. Please change the name of the 510(k) to "ON-Q Pump".

Per our conversation, I-Flow has modified our Indications for Use page to delete bullet item 1 with the exception of moving "epidural" as a route to the end of bullet item 2. This is an appropriate modification given that the pump is cleared for epidural use and the epidural route clearly fits the description of bullet item 2. The Directions for Use for the ON-Q Pump has been updated to exactly match the revised Indications for Use page.

Please see Attachment 1, revised Indications for Use page.

Please see Attachment 2, revised ON-Q Pump Directions for Use (part number 1304265).

a. Please provide a side-by-side comparison (in tabular form) of all models in which you intend to increase the size of the maximum fill volume to 770mL. This table should include the model name/identifier, 510(k) number in which the device was most recently cleared, the indication for which it was cleared, fill volume, flow control component, flow rate, bolus volume, bolus refill time, delivery sites, filter, check valve. Please insure that all values within this table are the identical values for which the device has been cleared in the 510(k) submission.

Sponsor's Response

The table below has been updated to reflect the identical values as cleared in previous 510(k)s. This replaces Table 11.3.3 originally provided on page 32 of K063530.

Table 11.3.3

Model Name	ON-Q Pump	ON-Q Pump with Select-A-Flow	ON-Q Pump with OnDemand
Previous 510(k)	K052117	K023883	K023318
Subsequent 510(k) Clearances	None (***K063530*** under FDA review)	K040337 and K052117	K040337 and K052117
Fill Volume	50 to 500 ml	50 to 500 ml	50 to 500 ml
Indications for Use	These are repeated in our response to Question #2.	The indications were updated per ***K040337***. These are repeated in our response to Question #2.	The indications were updated per ***K040337***. These are repeated in our response to Question #2.
Flow Control Component	(b)(4) (b)(4)		
Basal Flow Rate	0.5 to 250 ml/hr	0.5 to 3.5 ml/hr, 1 to 7 ml/hr,r 2 to 14 ml/hr	none to 5 ml/hr
Bolus Delivery	n/a	n/a	2 to 10 ml volume, 30 to 60 min. refill
Filter	Yes	Yes	Yes
Y-adapter [1]	optional	optional	Optional

[1] The optional Y-adapter for the models was cleared per ***K052117***. It can split the administration line for multi-site delivery or provide a combination of administration set options such as the Select-A-Flow component for basal flow rate delivery and the OnDemand component for bolus delivery.

*Discussion (**Acceptable**)* (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

b. Please amend your 510(k) summary to only include those models in which you intend to increase the size of the maximum fill volume to 770mL.

Sponsor's Response

11

Please see Attachment 3, revised 510(k) Summary which has been updated per your request.

*Discussion (**Acceptable**):* (b)(4), (b)(5) (b)(4), (b)(5)

c. Please identify the product labeling (reference page numbers from original 510k application) for which you intend to increase the size of the maximum fill volume to 770mL.

Sponsor's Response

Per our conversation, I-Flow's response is included under question #2 below.

*Discussion (**Acceptable**):* (b)(4), (b)(5) (b)(4), (b)(5)

d. Please be advised that since you have only identified the volumetric change to your predicate device that the only modification that has been reviewed in this application is the volumetric change and that no other modification to your device has been reviewed. If there are additional modifications to your device components, please provide a list for our review.

Sponsor's Response

There are no additional modifications to device components.

*Discussion (**Acceptable**)* (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

2. You have provided product labeling for various models of your device in Tab 23 of your application. However, the indications for these various models do not match the indication page that you have provided in Tab 4 of this application. Please provide a table of all device models in which you intend to increase the maximum fill volume to 770mL. In this table please identify the device model, the product label indication, and the 510(k) number for which this indication was previously cleared. If there is no 510(k) number for which the identical product label indication was cleared, please justify why you believe the product label indication is similar to the indication page provided in Tab 4. Please be advised that if a reasonable justification cannot be provided, modification of your product labeling may be required.

Sponsor's Response

As indicated above, I-Flow will limit the proposed volume change to just the ON-Q models identified as Type 5 – 7 in Table 11.3.3 on page 32 of *K063530*. The Directions for Use for the ON-Q Pumps have been revised to be identical with the revised Indications for Use for *K063530*. The table below provides the information you requested.

Model Name	**ON-Q Pump**	**ON-Q Pump with Select-A-Flow**	**ON-Q Pump with OnDemand**
Previous 510(k)	K052117	K023883	K023318
Subsequent 510(k) Clearances	None (***K063530*** under FDA review)	K040337 and K052117	K040337 and K052117
510(k) Indications	Note: The indications for use were updated for all models of the I-Flow Elastomeric Pump per ***K040337***. The indications from this 510(k) are repeated below. These are the same indications as provided in the predicate ***K052117***. 1. The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural. 2. The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous. 3. The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when		

12

	compared with narcotic only pain management.
Label Indications	As discussed above, the first bullet item was deleted with the exception of moving "epidural" as a route to the end of the second bullet item. The label indications are identical for all three models and are repeated below. Please see the attached revised Directions for Use (part number 1304265). 1. The ON-Q Pump is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. 2. The ON-Q Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

*Discussion (**Acceptable**)*: (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

3. Your 510(k) summary that you have provided in Tab 5 (p. 18) of your application needs modification. In your 510(k) summary you did not provide the intended use/indication of your device. According to 807.92(a)(5), the intended use/indication of the device should be included in the 510(k) summary. Please include the intended use/indication in your 510(k) summary and ensure that this intended use/indication is identical to your indication page that you have provided in Tab 4 of your application.

Sponsor's Response

Please see Attachment 3, revised 510(k) Summary which has been updated per your request.

*Discussion (**Acceptable**)*: (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5)

1/25/07

Name
Charles Zimliki, Ph.D.
Biomedical Engineer / Reviewer
CDRH/ODE/DAGID/GHDB
1-240-276-3671
Charles.Zimliki@fda.hhs.gov

1/26/07

13

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Charles Zmuldzinski

Subject: 510(k) Number K063530

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.

☒ Requires additional information (other than refuse to accept). Phone Hold

☐ Is substantially equivalent to marketed devices.

☐ NOT substantially equivalent to marketed devices.

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: _____ 12/27/06
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:4/2/03

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K063530

Date: December 21, 2006

From: Charles Zimliki, Ph.D., Biomedical Engineer (HFZ-480) CZ **Division:** DAGID/GHDB

Device Name: I-Flow Elastomeric Pumps

Classification: **MEB**, Pump, Infusion, Elastomeric, 21 CFR 880.5725, Class II

Company: I Flow Corporation
20202 Windrow Drive
Lake Forest CA 92630

Contact: Shane Noehre, Director of Regulatory Affairs
(Phone (b)(4) (b)(4) Fax : (b)(4) (b)(4) Email: (b)(4) (b)(4)

Dated: November 20, 2006
Received: November 22, 2006

Recommendation: I recommend that additional information (**Phone Hold**) is required to determine equivalence.

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   - I-Flow Elastomeric Pumps (K052117)

*Discussion (**Additional Info Required**).* (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

- (b)(4), (b)(5)
- (b)(4), (b)(5)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

- Subject Device (K063530)
  - The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular, and epidural
  - The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) **to or around surgical wound sites** and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous
  - The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to delivery local anesthetics **to or around surgical wound sites** or close proximity to nerves when compared with narcotic only pain management.

- Predicate Device (K052117)
  - The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular, and epidural
  - The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) **to surgical wound sites** and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous
  - The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to delivery local anesthetics **to surgical wound sites** or close proximity to nerves when compared with narcotic only pain management.

*Discussion (**Acceptable**).* (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

- The following modifications were made to the subject device when compared to the predicate device (K052117) (Tab 12, p. 36). Engineering diagrams were provided in Tab 22.
  - Increase in maximum fill volume size from 550 mL (K052117) to 770mL (subject device) and an increase in nominal fill volume from 400mL (K052117) to 600mL (subject device)
    - Note, since the subject device is bigger and the device uses an elastomeric pumping mechanism, the pump pressure will be lower in the subject device.

*Discussion (**Acceptable**):* (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.

- Labeling (K063530, Tab 23)

In reviewing the product labeling, I noticed that the product labeling indication did not match the indication page submitted in this application. Below is a list of all the models associated with the I-Flow pump and the product labeling indication.

- Homepump Eclipse (p. 101)
  - Continuous delivery of medications through intravenous routes
- Homepump C-Series (p. 106)
  - Continuous delivery of medication through intravenous, intra-arterial, intramuscular, subcutaneous or epidural routes
- Easypump Basal with Bolus (p. 111)
  - To provide a continuous basal level infusion of medication and to allow patient-controlled bolus delivery. The bolus component of the PCA module enables fixed boluses to be delivered upon demand by the patient or healthcare provider. Routes of administration include intravenous, epidural, intramuscular and subcutaneous.
    - *Discussion (**Concern**): Not even close to subject device indication. There is no mention of patient-controlled bolus delivery*
- One Step KVO (p. 114)
  - For continuous delivery (keep vein open) through intravenous access devices
    - *Discussion (**Concern**): Not even close to subject device indication. There is no mention about keeping vein open*
- Easypump Bolus Accessory Kit (p. 118)
  - In combination with a positive pressure, continuous flow infusion pump, is intended to allow the patient or healthcare provider controlled bolus delivery on demand.
    - *Discussion (**Concern**): Not even close to subject device indication. This is probably due to the fact that this is not a pump, but an accessory kit. This information should not have been provided.*
- ON-Q Pump (p. 122)
  - To provide delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative & postoperative regional ansesthesia and/or pain management. Routes of administration include: intraoperative site, perineural, percutaneous and epidural
    - *Discussion (**Concern**): The sponsor appears to have used indication #2 from the indication, but added the epidural route of administration from indication #1. Sponsor should clarify this issue.*
  - On-Q is indicated to significantly decrease pain and narcotic use when compared to narcotic only pain management
- ON-Q PainBuster Bolus (p. 134)

28

- To provide boluses of medication upon demand by the patient or healthcare provider to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, perineural or percutaneous
  - *Discussion (**Concern**):* (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5)
- To significantly decrease pain and narcotic use when compared to narcotic only pain management

- Intended Use Subject device is identical to the predicate device.
- Physical Characteristics The subject device is identical to the predicate device in regards to device components. The sponsor has only increased the volume of the chamber size from a maximum of 550mL to 700mL.

*Discussion (**Additional Info Required**).* (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

5. A **Design Control Activities Summary** which includes:

A Design Control Activities Summary (DCAS) was provided by the sponsor.

a) Risk Analysis
   - Risk analysis (K063530, Tab 21) used the Failure Mode and Effects Analysis (FMEA).

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   - Information provided in Tabs 21 & 18

c) Declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

- Tab 9, p. 26

ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
- Tab 9, p. 26

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**
- Truthful and Accuracy Statement –Tab 6
- 510(k) Summary –Tab 5
- Indication for Use page – Tab 4

*Discussion (**Additional Info Required**):* (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

Contact History/Requests for More Information:
12-22-06 Informed sponsor via email & phone that their application has been put on hold.

K063530 Deficiencies

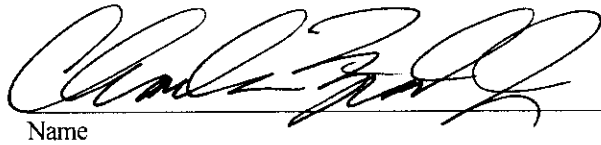
The sponsor must provide additional information for me to determine if the subject device is substantially equivalent to the predicate device.

1. You have indicated that you intend to increase the maximum fill volume of your device to 770mL. In your submission, you have identified various models (i.e., ON-Q, Painbuster, C-Bloc, Select-A-Flow, OnDemand, Easypump, Homepump, Eclipse, C-Series, One•Step KVO), but it is unclear which model will be modified. Please provide the following information on the models that will be modified.
   a. Please provide a side-by-side comparison (in tabular form) of all models in which you intend to increase the size of the maximum fill volume to 770mL. This table should include the model name/identifier, 510(k) number in which the device was most recently cleared, the indication for which it was cleared, fill volume, flow control component, flow rate, bolus volume, bolus refill time, delivery sites, filter, check valve. Please insure that all values within this table are the identical values for which the device has been cleared in the 510(k) submission.
   b. Please amend your 510(k) summary to only include those models in which you intend to increase the size of the maximum fill volume to 770mL.
   c. Please identify the product labeling (reference page numbers from original 510k application) for which you intend to increase the size of the maximum fill volume to 770mL.
   d. Please be advised that since you have only identified the volumetric change to your predicate device that the only modification that has been reviewed in this application is the volumetric change and that no other

modification to your device has been reviewed. If there are additional modifications to your device components, please provide a list for our review.

2. You have provided product labeling for various models of your device in Tab 23 of your application. However, the indications for these various models do not match the indication page that you have provided in Tab 4 of this application. Please provide a table of all device models in which you intend to increase the maximum fill volume to 770mL. In this table please identify the device model, the product label indication, and the 510(k) number for which this indication was previously cleared. If there is no 510(k) number for which the identical product label indication was cleared, please justify why you believe the product label indication is similar to the indication page provided in Tab 4. Please be advised that if a reasonable justification cannot be provided, modification of your product labeling may be required.

3. Your 510(k) summary that you have provided in Tab 5 (p. 18) of your application needs modification. In your 510(k) summary you did not provide the intended use/indication of your device. According to 807.92(a)(5), the intended use/indication of the device should be included in the 510(k) summary. Please include the intended use/indication in your 510(k) summary and ensure that this intended use/indication is identical to your indication page that you have provided in Tab 4 of your application.



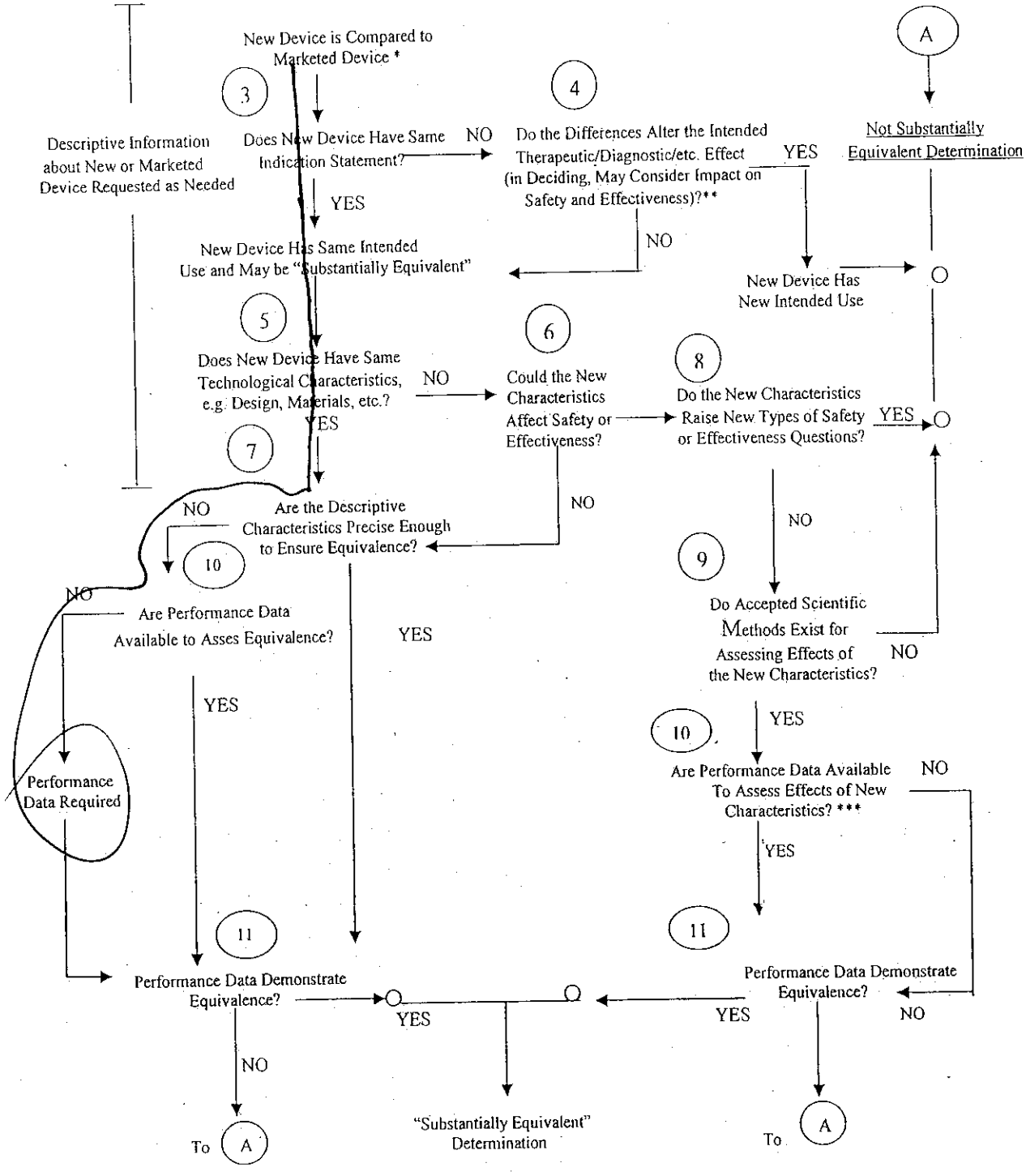
12/21/06

Name
Date

Charles Zimliki, Ph.D.
Biomedical Engineer / Reviewer
CDRH/ODE/DAGID/GHDB
1-240-276-3671
Charles.Zimliki@fda.hhs.gov

12/21/06

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓ ✓
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		✓ ✓
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	✓
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓ ✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓ ✓

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K063530

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard**, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes _____ No

Reviewer: CZ

Concurrence by Review Branch: _____

Date: NOV 3 0 2006

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 063530

Reviewer: Chip Zimlik

Division/Branch: DAGID/GHDB

Device Name: I-Flow Elastomeric Pumps

Product To Which Compared (510(K) Number If Known): K052117

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	~~If~~ NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?		✓	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough: There is discrepancy in the indication page when compared to product Labeling.

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

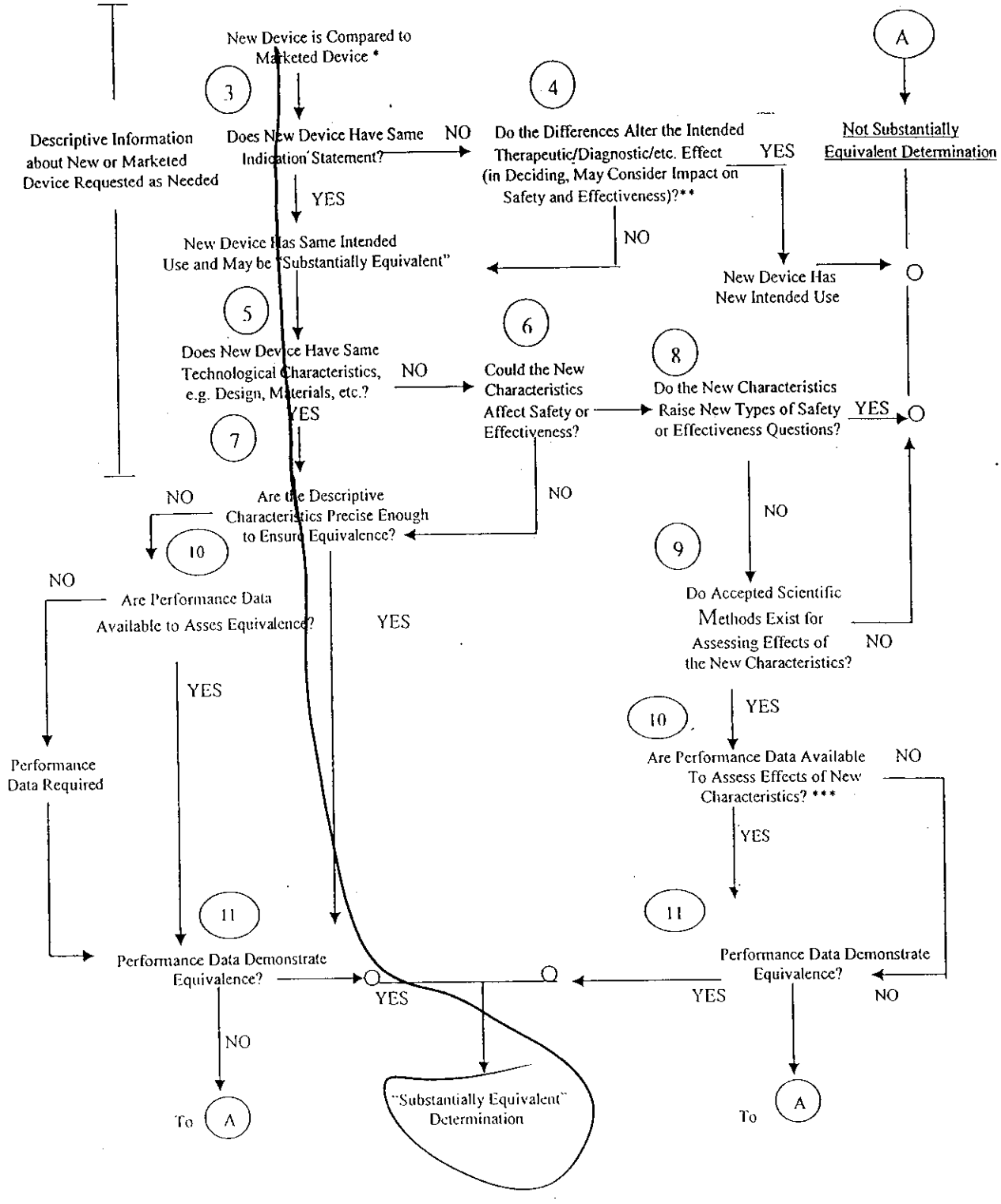
9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed: Clarification is needed on what devices sponsor is modifying & product Labeling

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 29, 2006

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: JAMES J. DAL PORTO

510(k) Number: K063530
Product: ON-Q,
PAINBUSTER,
C-BLOC,
SELECT-A-FLOW,

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

14

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

15

K063530/S1

I-FLOW Corporation
20202 Windrow Drive
Lake Forest, CA 92630
USA
Tele: (800) 448-3569
(949) 206-2700
Fax: (949) 206-2600
Visit us on the web at:
www.iflo.com
www.AskYourSurgeon.com

December 28, 2006

Attn: Charles "Chip" Zimliki, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ – 401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Dear Chip,

This letter is a response to your e-mail dated December 27, 2006 and our telephone conversation on the same day. Your questions appear below in italics followed by our response (in **bold**).

1. You have indicated that you intend to increase the maximum fill volume of your device to 770mL. In your submission, you have identified various models (i.e., ON-Q, Painbuster, C-Bloc, Select-A-Flow, OnDemand, Easypump, Homepump, Eclipse, C-Series, One•Step KVO), but it is unclear which model will be modified. Please provide the following information on the models that will be modified.

In an effort to expedite the 510(k) review process, I-Flow will limit the proposed volume change to just the ON-Q models identified as Type 5 – 7 in Table 11.3.3 on page 32 of *K063530*. Please change the name of the 510(k) to "ON-Q Pump".

Per our conversation, I-Flow has modified our Indications for Use page to delete bullet item 1 with the exception of moving "epidural" as a route to the end of bullet item 2. This is an appropriate modification given that the pump is cleared for epidural use and the epidural route clearly fits the description of bullet item 2. The Directions for Use for the ON-Q Pump has been updated to exactly match the revised Indications for Use page.

Please see Attachment 1, revised Indications for Use page.

Please see Attachment 2, revised ON-Q Pump Directions for Use (part number 1304265).

a. Please provide a side-by-side comparison (in tabular form) of all models in which you intend to increase the size of the maximum fill volume to 770mL. This table should include the model name/identifier, 510(k) number in which the device was most recently cleared, the indication for which it was cleared, fill volume, flow control component, flow rate, bolus volume, bolus refill time, delivery sites, filter, check valve. Please insure that all values within this table are the identical values for which the device has been cleared in the 510(k) submission.

The table below has been updated to reflect the identical values as cleared in previous 510(k)s. This replaces Table 11.3.3 originally provided on page 32 of K063530.

Table 11.3.3

Model Name	ON-Q Pump	ON-Q Pump with Select-A-Flow	ON-Q Pump with OnDemand
Previous 510(k)	K052117	K023883	K023318
Subsequent 510(k) Clearances	None (*K063530* under FDA review)	K040337 and K052117	K040337 and K052117
Fill Volume	50 to 500 ml	50 to 500 ml	50 to 500 ml

K3

Model Name	ON-Q Pump	ON-Q Pump with Select-A-Flow	ON-Q Pump with OnDemand
Indications for Use	These are repeated in our response to Question #2.	The indications were updated per ***K040337***. These are repeated in our response to Question #2.	The indications were updated per ***K040337***. These are repeated in our response to Question #2.
Flow Control Component	(b)(4), (b)(5)	(b)(4), (b)(5)	
Basal Flow Rate	0.5 to 250 ml/hr	0.5 to 3.5 ml/hr, 1 to 7 ml/hr,r 2 to 14 ml/hr	none to 5 ml/hr
Bolus Delivery	n/a	n/a	2 to 10 ml volume, 30 to 60 min. refill
Filter	yes	yes	yes
Y-adapter [1]	optional	optional	optional

[1] The optional Y-adapter for the models was cleared per ***K052117***. It can split the administration line for multi-site delivery or provide a combination of administration set options such as the Select-A-Flow component for basal flow rate delivery and the OnDemand component for bolus delivery.

b. Please amend your 510(k) summary to only include those models in which you intend to increase the size of the maximum fill volume to 770mL.

Please see Attachment 3, revised 510(k) Summary which has been updated per your request.

c. Please identify the product labeling (reference page numbers from original 510k application) for which you intend to increase the size of the maximum fill volume to 770mL.

Per our conversation, I-Flow's response is included under question #2 below.

d. Please be advised that since you have only identified the volumetric change to your predicate device that the only modification that has been reviewed in this application is the volumetric change and that no other modification to your device has been reviewed. If there are additional modifications to your device components, please provide a list for our review.

There are no additional modifications to device components.

2. You have provided product labeling for various models of your device in Tab 23 of your application. However, the indications for these various models do not match the indication page that you have provided in Tab 4 of this application. Please provide a table of all device models in which you intend to increase the maximum fill volume to 770mL. In this table please identify the device model, the product label indication, and the 510(k) number for which this indication was previously cleared. If there is no 510(k) number for which the identical product label indication was cleared, please justify why you believe the product label indication is similar to the indication page provided in Tab 4. Please be advised that if a reasonable justification cannot be provided, modification of your product labeling may be required.

As indicated above, I-Flow will limit the proposed volume change to just the ON-Q models identified as Type 5 – 7 in Table 11.3.3 on page 32 of *K063530*. The Directions for Use for the ON-Q Pumps have been revised to be identical with the revised Indications for Use for *K063530*. The table below provides the information you requested.

Model Name	ON-Q Pump	ON-Q Pump with Select-A-Flow	ON-Q Pump with OnDemand
Previous 510(k)	K052117	K023883	K023318
Subsequent 510(k) Clearances	None (***K063530*** under FDA review)	K040337 and K052117	K040337 and K052117

I-FLOW

I-Flow Corporation

Model Name	ON-Q Pump	ON-Q Pump with Select-A-Flow	ON-Q Pump with OnDemand
510(k) Indications	Note: The indications for use were updated for all models of the I-Flow Elastomeric Pump per ***K040337***. The indications from this 510(k) are repeated below. These are the same indications as provided in the predicate ***K052117***. 1. The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural. 2. The I-Flow Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous. 3. The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.		
Label Indications	As discussed above, the first bullet item was deleted with the exception of moving "epidural" as a route to the end of the second bullet item. The label indications are identical for all three models and are repeated below. Please see the attached revised Directions for Use (part number 1304265). 1. The ON-Q Pump is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. 2. The ON-Q Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.		

3. Your 510(k) summary that you have provided in Tab 5 (p. 18) of your application needs modification. In your 510(k) summary you did not provide the intended use/indication of your device. According to 807.92(a)(5), the intended use/indication of the device should be included in the 510(k) summary. Please include the intended use/indication in your 510(k) summary and ensure that this intended use/indication is identical to your indication page that you have provided in Tab 4 of your application.

Please see Attachment 3, <u>revised 510(k) Summary</u> which has been updated per your request.

I-Flow believes the above-enumeratcd responses and attached documents answer your questions. If you have any questions, please call me for an expedited response.

Sincerely,

Shane Noehre

Shane Noehre
Director of Regulatory Affairs

I-Flow Corporation
Phone: (b)(4)
Fax: (b)(4)
E-mail:

K063530

18

ATTACHMENT 1

Applicant: I-Flow Corporation

510(k) Number (if known): K063530

Device Name: *ON-Q Pump*

Indications For Use:

1. The *ON-Q Pump* is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.
2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ON-Q Pump Directions for Use
READ FIRST

ATTACHMENT 2

ON-Q® Pump
Redefining Recovery™

For Customer Service please call:

(800) 448-3569

(949) 206-2700

Visit www.iflo.com for the latest product information and Technical Bulletins.

www.AskYourSurgeon.com

20

Rx only

DO NOT USE IF PACKAGE HAS BEEN OPENED, IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.

1304265C
3/2006

ON-Q® Pump
Redefining Recovery™

Refer to ON-Q Pump Insert for Model Specific Information

I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

I•FLOW®

CE 0123 EC REP
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

K063530

ON-Q Pump Directions for Use

ILLUSTRATION AND NOMENCLATURE

Figure 1

1. E-Clip
2. Fill Port
3. ON-Q Pump
4. Clamp
5. Filter
6. Flow Controller (see Pump Insert)

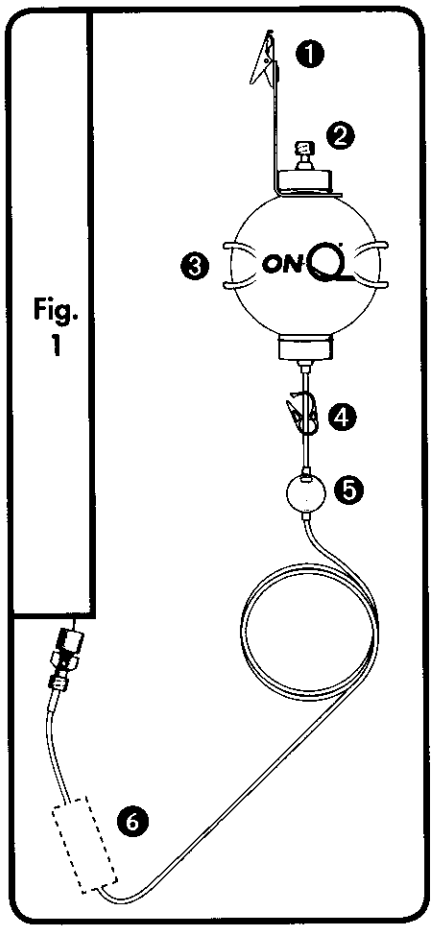


Fig. 1

INDICATIONS FOR USE

- The ON-Q Pump is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.
- The ON-Q Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

CAUTIONS

- Do not use if package is open, damaged or a protector cap is missing.
- Do not resterilize, refill, reuse or exceed maximum fill volume of pump.
- The ON-Q Pump is sterile, non-pyrogenic and single use only.
- Storage conditions: protect from sunlight, 10°–40°C, 10–90% relative humidity

WARNINGS

- Vasoconstrictors such as Epinephrine are not recommended for continuous infusions.
- Medications must be administered per instructions provided by drug manufacturer.
- Limit volumes, flow rates and tight dressings, particularly with hand or foot surgery, to avoid fluid build up in restricted spaces that may lead to wound complications (e.g. necrosis).
- Epidural infusion of analgesics is limited to uses of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.

CONTRAINDICATIONS

- ON-Q is not intended for blood, blood products, lipids, fat emulsion or intravascular delivery.

DIRECTIONS FOR USE

Use Aseptic Technique

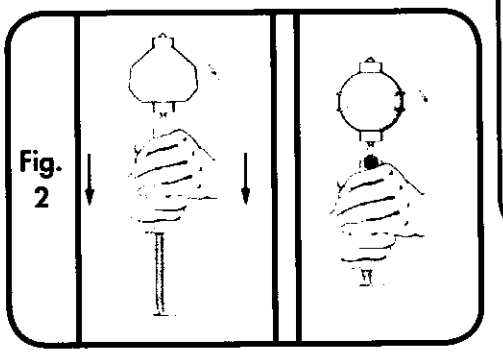


Fig. 2

FILLING THE ON-Q PAINBUSTER PUMP

Figure 2

- Close clamp.
- Un-cap the fill port.
- Attach filled syringe to fill port. Invert pump as shown. Grasp syringe with both hands. Push down on plunger continuously until volume is dispensed. Do not handle pump while filling, as the syringe tip may break. Repeat as necessary.
  Note: Filling Extension Sets are provided with 400 ml pumps (see product insert).
- Do not fill less than minimum or exceed maximum fill volume. See ON-Q Pump Insert for model specific information on fill volumes.
- Replace fill port cap. Label with the appropriate pharmaceutical and patient information.
  Note: The ON-Q contains either an E-Clip or Carry Case for holding the pump. If using the E-Clip, attach to top of pump.

PRIMING THE ADMINISTRATION SET

Refer to ON-Q Pump Insert for model specific information for priming the administration set, starting the infusion, and Flow Controller information.

END OF INFUSION

Figure 3

- Infusion is complete when pump is no longer inflated. Dispose of pump according to your institution's protocol.

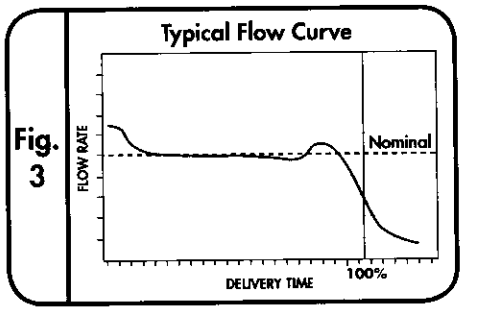


Fig. 3

CAUTIONS

1. The nominal infusion rate and fill volume for each pump is labeled on the fill port.
2. Actual infusion times may vary due to:
   - Filling the pump less than nominal results in faster flow rate.
   - Filling the pump greater than nominal results in slower flow rate.
   - Viscosity and/or drug concentration.
   - Positioning the pump above (increases flow rate) or below (decreases flow rate) the catheter site.
   - Temperature: Refer to ON-Q Pump Insert for model specific information on temperature.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
4. If refrigerated, allow pump to warm to room temperature before using.
5. Start delivery within 8 hours of filling. Storage of a filled ON-Q pump for more than 8 hours prior to starting infusion may result in a slower flow rate.
6. Avoid contact of cleansing agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
7. Roll tubing between fingers to promote flow if clamped for extended time.

NOTE

Latex is not in fluid pathway or in contact with human. Technical Bulletin available upon request.

K063530

510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	I-Flow Corporation 20202 Windrow Drive Lake Forest, CA. 962630
Contact:	Shane Noehre Director, Regulatory Affairs I-Flow Corporation
Trade Names:	ON-Q Pump, ON-Q Pump with Select-A-Flow, ON-Q Pump with OnDemand
Common Name:	Elastomeric Infusion Pump
Existing Device:	I-Flow Elastomeric Pump (K052117)
Design Change:	This Special 510(k) submission proposes an increase in the maximum fill volume from 500 to 770 ml.
Device Description:	The *ON-Q Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 770 ml. Flow rates range from 0.5 to 250 ml/hr. The administration line typically consists of fixed flow rate control tubing or orifice but may contain any of the following optional features: • Select-A-Flow component that provides a range of flow rates that may be dialed depending on the needs of the healthcare professional. • Bolus component (e.g. OnDemand) that provides basal and/or bolus delivery. • Y-adapter component that may split the administration line into two or more delivery sites. The Y-adapter component may also be used to provide a combination of options (such as both the Select-A-Flow and OnDemand components) for one delivery site. • Air and particulate eliminating filter. The pump may be sold as a kit with additional medical devices or accessories such as the following: • Catheter, introducer needle, Tunneler, syringe, dressing, filling extension set, carry case, E-clip, nerve block accessories, etc.
Indications for Use	1. The *ON-Q Pump* is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. 2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.
Technology Comparison:	There is no change in fundamental scientific technology. The design remains the same as previously cleared devices.
Conclusion:	The *ON-Q Pump* with fill volumes up to 770 ml are substantially equivalent to the existing I-Flow elastomeric pumps currently marketed.