USER: **WEEKS, SUSAN M (smw)**

FOLDER: **K033568 - 69 pages (FOI:07004171)**

COMPANY: **ETHICON, INC. (ETHICON)**

PRODUCT: **MESH, SURGICAL, POLYMERIC (FTL)**

SUMMARY: **Product: GYNECARE TVT OBTURATOR SYSTEM**

DATE REQUESTED: **Tue Jul 17 24:00:00 2007**

DATE PRINTED: **Wed Aug 22 09:15:54 2007**

Note: **Releasable Version**

Table of Contents

DEC - 8 2003

ATTACHMENT V

K033568 1/2

510(k) SUMMARY

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements ...." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME:	GYNECARE TVT Obturator device
PREDICATE DEVICE NAME:	GYNECARE TVT device

Device Description

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) covered by a plastic sheath overlapping in the middle. Medical grade plastic tube receptacles are attached at each end of the mesh to accommodate the Helical Passers. The Helical Passers come assembled to the GYNECARE TVT Obturator device and are used to deliver of the mesh implant via the trans-obturator "inside-out" approach. The "inside-out" approach delivers the mesh trans-vaginally, along the posterior ischiopubic ramus and through the obturator membrane.

Intended Use

A pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Indications Statement

GYNECARE TVT Obturator is indicated for the treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

510(K) SUMMARY(continued)

Technological Characteristics	The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.
Performance Data	Results of verification testing indicates that the product meets the established performance requirements.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

Contact Sean M. O'Bryan
Senior Project Manager, Regulatory Affairs
ETHICON, Inc.
Rt. 22 West
Somerville, NJ 08876-0151

Date November 7, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2003

Mr. Sean O'Bryan
Senior Project Manager, Regulatory Affairs
Ethicon, Inc.
Route 22 West
Somerville, New Jersey 08876

Re: K033568
Trade/Device Name: GYNECARE TVT Obturator Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 10, 2003
Received: November 13, 2003

Dear Mr. O'Bryan:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K033568

Device Name: **GYNECARE TVT Obturator device**

Indications for Use: The GYNECARE TVT *Obturator* device is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033568

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2003

Mr. Sean O'Bryan
Senior Project Manager, Regulatory Affairs
Ethicon, Inc.
Route 22 West
Somerville, New Jersey 08876

Re: K033568
Trade/Device Name: GYNECARE TVT Obturator Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
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Dated: November 10, 2003
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Dear Mr. O'Bryan:

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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.

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Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2

INDICATION FOR USE

510(k) Number (if known): K033568

Device Name: **GYNECARE TVT Obturator device**

Indications for Use: The GYNECARE TVT *Obturato*r device is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033568

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

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 14, 2003

ETHICON, INC.
ROUTE 22 WEST
SOMERVILLE, NJ 08876
ATTN: SEAN O'BRYAN

510(k) Number: K033568
Received: 13-NOV-2003
Product: GYNECARE TVT
OBTURATOR SYSTEM

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 any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

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 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.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

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

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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 12, 2003

ETHICON, INC.
ROUTE 22 WEST
SOMERVILLE, NJ 08876
ATTN: SEAN O'BRYAN

510(k) Number: K033568
Received: 12-NOV-2003
Product: GYNECARE TVT
User Fee ID Number: 11869SYSTEM

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 any 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 (301) 594-2977 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 http://www.fda.gov/oc/mdufma.

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 an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

K033568

GYNECARE

a division of ETHICON, INC.
a Johnson & Johnson company

November 10, 2003

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

RE: Special 510(k): Device Modification- GYNECARE TVT Obturator System

2003 NOV 12 A 11:51

ATTENTION: Document Mail Clerk

To Whom It May Concern:

Modified Device

GYNECARE a Division of ETHICON, Inc. submits this Notification of Intent to market a modification to Tension-free Vaginal Tape (TVT) System as described within this Special 510(k) Device Modification Premarket Notification. The extent of the modifications are as follows:

- Stainless Steel needles replaced with plastic tube receptacles
- Add accessories to facilitate delivery of TVT via a trans-obturator approach;
  - Helical Passer
  - Winged Guide

The modifications are eligible for the Special 510(k) process since they do not affect the intended use of the device or alter the fundamental scientific technology of the device.

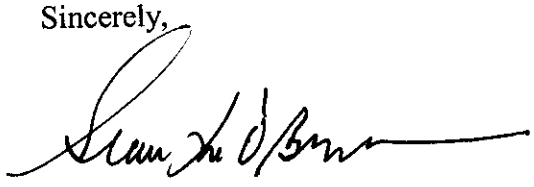
Substantial Equivalence

A discussion of our substantial equivalence conclusion is enclosed with this Notification. The conclusion is formatted in accordance with 21 CFR 807.81(a)(3) and the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device". This discussion format is convenient to use as a summary of substantial equivalence to anyone requesting it from the agency.

SK29 SU II 14

Summary of Safety and Effectiveness; Decision Tree	Included in this Special 510(k) Device Modification Notification is a Summary of Safety and Effectiveness and the Decision Tree used to support substantial equivalence as defined under Section 513(I)(3)(A) the Federal Food, Drug and Cosmetic Act.
User Fee	A copy of the Medical Device User Fee Cover Sheet is appended to this letter.
Contact	Please contact the undersigned at (908) 218-2456 or by fax at (908) 218-2595 for any questions regarding this notification.

Sincerely,



Sean O'Bryan
Senior Project Manager, Regulatory Affairs

/kel
Submitted in Duplicate

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: **011869 - 956733**
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 submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a 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.htm#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed 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)

ETHICON, INC.
ROUTE 22 WEST
SOMERVILLE, NJ 08876

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
223417170

2. CONTACT NAME
SEAN O'BRYAN

2.1 E-MAIL ADDRESS

2.2 TELEPHONE NUMBER (Include Area Code)

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)

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/oc/mdufma

Select an application type:
- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ 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:
- ☑ 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
- ☑ 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 section 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 ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

$3,480.00

Premarket Notification 510(k)
Reviewer's Screening Checklist
Device Name: **GYNECARE TVT *Obturator* System**
Company: **GYNECARE, a Division of ETHICON, Inc.**

Item No.	Item	Present		Needed ? (Y/N)	510(k) Page No.
		Yes	No		
1	General information (i.e., trade and classification name, Establishment Registration No., device class, meets special controls or performance standards, etc.)	X		Y	1-3
1a.	Reason for 510(k) - new device or modification	X		Y	2
1b.	Identification of legally marketed equivalent device	X		Y	ii,1-2
1c.	Indications for Use	X		Y	iii, 8
2	Proposed labeling, labels, advertisements	X		Y	12-21
2a.	Description of modified device	X		Y	4-5
2b.	Intended use statement	X		Y	iii, 11
2c.	Diagrams, engineering drawings, photographs	X		Y	Att III
3	Comparison of similarities/differences to named legally marketed equivalent device	X		Y	4-5
3a.	Equivalent device labeling, labels, advertising	X		Y	22-30
3b.	Intended use of equivalent device	X		Y	4-5
4	List of all patient contacting materials in new device	X		Y	6-7
4a.	Comparison of materials of equivalent device		X	N	-
5	Biocompatibility information/data for patient contacting materials	X		N	6-7
5a.	Certification - identical material/formulation		X	N	-
6	Performance data	X		Y	8-10
6a.	Bench data	X		Y	8-10
6b.	Animal data		X	N	-
6c.	Clinical data		X	N	-
7	Sterilization information	X		Y	4
8	Software validation and verification		X	N	-
9	510(k) summary or statement	X		Y	38-39
10	If Class III, Class III Certification and Summary	X		Y	11
11	If kit, Kit Certification	X		Y	11
12	Truth and Accuracy Statement	X		Y	40

CONFIDENTIALITY OF INFORMATION

In accordance with the Premarket Notification Procedures regarding Confidentiality of Information (21 CFR 807.95), ETHICON, Inc. wishes to certify to the Food and Drug Administration that it has complied with all parts of that section, and considers the content of the submission and its intention to market this device as confidential commercial information.

USE OF TERMS

Modified device	"Modified device" is used interchangeably with the subject of the Premarket Notification submission, namely Modified Tension-free Vaginal Tape (TVT) *Obturator* device, herein referred to as Modified TVT Obturator device. The accessories which include the GYNECARE Helical Passers and GYNECARE Winged Guide used to facilitate the trans-obturator approach for the GYNECARE TVT Obturator device are herein referred to as the Helical Passers and the Winged Guide respectively.
Predicate device	"Predicate device" is used interchangeably with the currently marketed GYNECARE TVT device, 510(k) K974098

INDICATION FOR USE

510(k) Number (if known): K033568

Device Name: **GYNECARE TVT Obturator device**

Indications for Use: The GYNECARE TVT *Obturato*r device is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

SECTION 1

MODIFIED DEVICE AND DESCRIPTION

Name of the Device

CLASSIFICATION NAME	COMMON NAME	TRADE NAME/ PROPRIETARY NAME
Mesh, Surgical, Polymeric (21CFR, §878.3300)	Pubo-urethral Sling	GYNECARE TVT Obturator System

Establishment Registration Number

GYNECARE is a Division of ETHICON, Inc a *Johnson and Johnson* Company. The establishment registration number for GYNECARE, a Division of ETHICON, Inc. is #2210968.

Device Classification

Surgical mesh is classified by the FDA as a Class II Medical Device, General and Plastic Surgery Devices (21CFR, §878.3300, Product Code 79FTL).

Predicate Device(s)

The fundamental scientific technology of the GYNECARE TVT Obturator device is unchanged from the predicate device. GYNECARE TVT Obturator device is a modification of the currently marketed GYNECARE TVT device covered under 510(k) K974098 cleared January 28, 1998. It contains the same blue pigmented polypropylene monofilaments as the currently cleared TVT Blue with Abdominal Guides K012628 cleared on October 26, 2001.

The predicate device for the accessories; Helical Passers and Winged Guide is the GYNECARE TVT AA Abdominal Guides covered under 510(k) K012628 cleared on October 26, 2001. Another similar predicate device is the American Medical Systems' MONARC™ Subfacial Hammock Helical Needles covered under 510(k) K02356 cleared on November 19, 2002.

Change or Modification to an Existing Device

GYNECARE TVT Obturator System maintains the same fundamental scientific technology as the predicate device. The primary change to the device is the replacement of the needles with plastic tube receptacles to accommodate the accessory; Helical Passer (provided assembled for convenience). The PROLENE mesh implant and plastic sheath remain unchanged.

Two accessories are provided with the GYNECARE TVT Obturator device; 1) GYNECARE Helical Passer, 2) GYNECARE Winged Guide. The Helical Passer and Winged guide are provided to facilitate placement of the TVT Obturator device.

For comparison, photos of the modified and predicate device are included in Attachment III.

The GYNECARE TVT Obturator device will be primary packaged together with Helical Passers and Winged Guide in a plastic tray (workstation) placed within a plastic 'tub'with a tyvek label that serves as the sterility barrier, and placed in a labeled carton.

Physical Description

GYNECARE TVT Obturator System includes the device and its accessories. The device and accessories are sold as a set. The system consists of the following:

Device:
GYNECARE TVT Obturator device (Sterile, Single-Use)

Accessories (used in conjunction with the device):
GYNECARE TVT Helical Passers (Sterile, Single Use)
GYNECARE TVT Winged Guide (Sterile, Single Use)

Physical Description Continued on Next Page

GYNECARE TVT Obturator device:

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) covered by a plastic sheath overlapping in the middle. Medical grade plastic tube receptacles are attached at each end of the mesh to accommodate the Helical Passers. The Helical Passers come assembled to the GYNECARE TVT Obturator device and are used to deliver of the mesh implant via the trans-obturator "inside-out" approach. The "inside-out" approach delivers the mesh trans-vaginally, along the posterior ischiopubic ramus and through the obturator membrane.

GYNECARE TVT Helical Passers:

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles and are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device.

GYNECARE TVT Winged Guide

The GYNECARE TVT Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract. This accessory is offered as an adjunct to the device.

Substantial Equivalence

The modified GYNECARE TVT Obturator device has the following similarities to the predicate device (GYNECARE TVT device) which previously received 510(k) clearance.

- Has the same indications
- Uses the same operating principle
- Incorporates the same basic design
- Patient contacting materials(Limited Patient Contact, <24hrs.) are the same except materials used on the plastic tube (Fina Finathene 6006) and the mesh-plastic tube assembly sleeve (Pellethane). These materials have been determined to be biocompatible (see Patient Contacting Material, Section 3).
- Sterilization method is unchanged

In summary, the GYNECARE TVT Obturator device described in this submission is substantially equivalent to the predicate device. See the table on the following page for further comparisons:

Continued on the next page

FEATURE	Predicate GYNECARE TVT Device	Modified GYNECARE TVT *Obturator* device
Intended Use of Device	A pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.	Same
Implant Device	Knitted filaments of polypropylene (unpigmented and pigmented blue) PROLENE* Stainless steel needles attached to each end of mesh	Same Plastic tubes with receptacle ends attached to each end of mesh
Tape Placement	Midurethra	Same
Implant	Nonabsorbable PROLENE mesh	Same
Sterilization	Eto Sterilization	Same
Re-Use	Single Use Device	Same
Package	Blister Package with Tyvek Lid Accessories packaged separately	Same Accessories packaged with the device
Accessories	TVT Abdominal Guides, disposable, single-use	GYNECARE TVT Helical Passers, disposable, single-use GYNECARE TVT Winged Guide, disposable, single-use

The GYNECARE TVT Helical Passer accessory does not change the intended use or the application of the TVT tape. It offers an alternative "inside-out" trans-obturator approach versus the existing transvaginal approach. The placement of the mesh (tape) remains unchanged.

Pages 26 through 30 have been removed.

510(k) Summary	A 510(k) Summary for the GYNECARE TVT Obturator device is provided in Attachment V.
Kit Certification	The GYNECARE TVT Obturator device will not be available as components or other custom procedural kits.
Class III Statement	GYNECARE TVT Obturator device is not a Class III device; therefore no Class III certification is required.
Truthful and Accuracy	A Truthful and Accuracy Statement is provided in Attachment VI.

ATTACHMENT I

Proposed Labeling
GYNECARE TVT Obturator System

Introduction	The device labeling for the GYNECARE TVT Obturator device is comprised of the primary package label, box label and package insert
Primary Label	The primary label is printed on Tyvek which is used as the sterile barrier for the device primary package.
Box Label	Individual box labels
Package Insert	The text for the package insert has been updated to reflect the modified device.

GYNECARE TVT*

Obturator System

Tension-free Support for Incontinence

GYNECARE TVT* *obturatorsysteem*
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT* *obturatorsystem*
Spændingsfri støtte til inkontinens

GYNECARE TVT* *-obturaattorijärjestelmä*
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

GYNECARE TVT* *Obturator System*
Spannungsfreie Unterstützung bei Inkontinenz

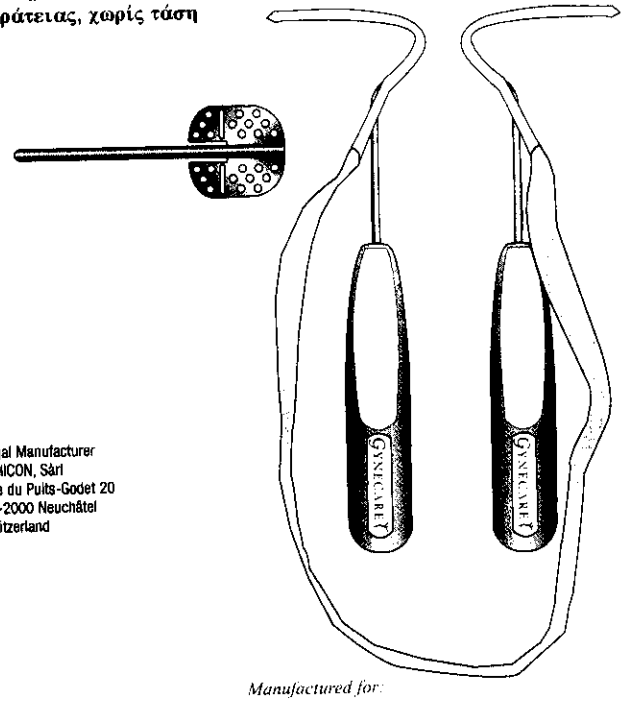
Sistema otturatorio GYNECARE TVT*
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

GYNECARE TVT* *obturatoriabandsystem*
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT*
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

Manufactured for:

GYNECARE WORLDWIDE
A division of ETHICON, Inc.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

RMC P18070/A

ENGLISH

GYNECARE TVT* *Obturator System*
Tension-free Support for Incontinence

GYNECARE TVT *Obturator* Device, Sterile Single Use

GYNECARE TVT *Obturator* Helical Passers, Sterile Single Use

GYNECARE TVT *Obturator* Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:
This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator* System, including the GYNECARE TVT *Obturator* device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator* device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION
The GYNECARE TVT *Obturator* System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device
The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color Index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers
The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator* device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide
The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS
The GYNECARE TVT *Obturator* device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE
(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

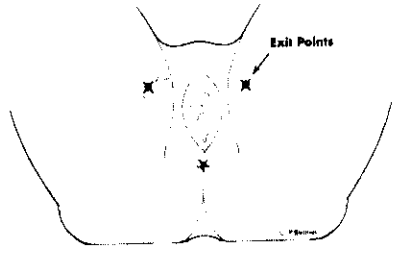


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward *(See Figure 2)*. Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. *(See Figure 2)*

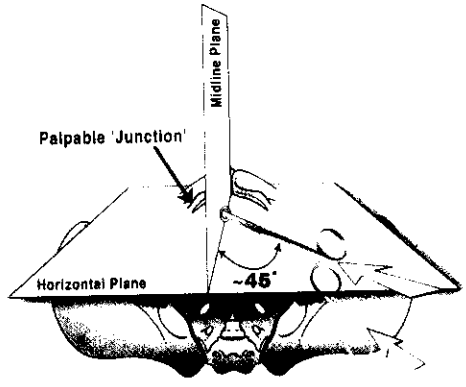


FIG. 2

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. *(See Figure 3)*

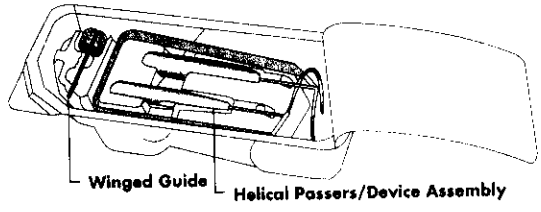


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

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9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT *Obturator* device assembly from the sterile pack *(See Figure 3 for components).*

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

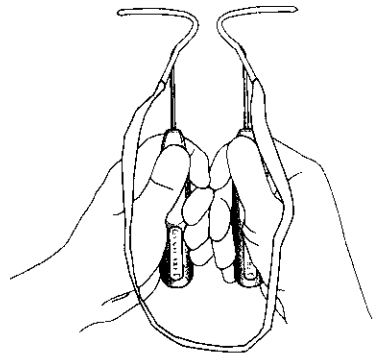


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

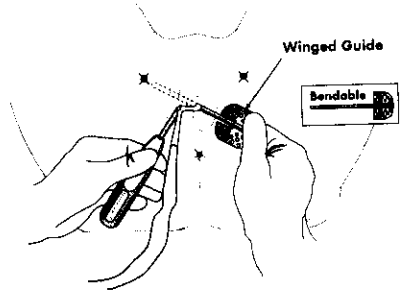


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

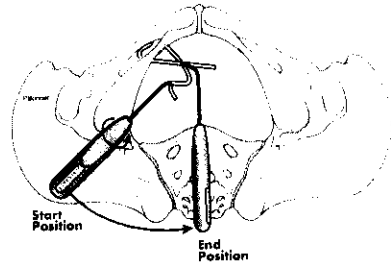


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. *(See Figure 6)* ***(Note: Never allow the handle to be orientated in a horizontal position.)***

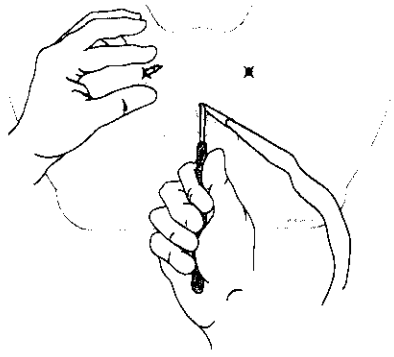


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points *(See Figure 7)*. However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

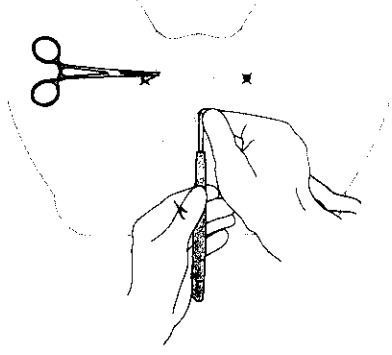


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

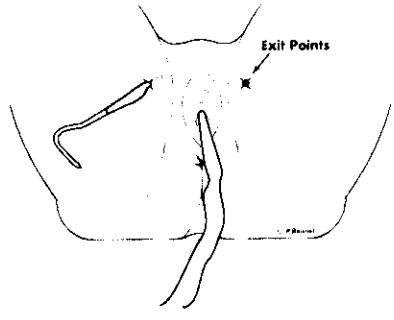


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

    (Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

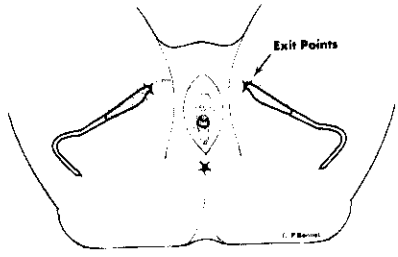


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. *(See Figure 11)*

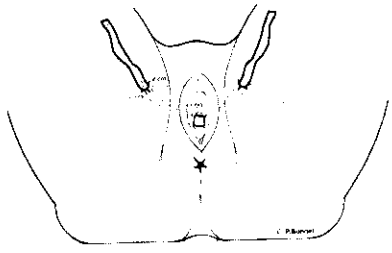


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

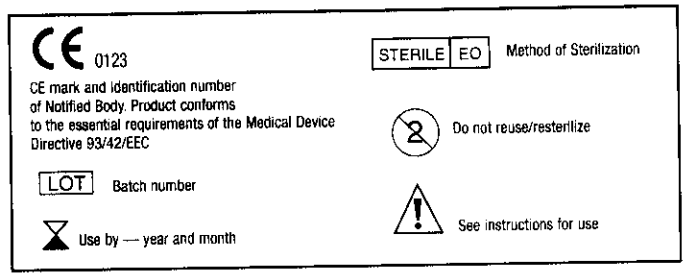
The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

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

*Trademark



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GYNECARE TVT* *Obturator* System
Tension-free Support for Incontinence

Contains: 1 GYNECARE TVT *Obturator* Device
2 Helical Passers
1 Atraumatic Winged Guide

Sterile. Do not use if package is damaged or opened

GYNECARE TVT* obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

Inhoud: 1 GYNECARE TVT obturator steunbandje
2 gebogen inbrenginstrumenten
1 atraumatische vleugel applicatiegeleider

Steriel - gebruik het product niet wanneer de verpakking beschadigd of geopend is.
*Handelsmerk

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

Contenu : 1 dispositif obturateur GYNECARE TVT
2 spirales
1 guide atraumatique à ailettes

Stérile - ne pas utiliser si l'emballage est endommagé ou ouvert
*Marque déposée

GYNECARE TVT* Obturator System
Spannungsfreie Unterstützung bei Inkontinenz

Inhalt: 1 GYNECARE TVT Obturator-Implantat
2 Applikatoren
1 Atraumatische Flügelsonde

Steril - nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist!
*Warenzeichen

Sistema otturatorio GYNECARE TVT*
Dispositivo privo di tensione per incontinenza

Contenuto: 1 dispositivo otturatorio GYNECARE TVT
2 tunnellizzatori alcoldali
1 guida atraumatica con alette

Sterile - non usare se la confezione è stata danneggiata o aperta
*Marchio di fabbrica

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinences

Conteúdo: 1 dispositivo obturador GYNECARE TVT
2 passadores helicoidais
1 guia com abas atraumática

Estéril - não utilizar se a embalagem estiver aberta ou danificada
*Marca comercial

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

Contenido: 1 dispositivo del obturador GYNECARE TVT
2 pasadores helicoidales
1 guía con aletas atraumática

Estéril - no utilizar si el paquete está abierto o dañado
*Marca

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

STERILE EO

See instructions for use

Do not reuse: Nicht wiederverwenden

©ETHICON, INC. 2003 *Trademark
U.S. Patent 6,493,703

810081 P01
P18040/A

CE 0123

Made in Switzerland

EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits Godet 20
CH-2000 Neuchâtel
Switzerland

Manufactured for:

GYNECARE

WORLDWIDE

ETHICON

PLACEMENT FOR
PRIMARY BARCODE
&
LOT NO. & EXPIRY DATE
BARCODE

810081

000020

40

810081

GYNECARE TVT* obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie
Inhoud: 1 GYNECARE TVT obturator steunbandje, 2 gebogen inbrenginstrumenten, 1 atraumatische vleugel-spoiladergeleider
Steriel - gebruik het product niet wanneer de verpakking beschadigd of geopend is.
*Handelsmerk

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences
Contenu: 1 dispositif obturateur GYNECARE TVT, 2 aiguilles, 1 guide atraumatique à ailettes
Stérile - ne pas utiliser si l'emballage est endommagé ou ouvert.
*Marque déposée

GYNECARE TVT* Obturator System
Spannungsfreie Unterstützung bei Inkontinenz
Inhalt: 1 GYNECARE TVT Obturator Implantat, 2 Applikatoren, 1 Atraumatische Flügelsonde
Steril - nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist
*Warenzeichen

Sistema otturatorio GYNECARE TVT*
Dispositivo privo di tensione per incontinenza
Contenuto: 1 dispositivo otturatorio GYNECARE TVT, 2 tunnellizzatori elicoidali, 1 guida atraumatica con alette
Sterile - non usare se la confezione è stata danneggiata o aperta
*Marchio di fabbrica

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinences
Conteúdo: 1 dispositivo obturador GYNECARE TVT, 2 passadores helicoidais, 1 guia atraumático com asas
Estéril - não utilizar se a embalagem estiver aberta ou danificada
*Marca comercial

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia
Contenido: 1 dispositivo del obturador GYNECARE TVT, 2 pasadores helicoidales, 1 guía con aletas atraumática
Estéril - no utilizar si el paquete está abierto o dañado.
*Marca

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ETHICON GmbH
Robert-Koch-Straße 1
D-22851 Norderstedt
Deutschland

PLACEMENT FOR
PRIMARY BARCODE
&
LOT NO. & EXPIRY DATE
BARCODE

GYNECARE TVT* *Obturator* System
Tension-free Support for Incontinence

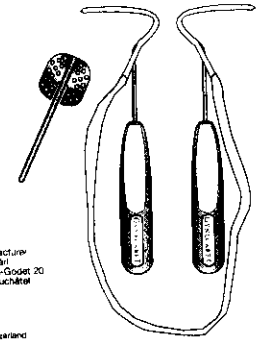
810081

GYNECARE TVT* *Obturator* System
Tension-free Support for Incontinence

Contents: 1 GYNECARE TVT *Obturator* Device
2 Helical Passers
1 Atraumatic Winged Guide

Sterile. Do not use if package is damaged or opened.

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



EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

CE 0123
Made in Switzerland

STERILE EO | Do not resterilize | See instructions for use

Manufactured for:
GYNECARE
WORLDWIDE
A division of ETHICON, Inc.
a Johnson & Johnson company
Somerville, New Jersey 08876-1051

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GYNECARE TVT* *Obturator* System
Tension-free Support for Incontinence

GYNECARE

GYNECARE

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GYNECARE TVT* *Obturator* System
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GYNECARE TVT* *Obturator* System
Tension-free Support for Incontinence

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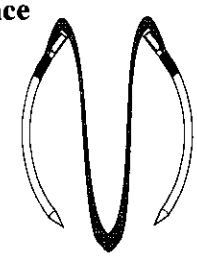
ATTACHMENT II

Predicate Labeling
GYNECARE TVT with Abdominal Guides

GYNECARE TVT*

with abdominal guides

Tension-free Support for Incontinence



with abdominal guides
Tension-free Support for Incontinence
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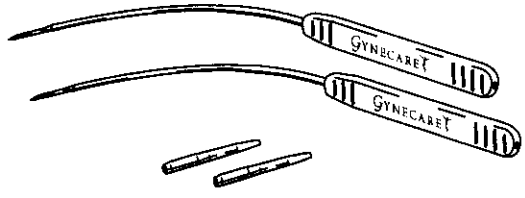

EC
Legal Manufacturer
ETHICON, SaRL
Rue du Puits Godet 20, CH-2000
Neuchatel, Switzerland

Manufactured for:

GYNECARE
WORLDWIDE
A division of ETHICON, Inc.
a Johnson & Johnson company

Made in Switzerland

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GYNECARE TVT *with abdominal guides*
Tension-free Support for Incontinence

GYNECARE TVT Single Use Device
GYNECARE TVT Reusable Introducer
GYNECARE Reusable Rigid Catheter Guide
GYNECARE TVT Abdominal Guides and Couplers

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

IMPORTANT:
This package insert is designed to provide instructions for use of the GYNECARE TVT *with abdominal guides* Tension-free Support for Incontinence System, including single use device, reusable introducer, and reusable rigid catheter guide and disposable abdominal guides and couplers. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION (System)
GYNECARE TVT consists of the following:

GYNECARE TVT Single-Use Device, provided sterile (available separately)
GYNECARE TVT Reusable Introducer, provided non-sterile (available separately)
GYNECARE TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)
GYNECARE TVT *with abdominal guides* - Disposable Abdominal Guides and Couplers, provided sterile (available separately in some locations)

GYNECARE TVT DEVICE
The GYNECARE TVT Tension-free Support for Incontinence device is a sterile single use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Colour index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE* polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT INTRODUCER
The GYNECARE TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the GYNECARE TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

GYNECARE TVT RIGID CATHETER GUIDE
The GYNECARE TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

GYNECARE TVT ABDOMINAL GUIDE

The GYNECARE TVT abdominal guide is a sterile disposable instrument intended to facilitate passage of the GYNECARE TVT device. Two abdominal guides are included in each kit with the GYNECARE TVT couplers.

GYNECARE TVT COUPLER

The GYNECARE TVT coupler is a sterile disposable polypropylene connector used to connect the GYNECARE TVT abdominal guide to the GYNECARE TVT needle. Two couplers are included in each kit with the abdominal guides.

INDICATIONS

The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT introducer, rigid catheter guide and GYNECARE TVT abdominal guides and couplers are available separately and intended to facilitate the placement of the GYNECARE TVT device.

INSTRUCTIONS FOR USE

The patient should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°. The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into or passed through the paraurethral dissection. Then, two abdominal skin incisions of 0.5 –1 cm are made one on each side of the midline just above the symphysis not more than 4–5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The GYNECARE TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, the bladder should be empty. The threaded end of the introducer is screwed into the end of one of the needles. If the abdominal access device is utilized, the tip of the GYNECARE TVT needle is inserted firmly into the distal (wider) end of the coupler. Ensure there is a snug connection between the coupler and TVT needle.

Abdominal Approach

GYNECARE TVT Tension-Free Vaginal Tape can be placed in position by either an abdominal or a vaginal approach. If the abdominal approach is utilized follow instructions above for paraurethral dissection. Holding the abdominal guide, gently insert it in a vertical, downward and saggital direction, through one of the abdominal incisions until the rectus fascia is reached. Firm pressure on the abdominal guide will pierce the rectus fascia and bring the abdominal guide into the retropubic space. Upon entering the retropubic space, the operator will feel a significant decrease in resistance. Pass the abdominal guide through the retropubic space taking care to keep it close to the posterior surface of the pubic bone. Using a vaginal finger (of the non-dominant hand), palpate the descent of the abdominal guide along the posterior surface of the pubic bone. When the tip of the abdominal guide is palpable just inferior to the pubic bone and superior to the anterior vaginal wall, rotate the tip of the abdominal guide towards the midline. Confirm that you are 1 cm lateral to the catheter guide (midurethra). Using digital counter-traction against the urogenital diaphragm, guide it out through the diaphragm and out the midline vaginal incision. Once the abdominal guide is brought through the vaginal incision, cystoscopy should be performed to ascertain that no

bladder or urethral injury has taken place.

Empty the bladder once bladder integrity has been confirmed. Screw the threaded end of the introducer into the end of one of the needles. Insert the tip of the needle firmly into the distal (wider) end of the coupler. Next pick up the GYNECARE TVT device with attached coupler, and holding the abdominal guide steady, firmly insert the tapered end of the coupler (with attached needle) over the guide. Ensure there is a snug connection between the coupler and abdominal guide. Be sure that this interlocked system (the abdominal guide, GYNECARE TVT needle, coupler and reusable introducer) is oriented in the same plane. Using the non-dominant hand on the abdominal portion of the guide and the dominant hand gripping the introducer, **push** the system upward toward the abdomen following the curvature of the interlocked system. **The abdominal guide should not be used to pull the interlocked system upward toward the abdomen.** The interlocked system should be pushed up toward the abdomen until the tip of the GYNECARE TVT needle is visible through the abdominal incision. Disarticulate the reusable introducer and pull the remaining portion of the GYNECARE TVT needle through the abdominal incision. Cut the tape close to the needles. The exact same procedure is carried out on the other side.

Pull the abdominal ends of the tape upward to bring the vaginal aspect of the tape (sling) loosely, i.e. without tension, under the midurethra. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. **To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths.** Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. Cut the abdominal ends of the tape so that the ends are in the subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

Vaginal Approach

If the vaginal approach is used for placement of the GYNECARE TVT Tension-Free Vaginal Tape, the abdominal guides and couplers are not necessary.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand, grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again, observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm, you will feel that the resistance is significantly reduced.

Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way. When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. Disarticulate the reusable introducer and pull the remaining portion of the GYNECARE TVT needle through the abdominal incision. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra

and the tape during removal of the plastic sheaths. Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in the GYNECARE TVT implantation procedure before employing the GYNECARE TVT device. It is important to recognize that GYNECARE TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- The abdominal guide should not be used to pull the interlocked system upward toward the abdomen.
- Ensure there is a snug connection between the guide and coupler and the coupler and TVT needle.
- Acceptable surgical practice should be followed for the GYNECARE TVT procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should then be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the GYNECARE TVT procedure, in case of pregnancy delivery via cesarean section is recommended.
- Post operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the GYNECARE TVT procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.

- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS

(GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide) To ensure the reliability and functionality of GYNECARE TVT Introducer and GYNECARE TVT Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the GYNECARE TVT introducer should be separated into its component parts (handle and threaded shaft). The Introducer is reassembled after cleaning and before sterilization.

Manual method

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water — 1 minute
- Wash 176°F (80°C) — 12 minutes
- Rinse Cycle — 1 minute
- Rinse Cycle — 12 minutes
- Final Rinse — 2 minutes
- Rinse with Demineralized water 176°F (80°C) — 2 minutes
- Dry 199.4°F (93°C) — 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS

(GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)

The GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE

- GYNECARE TVT Introducer
  Before each use, inspect the threaded parts of the inner shaft.
- GYNECARE TVT Rigid Catheter Guide
  Before each use, inspect the instrument. Check to ensure that the long end, which traverses the catheter channel, has no sharp edges or burrs.

HOW SUPPLIED

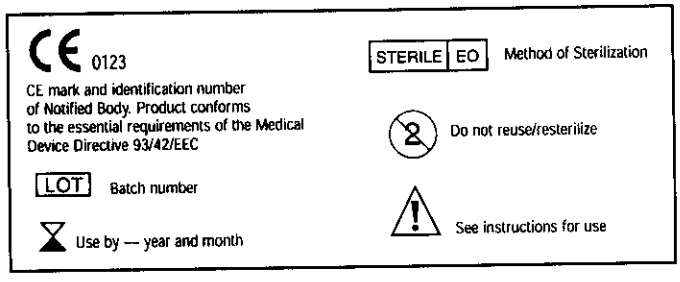
The GYNECARE TVT device and Abdominal Guides and Couplers are provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable GYNECARE TVT introducer, GYNECARE TVT rigid catheter guide are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the GYNECARE TVT single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

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

*Trademark



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Authorized Representative • Autoriseret repræsentant
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Représentant autorisé • Autorisierter Vertreter
Rappresentante autorizzato • Representante autorizado
Representante autorizado • Auktoriserad representant
Εξουσιοδοτημένος Αντιπρόσωπος

ETHICON GmbH
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Deutschland

Distributors • Distributører • Distributeurs
Tukkumyyjät • Distributeurs • Vertrieb durch
Distributori • Distribuidores • Distribuidores
Distributörer • Διανομείς

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Bankhead Avenue
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United Kingdom

CH: Johnson & Johnson AG
Rotzenbuehlstrasse 55
8957 Spreitenbach

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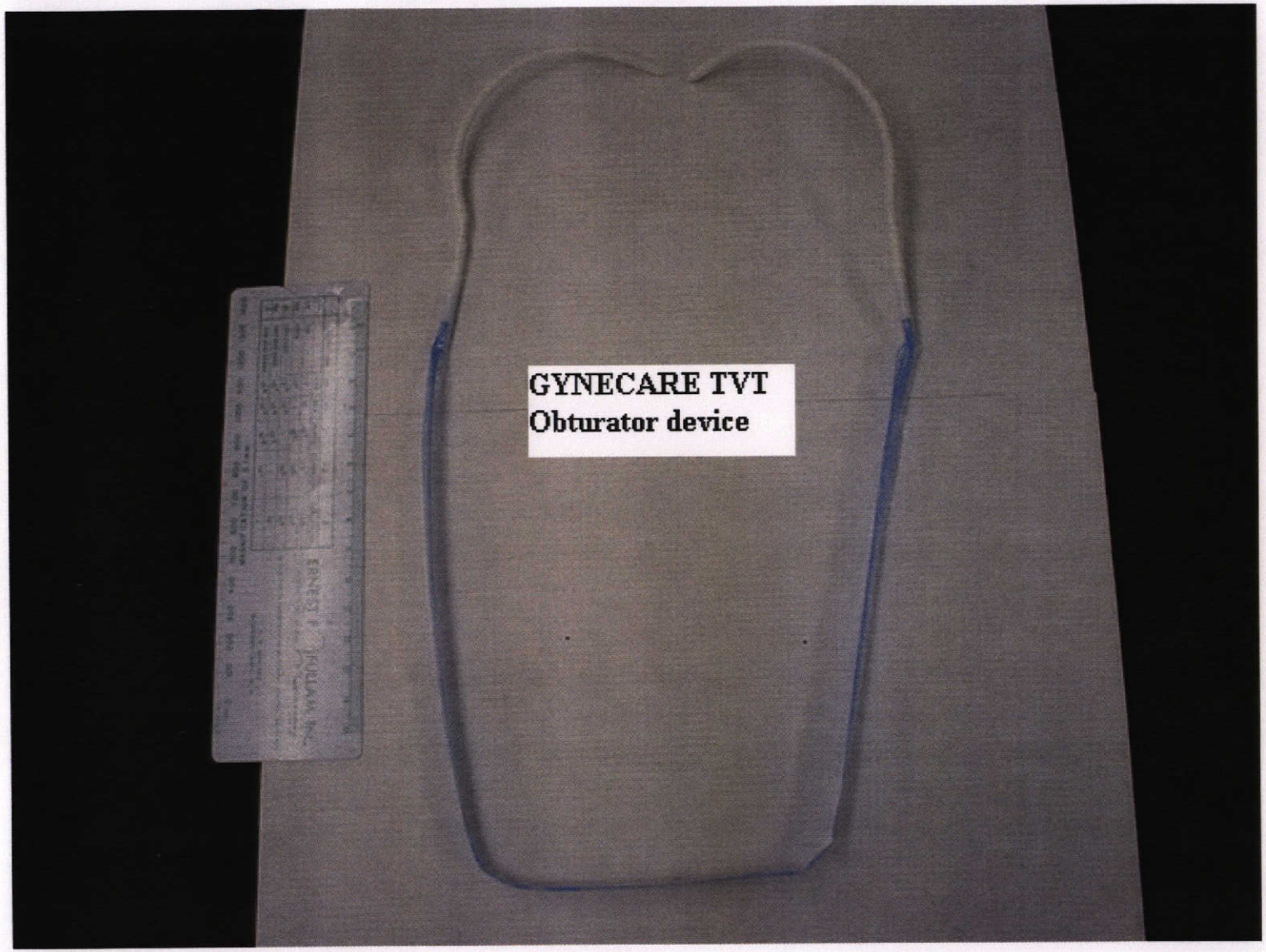
ATTACHMENT III

PHOTOS



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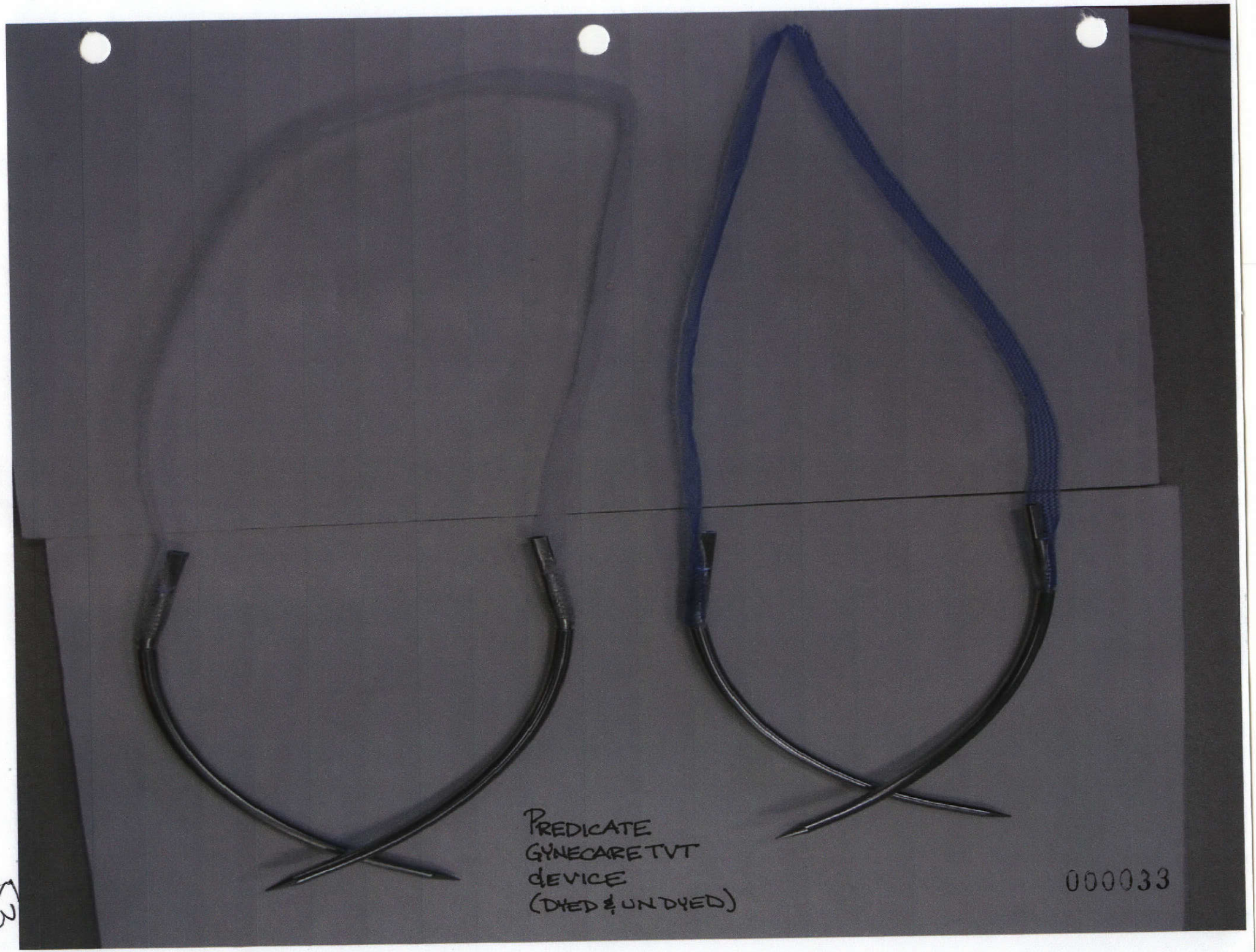
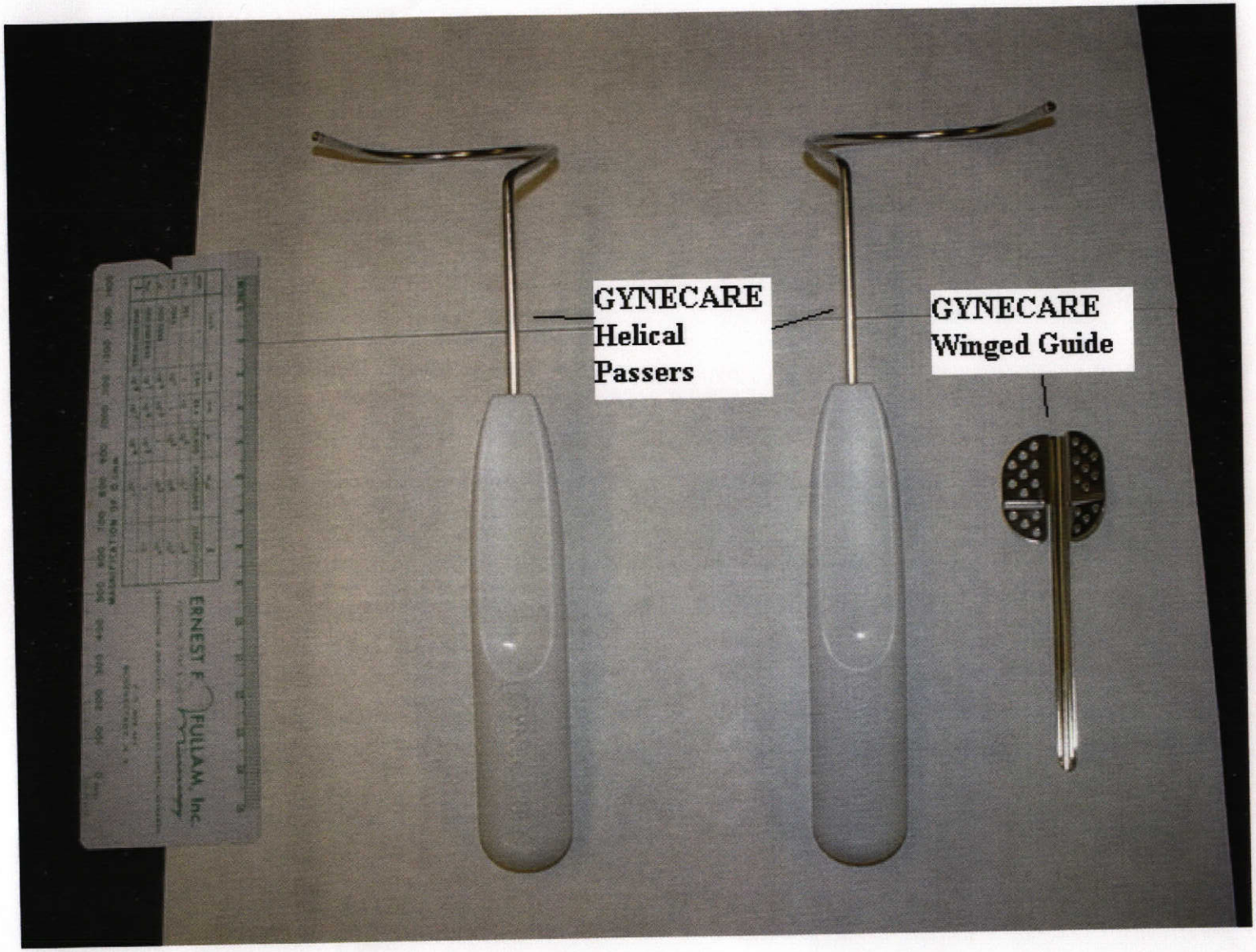

PREDICATE
GYNECARE TVT
DEVICE
(DYED & UNDYED)
000033


GYNECARE
Helical
Passers
GYNECARE
Winged Guide
ERNEST F. FULLAM, Inc.

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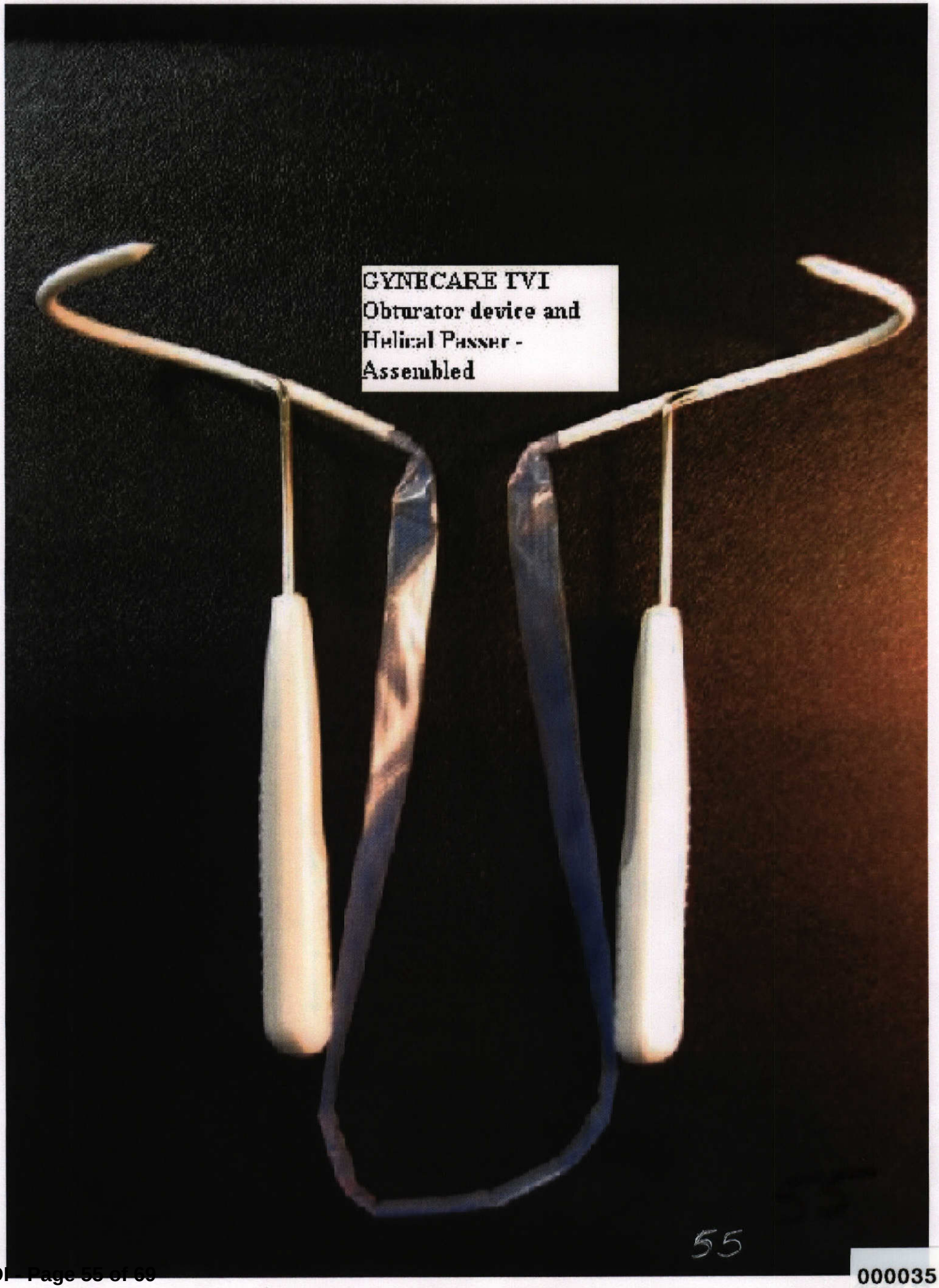
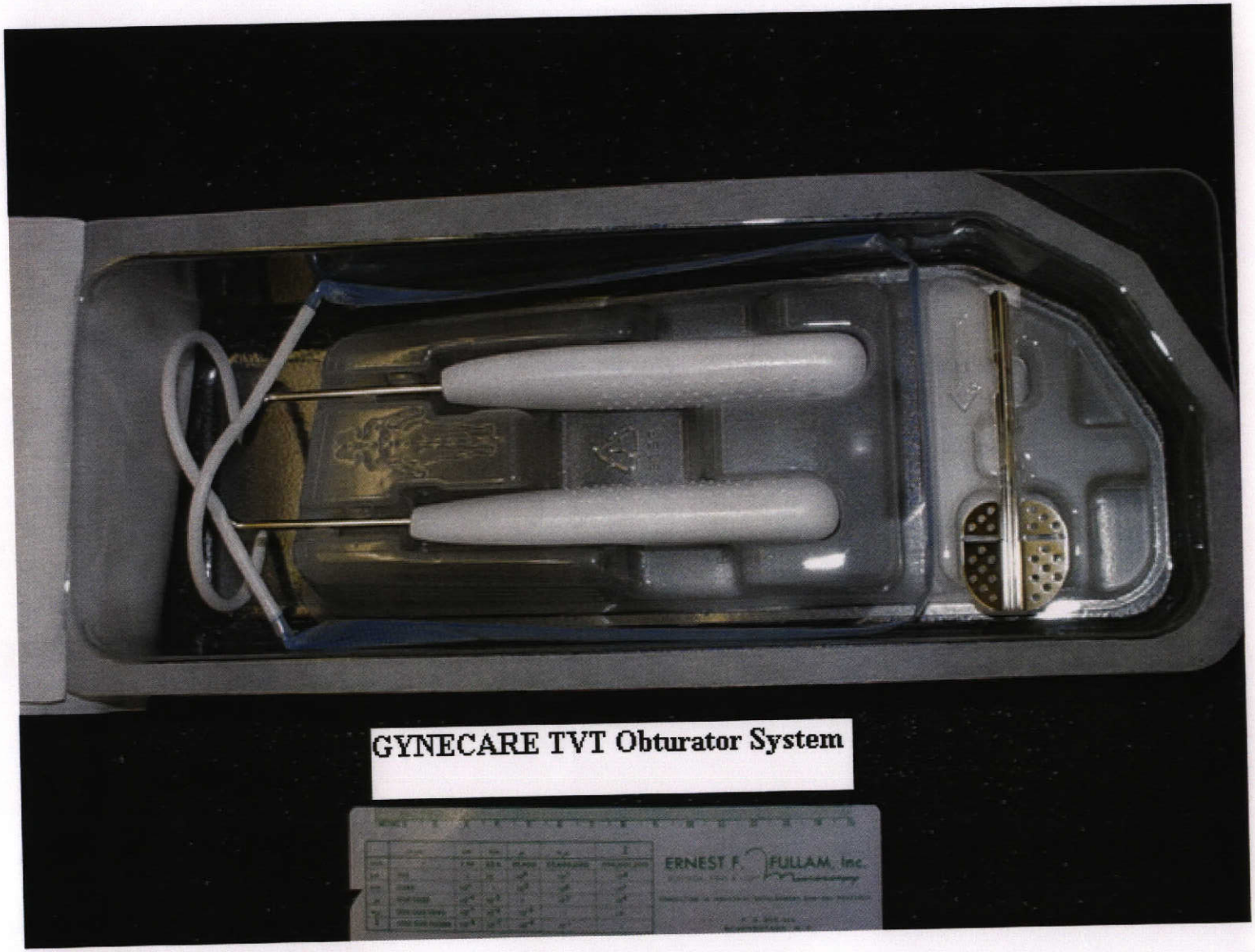

GYNECARE TVI
Obturator device and
Helical Passer -
Assembled



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ATTACHMENT IV

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Name: Dan Smith
Title: Principal Engineer

11/10/03
Date

Manufacturing Facility

To the best of my knowledge, the ETHICON, Inc. manufacturing facility is in conformance with the design control requirements as specified in 21 CFR § 820.30 and the records are available for review.

Name: Dan Smith
Title: Project manager
R&D, GYNECARE

11/10/03
Date

ATTACHMENT V

510(k) SUMMARY

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements ...." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME:	GYNECARE TVT Obturator device
PREDICATE DEVICE NAME:	GYNECARE TVT device

Device Description

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) covered by a plastic sheath overlapping in the middle. Medical grade plastic tube receptacles are attached at each end of the mesh to accommodate the Helical Passers. The Helical Passers come assembled to the GYNECARE TVT Obturator device and are used to deliver of the mesh implant via the trans-obturator "inside-out" approach. The "inside-out" approach delivers the mesh trans-vaginally, along the posterior ischiopubic ramus and through the obturator membrane.

Intended Use

A pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Indications Statement

GYNECARE TVT Obturator is indicated for the treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Technological Characteristics	The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.
Performance Data	Results of verification testing indicates that the product meets the established performance requirements.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

Contact Sean M. O'Bryan
Senior Project Manager, Regulatory Affairs
ETHICON, Inc.
Rt. 22 West
Somerville, NJ 08876-0151

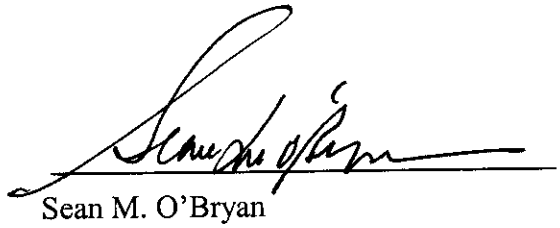
Date November 7, 2003

ATTACHMENT VI

TRUTHFUL AND ACCURACY STATEMENT

(As Required by 21 CFR 807.87(j))

Pursuant to 21 CFR. 807.87(j), I, Sean O'Bryan, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Senior Project Manager, Regulatory Affairs and Quality Assurance of ETHICON a Johnson & Johnson company and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts materials to a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Sean M. O'Bryan
Senior Project Manager
GYNECARE, a division of ETHICON

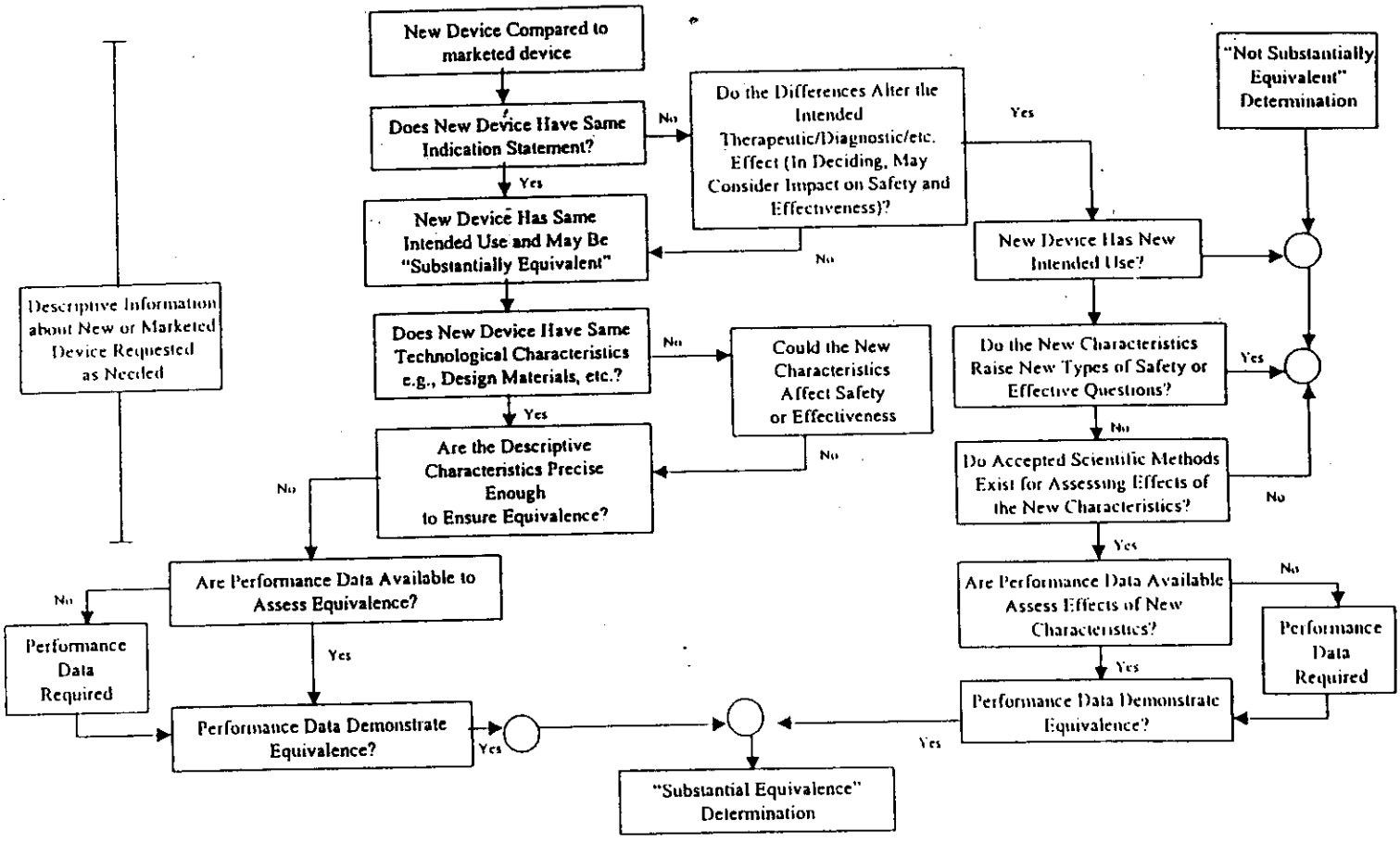
November 7, 2003
Date

ATTACHMENT VII

DECISION MAKING PROCESS FLOWCHART

510(k) "Substantial Equivalence" Decision-Making Process

510(k) Substantial Equivalence
Decision-Making Process (Detailed)



Pages 63 through 69 have been removed.