HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TachoSil safely and effectively. See full prescribing information for TachoSil.

TachoSil® (Absorbable Fibrin Sealant Patch)
Initial U.S. Approval: 2010

----------INDICATIONS AND USAGE----------

TachoSil is indicated as an adjunct to hemostasis for use in cardiovascular surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Limitations of TachoSil Use

- Do not use TachoSil in the renal pelvis or near the ureter. (1.1)
- Do not use TachoSil in the closure of skin incisions. (1.1)
- Do not use TachoSil in neurosurgical procedures. (1.1)

----------DOSAGE AND ADMINISTRATION----------

Apply on the surface of tissue only. Do not use intravascularly. (2)
The number of TachoSil patches to be applied should be determined by the size of the bleeding area. (2)
Apply the **yellow, active side** of the patch to the bleeding area. (2)
Exposure to solutions containing alcohol, iodine or heavy metals may cause TachoSil to be denatured. (2.2)
Once removed from inner pouch, TachoSil cannot be resterilized. Discard unused, opened packages of TachoSil. (2.2)
Once TachoSil adheres, leave in place. If deemed medically necessary, use care to remove or reposition unattached patch. (2.2)
Do not exceed 7 patches sized 9.5 x 4.8 cm, 14 patches sized 4.8 x 4.8 cm, or 42 patches sized 3.0 x 2.5 cm. (3, 5.5)

----------DOSAGE FORMS AND STRENGTHS----------

TachoSil is supplied in the following pack sizes (3):

- Package with 1 patch of 9.5 cm x 4.8 cm
- Package with 2 patches of 4.8 cm x 4.8 cm
- Package with 1 patch of 3.0 cm x 2.5 cm
- Package with 5 patches of 3.0 cm x 2.5 cm

Strength: TachoSil contains per cm^2: Human fibrinogen 3.6-7.4 mg (5.5 mg); Human thrombin 1.3-2.7 Units (2.0 U). (3)

----------CONTRAINDICATIONS----------

Do not apply TachoSil intravascularly. Intravascular application of TachoSil may result in life-threatening thromboembolic events. (4.1)
Do not use TachoSil in individuals with known hypersensitivity to human blood products or horse proteins. (4.2)

----------WARNINGS AND PRECAUTIONS----------

Do not use TachoSil in the treatment of severe or brisk arterial bleeding. (5.1)
Do not use TachoSil in place of sutures, ligature, cautery or other primary modes for control of hemostasis. (5.2)
Hypersensitivity or allergic/anaphylactoid reactions may occur with first-time or repetitive application of TachoSil (5.3)
Do not leave TachoSil in an infected or contaminated space. (5.4)
When placing TachoSil into cavities or closed spaces, exercise care to avoid over-packing. Use only the minimum amount of TachoSil patches necessary to achieve hemostasis. Unattached pieces of TachoSil should be carefully removed. (3, 5.5)
May carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agents, despite manufacturing steps designed to reduce the risk of viral transmission. (5.6)

----------ADVERSE REACTIONS----------

The most common adverse reactions reported in > 5% of patients were atrial fibrillation and pyrexia. Atrial fibrillation was reported in 6.1% of TachoSil cases (5.9% of controls) and pyrexia in 5.8% of TachoSil cases (4.9% of controls). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare Corporation at 1-866-888-2472 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

_____USE IN SPECIFIC POPULATIONS_____

Pregnancy: No human or animal data. Use only if clearly needed. (8.1)

See 17 for PATIENT COUNSELING INFORMATION

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

TachoSil is indicated as an adjunct to hemostasis for use in cardiovascular surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

1.1 Limitations of TachoSil Use

- Do not use TachoSil in renal pelvis or ureter procedures because it may become potential foci for calculus formation.
- Do not use TachoSil in the closure of skin incisions because it may interfere with the healing of skin edges or cause wound dehiscence.
- Do not use TachoSil in neurosurgical procedures as safety and efficacy has not been evaluated in neurosurgery.

2. DOSAGE AND ADMINISTRATION

- **Apply on the surface of tissue only.** Do not use intravascularly.
- The number of TachoSil patches to be applied should be determined by the size of the bleeding area to be treated.
- Apply the **yellow, active side** of the patch to the bleeding area.
- Do not exceed 7 patches sized 9.5 x 4.8 cm, 14 patches sized 4.8 x 4.8 cm, or 42 patches sized 3.0 x 2.5 cm. (See Table 1 under (See DOSAGE FORMS AND STRENGTHS (3) and WARNINGS AND PRECAUTIONS, Closed Spaces (5.5)).

2.1 Preparation for Application of TachoSil patch

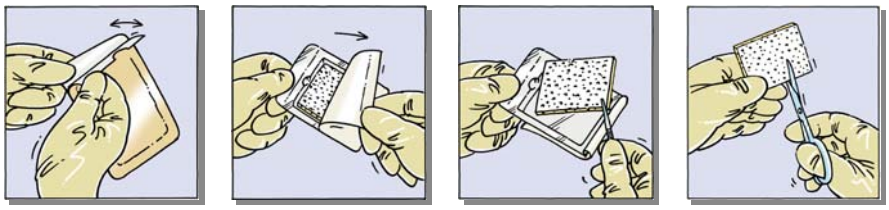
- TachoSil comes ready to use in sterile packages and must be handled accordingly. Use only undamaged packages as resterilization is not possible.

- When in the operating room, the outer aluminum foil pouch may be opened in a non-sterile environment (Fig. 1A). The **inner sterile blister must be opened in a sterile environment** (Fig. 1B).

- Remove the TachoSil patch from the blister (Fig. 1C), which can be used as a container for premoistening of the patch, if needed.

- Tailor the selection and application of TachoSil according to the size of the bleeding area. Select the appropriate TachoSil patch so that it extends 1 - 2 cm beyond the margins of the wound. The patch can be cut to the correct size and shape if desired (Fig. 1D). If more than one patch is used, overlap patches by at least 1 cm.

Figure 1: Pictures illustrating steps for preparation for application of TachoSil



A B C D

2.2 Method of Application

- Prior to application, cleanse the area to be treated to remove disinfectants and other fluids. The fibrinogen and thrombin proteins can be denatured by alcohol, iodine or heavy metal ions. If any of these substances have been used to clean the wound area, thoroughly irrigate the area before the application of TachoSil.

- Apply TachoSil directly to the bleeding area either wet or dry. If applied wet, pre-moisten TachoSil in 0.9% saline solution for no more than 1 minute and then apply immediately. In the case of a wet tissue surface (e.g., oozing bleeding) TachoSil may be applied without pre-moistening.

- Apply the yellow, active side of the patch to the bleeding area (Fig. 2A) and hold in place with gentle pressure applied through moistened gloves or a moist pad for **at least 3 minutes** (Fig. 2B).

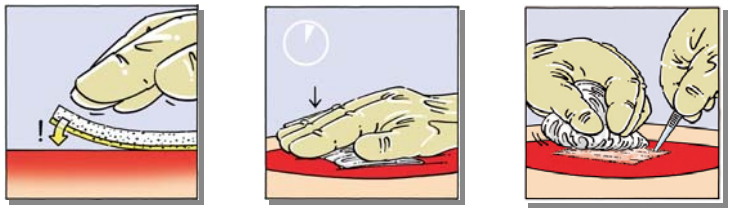
- When applying TachoSil, use precaution because the white, inactive side of TachoSil may also adhere to surgical instruments (e.g., forceps) or gloves covered with blood due to the affinity of collagen to blood. Pre-moisten surgical instruments and gloves with saline solution to reduce the adherence.

- After gently holding TachoSil to the bleeding area for **at least 3 minutes**, remove the gloved hand or moistened pad carefully from the patch. To avoid pulling the patch loose, first place a pre-moistened surgical instrument at one end of the patch before relieving the pressure (Fig. 2C). Gentle irrigation may also aid in removing the premoistened pad or glove hand without removing TachoSil from the bleeding area.

- Leave TachoSil in place once it adheres to organ tissue. Remove unattached TachoSil patches (or part of) and replace with new patches.

- TachoSil cannot be resterilized once removed from inner pouch. Discard unused, opened packages of TachoSil.

Figure 2: Pictures illustrating steps for method of application of TachoSil



A B C

For record-keeping purposes, record patient name and TachoSil batch number every time that TachoSil is administered to a patient.

3. DOSAGE FORMS AND STRENGTHS

Each patch is packaged in an appropriately sized blister pack of polystyrene formed foil and grid varnish coated medicinal paper and overwrapped with an aluminum laminate foil pack with a desiccant bag.

Each TachoSil patch is packaged individually and is supplied in the following pack sizes:

- Package with 1 patch of 9.5 cm x 4.8 cm
- Package with 2 patches of 4.8 cm x 4.8 cm
- Package with 1 patch of 3.0 cm x 2.5 cm
- Package with 5 patches of 3.0 cm x 2.5 cm

Strength: Each square centimeter of TachoSil contains:

Human fibrinogen	3.6 – 7.4 mg (5.5 mg)
Human thrombin	1.3 – 2.7 Units (2.0 U)

When applying TachoSil, do not exceed the maximum number of TachoSil patches shown in Table 1 (See WARNINGS AND PRECAUTIONS, Closed Spaces (5.5)).

Table 1

Amount of Fibrinogen and Thrombin per total patch size and maximum number of patches to be applied

TachoSil Patch Size	Amount of Human Fibrinogen/ Total Patch Size (mg)	Amount of Human Thrombin/Total Patch Size (Units)	Maximum Number of TachoSil Patches to be Applied
9.5 cm x 4.8 cm	337.4	123.1	7
4.8 cm x 4.8 cm	170.5	62.2	14
3.0 cm x 2.5 cm	55.5	20.3	42

Additional inactive ingredients: Equine collagen, human albumin, riboflavin (E 101), sodium chloride, sodium citrate, L-arginine hydrochloride.

4. CONTRAINDICATIONS

4.1 Intravascular Application

Do not apply TachoSil intravascularly. Intravascular application of TachoSil may result in life-threatening thromboembolic events (See ADVERSE REACTIONS, Post Marketing Experience (6.2)).

4.2 Hypersensitivity

Do not use TachoSil in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins (See ADVERSE REACTIONS, Post Marketing Experience (6.2)).

5. WARNINGS AND PRECAUTIONS

5.1 Arterial Bleeding

Do not use TachoSil for the treatment of severe or brisk arterial bleeding because TachoSil has not been evaluated in this treatment.

5.2 Primary Hemostasis

Do not use TachoSil as the primary mode to control hemostasis. TachoSil is not intended as a substitute for meticulous surgical technique and the proper application of suture, ligature or other conventional procedures for hemostasis.

5.3 Hypersensitivity/Allergic/Anaphylactic Reactions

Hypersensitivity or allergic/anaphylactoid reactions may occur with TachoSil. Symptoms associated with allergic anaphylactic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock. These reactions may occur in patients receiving TachoSil for the first time or may increase with repetitive applications of TachoSil.

In the event of hypersensitivity reactions, discontinue administration of TachoSil. Mild reactions can be managed with antihistamines. Severe hypotensive reactions require immediate intervention using current principles of shock therapy.

5.4 Contaminated Spaces

Do not leave TachoSil in an infected or contaminated space because it may potentiate an existing infection.

5.5 Closed Spaces

When placing TachoSil into cavities or closed spaces, avoid over-packing because this may cause compression of underlying tissue. Use only the minimum amount of TachoSil patches necessary to achieve hemostasis (See DOSAGE FORM AND STRENGTHS (3)). Carefully remove or reposition unattached pieces of TachoSil, if medically necessary (See DOSAGE AND ADMINISTRATION, Method of Application (2.2)).

5.6 Transmissible Infectious Agents

The active substances of TachoSil are made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain virus infections, and by inactivating and removing certain viruses (see DESCRIPTION, Viral Clearance (11)). Despite these measures, such products can still potentially transmit disease. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. All infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Baxter Healthcare Corporation, telephone # 1-800-423-2862. The physician should discuss the risks and benefits of this product with the patient.

Some viruses, such as parvovirus B19, are particularly difficult to remove or inactivate at this time. Parvovirus B19 most seriously affects pregnant women (fetal infection), immune-compromised individuals or individuals with an increased erythropoiesis (e.g. hemolytic anemia). (See USE IN SPECIAL POPULATIONS, Pregnancy (8.1) and PATIENT COUNSELING INFORMATION (17))

6. ADVERSE REACTIONS

The most common adverse reactions reported in > 5% of patients were atrial fibrillation and pyrexia. Atrial fibrillation was reported in 6.1% of TachoSil cases (5.9% of controls) and pyrexia in 5.8% of TachoSil cases (4.9% of controls).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In the cardiovascular study the most frequently reported adverse reactions were atrial fibrillation (18 patients [29.0%] in the TachoSil group and 14 patients [24.6%] in the comparator group) and pleural effusion (14 patients [22.6%] in the TachoSil group and 11 patients [19.3%] in the comparator group), see Table 2.

Table 2

Clinically Relevant Adverse Reactions Reported in at Least 5% of Patients in Either Treatment Group (cardiovascular study), Irrespective of Causality

Adverse Reaction (Preferred Term)	TachoSil N = 62[2] n (%)	Comparator N = 57[2] n (%)
At least 1 adverse event[1]	**46 (74.2%)**	**43 (75.4%)**
Atrial fibrillation	18 (29.0%)	14 (24.6%)
Pleural effusion	14 (22.6%)	11 (19.3%)
Hemorrhagic anemia	5 (8.1%)	6 (10.5%)

Tachyarrhythmia	4 (6.5%)	4 (7.0%)
Pyrexia	4 (6.5%)	3 (5.3%)
Pericardial effusion	3 (4.8%)	4 (7.0%)
Post procedural hemorrhage	3 (4.8%)	3 (5.3%)

[1] The table presents the number of patients experiencing at least 1 adverse reaction (regardless of causality. At each level of patient summarization, please note that a patient is counted once regardless of whether the patient had one or more events reported.
[2] As treated population (safety data set).

6.2 Post Marketing Experience

The following adverse reactions have been reported in post marketing experience with TachoSil in the EU and could reasonably be expected to occur with TachoSil in the US:

General disorders and administration site conditions: drug ineffective, inflammation, granuloma, catheter related complication, multiorgan failure, pyrexia
Injury, poisoning and procedural complications: post procedural hemorrhage, foreign body trauma, post procedural pulmonary embolism
Vascular disorders: phlebitis, hematoma, hemorrhage, thrombosis
Infections and infestations: hepatitis C, abscess
Respiratory, thoracic and mediastinal disorders: respiratory distress, laryngeal edema, hemothorax
Blood and lymphatic system disorders: splenic hemorrhage, eosinophilia
Hepatobiliary disorders: biloma, portal vein thrombosis
Renal and urinary disorders: renal artery thrombosis, renal failure
Endocrine disorders: parathyroid disorder
Eye disorders: mydriasis
Nervous system disorders: nerve compression

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

7. DRUG INTERACTIONS

No drug interactions are known.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with TachoSil. There are no adequate and well-controlled studies in pregnant women. It is also not known whether TachoSil can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Some viruses, such as parvovirus B19, are particularly difficult to remove or inactivate at this time. Parvovirus B19 most seriously affects pregnant women (fetal infection). TachoSil should be administered to pregnant women only if clearly needed (see PATIENT COUNSELING INFORMATION (17)).

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TachoSil is administered to nursing mothers.

8.4 Pediatric Use

The safety and effectiveness of TachoSil in pediatric patients undergoing cardiovascular surgery have not been established.

8.5 Geriatric Use

Clinical trials included 219 patients older than 65 years of age receiving TachoSil. No overall differences in safety or effectiveness were observed between the elderly and younger patients. However, greater susceptibility of some older patients to adverse reactions cannot be ruled out.

11. DESCRIPTION

TachoSil is a fibrin sealant patch consisting of an off-white, closed cell, equine collagen sponge coated on one side with two active ingredients: human fibrinogen and human thrombin. Riboflavin is included in the coating mixture as a yellow colorant to signify the active surface. Each square centimeter contains approximately 5.5 mg of human fibrinogen and 2.0 units of human thrombin. Other inactive ingredients include equine collagen, human albumin, sodium chloride, sodium citrate and L-arginine hydrochloride.

Each patch is packaged in an appropriately sized blister pack of polystyrene formed foil and grid varnish coated medicinal paper and overwrapped with an aluminum laminate foil pack with a desiccant bag.

Viral Clearance

The manufacturing procedure of TachoSil and its active substances Fibrinogen and Thrombin includes processing steps designed to reduce the risk of viral transmission. In particular, pasteurization, precipitation and adsorption steps are included in the manufacturing of Fibrinogen and Thrombin and pH treatment in the manufacturing of Collagen Sponge.

Validation studies for Fibrinogen and Thrombin and Collagen Sponge manufacturing steps were conducted for their capacity to inactivate and/or remove viruses. These in vitro validation studies were conducted, using samples from manufacturing intermediates spiked with virus suspensions of known titers followed by further processing under conditions equivalent to those in the respective manufacturing steps. The cumulative virus reduction factors (expressed as $\log_{10}$) are shown in Table 3 for each virus tested.

TachoSil is sterilized by gamma irradiation after completion of inner and outer packaging, resulting in a sterile product in a sterile inner package. A validation study was conducted evaluating the capacity of gamma irradiation to inactivate viruses. The

virus reduction factors (expressed as $\log_{10}$) for the final sterilization of TachoSil by gamma irradiation are shown in Table 4 for each virus tested.

Table 3

Cumulative virus reduction factors for the components of TachoSil

Cumulative Reduction Factors for Virus Removal/Inactivation of Human Thrombin					
	Reduction Factors [$\log_{10}$] of Virus[1] tested				
Manufacturing step	HIV-1	HSV	BVDV	CPV	HAV
Pasteurization, precipitation and adsorption steps	≥ 19.6	≥ 21.4	≥ 13.4	6.6	8.7
Cumulative Reduction Factors for Virus Removal/Inactivation of Human Fibrinogen					
	Reduction Factors [$\log_{10}$] of Virus[1] tested				
Manufacturing step	HIV-1	HSV[2]	BVDV	CPV	HAV
Pasteurization, precipitation and adsorption steps	≥9.6	≥ 9.1	≥ 11.2	4.4	≥ 6.7
Reduction Factors for Virus Removal/Inactivation of the Collagen Sponge (equine)					
	Reduction Factors [$\log_{10}$] of Virus[1] tested				
Manufacturing step	PRV	PI-3	PPV	Reo3	
pH treatment	≥ 5.7	≥ 5.9	---	---	

[1] HIV-1: Human Immunodeficiency Virus 1
HSV: Herpes Simplex Virus
BVDV: Bovine Viral Diarrhoea Virus
HAV: Hepatitis A Virus
PRV: Pseudorabies Virus
PI-3: Parainfluenza Virus type 3
PPV: Porcine Parvovirus
Reo 3: Reo Virus type 3

[2] Additional reduction factor [log10] of 1.6 for PRV not included in cumulative reduction factor for HSV

Table 4

Virus reduction factors for the final sterilization by gamma irradiation

Reduction Factor of Gamma Irradiation (Final Sterilization of TachoSil)				
	Reduction Factors [$\log_{10}$] of Virus[1] tested			
Manufacturing step	PRV	PI-3	PPV	Reo3
Gamma Irradiation	≥ 4.7	≥ 4.0	3.0	≥ 6.2

[1] PRV: Pseudorabies Virus
PI-3: Parainfluenza Virus type 3
PPV: Porcine Parvovirus
Reo 3: Reo Virus type 3

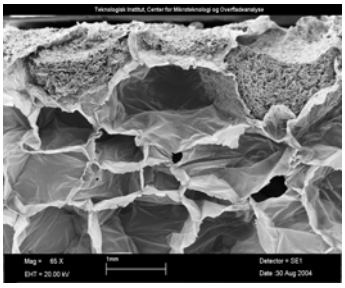
All infections considered by a physician possibly to have been transmitted by this product should be reported to Baxter. (See WARNINGS AND PRECAUTIONS, Transmissible Infectious Agents (5.6))

12. CLINICAL PHARMACOLOGY

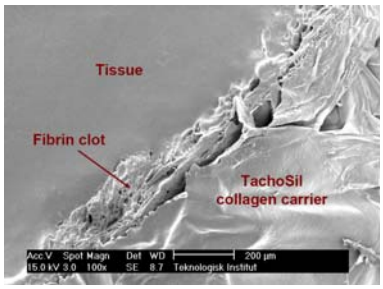
12.1 Mechanism of Action

TachoSil contains human fibrinogen and human thrombin as a dried coating on the surface of an equine collagen patch (Fig. 3A). When TachoSil is in contact with physiological fluids, the components of the coating dissolve and partly diffuse into the wound surface. Soluble fibrinogen is transformed into fibrin, by the enzymatic action of thrombin, which polymerizes into a fibrin clot that adheres the collagen patch to the wound surface and achieves hemostasis (Fig 3B). TachoSil exhibits flexibility to accommodate for the physiological movements of tissues and organs and can withstand pressures up to 61.4 hPa (46.1 mm Hg).

Figure 3: SEM (Scanning Electron Microscopy) photos of TachoSil



A. This side view of the TachoSil patch shows the coating of the human plasma components anchored to the indentations of the collagen carrier.



B. The deposition of a fibrin clot formed from the fibrinogen and thrombin of the coating causes hemostasis and conglutination of the TachoSil patch to the tissue wound.

In animal studies, TachoSil progressively biodegrades with only a few remnants left after 13 weeks. After complete biodegradation, no remnants of the TachoSil patch remained in the body.

12.2 Pharmacodynamics

Clinical studies demonstrating hemostasis were conducted in a total of 119 patients undergoing cardiovascular surgery. Efficacy data is provided in section 14.

12.3 Pharmacokinetics

Pharmacokinetic studies have not been performed. Because TachoSil is applied only topically, systemic exposure or distribution to other organs or tissues is not expected.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies to evaluate the carcinogenic potential of TachoSil or studies to determine the genotoxicity or the effect of TachoSil on fertility have not been performed.

14. CLINICAL STUDIES

An open-label, multicenter, 1:1 randomized, parallel-group study comparing TachoSil with comparator (hemostatic fleece without additional active coagulation stimulating compounds) treatment was conducted to evaluate TachoSil for control of bleeding in 119 patients undergoing cardiovascular surgery requiring cardiopulmonary bypass procedure.

In the Intention to Treat (ITT) population (119 patients), 59 patients were treated with TachoSil and 60 patients were treated with the comparator. A larger proportion of patients in the TachoSil treatment group (44/59; 74.6%) than in the comparator treatment group (20/60; 33.3%) achieved hemostasis within 3 minutes, which was a statistically significant difference ($p<0.0001$, CMH test controlling for center). Fifty-six out of 59 (94.9%) patients in the TachoSil treatment group achieved hemostasis at 6 minutes compared to 43 out of 60 (71.7%) in the comparator treatment group, which was statistically significant ($p=0.0006$, CMH test controlling for center), see Table 5.

Table 5

Efficacy results in cardiovascular surgery, by treatment, ITT population (n = 119)

Treatment	Total number of patients who achieved hemostasis	Proportion of patients who achieved hemostasis	95% CI for proportion[a]	p-value[b]
Hemostasis at 3 min				
TachoSil (n =59)	44	0.746	[0.635; 0.857]	< 0.0001
Comparator[c] (n=60)	20	0.333	[0.214; 0.453]	
Hemostasis at 6 min				
TachoSil (n =59)	56	0.949	[0.893;1.000]	< 0.0006
Comparator[c] (n=60)	43	0.717	[0.603; 0.831]	

[a] Normal approximation to the binominal distribution is used to construct the asymptotic confidence intervals
[b] Cochran-Mantel-Haenszel test controlling for center
[c] Hemostatic fleece material without additional active coagulation stimulating compounds

16. HOW SUPPLIED/STORAGE AND HANDLING

Each patch is packaged in an appropriately sized blister pack of polystyrene formed foil and grid varnish coated medicinal paper and overwrapped with an aluminum laminate foil pack with a desiccant bag. Each patch is packaged individually.

TachoSil is supplied in the following pack sizes:

- Package with 1 patch of 9.5 cm x 4.8 cm (NDC 0944-XXXX-XX)_
- Package with 2 patches of 4.8 cm x 4.8 cm (NDC 0944-XXXX-XX)_
- Package with 1 patch of 3.0 cm x 2.5 cm (NDC 0944-XXXX-XX)_
- Package with 5 patches of 3.0 cm x 2.5 cm (NDC 0944-XXXX-XX)_

Storage
TachoSil should be stored between 2ºC and 25ºC.
TachoSil does not require refrigeration. Do not freeze.

17. PATIENT COUNSELING INFORMATION

Advise patients that, because TachoSil is made from human blood, it may carry a risk of transmitting infections agents, e.g., viruses, and, theoretically, the Creutzfeldt-Jakob (CJD) agent (See WARNINGS AND PRECAUTIONS, Transmissible Infectious Agents (5.6) and DESCRIPTION (11)).

Instruct patients to consult their physician if symptoms of B19 virus infection appear (fever, drowsiness, chills and runny nose followed about two weeks later by a rash and joint pain (see USE IN SPECIFIC POPULATIONS, Pregnancy (8.1)).

Distributed by:
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