

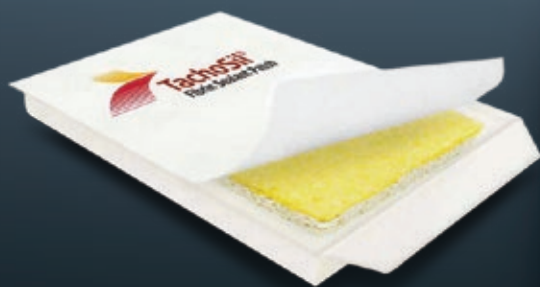


READY-TO-USE
+
CONFORMABLE

TACHOSIL® FIBRIN SEALANT PATCH A

BioLOGICAL

HEMOSTATIC CHOICE



TachoSil® is a fibrin sealant patch indicated for use with manual compression in adult and pediatric patients as an adjunct to hemostasis in cardiovascular and hepatic surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Not for use in place of sutures or other forms of mechanical ligation in treatment of major arterial or venous bleeding. Not for use in children under one month of age.

For detailed Important Risk Information, please see back page and accompanying full Prescribing Information.

Baxter



PACKAGE TO PATIENT + HEMOSTASIS POWER

Adjunctive hemostasis to control mild-to-moderate intraoperative bleeding¹. Do not use for the treatment of major arterial or venous bleeding.

TachoSil® patch harnesses the efficacy of a fibrin sealant in the convenience of a surgical patch for targeted bleeding coverage. The coating of active biological ingredients fibrinogen and thrombin on one side of the collagen patch promote hemostasis by triggering the last stage of the coagulation cascade to create a fibrin clot.

Ready-to-use

- No mixing
- No thawing
- No refrigeration
- No special apparatus

Conformable

- Maintains flexibility that accommodates tissue and organ movement
- Can be cut to size and shape of wound
- Wet or dry field application

Staying Power

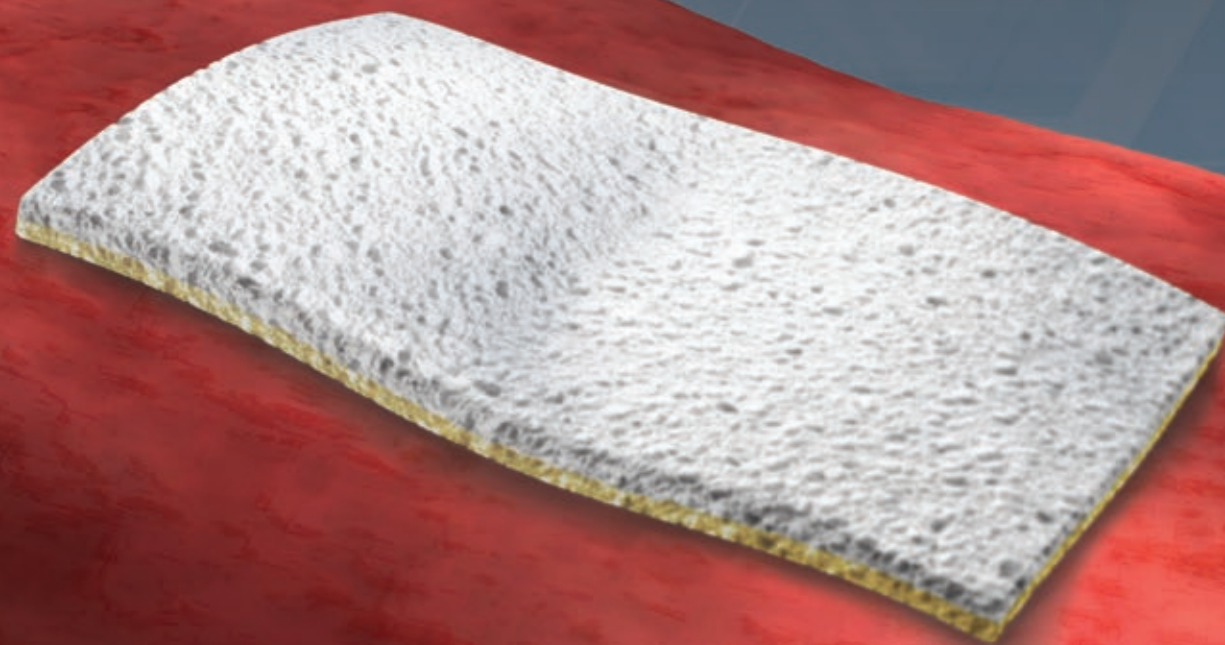
- High adhesive strength shown to withstand pressures up to 61.4 hPa (46.1 mmHg)¹
- Does not have to be removed
- **TachoSil®** was applied to swine liver wounds and showed progressive degradation. Remnants of the patch may remain present up to 12 months*

*Preclinical results may not correlate with results in humans.

Selected Important Risk Information

- Be sure **TachoSil®** Fibrin Sealant Patch extends 1 to 2 cm beyond the margins of the wound.
- Avoid packing in cavities or closed spaces.
- Use only the minimum amount of patches necessary to achieve hemostasis.
- Unattached pieces of **TachoSil®** Fibrin Sealant Patch should be carefully removed.

For detailed Important Risk Information, please see back page and accompanying full Prescribing Information.



FIBRINOGEN + THROMBIN

The equine collagen is structured in a honeycomb-like, closed cell formation, and can serve as a mechanical carrier.

- Remains flexible¹
- Will not swell¹

The fibrinogen-thrombin reaction initiates the last step in the coagulation cascade to form the fibrin clot. Compress **TachoSil®** patch gently over the wound area for at least 3 minutes until coagulation is triggered.¹

Hemostasis is achieved when the formed fibrin clot adheres the collagen patch to the wound surface, thus providing a physical barrier to bleeding.

TachoSil® patch is coated with two active human coagulation factors: fibrinogen and thrombin. Upon contact with a bleeding wound surface, the active substances become dissolved and partly diffuse into the wound surface.¹

Microscopic side view of **TachoSil®** patch. The thrombin and fibrinogen is anchored to the honeycomb-like indentations of the collagen carrier.

Selected Important Risk Information

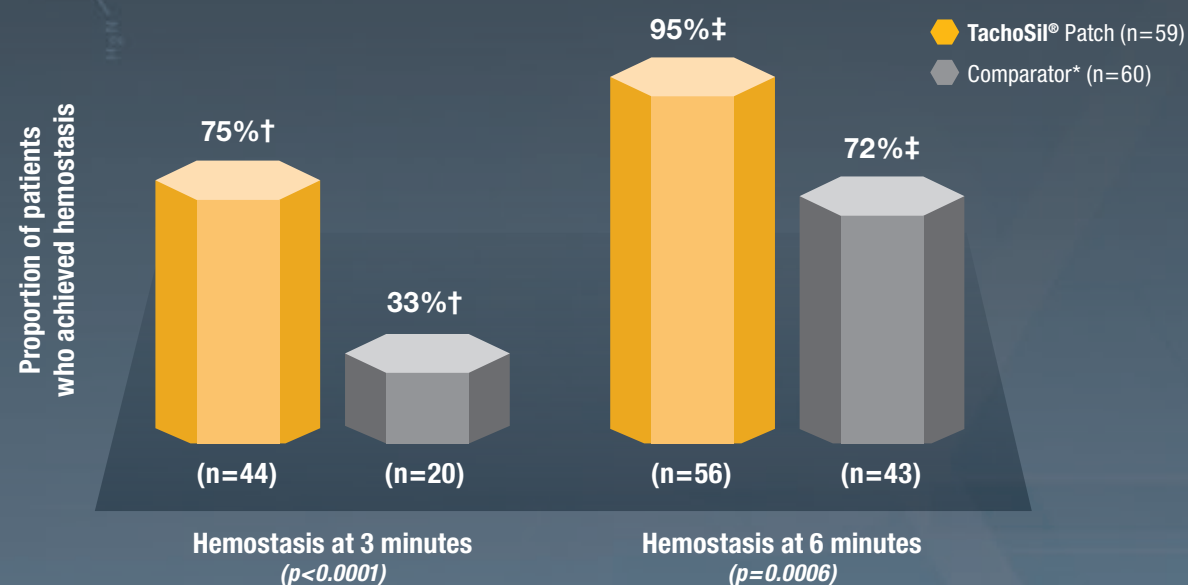
- ◆ Do not use **TachoSil®** Fibrin Sealant Patch in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins.
- ◆ Can cause hypersensitivity or allergic/anaphylactoid reactions with first-time or repetitive application.
- ◆ Avoid application to contaminated areas of the body or in the presence of active infection.

For detailed Important Risk Information, please see back page and accompanying full Prescribing Information.

PROVEN + EFFECTIVE

Efficacy Results in Cardiovascular Surgery, by Treatment, Intent-to-Treat Population

Bleeding controlled at 3 minutes in approximately 75%
of patients treated with TachoSil® patch[†]



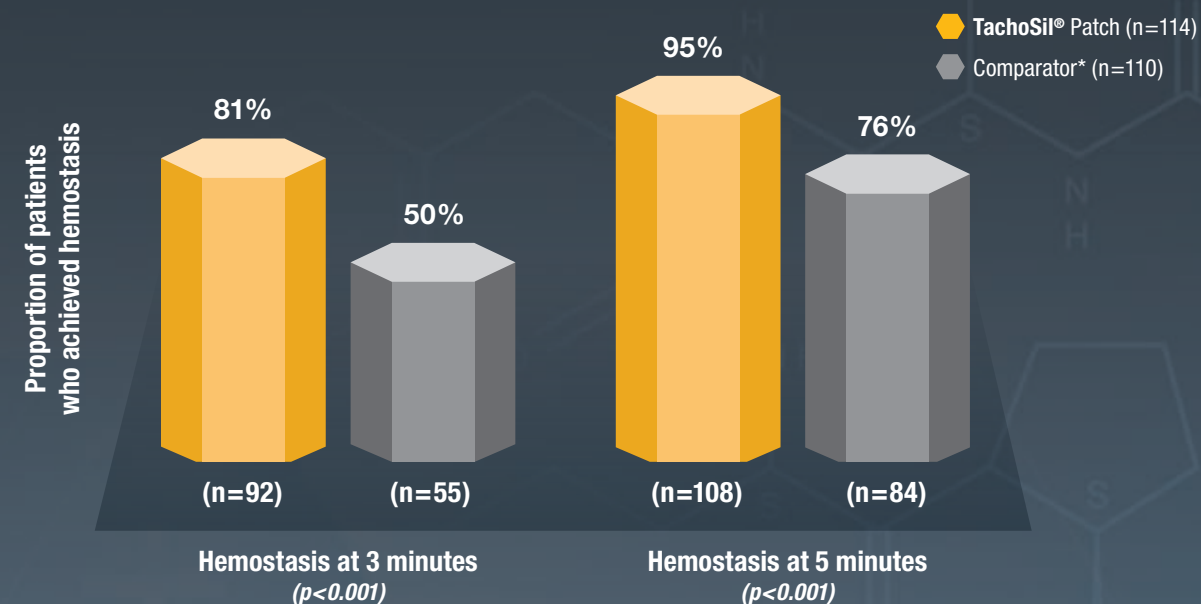
* The comparator group was treated using hemostatic fleece without additional active coagulation-stimulating compounds.
[†] The 95% confidence intervals at 3 minutes were 0.635 to 0.857 (TachoSil®) and 0.214 to 0.453 (comparator).
[‡] The 95% confidence intervals at 6 minutes were 0.893 to 1.000 (TachoSil®) and 0.603 to 0.831 (comparator).

The ability of TachoSil® patch to control bleeding in cardiovascular surgery was evaluated in an open-label, 1:1 randomized, parallel-group study comparing TachoSil® patch with a comparator treatment.* ITT population = 119 patients.

The most common ARs in the TachoSil® (N=62) vs. comparator (N=57) groups, respectively, of the CV trial were atrial fibrillation (29% vs. 25%), pleural effusion (23% vs. 19%) and pyrexia (6% vs. 5%).

Efficacy Results in Hepatic Surgery, by Treatment, Intent-to-Treat Population

Bleeding controlled at 3 minutes in approximately 81%
of patients treated with TachoSil® patch[†]



* The comparator group was treated with hemostatic fleece material made of oxidized cellulose polymer.

The ability of TachoSil® patch to control bleeding in hepatic resection surgery was evaluated in a randomized, open label, parallel-group, multi-center trial to compare the efficacy and safety of TachoSil® versus a comparator treatment.* ITT population = 224 patients.

The most common ARs in the TachoSil® (N=114) vs. comparator (N=109) groups, respectively, of the hepatic resection trial were nausea (30% vs. 27%) and anemia (23% vs. 21%).

Selected Important Risk Information

- Do not use TachoSil® Fibrin Sealant Patch in place of sutures, ligature, cautery or other primary modes for control of hemostasis.
- Do not use TachoSil® Fibrin Sealant Patch in individuals with known hypersensitivity to human blood products or horse proteins.

For detailed Important Risk Information, please see back page
and accompanying full Prescribing Information.

TachoSil® Fibrin Sealant Patch

Indications and Usage

Indicated for use with manual compression in adult and pediatric patients as an adjunct to hemostasis in cardiovascular and hepatic surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Not for use in place of sutures or other forms of mechanical ligation in treatment of major arterial or venous bleeding. Not for use in children under one month of age.

Important Risk Information

- ◆ Do not apply **TachoSil®** Fibrin Sealant Patch intravascularly. Intravascular application of **TachoSil®** can result in life-threatening thromboembolic events. Thrombosis can occur if **TachoSil®** is exposed intravascularly. Ensure that **TachoSil®** is applied to the surface of cardiac, vascular or hepatic tissue only.
- ◆ Do not use **TachoSil®** Fibrin Sealant Patch in individuals with known hypersensitivity to human blood products or horse proteins.
- ◆ Can cause hypersensitivity or allergic/anaphylactoid reactions with first-time or repetitive application.
- ◆ Avoid application to contaminated areas of the body or in the presence of active infection.
- ◆ **TachoSil®** Fibrin Sealant Patch contains collagen which may adhere to bleeding surfaces. May carry a risk of gastrointestinal obstruction in abdominal surgery due to tissue adhesions. To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the application area are adequately cleansed before administration of **TachoSil®**.
- ◆ Avoid packing in cavities or closed spaces because this may cause compression of underlying tissue.
- ◆ Use the least number of patches required to cover the entire bleeding area. Do not pack. Remove any unattached pieces of **TachoSil®** Fibrin Sealant Patch.
- ◆ May carry a risk of transmitting infectious agents, such as viruses, and theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent and the Creutzfeldt-Jakob disease (CJD) agents, despite manufacturing steps designed to reduce the risk of viral transmission.
- ◆ The most common adverse reactions reported in >1% of patients during clinical trials were anemia, nausea and vomiting, fever, abdominal pain, increased white blood cell count, ascites, itching, atrial fibrillation, pleural effusion, gastrointestinal hemorrhage, wound infection, hypophosphatemia, urinary tract infection and post-procedural bile leakage in hepatic surgery.

| Reorder Number | Size | Qty |
|----------------|-----------------------------------|-----|
| 1144922 | 3.7 in x 1.9 in (9.5 cm x 4.8 cm) | 1 |
| 1144923 | 1.9 in x 1.9 in (4.8 cm x 4.8 cm) | 2 |

Reference:

1. **TachoSil®** patch [package insert]. Baxter Healthcare Corporation. 07/2016.

Please see accompanying full Prescribing Information.

For questions or ordering information, please call 888-229-0001.

www.tachosilus.com

Baxter

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USBS/421/14-0008(1)a(2) 12 / 2016