



TachoSil[®]
Fibrin Sealant Patch

Compendium



 **corzamedical**

>11.5 million applications
all around the world prove
the versatility of TachoSil[®]



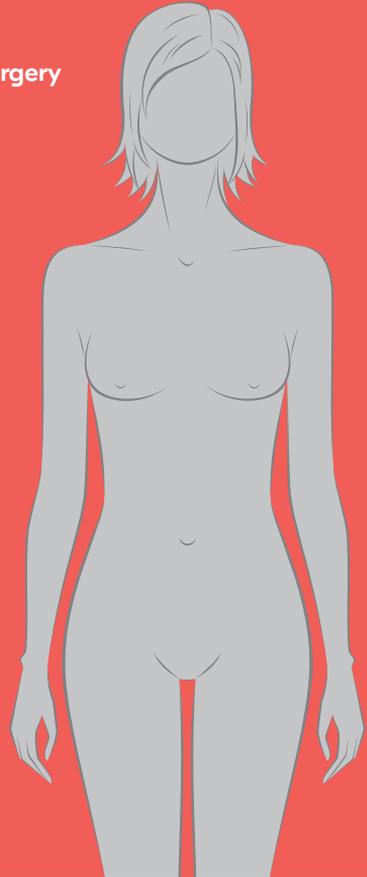
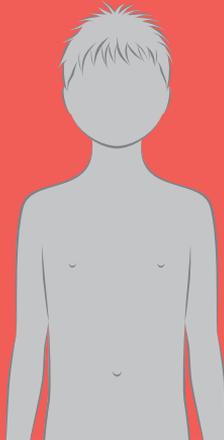
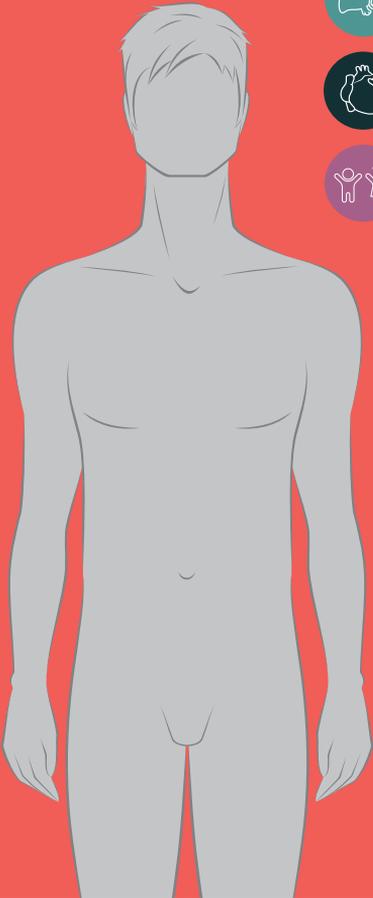
Hepatic surgery



Cardiovascular surgery



Pediatric surgery



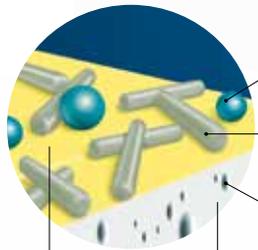
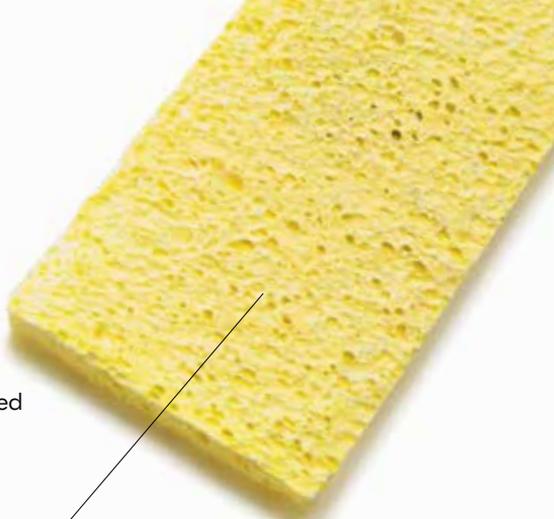
... for minimally invasive,
robotic-assisted and open
procedures.

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What is TachoSil®?

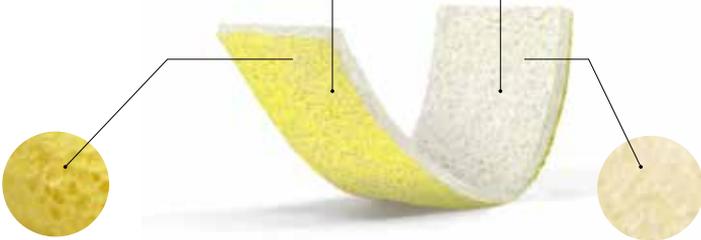
TachoSil® is a closed cell collagen matrix that has both hemostatic and air and liquid tight properties. It is coated with human fibrinogen and human thrombin (coloring: riboflavin).¹



Human thrombin
(2 IU/cm²)

Human fibrinogen
(5.5mg/cm²)

Collagen
honeycombs



Yellow active side

Human fibrinogen + thrombin
(coloring agent: riboflavin)

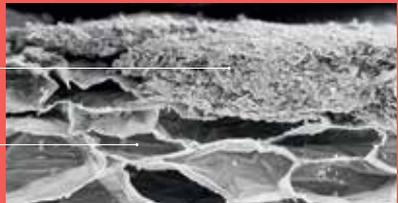
Base matrix

Foamed equine collagen

The scanning electron microscope image shows the honeycomb structure of the collagen base matrix and the adhesive layer of fibrinogen and thrombin.

Active side

Base matrix



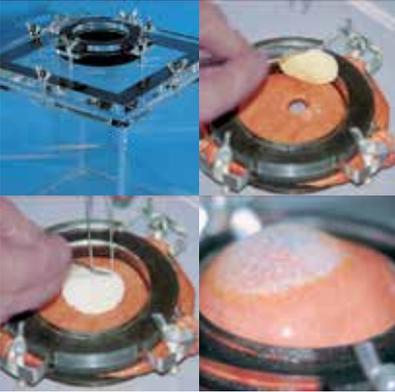
Mag = 100X
EHT = 20.00kV

1 mm

Detector = SE1
Date: 9 Aug. 2004

What can TachoSil® do?

TachoSil® and its **mechanical** properties*



- Up to 2.5 times more elastic when moistened than when dry²
- When moistened, adapts to organ movements
- Easy to shape even to irregular surfaces
- Withstands pressure of 61.4 hPa (approx. 46 mmHg)² (A cough reaches a pressure of up to 60 hPa)
- Adheres twice as firmly as a manually coated patch and 6 times more firmly than liquid adhesives³

TachoSil® and its **hemostatic** properties

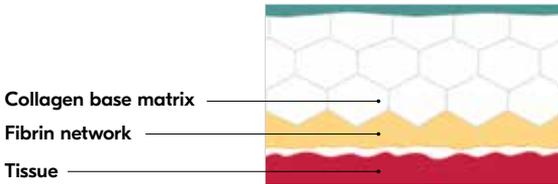
- Ready-to-use fixed combination
- Hemostasis after 3 minutes of pressing in place, regardless of coagulation status³
- Atraumatic and tissue conserving
- Interacts with all physiological fluids
- Secures sutures in vascular surgery¹
- Ideal for suture support



* Determined using in vitro material science and animal experiment tests.

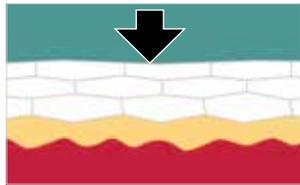
How does TachoSil® work?

1.



TachoSil® collagen patch is coated with human fibrinogen and thrombin.¹

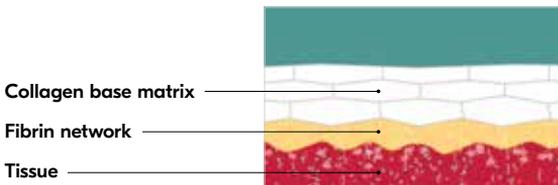
2.



On contact with bodily fluids such as blood or lymph, or with normal saline solution, the solid fibrinogen and thrombin components are activated and diffused, partially into the wound surface.

The subsequent fibrinogen-thrombin reaction completes the last stage of the coagulation cascade. The fibrinogen is converted to the fibrin monomer, which is ultimately polymerized to a fibrin clot.¹

3.



A strong, mechanically stable fibrin network is formed with good adhesive properties.¹ With adhesive properties that results in conglutination to parenchymal surface.

How does TachoSil[®] biodegrade?

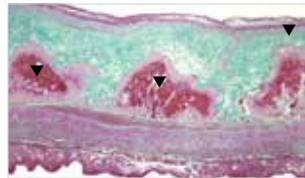
TachoSil[®] and all of its components have a high level of tissue compatibility (histocompatibility) and it is broken down by resorptive granulation tissue.^{4,5}

The adhesive layer of the product is metabolized just like endogenous fibrin by fibrinolysis and phagocytosis.¹

In animal experiments, TachoSil[®] is biodegraded after application to a wound surface with little residue after 13 weeks. [...] No evidence of local intolerance was observed in animal experiments.¹



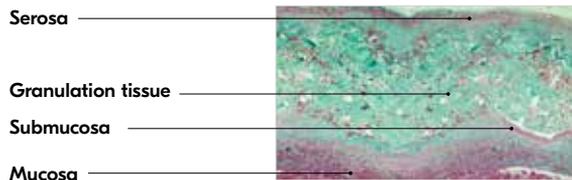
Histology (rabbit model)



The collagen patch (here TachoComb[®] H) is completely coated with serosa containing dense connective tissue with blood vessels among the mesothelial cells. Residual fleeces marked by (▼).



Histology (rabbit model)



Increasing resorption of the patch by granulation tissue.
(Figures mod. from Schneider A et al.)⁵

Where is TachoSil[®] used?

TachoSil[®] is a fibrin sealant patch indicated for the use with manual compression in adult and pediatric patients from one month 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.¹





Hepatic surgery

Hemostasis

- in parenchymal organs such as the liver⁶
- after resections, transplantation, trauma or incidental injury
- stitch bleeding (vascular prostheses)

Examples of use



TachoSil® to support hemostasis after liver lobe removal as part of a living liver donation. **Photo: Dr. S. Hinz**



TachoSil® for hemostasis of liver resection surfaces in hepatocellular carcinoma. **Photo: Dr. C. Prinz**



Overlapping TachoSil® application after partial liver resection. **Photo: Dr. J. Figueras**



TachoSil® for hemostasis after traumatic liver injury. **Photo: Dr. E. John**

Further possible applications for hemostasis

- after tumor resection of the liver and laparoscopic cholecystectomy

Where is TachoSil[®] used?

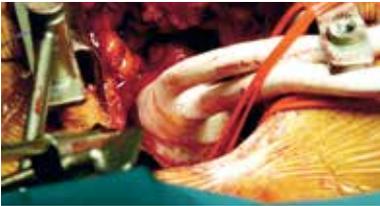


Cardiovascular surgery

Hemostasis

- stitch bleeding⁷ (vascular prostheses)
 - diffuse and extensive bleeding in the heart⁸⁻¹⁰
 - vascular anastomoses⁷
-

Examples of use



Application of a TachoSil[®] patch to secure the sutures of an aortic anastomosis.

Photo: Prof. Dr. L. Gürke



TachoSil[®] to support hemostasis after transapical aortic valve replacement.

Photo: Prof. Dr. M. Czerny



TachoSil[®] to support hemostasis after replacement of the ascending aorta and arcuate aorta. **Photo: Prof. Dr. M. Czerny**

Further possible applications for hemostasis

- for localized bleeding during cardiac intervention
- in the region of the apex of the heart after transapical aortic valve replacement



Pediatric surgery

Hemostasis

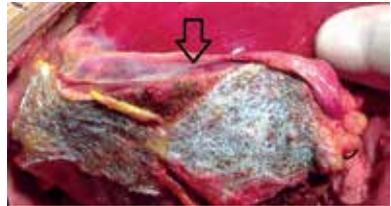
- after liver resections¹¹ or liver transplantations¹²
 - after hepatic trauma or incidental injury
 - in cardiovascular surgery¹³
-

Examples of use



TachoSil® for better hemostasis after excision of a large hepatic cyst in an 18-month-old child.

Photo: MD N. Matsushita



TachoSil® for better hemostasis in the wound area of the hepatic graft in pediatric liver transplantation.

Photo: Dr. F. Vicentine

Further possible applications for hemostasis

- for liver resections
- after resection of liver cysts

Selected literature

Study	Type of study / purpose
● Hepatic surgery	
Frilling et al. 2005, Langenbeck's Arch Surg, 390:114 – 120 ^a	Randomised prospective trial comparing the efficiency of TachoSil [®] and argon beamer for liver resections
Fischer et al. 2011, Surgery, Volume 149, Issue 1, pages 48 – 55 ^d	International controlled, randomised multicentre trial with parallel groups
Kakaei et al. 2013, HPB Surg. 2013:587608 ^b	Randomized clinical trial comparing efficacy of TachoSil [®] vs. Surgicel [™] to control oozing after liver resection
Kawasaki et al. 2017, Langenbecks Arch Surg. 402(4):591 – 598 ^c	Randomized, double-blind, non-inferiority trial to show the efficacy of two different patches in persistent exudative bleeding during liver resection/removal for donation
Moench et al. 2014, Langenbecks Arch Surg. 399(6):725 – 33 ^f	Randomized clinical trial to show efficacy of two different patches in secondary hemostasis after liver resection
Öllinger et al. 2013, HPB (Oxford). 15(7):548 – 58 ^b	Randomized clinical trial to compare the use of two different patches in the management of diffuse bleeding after hepatic surgery

● Cardiovascular surgery	
Maisano et al. 2009, European Journal of Cardiothoracic Surgery 10; p S1873 – 734X ^f	Prospective, randomised controlled trial on controlling bleeding in cardiovascular surgery
Glineur et al. 2018, Med Devices. 11:65 – 75 ^g	Randomized clinical trial to control bleeding with two different patches in open cardiovascular surgery involving the aorta or CABG

● Pediatric surgery	
Genyk et al. 2016, J Am Coll Surg. 222(3): 261 – 8 ^h	Randomized, open-label study to show the efficacy of two different patches for the secondary treatment of local bleeding after hepatic resection in adult and pediatric patients
Vicentine et al. 2016, Arq Bras Cir Dig. 29(4):236 – 239 ²	Prospective, single centre clinical trial with pediatric patients (< 18 years) with the need of liver transplantation with the ex-situ liver transection technique and with the use of TachoSil [®]
Mirza et al. 2011, Eur J Pediatr Surg. 21(2):111 – 5 ²⁰	Prospective, open-label, single arm, multicentric trial in children to show efficacy of TachoSil [®] in case of minor or moderate bleeding after primary hemostatic treatment

Further studies can be found on www.corza.com

Patient collective	Result (time to hemostasis)
n = 121 patients n = 59 TachoSil® n = 62 argon beamer	3.9 min. (TachoSil®) vs. 6.3 min. (argon) p < 0.001
n = 119 patients n = 60 TachoSil® n = 59 argon beamer	3.6 min. (TachoSil®) vs. 5 min. (argon) p = 0.001
n = 45 patients n = 15 TachoSil® n = 15 Surgicel™	3.0 min. (TachoSil®) vs. 3.2 min. (Surgicel™) p = 0.4
n = 108 patients n = 54 TachoSil® n = 54 TachoComb®	5 min (TachoSil®) vs. 5 min. (TachoComb®) p = 1.0
n = 128 patients n = 65 TachoSil® n = 61 Sangustop®	2.2 min. (TachoSil®) vs. 3.4 min. (Sangustop®)
n = 50 patients n = 18 TachoSil® n = 32 Veriset™	3 min. (TachoSil®) vs. 1 min. (Veriset™) p < 0.001
n = 119 patients n = 59 TachoSil® n = 60 standard treatment	Primary endpoint Hemostasis after 3 min.; p < 0.0001 TachoSil®: 75% / Control group: 33% Secondary endpoint Hemostasis after 6 min.; p = 0.0006 TachoSil®: 95% / Control group: 72%
n = 90 patients n = 45 TachoSil® n = 41 Veriset™	1.5 min. (TachoSil®) vs. 3 min. (Veriset™) p < 0.0001 Proportion of patients achieving hemostasis at all treated bleeding sites within 3 min.: 41 (TachoSil®) vs. 36 (Veriset™)
n = 29 pediatric patients (16 liver resections, 13 segmental liver transplants) n = 17 randomised pediatric patients: n = 8 TachoSil® n = 9 Tabotamp® n = 12 in the extension phase of the study with TachoSil® treatment	Hemostasis within 3 min.: 17 out of 20 (85.0%) children (TachoSil®) vs. 4 out of 9 (44.4%) (Tabotamp®) Hemostasis after 5 min.: 95% (TachoSil®) vs. 77.8% (Tabotamp®)
n = 80 patients n = 21 TachoSil® n = 59 control group	There were fewer reoperations due to bleeding in the wound area in the TachoSil® group (14.2%) compared to the control group (41.7%, p = 0.029)
n = 16 children enrolled n = 13 children with whole liver resection n = 3 with segmental resection	13 children (81.3% ; 95% CI: 61.8 – 100%) with hemostasis at 3 min. and in 1 child at 8 min.

Further literature

● Hepatic surgery

Apstegui C et al. Control of Severe Portal Bleeding by Carrier-Bound Fibrin Sealant. *Surgery Today* 2009; 39: 363–365.

Briceño J et al. A Prospective Study of the Efficacy of Clinical Application of a New Carrier-Bound Fibrin Sealant After Liver Resection. *Arch Surg* 2010; 145: 482–48.

Broelsch CE et al. TachoSil® as hemostatic treatment in hepatic surgery. *HPB* 2005; 7(Suppl 1):28.

Droghetti A et al. Prospective randomized trial comparing completion technique of fissures for lobectomy: Stapler versus precision dissection and sealant. *J Thorac Cardiovasc Surg* 2008; 136: 383–391.

Frena A et al. How to improve biliostasis in liver surgery. *Chirurgia Italiana* 2006; 58: 793–795.

Lempa M et al. Blutstillung mittels TachoComb® während laparoskopischer Cholezystektomie bei Leberzirrhose. *Minimal invasive Chirurgie* 2000; 9: 107–109.

Mehrabi A et al. Transplantation of a severely lacerated liver – a case report with review of the literature. *Clin Transplant*; 2009: 321–328.

Toro A et al. TachoSil®: Use in abdominal surgery – A review. *Journal of Blood Medicine* 2011; 231–236.

Toti L et al. Reduction of bile leaks following adult split liver transplant using a fibrin-collagen sponge: A pilot study. *Digestive and Liver Disease* 2010; 42: 205–209.

Zentai C et al. Fibrin patch in a pig model with blunt liver injury under severe hypothermia. *J Surg Res* 2014; 187: 616–624.

● Cardiovascular surgery

Apstegui C et al. Control of severe portal bleeding by carrier-bound fibrin sealant. *Surg Today* 2009; 39: 363–365.

Celiento M et al. Repair of coronary artery perforation following angioplasty using TachoSil patches. *Interact Cardiovasc Thorac Surg* 2010; 10: 328–330.

Czerny et al. Collagen patch coated with fibrin glue components. *J Cardiovasc Surg* 2000; 41: 553–557.

Gocol R et al. Aortic Root Reconstruction with TachoSil Fibrin Sealant Patch in Acute Type A Aortic Dissection. *Ann Thorac Cardiovasc Surg.* 2021; 27(4):267–272.

Kimura N et al. Pitfalls of Sutureless Repair of a Blow-out Type Left Ventricular Free Wall Rupture. *Jpn J Thorac and Cardiovasc Surg* 2005; 53: 382–385.

Kudo M et al. A Surgical Case of Ventricular Septal Perforation after Repairing Left Ventricular Free Wall Rupture. *Ann Thorac Cardiovasc Surg* 2005; 11: 121–124.

Lisy M et al. Fibrin sealant patch for repair of acute type a aortic dissection. *J Card Surg.* 2013; 28:736–41.

Nishizaki K et al. Sutureless patch repair for small blowout rupture of the left ventricle after myocardial Infarction. *Jpn J Thorac Cardiovasc Surg* 2004; 52: 268–271.

Okamura H et al. Sutureless repair for postinfarction left ventricular free wall rupture. *J Thorac Cardiovasc Surg.* 2019; 158(3):771 – 777.

Onorati F et al. Aortic tube grafts wrapping with Hemostatic fleeces reduces postoperative pericardial effusions. *J Cardiovasc Surg* 2008; 49: 393 – 397.

Ostrowski S et al. Does the additional usage of a local hemostatic patch reduce bleeding after aortic reimplantation? *Arch Med Sci.* 2018; 17(6):1613 – 1617.

Rupprecht H, Gaab K. Delayed Cardiac Rupture Induced by Traumatic Myocardial Infarction: Consequence of a 45-Magnum Blast Injury; A Comprehensive Case Review. *Bull Emerg Trauma.* 2018; 6(1):1 – 7.

Schütz A et al. Off-Pump Epicardial Tissue Sealing – A Novel Method for Atrioventricular Disruption Complicating Mitral Valve Procedures. *Ann Thorac Surg* 2004; 78: 569 – 574.

Shimamoto T. The TachoSil®-Pledget Stitch: Towards Eradication of Suture Hole Bleeding. *Ann Thorac Surg* 2008; 86: 2002 – 2004.

● Pediatric surgery

Carbon RT et al. Neue Ansätze für Gewebemanagement auf dem Gebiet minimal invasiver Kinderchirurgie [New approaches to tissue management in minimal invasive pediatric surgery]. *Langenbecks Arch Chir Suppl Kongressbd.* 1998; 115:1175 – 8.

Carbon RT et al. Minimal invasive pediatric surgery: development and progress by innovative technology. *Klin Padiatr.* 2001; 213(3):99 – 103.

Giordano R et al. Use of biological hemostatic support TachoSil® for reoperation in pediatric cardiac surgery. *Minerva Padiatr.* 2016; 68(3):240 – 1.

Haas S. The use of a surgical patch coated with human coagulation factors in surgical routine: a multicenter postauthorization surveillance. *Clin Appl Thromb Hemost.* 2006; 12(4):445 – 50.

Matsushita N et al. Laparoscopic complete excision of an enormous simple hepatic cyst occupying the entire abdomen in a child: a case report and literature review. *Surg Case Rep.* 2022; 8(1):87.

Open procedures¹



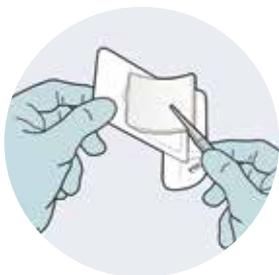
1.

Open the peel-away film of the external packaging (aluminium blister) – can be opened in a non-sterile zone.



2.

Open the packaging in a sterile zone with sterile gloves.



3.

Remove the patch from the sterile packaging with forceps.



4.

The patch can be trimmed to size, but it is important that it extends 1–2 cm beyond the wound margin.



5.

If the wound is dry, it is recommended to moisten the TachoSil® before application. If the wound is already wet, it can be applied dry.



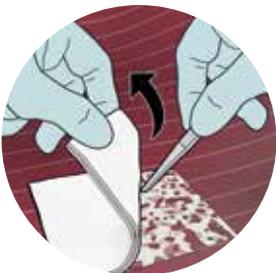
6.

The patch is applied with the yellow active side facing the treated area. If larger areas need to be treated with more than one patch, they should be overlapped like roof tiles.



7.

The patch must be pressed in place gently for up to 3 minutes, ideally with a moist compress.



8.

Remove the moist compress carefully, using forceps if necessary.

Minimally invasive procedures



1.

Insert

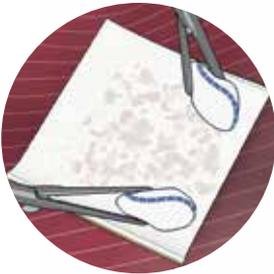
After pre-compression and self-rolling, the TachoSil® patch is inserted through a dry trocar ≥ 10 mm.



2.

Unroll

The patch is unrolled with the yellow side on the wound.



3.

Gently compress

TachoSil® is moistened and adheres to the wound after being manually compressed in place.



Tips & tricks for the use of TachoSil®

Open procedures¹

- Gloves and instruments should be completely dry to prevent the patch from adhering to them.
- If the wound surface is dry, the patch should not be moistened until immediately before application. If the wound surface is wet, dry patch is applied.
- It is essential to apply the yellow active side to the wound using slight pressure for up to 3 minutes.
- If larger areas need to be treated with more than one patch, they should be overlapped like roof tiles (≥ 1 cm).
- The patch can be trimmed to any shape or size, while it is dry.
- The patch can be compressed to make it easier to shape.

Minimally invasive surgery (MIS)¹

- Gloves and instruments should be completely dry to prevent the patch from adhering to them.
- The patch should be dry when passed through the trocar.
- In MIS a moist gauze should be used to compress TachoSil® for up to 3 minutes.
- No additional instruments are needed.



How is TachoSil[®] packaged?

TachoSil[®] comes in a double sterile package. The folding box contains the package leaflet and an aluminium composite foil container. Air and thus moisture are kept out by this heat-sealed aluminium foil. This ensures that fibrinogen and thrombin do not react with each other prematurely and the full adhesive strength remains until it is applied.

There is a small polystyrene recess in this aluminium packaging that is sealed with grid lacquer coated paper. This steam-permeable paper is necessary in order to bind the residual humidity in the inner packaging in the desiccant to prevent the premature start of the reaction of fibrinogen and thrombin. This sterile inner packaging is passed by the sterile surgical personnel.

After peeling off the paper lid, the sterile surgical personnel takes out the TachoSil[®] patch using forceps and hands it to the surgeon. The desiccant in the packaging is there to bind residual humidity and protect the product. This desiccant is a heavy metal free granulated indicator gel "Orange".

This indicator is colored orange when in a dry state. If it absorbs 6% of its own weight in water, it becomes colorless.



What sizes is TachoSil[®] available in?

Illustrated in original sizes

LARGE 9.5 x 4.8 cm

MIDI 4.8 x 4.8 cm



Where is TachoSil® made?



TachoSil® is produced in Linz, Austria. After internal quality controls, the highest German authority, the Paul Ehrlich Institute (PEI), checks each batch again. The product is released for sale only after passing this strict quality control.

This ensures that you only receive products that comply with the high requirements of the pharmaceutical product specification and pharmaceutical safety.

Batch documentation requirement for TachoSil®?

Since TachoSil® contains components of human blood, batch documentation is required. The Summary of Product Characteristics for TachoSil® provides the following information: *"To improve the traceability of biological medicinal products, the name of the medicinal product and the batch number of the medicinal product used must be documented unambiguously."*

Every package of TachoSil® contains self-adhesive labels with the corresponding information.

How is TachoSil[®] stored?

TachoSil[®] can be stored at room temperature – not over 25°C.¹ Do not freeze.

Under these conditions, the product can be stored up to three years.

However, this is provided that the outer packaging (aluminium blister) is intact.¹

The advantage for surgeons is that they can have TachoSil[®] ready at the operating table and if it is not needed, it can be returned easily (provided the aluminium packaging is intact).

Pieces of TachoSil[®] remaining after the operation must be discarded.

Resterilization is not possible.¹ Considering this aspect, it is useful to have the different sizes of TachoSil[®] available to keep waste to a minimum.

TachoSil[®] is a lifesaving, organ sparing package to patient product that needs to be readily available for its use. It should be stored in the sterile core or on suture carts where surgeons have immediate access.

Pharmaceutical product or medical device?

Since TachoSil[®] contains fibrinogen and thrombin as a dry coating on the surface of a collagen patch and these components trigger a pharmacological effect, TachoSil[®] is a pharmaceutical product. A medical device, on the other hand, acts primarily through its physical properties.

And it was approved as a combination medicinal product & medical device by the FDA (US Food and Drug Administration, Maryland, USA) in 2010.

PHARMACEUTICAL
PRODUCT

≠

MEDICAL
DEVICE

Required information



TachoSil® SEALANT MATRIX (human fibrinogen, human thrombin)

Presentation: TachoSil® is a topical fibrin sealant patch consisting of human fibrinogen and human thrombin coated onto an equine collagen sponge. The active side of the patch is yellow in color due to the presence of a colorant riboflavin (E101); and the non-active side is off-white in color.

Indication and Important Safety Information

Indications: 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.

Limitations for Use: • TachoSil® cannot safely or effectively be used in place of sutures or other form of mechanical ligation for the treatment of major arterial or venous bleeding. • Not for use in children under one month of age.

Dosage & Administration: For topical use on cardiovascular or hepatic tissue only • Determine the number of patches to be applied by the size of the bleeding area. • Apply the yellow, active side of the patch to the bleeding area. • When applying TachoSil®, do not exceed the maximum number of patches.

Refer to the Full Prescribing Information for details on administration and maximum number of patches.

Contraindications: • Do not apply TachoSil® intravascularly. Intravascular application of TachoSil® may result in life threatening thromboembolic events. • Do not use TachoSil® in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins.

Warnings & Precautions:

Thrombosis. Thrombosis can occur if TachoSil® is applied intravascularly. Ensure that TachoSil® is applied to the surface of cardiac, vascular, or hepatic tissue only.

Hypersensitivity Reactions. Hypersensitivity or allergic/anaphylactoid reactions may occur in patients receiving TachoSil® for the first time or may increase with repetitive applications.



Infection. Avoid application to contaminated or infected areas of the body, or in the presence of active infection.

Adhesions. TachoSil® 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 desired application area are adequately cleansed before administration of TachoSil®.

Compression. Avoid packing in cavities or closed spaces because this may cause compression of underlying tissue.

Dislodged Material. Use only the minimum number of TachoSil® patches necessary to achieve hemostasis. Do not pack. Remove unattached pieces of TachoSil®.

Transmissible Infectious Agents. 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.

Use in specific populations: *Pediatric Use:* Use of TachoSil® in children under the age of one month may be unsafe or ineffective due to small size and limited ability to apply the patch as recommended.

Adverse Reactions: The adverse reactions reported in more than 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.

Refer to the Full prescribing Information for details on, contraindications, warnings, precautions, and adverse reactions.

Marketing Authorisation Holder: Corza Medical GmbH, Speditionstrasse 21, 40221 Düsseldorf, Germany.

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TachoSil®
Fibrin Sealant Patch

Ordering Information

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