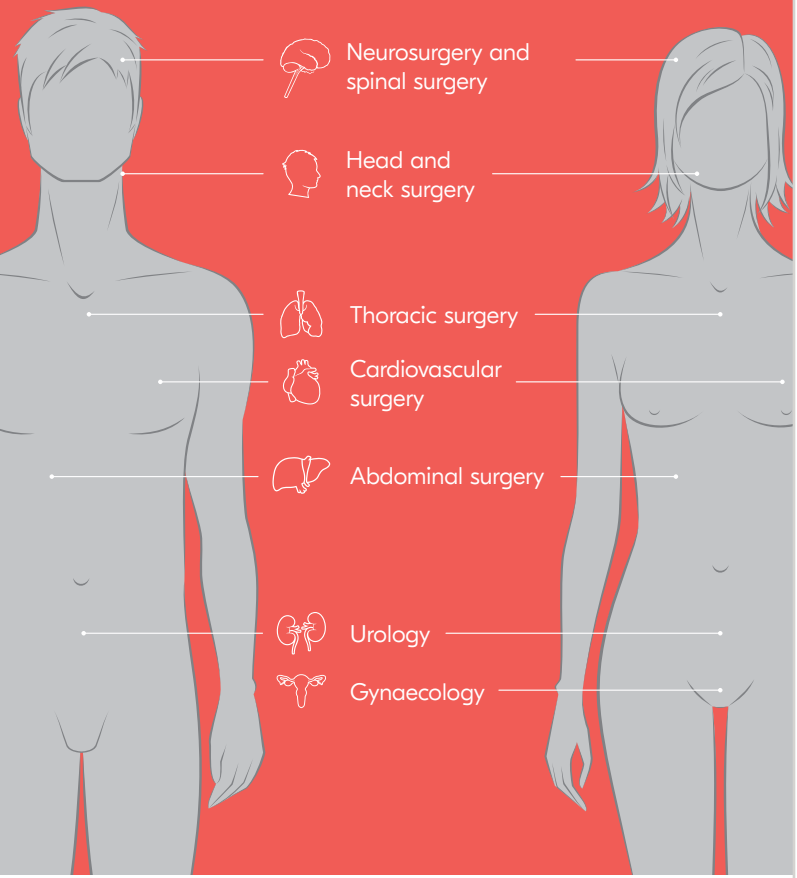
TachoSil SEALANT MATRIX

# Compendium

corzamedical

# >9.6 million applications all around the world prove the versatility of TachoSil®



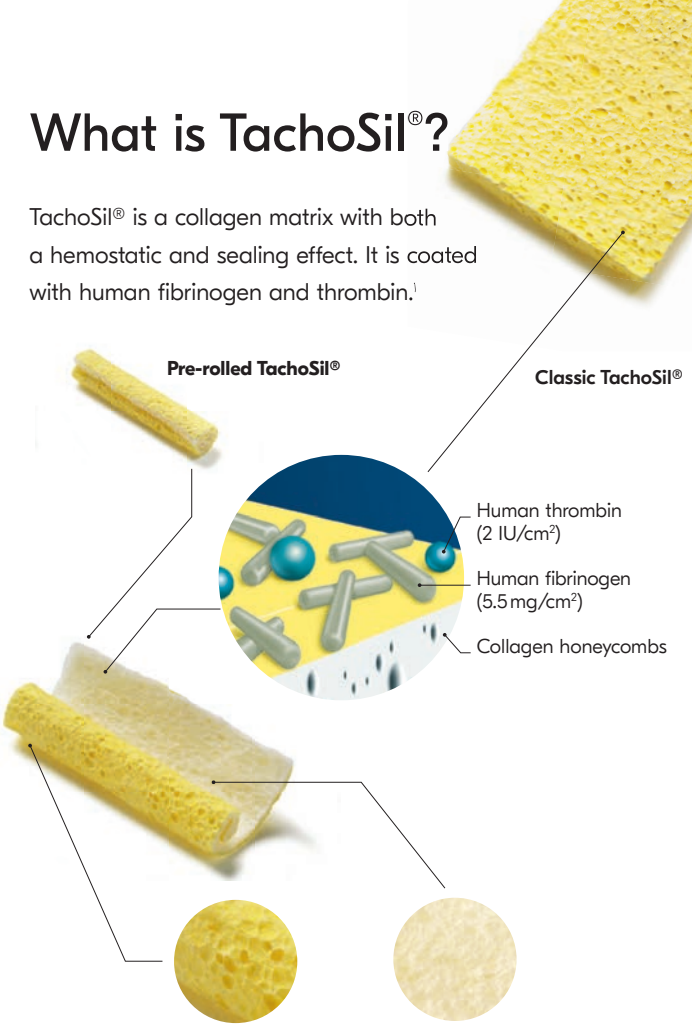

... for minimally invasive and open procedures.



# Contents

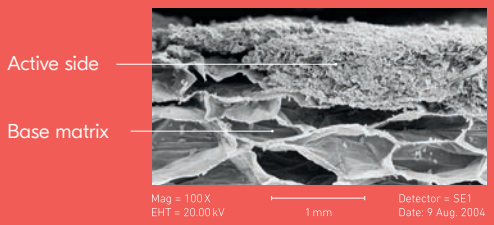
# What is TachoSil®?

TachoSil® is a collagen matrix with both a hemostatic and sealing effect. It is coated with human fibrinogen and thrombin.[1]




**Yellow active side**
Human fibrinogen + thrombin (colouring agent: riboflavin)

**Base matrix**
Foamed equine collagen

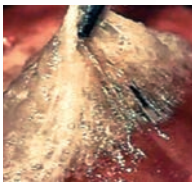



The scanning electron microscope image shows the honeycomb structure of the collagen base matrix and the adhesive layer of fibrinogen and thrombin.



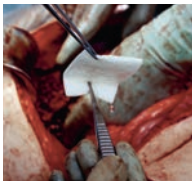
# What can TachoSil® do?

## TachoSil® and its mechanical properties:*



- Up to 2.5 times more elastic when moistened than when dry[3]
- When moistened, adapts to organ movements
- Easy to shape even to irregular surfaces
- Withstands pressure of 61.4 hPa (approx. 46 mmHg)[3] (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 adhesives[3]

## TachoSil® and its hemostatic properties:



- Ready-to-use fixed combination
- Hemostasis and sealing after 3–5 minutes of pressing in place, regardless of coagulation status[4]
- Atraumatic and tissue conserving
- Interacts with all physiological fluids

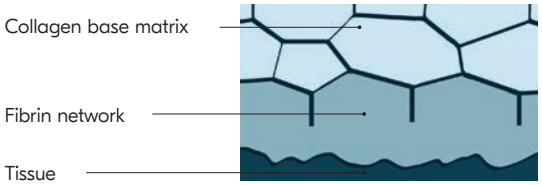
## TachoSil® and its sealing properties:

- Firm adhesion with the wound surface**
- Reduces air[29] and fluid leakage[6]
- Secures sutures in vascular surgery[1]
- Seals the dura mater[1]

* Determined using in vitro material science and animal experiment tests.
** After pressing onto the wound surface for 3–5 minutes.

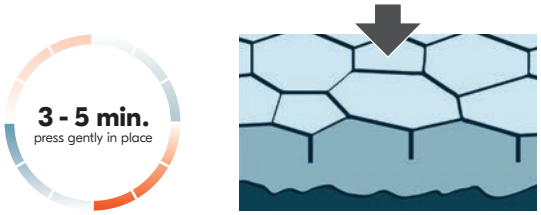
# How does TachoSil® work?

**1.**




TachoSil® sealant matrix is coated with human fibrinogen and thrombin.

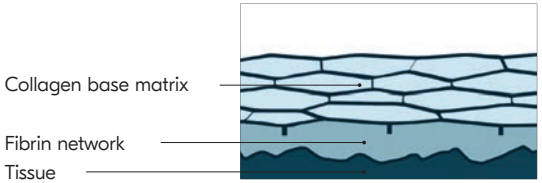
**2.**




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 polymerised to a fibrin clot.

**3.**




A strong, mechanically stable fibrin network is formed with good adhesive properties.



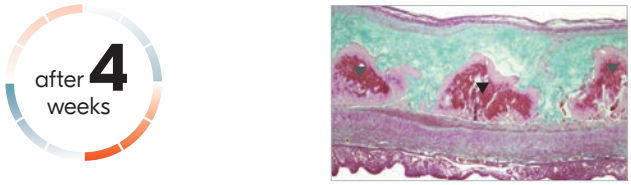
# How is TachoSil® biodegraded?

TachoSil® and all of its components have a high level of tissue compatibility (histocompatibility) and it is broken down by resorptive granulation tissue.[7,8]

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

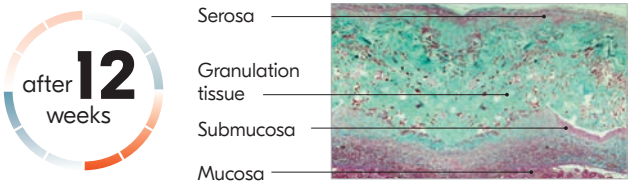
In animal experiments, TachoSil® is biodegraded after application to a wound surface with little residue after 13 weeks. [...] No evidence of local intolerance was observed in animal experiments.[1]

**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 patch marked by (▼).

**Histology** (rabbit model)




Increasing resorption of the patch by granulation tissue. (Figures mod. from Schneider A et al.)[9]

# Where is TachoSil® used?

## Abdominal surgery

**Hemostasis**

- In parenchymal organs such as the liver[10], spleen and pancreas[4,11]
- After resections, trauma or incidental injury

**Sealing**

- Puncture channel bleeding[13,14] (vascular prostheses)
- Lymphadenectomies[15]

## Thoracic surgery

**Hemostasis**

- Diffuse bleeding in the lungs and thoracic soft tissue[2]
- Puncture channel bleeding[13,14] (vascular prostheses)

**Sealing**

- Adhesion of lung resection margins[2]
- Atraumatic with emphysema tissue[16]
- Mediastinal lymphadenectomy[15]
- Sealing of staple lines[17]

## Cardiovascular surgery

**Hemostasis**

- Puncture channel bleeding[13,14,18] (vascular prostheses)
- Diffuse and extensive bleeding in the heart[18,19,20]

**Sealing**

- Vascular anastomoses[13] and vascular prostheses[14,18]

**... and other applications**



## Neurosurgery and spinal surgery

**Possible indications**

- Sealing of the dura mater[1,35]
- Reduction of postoperative CSF leakages[1,35]

## Gynaecology

**Hemostasis**

- Radical hysterectomy[21]
- Caesarean section and uterus rupture[21,22]
- Endometriosis and myomectomy[21]

**Sealing**

- Pelvic[23] and para-aortic lymphadenectomy[21]
- Axillary lymphadenectomy with breast cancer[21]
- Reconstruction of the Fallopian tubes[21]

## Urology

**Hemostasis**

- Visceral injuries[4,10,12]
- After partial nephrectomy[24]

**Sealing**

- Protection of the vascular and nerve bundles after radical prostatectomy[25]
- After lymphadenectomies[15]
- Peyronie's disease (reconstruction of the tunica albuginea)[26]

## Head and neck surgery

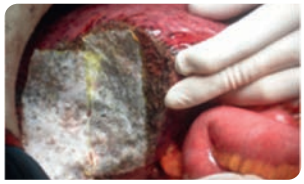
**Possible indications**[12,27]

- Postoperative secondary bleeding after thyroid surgery
- In parotid surgery to protect the facial nerve
- In paranasal sinus surgery
- Tonsillectomy
- Tumour surgery

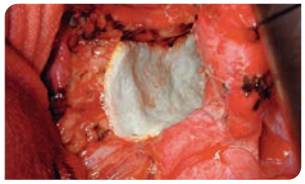
# Examples of use

TachoSil® is used in adults for supportive treatment in surgery for improvement of hemostasis, to promote tissue sealing, for suture support in vascular surgery where standard techniques are insufficient, and for supportive sealing of the dura mater to prevent postoperative cerebrospinal fluid leakage following neurosurgical procedures.

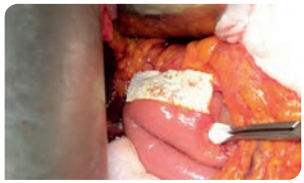
## Abdominal surgery



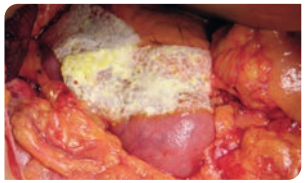
Overlapping TachoSil® application after partial liver resection
**Photo: Dr. med. J. Figueras**



TachoSil® application after an abdominoperineal resection of the rectum
**Photo: Dr. med. R. Vandoni**

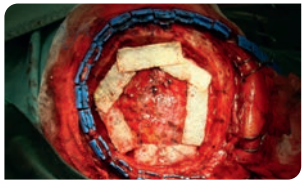


TachoSil® application for sealing after pancreatico-jejunostomy
**Photo: Prof. Dr. med. B. Gloor**



TachoSil® application for sealing after a spleen-preserving, left-sided pancreatic resection
**Photo: Prof. Dr. med. B. Gloor**

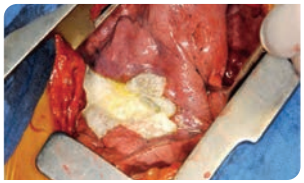
## Neurosurgery and spinal surgery



Supportive sealing of the dural suture of an autologous dural graft for meningioma
**Photo: Prof. Dr. med. Piek**



## Thoracic surgery

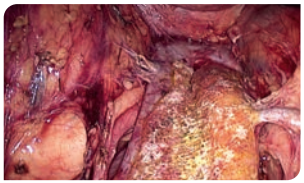


Application of multiple TachoSil® patches after a pulmonary lobectomy
**Photo: Prof. Dr. med. A. Maier**

## Cardiovascular surgery

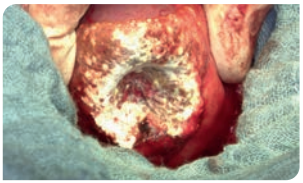
Application of TachoSil® to secure the sutures of a vascular anastomosis
**Photo: Prof. Dr. med. L. Gürke**

## Gynaecology



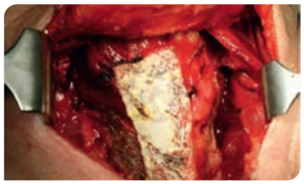
Application of TachoSil® sealant matrix after a paraaortic lymphadenectomy
**Photo: Dr. med. Dimitri Sarlos**

## Urology

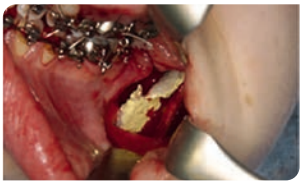


Placement of TachoSil® sealant matrix after a partial kidney resection
**Photo: Dr. med. M. Rauchenwald**

## Head and neck surgery



Atraumatic application of TachoSil® on the struma
**Photo: Prof. Dr. med. D. Oertli**



Reduction of bleeding with TachoSil® in a sagittal splitting for surgical correction of the position of the mandible
**Photo: Dr. med. C. Zizelmann and PD Dr. med. D. Rohner**

# Selected literature

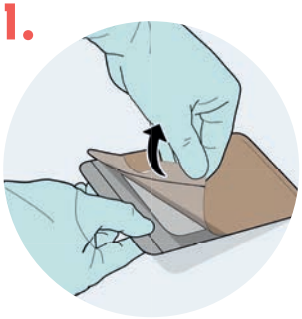
| Study | Type of study / purpose | Patient collective | Primary endpoint | Result |
|---|---|---|---|---|
| **Abdominal surgery** | | | | |
| Frilling et al. 2005, Langenbeck's Arch Surg, 390:114 – 120[10] | Randomised prospective trial comparing the efficiency of TachoSil® and argon beamer for liver resections | n = 121 patients (n = 59 in the TachoSil® group; n = 62 in the argon beamer group) | Time to hemostasis | Time to hemostasis: 3.9 min (TachoSil®) vs. 6.3 min (argon); p < 0.001 |
| Fischer et al. 2011; Surgery, Volume 149, Issue 1, pages 48 – 55[28] | International controlled, randomised multicentre trial with parallel groups | 119 patients who required an elective partial liver resection. Treated with TachoSil® (n = 60) or argon beamer (n = 59). | Time to hemostasis | Time to hemostasis: 3.6 min (TachoSil®) vs. 5 min (argon); p = 0.0018 |
| **Thoracic surgery** | | | | |
| Anegg et al. 2007; European Journal of Cardiothoracic Surgery 2007; 31:198 – 202[2] | Prospective, randomised, controlled trial on sealing air fistulas with TachoSil® | 152 of 173 patients after primary surgical treatment exhibited an air leakage (23 patients with air fistula grade 0 not randomised). Treatment was either with TachoSil® (n = 75) or conventional surgery (manual suture, stapler, diathermy; n = 77) | Postoperative quantitative assessment of air loss from the fistula on postoperative days 1 and 2 | This significant difference was also confirmed on the first and second postoperative day (43.6 and 20.1 ml / min vs. 86.1 and 42.5 ml / min). |
| Marta et al. 2010; European Journal of Cardiothoracic Surgery (2010) 38; 6: 683 – 689[29] | Prospective, randomised clinical trial to assess the safety and efficacy of TachoSil® for sealing grade 1 or 2 air fistulas after lobectomy. | 299 patients with an elective pulmonary lobectomy and intraoperative grade 1 and 2 air leakage after primary surgical treatment: n = 148: Treatment of air fistula with TachoSil®; n = 151: Standard treatment | Duration of postoperative air leakage | The duration (h) of the postoperative air fistulas was reduced by an average of 5 h. |
| **Cardiovascular surgery** | | | | |
| Maisano et al. 2009; European Journal of Cardiothoracic Surgery 10; p S 1873 – 734X[30] | Prospective, randomised controlled trial on controlling bleeding in cardiovascular surgery | n = 59 in the TachoSil® group, n = 60 with standard treatment | Time to hemostasis | In 75% of the patients in the TachoSil® group, hemostasis was achieved after 3 min. compared to 33% in the control group. After 6 min. the ratio was 95% vs. 72%. Both results are highly significant. |
| Onorati et al. 2008; The Journal of Cardiovascular Surgery 2008, 49:1 – 5[18] | Controlled, prospective observational study | 29 patients with an aortic aneurysm in the ascending aorta. In 11 of the 29 patients, after implanting the graft and shortly before closing the sternum, the proximal end of the prosthesis was wrapped in two large overlapping TachoSil® patches. In the other 18 patients, standard treatment was given without wrapping in TachoSil® | Differences at discharge, such as drainage quantity | The application of TachoSil® in aortic grafts reduced pericardial effusions (TS = 104.5 ml vs. 403.6 ml without TS; p = 0.026) and the drainage quantity (TS = 832.7 ml vs. without TS 1458.5 ml; p < 0.0001). |

# Selected literature

| Study | Type of study / purpose | Patient collective | Primary endpoint | Result |
|---|---|---|---|---|
| **Gynaecology** | | | | |
| Buda et al. 2012, International Journal of Gynecology and Obstetrics 2012, 117: 217 – 219[21] | Case-control study | n = 24 patients, n = 8 in the TachoSil® group, n = 126 standard treatment | Drainage volume and drainage time | The mean daily drainage volume in the TachoSil® group was significantly smaller compared with the control group (133 ± 102 ml vs. 320 ± 107 ml, p < 0.001). The mean drainage time in the TachoSil® group was also significantly shorter than in the control group (3.5 ± 1.1 d vs. 5.3 ± 1.8 d; p = 0.003). |
| Tinelli et al. 2013, Int J Gynecol Cancer. June 2013, Volume 23, Issue 5, p 956 – 963[23] | Open, randomised, prospective controlled trial on the prevention of lymphoceles with TachoSil® after pelvic laparascopic lymphadenectomy | 55 consecutive tumour patients divided into two laparoscopic groups: Group 1 – pelvic lymphadenectomy plus TachoSil® (n = 26) and group 2 – pelvic lymphadenectomy without TachoSil® (control group, n = 29) | Development of symptomatic or asymptomatic lymphoceles and the postoperative drainage volume | The TachoSil® group (group 1) exhibited a significantly lower average drainage volume (65 ± 15 ml versus 150 ± 40 ml, p < 0.01). In the TachoSil® group, 5 lymphoceles were observed compared with 15 lymphoceles in the control group (p = 0.024). Of these, only 2 were symptomatic in group 1 compared with 5 symptomatic lymphoceles in the control group; this was, however, not significant. |
| **Urology** | | | | |
| Siemer S et al. 2007, Eur Uro 2007, 52(4): 1156 – 1163[24] | Open, prospective, randomised controlled multicentre trial on the use of TachoSil® as a hemostatic agent after partial kidney resection vs. Standard suture in nephron-sparing surgery (NSS) in patients with renal cell carcinoma (RCC). | Of 208 screened patients, 185 were included in the trial and assigned randomly to either the TachoSil® group (n = 92) or the control group (n = 93). | Time to hemostasis | Time to hemostasis (primary endpoint) was 5.3 minutes (3–17 min) in the TachoSil® group. Compared with 9.5 minutes (3–27 min) in the control group, this was highly significantly shorter. |
| Simonato et al. 2007, Eur Urol[6] | Prospective, randomised controlled trial on the use of a surgical patch to prevent lymphoceles after extraperitoneal lymphadenectomy in the pelvis in prostate cancer. | 60 consecutive patients, randomisation 30:30 | The occurrence of symptomatic or asymptomatic lymphoceles | 5 lymphoceles in theTachoSil® group, 19 lymphoceles in the control group, p = 0.001319 |

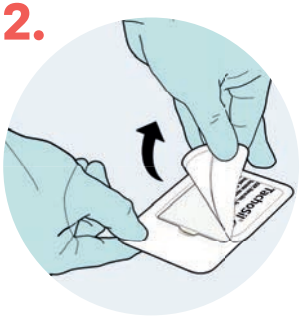
# Open procedures

**1.**



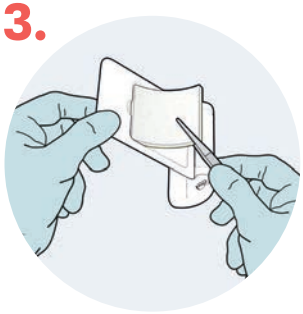
Open the peel-away film of the external packaging (aluminium blister) – can be opened in a non-sterile zone.

**2.**



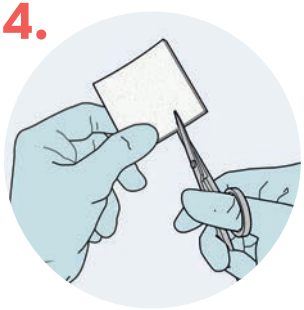
Open the packaging in a sterile zone with sterile gloves.

**3.**



Remove the patch from the sterile packaging with forceps.

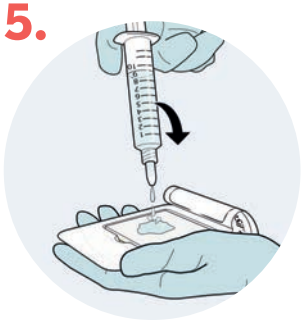
**4.**



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 the 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, the patches should be overlapped like roof tiles.

**7.**


The patch must be pressed in place slightly for at least 3 – 5 minutes, ideally with a moist compress.

**8.**

Remove carefully, using forceps if necessary.

# Minimally invasive procedures

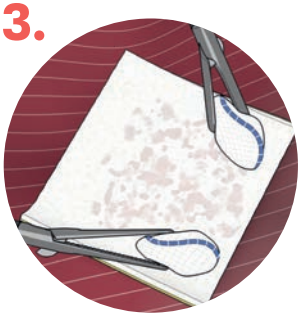
**1.**

**Insert**
Pre-rolled TachoSil® is inserted through a dry trocar ≥10 mm.

**2.**

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

**3.**



**Press in place**
TachoSil® is moistened and adheres to the wound after being manually pressed in place.




Pre-rolled 4.8 x 4.8 cm

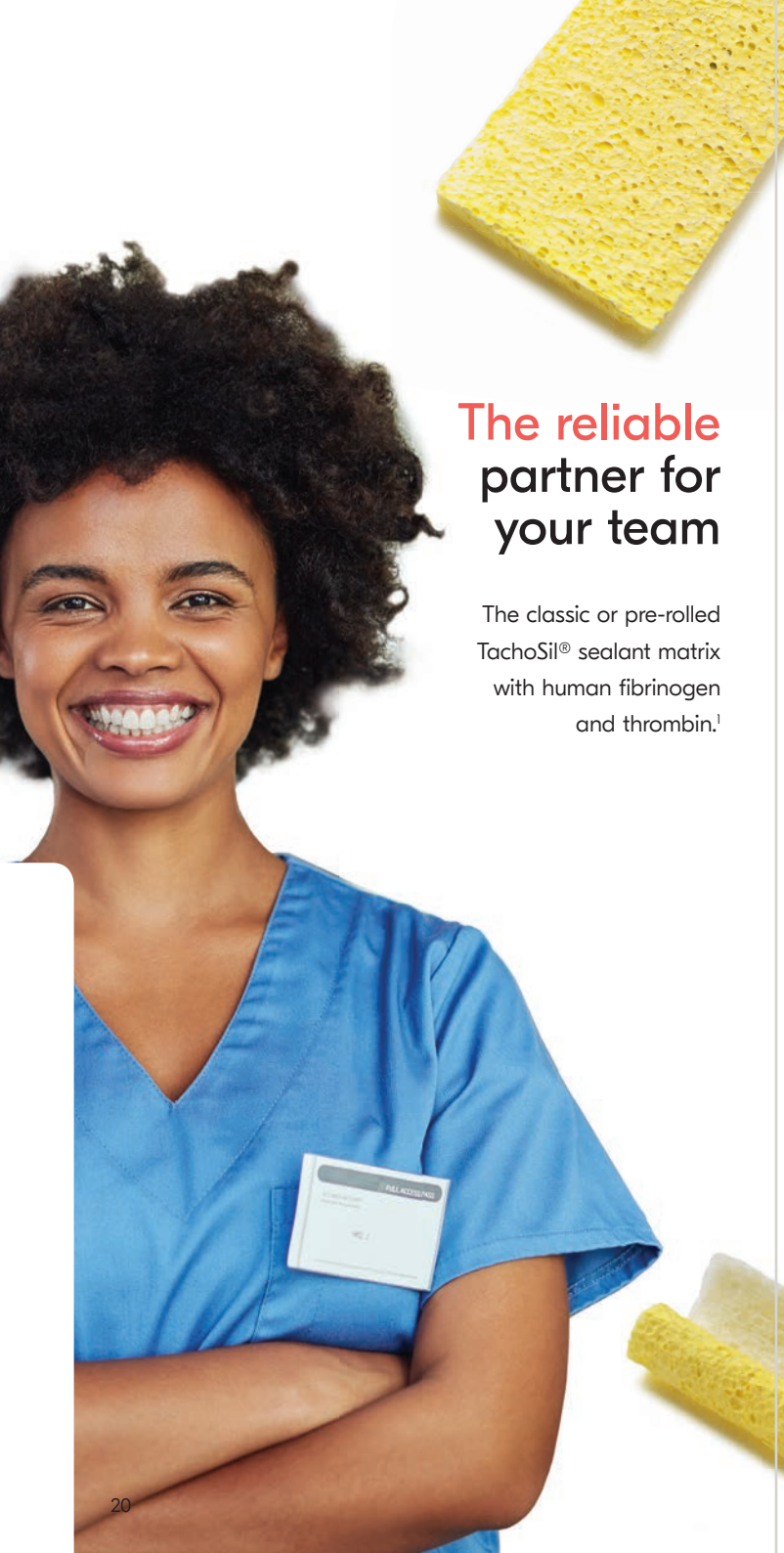


# Pre-rolled TachoSil®

**Especially adapted to the requirements of minimally invasive surgery.**

- Can be immediately inserted in the trocar
- Facilitates entry into small cavities
- Hemostasis and sealing in one*
- Helps reduce complications*
- Many years of experience and extensive clinical data*

*Colombo et al. Vasc Health and Risk Manag 2014; 10: 569–576



# The reliable partner for your team

The classic or pre-rolled TachoSil® sealant matrix with human fibrinogen and thrombin.[1]

# Tips & tricks for open procedures

- Gloves and instruments should be either dry or completely wet 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, a dry patch is applied.
- It is essential to apply the yellow active side to the wound using slight pressure for at least 3–5 minutes.
- If larger areas need to be treated with more than one patch, the patches should be overlapped like roof tiles (≥ 1 cm).
- The patch can be trimmed to any shape or size.
- The patch can be pressed flat to make it easier to shape.

# Tips & tricks for use in minimally invasive surgery (MIS)[31]

- Gloves and instruments should be completely dry to prevent the patch from adhering to them.
- The patch can also be applied when dry or wet in MIS.
  To press in place, a moist compress can be helpful.
- 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 non-sterile nurse. After peeling off the paper, the sterile surgical personnel takes out the TachoSil® sealant matrix 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 coloured orange when in a dry state. If it absorbs 6% of its own weight in water, it becomes colourless.

# What sizes is TachoSil® available in?

TachoSil® is available in four versions and three sizes:

| | |
|---|---|
| Maxi | 9.5 x 4.8 cm |
| Midi | 4.8 x 4.8 cm |
| Pre-rolled | 4.8 x 4.8 cm |
| Mini | 3.0 x 2.5 cm |

Illustrated in original sizes

## Where is TachoSil® made?

TachoSil® is produced in Linz, Austria in Takeda's production facility. Only after several strict quality controls, the product is released for sale.

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

## How is TachoSil® stored?

TachoSil® can be stored at temperatures between 2°C and 25°C - 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.

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

Pieces of TachoSil® remaining after the operation must be discarded. Resterilisation is not possible. Considering this aspect, it is useful to have the different sizes of TachoSil® available to keep waste to a minimum.



## Is TachoSil® a medicinal product or a medical device?

TachoSil® is a medicinal product that was approved by the European authority (European Medicines Agency, EMA) in June 2004.

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

## Is there a 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:
"In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded."

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

## How is the viral and immunological safety of TachoSil® assessed?

To prevent infections from the use of medicinal products made from human blood, only blood of selected persons is used which, just as the plasma pool has undergone screening for specific infection markers.

And in addition, the production of fibrinogen and thrombin includes effective steps towards inactivation or elimination of viruses. The methods used are considered to be effective against enveloped viruses such as HIV, HBV and HCV and the non-enveloped virus HAV.[1]

After packaging, TachoSil® is irradiated with gamma radiation from a cobalt-60 source (approx. 28 kGy). This treatment can reduce an infection titer of conventional viruses (DNA and RNA viruses, single-stranded and double-stranded nucleic acid) by several powers of 10. Irradiation is thus an additional safety measure.

Unlike its predecessor products, TachoSil® no longer contains bovine components. The elimination of the bovine aprotonin simultaneously eliminates the immunological risk of forming antibodies against this protein.

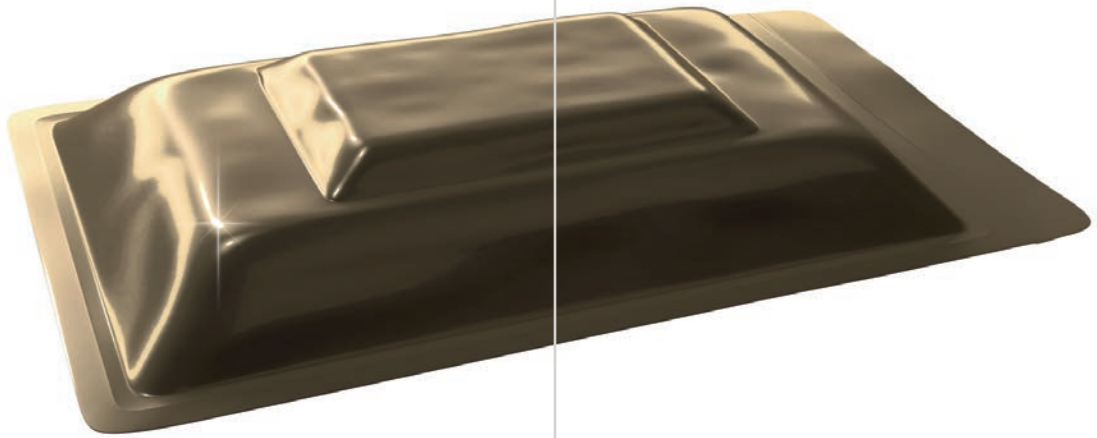
Nevertheless, in rare cases, patients who have been treated with a fibrin product can develop hypersensitivity or allergic reactions. In isolated cases, these reactions can lead to severe anaphylaxis. Such reactions may occur especially after repeated application or in patients with known hypersensitivity to one of the components of the product. If such reactions occur, application must be discontinued immediately. In the event of shock, the usual medical steps for shock treatment should be carried out. With respect to immunogenicity, in rare cases, antibodies against components of fibrin adhesive products / hemostatic agents can occur. However, in a clinical trial with TachoSil in liver operations in which the patients were examined regarding the formation of antibodies, in 26% of the 96 patients treated with TachoSil and tested, the formation of antibodies against equine collagen was detected. The equine collagen antibodies that formed in some patients after treatment with TachoSil did not react with human collagen. One patient developed antibodies against human fibrinogen. There were no adverse events attributed to the formation of antibodies against human fibrinogen or equine collagen.

## What toxicity data are available for TachoSil®?

Toxicity studies with single doses in different animal species show no evidence of an acute toxic effect.[1]

The number of the TachoSil® patches to be used depends on the size of the wound surface. The surgeon must adapt the application of TachoSil® to the individual case. In clinical trials, the individual doses typically ranged between 1—3 patches (9.5 cm × 4.8 cm). There are reports of the use of up to 10 patches.[1]

# Required information



**TACHOSIL® SEALANT MATRIX (human fibrinogen, human thrombin) PRESCRIBING INFORMATION Refer to Summary of Product Characteristics (SmPC) before prescribing.**

**Presentation:** An off-white sealant matrix coated with human fibrinogen 5.5mg and human thrombin 2.0IU per cm2. The active side of the matrix is marked by a yellow colour. Supplied, ready to use, in sterile packaging. **Indication:** In adults for supportive treatment in surgery for improvement of haemostasis, to promote tissue sealing, for suture support in vascular surgery where standard techniques are insufficient, and for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurological surgery. **Dosage & Administration:** For epilesional use only. Use should be restricted to experienced surgeons. The quantity of sealant matrices to be used is governed by the size of wound area, and the underlying clinical need for the patient. Application of TachoSil must be individualised by the treating surgeon. In clinical trials the individual dosages have typically ranged from 1-3 units (9.5 cm x 4.8 cm). In minimally invasive surgery, use of the smaller size matrices (4.8 cm x 4.8 cm, 3.0 cm x 2.5 cm or pre- rolled 4.8 cm x 4.8 cm) is recommended. Matrices should be used under sterile conditions and used immediately after opening the inner sterile cover. Prior to application, the wound area should be cleansed, e.g. from blood, disinfectants and other fluids. The matrix should be pre-moistened in saline solution and applied immediately. The yellow, active side of the matrix is applied to the bleeding/leaking surface and held against it with a gentle pressure for 3-5 minutes. Pre-rolled TachoSil® can be used for both open surgery and in minimally invasive surgery, and it can pass through a 10 mm or larger port or trocar. After removal of the pre-rolled TachoSil® from the sterile package it should be applied immediately through the trocar without pre-moistening. While unrolling the matrix the yellow, active side of the matrix is applied to the bleeding/leaking surface using e.g. a pair of cleansed forceps and held against it with a moist pad under a gentle pressure for 3-5 minutes. This procedure enables an easy adhesion of TachoSil® to the wound surface. Pressure is applied with moistened gloves or a moist pad. Due to the strong affinity of collagen to blood, sealant matrix may also stick to surgical instruments or gloves covered with blood; cleansing them before application helps avoid this. After pressing the matrix to the wound, the glove or the pad must be removed carefully. To avoid the matrix from being pulled loose it may be held in place at one end, e.g. with a pair of forceps. In the case of stronger bleeding, it may be applied without pre-moistening, while also pressing gently to the wound for 3-5 minutes. The active side of the matrix should be applied so that it extends 1-2 cm beyond the margins of the wound. Matrices should be overlapped if more than one is used and can be cut to the correct size and shaped if too large. In neurosurgery, TachoSil® should be applied on top of the primary dura closure. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. **Contraindications:** Intravascular use; hypersensitivity to the active substances or to any of the excipients. **Warnings & Precautions:** No specific data available on the use of this product in gastrointestinal anastomosis surgery. It is not known whether recent radiation therapy affects the efficacy of Tachosil® when used for dura mater sealing. Allergic type hypersensitivity reactions are possible, as with any protein-containing product. If hypersensitivity reactions occur, product must be discontinued immediately. In the case of shock, the current medical standards should be followed. Standard measures to prevent infections from products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV and for the non-enveloped virus HAV. Measures may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for immunodeficient patients or those who have increased erythropoeisis e.g. haemolytic anaemia. Risk of transmission of infective agents cannot be totally excluded, including pathogens of hitherto unknown nature. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. 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®. Events of adhesions to gastrointestinal tissues leading to gastrointestinal obstruction have been reported with use in abdominal surgery carried out in proximity to the bowel. **Interactions:** No formal interaction studies have been performed. In comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine or heavy metals. **Fertility Pregnancy & Lactation:** Safety for use in human pregnancy or breastfeeding has not been established. Only administer to pregnant and breastfeeding women if clearly needed. **Undesirable Effects:** Frequency not known (cannot be estimated from the available data): anaphylactic shock, hypersensitivity, thrombosis, intestinal obstruction (in abdominal surgeries), adhesions. Refer to the SmPC for details on full side effect profile and interactions. **Legal Classification:** POM. **Marketing Authorisation:** PLGB 55087/0001. Further information is available from the suppliers: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf PI Approval Date: August 2021 **hemostasis.corza.com** Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**

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# A STRONG CONNECTION.

TachoSil SEALANT MATRIX

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