TachoSil SEALANT MATRIX

A STRONG CONNECTION.

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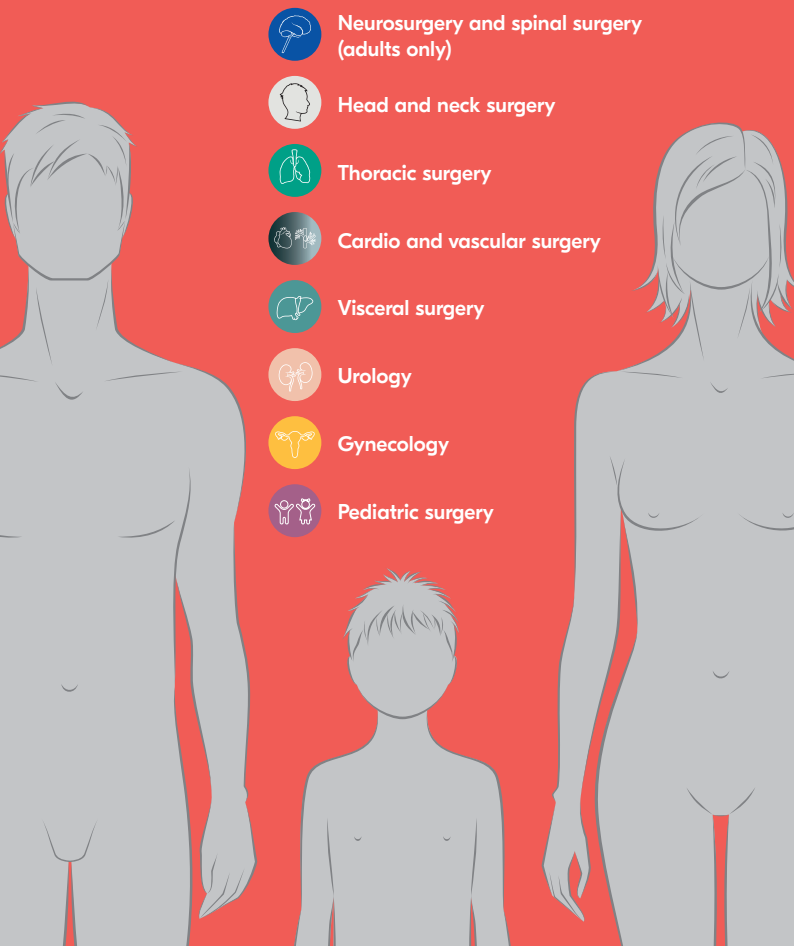
TachoSil SEALANT MATRIX

Compendium

corzamedical

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

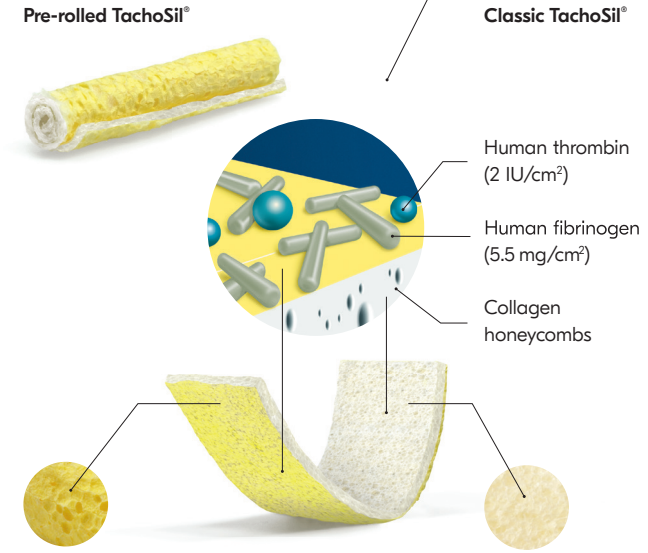


...for minimally invasive, robotic-assisted and open procedures.

Contents

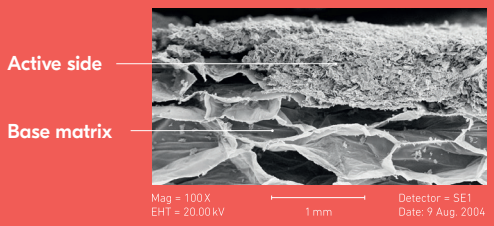
What is TachoSil®?

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



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

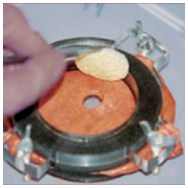
Base matrix
Foamed equine collagen

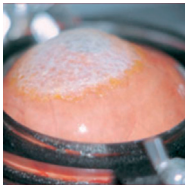


The scanning electron microscope image shows the honeycomb structure of the collagen base matrix and the adhesive layer of fibrinogen and thrombin.

What can TachoSil® do?

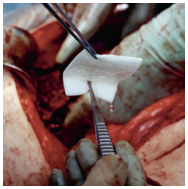
TachoSil® and its **mechanical** properties:*





- Up to 2.5 times more elastic when moistened than when dry[2]
- 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 fleece and 6 times more firmly than liquid adhesives[3]

TachoSil® and its **hemostatic** properties:



- Ready-to-use fixed combination
- Hemostasis and sealing after more than 3 minutes[1] of pressing in place, regardless of coagulation status[3]
- Atraumatic and tissue conserving
- Interacts with all physiological fluids[2]

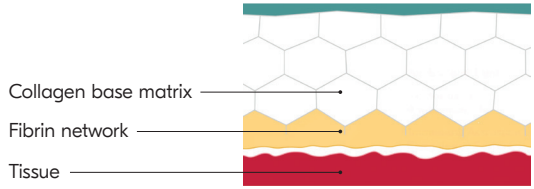
TachoSil® and its **sealing** properties:

- Firm adhesion with the wound surface**
- Reduces air and fluid leakage[4,5]
- 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 more than 3 minutes.

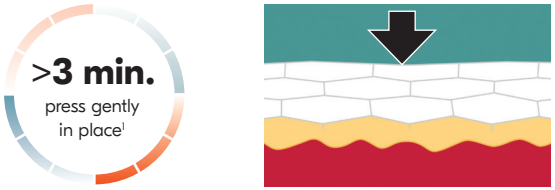
How does TachoSil® work?

1.



TachoSil® collagen fleece is coated with human fibrinogen and thrombin.

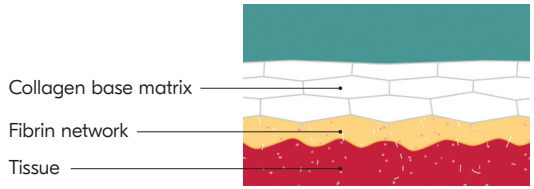
2.



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.[1]

3.



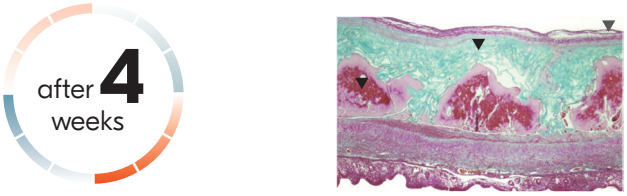
A strong, mechanically stable fibrin network is formed with good adhesive properties.[1]

How is TachoSil® biodegraded?

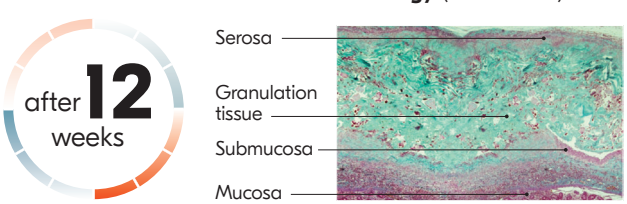
TachoSil® and all of its components have a high level of tissue compatibility (histocompatibility) and it is broken down by resorptive granulation tissue.[6,7]

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. Small remnants in animal model testing might be observable up to 12 months.[1] No evidence of local intolerance was observed in animal experiments.[1]



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



Increasing resorption of the fleece by granulation tissue.

Pictures mod. from Schneider A et al.[7]

Where is TachoSil® used?

TachoSil® is used in adults and pediatric patients > 1 month of age 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 (in adults only) to prevent postoperative cerebrospinal fluid leakage following neurosurgical procedures.[1]

Neurosurgery and spinal surgery (adults only)

Possible indications

- Sealing the dura mater[1, 8]
- Reduction of postoperative CSF leakages[1, 8]

Head and neck surgery

Possible indications

- After thyroid surgery for postoperative secondary hemostasis[9]
- In parotid surgery to protect the facial nerve
- In paranasal sinus surgery
- Tonsillectomy
- Tumour surgery

Thoracic surgery

Hemostasis

- Diffuse bleeding in the lungs and thoracic soft tissue[10]
- Puncture channel bleeding[11, 12] (vascular prostheses)
- In the area of the thoracic wall after segmental resection of the lung
- In the area of the thoracic dome after lobectomy

Sealing

- Adhesion of lung resection margins[10]
- Atraumatic with emphysema tissue[13]
- Mediastinal lymphadenectomy[14]
- Sealing of staple lines[15]

Cardio and vascular surgery

Hemostasis

- Diffuse and extensive bleeding in the heart[16–18]
- For localised bleeding during cardiac intervention
- In the region of the apex of the heart after transapical aortic valve replacement
- Puncture channel bleeding[11, 12, 16] (vascular prostheses)
- Vascular anastomoses[11]
- For venous bypass

Sealing

- Vascular anastomoses[11] and vascular prostheses[12, 16]
- Lymphadenectomies

Where is TachoSil® used?

Visceral surgery

Hemostasis

- In parenchymal organs such as the liver[19], gallbladder bed, spleen
- Of suture insufficiencies after sleeve gastrectomy and stapled sutures
- After resections, transplantation, trauma or incidental injury

Sealing

- For sealing tissues during gastrointestinal surgery[42 – 44]

Gynecology

Hemostasis

- Radical hysterectomy[24]
- Caesarean section and uterus rupture[25]
- Endometriosis and myomectomy[24]

Sealing

- Pelvic[26] and para-aortic lymphadenectomy[24]
- Axillary lymphadenectomy with breast cancer[24]
- Reconstruction of the Fallopian tubes[24]

Urology

Hemostasis

- Visceral injuries[3, 20]
- After partial nephrectomy[21]
- After prostatectomy, laparoscopic and robotic-assisted PCNL (Percutaneous Nephrolithotomy)[45]

Sealing

- Protection of the vascular and nerve bundles after radical prostatectomy[22]
- After lymphadenectomies
- Peyronie's disease (reconstruction of the tunica albuginea)[23]

Pediatric Surgery

Hemostasis

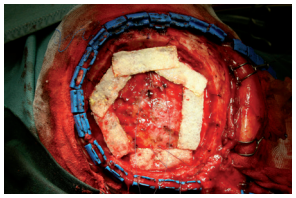
- After liver resections[27] or liver transplantations[28]
- After resection of liver cysts[28]
- After hepatic trauma or incidental injury
- In cardiovascular surgery[30]
- After exploratory emergency thoracotomy[31]

Sealing

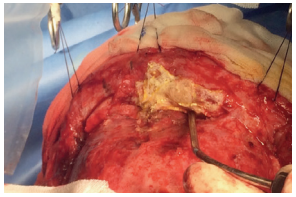
- Of lymphatic vessels

Examples of use

Neurosurgery and spinal surgery (adults only)

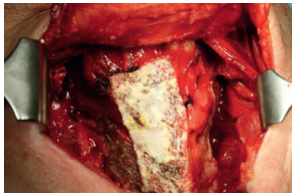


Supportive sealing of the dural suture of an autologous dural graft for meningioma.
Photo: Prof. Dr. J. Piek

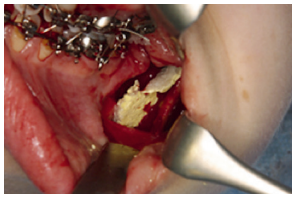


Frontal sinus sealing with TachoSil® before suturing of periosteum.
Photo: Dr. A. Warzecha

Head and neck surgery

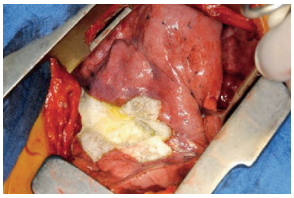


Atraumatic application of the TachoSil® fleece on the struma.
Photo: Prof. Dr. D. Oertli

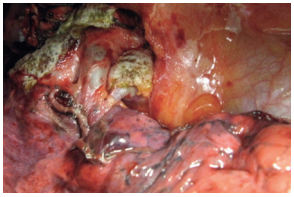


Reduction of bleeding with TachoSil® in a sagittal splitting for surgical correction of the position of the mandible.
Photo: Dr. C. Zizelmann and PD Dr. D. Rohner

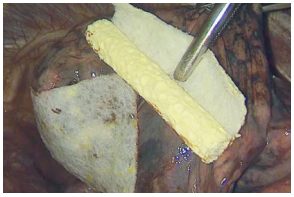
Thoracic surgery



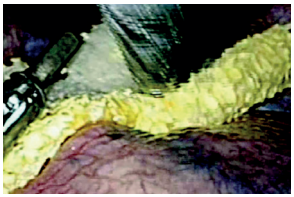
Application of multiple TachoSil® fleeces after a pulmonary lobectomy.
Photo: Prof. Dr. A. Maier



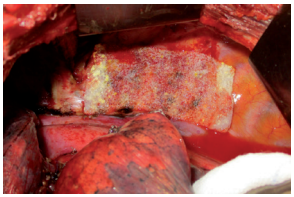
TachoSil® to support hemostasis on the stapled ends of the vessels in upper lobe resection due to lung cancer.
Photo: Prof. Dr. A. Kirschbaum



Pre-rolled TachoSil® for supportive sealing was placed over the lung parenchyma and the suture line of an air leak after VATS lobectomy.
Photo: Prof. Dr. C. Piwkowski



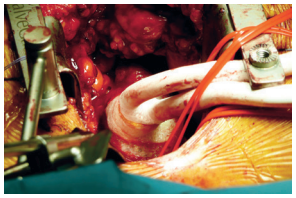
TachoSil® for sealing of an alveolar-pleural fistula in the upper lobe as a result of puncture damage.
Photo: Prof. Dr. W. Schreiner



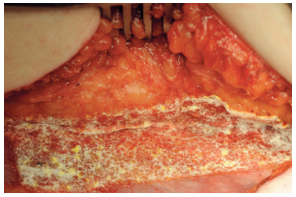
TachoSil® to support hemostasis in anatomical segment 6 resection due to lung cancer.
Photo: Prof. Dr. A. Kirschbaum

Examples of use

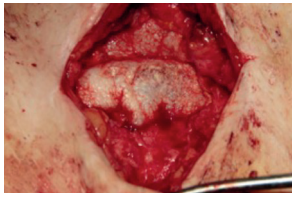
Cardio and vascular surgery



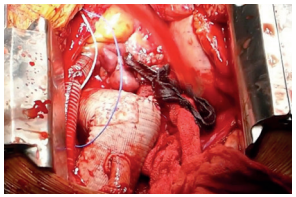
Application of a TachoSil® fleece to secure the sutures of a vascular anastomosis.
Photo: Prof. Dr. L. Gürke



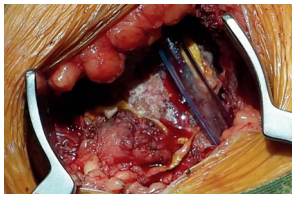
TachoSil® for supportive lymphatic sealing after endarterectomy and placement of a Dacron® patch.
Photo: Dr. J. Ukkat



TachoSil® to support hemostasis and to secure suture after the creation of a venous bypass in aneurysmatic disease.
Photo: Prof. Dr. T. Hölzenbein

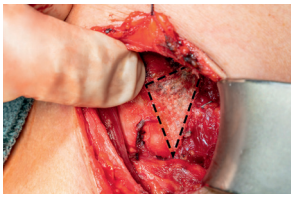


TachoSil® to support hemostasis after replacement of the ascending aorta and arcuate aorta.
Photo: Prof. Dr. M. Czerny

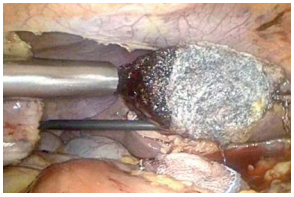


TachoSil® to support hemostasis after transapical aortic valve replacement.
Photo: Prof. Dr. M. Czerny

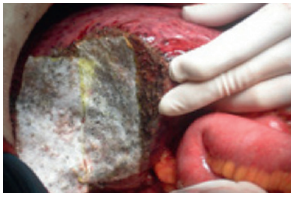
Visceral surgery



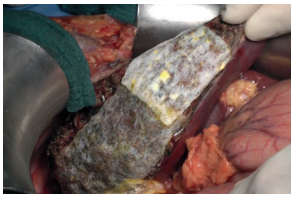
TachoSil® to support hemostasis with renouncement of electrocoagulation for nerve sparing during a thyroidectomie.
Photo: Dr. M. Philipp



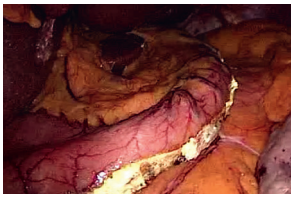
TachoSil® for hemostasis of liver resection surfaces in hepatocellular carcinoma.
Photo: Dr. C. Prinz



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



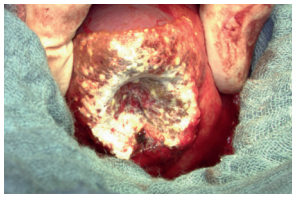
TachoSil® to support hemostasis after liver lobe removal as part of a living liver donation.
Photo: Dr. S. Hinz



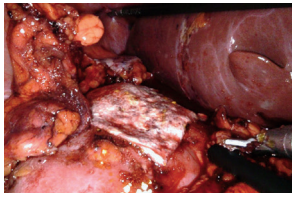
TachoSil® to support hemostasis and secure staple lines during laparoscopic sleeve gastrectomy due to adiposity permagna.
Photo: PD Dr. J. Heimbucher

Examples of use

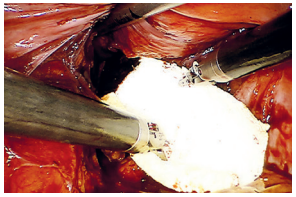
Urology



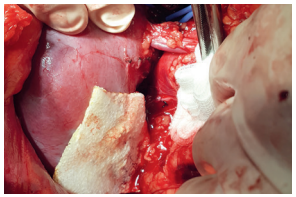
Placement of a TachoSil® fleece after a partial kidney resection.
Photo: Dr. M. Rauchenwald



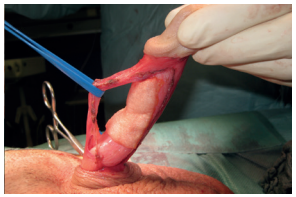
TachoSil® to support hemostasis, sealing and reinforcing sutures in da Vinci assisted partial right nephrectomy due to a renal tumour.
Photo: Prof. Dr. A. S. Merseburger



Pre-rolled TachoSil® to support hemoastasis and sealing in the region of the neurovascular bundle in a da Vinci® assisted radical prostatectomy due to prostate carcinoma.
Photo: PD Dr. D. Teber

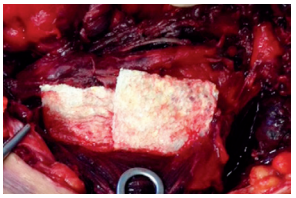


TachoSil® to support hemostasis in a right-sided kidney puncture wound.
Photo: Prof. Dr. T. Borkowski

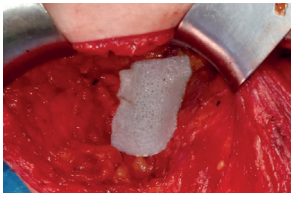


Atraumatic hemostasis and defect coverage with TachoSil® in the region of the tunica albuginea due to induratio penis plastica (IPP).
Photo: PD Dr. G. Hatzichristodoulou

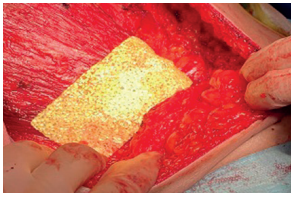
Gynecology



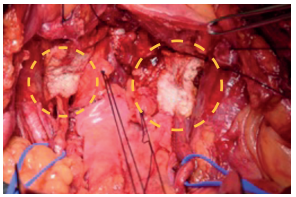
TachoSil® application for sufficient hemostasis because of diffuse bleeding in the area of the rectus abdominis muscle after a caesarean section under full heparinization.
Photo: Prof. Dr. M. K. Bohlmann



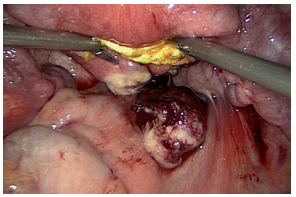
TachoSil® for sufficient sealing after axillary lymphadenectomy due to breast cancer.
Photo: Dr. M. Gurrea-Almela



TachoSil® for sufficient hemostasis after radical mastectomy due to breast cancer.
Photo: Dr. P. De Gracia Díaz



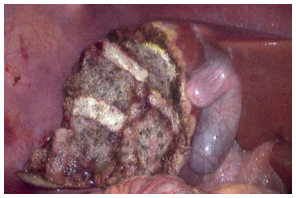
TachoSil® for sufficient hemostasis after a radical abdominal hysterectomy.
Photo: Dr. P. López



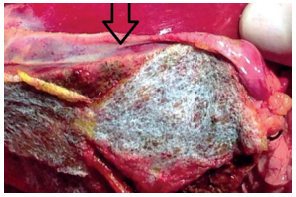
Pre-rolled TachoSil® for better hemostasis and suture support after laparoscopic enucleation of an uterine myoma.
Photo: Dr. D. Bolovis

Examples of use

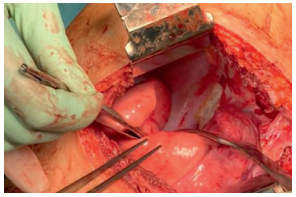
Pediatric Surgery



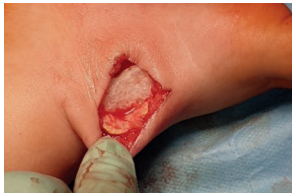
TachoSil® for better hemostasis after excision of an enormous hepatic cyst in an 18-month-old child.
Photo: Dr. MD N. Matsushita



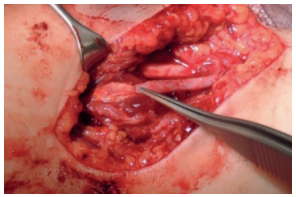
TachoSil® for better hemostasis in the wound area of the hepatic graft in pediatric liver transplantation.
Photo: Dr. F. Vicentine



Use of TachoSil® for efficient hemostasis during emergency exploratory thoracotomy in an 13-year-old boy.
Photo: Dr. A. Kalińska-Lipert & Dr. M. Nosek-Kościołek



Application of TachoSil® for efficient hemostasis and sealing after tumor resection in an 11-month-old child.
Photo: Dr. A. Kalińska-Lipert & Dr. M. Nosek-Kościołek



TachoSil® for sufficient sealing of a vein interposition for acute occlusion of the brachial artery in an 5-year-old child.
Photo: Dr. J. Suß

Selected literature

Study	Type of study / purpose	Patient collective	Primary endpoint / aim of the study	Result
Neurosurgery				
George et al. Neurosurgery. 2017; 80(6): 847 – 853[82]	Randomized, controlled trial investigating the efficacy of TachoSil® for supportive sealing of the dura mater in patients after skull base surgery versus a control group without TachoSil® application.	726 total patients n = 362 TachoSil® n = 364 control group	The effectiveness was investigated post-operatively on the basis of cerebrospinal fluid leaks (CSF) or pseudomeningoceles or treatment failure during the operation	A superiority compared to the current practice could not be shown in this study. Two application techniques for TachoSil® were evaluated: Application on the dura and application on both sides of the dura. The results did not support the second method. TachoSil® was well tolerated in both supportive sealing of the dura in neurosurgery
Thoracic surgery				
Anegg et al. European Journal of Cardiothoracic Surgery 2007; 31:198 – 202[0]	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: n = 75 TachoSil® n = 77 conventional surgery (manual suture, stapler, diathermy)	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 1st postop day: 43.6 ml/min (TachoSil®) and 20.1 ml/min (conventional therapy) 2nd postop day: 86.1 ml/min (TachoSil®) and 42.5 ml/min (conventional therapy)
Marta et al. European Journal of Cardiothoracic Surgery 2010; 38;6:683 – 690[4]	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 intra-operative grade 1 and 2 air leakage after primary surgical treatment. Treatment of air fistula: n = 148 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
Cardio and vascular surgery				
Maisano et al. Eur J Cardio-thorac Surg 2009; 36(4):708 – 14[85]	Prospective, randomised controlled trial on controlling bleeding in cardiovascular surgery	n = 119 patient n = 59 TachoSil® n = 60 standard treatment	Time until hemostasis	Hemostasis after 3 min.: 75% (TachoSil®) compared to 33% (control group) Hemostasis after 6 min.: 95% (TachoSil®) vs. 72% (control group) Both results were highly significant
Onorati et al. J Cardiovasc Surg 2008; 49:393 – 7[6]	Controlled, prospective observational study	29 patients with an aortic aneurysm in the ascending aorta. Treatment: n = 11 TachoSil® n = 18 standard treatment	Differences at discharge, such as drainage quantity	Pericardial effusions: 104.5 ml (TachoSil®) vs. 403.6 ml (standard treatment), p = 0.026 Drainage quantity: 832.7 ml (TachoSil®) vs. 1458.5 ml (standard treatment), p < 0.0001
Glineur et al. Med Devices 2018; 11:65 – 75[53]	Randomized clinical trial to control bleeding with two different patches in open cardiovascular surgery involving the aorta or CABG	n = 90 patients n = 45 TachoSil® n = 41 Veriset™	To assess the effectiveness and safety of hemostatic patches in treating cardiovascular bleeding	1.5 min. (TachoSil®) vs. 3 min. (Veriset™) p < 0.0001 Proportion of patients achieving hemo-stasis at all treated bleeding sites within 3 min.: 41 (TachoSil®) vs. 36 (Veriset™)

Further studies can be found on **www.corza.com**

Selected literature

Study	Type of study / purpose	Patient collective	Primary endpoint / aim of the study	Result
Visceral surgery				
Frilling et al. Langenbeck's Arch Surg 2005; 390:114 – 120[9]	Randomised prospective trial comparing the efficiency of TachoSil® and argon beamer for liver resections	n = 121 patients n = 59 TachoSil® n = 62 argon beamer	Time until hemostasis	3.9 min. (TachoSil®) vs. 6.3 min. (argon beamer) p < 0.001
Fischer et al. Surgery 2011; 149(1):48 – 55[34]	International controlled, randomised multicentre trial with parallel groups	n = 119 patients n = 60 TachoSil® n = 59 argon beamer	Time until hemostasis	3.6 min. (TachoSil®) vs. 5 min. (argon beamer) p = 0.001
Kakaei et al. HPB Surg 2013; 2013:587608[36]	Randomized clinical trial comparing efficacy of TachoSil® vs. Surgicel™ to control oozing after liver resection	n = 45 patients n = 15 TachoSil® n = 15 Surgicel™	To evaluate effects of 3 different types of hemostatics in patients with liver resection	3.0 min. (TachoSil®) vs. 3.2 min. (Surgicel™) p = 0.4
Kawasaki et al. Langenbecks Arch Surg 2017; 402(4): 591 – 598[37]	Randomized, double-blind, non-inferiority trial to show the efficacy of two different patches in persistent exudative bleeding during liver resection / removal for donation	n = 108 patients n = 54 TachoSil® n = 54 TachoComb®	To demonstrate the noninferior efficacy of TachoSil® vs. TachoComb® in Japanese patients undergoing liver resection	5 min. (TachoSil®) vs. 5 min. (TachoComb®) p = 1.0
Moench et al. Langenbecks Arch Surg 2014; 399(6):725 – 33[38]	Randomized clinical trial to show efficacy of two different patches in secondary hemostasis after liver resection	n = 128 patients n = 65 TachoSil® n = 61 Sangustop®	To compare the hemostatic effect of a collagen hemostat vs. a carrier-bound fibrin sealant after hepatic resection	2.2 min. (TachoSil®) vs. 3.4 min. (Sangustop®)
Öllinger et al. HPB (Oxford) 2013; 15(7):548 – 58[39]	Randomized clinical trial to compare the use of two different patches in the management of diffuse bleeding after hepatic surgery	n = 50 patients n = 18 TachoSil® n = 32 Veriset™	To compare the use of a Veriset™ hemostatic patch with a fibrin sealant patch (TachoSil®) (control) in the management of diffuse bleeding after hepatic surgery	3 min. (TachoSil®) vs. 1 min. (Veriset™) p < 0.001
Urology				
Siemer et al. Eur Urol 2007; 52(4): 1156 – 1163[31]	Open, prospective, randomised controlled multicentre trial on the use of TachoSil® as a hemostyptic agent after partial kidney resection vs. Standard suture in nephron-sparing surgery (NSS) in patients with renal cell carcinoma (RCC)	n = 185 patients n = 92 TachoSil® n = 93 control group	Time until hemostasis	Time until hemostasis (primary endpoint): 5.3 min. (TachoSil®) vs. 9.5 min. (control group), this was highly significantly shorter
Simonato et al. J Urol 2009; 182: 2285–2290[40]	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 (TachoSil®) vs. 19 lymphoceles (control group), p = 0.001319

Further studies can be found on **www.corza.com**

Selected literature

Study	Type of study / purpose	Patient collective	Primary endpoint / aim of the study	Result
Gynecology				
Buda et al. Int J Gynaecol Obstet. 2012; 117:217 – 219[81]	Case-control study	n = 24 patients n = 8 TachoSil® n = 126 standard treatment	Drainage volume and drainage time	Mean daily drainage volume: 133 ± 102 ml TachoSil® vs. 320 ± 107 ml control group, p < 0.001 Mean drainage time: 3.5 ± 1.1 d TachoSil® vs. 5.3 ± 1.8 d control group; p = 0.003
Tinelli et al. Int J Gynecol Cancer 2013; 23(5):956 – 63[86]	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	Average drainage volume: (65 ± 15 ml TachoSil® vs. 150 ± 40 ml control group, p < 0.01). n = 5 lymphoceles (TachoSil®) vs. 15 lymphoceles (control group), p = 0.024. n = 2 lymphoceles symptomatic (TachoSil®) vs. n = 5 symptomatic lymphoceles (control group)
Pediatric surgery				
Genyk et al. J Am Coll Surg 2016; 222(3):261 – 8[87]	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	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	Primary endpoint was the proportion of adult patients with intraoperative hemostasis at the target bleeding site within 3 minutes of application of 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®)
Vicentine et al. Arq Bras Cir Dig 2016; 29(4):236 – 239[88]	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®	n = 80 patients n = 21 TachoSil® n = 59 control group	Compare pediatric liver transplants with ex-situ liver transection (reduction or split) with or without the human fibrinogen and thrombin sponge	reoperations due to bleeding in the wound area: 14.2% (TachoSil®) compared to 41.7% (control group), p = 0.029

Further studies can be found on **www.corza.com**

Further literature

Neurosurgery

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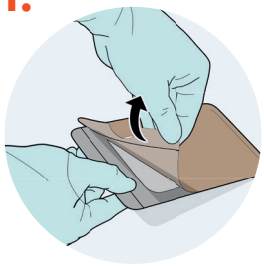
Open procedures

1.

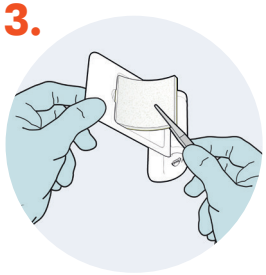


Open the peel-away film of the external packaging (aluminium blister) — can be opened in a non-sterile zone

2.

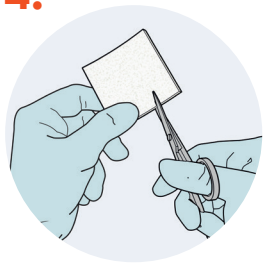
Open the packaging in a sterile zone with sterile gloves

3.



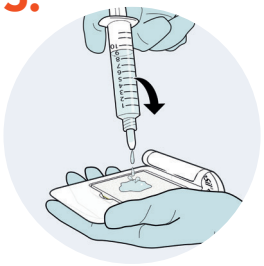
Remove the fleece from the sterile packaging with forceps

4.



The fleece 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 fleece is applied with the yellow active side facing the treated area

If larger areas need to be treated with more than one fleece, the fleeces should be overlapped like roof tiles

7.

The fleece must be pressed in place slightly for at least 3 minutes, ideally with a moist compress

8.

Remove carefully, using forceps if necessary

Minimally invasive surgery with Pre-rolled TachoSil®

1.

Clamp

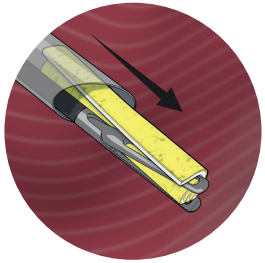
Grasp the Pre-rolled TachoSil® with dry atraumatic forceps

Note: Overlap 2 mm so the fleece is not damaged on insertion

2.

Insert

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



Note: It is not usually necessary to unscrew the valve

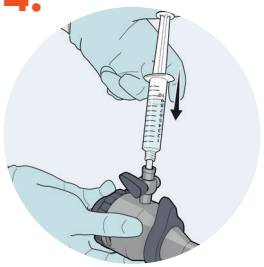
3.

Unroll

Press it right on the application site with a swab and unroll it with the forceps closed

The fleece is unrolled with the yellow side on the wound

4.

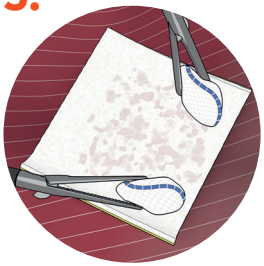


Moisten

Moisten TachoSil®, e.g. with saline solution through the CO_2 valve along the forceps

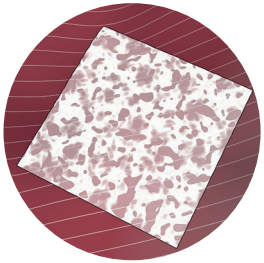
... or directly through the rinsing suction

5.



Press in place

TachoSil® adheres to the wound after being held in place for more than 3 min.



The typical leopard skin pattern will develop

The reliable partner for your team

The classic or Pre-rolled TachoSil® collagen fleece with human fibrinogen and thrombin.[1]

Tips & tricks for open procedures

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

Tips & tricks for use in minimally invasive surgery (MIS)[3]

- Gloves and instruments should be completely dry to prevent the fleece from adhering to them.
- The fleece 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 sterile nurse. After peeling off the paper lid, the sterile surgical personnel takes out the TachoSil® fleece 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

APPROVED also for children from 1 month TACHOSIL®

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 medicinal product specification and pharmaceutical safety.

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.

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.

Pharmaceutical product or medical device?

TachoSil® is a medicinal product that was approved by the European authority (European Medicines Agency, EMA, Amsterdam) in June 2004. This means that the product is approved in all Member States of the European Union.

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

Since TachoSil® contains fibrinogen and thrombin as a dry coating on the surface of a collagen fleece 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.

PHARMACEUTICAL PRODUCT ≠ MEDICAL DEVICE

Batch documentation requirement for TachoSil®?

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.

Viral & 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 contain 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.

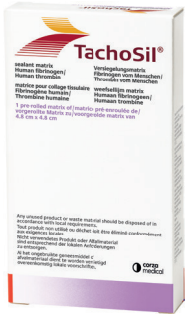
Toxicity data are available for TachoSil®?

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

The number of the TachoSil® fleeces 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 fleeces (9.5 x 4.8 cm). There are reports of the use of up to 10 fleeces.[1]

Required information



TachoSil Sealant Matrix (5.5 mg per cm^2 of human fibrinogen, 2.0 IU per cm^2 of human thrombin)

Statement: Before prescribing, consult/refer to the full prescribing information. **Presentation:** An off-white sealant matrix. The active side of the matrix is coated with fibrinogen and thrombin, is marked by a yellow colour. Supplied, ready to use, in sterile packaging. **Legal Classification:** Restricted prescription only medicine. **Indications:** In adults and children from 1 month old, for supportive treatment in surgery for improvement of haemostasis, to promote tissue sealing, and for suture support in vascular surgery where standard techniques are insufficient; also, in adults for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurosurgical procedures. **Dosage & Administration:** For epilesional use only. Use is restricted to experienced surgeons. The quantity to be applied is governed by the size of wound area, and the underlying clinical need for the patient. In clinical studies, the individual dosages have typically ranged from 1-3 units (9.5 cm x 4.8 cm); application of up to 10 units has been reported. For smaller wounds, the smaller size matrices (4.8 cm x 4.8 cm or 3.0 cm x 2.5 cm) or the pre-rolled matrix (based on a matrix of 4.8 cm x 4.8 cm) is recommended. TachoSil should be used under sterile conditions and immediately after opening the inner sterile cover. Prior to application, the wound area should be cleansed, e.g. from blood, disinfectants and other fluids. For Flat TachoSil, the sterile package 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. For pre-rolled TachoSil, after removing from the sterile package, it should be applied immediately through the trocar without pre-moistening. 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 gentle pressure for 3-5 minutes. Pressure is applied with moistened gloves or a moist pad. Avoid TachoSil sticking to surgical instruments, gloves or adjacent tissues covered with blood by cleansing them before application. After pressing TachoSil to the wound, the glove or the pad must be removed carefully. To avoid TachoSil 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 TachoSil should be applied so that it extends 1-2 cm beyond the margins of the wound. If more than one matrix is used, they should overlap. TachoSil 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. **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 anastomoses surgery. Life threatening thromboembolic complications may occur if the preparation is applied intravascularly. Allergic type hypersensitivity reactions are possible, as with any protein product. If hypersensitivity reactions occur, the administration must be discontinued immediately. To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the desired application area are adequately cleansed before administration. In the case of shock, the current medical standards for shock treatment should be followed. Standard measures to prevent infections resulting from the use of medicinal 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 (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g., haemolytic anaemia). It is recommended to record the name and the batch number of the product administered to the patient. Some cases of product non-adhesion issues have been reported in the form of lack of product adhesion / lack of efficacy. Correct product handling and application is required **Interactions:** No interaction studies have been performed. Similar to comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine, or heavy metals. Such substances should be removed to the greatest possible extent before applying the sealant. **Fertility, Pregnancy & Lactation:** Safety for use in human pregnancy or breastfeeding has not been established in the clinical studies. Only administer to pregnant and breastfeeding women if clearly needed. **Effects on Ability to Drive and Use Machines:** Not relevant. **Undesirable Effects:** Hypersensitivity or allergic reactions (in isolated cases these reactions may progress to severe anaphylaxis; some cases of product residue causing granuloma), thromboembolic complications may occur if used intravascularly, and adhesions and intestinal obstruction when used in abdominal surgery. Refer to the SmPC for details on full side effect profile and interactions. **Overdose information:** No case of overdose has been reported. **Interactions with Other Medicinal Products:** No interaction studies have been performed. Similar to comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine or heavy metals (e.g., antiseptic solutions). Such substances should be removed to the greatest possible extent before applying the sealant. **Use in Special Populations:** Limited data are available to support efficacy and safety of TachoSil in the paediatric population. In clinical studies, a total of 36 paediatric patients aged 0-13 years were treated with TachoSil in hepatic surgery.
Pack Sizes: Package with 1 matrix of 9.5 cm x 4.8 cm; Package with 2 matrices of 4.8 cm x 4.8 cm Package with 1 matrix of 3.0 cm x 2.5 cm; Package with 5 matrices of 3.0 cm x 2.5 cm Package with 1 pre-rolled matrix of 4.8 cm x 4.8 cm; Not all pack sizes may be marketed.

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

The full SmPC can be obtained from Corza Medical GmbH.
Marketing Authorisation Numbers: EU/1/04/277/001-005
Date of Revision of the Text: 8 May 2025
Link to Full SmPC or Prescribing information

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