

**TachoSil** SEALANT MATRIX

**A compilation of  
case reports**



**Cardiovascular  
surgery**



# Consequences of demographic change

The number of elderly people in the population is growing.<sup>1,2</sup>

Population of Germany in absolute numbers (millions)  
Percentages of age groups (%)

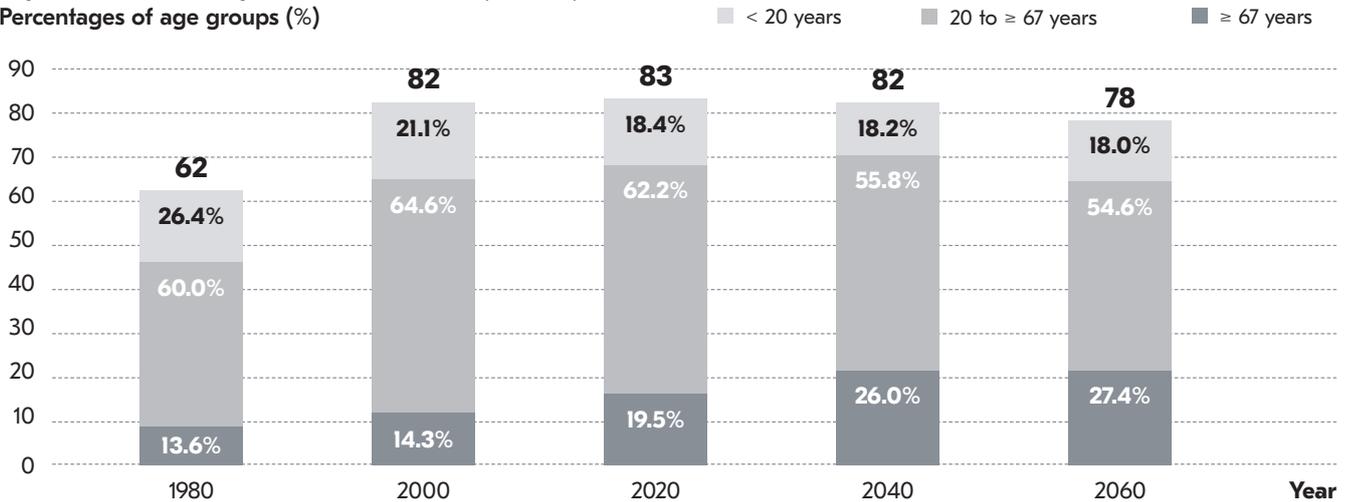
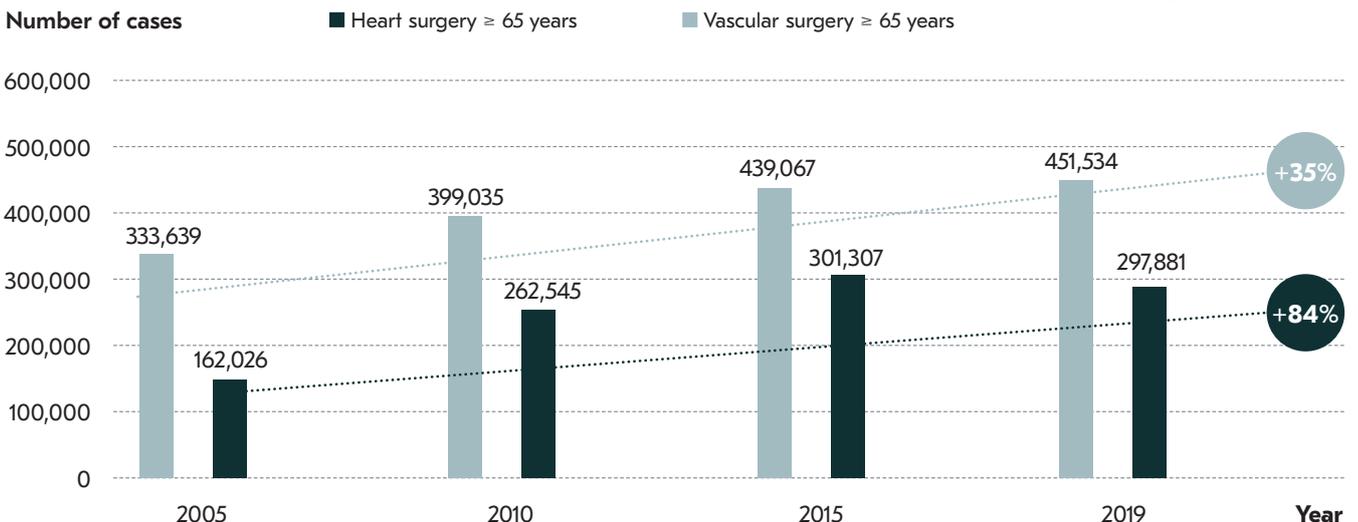


Figure adapted from <sup>1,2</sup>

Over 50% of operations and procedures are performed on patients over 65 years of age.<sup>3\*</sup>

Cardiovascular surgery cases are increasing <sup>4#</sup>



Increasing number of patients ≥ 65 years.

\* Applies to inpatient treatments

# Operations and procedures on inpatients in hospitals. 5–35 to 5–37, 5–38 to 5–39.

1 Population of Germany by 2060. German Federal Statistical Office (Destatis), 2019.

2 German Federal Agency for Civic Education. 19.09.2019, <https://www.bpb.de/nachschlagen/zahlen-und-fakten/soziale-situation-in-deutschland/61541/altersstruktur>, accessed on 16.06.2020.

3 Statistical Yearbook 2019, Chapter 4.

4 Health reporting by the federal government. The numbers were accessed on 25.08.2021 at [www.gbe-bund.de](http://www.gbe-bund.de).

# TachoSil® — versatile applications in cardiovascular surgery

**Ready-to-use fixed combination of a sealant matrix and active coagulation factors, used in adults for:<sup>1</sup>**

- Improving hemostasis
- Supporting tissue sealing
- Securing sutures in vascular surgery
- Supporting sealing of the dura mater

## TachoSil® — four versions, three sizes

Illustrated in original size.



**TachoSil® —  
used more than 9.6 million times around the world.**



# Examples of use in cardiac surgery

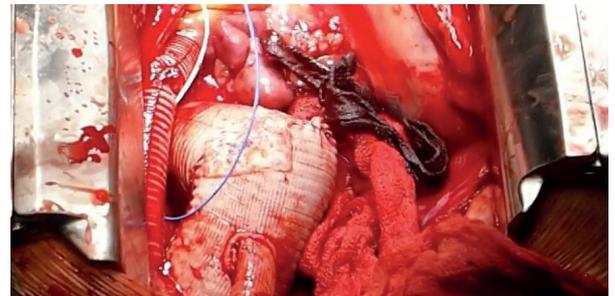
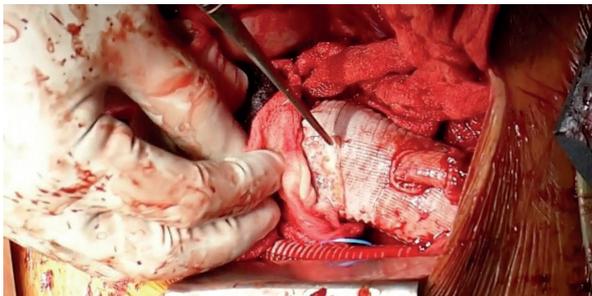
## 1 Aortic arch replacement using the FET technique\* after aneurysm<sup>1</sup>

**Patient history:** Aneurysm of the ascending aorta (maximum diameter of 55 mm) and aneurysm in the aortic arch and proximal descending aorta (50 mm long). Secondary diagnosis: arterial hypertension.

**Surgery:** Complete aortic arch replacement with the additional use of a stent graft prosthesis connected in continuity to the main prosthesis. Topical application of a TachoSil® (4.8x4.8 cm) in the region of persistent

puncture channel bleeding between the aortic arch graft and the ascending aortic graft.

**Conclusion:** TachoSil® led to very good hemostasis in the area of the graft sutures. The time until complete hemostasis was reduced by 10 minutes; the operation time was reduced by 15 minutes.



Application of TachoSil® in the area of the connection between the two grafts to support topical hemostasis.

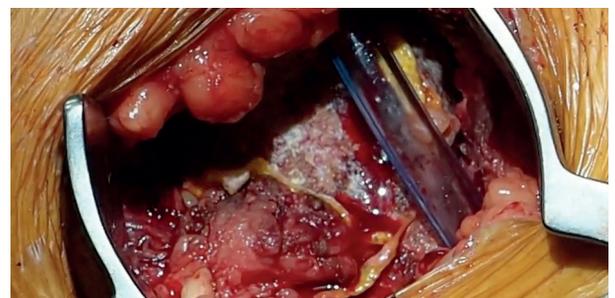
## 2 TAVI\*\* for high-grade aortic valve stenosis<sup>1</sup>

**Patient history:** High-grade aortic valve stenosis. Status post aortocoronary bypass surgery. Secondary findings: Morbid obesity, stage II renal insufficiency, pronounced arterial hypertension.

**Surgery:** Anterolateral thoracotomy in the left 5th ICS. Two purse-string sutures were prepared at the cardiac apex, then the graft was inserted under fluoroscopy guidance. To finish, the purse-string sutures in the area

of the puncture site at the cardiac apex were closed. Due to fragile tissue, a TachoSil® (4.8x4.8 cm) was applied over the sutures for additional hemostasis.

**Conclusion:** TachoSil® reduced the time to complete hemostasis by 10 minutes, the cardiac apex was sealed well and securely. Moreover, the operation was tissue sparing.



Application of TachoSil® at the cardiac apex to support topical hemostasis.

\* Frozen elephant trunk technique.

\*\* Transapical transcatheter aortic valve implantation.

<sup>1</sup> According to information from Prof. Dr. Martin Czerny, Universitäts-Herzzentrum Freiburg, Bad Krozingen GmbH.

# Examples of use in vascular surgery

## 1 Patch graft after carotid thromboendarterectomy (TEA)<sup>1</sup>

**Patient history:** High-grade, symptomatic subtotal stenosis of the left internal carotid artery (NASCET\* 90%) with TIA and hemiparesis on the right side. Dual antiplatelet therapy (DAPT) with ASA and Brilique® (ticagrelor) due to a coronary stent three months ago.

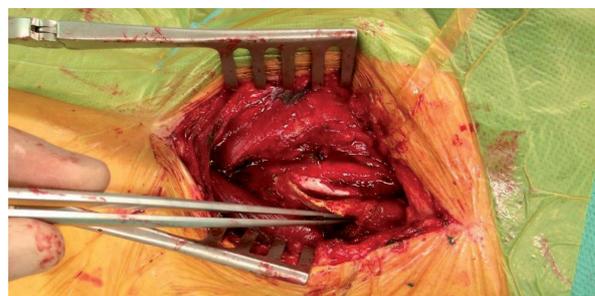
**Surgery:** TEA, desobliteration of the internal carotid artery (ICA) and common carotid artery (CCA), placement of a patch graft between the left CCA

and ICA, support of the graft sutures with TachoSil® (3.0x2.5 cm).

**Conclusion:** TachoSil® reduced the postoperative risk of bleeding and improved safety. This resulted in a reduction of the intraoperative hemostasis time and operation time by around 30 minutes each. The operation was tissue sparing.



Exposed common carotid artery, internal carotid artery and external carotid artery.



Patch graft after desobliteration of the ICA and CCA and suture support using TachoSil®.

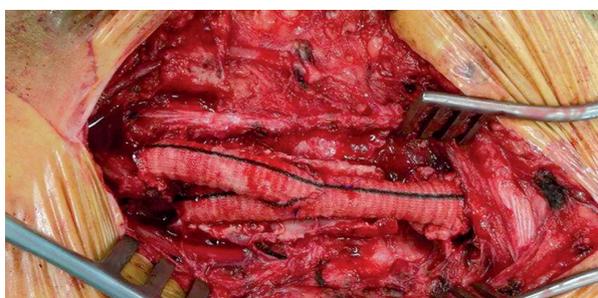
## 2 Y-graft interposition after resection of an anastomosis aneurysm<sup>1</sup>

**Patient history:** Patient with incomplete ischaemia in the left leg with thrombotic suture aneurysm in the left groin.

**Surgery:** Thrombectomy in the area of the left common iliac artery, resection of the aneurysm, Y-graft interposition from the external iliac artery via the deep femoral artery and superficial femoral artery on the left.

Support for the three anastomosis sutures with TachoSil®.

**Conclusion:** TachoSil® reduced the postoperative risk of bleeding and improved safety. The intraoperative hemostasis time was reduced by approx. 15 minutes and the total operation time was reduced by approx. 20 minutes. Tissue-sparing surgery, important due to PAOD, was possible.



View of the Y-graft of the external iliac artery via the deep femoral artery and superficial femoral artery.



Support for the three anastomosis sutures with TachoSil® due to ongoing treatment with rivaroxaban.



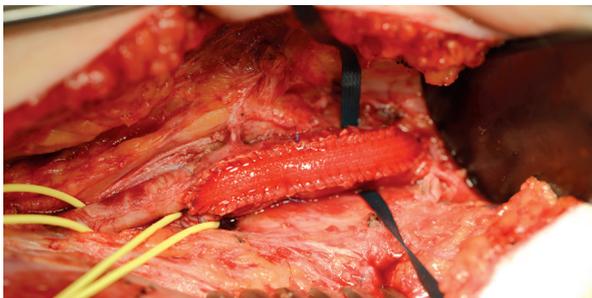
## Examples of use in vascular surgery

### 3 Dacron® patch graft after endarterectomy<sup>1</sup>

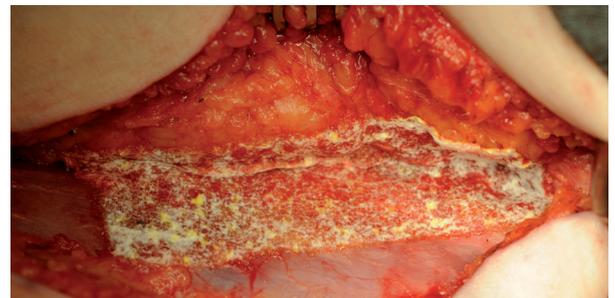
**Patient history:** PAOD III, intermittent claudication with an ever shorter pain-free walking distance, resting pain at night in the left leg. Doppler pressure index 0.58. Occlusion of the left common femoral artery. Increased risk of bleeding due to anticoagulant intake.

**Surgery:** Endarterectomy of the common femoral artery and placement of a Dacron® patch graft. TachoSil® (9.5x4.8 cm) in the left groin for lymph sealing and compartmentalisation of the wound.

**Conclusion:** TachoSil® reduces the risk of postoperative complications, shortens the drainage time and hospital stay.



Endarterectomy of the common femoral artery and patch graft with a Dacron® patch.



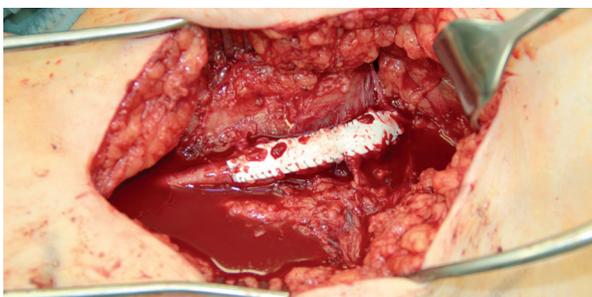
Sealing of the lymphatic-adipose tissue compartment adapted with Vicryl sutures using TachoSil®.

### 4 ePTFE\* patch graft after TEA<sup>2</sup>

**Patient history:** Extensive PAOD, intermittent claudication, occlusion of the left common femoral artery, PAOD III of the left lower limb. Anticoagulation, CHD, PAOD and previous operations.

**Surgery:** Hybrid procedure, open and endovascular, with multi-level occlusion in the leg-pelvis region. TEA of the common femoral artery and external iliac artery, stent implantation in the proximal external iliac artery. Covering of the arteriotomy with an ePTFE patch. TachoSil® to improve intraoperative hemostasis.

**Conclusion:** TachoSil® resulted in a shorter operation time, the hospital stay was shorter.



S/p TEA of the common femoral artery, covered by an ePTFE patch.



Hemostasis of puncture channel bleeding by covering with TachoSil®.

\* Teflon expanded polytetrafluoroethylene.

<sup>1</sup> According to information from Dr. med. Jörg Ukkaß, Department of General, Visceral and Vascular Surgery, Universitätsklinikum Halle.

<sup>2</sup> According to information from Prof. Dr. med. Thomas Hölzenbein, University Hospital for Vascular and Endovascular Surgery, PMU Salzburg.

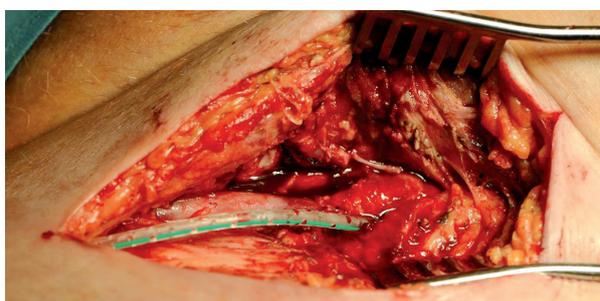
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## Venous bypass after occlusion of the superficial femoral artery<sup>1</sup>

**Patient history:** PAOD IIb–III, intermittent claudication with a short pain-free walking distance, occasional resting pain at night in the left leg. Doppler pressure index 0.52. Duplex ultrasound: long-segment occlusion of the superficial femoral artery and the popliteal artery, segments I and II, filling in the P III segment. Anticoagulant intake.

**Surgery:** Placement of a venous bypass with anastomosis to the common femoral artery. Lymph sealing and compartmentalisation of the wound with TachoSil® (9.5x4.8 cm).

**Conclusion:** TachoSil® reduces the risk of postoperative complications, shortens the drainage time and hospital stay.



Left groin, venous bypass anastomosed to the common femoral artery, one deep perivascular drainage placed.



Sealing of the deep compartment with TachoSil®.

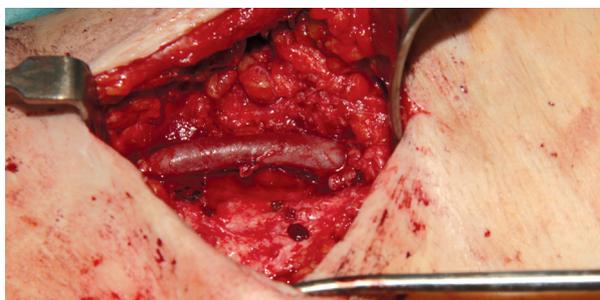
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## Venous bypass after resection of an aneurysm in the superficial femoral artery<sup>2</sup>

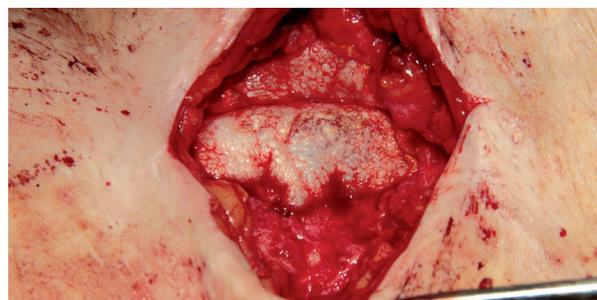
**Patient history:** Patient with bypass due to thrombotic aneurysm in the contralateral popliteal artery, status post abdominal aortic aneurysm, stent implantation due to aneurysm of the ipsilateral popliteal artery. Anticoagulation with phenprocoumon (Marcumar).

**Surgery:** Resection of the superficial femoral artery, reconstruction of the artery with a short venous bypass from the great saphenous vein.

**Conclusion:** In patients with aneurysmal disease requiring permanent anticoagulation, TachoSil® provides additional safety. Anticoagulation can be continued, surgery time is shorter, bleeding from puncture channels is reliably stopped.



Interposition with venous bypass after aneurysm resection.



Puncture channel bleeding from the artery at the anastomosis stopped by covering with TachoSil®.

<sup>1</sup> According to information from Dr. med. Jörg Ukkat, Department of General, Visceral and Vascular Surgery, Universitätsklinikum Halle.

<sup>2</sup> According to information from Prof. Dr. med. Thomas Hölzenbein, University Hospital for Vascular and Endovascular Surgery, PMU Salzburg.

# A STRONG CONNECTION.

## Order at

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### TachoSil Sealant Matrix (5.5 mg per cm<sup>2</sup> of human fibrinogen, 2.0 IU per cm<sup>2</sup> 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 epislonal 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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