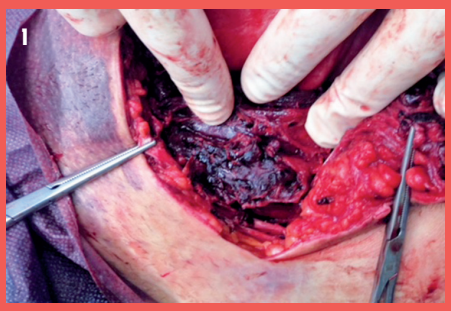
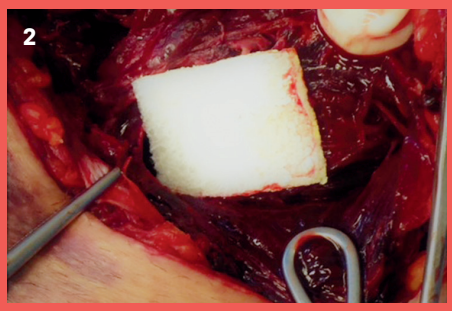
TachoSil SEALANT MATRIX

Case example:
TachoSil® application for sufficient hemostasis after a caesarean section under full heparinization

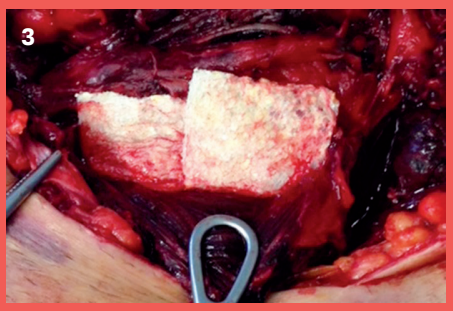
Treatment of diffuse bleeding in the area of the rectus abdominis muscle.



1: Diffuse bleeding in the area of the rectus abdominis muscle.



2: Application of the first TachoSil® (3.0 x 2.5 cm).



3: Cessation of bleeding after applying two TachoSil® patches (3.0 x 2.5 cm).

Preliminary remarks:

- The risk of venous thromboembolism is increased in pregnancy and the post-partum period compared with women who are not pregnant.[1]
- The method of choice in patients with transient risk factors for venous thromboembolism like pregnancy and puerperium is anticoagulation.[2]
- Under therapeutic anticoagulation, the risk of peri- or postoperative bleeding is naturally significantly increased.
- TachoSil® can be an efficient method of hemostasis without needing to discontinue or adjust therapeutic anticoagulation.[3]

Patient history:

- 36-year-old female with primary re-re-caesarean section performed elsewhere.
- Extensive bilateral pulmonary artery embolism in the postpartum period.
- Consecutive full heparinization and transfer to a perinatal centre.
- On the fifth postnatal day, development of a large, Hb-relevant hematoma on the abdominal wall requiring transfusion of four units of red cell concentrate and indication for re-laparotomy.

Quellen: 1. Pastori D et al. A Comprehensive Review of Risk Factors for Venous Thromboembolism: From Epidemiology to Pathophysiology. Int J Mol Sci. 2023;24(4):3169. 2. Ortel TL et al. American Society of Hematology 2020 guidelines for management of venous thromboembolism: treatment of deep vein thrombosis and pulmonary embolism. Blood Adv. 2020;4(19):4693-4738. 3. TachoSil® Summary of Product Characteristics (SmPC), March 2023.

Reference: According to information and estimates from Prof. Dr. Michael K. Bohlmann, MaHM, Department of Gynecology and Obstetrics, Mannheim University Hospital, Germany.

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Case example:

TachoSil® application for sufficient hemostasis after a caesarean section under full heparinization. Treatment of diffuse bleeding in the area of the rectus abdominis muscle.

Surgical procedure:

- Explorative re-laparotomy.
- Hematoma evacuation (→500 ml) with additional evidence of a diffuse, difficult-to-stem oozing in the deeper layers of the left rectus muscle.
- Exclusion of additional intraabdominal sources of bleeding and cleaning the adjacent tissue covered with blood.
- Diffuse bleeding in the area of the rectus abdominis muscle treated with two TachoSil® patches (3.0 x 2.5 cm).
- After cessation of bleeding, insertion of a Robinson drainage in the lower abdomen and closure of the abdominal wall.

Conclusion:

- The diffuse bleeding could be stopped using TachoSil®, no further bleeding episodes in the postoperative period.
- No new hematoma developed, the postoperative course after re-laparatomy was then uncomplicated under continuance of the previous anticoagulation.
- By applying TachoSil®, local hemostasis was rapidly improved. The duration of the intervention was shortened. A further operation was not necessary.

Reference: According to information and estimates from Prof. Dr. Michael K. Bohlmann, MaHM, Department of Gynecology and Obstetrics, Mannheim University Hospital, Germany.

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TachoSil Sealant Matrix (*5.5* mg per cm² of human fibrinogen, 2.0 IU per cm² 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