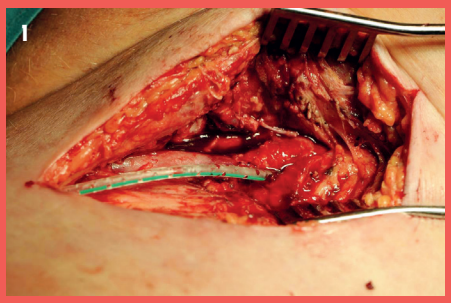
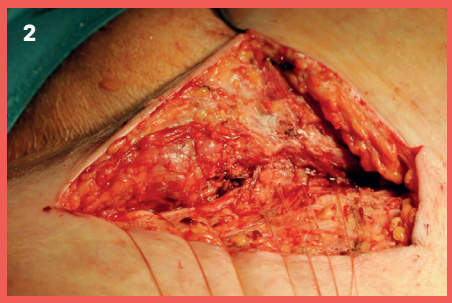
TachoSil SEALANT MATRIX

# Case example:
# Lymph sealing with TachoSil® after a venous bypass due to vascular occlusion

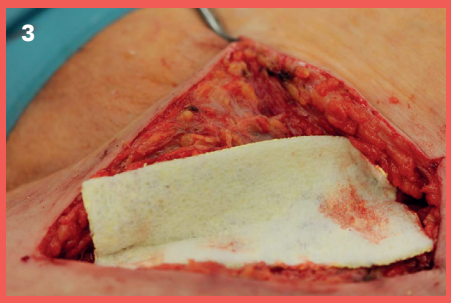
**Venous bypass with anastomosis to the common femoral artery.**



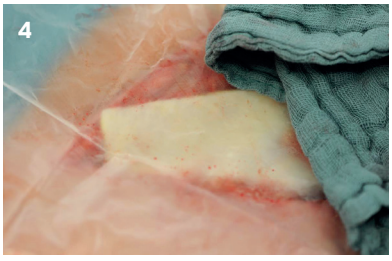

1: Left groin, venous bypass anastomosed to the common femoral artery, one deep drainage.



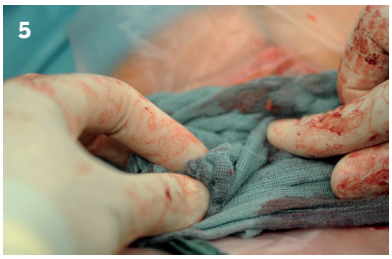

2: Over the drainage, the severed lymphatic-adipose tissue compartment is adapted with simple interrupted stitches.



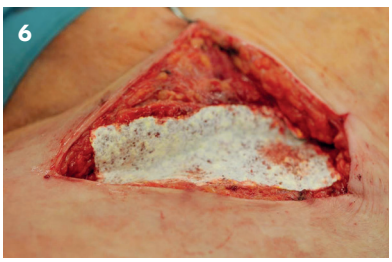

3: Application of a dry TachoSil® on the adapted tissue.




4: Plastic film placed on TachoSil®.




5: Shaping of the sealant matrix.




6: Finished sealing of the deep compartment.

**Preliminary remarks:**

- With fragile tissue or fragile, thin-walled vessels, there is a risk of diffuse bloody oozing and bleeding from stitch canals after a patch graft.
- In addition, there is a risk of increased lymph production and seroma formation.

**Patient history:**

- 68-year-old patient with PAOD stage IIb-III.
- Intermittent claudication with a short pain-free walking distance (approx. 30 m), 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.
- Increased risk of bleeding due to anticoagulant intake.
- Indication for elective primary procedure for a venous bypass.

**Surgical procedure:**

- Step-wise dissection until the common femoral artery is clearly exposed.
- Placement of a venous bypass with anastomosis to the common femoral artery.
- Insertion of a perivascular drainage and adaptation of the lymphatic-adipose tissue compartment with simple interrupted sutures.
- Lymph sealing with a TachoSil® sealant matrix (9.5 x 4.8 cm) and compartmentalisation of the wound to achieve wound closure, even if a seroma develops in the deep tissue.

**Reference:** According to information and estimates from Dr. med. Jörg Ukkat, Department of General, Visceral and Vascular Surgery, Universitätsklinikum Halle.

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## Case example:

# Lymph sealing with TachoSil® after a venous bypass due to vascular occlusion.

## Venous bypass with anastomosis to the common femoral artery.

**Conclusion:**

- Hospital stay shortened by one day.
- Drainage time shortened from three days to one.
- Lower likelihood of postoperative complications.

**Reference:** According to information and estimates from Dr. med. Jörg Ukkat, Department of General, Visceral and Vascular Surgery, Universitätsklinikum Halle.

**TachoSil® sealant matrix (coated with human fibrinogen and human thrombin)**

**PRESCRIBING INFORMATION**

**Refer to Summary of Product Characteristics (SmPC) before prescribing.**

**Presentation:** An off-white sponge coated with human fibrinogen 5.5 mg and human thrombin 2.0 IU per $cm^2$. The active side of the sponge is marked by a yellow colour. Supplied, ready to use, in sterile packaging.

**Indications:** In adults, for supportive treatment in surgery for improvement of hemostasis, to promote tissue sealing, and 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 neurosurgical procedures.

**Dosage & Administration:** For epilesional use only. Use is restricted to experienced surgeons. The number of sponges to be used is governed by the size of wound area, and the underlying clinical need for the patient. In clinical trials the individual dosages have typically ranged from 1–3 sponges. Sponges 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. The sponge should be pre-moistened in saline solution and applied immediately. The yellow, active side of the sponge is applied to the bleeding/leaking surface and held against it with a gentle pressure for 3–5 minutes. Pressure is applied with moistened gloves or a moist pad. If covered with blood, surgical instruments and gloves may be pre-moistened with physiological saline solution to avoid the sponge sticking to them. After pressing the sponge to the wound, the glove or the pad must be removed carefully. To avoid the sponge 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 sponge should be applied so that it extends 1–2 cm beyond the margins of the wound. Sponges should be overlapped if more than one is used and can be cut to the correct size and shaped if too large. 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. Allergic type hypersensitivity reactions are possible, as with any protein product. If hypersensitivity reactions occur, the administration 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 (foetal infection) and for immunodeficient patients or those who have increased erythropoiesis e.g. haemolytic anaemia. Risk of transmission of infective agents cannot be totally excluded, including pathogens of hitherto unknown nature. It is recommended to record the name and the batch number of the product administered to the patient.

**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.

**Pregnancy & Lactation:** Safety use in human pregnancy or breastfeeding has not been established. Only administer to pregnant and breastfeeding women if clearly needed.

**Undesirable Effects:** Hypersensitivity or allergic reactions (in rare cases these reactions may progress to severe anaphylaxis); thromboembolism may occur if unintentionally 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.**

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

**Marketing Authorisation Numbers:** EU/1/04/277/001-005.

**Date of revision of the text:** September 2021. Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/