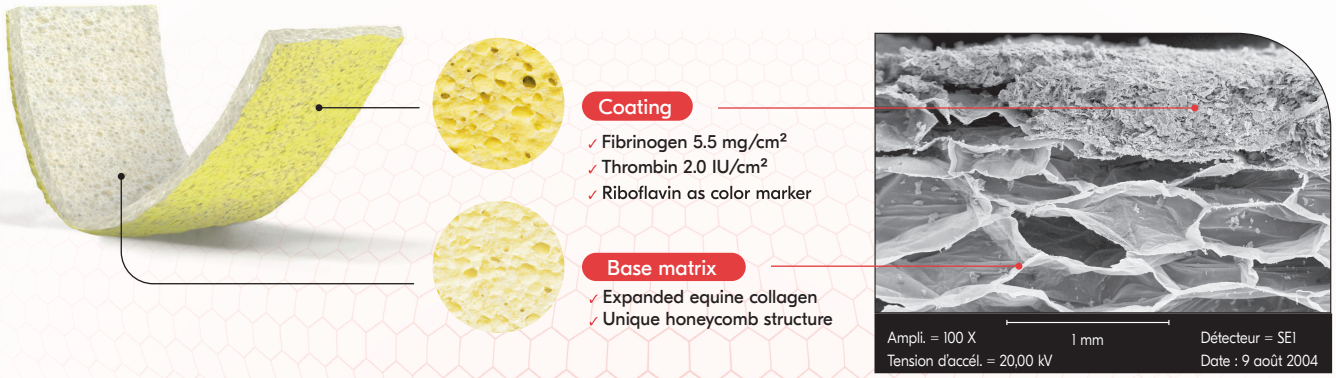
TachoSil SEALANT MATRIX by corzamedical & Lymphsealing

Anatomical disruption of the lymphatic vessels can lead to lymph oozing, which can accumulate to form a lymphocele, become infected, develop symptoms and contribute to the appearance of lymphedema[1,2,3]

TachoSil® is an effective treatment for prevention and reduction of these complications[3]

High elasticity provided by honeycomb structure:

- ✓ Up to 2.5 times more elastic when moistened than when dry[4]
- ✓ When moistened, adapts to organ movements[4]



Unique properties create a strong seal

- ✓ Activation of the coagulation factors and the collapse of the collagen cells conglutinate the TachoSil® patch with the tissue surface
- ✓ A seal is created between collagen patch and tissue

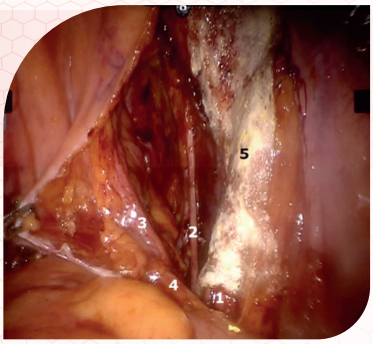
The rate of lymphatic complications depends on different factors, such as localisation of radical lymph node dissection[3] (RLND) and placement of TachoSil® patch

GENERAL LYMPHSEALING

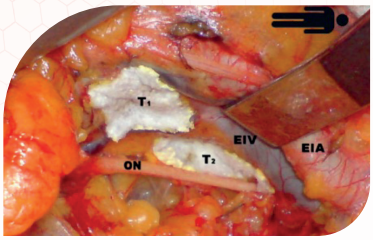
The Efficacy of Fibrin Sealant Patches (TachoSil®) in Reducing the Incidence of Lymphatic Morbidity After Radical Lymphadenectomy: A Meta-Analysis[3]

The analysis of 10 studies involving 720 patients showed significant benefits favoring TachoSil®:

- ✓ Reduced incidence of lymphoceles ($p<0.0001$) and symptomatic lymphoceles ($p<0.0001$)
- ✓ Decreased rate of percutaneous drainage procedures ($p<0.00001$)
- ✓ Substantial decrease in total drained lymph volume ($p<0.00001$)
- ✓ Shortened duration of drainage ($p<0.00001$)



Placement of the left TachoSil® patch in a fashion that it covers the left external iliac artery and vein and the location of the deep inguinal lymph node (Cloquet node): **1**, external iliac artery and vein; **2**, obturator nerve; **3**, medial umbilical ligament; **4**, Ureter; **5**, TachoSil®[5]



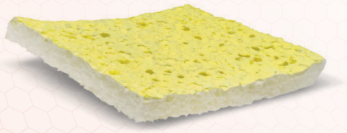
Standard technique. At end of lymphadenectomy TachoSil® was put in femoral canal (T1) and on obturator fossa (T2) based on anatomical considerations. EIV, external iliac vein. EIA, external iliac artery. ON, obturator nerve[6]

SCAN ME

Discover the collection of clinical cases on the use of TachoSil®

Based on high-quality clinical evidence, **TachoSil® is a valuable tool for managing the complications associated with lymphatic leakage**

TachoSil® Clinical Evidence



UROLOGY

- ✓ Reduces the incidence of radiographic lymphoceles one week (p=0.024) and one month (p=0.047) after pelvic RLND in prostate cancer patients[5]
- ✓ Reduces the incidence of lymphoceles in kidney transplant patients[7]
- ✓ Reduces drainage volumes (p=0.009) and decreases incidence of lymphoceles (p=0.001) after extraperitoneal pelvic RLND for prostate cancer[8]

METASTATIC MELANOMA

- ✓ Reduces drainage time (p=0.01) in patients undergoing axillary or ilioinguinal RLND[9]
- ✓ Decreases mean daily lymphorrhea volume and mean drainage persistence (p<0.0001) in patients undergoing RLND for stage III melanoma[10]
- ✓ Effective in reducing lymphorrhea and drainage time, independent of patient BMI[10]

BREAST CANCER

- ✓ Decreases drainage volumes (p<0.001) and length of hospital stay (p<0.001) in N+ breast cancer patients[11]
- ✓ Decreases number of evacuation punctures (p<0.001)[11]
- ✓ Associated with non-occurrence of seroma (p=0.002) patients treated with axillary RLND[12]

GYNECOLOGY

- ✓ Reduces drainage volume at day 30 (p=0.01) in patients with stage IB to II endometrial and cervical cancer undergoing hysterectomy and pelvic RLND[13]
- ✓ Reduces rate of lymphocele (p<0.05)in patients undergoing pelvic RLND for endometrial cancer[6]
- ✓ Reduces daily and total drainage volume, (p=0.004) in patients undergoing inguinofemoral RLND for gynecological malignancy[14]

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https://corza.com/global/contact/

TachoSil® is available through distribution or direct. For procedural videos, follow Corza Medical on MedTube or directly on corza.com/global

corza.com

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Quill manufactured by Surgical Specialties México S. DE R.L. DE C.V., Corredor Tijuana-Rosarito 2000, #24702-B, Ejido Francisco Villa, Tijuana, B.C., C.P. 22235, Mexico.

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TachoSil SEALANT MATRIX

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

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Link to Full SmPC or Prescribing information