TachoSil SEALANT MATRIX

Basics

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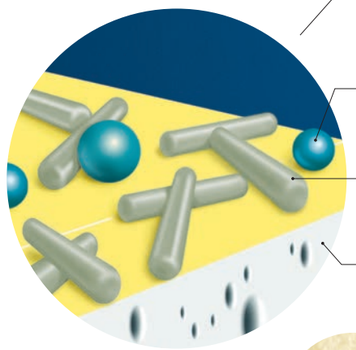
The reliable partner for your team

TachoSil® collagen matrix with human fibrinogen and thrombin.[1]

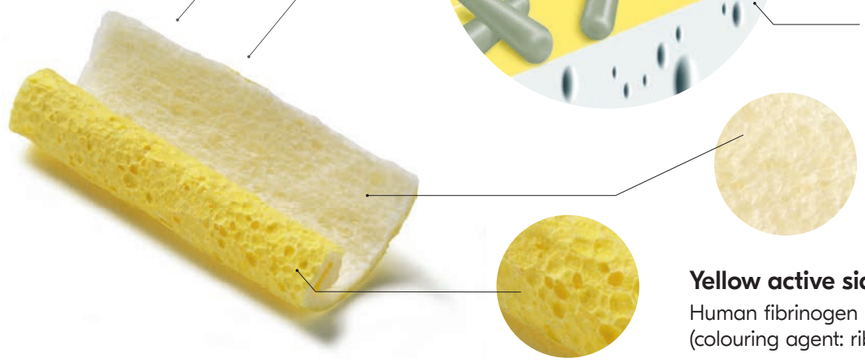
Pre-rolled TachoSil



Human thrombin (2 IU/cm²)

Human fibrinogen (5.5 mg/cm²)

Collagen honeycombs



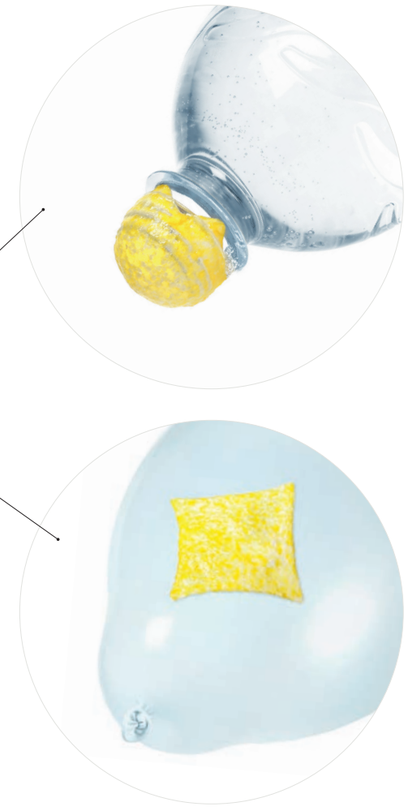
Base matrix

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

Can reduce air and fluid leakages

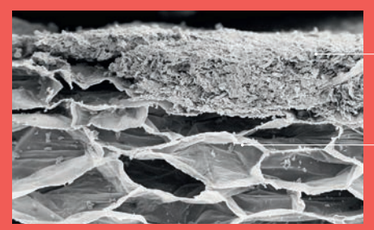
- Reduction of air and fluid leakage[4]
- Can be applied when wet or dry[1]
- No increase in volume
- The collagen matrix consists of 5–8 honeycomb layers

Tests to demonstrate air and liquid-tight seal**



Electron Microscope Image

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



Active side

Base matrix

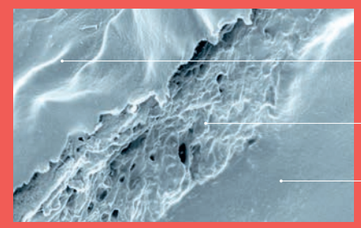
Mag = 100 X
EHT = 20.00 kV

1 mm

Detector = SE1
Date: 9 Aug. 2004

Hemostasis and sealing

- Ready-to-use fixed combination
- Hemostasis regardless of coagulation status[2,3]
- Interacts with all physiological fluids
- The fibrin network binds the collagen matrix firmly to the wound surface[1,*]



Collagen matrix

Fibrin network

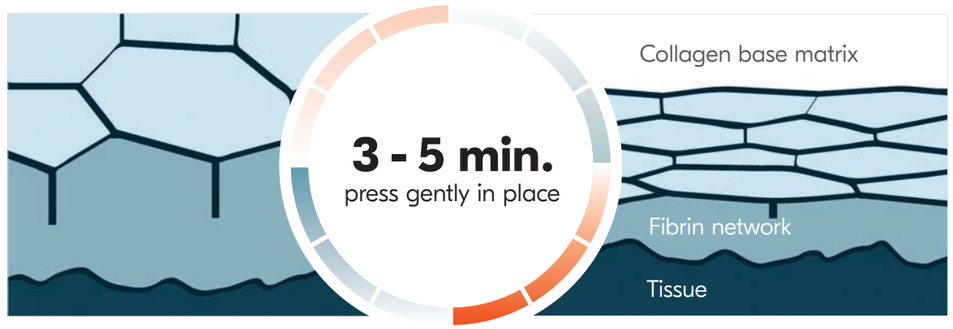
Wound surface

[1] Summary of Product Characteristics TachoSil® sealant matrix, current status.

[2] Haas S. Clin Appl Thromb Hemostat 2006; 12(4): 445–450. [3] Maisano F et al. European Journal of Cardio-thoracic Surgery 2009; 36: 708–714.
[4] Colombo G et al. Vascular Health and Risk Management 2014 10: 569–576. * After pressing onto the wound surface for 3–5 minutes.
** An air and liquid-tight seal with TachoSil® can be demonstrated using simple tests on a water bottle and balloon.

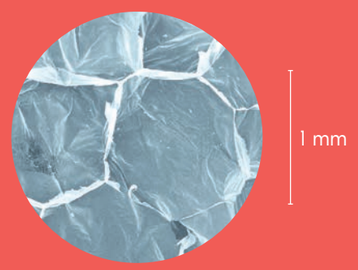
Unique collagen structure

Application:
The time it is pressed in place is decisive.
After 3–5 minutes of pressing it on,
a stable fibrin network is formed.[1]



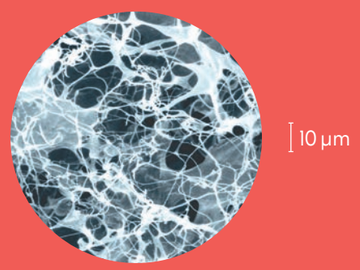
Characteristics of a foamed equine collagen base matrix:
- Physiologically compatible base substance, tested in animal experiments[2]
- Low risk of zoonosis or infection[3], e.g. BSE

Foamed equine collagen (TachoSil®)



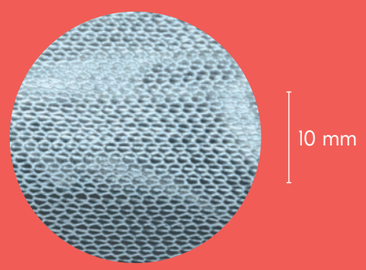
Mag = 100X
EHT = 20.00 kV
Detector = SE[1]
Date: 9 Aug 2004

Lyophilised bovine collagen



10.0 kV
≥45/08 19/02 KR
1.01 E3

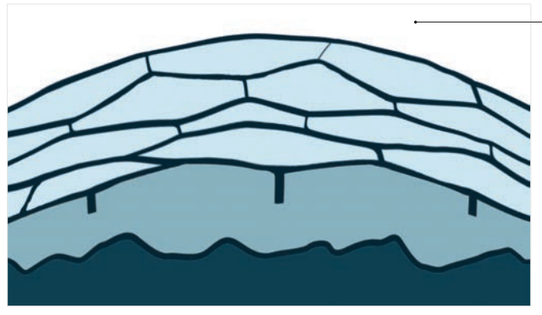
Cellulose



[1] Summary of Product Characteristics TachoSil® sealant matrix, current status.
[2] Adelmann-Grill BC and Otto K. Drug Research 1987; 37(II) 7: 802–805.
[3] Toro A et al. J Blood Med. 2011; 2: 31–36.

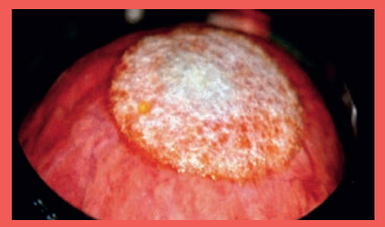
Elastic and flexible[4,*]

The honeycomb structure of the collagen matrix ensures high elasticity.
- Up to 2.5 times more elastic when moistened than when dry[4]
- When moistened, adapts to organ movements
- Easy to shape even to irregular surfaces

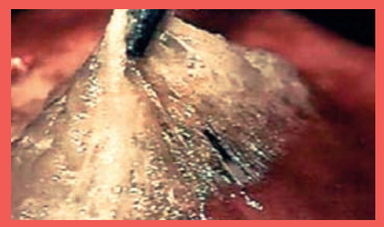


Adheres firmly and reliably[4,*]
- Withstands pressure of 61.4 hPa (approx. 46 mmHg, A cough reaches a pressure of up to 60 hPa.)[4]
- Adheres twice as firmly as a manually coated patch and 6 times more firmly than liquid adhesives[4]

The fibrin network is anchored in the honeycomb surface and binds the collagen matrix firmly to the wound surface.



Pressure chamber test with TachoSil®[4]



Firmness of adhesion (stringiness)[4]

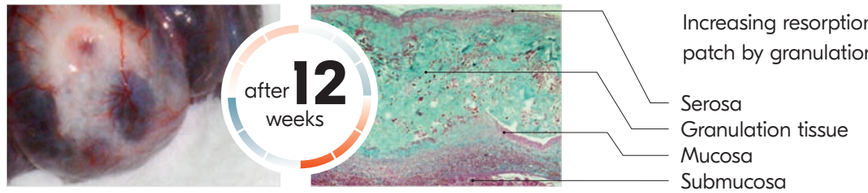
[4] Carbon RT et al. Tissue Management with Fleece-Bound Sealing. 6th World Congress on Trauma, Shock, Inflammation, and Sepsis – Pathophysiology, Immune Consequences, and Therapy, Munich, March 2–6, 2004, by Medimond International Proceedings, Bologna, 257–267.
* Determined using in vitro material and animal experiment tests.

Compatible with tissue and absorbable[1,*]

Situs Histology

The collagen patch (here TachoComb® H) is completely coated with serosa containing dense connective tissue with blood vessels among the mesothelial cells.

(Black tissue: appendix serosa, rabbit. In the histological presentation, patch residues are marked by ▼)



Situs Histology

Increasing resorption of the patch by granulation tissue.

Figures mod. from Schneider A et al.[2] in an animal experiment

Illustrated in original size

Four versions, three sizes.

Safety. Essential and proven.

- TachoSil® has been approved by the EMA and the FDA as a medicinal product with proven efficacy and tolerability
- No bovine components
- Complies with the requirements for medicinal product specification and safety

TachoSil. Efficacy in hemostasis and sealing.

Ready-to-use fixed combination of collagen matrix and active coagulation factors, used in adults:

- To improve hemostasis
- To promote tissue sealing
- To support sutures in vascular surgery
- To support sealing of the dura mater

Medicinal product, batch documentation required.
Shelf life & storage: 3 years, do not store above 25 °C

[1] Summary of Product Characteristics TachoSil® sealant matrix, current status.
[2] Schneider A et al. Digestive Disease and Sciences 2006; 51(3): 566–570.
* In animal experiments, TachoSil® is biodegraded after application to a wound surface with little residue after 13 weeks. [...] No evidence of local intolerance was observed in animal experiments.

A STRONG CONNECTION.

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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
www.ema.europa.eu/en/documents/product-information/tachosil-epar-product-information_en.pdf

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