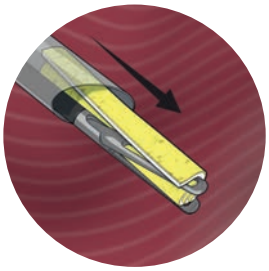
How to use
Pre-rolled TachoSil®

TachoSil SEALANT MATRIX

Instructions on the application in MIS

1. Clamp

Grasp the Pre-rolled TachoSil® with dry atraumatic forceps.
Note: Overlap 2 mm so the patch is not damaged on insertion.

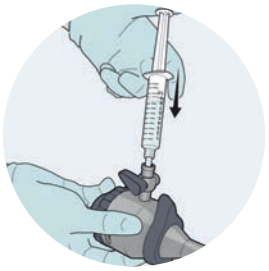


2. Insert

TachoSil® is easily inserted through the dry trocar ≥ 10 mm.
Note: It is not usually necessary to unscrew the valve.

3. Unroll

Press it right on the application site with a swab and unroll it with the forceps closed.
Note: "Yellow on red ..." / The patch is unrolled with the yellow side on the wound.

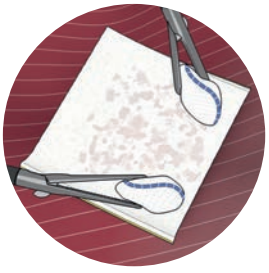


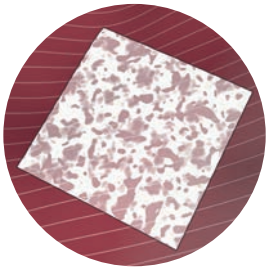
4. Moisten

Moisten TachoSil®, e.g. with saline solution

A. through the CO_2 valve along the forceps

B. or directly through the rinsing suction





5. Press in place

TachoSil® adheres to the wound after being held in place for 3-5 min.

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The TachoSil®
product family

Hemostasis and sealing in one. Four versions, three sizes.

Illustrated in original size

Maxi	9.5 x 4.8 cm
Midi	4.8 x 4.8 cm
Pre-rolled	4.8 x 4.8 cm
Mini	3.0 x 2.5 cm

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TACHOSIL® SEALANT MATRIX (human fibrinogen, human thrombin) PRESCRIBING INFORMATION Refer to Summary of Product Characteristics (SmPC) before prescribing.
Presentation: An off-white sealant matrix coated with human fibrinogen 5.5mg and human thrombin 2.0IU per cm2. The active side of the matrix is marked by a yellow colour. Supplied, ready to use, in sterile packaging. **Indication:** In adults for supportive treatment in surgery for improvement of haemostasis, to promote tissue sealing, 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 neurological surgery. **Dosage & Administration:** For epilesional use only. Use should be restricted to experienced surgeons. The quantity of sealant matrices to be used is governed by the size of wound area, and the underlying clinical need for the patient. Application of TachoSil must be individualised by the treating surgeon. In clinical trials the individual dosages have typically ranged from 1-3 units (9.5 cm x 4.8 cm). In minimally invasive surgery, use of the smaller size matrices (4.8 cm x 4.8 cm, 3.0 cm x 2.5 cm or pre- rolled 4.8 cm x 4.8 cm) is recommended. Matrices should be used under sterile conditions and used 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 matrix 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. Pre-rolled TachoSil® can be used for both open surgery and in minimally invasive surgery, and it can pass through a 10 mm or larger port or trocar. After removal of the pre-rolled TachoSil® from the sterile package it should be applied immediately through the trocar without pre-moistening. While unrolling the matrix 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 a gentle pressure for 3-5 minutes. This procedure enables an easy adhesion of TachoSil® to the wound surface. Pressure is applied with moistened gloves or a moist pad. Due to the strong affinity of collagen to blood, sealant matrix may also stick to surgical instruments or gloves covered with blood; cleansing them before application helps avoid this. After pressing the matrix to the wound, the glove or the pad must be removed carefully. To avoid the matrix 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 the matrix should be applied so that it extends 1-2 cm beyond the margins of the wound. Matrices should be overlapped if more than one is used and 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. 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. It is not known whether recent radiation therapy affects the efficacy of Tachosil® when used for dura mater sealing. Allergic type hypersensitivity reactions are possible, as with any protein-containing product. If hypersensitivity reactions occur, product 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 (fetal infection) and for immunodeficient patients or those who have increased erythropoeisis e.g. haemolytic anaemia. Risk of transmission of infective agents cannot be totally excluded, including pathogens of hitherto unknown nature. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the desired application area are adequately cleansed before administration of TachoSil®. Events of adhesions to gastrointestinal tissues leading to gastrointestinal obstruction have been reported with use in abdominal surgery carried out in proximity to the bowel. **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. **Fertility Pregnancy & Lactation:** Safety for use in human pregnancy or breastfeeding has not been established. Only administer to pregnant and breastfeeding women if clearly needed. **Undesirable Effects:** Frequency not known (cannot be estimated from the available data): anaphylactic shock, hypersensitivity, thrombosis, intestinal obstruction (in abdominal surgeries), adhesions. Refer to the SmPC for details on full side effect profile and interactions. **Legal Classification:** POM. **Marketing Authorisation:** PLGB 55087/0001. Further information is available from the suppliers: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf PI Approval Date: August 2021 **hemostasis.corza.com** Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**

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