

TachoSil SEALANT MATRIX

Interesting facts about Cardiovascular Surgery





TachoSil® – selected studies...

Clinical studies

RANDOMIZED CLINICAL TRIALS

Bajardi G, Pecoraro F, Mirabella D. Efficacy of TachoSil patches in controlling Dacron suture-hole bleeding after abdominal aortic aneurysm open repair. *J Cardiothorac Surg.* 2009;4:60. doi: 10.1186/1749-8090-4-60. PMID: 19889206; PMCID: PMC2776591.



Maisano F, Kjaergård HK, Bauernschmitt R, Pavie A, Rábago G, Laskar M, Marstein JP, Falk V. TachoSil surgical patch versus conventional hemostatic fleece material for control of bleeding in cardiovascular surgery: a randomised controlled trial. *Eur J Cardiothorac Surg.* 2009;36(4):708-14. doi: 10.1016/j.ejcts.2009.04.057. PMID: 19595605.



Ostrowski S, Jaszewski R, Skowroński T, Jander S, Zwoliński R. Does the additional usage of a local hemostatic patch reduce bleeding after aortic reimplantation? *Arch Med Sci.* 2018;17(6):1613-1617. doi: 10.5114/aoms.2018.73124. PMID: 34900040; PMCID: PMC8641524.



CASE SERIES

Gocół R, Bis J, Hudziak D, Morkisz Ł, Deja MA. Aortic Root Reconstruction with TachoSil Fibrin Sealant Patch in Acute Type A Aortic Dissection. *Ann Thorac Cardiovasc Surg.* 2021;27(4):267-272. doi: 10.5761/atcs.nm.20-00198. Epub 2021 Feb 9. PMID: 33563845; PMCID: PMC8374091.



Okamura H, Kimura N, Mieno M, Matsumoto H, Yuri K, Yamaguchi A. Sutureless repair for postinfarction left ventricular free wall rupture. *J Thorac Cardiovasc Surg.* 2019;158(3):771-777. doi: 10.1016/j.jtcvs.2019.01.124. Epub 2019 Feb 14. PMID: 30878160.



Onorati F, Pasceri E, Scalas C, Santarpino G, Mastroroberto P, Indolfi C, Renzulli A. Aortic tube grafts wrapping with hemostatic fleeces reduces postoperative pericardial effusions. *J Cardiovasc Surg (Torino).* 2008;49(3):393-7. PMID: 18446127.



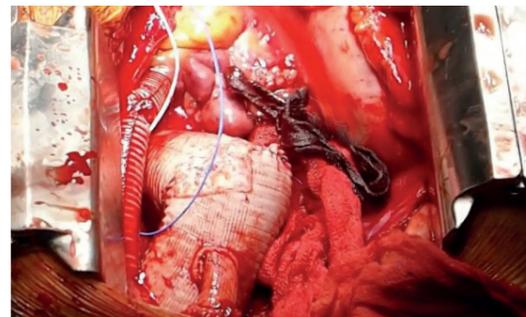
CASE REPORT

Rupprecht H, Gaab K. Delayed Cardiac Rupture Induced by Traumatic Myocardial Infarction: Consequence of a 45-Magnum Blast Injury; A Comprehensive Case Review. *Bull Emerg Trauma.* 2018;6(1):1-7. doi: 10.29252/beat-060101. PMID: 29379803; PMCID: PMC5787357.



Case examples

1 TachoSil® application to support hemostasis and suture support after ascending aorta and aortic arch replacement



The application of TachoSil® (4.8 x 4.8 cm) supported a sufficient hemostasis and suture support in the region of the graft sutures. Through the use of a collagen patch the time until hemostasis and the operating time were reduced.

Reference: According to information and estimates from Prof. Dr. Martin Czerny, Freiburg University Heart Centre, Bad Krozingen GmbH

2 Use of TachoSil® for efficient hemostasis and sealing after transcatheter aortic valve implantation (TAVI) due to aortic valve stenosis



Through the use of TachoSil® (4.8 x 4.8 cm) the cardiac apex was securely and well sealed. The time until hemostasis was reduced, the operation was tissue sparing, which is an advantage in elderly patients who often have fragile tissue.

Reference: According to information and estimates from Prof. Dr. Martin Czerny, Freiburg University Heart Centre, Bad Krozingen GmbH

...and case examples

Case examples

3 Use of TachoSil® for efficient hemostasis and suture support in the case of stitch canal bleedings in vascular anastomoses*



TachoSil® shortened the hemostasis time and the surgery duration. The use of collagen fleece increased the safety in a patient under oral anticoagulation.

Reference: According to information and estimates from PD Dr. med. Arndt Hribaschek, Department of Vascular Surgery, Klinikum Magdeburg

* In the context of a Y-graft interposition after resection of an anastomotic aneurysm

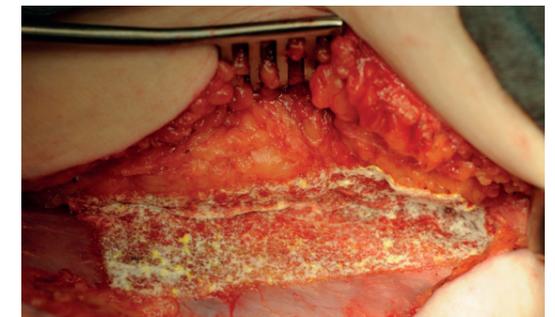
4 Application of TachoSil® for suture support and efficient hemostasis following a venous bypass of an aneurysm



The use of TachoSil® shortened the surgery duration, improved hemostasis and supported the sutures. Moreover the use of collagen fleece had clinical and economic benefits due to a shorter hospital stay.

Reference: According to information and estimates from Prof. Dr. med. Thomas Hölzenbein, University Hospital for Vascular and Endovascular Surgery, PMU Salzburg

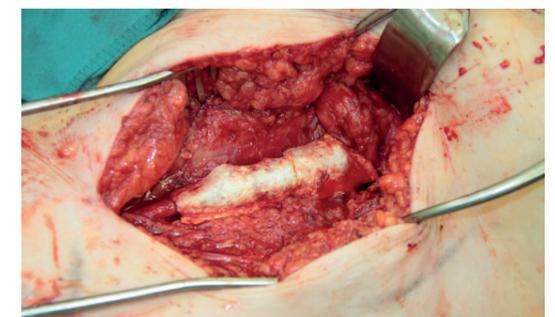
5 TachoSil® for lymph sealing after placement of a Dacron® patch graft for peripheral arterial occlusive disease (PAOD) stage III



The use of TachoSil® (9.5 x 4.8 cm) in the groin reduced complications as development of a seroma in the deeper tissue, shortened drainage time and duration of hospitalization.

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

6 Use of TachoSil® for efficient hemostasis after thromboendarterectomy (TEA) and placement of a ePTFE patch*



TachoSil® improved intraoperative hemostasis, shortened surgical time and postoperative hospital stay. Discontinuation of anticoagulation was not necessary.

Reference: According to information and estimates from Prof. Dr. med. Thomas Hölzenbein, University Hospital for Vascular and Endovascular Surgery, PMU Salzburg

* Hybrid procedure for multilevel occlusion in the leg-pelvis region and use of a Teflon expanded poly-tetra-fluoroethylene patch

TachoSil® – Four versions, three sizes*

Illustrated in original size

TachoSil®

SEALANT
MATRIX



	MAXI	MIDI	Pre-rolled	MINI	
Size	9,5 x 4,8 cm	4,8 x 4,8 cm	4,8 x 4,8 cm	3,0 x 2,5 cm	
Package	1 Patch	2 Patches	1 Patch	1 Patch	5 Patches
PZN	03101150	03101167	10963461	03101204	03103841
Article Number	1130677	1130693	6111405	1130699	1130702

*Not all versions are available in all countries

Order at

Tel.: 0800 64 500 11
 Fax: 0800 64 500 88
corzamedical@arvato-scs.com

MedInfo Kontakt

Tel.: +44 8081 686 908
 (gebührenfrei)
medinfo@corza.com

Corza Medical GmbH

Speditionstraße 21
 40221 Düsseldorf
 Deutschland

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
© 2025 Corza Medical. All rights reserved.