TachoSil SEALANT MATRIX

Interesting facts about Thoracic surgery

corzamedical

www.corza.com

TachoSil® — selected studies...

Clinical studies

Zhou J, Lyu M, Pang L, Gao Y, Ning K, Wang Z, Liu L. Efficiency and safety of TachoSil® in the treatment of postoperative air leakage following pulmonary surgery: a meta-analysis of randomized controlled trials. Jpn J Clin Oncol. 2019 Sep 1;49(9):862-869. doi: 10.1093/jjco/hyz076. PMID: 31135918.

Anegg U, Lindenmann J, Matzi V, Smolle J, Maier A, Smolle-Jüttner F. Efficiency of fleece-bound sealing (TachoSil®) of air leaks in lung surgery: a prospective randomised trial. Eur J Cardiothorac Surg. 2007 Feb;31(2):198-202. doi:10.1016/j.ejcts.2006.11.033. Epub 2006 Dec 21. PMID: 17187983.

Droghetti A, Schiavini A, Muriana P, Folloni A, Picarone M, Bonadiman C, Sturani C, Paladini R, Muriana G. A prospective randomized trial comparing completion technique of fissures for lobectomy: stapler versus precision dissection and sealant. J Thorac Cardiovasc Surg. 2008 Aug;136(2):383-91. doi: 10.1016/j.jtcvs.2008.04.014. Epub 2008 Jun 16. PMID: 18692646.

Filosso PL, Ruffini E, Sandri A, Lausi PO, Giobbe R, Oliaro A. Efficacy and safety of human fibrinogen-thrombin patch (TachoSil®) in the treatment of postoperative air leakage in patients submitted to redo surgery for lung malignancies: a randomized trial. Interact Cardiovasc Thorac Surg. 2013 May;16(5):661-6. doi: 10.1093/icvts/ivs571. Epub 2013 Feb 17. PMID: 23420053; PMCID: PMC3630418.

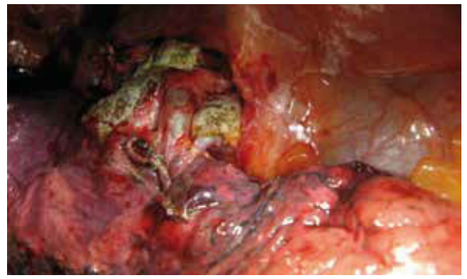
Lopez C, Facciolo F, Lequaglie C, Rendina EA, Saita S, Dell'Amore D, Solli9o F, Urciuoli G, Loizzi M, Cisternino ML, Granone P, Angelelli A, Cardillo G, Mucilli F, Di Rienzo G. Efficacy and safety of fibrin sealant patch in the treatment of air leakage in thoracic surgery. Minerva Chir. 2013 Dec;68(6):559-67. PMID: 24193288.

Marta GM, Facciolo F, Ladegaard L, Dienemann H, Csekeo A, Rea F, Dango S, Spaggiari L, Tetens V, Klepetko W. Efficacy and safety of TachoSil® versus standard treatment of air leakage a]er pulmonary lobectomy. Eur J Cardiothorac Surg. 2010 Dec;38(6):683-9. doi: 10.1016/j.ejcts.2010.03.061. Epub 2010 Jun 11. PMID: 20541949.

Rena O, Papalia E, Mineo TC, Massera F, Pirondini E, Turello D, Casadio C. Air-leak management after upper lobectomy in patients with fused fissure and chronic obstructive pulmonary disease: a pilot trial comparing sealant and standard treatment. Interact Cardiovasc Thorac Surg. 2009 Dec;9(6):973-7. doi: 10.1510/icvts.2009.202770. Epub 2009 Sep 23. PMID: 19776082.

Case examples

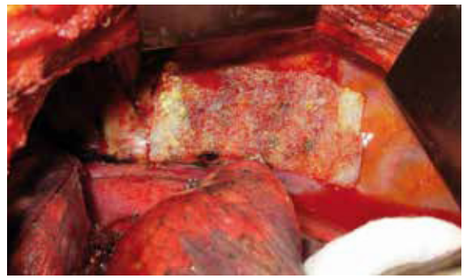
1 TachoSil® application to support efficient hemostasis and sealing in upper lobe resection due to lung cancer



With TachoSil® intraoperatively a complete hemostasis and successful sealing was achieved in the area of the staple line. The risk of postoperative complications was reduced.

Reference: According to information and estimates from Prof. Dr. Andreas Kirschbaum, Department of Thoracic Surgery, University Hospital Marburg UKGM.

2 Use of TachoSil® to support efficient hemostasis in anatomical segment 6 resection due to lung cancer



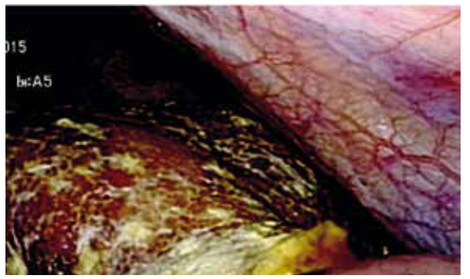
TachoSil® additionally supported hemostasis in the area of the thoracic wall. The risk of oozing and diffuse rebleeding in the thoracic wall was reduced.

Reference: According to information and estimates from Prof. Dr. Andreas Kirschbaum, Department of Thoracic Surgery, University Hospital Marburg UKGM.

...and case examples

Case examples

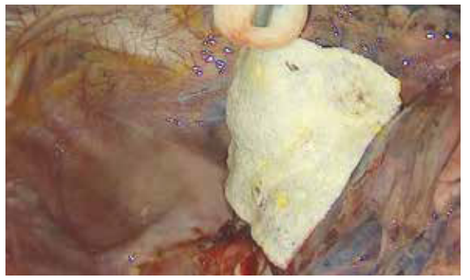
3 Use of TachoSil® for supportive sealing of an alveolar-pleural fistula in the upper lobe because of puncture damage



Insertion of TachoSil® allowed atraumatic closure of the alveolar-pleural fistula without wedge resection in the right upper lobe. Postoperatively, the lung was radiologically completely expanded.

Reference: According to information and estimates from Dr. Waldemar Schreiner, Thoracic Surgery, Erlangen University Hospital.

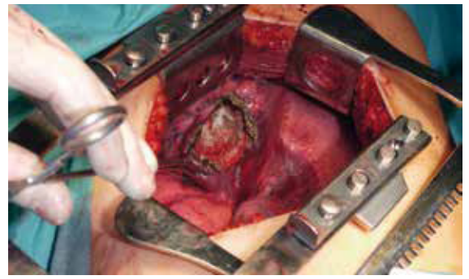
4 Pre-rolled TachoSil® for supportive sealing of air leakage after VATS lobectomy



With TachoSil® the leakage in the damaged lung parenchyma was successfully closed. The postoperative course after re-intervention was uneventful.

Reference: According to information and estimates from Piwkowski C. Treatment of air leakage a]er VATS lobectomy with the use of TachoSil®; 19-25, ISBN 978-83-936618-1-7; Effective haemostasis and tissue sealing, the use of TachoSil® in various clinical cases; part 2; scientific editors: Prof K. Pityński, Prof G. Wallner, Poland.

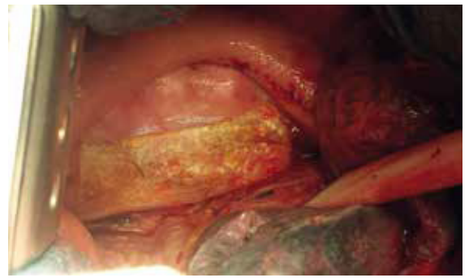
5 Application of TachoSil® for supportive sealing of lung parenchyma after tuberculoma resection



TachoSil® enabled effective sealing of the pulmonary parenchyma and the prevention of persistent air leakage. The overall treatment time was significantly reduced.

Reference: According to information and estimates from Rybojad P et al. The use of TachoSil® in thoracic surgery, with particular focus on the treatment of the tumor bed after dissected tumors with the use of surgical laser; pages: 44-49, ISBN 978-83-936618-0-0; Effective haemostasis and tissue sealing, the use of TachoSil® in various clinical cases; scientific editor: Prof P. Szyber, Poland.

6 Use of TachoSil® for supportive sealing of an open thoracic duct after abdominothoracic esophagectomy



Vessel ends and injured side branches were successfully sealed. The lymphatic fistula disappeared and the chylothorax was repaired. The postoperative course was free of complications.

Reference: According to information and estimates from Dr. Jamal El Chafchak, Surgical Clinic I, Bayreuth Hospital, Academic Teaching Hospital.

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

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

000000000_EN

www.corza.com

corzamedical