TachoSil SEALANT MATRIX

Interesting facts about Neurosurgery

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TachoSil® – Selected studies...

Clinical studies

George B, Matula C, Kihlström L, Ferrer E, Tetens V. Safety and Efficacy of TachoSil® (Absorbable Fibrin Sealant Patch) Compared With Current Practice for the Prevention of Cerebrospinal Fluid Leaks in Patients Undergoing Skull Base Surgery: A Randomized Controlled Trial. Neurosurgery 2017;80(6):847-853. doi: 10.1093/ neuros/nyx024. PMID: 28327892.

Hutter G, von Felten S, Sailer MH, Schulz M, Mariani L. Risk factors for postoperative CSF leakage after elective craniotomy and the efficacy of fleece-bound tissue sealing against dural suturing alone: a randomized controlled trial. J Neurosurg 2014;121(3):735-44. doi: 10.3171/2014.6.JNS131917. Epub 2014 Jul 18. PMID: 25036199.

Kivelev J, Göhre F, Niemelä M, Hernesniemi J. Experiences with TachoSil® in microneurosurgery. Acta Neurochir Wien 2015;157(8):1353-7; discussion 1357. doi: 10.1007/s00701-015-2473-x. Epub 2015 Jul 3. PMID: 26136196.

Montano N, Pignotti F, Auricchio AM, Fernandez E, Olivi A, Papacci F. Results of TachoSil® associated with fibrin glue as dural sealant in a series of patients with spinal intradural tumors surgery. Technical note with a review of the literature. J Clin Neurosci 2019;61:88-92. doi: 10.1016/j.jocn.2018.10.138.

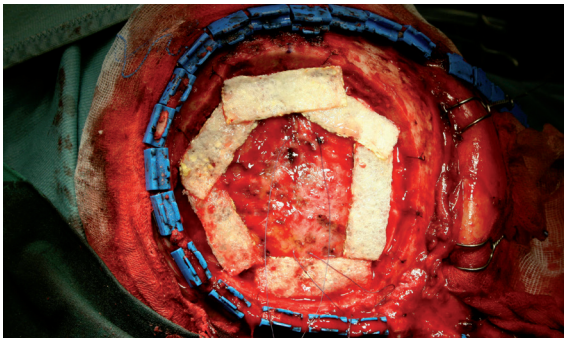
Papavero L, Engler N, Kothe R. Incidental durotomy in spine surgery: first aid in ten steps. Eur Spine J 2015;24(9):2077-84. doi: 10.1007/s00586-015-3837-x. Epub 2015 Mar 4. PMID: 25735610.

Preclinical study

Ebel F, Wanderer S, Jesse CM, Schär RT, Zubak I, Ulrich CT, Raabe A. A standardized model for in vitro testing of sutures and patches for watertight dural closure. J Neurosurg 2021;8:1-10. doi: 10.3171/2021.5.JNS21369. Epub ahead of print. PMID: 34624865.

Case examples

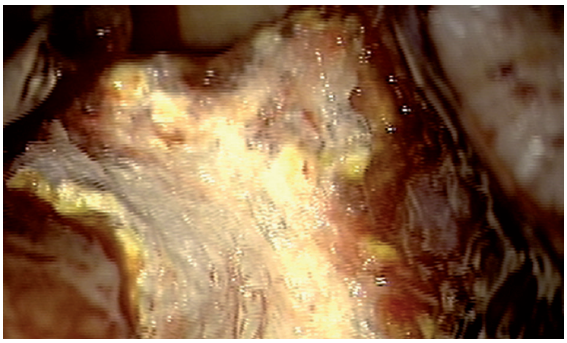
1 **Supportive sealing of a dural suture with TachoSil® after tumour extirpation due to an infiltrating falx meningioma.**



The use of TachoSil® led to a reduction of the operating time, an unremarkable postoperative course and a discharge with an unremarkable neurological state.

Reference: According to information and estimates from Prof. Dr. med. Jürgen Piek, Head of the Department of Neurosurgery, Universitätsmedizin Rostock.

2 **Supportive sealing of the closure site of a cerebrospinal fluid fistula with TachoSil® in the area of the sphenoid sinus and ethmoid bone.**



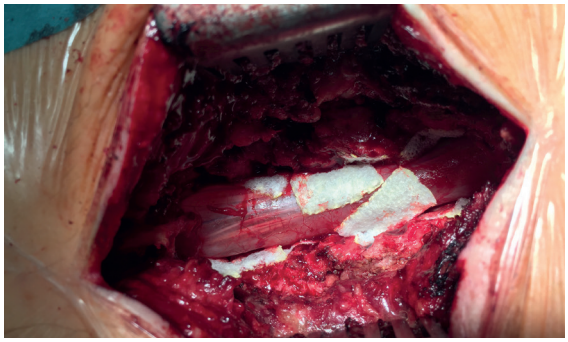
The use of TachoSil® supported a postoperative immediate cessation of the fistula with no evidence of recurrence at follow-up.

Reference: According to information and estimates from Prof. Dr. med. Jürgen Piek, Head of the Department of Neurosurgery, Universitätsmedizin Rostock.

...and case examples

Case examples

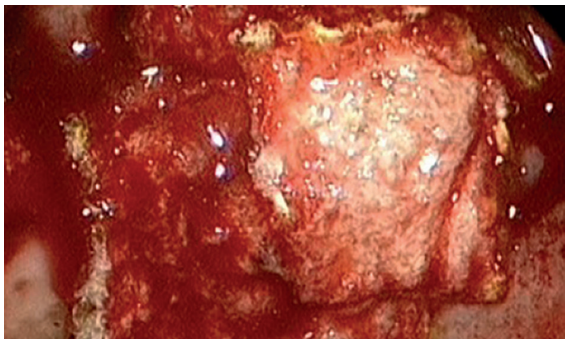
3 Application of TachoSil® for efficient hemostasis and sealing of a pleural deficiency after total Th12 vertebrectomy (en bloc resection).*



After the application of TachoSil® a full sealing of the pleural cavity was achieved and allowed to shorten the time of pleural drainage. Chest drain was removed three days after surgery. The postoperative course was uneventful.

Reference: According to information and estimates from Prof. Dr. hab. med. Andrzej Maciejczak Department of Neurosurgery, Medical College, University of Rzeszów, Polen and Department of Neurosurgery, St Luke Hospital, Tarnów.

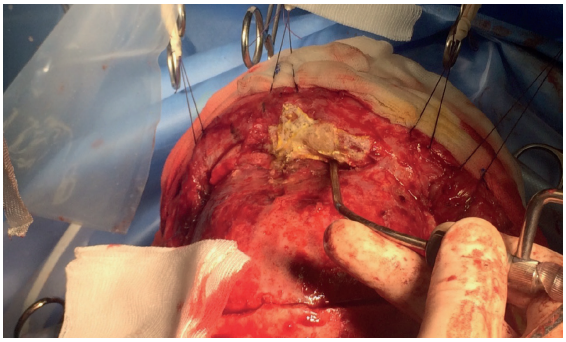
4 TachoSil® supporting the fixation of a tissue flap to close a dura mater deficiency after endoscopic resection of a retrochiasmatic craniopharyngioma.



TachoSil® supported the closure of the sella turcica and the sealing of the cranial base deficiency repair.**

Reference: According to information and estimates from Tomasz Łyson[1], Robert Chrzanowski[1], Andrzej Sieskiewicz[2], Marek Rogowski[2], Zenon Mariak[1]. 1. Department of Neurosurgery and 2. Department of Otolaryngology, Medical University of Białystok, Poland.

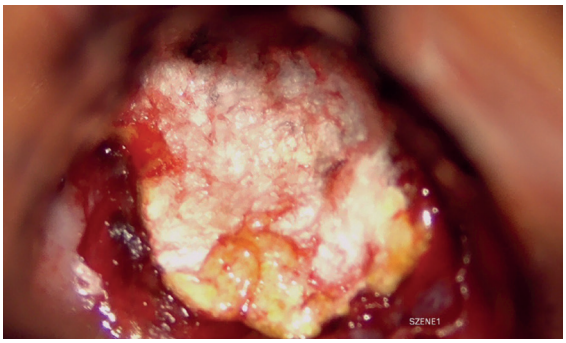
5 Use of TachoSil® as a sealant matrix in the plastic of the anterior cranial fossa after excessive craniocerebral trauma.



The application of TachoSil® resulted in successful closure of the fistula between the frontal sinus and cranial cavity. TachoSil® as supplement to the layered plasty of anterior fossa of the cranial base was a feasible application.

Reference: According to information and estimates from Adam Warzecha[1], Tomasz Wójcikiewicz[1], Bartosz Czapski[1,3], Mirosław Ząbek[1,2]. 1. Department of Neurosurgery and Trauma of the Nervous System, Mazowiecki Szpital Bródnowski, Warsaw; 2. Medical Centre for Postgraduate Education, Warsaw; 3. Postgraduate School of Molecular Medicine, Warsaw.

6 Use of TachoSil® for final hemostasis and sealing in the area of the dura mater in resection of an intra/suprasellar pituitary adenoma.



The use of TachoSil® had a positive influence on the intraoperative course. It reduced the time to hemostasis and shortened the operating time.

Reference: According to information and estimates from PD Dr. Christian Ewelt, Klinik für Neurochirurgie, St. Barbara Klinik Hamm GmbH.

* This case demonstrates the use of TachoSil® for effective complication management in neurosurgery.
** This case example does not demonstrate a typical application of TachoSil®, but the use described is in-label.

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

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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

Date of Revision of the Text: 8 May 2025
Link to Full SmPC or Prescribing information

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