

Interesting facts about pediatric surgery





TachoSil® – selected studies...

Clinical studies

Genyk Y, Kato T, Pomposelli JJ, Wright JK Jr, Sher LS, Tetens V, Chapman WC. Fibrin Sealant Patch (TachoSil) vs Oxidized Regenerated Cellulose Patch (Surgicel Original) for the Secondary Treatment of Local Bleeding in Patients Undergoing Hepatic Resection: A Randomized Controlled Trial. *J Am Coll Surg.* 2016;222(3):261-8. doi: 10.1016/j.jamcollsurg.2015.12.007. Epub 2015 Dec 18. PMID: 26776356.



Kim YW, Kang MJ, Lee HJ, Woo CK, Mun MJ, Cho KS. The efficacy of TachoComb on reducing postoperative complications after tonsillectomy in children. *Int J Pediatr Otorhinolaryngol.* 2015;79(8):1337-40. doi: 10.1016/j.ijporl.2015.06.006. Epub 2015 Jun 12. PMID: 26100056.



Mele E, Ceccanti S, Schiavetti A, Bosco S, Masselli G, Cozzi DA. The use of Tachosil as hemostatic sealant in nephron sparing surgery for Wilms tumor: preliminary observations. *J Pediatr Surg.* 2013;48(3):689-94. doi: 10.1016/j.jpedsurg.2013.01.019. PMID: 23480936.



Matsushita N, Kaneko K, Kato S, Odashima T, Kondo R, Fukuyama T, Saito T, Fukami Y, Komatsu S, Sano T. Laparoscopic complete excision of an enormous simple hepatic cyst occupying the entire abdomen in a child: a case report and literature review. *Surg Case Rep.* 2022;8(1):87. doi: 10.1186/s40792-022-01445-2. PMID: 35522346; PMCID: PMC9076767.



Pelizzo G, Arbustini E, Pasqua N, Morbini P, Calcaterra V. Thoracoscopic Treatment of Pneumothorax in Marfan Syndrome: Hemostatic Patch to Support Lung Resection Recovery. *Case Rep Surg.* 2018; 2018:7597215. doi: 10.1155/2018/7597215. PMID: 30254783; PMCID: PMC6142756.



Vida VL, Padalino MA, Barzon E, Stellin G. Efficacy of fibrinogen/thrombin-coated equine collagen patch in controlling lymphatic leaks. *J Card Surg.* 2012;27(4):441-2. doi: 10.1111/j.1540-8191.2012.01461.x. Epub 2012 May 14. PMID: 22583120.

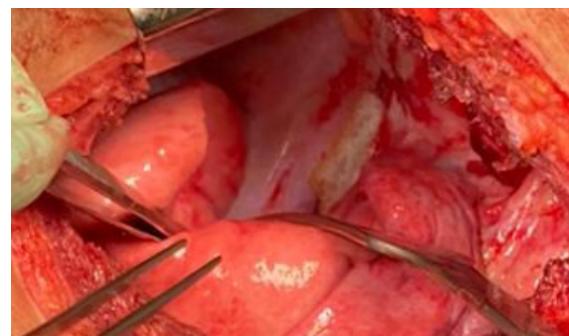


Vida VL, De Franceschi M, Barzon E, Padalino MA, Scattolin F, Stellin G. The use fibrinogen/thrombin-coated equine collagen patch in children requiring re-operations for congenital heart disease. A single center clinical experience. *J Cardiovasc Surg (Torino).* 2014;55(3):401-6. PMID: 24755705.



Case examples

1 Use of TachoSil® for efficient hemostasis during emergency exploratory thoracotomy in an 13-year-old boy



The use of TachoSil® (3.0 x 2.5 cm) in the pleural cavity after using standard methods stopped local bleeding from the area of the pulmonary ligament.

Reference: According to information and estimates from Dr. n. med. Małgorzata Nosek-Kościelak, Dr. n. med. Anita Kalińska-Lipert, Department of Paediatric Surgery and Traumatology at the University Children's Hospital in Lublin, Poland. Case report: Use of the hemostatic agent TachoSil® during emergency exploratory thoracotomy in an 13-year-old boy due to bleeding into the pleural cavity.

2 TachoSil® to cover the resected hepatic surface for better hemostasis and tissue sealing after excision of an enormous hepatic cyst in an 18-month-old child



After removal of the hepatic cyst en bloc together with the attached hepatic parenchyma the resected surface was covered with TachoSil® to improve hemostasis.

Reference: Matsushita N et al. Laparoscopic complete excision of an enormous simple hepatic cyst occupying the entire abdomen in a child: a case report and literature review. *Surg Case Rep.* 2022;8(1):87.



...and case examples

Case examples

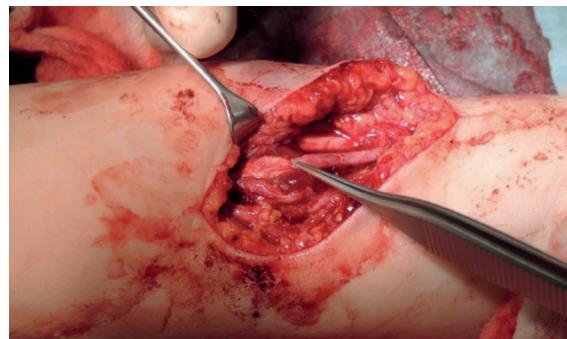
3 Application of TachoSil® for efficient hemostasis and sealing after tumor resection in an 11-month-old child



After removal of the lymphatic malformation, additional TachoSil® (3.0 x 2.5 cm) was effective and safe for improving hemostasis and promoting tissue sealing in the area of the wound surface.

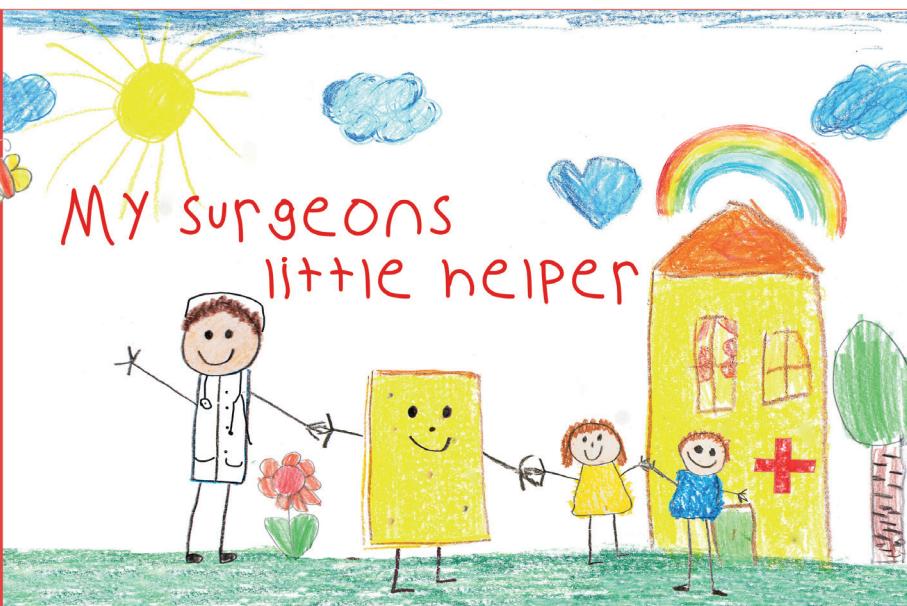
Reference: According to information and estimates from Dr. n. med. Anita Kalńska-Lipert und Dr. n. med. Małgorzata Nosek-Kościołek. Department of Paediatric Surgery and Traumatology, Prof. Antoni Gęba University Children's Hospital in Lublin, Poland: Case report: Use of TachoSil® during removal of a lymphatic and venous malformation tumour from the metatarsal region in an 11-month-old child.

4 Use of TachoSil® for sufficient sealing of a vein interposition in a 5-year old child



After open treatment of a supracondylar humerus fracture and creation a vein interposition due to acute occlusion of the brachial artery, TachoSil® (2 pieces: 1cm x 0.5cm) was applied for additional vessel sealing.

Reference: According to information and estimates from Joachim Suß, M.D., Chief of Surgery, Catholic children's hospital Wilhelmstift gmbh, Hamburg-Rahlstedt, Germany.



TachoSil® – four versions, three sizes*

Illustrated in original size

TachoSil

SEALANT MATRIX



*Not all versions are available in all countries

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 mm 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

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Link to Full SmPC or Prescribing Information:
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