TachoSil SEALANT MATRIX

Interesting facts about pediatric surgery

APPROVED also for children from 1 month TACHOSIL®

corzamedical

www.corza.com

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.

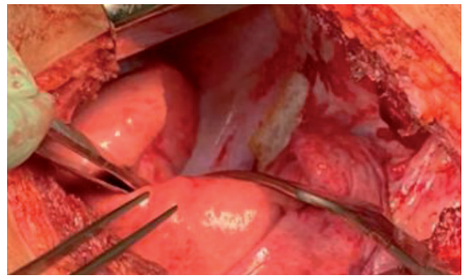
Pelizzo G, Arbustini E, Pasqua N, Morbini P, Calcaterra V. Thoracoscopic Treatment of Pneumothorax in Marfan Syndrome: Hemostatic Patch to Support Lung Resection Recovery. Case Rep Surg. 2018; 2018:7597215. doi: 10.1155/2018/7597215. PMID: 30254783; PMCID: PMC6142756.

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

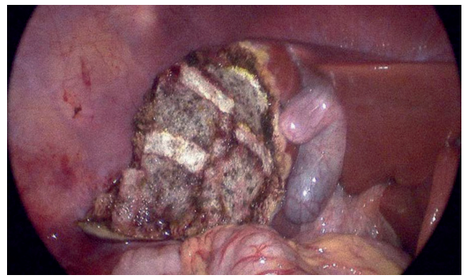
1 Use of TachoSil® for efficient hemostasis during emergency exploratory thoracotomy in an 13-year-old boy



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. Marzena Nosek-Kościołek, 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



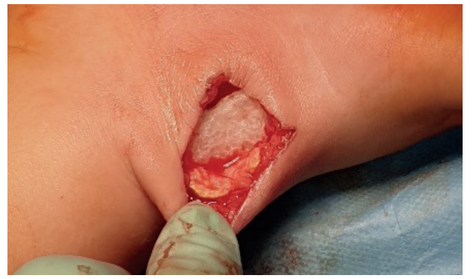
After removal of the hepatic cyst en bloc together with the attached hepatic parenchyma the resected surface was covered with TachoSil® to improve hemostasis.

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

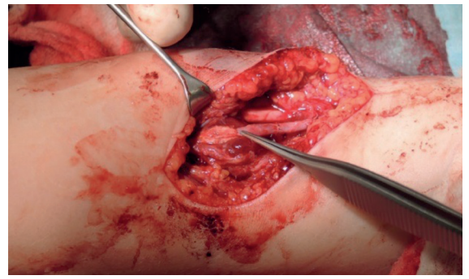
3 Application of TachoSil® for efficient hemostasis and sealing after tumor resection in an 11-month-old child



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.

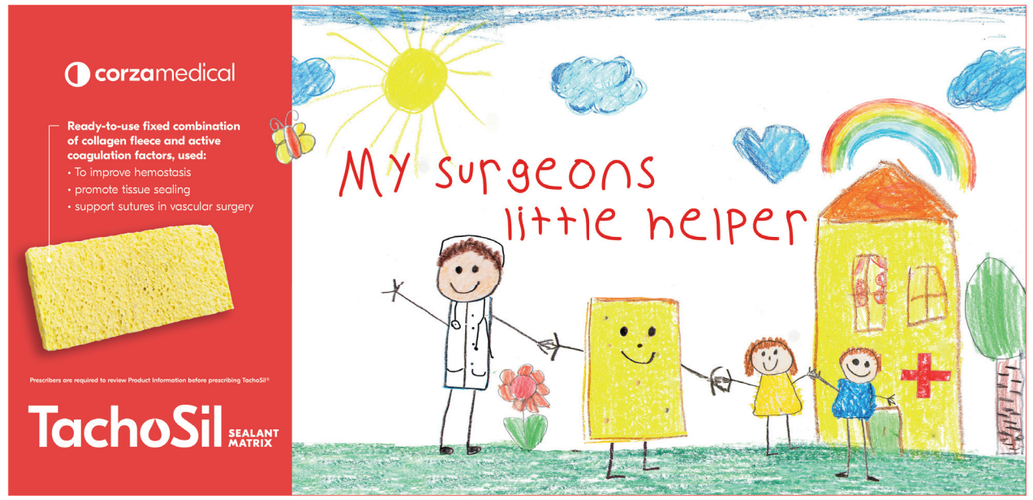
Reference: According to information and estimates from Dr. n. med. Anita Kalińska-Lipert und Dr. n. med. Marzena Nosek-Kościołek. Department of Paediatric Surgery and Traumatology, Prof. Antoni Gębala University Children's Hospital in Lublin, Poland: Case report: Use of TachoSil® during removal of a 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: 1 cm x 0.5 cm) 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 gem. 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 (coated with human fibrinogen and human thrombin)

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: An off-white sponge coated with human fibrinogen 5.5 mg and human thrombin 2.0 IU per cm^2. The active side of the sponge is marked by a yellow colour. Supplied, ready to use, in sterile packaging.

Indications: In adults and children from 1 month old, for supportive treatment in surgery for improvement of hemostasis, 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 number of sponges to be used is governed by the size of wound area, and the underlying clinical need for the patient. In clinical trials the individual dosages have typically ranged from 1–3 sponges. Sponges 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. The sponge should be pre-moistened in saline solution and applied immediately. The yellow, active side of the sponge is applied to the bleeding/leaking surface and held against it with a gentle pressure for 3–5 minutes. Pressure is applied with moistened gloves or a moist pad. If covered with blood, surgical instruments and gloves may be pre-moistened with physiological saline solution to avoid the sponge sticking to them. After pressing the sponge to the wound, the glove or the pad must be removed carefully. To avoid the sponge 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 sponge should be applied so that it extends 1–2 cm beyond the margins of the wound. Sponges should be overlapped if more than one is used and can be cut to the correct size and shaped if too large. 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. Allergic type hypersensitivity reactions are possible, as with any protein product. If hypersensitivity reactions occur, the administration 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 (foetal infection) and for immunodeficient patients or those who have increased erythropoiesis e.g. hemolytic anaemia. Risk of transmission of infective agents cannot be totally excluded, including pathogens of hitherto unknown nature. It is recommended to record the name and the batch number of the product administered to the patient.

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 use in human pregnancy or breastfeeding has not been established. Only administer to pregnant and breastfeeding women if clearly needed.

Undesirable Effects: Hypersensitivity or allergic reactions (in rare cases these reactions may progress to severe anaphylaxis; some cases of product residue causing granuloma); thromboembolism may occur if unintentionally 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.

Marketing Authorisation Holder: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf, Germany.

Marketing Authorisation Numbers: EU/1/04/277/001-005.

Date of revision of the text: March 2023

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/

www.corza.com

corzamedical