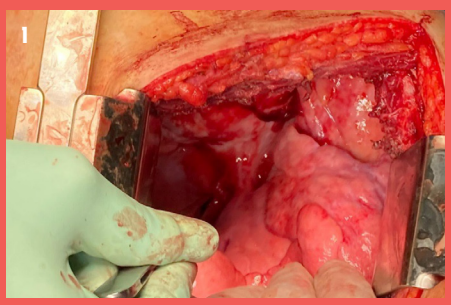
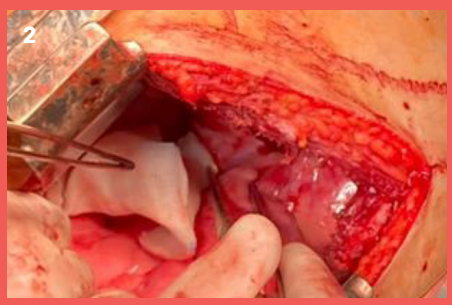
TachoSil SEALANT MATRIX

Case example: Use of TachoSil® for efficient hemostasis during emergency exploratory thoracotomy in a 13-year-old boy

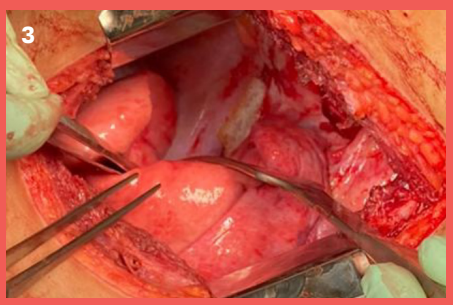
Bleeding into the pleural cavity.



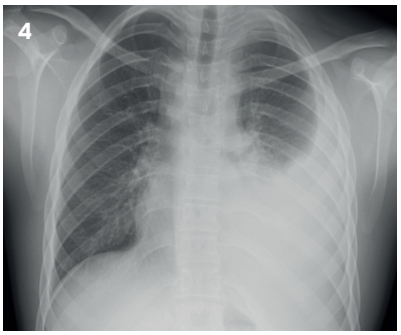
1: Surgical site with bleeding from the damaged pulmonary ligament.



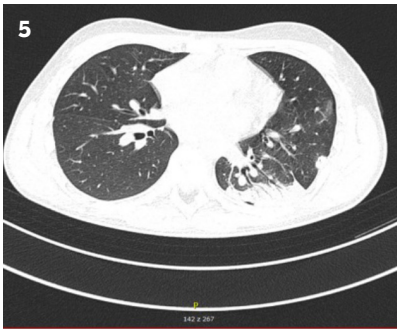
2: Application of TachoSil® 3.0 x 2.5 cm for persistent bleeding from the pleural cavity in the area of the pulmonary ligament after using standard methods



3: TachoSil® was gently pressed using a damp swab. 5 minutes after applying TachoSil® local bleeding from the area of the pulmonary ligament was successfully stopped.



4: Chest x-ray on the day of presentation in the emergency department: Area of increased opacity in the left pleural cavity due to fluid.



5: Chest CT scan on the day of presentation in the emergency department: Atelectatic and inflammatory lesions in the lower lobe of the left lung, with a predominance of atelectatic lesions, no signs of active bleeding.

Preliminary remarks:

- Isolated chest trauma in children is very rare because of an extremely flexible thorax on account of its cartilaginous structure.
- In cases of accidents injuries are usually closed and blunt.
- If the pleural cavity is found to be filled with fluid, a pleural suction drain must be used, an exploratory thoracotomy might be necessary.
- Blood loss into the pleural cavity may account for up to 30 – 40% of circulating blood, which is due to low vascular resistance and high pulmonary compliance.[1]
- TachoSil® can be used to improve hemostasis during surgery.

Patient history:

- Presentation of a 13-year-old boy in the emergency room with fainting spells at school and chest pains.
- Blunt chest trauma around 2 months earlier as a result of falling off his skateboard.
- Ultrasound of the pleural cavities: accumulated fluid in the left pleural cavity, with pleural thickening of 40 mm.
- Emergency insertion of a drain in the left pleural cavity, 1.500 ml of bloody pleural fluid was drained.
- The deterioration of a general condition at the second day of hospitalization: symptoms of hemorrhagic shock and indication for exploratory emergency thoracotomy.

Surgical procedure:

- The left pleural cavity was opened in the 6th intercostal space, 1 litre of clots under a intact left lung was found.
- The diaphragm contained tissue mass, which was removed.
- On the dome of the diaphragm a heavily bleeding artery was identified.

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. Case report: Use of the hemostatic agent TachoSil® during emergency exploratory thoracotomy in a 13-year-old boy due to bleeding into the pleural cavity.

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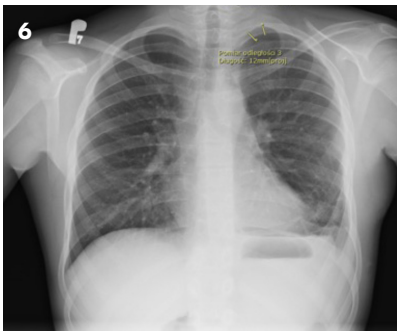
TachoSil SEALANT MATRIX

Case example:

Use of TachoSil® for efficient hemostasis during emergency exploratory thoracotomy in a 13-year-old boy. Bleeding into the pleural cavity.



6: Chest x-ray on the 7th postoperative day after removing the pleural drain: only slight traces of a pneumothorax at the top of the left pleural cavity.

- Moreover, there were multi-site venous bleeding in the pleural cavity as a result of injury to the pulmonary ligament.
- Hemostasis was performed using standard methods.
- As the bleeding from the pleural cavity in the area of the pulmonary ligament still persisted, TachoSil® was used to improve hemostasis.
- 5 minutes after the application of TachoSil® the bleeding stopped, localised hemostasis was found to have been successful.
- A chest drain was inserted through the 7th intercostal space and left in the pleural cavity. The thoracic injuries were closed layer by layer in the usual manner.

Conclusion:

- TachoSil® in children as a ready-to-use product is an effective and rapid way to improve hemostasis where standard techniques are insufficient, especially when it is not possible to stop the bleeding of several small blood vessels.
- As the absorption time of TachoSil® is long (28 days to 13 weeks)[2-4], the lung can expand in case of pleural drainage and provides additional mechanical protection for the matrix-covered surface.
- The use of TachoSil® helps to make surgery safer and to reduce surgical time.

Sources: 1. Grochowskiego J. Urazy u dzieci pod redakcją. Wydaw.Lekarskie PZWL, 2000; 93-97. ISBN 83-200-2427-7. 2. Shigeta K et al. The efficacy of the TachoSil binding suturing technique in laparoscopic partial nephrectomy to prevent the development of pseudoaneurysm. Asian Journal of Surgery 2020; 43; 668-675. 3. Filosso PL, Guerrera F, Sandri A, Zenga F. Efficacy and safety of human fibrinogen-thrombin patch (TachoSil®) in the management of diffuse bleeding after chest wall and spinal surgical resection for aggressive thoracic neoplasms. J Thorac Dis 2016;8(1):E152-6. 4. Prescribing Information TachoSil®, current version.

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. Case report: Use of the hemostatic agent TachoSil® during emergency exploratory thoracotomy in a 13-year-old boy due to bleeding into the pleural cavity.

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 color. 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 (fetal infection) and for immunodeficient patients or those who have increased erythropoiesis e.g. hemolytic anemia. 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 Authorization Holder: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf, Germany.

Marketing Authorization 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/