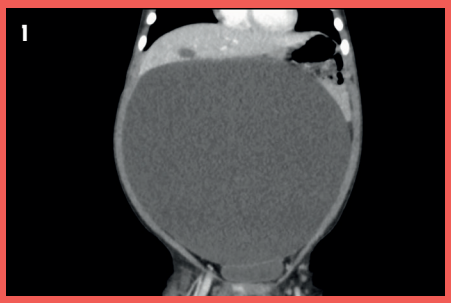
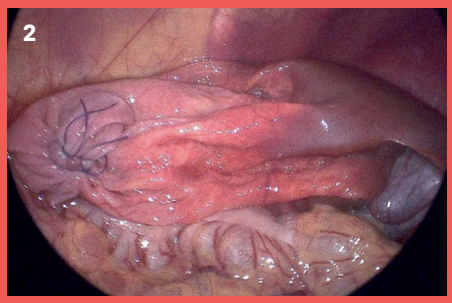
TachoSil SEALANT MATRIX

Case example:
Use of TachoSil® after laparoscopic excision of an enormous hepatic cyst in an 18-month-old child

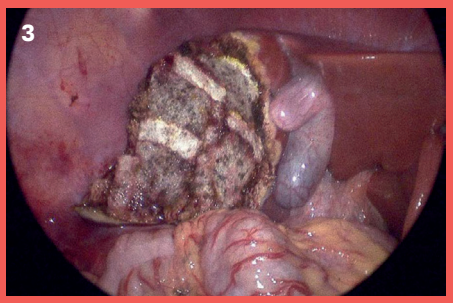
Covering the resected hepatic surface with TachoSil® for better hemostasis and tissue sealing.



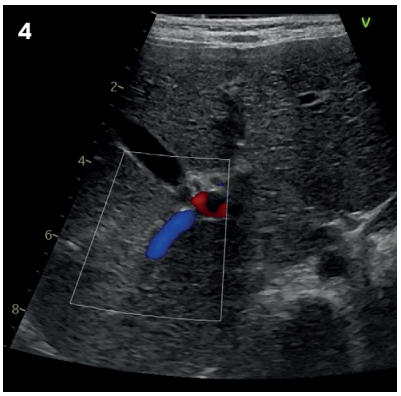
1: Dynamic computed tomography image of a huge abdominal cyst. The wall was thin, smooth, and not enhanced by contrast agent.



2: Intraoperative findings. After decompression, laparoscopy revealed that the cyst originated from the inferior surface of liver segments 5 and 6.



3: Post-excision view. The cyst with attached hepatic parenchyma was completely removed. The resected surface was covered with a collagen fleece.



4: Ultrasonography one year after the operation: a good portal flow at the posterior branch and no liver atrophy.

Preliminary remarks:

- Simple hepatic cysts are common lesions in adults, but rare in children.
- Because of their benign nature, simple hepatic cysts are not detected until they grow too large to be easily diagnosed and resected with minimally invasive procedures.
- A complete excision is desirable because there is a possibility of recurrence or other diseases that require total removal, including hydatid cysts and mesenchymal hamartomas.
- TachoSil® can be used to improve hemostasis and promote tissue sealing.

Patient history:

- An 18-month-old girl with abdominal distension but without abdominal pain.
- Ultrasonography: a large unilocular, sonolucent cyst occupying the entire abdomen.
- Abdominal computed tomography (CT): enormous unilocular cyst occupying the entire abdomen, hepatic origin of the cyst.
- Indication for resection by laparoscopic surgery.

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. Surgical Case Reports (2022) 8:87 https://doi.org/10.1186/s40792-022-01445-2.

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Surgical procedure:

- The umbilicus was opened by the three-triangular-skin-flap technique, thus creating a working space that enabled laparoscopic surgery.
- A purse-string suture was placed on the partially exposed cyst, and a catheter was inserted without spillage.
- 1.520 ml of yellow serous fluid was aspirated. The cystic fluid did not contain bile.
- The cyst was decompressed.
- A single-port laparoscopic surgery device was applied to the umbilicus, and another 3-mm port was placed in the right lower abdomen.
- Using an ultrasonic coagulation incision device, the cyst was excised en bloc together with the attached hepatic parenchyma.
- To improve hemostasis the resected surface was covered with TachoSil®.

Conclusion:

- The operating time was 125 min, and the blood loss was only 50 g.
- The child was discharged on the 4th postoperative day with no complications.
- At the 1-year follow-up the girl felt well.

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. Surgical Case Reports (2022) 8:87 https://doi.org/10.1186/s40792-022-01445-2.

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/