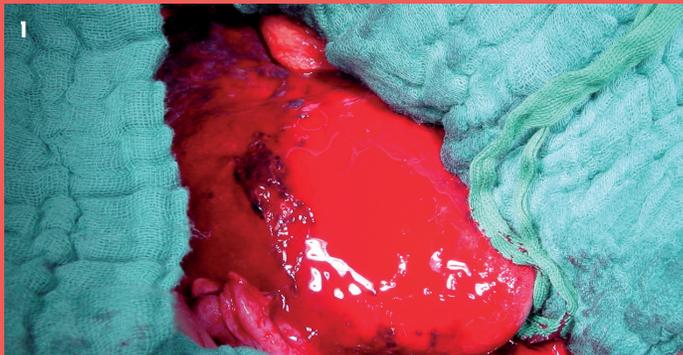


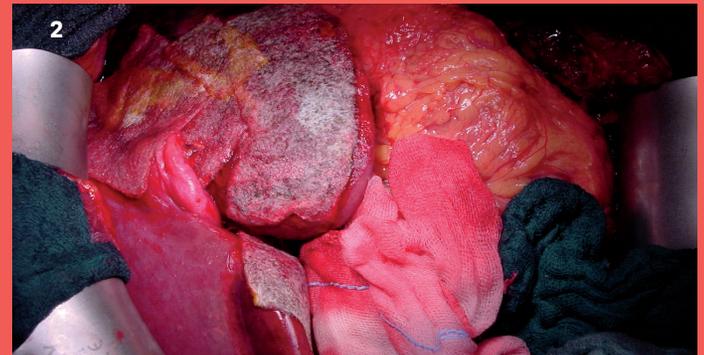
Case example:

Hemostasis following traumatic liver injury

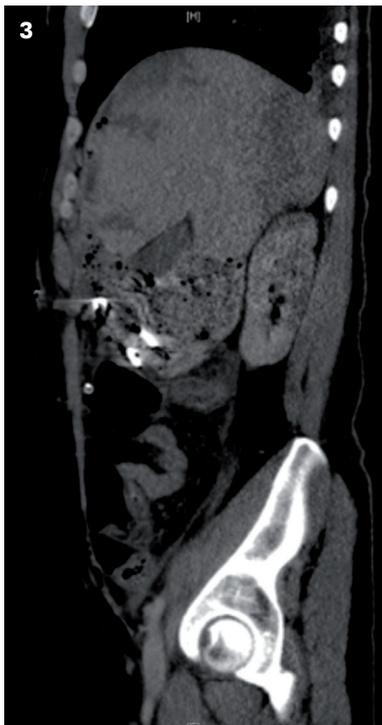
Hemostasis of hepatic bleeding using a closed cell collagen matrix.



1: Injury to the left lobe of the liver.



2: Hemostasis using TachoSil®.



3: Spiral CT for trauma with imaging of the ventral laceration of the left liver lobe.

Preliminary remarks:

- After the spleen, the liver is the second most commonly affected organ when it comes to blunt abdominal trauma.
- The main complications are blood loss, loss of functional hepatic tissue and the occurrence of necroses and gallbladder fistula.
- Due to the parenchymatic tissue, the surgical treatment options are limited.
- Emergency partial liver resection is associated with high perioperative morbidity and leads to the loss of valuable liver tissue.
- The application of a fibrin sealant patch facilitates adequate hemostasis and superficially leads to capsule stabilization. It can also be combined with liver packing.

Patient history:

- 31-year-old male patient with a traumatic injury to the left lobe of the liver (Moore Score II – III°) further to a violent altercation.

Case example:

Hemostasis following traumatic liver injury. Hemostasis of hepatic bleeding using a closed cell collagen matrix.

Surgical procedure:

- Emergency laparotomy.
- Exploration of the upper abdomen, manual compression of the left liver lobe and exclusion of further intraabdominal injuries.
- Treatment of the ventral capsule of the left liver lobe using four large TachoSil® patches (9.5 x 4.8 cm).
- Once cessation of bleeding is confirmed, insert drain and definitive closure of the abdominal wall.

Conclusion:

- The operating time was reduced by 60 minutes.
- Blood reserves could be spared.
- The period spent in intensive care was shortened from around ten days to three.
- Patient hospitalization period was reduced from approx. 21 days to 14 days.
- Atraumatic and tissue-conserving surgery was possible.
- The likelihood of postoperative complications was lower.
- Further surgery was not necessary.
- In diffuse superficial liver capsule injuries, fibrin sealant patches offer a good alternative to overstitching or liver packing with their frequent complications and the need for a second look laparotomy.

Reference: According to information and estimates from Dr. Endres John, University Hospital and Polyclinic for General, Visceral and Vascular Surgery, Halle, Germany.

TachoSil® SEALANT MATRIX (human fibrinogen, human thrombin)

Presentation: TachoSil® is a topical fibrin sealant patch consisting of human fibrinogen and human thrombin coated onto an equine collagen sponge. The active side of the patch is yellow in color due to the presence of a colorant riboflavin (E101); and the non-active side is off-white in color.

Indication and Important Safety Information

Indications: TachoSil® is a fibrin sealant patch indicated for use with manual compression in adult and pediatric patients as an adjunct to hemostasis in cardiovascular and hepatic surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Limitations for Use: • TachoSil® cannot safely or effectively be used in place of sutures or other form of mechanical ligation for the treatment of major arterial or venous bleeding. • Not for use in children under one month of age.

Dosage & Administration: For topical use on cardiovascular or hepatic tissue only • Determine the number of patches to be applied by the size of the bleeding area. • Apply the yellow, active side of the patch to the bleeding area. • When applying TachoSil®, do not exceed the maximum number of patches.

Refer to the Full Prescribing Information for details on

administration and maximum number of patches.

Contraindications: • Do not apply TachoSil® intravascularly. Intravascular application of TachoSil® may result in life threatening thromboembolic events. • Do not use TachoSil® in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins.

Warnings & Precautions:

Thrombosis. Thrombosis can occur if TachoSil® is applied intravascularly. Ensure that TachoSil® is applied to the surface of cardiac, vascular, or hepatic tissue only.

Hypersensitivity Reactions. Hypersensitivity or allergic/anaphylactoid reactions may occur in patients receiving TachoSil® for the first time or may increase with repetitive applications.

Infection. Avoid application to contaminated or infected areas of the body, or in the presence of active infection.

Adhesions. TachoSil® contains collagen, which may adhere to bleeding surfaces. May carry a risk of gastrointestinal obstruction in abdominal surgery due to tissue adhesions. To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the desired application area are adequately cleansed before administration of TachoSil®.

Compression. Avoid packing in cavities or closed spaces

because this may cause compression of underlying tissue.

Dislodged Material. Use only the minimum number of TachoSil® patches necessary to achieve hemostasis. Do not pack. Remove unattached pieces of TachoSil®.

Transmissible Infectious Agents. May carry a risk of transmitting infectious agents, such as viruses, and theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent and the Creutzfeldt-Jakob disease (CJD) agents.

Use in specific populations: Pediatric Use: Use of TachoSil® in children under the age of one month may be unsafe or ineffective due to small size and limited ability to apply the patch as recommended.

Adverse Reactions: The adverse reactions reported in more than 1% of patients during clinical trials were anemia, nausea and vomiting, fever, abdominal pain, increased white blood cell count, ascites, itching, atrial fibrillation, pleural effusion, gastrointestinal hemorrhage, wound infection, hypophosphatemia, urinary tract infection, and post-procedural bile leakage in hepatic surgery.

Refer to the Full prescribing Information for details on, contraindications, warnings, precautions, and adverse reactions.

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

US License no. 2294. **Revision date:** 11/2022