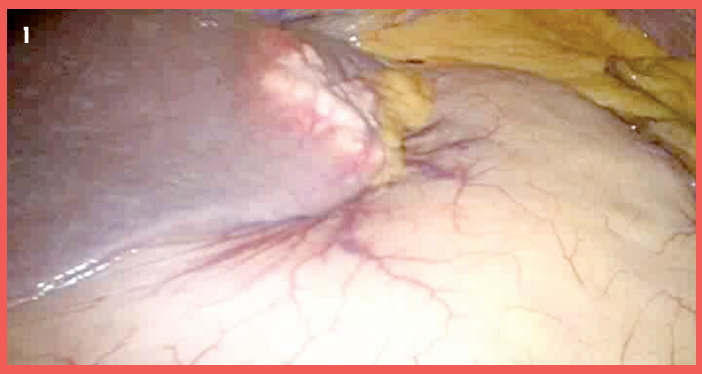
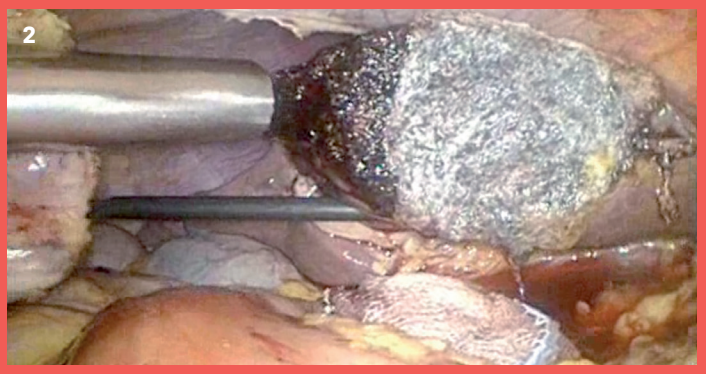
TachoSil®
Fibrin Sealant Patch

Case example:
Hemostasis of liver resection surfaces in the case of hepatocellular carcinoma

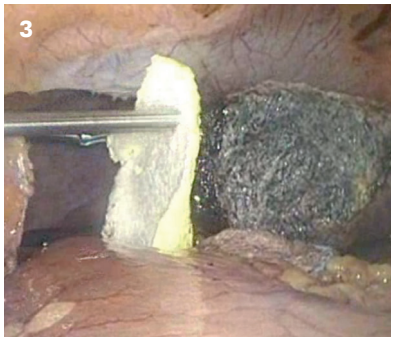
Laparoscopic left lateral sectorectomy of liver segments II and III.



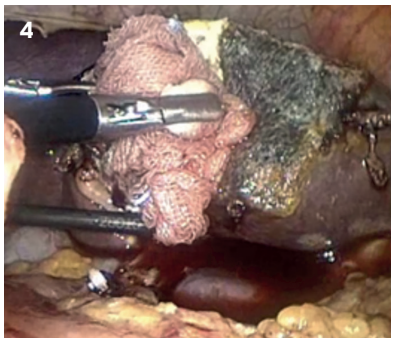
1: View of the tumor.



2: Treatment of the resection surfaces with an initial fibrin sealant patch.



3: Treatment of the resection surfaces with a second fibrin sealant patch.



4: The fibrin sealant patch is pressed on using a moist swab. Utilizing TachoSil® on the parenchymal surfaces reduces the risk of secondary bleeding and gallbladder.

Preliminary remarks:

- Air and liquid tight control of liver resection surfaces reduces the risk of secondary bleeding and gallbladder leakage and can be useful in the prevention of postoperative complications.

Patient history:

- 75-year-old female patient with histologically confirmed hepatocellular carcinoma (HCC) of the left liver lobe (25 x 30 mm) (first diagnosed 06/2013). Also multiple hepatic cysts in the liver and kidney area, pituitary microadenoma of consistent size (first diagnosed 2004).
- Status post appendectomy (AE), status post two occurrences of apoplexy (use of Clopidogrel for up to seven days preoperatively), high blood pressure WHO Grade III.

Surgical procedure:

- Laparoscopic inspection of the abdomen: In the left liver lobe, in segment III, a 3 cm large mass, multiple liver cysts, right kidney shows large cyst, adhesions post AE.
- Inspection of left upper abdomen: Enlarged lymph nodes along the hepatic artery, lymph node sampling along the common hepatic artery, the hepatic artery proper and the hepatoduodenal ligament.
- Laparoscopic left lateral sectorectomy of liver segments II and III and specimen recovery.

Reference: According to information and estimates from Dr. Christoph Prinz, Clinic for General, Visceral and Vascular Surgery, KMG Hospital Güstrow GmbH – Academic Teaching Hospital at University of Rostock, Germany.

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Case example:

Hemostasis of liver resection surfaces in the case of hepatocellular carcinoma.

Laparoscopic left lateral sectorectomy of liver segments II and III.

- Hemostasis achieved using argon beamer and using two pieces of TachoSil® (4.8 x 4.8 cm).
- Lavage, frozen section analysis, final site control without fluids, insertion of a Robinson type 21 drainage system, postoperative fast track protocol.

Conclusion:

- Time until hemostasis shortened by approx. 10 minutes.
- Blood reserves and blood substitutes spared.
- Drain removed as early as two days postoperatively.
- Period spent in intensive care: One day instead of the usual three.
- Hospitalization period reduced from eight to six days.
- Likelihood of postoperative complications reduced.

Reference: According to information and estimates from Dr. Christoph Prinz, Clinic for General, Visceral and Vascular Surgery, KMG Hospital Güstrow GmbH — Academic Teaching Hospital at University of Rostock, 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.

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