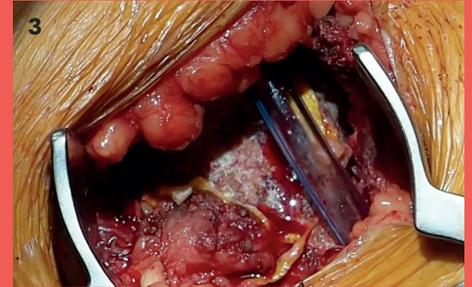
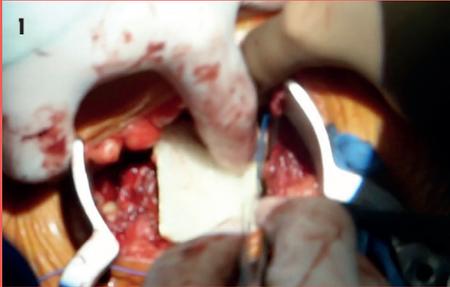


Case example:

Use of TachoSil® after transcatheter aortic valve implantation (TAVI*) due to aortic valve stenosis

Enhanced hemostasis resulting in air and liquid tight barrier.



1 – 2: Application of TachoSil® at the cardiac apex.

3: Local dry and additionally reinforced conditions after application of TachoSil®.

Preliminary remarks:

- Transapical transcatheter aortic valve implantation (TAVI) is a gentler treatment strategy than open surgery for the indication for an aortic valve replacement, especially for elderly and multimorbid patients.
- TAVI is associated with an increased perioperative risk and should be performed by an interdisciplinary team in a hybrid operation.
- Additional support of the puncture site at the cardiac apex can contribute to the success of the operation.

Patient history:

- 70-year-old patient with high-grade aortic valve stenosis.
- Status post ACVB (aortocoronary venous bypass) operation.
- Indication for TAVI.

Surgical procedure:

- Re-intervention.
- Anterolateral minithoracotomy on the left side for transapical implantation of a new aortic valve.
- After successful implantation and withdrawal of the catheter, application of TachoSil® (4.8 x 4.8 cm) at the cardiac apex.

* TAVI: transcatheter aortic valve implantation

Reference: According to information and estimates from Prof. Dr. Martin Czerny, Freiburg University Heart Centre, Bad Krozingen GmbH, Germany.

Case example:

Use of TachoSil® after transcatheter aortic valve implantation (TAVI) due to aortic valve stenosis. Enhanced hemostasis resulting in air and liquid tight barrier.

Conclusion:

- Time until hemostasis was reduced by 10 minutes.
- The additional application of TachoSil® resulted in the air and liquid tight closure of the cardiac apex.
- Moreover, the operation was tissue sparing, which is an advantage in elderly patients who often have fragile tissue.
- The use of TachoSil® for hemostasis in the area of the cardiac apex after TAVI is standard procedure in our hospital.

Reference: According to information and estimates from Prof. Dr. Martin Czerny, Freiburg University Heart Centre, Bad Krozingen GmbH, 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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