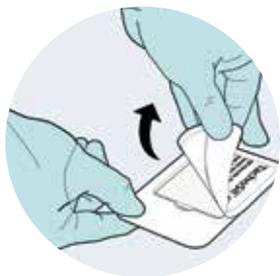


Open procedures¹



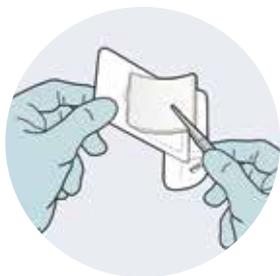
1.

Open the peel-away film of the external packaging (aluminium blister) – can be opened in a non-sterile zone.



2.

Open the packaging in a sterile zone with sterile gloves.



3.

Remove the patch from the sterile packaging with forceps.



4.

The patch can be trimmed to size, but it is important that it extends 1–2 cm beyond the wound margin.



5.

If the wound is dry, it is recommended to moisten the TachoSil® before application. If the wound is already wet, it can be applied dry.



6.

The patch is applied with the yellow active side facing the treated area. If larger areas need to be treated with more than one patch, they should be overlapped like roof tiles.



7.

The patch must be pressed in place gently for up to 3 minutes, ideally with a moist compress.



8.

Remove the moist compress carefully, using forceps if necessary.

Minimally invasive procedures



1.

Insert

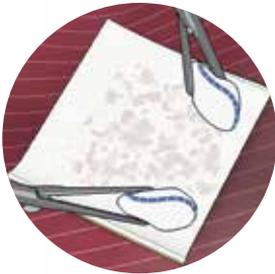
After pre-compression and self-rolling, the TachoSil® patch is inserted through a dry trocar ≥ 10 mm.



2.

Unroll

The patch is unrolled with the yellow side on the wound.



3.

Gently compress

TachoSil® is moistened and adheres to the wound after being manually compressed in place.



Tips & tricks for the use of TachoSil®

Open procedures¹

- Gloves and instruments should be completely dry to prevent the patch from adhering to them.
- If the wound surface is dry, the patch should not be moistened until immediately before application. If the wound surface is wet, dry patch is applied.
- It is essential to apply the yellow active side to the wound using slight pressure for up to 3 minutes.
- If larger areas need to be treated with more than one patch, they should be overlapped like roof tiles (≥ 1 cm).
- The patch can be trimmed to any shape or size, while it is dry.
- The patch can be compressed to make it easier to shape.

Minimally invasive surgery (MIS)¹

- Gloves and instruments should be completely dry to prevent the patch from adhering to them.
- The patch should be dry when passed through the trocar.
- In MIS a moist gauze should be used to compress TachoSil® for up to 3 minutes.
- No additional instruments are needed.

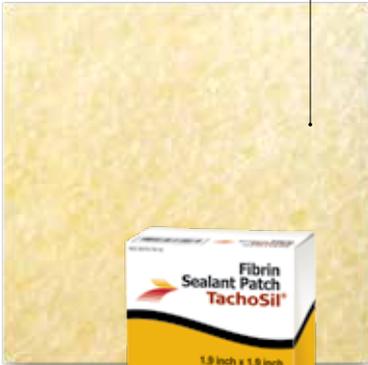


What sizes is TachoSil[®] available in?

Illustrated in original sizes

LARGE 9.5 x 4.8 cm

MIDI 4.8 x 4.8 cm



Required information



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



TachoSil[®]
Fibrin Sealant Patch

Ordering Information

McKesson 3PL Distribution
Telephone (1-833-433-1253) or
Email: corzacs@mckesson.com

Corza Medical

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MA 02090