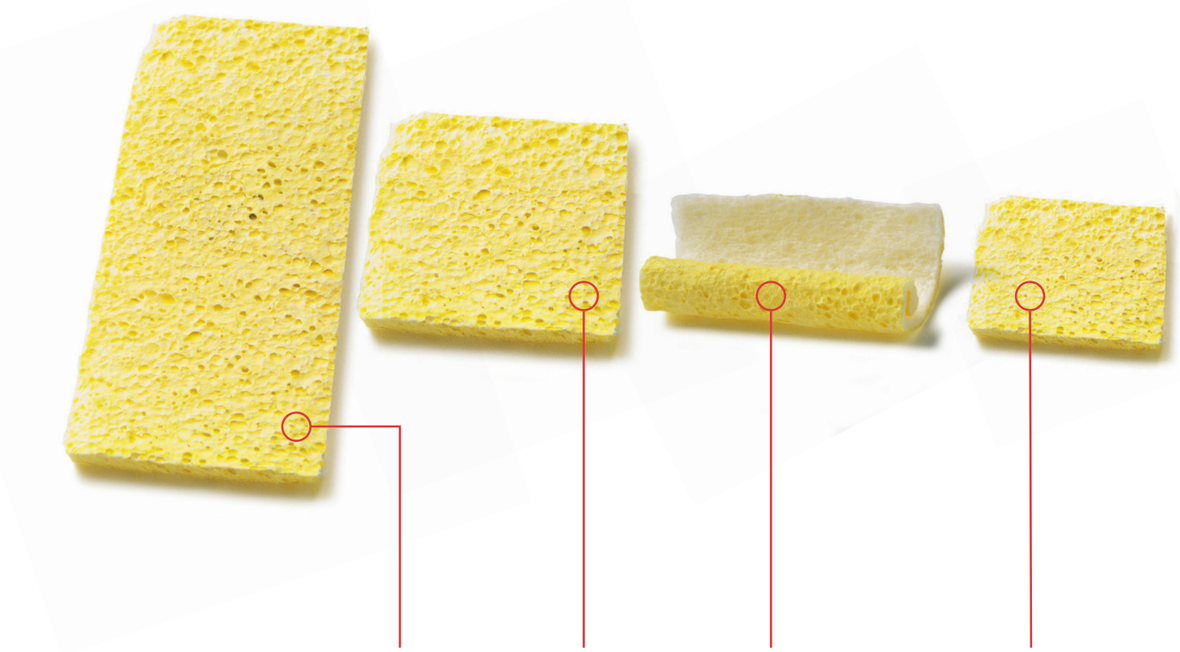
TachoSil® SEALANT MATRIX

TachoSil® - Four versions, three sizes.

Illustrations represent actual size



	MAXI	MIDI	Pre-rolled	MINI
Size	9.5 x 4.8 cm	4.8 x 4.8 cm	4.8 x 4.8 cm	3.0 x 2.5 cm
Package	1 patch	2 patches	1 patch	1 or 5 patches

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 cm². The active side of the sponge is marked by a yellow colour. 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 (foetal infection) and for immunodeficient patients or those who have increased erythropoiesis e.g. hemolytic anaemia. 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 Authorisation Holder:** Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf, Germany. **Marketing Authorisation 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/

www.corza.com

TSGLOB/23/006

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TachoSil® SEALANT MATRIX

New indication in pediatric surgery

Ready-to-use fixed combination of collagen fleece and active coagulation factors, used:

- to improve hemostasis
- promote tissue sealing
- suture support in vascular surgery

Prescribers are required to review Product Information before prescribing TachoSil®

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TachoSil® SEALANT MATRIX

Literature review

TachoSil® versus Surgicel®* Original for the Secondary Treatment of Local Bleeding in Adult and Pediatric Patients Undergoing Hepatic Resection Surgery Study

TC-2402-040-SP

Randomised, open-label, multicentre study that compared the efficacy and safety of TachoSil® for the secondary treatment of local bleeding after hepatic resection in adults (aged 17 years or older) and pediatric patients (new-born to 16 years).

Population:

- 20 pediatric patients recruited to TachoSil® arm. 8 randomised to TachoSil® arm; 12 included in the pediatric extension part to receive TachoSil® (no comparator was involved).
- Comparator group: 114 adults randomised to TachoSil® group.

Primary efficacy endpoint:

- Intraoperative hemostasis at target bleeding site within 3 minutes of application.

Results:

Proportion of patients achieving hemostasis within 3 minutes		
TC-2402-040-SP		
Adults (FAS n=114)	*Children*	
	FAS n=8	SAF n=20
80.7% 95% CI, 72.3 - 87.5	**87.5%** 95% CI, 47.3 - 99.7	**85%** 95% CI, 62.1 - 96.8

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Innovative Surgical Management of NEC – Results of 52 Consecutive Cases.

Carbon RT, Reingruber B, Baar S, Kriegelstein S, Schroth M.
7th World Congress on Trauma, Shock, Inflammation and Sepsis, pp. 29-44

Population and methods:

- TachoSil® was employed for sealing management and impregnated with gentamicin 120 mg.
- 52 preterm infants underwent laparotomy on the basis of tissue management with antimicrobially effective patch-bound sealing.
- In total, 84 operations were performed: 252 fibrin gluings with gentamicin 120 mg impregnated with TachoSil®.

Results:

- **142 (56.4%) sealings ultimately replaced suturing techniques** (anastomosis, overstitching).
- **110 sealings (43.6%) were carried out and did not involve resection measures;** a focal patch was applied instead to augment the intestinal wall.
- With the aid of the sealing technique, an average of 17.8 cm (range: 1.8-38 cm) of intestine (10.7% of the mean total length) per patient could be conserved.

*SURGICEL™ Original Absorbable Hemostat belongs to Ethicon, a Johnson&Johnson company.

New indication in pediatric surgery

The use of a fibrinogen/thrombin-coated equine collagen patch in children requiring reoperations for congenital heart disease.

Vida VL, De Franceschi M, Barzon E, Padalino MA, Scattolin F, Stellin G.
J.Cardiovasc Surg (Torino). 2014 Jun; 55(3):401-6.

Population and methods:

- 117 patients (median 2.1 years) reoperated on for treatment of congenital heart disease.
- Control group receiving other sealant or hemostatic agents during hemostasis as co-adjuvant for treatment of intraoperative bleeding.

Results:

- The percentage of patients requiring intraoperative packed **red blood cell transfusion was significantly lower in the TachoSil® group (n=90)** compared to the control group (n=27, p=0.004).
- The results of this study **confirmed the efficacy of TachoSil®** in the suppression of intraoperative bleeding in a pediatric population, suggesting that the response to treatment is adequate, as seen in adults.

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Efficacy of a fibrinogen/thrombin-coated equine collagen patch in controlling lymphatic leaks.

Vida VL, Padalino MA, Barzon E, Stellin G.
J Card Surg. 2012 Jul; 27(4):441-2.

Population and methods:

- A retrospective analysis of 6 cases of pediatric patients who underwent heart surgery. The median age at surgery was 8.8 months (range 5 to 38 months).
- The TachoSil® patch was used as first-choice therapy in 4 patients and as second-choice therapy in 2 for lymphatic leakage control.

Results:

- **In all 6 cases, the TachoSil® patch stopped the lymphatic leak.**
- The safety and efficacy of TachoSil® in preventing intraoperative lymphatic leaks, e.g. due to injury of the thoracic duct, was confirmed.

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