TachoSil SEALANT MATRIX

Interesting facts about Urology

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TachoSil® – selected studies...

Clinical studies

Bryniarski P, Rajwa P, Życzkowski M, Taborowski P, Kaletka Z, Paradysz A. A non-inferiority study to analyze the safety of totally tubeless percutaneous nephrolithotomy. Adv Clin Exp Med. 2018;27(10):1411-1416. doi: 10.17219/acem/71196. PMID: 30058789.

Cormio L, Perrone A, Di Fino G, Ruocco N, De Siati M, de la Rosette J, Carrieri G. TachoSil® sealed tubeless percutaneous nephrolithotomy to reduce urine leakage and bleeding: outcome of a randomized controlled study. J Urol. 2012;188(1):145-50. doi: 10.1016/j.juro.2012.03.011. Epub 2012. PMID: 22591964.

De Rosa P, Valeriani G, Barbato G, Cerbone V, Ciccone M, Russo E, Vicedomini D. Postexplant residual cavity hemostasis with a TachoSil patch. Transplant Proc. 2011;43(4):1069-71. doi: 10.1016/j.transproceed.2011.01.134. PMID: 21620055.

Shigeta K, Matsumoto K, Abe T, Komatsuda A, Takeda T, Mizuno R, Kikuchi E, Asanuma H, Arita Y, Akita H, Jinzaki M, Miyajima A, Oya M. The efficacy of the TachoSil binding suturing technique in laparoscopic partial nephrectomy to prevent the development of pseudoaneurysm. Asian J Surg. 2020;43(6):668-675. doi: 10.1016/j.asjsur.2019.09.002. Epub 2019. PMID: 31629637.

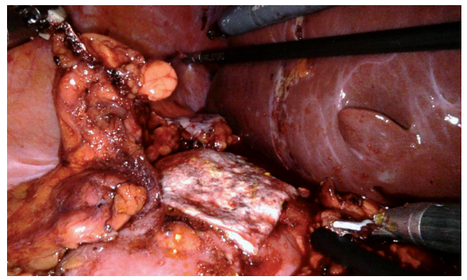
Simonato A, Varca V, Esposito M, Venzano F, Carmignani G. The use of a surgical patch in the prevention of lymphoceles after extraperitoneal pelvic lymphadenectomy for prostate cancer: a randomized prospective pilot study. J Urol. 2009;182(5):2285-90. doi: 10.1016/j.juro.2009.07.033. Epub 2009. PMID: 19762048.

Sokolakis I, Pyrgidis N, Hatzichristodoulou G. The use of collagen fleece (TachoSil) as grafting material in the surgical treatment of Peyronie's disease. A comprehensive narrative review. Int J Impot Res. 2021. doi: 10.1038/s41443-020-00401-8. Epub ahead of print. PMID: 33452519.

Stolzenburg JU, Do M, Kallidonis P, Ghulam N, Hellawell G, Haefner T, Liatsikos EN. Hemostasis during nerve-sparing endoscopic extraperitoneal radical prostatectomy. J Endourol. 2010;24(4):505-9. doi: 10.1089/end.2009.0160. PMID: 19619063.

Case examples

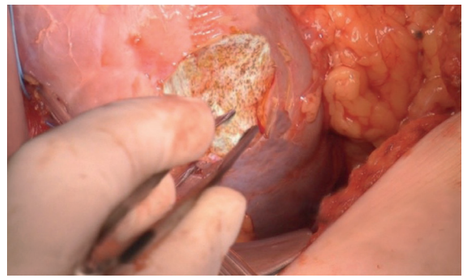
1 TachoSil® for efficient hemostasis in da Vinci robotic-assisted partial right nephrectomy due to a renal tumour



The application of TachoSil® reduced the time until hemostasis, the operating time and the duration of the hospital stay. The operation was tissue conserving, organ sparing and with a smaller probability of postoperative complications.

Reference: According to information from Prof. Dr. Axel S. Merseburger, Department of Urology, Schleswig-Holstein University Hospital. Lübeck.

2 TachoSil® for efficient hemostasis in nephron sparing surgery



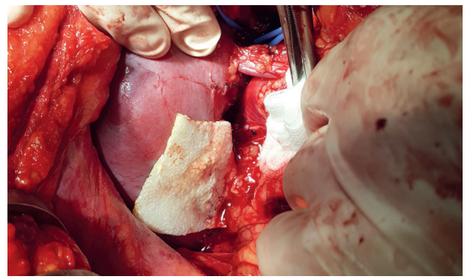
The use of TachoSil® mitigated the risk of parenchymal bleeding, minimized the organ damage by lack of vascular pedicle occlusion and prevention of hemostatic suture placement. The renal parenchymal bleeding time was shorter and lasted only 3 minutes.

Reference: According to information from Dr. hab. n. med. Tomasz Drewniak, Krzysztof Sołtys, Jacek Jakubowski, Maciej Rzepecki. Department of Urology, Rydygier Memorial Hospital, Cracow, Poland.

...and case examples

Case examples

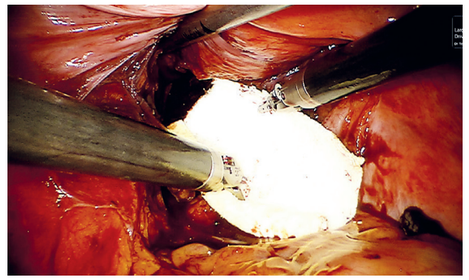
3 TachoSil® for efficient hemostasis in the case of a single kidney stab wound



The use of TachoSil® led to a reduction in the hemostasis time, mitigated the risk of complications and increased the chance of saving the kidney. Application of TachoSil® in this case has allowed for efficient treatment of a kidney stab wound.

Reference: According to information from Tomasz Borkowski, Grzegorz Pędzisz, Kamila Żebrowska. Department of General, Oncological and Functional Urology, Medical University of Warsaw, Poland.

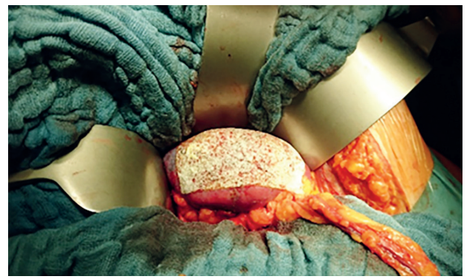
4 Pre-rolled TachoSil® for efficient hemostasis and sealing in a da Vinci-assisted radical prostatectomy due to prostate carcinoma



The use of Pre-rolled TachoSil® led to a reduction in the hemostasis time and the tissue near the tumour could be spared. By omitting coagulation in the area of the vessel-nerve bundle, potentially possible nerve damage could be avoided.

Reference: According to information from PD Dr. med. Dogu Teber, Urology Department, UniversitätsKlinikum Heidelberg.

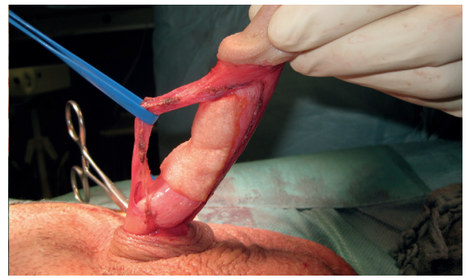
5 TachoSil® as a hemostatic agent during kidney transplantation



The application of TachoSil® reduced the bleeding from the vascular anastomoses and decreased the incidence of perioperative perirenal and retroperitoneal haematoma after kidney transplantation.

Reference: According to information from Prof. Dr. med. Dariusz Janczak. Department of Surgery, 4th Military Hospital, Department of Vascular, General and Transplantation Surgery, Wrocław Medical University, Wrocław, Poland.

6 TachoSil® as a sealing material for closing a defect after plaque excision due to induratio penis plastica (IPP)



The use of TachoSil® allowed an atraumatic hemostasis and defect coverage. No harvesting and adaptation of autologous graft material was necessary. The operation time could be reduced by approx. 60 minutes.

Reference: According to information from PD Dr. med. Georgios Hatzichristodoulou, Chief Physician, Urology Department, Martha-Maria Hospital Nuremberg.

TachoSil® — Four versions, three sizes*

Illustrated in original size

TachoSil SEALANT MATRIX

	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 Patch	5 Patches
PZN	03101150	03101167	10963461	03101204	03103841
Article Number	1130677	1130693	6111405	1130699	1130702

*Not all versions are available in all countries

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TachoSil SEALANT MATRIX

TachoSil Sealant Matrix (*5.5* mg per cm² of human fibrinogen, 2.0 IU per cm² of human thrombin)

Statement: Before prescribing, consult/refer to the full prescribing information. **Presentation:** An off-white sealant matrix. The active side of the matrix is coated with fibrinogen and thrombin, is marked by a yellow colour. Supplied, ready to use, in sterile packaging. **Legal Classification:** Restricted prescription only medicine. **Indications:** In adults and children from 1 month old, for supportive treatment in surgery for improvement of haemostasis, 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 quantity to be applied is governed by the size of wound area, and the underlying clinical need for the patient. In clinical studies, the individual dosages have typically ranged from 1-3 units (9.5 cm x 4.8 cm); application of up to 10 units has been reported. For smaller wounds, the smaller size matrices (4.8 cm x 4.8 cm or 3.0 cm x 2.5 cm) or the pre-rolled matrix (based on a matrix of 4.8 cm x 4.8 cm) is recommended. TachoSil 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. For Flat TachoSil, the sterile package should be pre-moistened in saline solution and applied immediately. The yellow, active side of the matrix is applied to the bleeding/leaking surface and held against it with a gentle pressure for 3-5 minutes. For pre-rolled TachoSil, after removing from the sterile package, it should be applied immediately through the trocar without pre-moistening. The yellow, active side of the matrix is applied to the bleeding/leaking surface using e.g., a pair of cleansed forceps and held against it with a moist pad under gentle pressure for 3-5 minutes. Pressure is applied with moistened gloves or a moist pad. Avoid TachoSil sticking to surgical instruments, gloves or adjacent tissues covered with blood by cleansing them before application. After pressing TachoSil to the wound, the glove or the pad must be removed carefully. To avoid TachoSil 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 active side of TachoSil should be applied so that it extends 1-2 cm beyond the margins of the wound. If more than one matrix is used, they should overlap. TachoSil can be cut to the correct size and shaped if too large. In neurosurgery, TachoSil should be applied on top of the primary dura closure. **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 anastomoses surgery. Life threatening thromboembolic complications may occur if the preparation is applied intravascularly. Allergic type hypersensitivity reactions are possible, as with any protein product. If hypersensitivity reactions occur, the administration must be discontinued immediately. To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the desired application area are adequately cleansed before administration. In the case of shock, the current medical standards for shock treatment should be followed. Standard measures to prevent infections resulting from the use of medicinal 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 individuals with immunodeficiency or increased erythropoiesis (e.g., haemolytic anaemia). It is recommended to record the name and the batch number of the product administered to the patient. Some cases of product non-adhesion issues have been reported in the form of lack of product adhesion / lack of efficacy. Correct product handling and application is required **Interactions:** No interaction studies have been performed. Similar to comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine, or heavy metals. Such substances should be removed to the greatest possible extent before applying the sealant. **Fertility, Pregnancy & Lactation:** Safety for use in human pregnancy or breastfeeding has not been established in the clinical studies. Only administer to pregnant and breastfeeding women if clearly needed. **Effects on Ability to Drive and Use Machines:** Not relevant. **Undesirable Effects:** Hypersensitivity or allergic reactions (in isolated cases these reactions may progress to severe anaphylaxis; some cases of product residue causing granuloma), thromboembolic complications may occur if 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. **Overdose information:** No case of overdose has been reported. **Interactions with Other Medicinal Products:** No interaction studies have been performed. Similar to comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine or heavy metals (e.g., antiseptic solutions). Such substances should be removed to the greatest possible extent before applying the sealant. **Use in Special Populations:** Limited data are available to support efficacy and safety of TachoSil in the paediatric population. In clinical studies, a total of 36 paediatric patients aged 0-13 years were treated with TachoSil in hepatic surgery. **Pack Sizes:** Package with 1 matrix of 9.5 cm x 4.8 cm, Package with 2 matrices of 4.8 cm x 4.8 cm, Package with 1 matrix of 3.0 cm x 2.5 cm, Package with 5 matrices of 3.0 cm x 2.5 cm, Package with 1 pre-rolled matrix of 4.8 cm x 4.8 cm. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf, Germany
The full SmPC can be obtained from Corza Medical GmbH.
Marketing Authorisation Numbers: EU/1/04/277/001-005

Date of Revision of the Text: 8 May 2025
Link to Full SmPC or Prescribing information

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