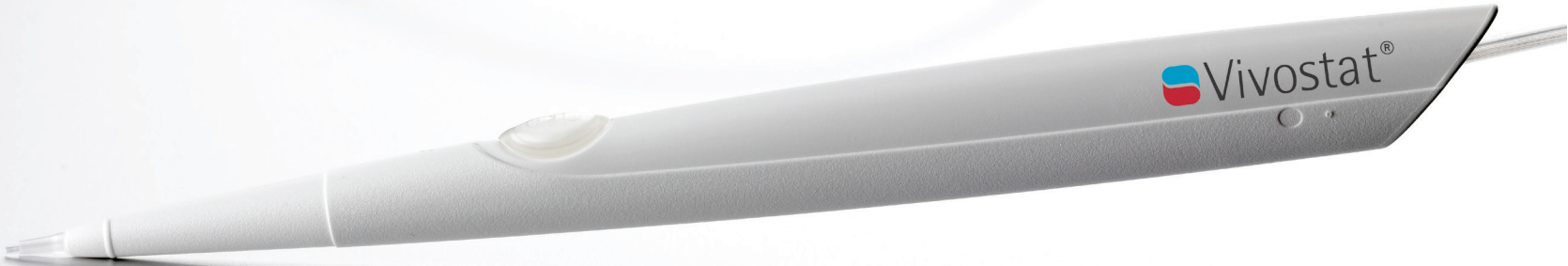
The Vivostat® System



Application system

Vivostat® Co-Delivery
Vivostat® has developed the revolutionary co-delivery system that makes it possible to simultaneously co-apply BMAC, stem cells, chondrocytes or medications (i.e. antibiotics) alongside Vivostat® products.

Multiple application devices
Whether you are doing open surgery, work in an endoscopic setting, need to treat fistulas or cavity wounds – Vivostat® provides an optimal application device.

Accurate application
With the Vivostat® application system it is possible to make pin point application with low impact on the tissue.

Minimum airflow
The Vivostat® application system uses a significantly lower airflow than competing application systems. This is also why the Vivostat® application system was not part of the warning concerning risk of air embolisms that has been issued by the FDA and the European Medicines Agency.

Different spray modes
The Vivostat® applicator offers the surgeon multiple different spray modes. This allows the surgeon to apply with different spray volumes, and apply without air e.g. relevant for endoscopic applications.

4 min. of non-stop application
From 5-6 ml of Vivostat® bioactive matrix or sealant it is possible to spray for up to 4 minutes non-stop depending on the selected spray mode.

No blockage
With the Vivostat® stop-and-go application system you experience minimum waste and no blockage, even through lengthy procedures.

Immediate polymerization
Vivostat® autologous matrix and sealant polymerizes immediately upon application with the Vivostat® application system.

Foot switch
Depending upon the preferences of the surgeon all Vivostat® application devices can also be controlled with the Vivostat® foot switch.

The Vivostat® System

Autologous uniqueness
The uniqueness of the Vivostat® System is a novel patented biotechnological process that enables reliable and reproducible[1] preparation of autologous fibrin sealant and autologous platelet rich fibrin matrixes without using cryoprecipitation and without the need for a separate thrombin component.

The solutions prepared with the Vivostat® System is intended to be used on surgical sites requiring haemostasis, tissue sealing and/or tissue regeneration.

Three components – one system
The Vivostat® System consist of:

- **Processor Unit**
  The Processor Unit is used to process the patient's blood and prepare the sealant/matrix solution.
- **Applicator Unit**
  The Applicator Unit controls the delivery of the sealant/matrix solution to the surgical site and offers a number of different spray modes.
- **Disposable Sets**
  The single-use Sets and Kits contains all components needed for prepratation and application of the Vivostat® solution.

Perfectly fittet for each surgical application
The system is designed to provide the best possible solution for many different settings independent of the surgical area in which it is used. With a range of unique application devices, it is easy to find the one perfectly fitted to each specific application within:

- Cardiac surgery
- General surgery
- Maxillofacial/ ENT surgery
- Neurosurgery
- Orthopaedics
- Thoracic surgery
- Urology
- Vascular surgery
- Wound treatment

1. R. A. Dodd, R. Cornwell, N. E. Holm, A. Garbarsch, D. A. Hollingsbee (2002), The Vivostat application system: a comparison with conventional fibrin sealant application systems, Technology and Health Care 2002 (10:401-411)-DOI: https://pubmed.ncbi.nlm.nih.gov/12368560/

Full portfolio of autologous sealants and matrixes

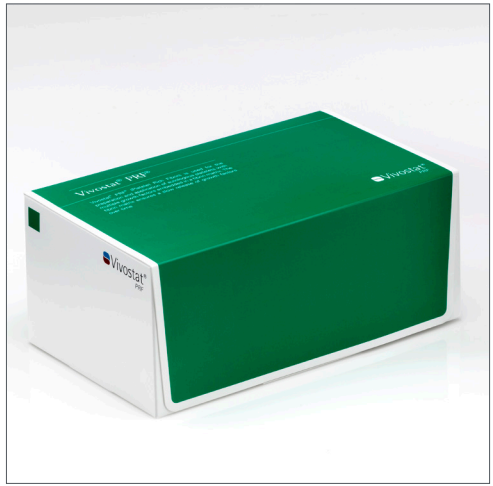
Vivostat solutions prepared on-site
The Vivostat® System is the first and only system for on-site preparation and application of fully autologous sealants and platelet rich bioactive matrixes.

The Processor Unit automatically prepares the Vivostat® solution from 120 ml of the patient's own blood, in a well-defined and reproducible dose.

Three steps to prepare and apply

- **STEP 1: Draw the patient's blood**
  120 ml of the patient's blood is drawn into the Preparation Unit.
- **STEP 2: Process the patient's blood**
  The preparation time is approx. 30 minutes and hereafter the sealant/matrix is ready for use.
- **STEP 3: Load Applicator Unit**
  The sealant/matrix is applied to the surgical site using a Vivostat® applicator.

Vivostat® Fibrin
A sealant for various surgical procedures with excellent sealing, gluing and haemostatic properties with immediate polymerisation, high elasticity and strong adhesive capabilities.



Vivostat® PRF
A matrix with high concentration of non-activated platelets with advanced sealing, healing and regenerative properties. Combining a fibrin sealant and a platelet concentrate generates a carrier and controlled release of growth factors.

ArthroZheal®

ArthroZheal® is designed to improve patient outcomes through fast recovery[1].

Transforming the overall arthroscopic surgery experience for patients and their surgeons while its bioactive and biocompatible properties successfully provides supportive effects for sealing, healing and regeneration of ligaments, tendons and cartilage.

Obsidian® ASG

Obsidian® ASG is an autologous, platelet rich bioactive matrix for anastomotic reinforcement and protection following resection surgery in the gastrointestinal tract. Obsidian® ASG is designed to effectively seal and heal anastomoses and is related to a low rate of anastomotic leaks.[2]

Obsidian® RFT

Obsidian® RFT is an autologous, platelet rich bioactive matrix for regenerative treatment of fistulas providing a sphincter-sparing minimally invasive procedure. Obsidian® RFT can close and heal fistulas and can be co-delivered with antibiotics embedded in Obsidian® RFT.[3-5]

1. Skarpas, G. A. (2022), Arthrozheal, a bioactive fibrin scaffold for joint cartilage, tendon and soft tissue lesions. Latest results and application perspectives, Surg Technol Int sti, 41, 1636, https://doi.org/10.52198/22.sti.41.os1636
2. Shamiyeh, A., Klugsberger, B., Aigner, C., Schimetta, W., Herbst, F., & Dauser, B. (2021), Obsidian ASG autologous platelet-rich fibrin matrix and colorectal anastomotic healing – a preliminary study, Surgical Technology International, 39, 147-154, https://doi.org/10.52198/21.sti.39.cr11508
3. Lara, F. J. P., Serrano, A. M., Moreno, J., Carmona, J. H., Márquez, M., Perez, L., Del Rey Moreno, A., & Muñoz, H. O. (2014). Platelet-rich fibrin sealant as a treatment for complex perianal fistulas: a multicentre study. Journal of Gastrointestinal Surgery, 19(2), 360–368. https://doi.org/10.1007/s11605-014-2698-7
4. Moreno-Serrano, A., García-Díaz, J. J., Ferrer-Márquez, M., Alarcón, R., Álvarez-García, A., & Reina-Duarte, Á. (2016), Using autologous platelet-rich plasma for the treatment of complex fistulas, Revista Espanola de Enfermedades Digestivas, 108(3), 123-8, https://doi.org/10.17235/reed.2016.3946/2015
5. Lara, F. J. P., González, J. M. S., Arjona, T. P., Donoso, F., & Fernández, J. D. (2022), A new, conservative treatment for perianal fistula that may halve the need for surgical intervention – case series, Surgical Innovation, 29(1), 50–55, https://doi.org/10.1177/15533506211015196

Application devices

Spraypen Kit (also available as Co-Delivery)

The Vivostat® Spraypen enables the surgeon to apply Vivostat® solutions intermittently throughout the entire procedure without experiencing blockage.

The spraypen gives the surgeon freedom to place the solution very accurately in pin point applications, micro anastomosis, and difficult to reach areas.

Spraypen Kit – Concorde

With its carefully optimized angle on the spraytip, the Concorde spraypen has been developed for surgical procedures where the Vivostat® solution must be applied in difficult to reach areas, for example anastomosis on the backside of the heart and sealing of the mammary bed.

Endoscopic Kit (also available as Co-Delivery)

The Vivostat® endoscopic catheter is used in various types of minimally invasive surgeries. The single-use endoscopic application catheter is easily loaded into the endoscopic handle, which is inserted via a 5 mm trocar. The pre-bent spraytip enables the surgeon to manipulate the tip and spray in multiple directions.

Endoscopic Kit – Straight

The Vivostat® Endoscopic Kit – Straight can be used for endoscopic applications and is ideal for all robotic platforms. It can further be used in deep wounds and fistulas. In combination with specially designed spray modes for the Applicator Unit, the flexible catheter completely fills wounds and fistulas without leaving any cavities. The straight catheter in the Obsidian® RFT Set has co-delivery option.

Vivostat® Co-Delivery

Vivostat®

Co-apply substance easily and effectively

The revolutionary Vivostat® Co-Delivery system makes it possible to co-apply a desired substance with the Vivostat® sealant and matrix solutions.

The opportunities with the Vivostat® Co-Delivery system are vast and the system allows the surgeon to apply a selected substance easily and effectively. Furthermore, it may be possible to reduce the total cost of a procedure by using the Vivostat® Co-Delivery system[1].

Options for co-delivery

Drugs
- Antimicrobials
- Chemotherapeutics
- Pain medications

Cells
- Stem cells
- Skin cells

Co-delivering drugs, cells etc. with the Vivostat® solutions offers the surgeon and the patient a number of benefits:

- Topical application
- Targeting affected/desired area
- Possible higher local dose
- Possible lower systemic impact
- Improved compliance

Slow release of substance

Moreover, no thrombin is added to Vivostat® products (unlike most other sealants and platelet rich fibrin products). This is beneficial to the co-delivery system as thrombin activation has been shown to have a negative effect on cell survival[2].

The fibrin membrane found in Vivostat® solutions has, furthermore, been shown to postpone the degradation process of the substance. This means that the fibrin membrane ensures a slow and sustained release of the substance offering a prolonged effect[3].

How does it work

Up to 5 ml of substance may be co-delivered together with the Vivostat® solution. The substance is applied using a Vivostat® Spraypen or endoscopoic catheter which enables the surgeon to apply the substance accurately and intermittently throughout the entire procedure. The substance and the Vivostat® solution is mixed once it leaves the tip of the application device and polymerizes immediately upon application – this way the substances stay where they are intended to act.

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2. Gugerell, A., Schossleitner, K., Wolbank, S., Nürnberger, S., Redl, H., Gulle, H., Goppelt, A., Bittner, M., & Pasteiner, W. (2012). High thrombin concentrations in fibrin sealants induce apoptosis in human keratinocytes. Journal of Biomedical Materials Research Part A, 100A(5), 1239–1247. https://doi.org/10.1002/jbm.a.34007
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