Vivostat®
Fibrin


A revolution in fibrin sealant technology

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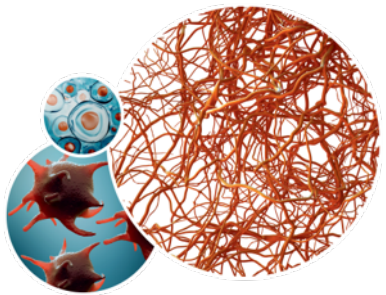
The fully automated Vivostat® system prepares 6 ml of ready-to-use autologous fibrin sealant from the patient's own blood

Compared to conventional sealant products, Vivostat® Fibrin Sealant offers a multitude of benefits to both the patient and the surgeon:

- **Excellent safety profile and high biocompatibility**
  Vivostat® Fibrin Sealant is derived from the patient's own blood and as such it demonstrates excellent biocompatibility. Unlike conventional products, which are most often based on pooled blood or bovine and synthetic components, the autologous nature of Vivostat® efficiently eliminates the risks of bovine or human-borne contaminants. This is the only way to protect the patient against viral diseases not yet identified.

- **Unique application devices**
  The wide selection of application devices provides the surgeon with unparalleled freedom in the use of fibrin sealant throughout surgery. The application devices can be used intermittently during the entire surgical procedure without experiencing the blockage that is common in conventional systems. Furthermore, Vivostat® Fibrin Sealant can be applied at very close range allowing for pinpoint application, and rapid polymerisation ensures that the fibrin remains where it is applied[1].

- **Superior physical properties**
  Clinical studies and comparative tests have demonstrated that Vivostat® Fibrin Sealant is superior to conventional fibrin sealants on important parameters such as time to haemostasis, elasticity, adhesion to tissue and impact on tissue.



The Vivostat® system is designed with emphasis on user-friendliness

You will find the system straightforward and easy to use. It can easily be moved between operating theatres if required. Furthermore, the innovative Danish design makes the system easy to operate, maintain and clean.

1) Successful application of keratinocyte suspension using autologous fibrin spray · Johnstone P et al. · Burns. 2017 May; 43(3): e27-e30. doi: 10.1016/j.burns.2016.05.010


COMPLETE
REMOVE PREP UNIT

The Vivostat® system

The Vivostat® process is a closed system, fully automated and easy to operate by the healthcare personnel

The uniqueness of the Vivostat® system is a novel patented biotechnological process that enables reliable and reproducible preparation of autologous fibrin sealant without the need for a separate thrombin component. The Vivostat® system consists of three components:

- **Processor Unit**
  The Processor Unit is used to process the patient's blood and prepare the fibrin solution. The display keeps the user informed at all times about the process.

- **Applicator Unit**
  The Applicator Unit controls the delivery of fibrin sealant to the surgical site and offers a number of different spray modes. The Co-Delivery Applicator, furthermore, allows drugs or cells to be co-delivered with Vivostat® Fibrin Sealant.

- **Disposable Set**
  The single-use set contains all components needed for preparation and application of Vivostat® Fibrin Sealant. It is available with a range of application devices each optimised for different surgical procedures.

The Processor Unit can be placed in any room or corridor in the surgical department. It is often placed centrally in the department to supply multiple operating theatres. It can, however, easily be moved between operating theatres if required.

The Applicator Unit is positioned outside the sterile field in the operating theatre. The integrated microprocessor technology automatically primes the application device and the large display informs the surgeon of the remaining volume of fibrin sealant at all times.

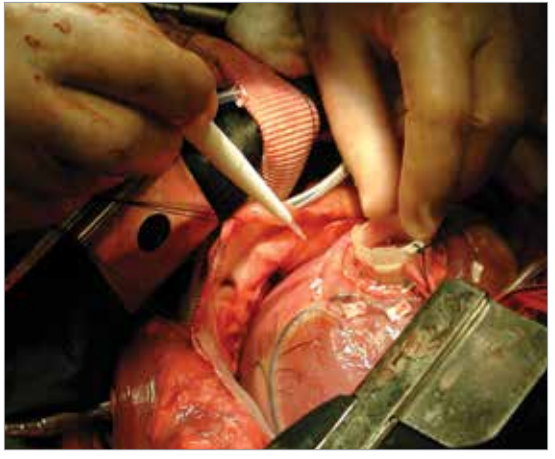
The Vivostat® Applicator Unit and Processor Unit

Vivostat®
Fibrin

Three easy steps to prepare Vivostat® Fibrin Sealant

1. Draw blood from the patient
At the time of surgery or up to 24 hours before, citrate (supplied with the kit) is added to the Preparation Unit. 120 ml of the patient's own blood is then drawn into the same unit.

2. Process the patient's blood
The Preparation Unit is placed in the Processor Unit. At the touch of a button the process starts; after approx. 24 minutes, an autologous fibrin sealant is ready for use.



3. Load the Applicator Unit and spray
The fibrin sealant is easily loaded into the Applicator Unit and applied to the surgical site using one of the different application devices.

Application devices for all situations

The Vivostat® system offers a variety of different application devices for all surgical approaches, designed for the delivery of fibrin sealant to the surgical site in a precise and targeted manner

Each application device has been developed using the knowledge of specialised surgeons to improve product performance. The application devices are used in conjunction with the Applicator Unit and are all based upon the Vivostat® micro-spray technology. The Applicator Unit continually displays the volume of fibrin sealant available and allows the surgeon to choose from a number of different spray modes to carefully control the delivery of fibrin to the surgical site.

Spraypen Kit
The Vivostat® Spraypen is a central and unique component of the Vivostat® system. It enables the surgeon to apply Vivostat® Fibrin Sealant accurately and intermittently throughout the entire procedure.

Endoscopic Kit-Straight 2.4 mm
The Vivostat® Endoscopic Kit-Straight allows the application of Vivostat® Fibrin Sealant in multiple different endoscopic solutions e.g. Colonoscopes, Bronchoscopes, Laparoscopes or Gastroscopes and it can be used to treat fistulas.

Endoscopic Kit 5 mm
The Vivostat® Endoscopic Kit is used in various types of Minimally Invasive Surgery. The single-use endoscopic application catheter is easily loaded into the reusable 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.


5.3 ml
HIGH
Vivostat®

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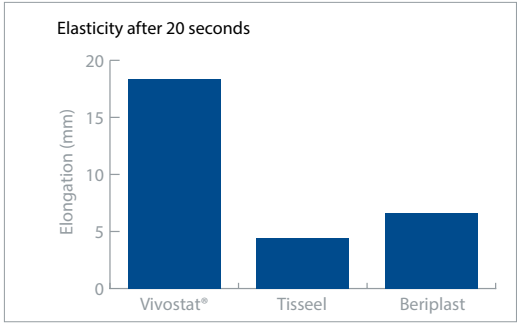
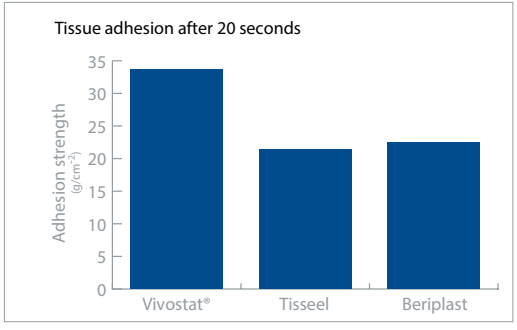
Vivostat® Fibrin Sealant - excellent elasticity and adhesion

Clinical studies and comparative tests have demonstrated that Vivostat® Fibrin Sealant outperforms other fibrin sealants on important parameters such as time to haemostasis, elasticity, adhesion to tissue and impact on tissue

In order to evaluate and compare the clinically important physical and adhesive properties of Vivostat® Fibrin Sealant, a series of in-vitro rheologicals, tensile tests and ex-vivo tissue adhesion models were developed[1].

The five parameters that are most important for the efficacy of surgical sealants have been tested and compared with two conventional fibrin sealants.

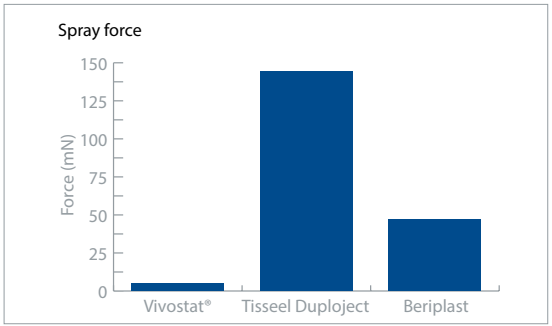


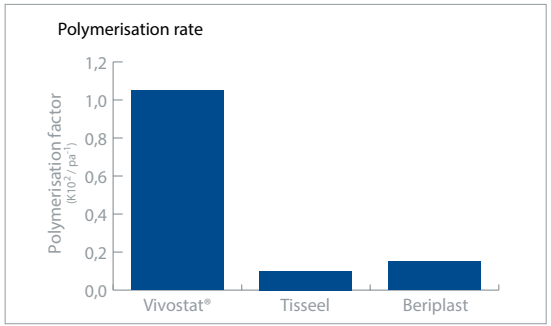


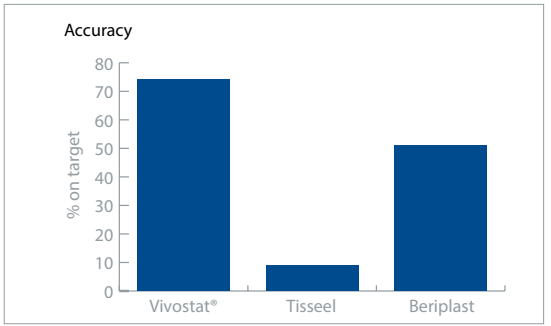
High elasticity
Surgical sealants must be very flexible to move with the tissue. This is especially important in thoracic procedures as the sealant is often applied when the lung is partly deflated. Most compounds have an inverse relationship between strength and elasticity. Comparative tests have, however, shown Vivostat® Fibrin Sealant to be extremely flexible[2], more than three times as flexible as conventional products while maintaining sufficient strength.

Strong adhesion
Numerous products focus on the tensile strength of the sealant, but neglect the most important parameter of adhesion to tissue. Provided that the internal strength of the sealant and the tissue itself are sufficiently high, it is the sealant:tissue adhesive strength that is the determining factor for tissue:tissue joint failure. The graph shows adhesion strength at first break and clearly demonstrates the superior performance of Vivostat® Fibrin Sealant[2].

1) Development of a model for measurement of adhesion strength of fibrin sealant to human tissue · Kjaergard H K et al. · European Surgical Research 1999; 31: 491-496
2) Comparative kinetics of polymerisation of three fibrin sealants and influence on timing of tissue adhesion · Kjaergard H K et al. · Thrombosis Research 2000; 98: 221-228







Low impact on tissue
All designers of spray systems face a challenge as they want to minimise disruption or damage to the tissue caused by the high flow rate of the propellant. The Vivostat® system solves this problem with the unique design of the application devices and the Applicator Unit, which provides efficient mixing and imparts very low forces on the tissue. The graph shows the spray force (impact on the tissue) 5 cm from the nozzle[3].

Immediate polymerisation
An efficient sealant needs to polymerise quickly in order to build up its internal strength and provide a rapidly effective barrier. The polymerisation of Vivostat® Fibrin Sealant is activated by a simple pH change and does not require an enzymic reaction. Po-lymerisation rates for Vivostat® Fibrin Sealant are therefore much faster than conventional sealants[2].

Great accuracy
The ability to accurately place the fibrin sealant increases the efficiency (faster haemostasis, rapid sealing etc.) and enables the surgeon to make better use of the fibrin that is available. Accuracy is most important in pinpoint application, in difficult to reach areas and small anastomoses. The graph shows the relative amount of fibrin that reaches a target area of 2 cm^2 at the manufacturer's recommended spray distance[3].

3) The Vivostat® application system: A comparison with conventional fibrin sealant application systems · Dodd R A, Cornwell R et al. · Technology and Health Care 2002; 10: 401-411

Vivostat® Fibrin

Vivostat® Co-Delivery

Vivostat® Fibrin Co-Delivery acts like an active autologous healing platform for co-application of different substances such as medications and cells

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 include:

Drugs
- Antibiotics
- Chemotherapeutics
- Pain medications

Cells
- Stem cells (i.e. BMAC)
- Chondrocytes
- Keratinocytes

Co-delivering drugs, stem cells etc. with the Vivostat® Fibrin Sealant 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

Moreover, no thrombin is added to Vivostat® Fibrin Sealant (unlike most other sealants). This is beneficial to the Co-Delivery system as thrombin activation has been shown to have a negative effect on cell survival.

The fibrin membrane found in Vivostat® Fibrin Sealant 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[2].

How does it work

It is possible to co-deliver more than 5 ml of substance together with Vivostat® Fibrin Sealant. The substance is applied using one of the different Vivostat® Co-Delivery application devices, which enables the surgeon to apply the substance accurately and intermittently throughout the entire procedure. The substance and the Vivostat® Fibrin Sealant is mixed as it leaves the tip of the application device and polymerises immediately upon application - this way the substance stays where it is intended to act.

1) Use of autologous bone marrow cells concentrate enriched with platelet-rich fibrin on corticocancellous bone allograft for posterolateral multilevel cervical fusion · Vadalà et al. · Journal of Tissue Engineering and Regenerative Medicine 2008; 2: 515–520.

2) In-vitro release pharmacokinetics of amikacin, teicoplanin and polyhexanide in a platelet rich fibrin- layer (PRF)- a laboratory evaluation of a modern, autologous wound treatment · Knafl et al. · PLoS ONE 12(7): e0181090. doi: 10.1371/journal.pone.0181090

Vivostat® Fibrin

Vivostat® Fibrin Sealant is used in various surgical procedures

Vivostat® Fibrin Sealant can be used intermittently in lengthy surgeries - 8 hrs at room temperature after preparation

Vivostat® Fibrin Sealant can be prepared and used intermittently throughout a lengthy operation without loss of properties and effectiveness. Studies have shown that storage of Vivostat® Fibrin Sealant for 8 hours at room temperature after preparation has no significant effect on the advanced physical properties of the derived sealant.

- Abdominal Surgery
- Cardiac Surgery
- ENT Surgery
- Neurosurgery
- Spine Surgery
- Thoracic Surgery
- Urology Surgery
- Vascular Surgery

Vivostat® offers a full portfolio of autologous sealants

Vivostat® Fibrin

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

Vivostat® Fibrin

Vivostat® PRF - a sealant 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.

Obsidian® ASG

Obsidian® ASG - an autologous, bioactive platelet rich sealant for anastomotic reinforcement and protection following gastrointestinal resection surgery. Obsidian® ASG is designed to effectively seal and heal anastomoses and is associated with a low rate of anastomotic leaks.

Vivostat® Co-Delivery

The Vivostat® Co-Delivery System enables surgeons to co-apply a substance such as medications and different kind of cells together with the choice of autologous Vivostat® product. The benefits include topical application targeting affected areas specifically, slow release of the substance over days, improved compliance, possible higher local dose and lower systemic impact.

ArthroZheal®

ArthroZheal®- a platelet rich fibrin sealant for arthroscopic surgery with bioactive and biocompatible properties offering synergistic effects for sealing, healing and regeneration of ligaments, tendons and cartilage. ArthroZheal® can be co-applied with stem cells, BMAC, chondrocytes or antibiotics by using the Vivostat® Co-Delivery System.

Obsidian® RFT

Obsidian® RFT - an autologous, bioactive platelet rich sealant for treatment of fistulas providing a sphincter-sparing minimally invasive procedure. Obsidian® RFT is designed to close and heal fistulas and can be co-delivered with antibiotics embedded in Obsidian® RFT.

For more information please visit **www.vivostat.com**

Product and order information

Vivostat® Fibrin Sets

(Preparation Kit and Application Kit)

Code	Product Description
VS 302	Fibrin Set
VS 312	Fibrin Set- Concorde
VS 322	Fibrin Set- Co-Delivery
VS 323	Fibrin Set- Endoscopic

Application Kits

(Including all necessary components for Application)

Code	Product Description
VS 305	Spraypen® Kit
VS 315	Spraypen® Kit- Concorde
VS 325	Endoscopic Kit
VS 335	Spraypen® Kit- Co-Delivery
VS 345	Endoscopic Kit- Straight
VS 355	Endoscopic Kit- Co-Delivery

Durables

Code	Product Description
APL 400	Applicator Unit
APL 404	Applicator Unit Co-Delivery
PRO 800	Processor Unit
VS 220	Endoscopic Applicator Handle
VS 222	Foot Switch

Vivostat® PRF Sets

(Preparation Kit and Application Kit)

Code	Product Description
VS 400	PRF Set
VS 410	PRF Set- Concorde
VS 420	PRF Set- Endoscopic
VS 422	PRF Set- Co-Delivery

Preparation Kits

(Including all necessary components for Preparation)

Code	Product Description
VS 306	Fibrin Preparation Kit
VS 406	PRF Preparation Kit

Other

Code	Product Description
VS 510	Vivostat Split Kit

Vivostat®
Fibrin

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