

# Obsidian<sup>®</sup> RFT

*Regenerative Fistula Treatment*



Obsidian<sup>®</sup> RFT is an autologous, platelet rich bioactive matrix for regenerative treatment of fistulas providing a sphincter-sparing minimally invasive procedure. Obsidian<sup>®</sup> RFT can close and heal fistulas and can be co-delivered with antibiotics embedded in Obsidian<sup>®</sup> RFT.<sup>1-3</sup>

# Obsidian® RFT effectively closes and heals fistulas<sup>1-3</sup>

## Common techniques in fistula surgery can be performed in combination with Obsidian® RFT.<sup>4</sup>

Obsidian® RFT is an autologous, platelet rich bioactive matrix with prolonged release of non-activated platelets which, upon contact with tissue, release growth factors over a period of 5-7 days improving tissue regeneration and healing of fistulas. The special fistula brush included in the Obsidian® RFT set makes it easy to prepare the fistula tract prior to application. Filling the fistula tract with Obsidian® RFT accelerates tissue proliferation to support healing and through the anti-inflammatory and antimicrobial platelet properties it may offer control of potential contamination. Obsidian® RFT is completely absorbable. With the use of the Vivostat® Co-delivery System, Obsidian® RFT can be co-applied with antibiotics, embedded in the platelet rich bioactive matrix.


## Obsidian® RFT is prepared and applied using the Vivostat® System



**The Vivostat® System** is the first and only system for on-site preparation and application of the fully autologous platelet rich bioactive matrix – **Obsidian® RFT**.


- **The Vivostat® Processor Unit** automatically prepares the **Obsidian® RFT** bioactive matrix from 120 ml of the patient's own blood, in a well-defined and reproducible dose.
- **Obsidian® RFT** is easily applied using the **Vivostat® Applicator Unit** with the endoscopic straight catheter in the fistula tract. Furthermore, the **Vivostat® Co-Delivery** system makes it possible to simultaneously co-apply antibiotics alongside **Obsidian® RFT**.

### 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 Obsidian® RFT is ready for use.



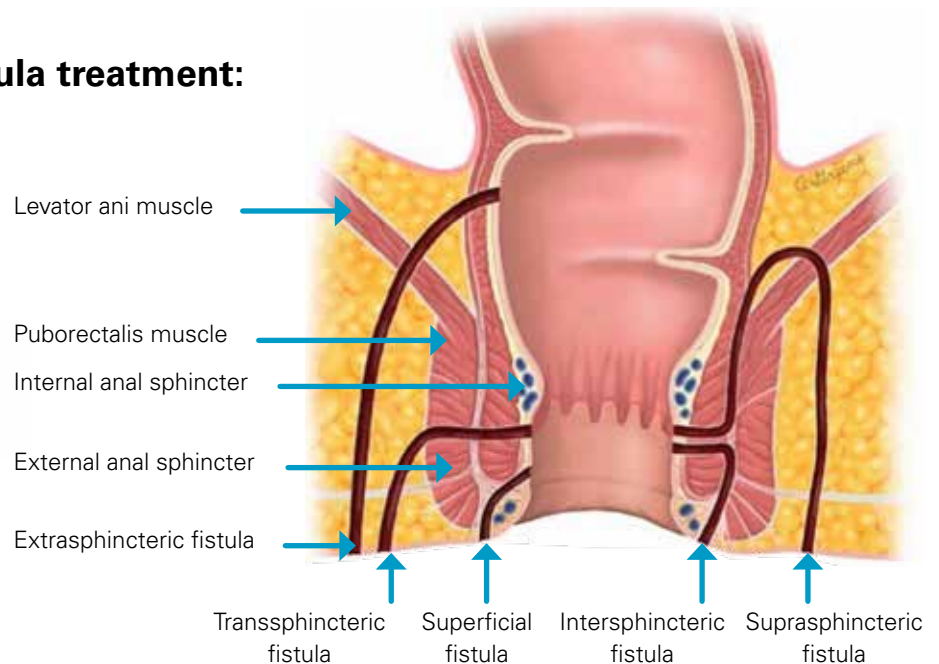
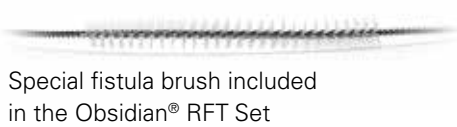
**Step 3: Load Applicator Unit**

Obsidian® RFT is applied to the fistula tract using the endoscopic straight catheter.

# Obsidian® RFT provides a sphincter-sparing minimally invasive procedure<sup>1-3</sup>

## Obsidian® RFT for anal fistula treatment:

Extrasphincteric, suprasphincteric, transsphincteric and intersphincteric fistulas.



## Obsidian® RFT surgical procedure

### PART 1: Preparation of the fistula tract

*Seton should be in place 4-6 weeks before surgical procedure*

1. Expose the fistula tract(s)
2. Insert fistula brush. Clean and debride fistula tract(s) with a back-and-forth motion (x20) removing non-vascularized tissue
3. Flush fistula tract(s) with saline solution (37°C)
4. Repeat debridement and rinsing cycle (steps 2 and 3) as needed. Important: Thoroughly clean the fistula brush between debridements.
5. Apply a Z-suture or optionally a mucosal flap
6. Perform Cava Test to check the rigidity and resistance of the internal os suture. Procedure: 1. Apply a Z-suture 2. Tighten the suture without completely closing it 3. Irrigate the area by applying a saline solution from the outer os with proper pressure 4. Make sure no fluid leaks from the inner os and the suture is tight enough 5. Loosen Z-suture and insert applicator device to apply Obsidian® RFT (see PART 2).

### PART 2: Application of Obsidian® RFT

1. Insert the Obsidian® RFT endoscopic catheter from the distal outer opening of the fistula to the intraluminal proximal inner fistula ostium
2. Apply Obsidian® RFT constantly while slowly retracting the catheter using the application setting "Jet No Air". Optionally, a second substance of 1-5 ml can be co-delivered with Obsidian® RFT (e.g. antibiotics).
3. Close the inner fistula opening via suture or via mucosa flap
4. Optionally inject the remaining Obsidian® RFT around the inner ostium of the fistula
5. The external fistula ostium remains open
6. Cover with non-adherent wound dressing

Treatment with Obsidian® RFT may be repeated for complete healing of fistula(s)

# Obsidian® RFT

Regenerative Fistula Treatment

## Obsidian® RFT

- ✓ **regenerative fistula treatment**
- ✓ **effectively closes and heals fistulas<sup>1-3</sup>**
- ✓ **provides a sphincter-sparing minimally invasive procedure<sup>1-3</sup>**
- ✓ **can be co-delivered with antibiotics embedded in the bioactive platelet rich sealant**



### Product and order information

Code	Product description
GM 740	Obsidian® RFT Set (Fistula brush included)
PRO 800	Processor Unit
APL 400	Applicator Unit
APL 404	Applicator Unit – Co-Delivery
VS 222	Foot Switch to be used with APL 400/404

### References:

**1.** F. J. Pérez Lara & A. Moreno Serrano & J. Ulecia Moreno & J. Hernández Carmona & M. Ferrer Marquez & L. Romero Pérez & A. del Rey Moreno & H. Oliva Muñoz. Platelet-Rich Fibrin Sealant as a Treatment for Complex Perianal Fistulas: A Multicentre Study. *J Gastrointest Surg* 2014. DOI 10.1007/s11605-014-2698-7. **2.** Almudena Moreno-Serrano, Juan José García-Díaz, Manuel Ferrer-Márquez, Raquel Alarcón-Rodríguez, Antonio Álvarez-García and Ángel Reina-Duarte1 Using autologous platelet-rich plasma for the treatment of complex fistulas *Rev Esp Enferm Dig (Madrid)* Vol. 108, N.º 3, 123-128, 201. **3.** Francisco Javier Perez Lara, Jose Manuel Hernandez Gonzalez, Tatiana Prieto-Puga Arjona, Francisco Javier Moya Donoso, and Juan Doblaz Fernandez. A New, Conservative Treatment for Perianal Fistula that May Halve the Need for Surgical Intervention: Case Series *Surgical Innovation* 2021, Vol. 0(0) 1–6. DOI: 10.1177/15533506211015196 journals.sagepub.com. **4.** García-Olmo et al. Surgical management of complex perianal fistula revisited in a systematic review: a critical view of available scientific evidence (PRISMA review). *BMC Surgery* (2023) 23:29; <https://doi.org/10.1186/s12893-023-01912->.

**Vivostat A/S**  
Borupvang 2  
3450 Allerød  
Denmark  
[www.vivostat.com](http://www.vivostat.com)

 **Vivostat®**