Obsidian® RFT Application Guide

SEALING I HEALING I REGENERATION

PART 1: Preparation of the fistula tract

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

- Expose the fistula tract(s)
- Insert fistula brush (Ovesco). 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 & 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)



