



CONTINENCE RESTORATION SYSTEM

INTRODUCER TOOL

INSTRUCTIONS FOR USE



Humanitarian Device

Authorized by Federal (USA) Law for use in the treatment of fecal incontinence in patients who are not candidates for or have previously failed conservative treatment and less invasive therapy options (e.g., injectable bulking agents, radiofrequency ablation, sacral nerve stimulation). The effectiveness of this device for this use has not been demonstrated.



Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

1. **SYSTEM DESCRIPTION**

The FENIX® Contenance Restoration System Introducer Tool is a surgical instrument that is used as an accessory to the FENIX Contenance Restoration System (packaged separately).

The FENIX Introducer Tool consists of a single formed stainless steel rod. The device has a distal cross-hole feature for connecting the FENIX Sizing Tool or FENIX Implant. An illustration of the FENIX Introducer Tool is provided in **Figure 1**.

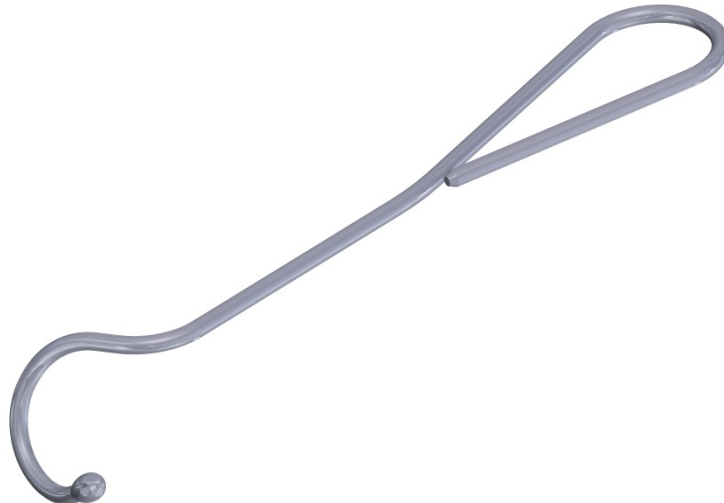


Figure 1 – Illustration of Introducer Tool

2. **INDICATION FOR USE**

The FENIX Contenance Restoration System is indicated for the treatment of fecal incontinence in patients who are not candidates for or have previously failed conservative treatment and less invasive therapy options (e.g., injectable bulking agents, radiofrequency ablation, sacral nerve stimulation).

3. **CONTRAINDICATIONS**

- 3.1. Do not use the FENIX Introducer Tool in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

4. **PRECAUTIONS**

- 4.1. The FENIX Introducer Tool should only be used by physicians who have received product specific training.
- 4.2. Please read all information. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments. All persons using this device should be knowledgeable in the use and handling of surgical instruments.
- 4.3. The device is packaged non-sterile and must be inspected, cleaned, and steam sterilized prior to use by qualified personnel. If the device is suspect or compromised, it should not be used.
- 4.4. The device is intended for re-use. Follow standard cleaning procedures for surgical tools and sterilize before each re-use.

5. **POTENTIAL COMPLICATIONS**

The following is a list of potential complications that may occur with the use of the FENIX Introducer Tool: These may include, but may not be limited to the following: bleeding, device failure, infection, injury to the anus, rectum, or vagina, and pain.

6. **DIRECTIONS FOR USE**

6.1. Every FENIX Introducer Tool must be thoroughly cleaned and steam sterilized before it is used. The FENIX Introducer Tool was developed for sterilization by autoclave.

6.2. Cleaning Before Use:

Clean and inspect the Introducer Tool carefully. Sterilize the FENIX Introducer Tool before surgery. Clean the instrument as follows:

6.2.1. Do not use corrosive cleaning agents. Cleaning solutions and rinses at or near a neutral pH (7.0) are best.

6.2.2. Do not use abrasive cleaners.

6.2.3. Rinse the FENIX Introducer Tool with tap water for two minutes while brushing with a soft bristled cleaning brush to remove all of the visible gross debris.

6.2.4. Place the FENIX Introducer Tool into an enzymatic bath for five (5) minutes following the enzymatic cleaner manufacturer's directions. Scrub the FENIX Introducer Tool with a soft bristled cleaning brush, paying close attention to the helical end. Pass an appropriately sized brush (i.e., 4.0 mm) through the cross-hole (**Figure 2**), a minimum of four passes (in/out equals two passes) to remove any remaining debris from the instrument.



Figure 2 – Illustration of Cross-hole

6.2.5. Rinse the FENIX Introducer Tool for two minutes using tap water.

6.2.6. Visually inspect the FENIX Introducer Tool under normal lighting to verify cleanliness. Thoroughly dry the Introducer Tool carefully with compressed air, or allow the FENIX Introducer Tool to air dry.

6.3. Sterilization Before Use

6.3.1. Steam autoclave sterilization is recommended. Do not sterilize in hot air. During sterilization, the device should be placed in a standard autoclave pouch.

6.3.2. Standard **gravity** autoclave steam cycle 132°C for 15 minutes followed by 15 minutes of dry time.

6.3.3. Standard **pre-vacuum** autoclave steam cycle 132°C for 4 minutes followed by 20 minutes of dry time.

6.4. Inspection and Functional Check

It is very important to carefully examine each FENIX Introducer Tool for bends, nicks, corrosion, or other malfunctions before use. **DO NOT USE DAMAGED INSTRUMENTS.**

- 6.5. Surgical Access
 - 6.5.1. Gain appropriate surgical access to the anal canal at the region of the external anal sphincter.
 - 6.5.2. Dissect the soft tissues away from the outside of the external anal sphincter. Tissue should be removed to expose the outer muscle of the anal sphincter. Using fingers, create a tunnel circumferentially around the external anal sphincter. Care should be taken to avoid injuring the pudendal nerve bundles.
- 6.6. Using the FENIX Introducer Tool
 - 6.6.1. Digitally probe around the outside of the external anal sphincter for the distal tip of the FENIX Introducer Tool. Once contact is established, guide the FENIX Introducer Tool around the anal canal in the tunnel created around the external anal sphincter.
 - 6.6.2. The FENIX Introducer Tool is ready for connection of the FENIX Sizing Tool or FENIX Implant by threading the suture through the cross-hole feature of the FENIX Introducer Tool.
 - 6.6.3. While holding the suture of the FENIX Sizing Tool, rotate the FENIX Introducer Tool back through the tunnel guiding the FENIX Sizing Tool around the external anal sphincter. The FENIX Introducer Tool can also be used to guide the FENIX Implant into position by attaching a length of suture to the device and repeating the steps listed above.
 - 6.6.4. Once the FENIX Introducer Tool is clear of the incision, the suture can be removed from the FENIX Introducer Tool.

7. PACKAGING/STORAGE

The FENIX Introducer Tool is provided non-sterile and designed to be sterilized by qualified personnel.







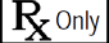
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4188 Lexington Avenue North
Shoreview, Minnesota 55126 USA
Phone: (651) 361-8900
Fax: (651) 361-8910
www.toraxmedical.com

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