FENIX®

CONTINENCE RESTORATION SYSTEM

Sizing Tool

Instructions for Use

TORAX® MEDICAL INC

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.

℞ Only

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

1. SYSTEM DESCRIPTION

The FENIX® Sizing Tool is a surgical instrument that is used as an accessory to the FENIX® Implant and FENIX® Introducer Tool (each packaged separately) as part of the FENIX® Continence Restoration System.

The FENIX Sizing Tool consists of (green) magnetic beads and (white) non-magnetic beads that are captured along a length of (USP 2) polyester suture. The numbers on the magnetic beads correspond to the size range of the FENIX Implant.

An illustration of the FENIX Sizing Tool is provided in **Figure 1**.

Figure 1 – Illustration of Sizing Tool

2. INDICATION FOR USE

The FENIX Continence 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 Sizing Tool in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

4. PRECAUTIONS

4.1. The FENIX Sizing Tool should only be used by physicians who have received product specific training.

4.2. The sterile packaging should be inspected prior to use. If sterility or performance of the device is suspect or compromised, it should not be used.

4.3. The FENIX Sizing Tool is intended for single use only. DO NOT re-sterilize the device. Functionality and sterility of the device can not be assured if re-used.

5. POTENTIAL COMPLICATIONS

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

6. DIRECTIONS FOR USE

6.1. Surgical Access

6.1.1. Gain appropriate surgical access to the anal canal at the region of the external anal sphincter.

6.1.2. 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.

6.1.3. Care should be taken to avoid injury to the pudendal nerve bundles, inferior hemorrhoidal artery and recto-vaginal septum.

6.2. Sizing of the Anal Canal

6.2.1. Bring the FENIX Sizing Tool into the surgical field.

6.2.2. With the FENIX Introducer Tool (packaged separately) already in place around the anal canal, thread the suture from the arrow bead end of the sizer through the tip of the introducer tool as shown in **Figure 2**. The FENIX Sizing Tool may be introduced by hand around the anal canal if the FENIX Introducer Tool is not available.

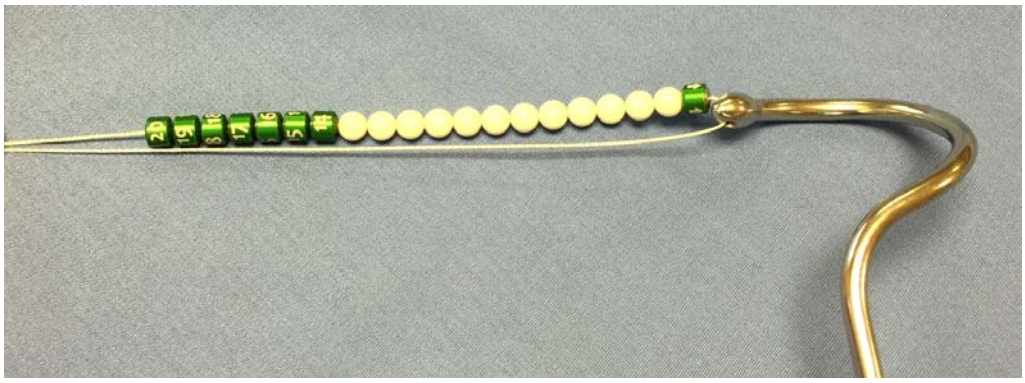

Figure 2 –Sizing Tool suture shown engaging tip of Introducer Tool

6.2.3. While holding both loose ends of suture, pull the sizing tool through the surgically created tunnel by rotating the introducer tool handle counterclockwise.

6.2.4. Remove the suture from the introducer tool and pull the remaining arrow bead suture through the anal canal.

6.2.5. At the site of the intended implant placement, connect the arrow bead to the numbered bead by connecting these two magnetic beads around the circumference of the anal canal.

6.2.5.1. Note that during implant sizing, there should be no foreign objects (e.g., gauze) in the anal canal as this could unintentionally result in sizing too large.

6.2.6. Slide the largest numbered bead to the end of the suture knot and re-connect the arrow bead to the remaining continguous beads. Continue this process until the smallest bead size that will remain fully closed around the anal canal when connected to the arrow bead is observed. This is the recommended FENIX Implant size (reference **Figure 3**).

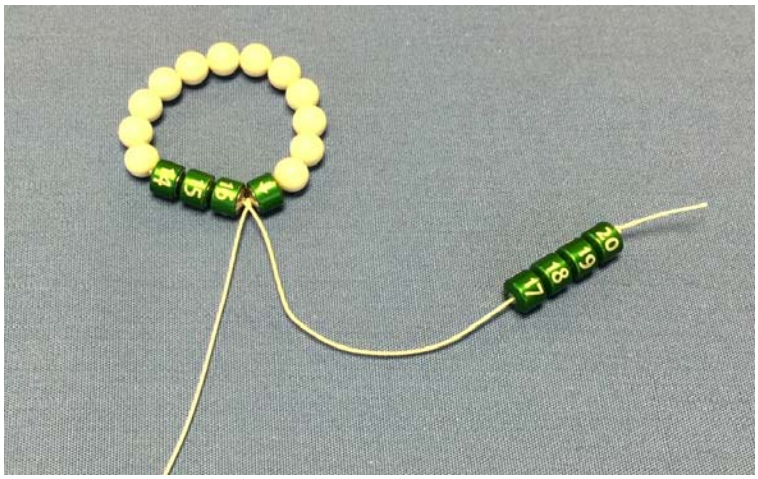

Figure 3 –Sizing Tool shown indicating a 16-Bead Implant

6.2.7. Fluoroscopy should be used after implant placement to verify correct sizing.

6.2.8. For easier sizing tool removal, the device should be pulled by the suture at the numbered bead end of the device.

7. PACKAGING/STORAGE

The FENIX device is provided sterile and designed to remain sterile unless the primary product pouch has been damaged or opened.

7.1. Store in a cool, dry place. Not to exceed 140ºF (60ºC).

7.2. If package is opened and device is not used, discard device or return device to Torax Medical Inc.

7.3. Do not re-use or re-sterilize.

8. LIMITED WARRANTY

(a) Torax warrants that the product shall be free from material defects in materials and/or workmanship, and shall perform substantially in accordance with the written specifications, through the earlier of (i) the expiration of the shelf-life as specified on the applicable product labeling or (ii) the date on which the products are used or implanted.

(b) This limited warranty does not extend to damage caused by (i) abuse or misuse of any product, (ii) accident or neglect by you or a third party; (iii) use of the product other than in accordance with Torax's instructions or specifications; or (iv) any alterations made to the product after shipment.

(c) Torax's entire liability and your exclusive remedies under this limited warranty are, at Torax's option, for Torax to use commercially reasonable efforts to fix or replace the defective product.

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