FENIX™

CONTINENCE RESTORATION SYSTEM

Instructions for Use

TORAX™ MEDICAL INC

1. SYSTEM DESCRIPTION

The FENIX™ Continence Restoration System is indicated for use for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative therapy. The FENIX™ System Implant is placed around the external anal sphincter to augment a weak anal sphincter and restore continence.

The FENIX™ System is comprised of the following components:

- FENIX™ System Implant
- FENIX™ System Anal Sphincter Sizing Tool (packaged separately)

The FENIX™ System Implant consists of a series of titanium beads with magnetic cores that are connected with independent titanium wires to form an annular shape (Figure 1). The attractive force of the magnetic beads is designed to provide additional strength to keep a weak anal sphincter closed (Figure 2).

The implant device is offered in multiple sizes to accommodate variation in sphincter size. The sizes are denoted by the model number (e.g., FS18 = 18 Bead Implant). The FENIX™ Anal Sphincter Sizing Tool, packaged separately, is utilized to associate the anal sphincter size to an appropriate FENIX™ System Implant.

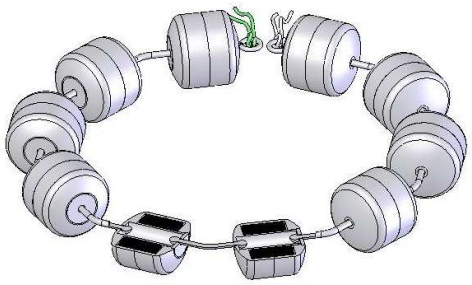

Figure 1 – Illustration of Implant

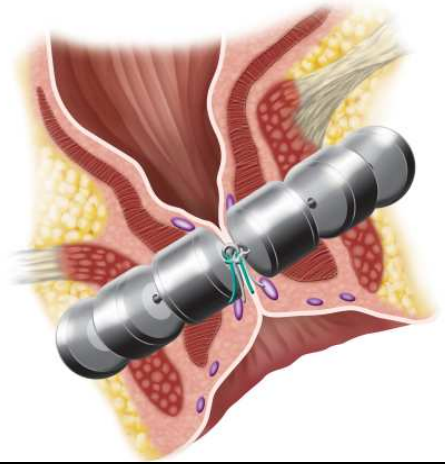

Figure 2 – Device Implanted

2. INDICATION FOR USE

The FENIX™ Continence Restoration System is indicated for use for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative therapy.

3. CONTRAINDICATIONS

3.1. Do not implant the FENIX™ System in patients with suspected or known allergies to titanium.

4. WARNINGS

4.1. Patients with diabetes, other immunocompromised disease, or open sores near the site of surgery may have increased risk of infection associated with a prosthesis. Infection that fails to respond to antibiotic therapy may result in removal of the device.

4.2. The FENIX™ Implant is considered MR Unsafe. After implantation, the patient should not be exposed to an MRI environment. The MRI environment could interfere with the magnetic strength and the function of the device. A recommendation should be made to patients receiving the FENIX™ System Implant to register their implant with the MedicAlert Foundation (www.medicalert.org) or equivalent organization. In the event alternative diagnostic procedures can not be used and MRI is required, the FENIX™ Implant can be safely removed.

4.3. The device should not be exposed to temperatures above 100°C (212°F) as this could adversely affect the magnets and the function of the device.

4.4. Erosion may be caused by infection, improper sizing, or tissue damage. The device may erode through the anal wall or through the perineal skin.

5. PRECAUTIONS

5.1. The safety and effectiveness of the FENIX™ System has not been established for the following conditions:

5.1.1. Anal sphincter sizes smaller or larger than offered FENIX™ System size range.

5.1.2. Prior anterior resection of the rectum.

5.1.3. Suspected or confirmed anal or rectal cancer.

5.1.4. External full thickness rectal prolapse.

5.1.5. Significant obstructed defecation or other significant chronic defecatory motility disorders.

5.1.6. Inflammatory Bowel Disease or Irritable Bowel Syndrome.

5.1.7. Active pelvic infection.

5.1.8. Systemic disease as source of FI (scleroderma, Crohn's).

5.1.9. Pregnant or plan to become pregnant.

5.2. Implantation of the device should only be performed by physicians who have received product specific training.

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

5.4. The device 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.

5.5. The device is magnetic and will be attracted to ferrous objects in the surgical field and other surgical instruments that are ferromagnetic.

6. POTENTIAL COMPLICATIONS

The following is a list of potential complications that may occur with the implantation of the FENIX™ System: These may include, but may not be limited to the following: Bleeding, Death, Device Erosion, Device explant/re-operation, Device Failure, Device migration (device does not appear to be at implant site), Impaction or defecatory disorder, Impaired colonic motility, Inability to pass gas, Infection, Injury to the anus, rectum, or vagina, pain, Pruritus ani, Recto-vaginal fistula, Worsening of pre-operative symptoms.

7. DIRECTIONS FOR USE

7.1. Surgical Access

7.1.1. Gain appropriate surgical access to the anus at the region of the external anal sphincter.

7.1.2. 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. Create a tunnel circumferentially around the external anal sphincter. Care should be taken to avoid injuring the pudendal nerve bundles.

7.2. Sizing of the Anus

7.2.1. Use the FENIX™ Sizing Tool to determine the FENIX™ Implant size. The FENIX™ Implant sizes are denoted by the model number (e.g., FS18 = 18 Bead Implant).

7.2.2. Bring the FENIX™ Sizing Tool into the surgical field.

7.2.3. Place the sizing tool around the anus in the dissected space around the exposed external anal sphincter muscle and through the tunnel created around the external anal sphincter.

7.2.4. Perform sizing per the appropriate sizing tool instructions for use.

7.3. Placement of the FENIX™ Implant

7.3.1. Bring the chosen FENIX™ Implant into the surgical field.

7.3.2. Place the device around the dissected space in the same location that was measured.

7.3.3. Using the suture provided, secure the ends of the device with a hand tied knot such that the eyelets of the device are touching or overlapping. Complete this method of securement for each set of white and green sutures for a total of two secured knots. Once secured, trim sutures.

8. DEVICE REMOVAL

If device removal is necessary, carefully free the device from surrounding tissue by dissecting along the outside of the beads, moving from anterior to posterior on each side of the anal canal. Bead links (wires) may be cut to facilitate the removal of individual segments. Particular care should be taken to avoid injury to the pudendal nerve bundles. The device should be disposed of according to your health care institution's standard disposal instructions.

9. PACKAGING/STORAGE

The FENIX™ System Implant is provided sterile and designed to remain sterile unless the primary product pouch has been opened or damaged. Store in a cool, dry place. If opened and not used, discard device or return device to Torax Medical Inc. Do Not Resterilize.

10. 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.

(d) EXCEPT AS EXPRESSLY STATED ABOVE, TORAX MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY OPERATION OF LAW OR OTHERWISE, OF ANY PRODUCTS OR SERVICES FURNISHED UNDER OR IN CONNECTION WITH THIS AGREEMENT. TORAX DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND THOSE WARRANTIES ARISING BY STATUTE OR OPERATION OF LAW, OR FROM A COURSE OF DEALING OR USAGE OR TRADE.

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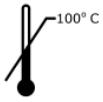
REF	Model Number
LOT	Lot Number
SN	Serial Number
	Use Before Date
	Caution, consult accompanying documents
	Refer to instructions for use
	Do no use if package is damaged
	Single Use Only
STERILE R	Contents Sterile: irradiation
	Manufacturer
	Maximum Storage Temperature 100ºC

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