FENIX®

CONTINENCE RESTORATION SYSTEM

Instructions for Use

TORAX MEDICAL INC

Humanitarian Device
Authorized by Federal 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® Continence Restoration System (FENIX System) is comprised of the following components:

- FENIX Implant
- FENIX Anal Sphincter Sizing Tool (packaged separately)
- FENIX Introducer Tool (packaged separately)

The FENIX 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 prevent involuntary opening of the anal canal (Figure 2).

The implant is offered in multiple sizes to accommodate variation in sphincter size. The sizes are denoted by the model number (e.g., FXS18 = 18 Bead Implant). The FENIX Sizing Tool is utilized to associate the anal sphincter size to an appropriate FENIX Implant. The FENIX Introducer Tool is used to assist in placing the sizing tool and the implant, if desired.

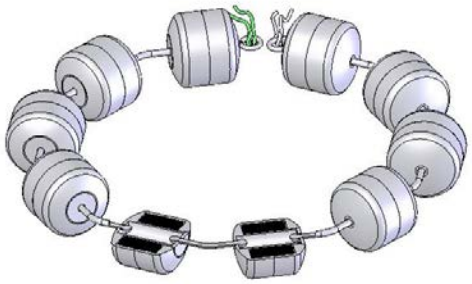


Figure 1 – Illustration of Implant

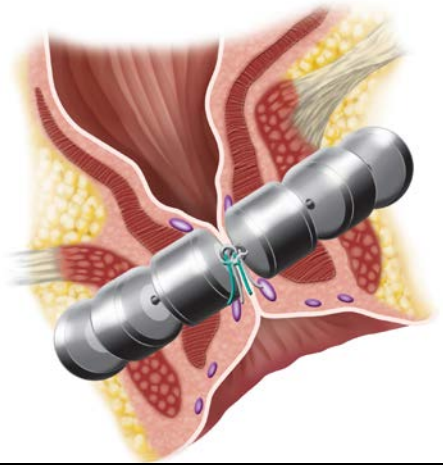


Figure 2 – Device Implanted

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 implant the FENIX device 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 implant.

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

4.3. The implant should not be exposed to temperatures above 60°C (140°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 implant may erode through adjacent tissue (e.g., the anal wall or through the perineal skin).

5. PRECAUTIONS

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

- 5.1.1. Anal sphincter sizes smaller or larger than offered FENIX Implant size range
- 5.1.2. Congenital anorectal/pelvic malformation
- 5.1.3. Suspected or confirmed anal or rectal cancer
- 5.1.4. History of pelvic radiation
- 5.1.5. No rectal reservoir due to resection
- 5.1.6. External full thickness rectal prolapse
- 5.1.7. Significant obstructed defecation or other significant chronic defecatory motility disorders
- 5.1.8. Inflammatory Bowel Disease (Crohn's and ulcerative colitis)
- 5.1.9. Watery diarrhea that is unmanageable by medication or diet changes
- 5.1.10. Active pelvic infection
- 5.1.11. Systemic disease as source of FI (e.g., scleroderma, dementia)
- 5.1.12. Pregnant or plan to become pregnant

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

5.3. The sterile package and implant 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 cannot be assured if re-used.

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

5.6. Patients should undergo a monthly rectal examination for 3 months after placement of the implant or if new onset or worsening of pain, wound drainage, or bleeding occurs to further mitigate the risk of infection or device erosion.

6. ADVERSE EVENTS

6.1. Adverse events that may result from the use of the FENIX Implant are those commonly associated with general surgical procedures as well as those associated with the device specifically.

6.2. Potential adverse events associated with general surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis, cardiac arrest, death, fever, hypotension, hypoxemia, infection, myocardial infarction, pneumonia, pulmonary embolism, respiratory distress, thrombophlebitis, and vomiting.

6.3. Potential adverse events associated specifically with the FENIX implant include 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, and worsening of pre-operative symptoms. Additional unknown risks may exist.

6.4. Safety results follow for a clinical study that enrolled 35 subjects. Adverse events were assessed and documented from the time of implant and throughout study participation. The reported adverse events are based on the investigator's reporting of onset, relatedness to device and/or procedure, severity and status. All data available at the time of the applicable report (including available data beyond 36 month visits) is presented for adverse events (AEs), serious adverse events (SAEs), explants, and other surgical interventions.

Table 1 below provides an accounting of the number of subjects that have completed each follow-up visit at the time of this report. Data sets through 36 months are considered complete, while the 48 and 60 month data sets are ongoing at the time of this report. The events reported in **Tables 2-5** include data from all follow-up visits completed at the time of this report.

Table 1 – Subject Accountability Through Study Completion

Subject Status	Month 12	Month 24	Month 36	Month 48	Month 60
Follow-up Visit Completed	28	26	24	16	6
Follow-up Visit Pending	0	0	0	8	18
Explanted	6	6	7	7	7
Deceased[×]	0	0	1	1	1
Missed Visit^/LTF[†]/Exited*	1	3	3	3	3
Total Subjects	35	35	35	35	35

*One patient enrolled at a site completed the study at 1 year post-implant.
^ One 24 month visit was missed
[†] One subject was Lost to Follow-up (LTF)
[×]Patient death reported as caused by cirrhosis of the liver; unrelated to device or procedure.

6.4.1. No deaths, life-threatening conditions or unanticipated adverse effects due to the device were reported in the clinical study. One patient death was reported as caused by cirrhosis of the liver and unrelated to the device or procedure.

6.4.2. A total of 25 adverse events in 19 subjects were reported as related to the device and/or procedure **(Table 2)**. The most frequently reported adverse events related to the device and/or procedure included pain, device erosion, infection, bleeding and impaction/defecatory disorder.

Table 2 – Adverse Events Related to Device and/or Procedure or Relationship Unknown (includes complete 36 month follow-up data set and partial data sets at 48 and 60 months)

	Related or Unknown		Mild[3]		Moderate[3]		Severe[3]	
Adverse Event	AE (n)	Subj. % (n)[1]	AE (n)	Subj. % (n)	AE (n)	Subj. % (n)	AE (n)	Subj. % (n)
Pain	6	17.1% (6)	4	11.4% (4)	2	5.7% (2)	0	0%
Impaction or defecatory disorder	5	11.4% (4)	1	2.9% (1)	3	5.7% (2)	1	2.9% (1)
Device Erosion	4	11.4% (4)	1	2.9% (1)	2	5.7% (2)	1	2.9% (1)
Infection	4	11.4% (4)	0	0%	0	0%	4	11.4% (4)
Bleeding	3	8.6% (3)	2	5.7% (2)	1	2.9% (1)	0	0%
Other[2]	3	8.6% (3)	2	5.7% (2)	1	2.9% (1)	0	0%
Total	25	54.3% (19)	10	25.7% (9)	9	22.9% (8)	6	17.1% (6)

[1]Subjects may have had more than one type of event. Subjects may have had more than one event of the same type.
[2]Events reported as 'Other' include: Perineal bleeding (mild), Sleeplessness (mild), and Allergy inflammation reaction (moderate).

[3]The rating of severity (mild, moderate or severe) describes the extent for which the adverse event impacts the subject's ability to perform usual activities. An AE is considered to be severe if found to be incapacitating with inability to do work or usual activities.

6.4.3. There were seven (7) events in six (6) subjects reported as serious adverse events (SAEs) related or unknown to the device and/or procedure. Adverse events are considered serious if the event results in death, is life-threatening, requires subject hospitalization (>24 hours), requires prolongation of existing hospitalization, results in persistent or significant disability, or requires intervention to prevent impairment. All six severe adverse events listed in Table 2 were also classified as serious adverse events in Table 3. The serious adverse event rate was 17.1% (6/35) **(Table 3)**. Four (4) subjects had the device explanted related to the SAE. Nearly all SAEs occurred <30 days after the implant procedure. The SAEs resolved with no residual effects in all cases.

Table 3 – Serious Adverse Events (Related or Unknown) (includes complete 36 month follow-up data set and partial data sets at 48 and 60 months)

Serious Adverse Event	Events (n)	Subjects %(n)[1]	Device Explant (n)	Days from Onset to Implant
Infection	4	11.4% (4)	3	7, 9, 15, and 251
Device erosion	1	2.9% (1)	1	28
Allergy, inflammation reaction	1	2.9% (1)	0	2
Impaction or defecatory disorder	1	2.9% (1)	0	23
Total	7	17.1 % (6)	4	Not Applicable

[1]Subjects may have had more than one type of event.

6.4.4. The device explant rate was 20% (7/35). Reasons for device explant included device erosion, infection and lack of effect **(Table 4)**. All device removals required a surgical intervention, with the exception of one that was reported as passing during defecation. Surgical removal was performed safely in all cases with no complications or clinical sequelae.

Table 4 – Device Explant by Reason and Number of Events (includes complete 36 month follow-up data set and partial data sets at 48 and 60 months)

Reason for Device Explant	Number of Events
Infection	3
Device erosion	3
Lack of effect	1
Total	7

6.4.5. A total of eight (8) subjects underwent device explant, other surgical intervention or a combination of device explant and other surgical intervention **(Table 5)** related to the device or the condition of FI. Other surgical interventions included stoma creation in three (3) subjects and placement of sacral nerve stimulation in one (1) subject.

Table 5 – Device Explants and Other Surgical Intervention (includes complete 36 month follow-up data set and partial data sets at 48 and 60 months)

Subject	Device Explant	Reason for Device Explant	Other Surgical Intervention	Number of Surgical Interventions
01	Yes	Device Erosion	No	None[*]
02	Yes	Device Erosion	No	1
03	Yes	Infection	No	1
04	Yes	Infection	No	1
05	Yes	Continuing FI	Stoma, lack of effect	1[†]

06	Yes	Infection	Stoma, lack of effect	2
07	Yes	Device Erosion	Sacral nerve stimulation, lack of effect	2
08	No	NA	Stoma, impaction/defecatory disorder	1

*Subject 01: Device eroded through mucosa and is suspected to have passed through the anus; no intervention required.
†Subject 05: Device explant and stoma performed during the same surgical procedure.

Details of the device explants and other surgical interventions are provided below:

- One subject upon pelvic x-ray was found to have the device separated at the suture. No intervention was performed. Subsequently, it was presumed that the device passed through the anal mucosa during toileting at 47 days post-implant. The event resolved without sequelae.
- One subject was noted to have device erosion during a rectal exam 27 days post-implant. The device was explanted 28 days post-implant.
- One subject developed an infection that was not responsive to antibiotics. The device was explanted 47 days post-implant due to the infection.
- One subject continued to have fecal incontinence symptoms and at 69 days post-implant elected to have the device removed and underwent reoperation for a stoma creation.
- One subject experienced an infection, which resulted in device explant 41 days post-implant. After removal, the subject underwent reoperation for the creation of a stoma.
- One subject elected to have the device explanted and sacral nerve stimulation implanted 906 days post-implant due to reoccurring vaginal discharge secondary to device erosion.
- One subject experienced an infection that resulted in device explant 261 days post-implant.
- One subject underwent stoma creation for defecatory disorder (constipation) 154 days post-implant. The FENIX Device was not explanted

7. CLINICAL STUDY

A multicenter, prospective, non-randomized clinical study was conducted to demonstrate the safety and probable benefit of the FENIX implant. A total of 35 subjects were enrolled. Fifteen (15) subjects were enrolled at two (2) institutions in the U.S and 20 subjects were enrolled at two (2) institutions outside the U.S. Subjects enrolled in the study had severe fecal incontinence (FI), and had previously failed conservative and/or less invasive therapies.

The primary safety parameter was the rate of all adverse events (AEs) monitored through the entire course of the clinical study from implant through subject withdrawal. AE reporting was based on the investigator's reporting of onset, relatedness to device and/or procedure, severity and status. Device and/or procedure-related events were summarized separately (Please see **Section 6.0** for safety results of this study).

Probable benefit of the FENIX implant was characterized as the reduction of FI symptoms evaluated by a subject-completed bowel diary and improved quality of life using a self-administered questionnaire, the Fecal Incontinence Quality of Life (FIQOL).

7.1. Eligibility

7.1.1. Inclusion Criteria

Enrollment was limited to subjects that met the following inclusion criteria:

- Age $\geq$ 19 years, < 85 years, life expectancy >3 years
- Documented history of severe fecal incontinence for at least 6 months

- Subject diary documents ≥ 2 episodes per week on average over diary period; leakage greater than seepage
- Subject had failed standard conservative and medical therapy
- Subject was a surgical candidate
- Subject was willing and able to cooperate with follow-up examinations
- Subject has been informed of the study procedures and the treatment and has signed an informed consent form and provided authorization to use and disclose information for research purposes.

7.1.2. Exclusion Criteria

Subjects were not permitted to enroll in the FENIX study if they met any of the following exclusion criteria:

- Patient had a history of significant obstructed defecation or other significant chronic defecatory motility disorders
- Patient had current, external full thickness rectal or vaginal prolapse
- Patient had an electric or metallic implant within 10cm of the area of device placement
- Patient had Inflammatory Bowel Disease
- Patient had Irritable Bowel Syndrome
- Patient has systemic disease as source of FI (scleroderma, neurologic disorders, Crohn's)
- Patient had active pelvic infection
- Patient had chronic diarrhea
- Patient diagnosed with anal, rectal, or colon cancer within 2 years
- Patient had prior anterior resection of the rectum
- Patient had undergone pelvic radiation therapy
- Patient had significant scarring of the recto-vaginal septum, or a history of recto-vaginal fistula
- Patient had previous anorectal posterior compartment surgery
- The FENIX procedure was an emergency procedure
- Patient was being treated with another investigational drug or device
- Patient couldn't understand trial requirements or was unable to comply with follow-up schedule
- Patient was pregnant, nursing, or planned to become pregnant
- Patient had a history of complex anal fistula.

7.2. Baseline Demographics and Characteristics

The baseline demographics are summarized below:

- There were 34 females (97.1%) and 1 male (2.9%)
- Mean age at the time of enrollment was 64.1 years (range 41.5 to 77.7 years)
- 100% were Caucasian
- Mean body mass index was 26.8 (range 18.1 to 48.5)
- Etiology of FI by percentage of subjects was 53.1% obstetric trauma, 25.0% neuropathic and 18.8% idiopathic
- FI incontinence type by percentage of subjects was 12.1% passive incontinence (no awareness of stool loss), 24.2% urge incontinence (inability to deter defecation), and 63.6% both.

7.3. Probable Benefit

7.3.1. Bowel Diary

Subjects completed a 21-day bowel diary to collect and evaluate the number of FI episodes per week, FI days per week, and number of urgent episodes per week. FI symptoms were considered improved if the bowel diary parameters showed at a least 50% reduction at follow-up compared to baseline.

Success criteria applied to the bowel diary data were as follows:

- Proportion of subjects achieving at least a 50% reduction in FI episodes per week when compared to baseline

- Proportion of subjects achieving at least a 50% reduction in FI days per week when compared to baseline
- Proportion of subjects achieving at least 50% reduction in urgent episodes per week when compared to baseline

For evaluable subjects (subjects completing a bowel diary at follow-up), a reduction of at least 50% was achieved in a clinically significant number of evaluated subjects for FI episodes, FI days, and urgent episodes **(Table 6)**. The treatment group (all subjects implanted) showed the majority of subjects had a reduction of at least 50% in FI episodes per week at all follow-up intervals through 36 months **(Table 7)**.

Table 6 – Reduction in FI from Baseline (Evaluable Subjects)

Outcome (per week)	6 Months % (n/N)	12 Months % (n/N)	24 Months % (n/N)	36 Months % (n/N)
≥50% reduction in FI episodes	82.1% (23/28)	78.6% (22/28)	70.4% (19/27)	90.9% (20/22)
≥50% reduction in FI days	71.4%(20/28)	67.9% (19/28)	59.3% (16/27)	77.3% (17/22)
≥50% reduction in urgent episodes	84.6% (22/26)	50.0% (13/26)	48.0% (12/25)	65.0% (13/20)

Table 7 – Reduction in FI from Baseline (Treatment Group)

Outcome (per week)	6 Months % (n/N)	12 Months % (n/N)	24 Months % (n/N)	36 Months % (n/N)
≥50% reduction in FI episodes	65.7% (23/35)	62.9% (22/35)	54.3% (19/35)	57.1% (20/35)
≥50% reduction in FI days	57.1% (20/35)	54.3% (19/35)	45.7% (16/35)	48.6% (17/35)
≥50% reduction in urgent episodes	62.9% (22/35)	37.1% (13/35)	34.3% (12/35)	37.1% (13/35)

Improvement in bowel diary parameters reported as number of FI episodes and urgent episodes, or days per week are presented in **Table 8**. The reduction in number of FI days per week, FI episodes per week, and urgency episodes per week as reported by subjects reduced significantly; from 13.9 episodes at baseline, to 3.4 episodes per week at 36 months. The mean number of FI days per week decreased from 6.0 days per week at baseline to 2.0 at 36 months, and urgency episodes decreased from 6.7 episodes per week to just 2.0 at 36 months post-implant.

Table 8 – Bowel Diary Parameters Reported as Mean FI Episodes or Days per Week[1]

Bowel Diary Parameters	Baseline N=35	6 Months N=28	12Months N=28	24 Months N=27	36 Months N=22
FI Episodes per Week	13.9±6.7	3.0±3.3	3.8±5.1	4.5±5.8	3.4±4.3
FI Days per Week	6.0±1.3	2.0±1.9	2.2±2.5	2.5±2.3	2.0±2.0
Urgency Episodes per Week[2]	6.7±5.5	1.7±2.7	3.5±4.9	3.8±4.5	2.0±3.0

[1]Values are means ±SD

[2]Two subjects had incomplete data for urgent episodes; therefore the number of subjects reporting this parameter is two less than the total for visit interval

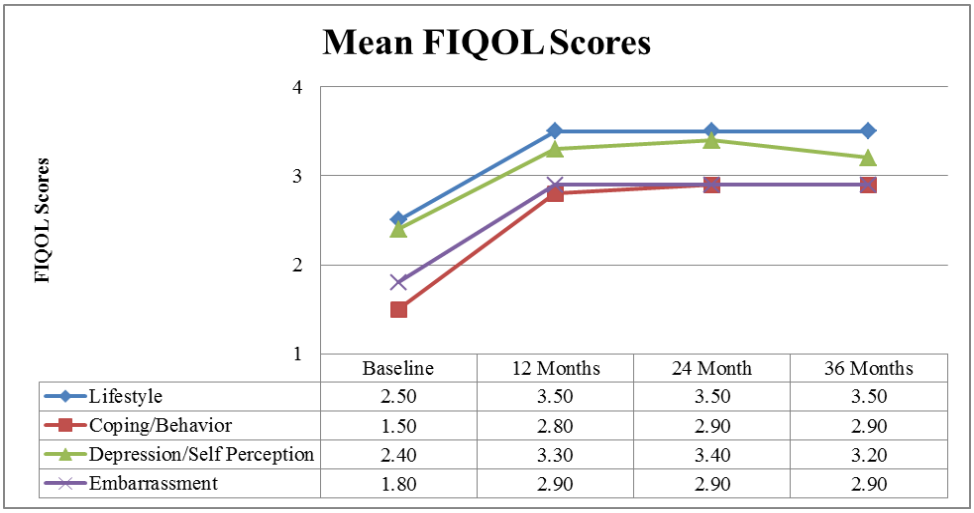
7.3.2. Fecal Incontinence Quality of Life (FIQOL) Questionnaire

The FIQOL questionnaire is a patient-completed questionnaire designed to assess the impact of FI on various aspects of a patient's life. The FIQOL questionnaire is comprised of four scales: Lifestyle, Coping/Behavior,

Depression/Self-Perception, and Embarrassment. Scores range from 1 to 4, with a score of 1 indicating the lowest functional status of quality-of-life. **Figure 3** presents the mean FIQOL data for subjects that fully completed the questionnaire. In some instances, subjects completed only a portion of the questionnaire, not providing sufficient data to calculate a score for that particular scale. This results in a varying number of respondents at each time point for each of the four scales.
The total subjects providing complete responses for each of the four scales at all intervals included in the mean FIQOL Score calculation are provided below. Improvements from baseline are seen in all four scales at all follow-up intervals.

- Lifestyle: Baseline (n=34), 12 months (n=28), 24 months (n= 25), 36 months (n=24)
- Coping/Behavior: Baseline (n=35), 12 months (n=28), 24 months (n=26), 36 months (n=24)
- Depression/Self Perception: Baseline (n=33), 12 months (n=27), 24 months (n=26), 36 months (n= 23)
- Embarrassment: Baseline (n=34), 12 months (n=28), 24 months (n=26), 36 months (n=24)

Figure 3 – Mean FIQOL Scores at Baseline, 12, 24 and 36 Months



	Baseline	12 Months	24 Month	36 Months
Lifestyle	2.50	3.50	3.50	3.50
Coping/Behavior	1.50	2.80	2.90	2.90
Depression/Self Perception	2.40	3.30	3.40	3.20
Embarrassment	1.80	2.90	2.90	2.90

8. DIRECTIONS FOR USE

8.1. Surgical Access

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

8.1.2. 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.

8.2. Sizing of the Anal Canal

8.2.1. Use the FENIX Sizing Tool to determine the FENIX Implant size. The FENIX Implant sizes are denoted by the model number (e.g., FXS18 = 18 Bead Implant).

8.2.2. Guide the FENIX Introducer Tool around the anal canal tunnel per the introducer tool instructions for use.

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

8.2.4. Thread the sizing tool suture through the cross-hole feature of the FENIX Introducer Tool.

8.2.5. Rotate the FENIX Introducer Tool to place the sizing tool around the anal canal in the surgically created tunnel.

8.2.6. Perform sizing per the appropriate sizing tool instructions for use and subsequently remove the sizing tool.

8.3. Placement of the FENIX Implant

8.3.1. Guide the FENIX Introducer Tool around the anal canal tunnel per the introducer tool instructions for use.

8.3.2. Bring the chosen FENIX Implant into the surgical field.

8.3.3. Thread the FENIX Implant suture through the cross-hole feature of the FENIX Introducer Tool.

8.3.4. Rotate the FENIX Introducer Tool to place the FENIX Implant around the anal canal in the surgically created tunnel.

8.3.5. Remove the FENIX Introducer Tool, leaving the FENIX Implant in place around the external anal sphincter with the ends of the implant sutures exposed.

8.3.6. Locate the implant around the dissected space in the same location that was measured.

8.3.7. Verify chosen FENIX Implant size is appropriate via fluoroscopy.

8.3.8. Using the suture provided, secure the ends of the implant with hand tied knots incorporating the green and white sutures such that the eyelets of the implant are touching or overlapping. Once secured, trim sutures above the knot and rotate the device to move the suture knot away from the surgical access wound.

9. IMPLANT REMOVAL

If implant removal is necessary, carefully free the implant 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 implant should be returned to Torax Medical Inc. to allow for technical device analysis.

10. PACKAGING/STORAGE

The FENIX 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 implant or return implant to Torax Medical Inc. Do Not Resterilize.

11. 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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