FENIX®

CONTINENCE RESTORATION SYSTEM

Patient Information

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.

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About This Booklet

This booklet is for patients who have discussed the FENIX® Continence Restoration System with their surgeon. You will learn about the device and how it could help you. If you have questions related to your treatment for fecal incontinence (also known as accidental bowel leakage or ABL), be sure to ask your doctor.

What is the FENIX Implant?

The FENIX implant is a small, flexible band of connected metal (titanium) beads with magnetic cores that is placed around the anal canal to treat accidental bowel leakage (ABL). The beads will separate temporarily to allow the controlled passage of stool. The magnetic force between the beads then brings the implant back to the closed position to prevent unexpected opening of the anal canal that may lead to ABL (also known as fecal incontinence, or FI).

Figure 1 - Closed Position of Implant

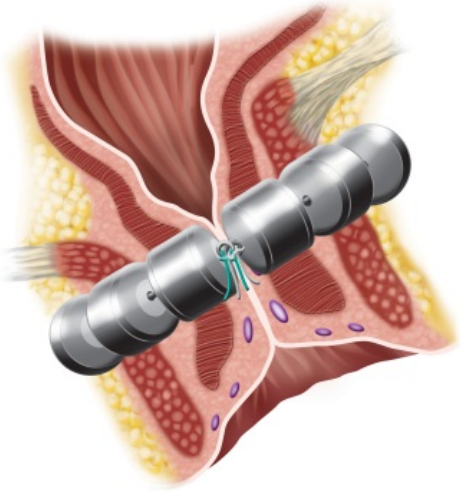
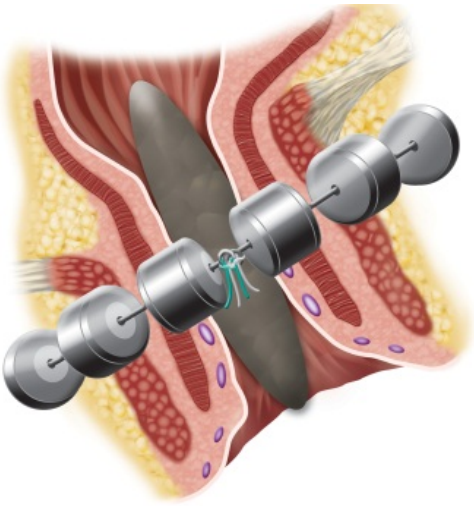


Figure 2 - Open Position of Implant



What conditions are treated with the FENIX implant?

The FENIX implant is used to treat Accidental Bowel Leakage (ABL) also known as Fecal Incontinence (FI) 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 symptoms of accidental bowel leakage (ABL) may range from not being able to hold gas to the loss of an entire bowel movement. Patients may experience stool leakage without knowing, referred to as passive incontinence or accidental

Contraindications: Who cannot have the FENIX Implant?

- Patients that have a suspected or known allergy to a specific type of metal (titanium) should not receive the FENIX implant. If you know or suspect that you are allergic to titanium, please inform your doctor.

Warnings: Things you must do to avoid serious harm

- Do not use this implant if you have diabetes. If you have diabetes, you may develop an infection and need antibiotics that may cause blood sugar levels to fluctuate. If the antibiotic does not clear your infection, your doctor would have to remove the device.
- Do not use this implant if you have any disease that suppresses your immune system. If you have any disease that suppresses your immune system you are more likely to develop recurrent infections and need antibiotics. If the antibiotic does not clear your infection, your doctor would have to remove the device.
- Do not use this implant if you have an open sore near the implant site. If you have an open sore you may develop an infection and need antibiotics. If the antibiotic does not clear your infection, your doctor would have to remove the device.
- The FENIX device cannot enter a MRI machine (MR Unsafe). **Magnetic resonance imaging (MRI)** is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. **After the device is in place, do not enter an MRI unit.** Entering an MRI unit could injure you and may interfere with your device. Other results of entering an MRI unit include any or all of the following:
    - Pain
    - Device movement (migration) requiring device removal
    - Loss of magnetic strength, so the device doesn't work

If you do receive a FENIX implant, you should register your device with the MedicAlertFoundation (www.medicalert.org) or a similar group. Registering your device alerts caregivers to your device and helps ensure that you do not enter an MRI unit after implant. Alternate exams such as X-ray, CT scan, PET scan, and ultrasound are available to patients implanted with the FENIX device.

- You should see your doctor for a monthly rectal exam for the first 3 months after surgery to make sure you are healing properly. Failing to attend monthly exams may result in delayed treatment of an infection or device erosion. Erosion is the breakdown of the tissue next to an implanted component allowing for movement of the implant.
- Tell your doctor if you notice any of the following around the surgical site:
    - Bleeding
    - Drainage (for example pus or fluid coming out of the wound)
    - Pain

  These may be signs of infection or device erosion and should be discussed with your doctor.

Precautions: Things you must do to avoid potential harm

Patients with the conditions listed below have not been studied. Therefore, it is unknown if the FENIX device is a safe option for them. Please discuss the conditions below with your doctor as the FENIX implant may not be right for you.

- Abnormal lower bowel due to birth defect
- Not able to store stool because your rectum has been removed or reduced
- Anal or rectal cancer treated with radiation (suspected or confirmed)
- Rectum pushes out of the anal opening (rectal prolapse)
- Difficulty having a bowel movement without straining and pushing hard
- Inflammatory Bowel Disease (Crohn's and ulcerative colitis)
- ABL due to diarrhea that is not helped with diet changes or medicine
- Active pelvic infection
- ABL due to a condition that affects your entire body or nervous system (scleroderma or dementia)
- Pregnant or plan to become pregnant

What are the observed adverse events and potential risks?

The observed adverse events and unobserved potential risks are provided below[1]:

- Observed serious adverse events during the clinical study:
  - Infection
  - Device Erosion
  - Straining and incomplete bowel emptying (Impaction or defecatory disorder)
  - Hospitalization due to shingles
- Observed non-serious adverse events during the clinical study (all having mild or moderate severity defined as easily tolerated discomfort up to discomfort that interferes with usual activities.)
  - Pain
  - Straining and incomplete bowel emptying (Impaction or defecatory disorder)
  - Device Erosion
  - Bleeding
- Observed serious and non-serious adverse events for device erosion, infection, and ongoing Accidental Bowel Leakage at times led to device explant/re-operation during the clinical study.
- Potential Risks that were <u>not</u> observed during the clinical study
  - Death related to the device or procedure
  - Device failure
  - Device does not appear to be at implant site
  - Slowing of stool through the bowel or colon Inability to pass gas
  - Anal itching
  - An opening forming between rectum and vagina
  - Other injury to the anus, rectum, or vagina
  - Worsening of pre-operative symptoms related to the device or procedure
  - Additional unknown risks may exist

[1] The observed adverse events were reported as potentially device or procedure related. An adverse event is defined as any undesirable/unusual experience that occurs to a patient during a clinical study.

Additionally, general surgery and anesthesia carries risk. These risks may include, but are not limited to the following:

- Headache, muscle pain, nausea (adverse reaction to anaesthesia)
- Life threatening allergic reaction
- Blood circulation stops (cardiac arrest)
- Death
- Fever
- Low blood pressure
- Inadequate oxygen in blood
- Infection
- Heart attack
- Lung infection (pneumonia)
- Blocked artery in lungs
- Breathing trouble (respiratory distress)
- Blood clot causing inflammation
- Vomiting

Who may benefit from the FENIX Implant?

Patients that have been diagnosed with accidental bowel leakage and aren't candidates for, or have already tried and failed less invasive options may benefit from the FENIX implant. Some examples of less invasive options include: material injected into the anal wall (injectable bulking agents), a heat probe applied to the inner anal wall (radiofrequency ablation), and electrical stimulation of the nerves that control the sphincter muscles (sacral nerve stimulation).

What are the probable benefits of this procedure?

Benefits of treatment with the FENIX implant may include:

- Improvement in quality of life
- Improvement in symptom severity
- Decrease in the number of ABL episodes per week
- Decrease in the number of days with ABL symptoms
- Decrease in the number of urgent episodes per week
- FENIX Implant does not require the patient to manipulate the device
- Patient's anatomy is not changed

How to decide about this treatment

Prior to making a decision regarding treatment with the FENIX implant, it's important that you've read and understand all of the information provided in this booklet, including the risks associated with the FENIX implant. You should discuss all available treatment options with your doctor before you decide, as there are other options available to treat your accidental bowel leakage.

What happens before the procedure?

Before the procedure, your doctor will perform tests to determine that you are well enough to undergo surgery and confirm that you are a good candidate for the FENIX implant. To better understand your condition, your physician may conduct specific tests such as endoanal ultrasound and anal manometry. Endoanal ultrasound is a test that uses ultrasound to show the condition of the anal sphincter muscles. Anal manometry is a test done to show the strength of your anal sphincter muscles. Your doctor will explain each of these tests in more detail if he/she feels they are necessary.

What happens during the procedure?

Before the procedure begins, you will be given medications that put you to sleep (general anesthesia) or you will be awake, but the area of the surgery will be numb (regional anesthesia). Your surgeon will make a cut in the area above the anus to gain access to the anal canal. A tunnel is then created around the canal in which to place the FENIX device. A sizing tool is passed through the tunnel to measure the size of the anal canal. The right size device is selected and placed in the created tunnel. The device is tied-off and the wound is closed with stitches. A typical procedure lasts about an hour. Your surgeon will keep you in the hospital for a couple days to ensure you are healing well and having bowel movements.

What happens after the procedure?

You and your doctor will discuss your recovery plan, but it's common to take it easy for a few weeks after any surgery. Your diet will not be limited in any way, but you may be given stool softeners to lessen the chance of having to strain during bowel movements for a period of time after the procedure.

Implant Card

You will receive a FENIX Implant Card from your doctor following your surgery. Carry your FENIX Implant Card with you as notification to care providers that you have received a FENIX device. If you lose this card, please contact your doctor's office to receive a replacement card.

When to call your doctor

After the procedure, your doctor will provide you with instructions about when to call. In general, you should contact your doctor if you have:

- Fever over 100.4 degrees or signs of infection (redness, swelling, and/or heat around the area of implant)
- Thinning of the skin or tissue over the implanted device
- If you have severe pain that lasts longer than expected
- If you experience significant wound drainage (pus or fluids) or bleeding
- You are told that you need to have an MRI exam. You must notify your doctor or MRI staff that you have been implanted with the FENIX device, **which is not safe to undergo MRI scanning**. **After implantation, you should not be placed in an MRI machine.** The MRI machine could injure you and interfere with the magnetic strength and the function of the device. The following imaging tests can be safely used, based upon physician recommendation:
    - CT scan (Computed Tomography)
    - Ultrasound (sonography)
    - Radiography / Fluoroscopy / Angiography
    - PET scan (Positron Emission Tomography)

Where you can find out more

Additional information about the FENIX device can be found at:

www.toraxmedical.com

Travel

You may travel as soon as advised by your doctor. The FENIX device should not interfere with airport security. You should carry your implant card when traveling so others will know you

have an implanted device in case of an emergency.

What the study showed

The FENIX device has been studied in 35 patients with accidental bowel leakage. At the time this brochure was written, follow-up for the study was ongoing. The total number of available follow-up visits at each interval is reported below.

- 28 patients were assessed at 1 year
- 26 patients were assessed at 2 years
- 24 patients were assessed at 3 years
- 16 patients were assessed at 4 years
- 6 patients were assessed at 5 years

Safety

No deaths related to the device or procedure were reported in the study. One patient death was reported as caused by cirrhosis of the liver and unrelated to the device or procedure. Complications reported in the study are listed below, along with percentage of patients who had the complication:

- Pain in 6 patients (17%)
- Straining and incomplete bowel emptying in 4 patients (11%)
- Device erosion in 4 patients (11%)
- Infection in 4 patients (11%)
- Bleeding in 3 patients (8%)
- Allergy, inflammation reaction in 1 patient (2%)

Mild pain or symptoms were defined as easily tolerated discomfort.

Moderate pain or symptoms were defined as discomfort that interferes with usual activities.

Severe pain or symptoms were defined as incapacitating with inability to perform usual activities.

Pain was usually mild or moderate and resolved by the 6 month follow-up visit in most patients. **Straining and incomplete bowel emptying** ranged from mild to severe and resolved in most patients by the 6 month visit.

Device erosions ranged from mild to severe, and resulted in removal of the device in 3 patients. Erosion is the breakdown of the tissue next to an implanted component allowing for movement of the implant from its original location.

All **infections** were considered serious and required hospitalization for antibiotics. In 3 of 4 patients, the infection did not resolve with antibiotics and the device had to be removed.

Bleeding was reported as mild or moderate, and in most cases resolved within two days of occurrence.

Allergy, inflammation reaction was reported in one patient and required extended hospitalization. The reaction resolved within two weeks of onset.

Device Removal

Overall, 7 patients (20%) had the device removed. The majority of device removals occurred within 3 months of the surgery. Two removals occurred later; one occurred 9 months after implant, and the other occurred about 2.5 years after the placement of the FENIX device. As noted above, reasons for device removal included infection in 3 patients, device erosion in 3 patients and ongoing accidental bowel leakage in 1 patient.

Other Surgical Procedures

A total of 3 patients (8.6%) underwent surgery to divert stool to a pouch outside the body (stoma). Reasons for the stoma procedure included dissatisfaction with continuing accidental bowel leakage in 2 patients and impaction or defecatory disorder in one patient. Additionally, one patient had the device removed due to device erosion and chose to try sacral nerve stimulation (SNS) therapy to treat ongoing accidental bowel leakage.

Probable Benefits

The following describes the potential benefits of treatment with the FENIX device. During a clinical study of 35 patients with 3 years follow-up completed, success was measured as a decrease in accidental bowel leakage after the FENIX procedure compared to before treatment. Quality of life was also assessed before and after FENIX implant.

While the FENIX implant has probable benefit for some patients, it is possible that you will not see any improvement in your ABL, and it's possible that your ABL will get worse.

Decrease in Accidental Bowel Leakage

Patients recorded their bowel accidents before and after the FENIX procedure to see if the accidents were reduced. The following was measured:

- Number of accidents per week
- Number of days per week with accidents

- Number of times per week a patient had to urgently get to a bathroom (urgent episodes)

Patients achieving at least a 50% decrease in accidents after treatment compared to before were counted as meeting the success criteria.

Of the 35 patients enrolled, 28 completed the 1 year diary, while 27 and 22 patients completed the 2 and 3 year diaries, respectively.

Number of accidents per week

The average number of accidents reported by patients before the FENIX implant (35 patients) was 13.9 accidents per week and was reduced to 3.8 at 1 year (28 patients reporting), 4.5 at 2 years (27 patients reporting), and 3.4 at 3 years (22 patients reporting). See **Table 1** for a summary of this data.

Number of days per week with accidents

The average number of days per week with an accident was 6 days per week before FENIX implant (35 patients) and reduced to 2.0 at 1 year (28 patients reporting), 2.5 at 2 years (27 patients reporting) and 2.0 at 3 years (22 patients reporting) after treatment. See **Table 1** for a summary of this data.

Number of urgent episodes per week

The average number of urgent episodes per week reported by patients was 6.7 episodes per week before the FENIX implant (35 patients) and had decreased to 3.5 at 1 year (28 patients reporting), 3.8 at 2 years (27 patients reporting), and 2.0 at 3 years (22 patients reporting). See **Table 1** for a summary of this data.

Table 1 – Bowel Diary Results: Average Number of Accidents

Success Criteria	**Pre-Implant** *(35 Patients Reporting)*	**1 Year** *(28 Patients Reporting)*	**2 Year** *(27 Patients Reporting)*	**3 Year** *(22 Patients Reporting)*
Number of ***Accidents Per Week*** *(Average)*	13.9	3.8	4.5	3.4
Number of ***Days Per Week With An Accident*** *(Average)*	6	2.0	2.5	2.0

*Number of **Urgent Episodes** Per Week (Average)*	6.7	3.5	3.8	2.0

Table 2 provides the percentage of patients reporting at least a 50% decrease in accidents per week, days per week with ABL, and urgent episodes per week.

Table 2 –Bowel Diary Results: Patients Reporting at Least a 50% Decrease In:

Accidents per week		
1 Year after FENIX	2 Years after FENIX	3 Years after FENIX
78% of 28 patients	70% of 27 patients	90% of 22 patients
ABL days per week		
1 Year after FENIX	2 Years after FENIX	3 Years after FENIX
67% of 28 patients	59% of 27 patients	77% of 22 patients
Urgent episodes per week		
1 Year after FENIX	2 Years after FENIX	3 Years after FENIX
50% of 28 patients	48% of 27 patients	65% of 22 patients

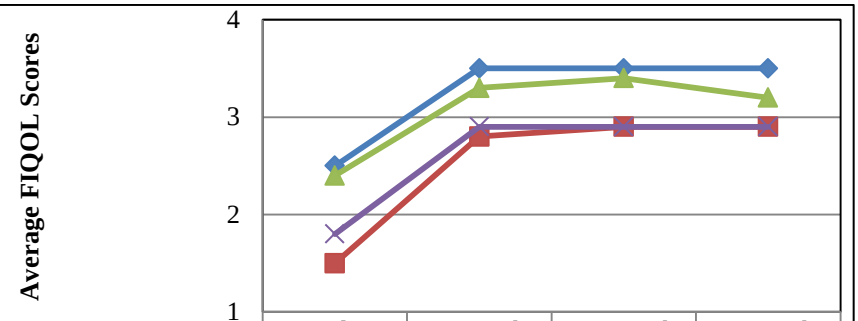
Quality of Life

Patients completed a survey to assess the effect of accidental bowel leakage on their quality of life before and after treatment. The survey is called the Fecal Incontinence Quality of Life (FIQOL) questionnaire. It includes four separate scales that ask questions relating to how accidental bowel leakage (also known as FI) affects four different areas of their life: Lifestyle, Coping/Behavior, Depression/Self-Perception, and Embarrassment. Possible scores range from 1 to 4 in each category, with 1 representing the lowest option, and 4 representing the highest, or best quality of life in each category. Improvements after the FENIX device compared to before treatment were seen across all four scales at 1 year and continued through 3 years for most patients. **Figure 1** presents the average scores reported for each of the four categories before, and for 3 years after the FENIX implant surgery. The total number of patients providing complete responses for each of the four FIQOL scales at 1, 2, and 3 years is provided below.

- 28 patients completed the FIQOL questionnaire at 1 year

- 26 patients completed the FIQOL questionnaire at 2 years
- 24 patients completed the FIQOL questionnaire at 3 years

Figure 1: Average FIQOL Scores Before and After the FENIX Implant Surgery



	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

Common questions

Q. Will I have to do anything to have a bowel movement once the FENIX device has been implanted?

A. No, the device will open up with the abdominal push required when one has a normal bowel movement. The device is designed to work on its own.

Q. Is there a risk of my body rejecting the FENIX device?

A. The FENIX device is designed to minimize the risk of rejection. All areas of the device that contact the body are made of materials that are used frequently in medical devices and have proven to be very stable. However, if you have a medical history that suggests you may be at increased risk of your body rejecting a medical device, it is important that you tell your doctor about this before receiving a FENIX device.

Q. Will the magnets wear out?

A. The FENIX device uses permanent magnets and therefore will not wear out.

Q. Will I need any follow up testing?

A. You and your doctor will discuss your follow-up plan; however, it is recommended that you are seen monthly for the first 3 months after the procedure to ensure you are healing properly. No additional testing should be needed unless you are having symptoms that your doctor feels require testing.

More about your condition

Common causes of accidental bowel leakage include: long-term constipation or diarrhea; damage to the anal sphincter muscles (from prior surgery or trauma); damage to the nerves of the anal sphincter muscles or the rectum (this may happen to women during pregnancy or childbirth); weakening of the anal sphincter muscles; weakening of the pelvic floor muscles.

Once you have been diagnosed with accidental bowel leakage, there are a number of treatment options that may improve your condition. You should have tried some of these options prior to being prescribed the FENIX implant. These options may include the following:

- Diet changes such as the addition of fiber or not eating certain foods
- Anti-diarrheal medicine to form more solid stool, or laxatives to soften the stool
- Muscle training (biofeedback) to relearn how to control your anal sphincter muscles
- Exercises to strengthen your anal sphincter muscles
- Material injected into the anal wall (injectable bulking agents) or a heat probe applied to the inner anal wall (radio-frequency ablation) to increase the thickness of the anal wall
- Surgery which may include sphincter repair (sphincteroplasty) and electrical stimulation of the nerves that control the sphincter muscles (sacral nerve stimulation). These procedures work by repairing or providing additional support to your anal sphincter muscles.

You can find additional information on accidental bowel leakage, or fecal incontinence at the National Institutes of Health's website:

http://www.bowelcontrol.nih.gov/

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