ETHICON

The FENIX® Continence Restoration System

On April 27, 2017 Torax Medical announced the discontinuation of sales and clinical studies of the FENIX® Continence Restoration System. This is solely a business decision based on fit with Torax and Ethicon's strategic business plans and is not due to any safety concerns with the FENIX system.

Clinical support for physicians and implanted patients is unaffected by this decision. The FENIX device does not require any adjustment or maintenance.

If you have had a FENIX system implanted and have any questions or concerns regarding your implant, please contact your physician directly.

Frequently Asked Questions

How is the FENIX device implanted?
The FENIX device is placed around the weakened anal sphincter muscles during a surgical procedure.

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

How long will the FENIX device last?
The FENIX device is designed to be a lifelong implant. The FENIX device uses permanent magnets that are designed to not wear out.

Can the patient go through airport security?
The FENIX device should not affect airport security.

Can the patient have an MRI?
The FENIX device is considered MR Unsafe. Patients with a FENIX device can safely undergo a wide range of diagnostic imaging tests, including: X-Ray, Ultrasound, PET SCAN and CT Scan. In the event other diagnostic procedures cannot be used and an MRI is required, the FENIX device can be removed.

FENIX® Continence Restoration System Brief Statement

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).

Humanitarian Device
Authorized by Federal (USA) Law for use in the treatment of fecal incontinence. The effectiveness of this device for this use has not been demonstrated.

Rx Only.

Contraindications: Do not implant the FENIX Device in patients with suspected or known allergies to titanium.

Warnings: The FENIX Device is considered 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. It is recommended that patients receiving the FENIX Implant 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.

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.

General Precautions: The FENIX Device is a long-term implant for use in patients 19 years or older. Medical management of adverse reactions may include antibiotic use, wound revision and explantation.

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.

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

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

Potential Side Effects: 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.

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.

For more information on the FENIX Continence Restoration System, contact your physician or Ethicon customer support at 1-877-ETHICON.

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