

THE FENIX™ SYSTEM: SO SIMPLE, IT'S REVOLUTIONARY

- Attraction forces augment the incompetent anal sphincter muscles
- Works in harmony with the body's native sphincter muscles
- Begins working immediately after implant
- Simple, intuitive design does not require activation by patient
- No post-implant adjustments required



Actual size

FECAL INCONTINENCE: THE FACTS

- In women living in the community, fecal incontinence occurs in 6% of those younger than 40 and increases to 15% in older women³
- In men living in the community, fecal incontinence occurs in 6-10% and increases slightly with age³
- Rates of fecal incontinence in nursing homes are nearly 50%^{4,5}
- Individuals with fecal incontinence miss approximately 15 days of work or school per year and 13% cannot attend work or school at all due to their condition⁶

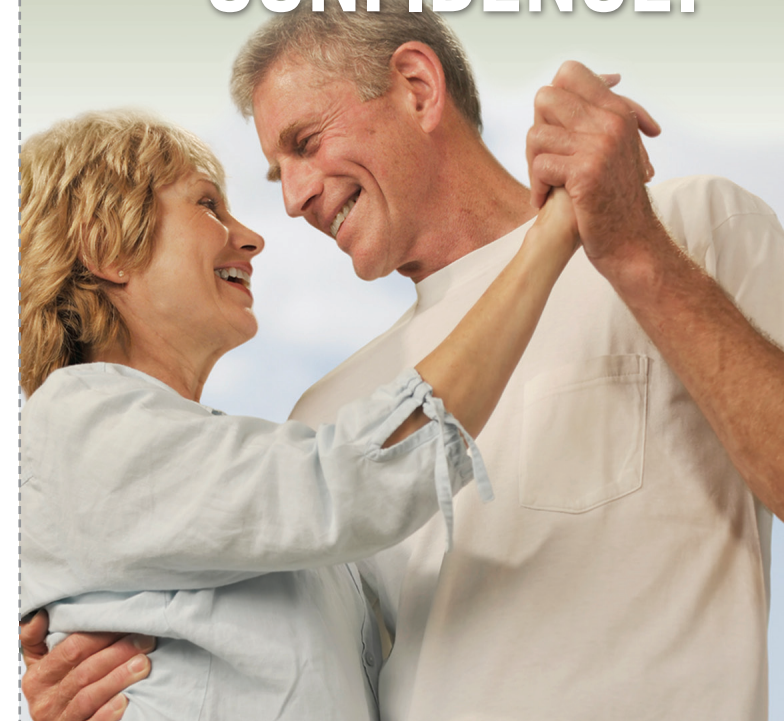


For more information on the FENIX™ Continenence Restoration System please visit www.toraxmedical.com or speak with your healthcare provider.

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RESTORE CONTROL. REGAIN CONFIDENCE.



UNDERSTANDING FECAL INCONTINENCE

Fecal Incontinence (FI) is the inability to control your bowel movements, causing stool to leak unexpectedly from your rectum. Fecal Incontinence can range from occasional leakage of a small quantity of stool to a complete loss of bowel control.¹ An incompetent anal sphincter can be a primary factor in fecal incontinence.

Causes of Fecal Incontinence²

Fecal incontinence can have several causes, including:

- Constipation
- Damage to the anal sphincter muscles
- Damage to the nerves of the anal sphincter muscles or the rectum
- Loss of storage capacity in the rectum
- Diarrhea
- Pelvic floor dysfunction

Symptoms of Fecal Incontinence¹

The symptoms of fecal incontinence may range from the inability to hold gas, “silent” leakage of stool during daily activities or exertion, or being unable to reach the toilet in time. Other intestinal symptoms such as diarrhea, constipation and abdominal discomfort may also be present.

References:

1. www.acg.gi.org
2. digestive.niddk.nih.gov

THE FENIX™ CONTINENCE RESTORATION SYSTEM: RESTORE CONTROL. REGAIN CONFIDENCE.

The FENIX™ Continenence Restoration System is designed to treat fecal incontinence by augmenting the incompetent anal sphincter muscles to restore continence.

The FENIX™ System is a small, flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads augments the anal sphincter muscles, creating a barrier to unexpected passage of fecal content (Figure 1). The magnetic bond is temporarily broken to allow the intentional passage of stool and restored immediately thereafter (Figure 2).

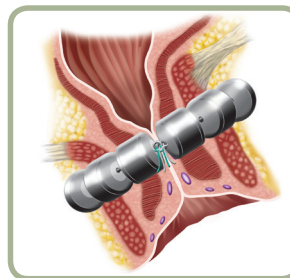


Figure 1: The magnetic attraction augments the anal sphincter muscles.

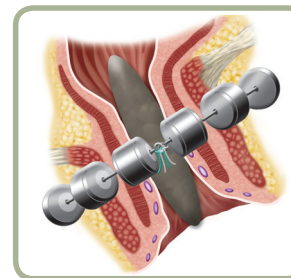


Figure 2: The FENIX™ System expands to allow intentional passage of stool.

References:

3. National Institutes of Health State-of-the-Science Conference Draft Statement. Prevention of Fecal and Urinary Incontinence in Adults. December 12, 2007.
4. Nelson R, Furner S, Jesudason V. Fecal Incontinence in Wisconsin Nursing Homes. *Diseases of the Colon and Rectum* Vol. 41, No. 10 October 1998.

THE PROCEDURE

The FENIX™ System is placed around the anal sphincter muscles in a procedure that generally requires an hour to complete. Patients are placed under general anaesthesia during the procedure.

A customized sizing tool is placed around the area of implant to ensure the optimal size FENIX™ System is selected. Fluoroscopy is used to confirm the correct size device has been implanted.

Once the device is implanted it begins working immediately.

Your physician can provide you additional information.

References:

5. Dey AN. Characteristics of elderly nursing home residents; data from the 1995 National Nursing Home Survey. *Advance data from vital and health statistics*; no. 289. Hyattsville, Maryland; National Center for Health Statistics 1997.
6. Drossman DA, Li Z, Andruzzi E, et al. U.S. Householder Survey of Functional Gastrointestinal Disorders: Prevalence, Sociodemography, and Health Impact. *Dig Dis Sci* 1993;38:1569-80.