New device approved for fecal incontinence

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(HealthDay)—The Fenix Continence Restoration System has been approved by the U.S. Food and Drug Administration to treat an inability to control bowel movements for people who can't tolerate or use other approved methods.

The inability to control the bowels, medically called fecal incontinence, is most often caused by muscle damage from vaginal childbirth or from certain medical disorders such as diabetes, the agency said Friday in a news release.

The Fenix system was evaluated in 35 adults, 15 of them from the United States. U.S. trial participants will be examined for five additional years to evaluate the device's performance, the FDA said.

The system should not be implanted in people with known or suspected allergies to titanium, stainless steel, nickel or iron. And people who have had the device implanted should not have a magnetic resonance imaging (MRI) scan, the agency warned.

Side effects of the system have included pain, infection, device erosion, additional surgery to remove the device, and bleeding.

The Fenix system is produced by Torax Medical, based in Shoreview, Minn.

More information: Visit the FDA to learn more.