Beyond Pads and Surgery: What Clinicians Should Know About Silicone Anal Inserts for Fecal Incontinence

Dr. Reyes had been following Mrs. Harmon for nearly two years. The 68-year-old had undergone a low anterior resection for early-stage rectal cancer, and while her oncologic outcomes were excellent, her quality of life told a different story.

Diet modification helped. Fiber supplementation reduced urgency somewhat. Six months of pelvic floor therapy improved her awareness and control. But Mrs. Harmon still arrived at each appointment with the same quiet frustration.

"I'm still wearing pads every day," she said. "I've canceled two trips to see my grandchildren. I just don't trust my body anymore."

She paused, then asked a question Dr. Reyes had heard before:

> "Isn't there something between these pads and surgery?"

For years, the honest answer was often "not much." Conservative measures help some patients, but many eventually plateau. Surgical and neuromodulation interventions can be effective, but they are not appropriate or desired for everyone.

As a result, many patients remain in a treatment gray zone, managing symptoms rather than progressing to a solution that fits their lives.

That picture is beginning to change.

Silicone anal inserts represent a newer approach within the conservative management spectrum of fecal incontinence.[1] Despite years of clinical use in European continence care programs, this device category remains unfamiliar to many clinicians in the United States.

This article provides an evidence-informed overview of silicone anal inserts, their clinical rationale, and practical considerations for incorporating them into fecal incontinence management.

The Gap in Fecal Incontinence Treatment Options

Fecal incontinence (FI), also called accidental bowel leakage (ABL), affects approximately 8 to 10 percent of community-dwelling adults.[2] Prevalence rises sharply in older populations and institutional settings, where estimates approach 50 percent.[3]

Despite these numbers, the condition remains underdiagnosed and undertreated. Many patients never broach the topic, and many clinicians do not routinely ask.[4]

Clinical guidelines from organizations including the American Society of Colon and Rectal Surgeons (ASCRS), the National Institute for Health and Care Excellence (NICE), and a joint European guideline supported by United European Gastroenterology (UEG), the European Society of Coloproctology (ESCP), the European Society of Neurogastroenterology and Motility (ESNM), and the European Society for Primary Care Gastroenterology (ESPCG) all recognize conservative management as first-line therapy.[5,6,7]

Common approaches include:

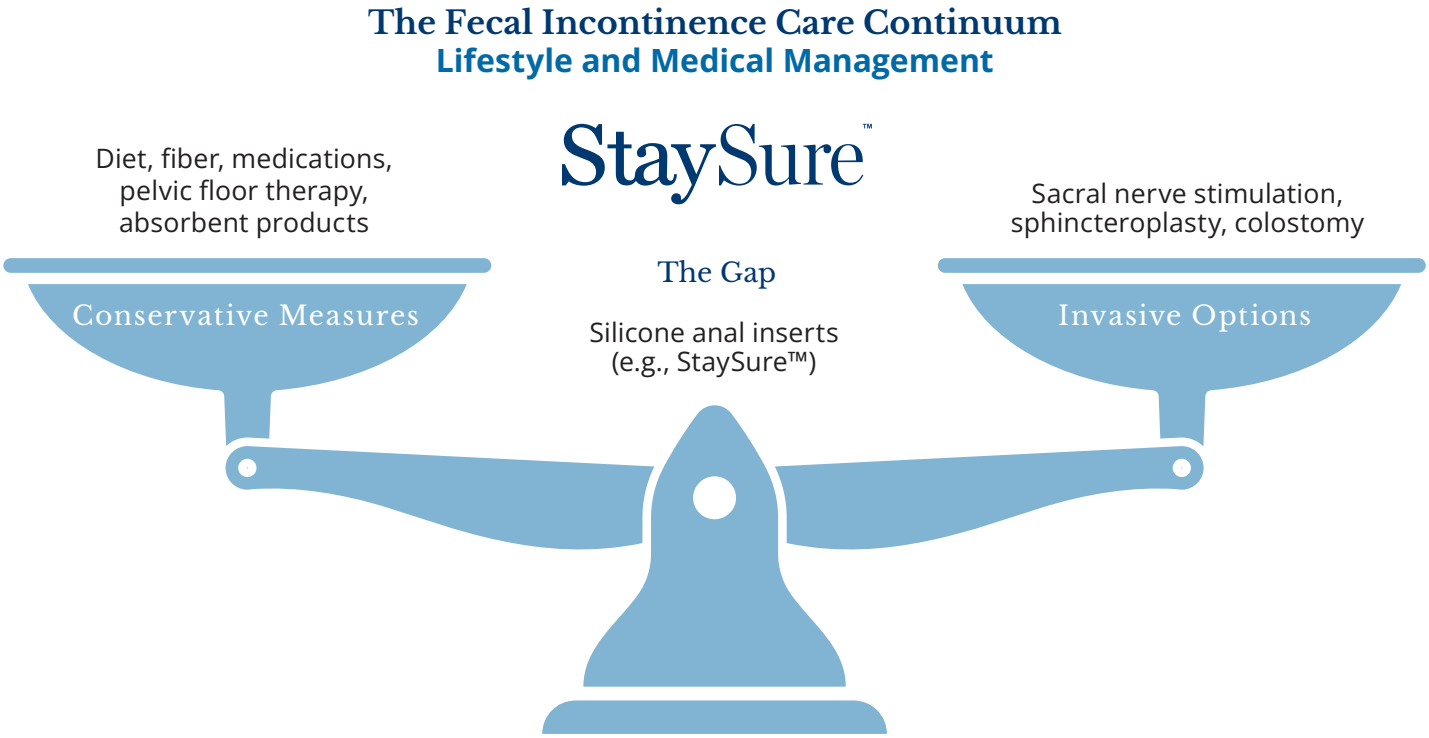
- Dietary modification
- Fiber supplementation
- Antidiarrheal medications
- Pelvic floor rehabilitation

These interventions meaningfully improve symptoms for many patients.

However, when conservative strategies plateau, the traditional next steps often involve more invasive interventions such as sacral nerve stimulation, injectable bulking agents, sphincteroplasty, or colostomy.[5] These treatments have important roles in FI management, but they also carry procedural risks, referral to specialists, and recovery considerations.

In the meantime, absorbent products frequently become the default. Pads and briefs serve an important containment function, but they manage leakage after it occurs rather than preventing it. For some patients, that distinction matters greatly.

This gap in the fecal incontinence care continuum has prompted growing interest in device-based approaches that aim to prevent accidental bowel leakage through mechanical support. Silicone anal inserts are generally considered within the conservative management spectrum of fecal incontinence care.



Silicone anal inserts may serve as a bridge for patients who have plateaued on behavioral strategies but are not candidates for, or do not want, surgical intervention.

Why Earlier Anal Plug Designs Did Not Gain Wider Use

The concept of using an anal insert to prevent fecal leakage is not new. Various designs have been explored over the past several decades, including polyurethane foam plugs and rigid or semi-rigid devices intended to occlude the anal canal.[1]

Clinical studies showed that when patients could tolerate these devices, they often worked. Continence improved. Quality-of-life scores increased. Patients reported greater confidence and reduced reliance on absorbent products.[1,8]

The primary challenge was tolerability.

A Cochrane systematic review noted dropout rates as high as 35 percent, with discomfort cited as the primary reason for discontinuation.[1] A 2021 review in Techniques in Coloproctology echoed these findings: while anal inserts could be effective, tolerability remained the central barrier to adoption.[8] Patients frequently described sensations of pressure, urgency, or persistent awareness of the device.

The clinical takeaway: the underlying concept was sound, but the design required improvement. What patients needed was a device capable of providing mechanical support without compromising comfort.

Evolution of Anal Insert Design

Earlier Anal Plugs	Modern Silicone Inserts
Rigid or semi-rigid foam	Soft, fluid-filled silicone
Static shape	Adapts dynamically with movement
High dropout due to discomfort	Designed for improved tolerability
Limited clinical adoption	Growing use in Europe since 2021

The Evolution of Silicone Anal Inserts

Newer silicone-based anal inserts were developed specifically to address the tolerability limitations of earlier devices.[8]

Key design innovations include:

- **Soft silicone construction** that conforms to individual anatomy
- **Fluid-filled structure** that allows the device to adapt dynamically with movement
- **Dual-seal mechanism** that forms contact at both the anorectal junction and within the anal canal
- **External retainer tab** that prevents migration and allows easy removal

This design relies on fluid dynamics. During insertion, the fluid within the device shifts, allowing it to narrow and pass comfortably through the anal canal. Once positioned, the insert gently expands to form a seal that helps prevent stool from passing unintentionally.

For many patients, the most meaningful benefit may simply be having an option that helps prevent leakage rather than managing it after the fact.

European Clinical Experience

The insert, manufactured by Minnesota Medical Technologies in the United States and sold in Europe under the Navina brand by Wellspect Healthcare, has been available in European markets since 2021.[9]

Post-market evaluations have reported:

- Improved patient confidence
- Reduced leakage episodes
- Enhanced quality of life

Clinical evaluations suggest the design changes, particularly soft silicone and fluid-adaptive mechanics, have improved tolerability compared with earlier plug designs.[1,8,9]

This international experience has helped establish silicone anal inserts as a practical device-based option within continence care programs, particularly for patients seeking additional support beyond absorbent products.

FDA Clearance and U.S. Availability

In July 2025, Minnesota Medical Technologies received 510(k) clearance from the U.S. Food and Drug Administration for StaySure™, a silicone anal insert designed to help manage symptoms of fecal incontinence.[10]

Key regulatory considerations include:

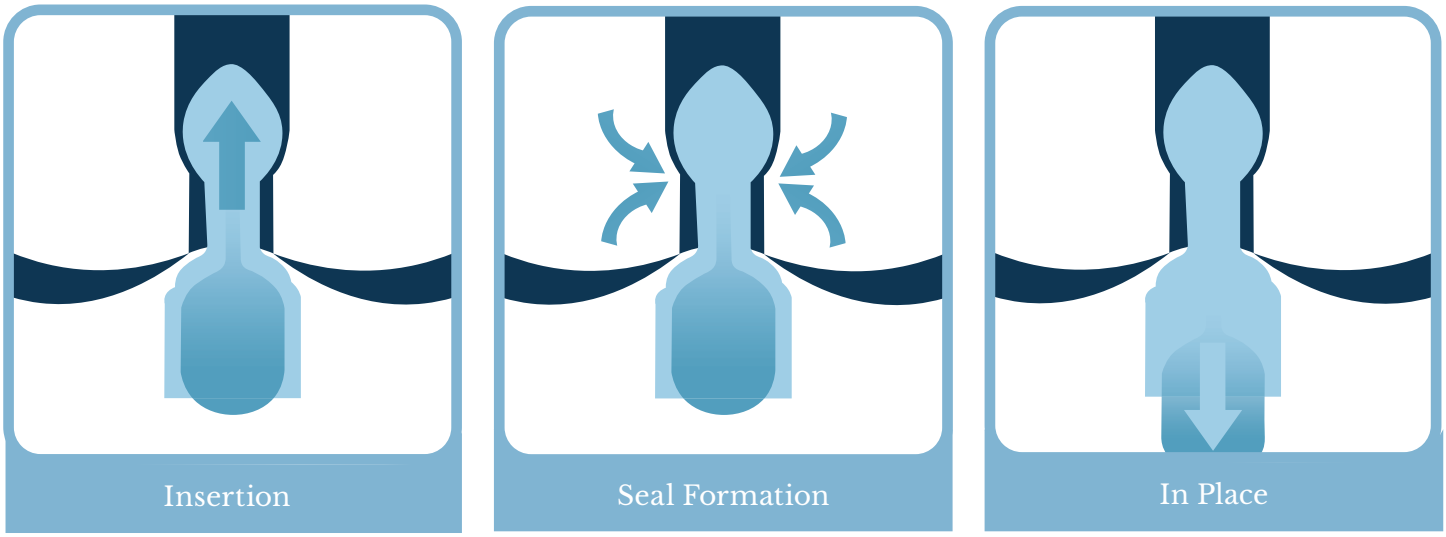
- 510(k) clearance establishes substantial equivalence to a legally marketed predicate device. It is a regulatory determination rather than an endorsement.
- StaySure™ and the Navina Insert are the same device, manufactured by Minnesota Medical Technologies and marketed under different brand names in the United States (StaySure™) and Europe (Navina Insert).[9]
- A clinical study conducted at Mayo Clinic (ClinicalTrials.gov identifier NCT03898778) evaluated the safety and effectiveness of the device in adults with fecal incontinence.[11] Results are expected to be published in the future.

StaySure™ is a prescription-only medical device intended to help manage symptoms of accidental bowel leakage in adults. It does not treat underlying conditions that may contribute to fecal incontinence.

StaySure™ at a Glance

- FDA 510(k) cleared (July 2025)
- Prescription-only silicone anal insert
- Designed to help prevent accidental bowel leakage
- Soft fluid-filled silicone construction
- Up to 24-hour wear time
- Single-use disposable device
- Standard and Large sizes available (evaluation kit available)
- Latex-free and biocompatible

How Silicone Anal Inserts Work



Fluid shifts to narrow device for comfortable passage

Dual seal forms at anorectal junction and anal canal

External retainer tab remains visible for security and removal

The device is inserted using a disposable applicator. Once positioned, the fluid-filled silicone conforms to the anatomy, creating a gentle seal that helps prevent accidental leakage.[9,10] The single-use insert may be worn between bowel movements or for up to 24 hours, after which it is removed manually and discarded.

The goal is mechanical symptom management, not alteration of underlying physiology. Silicone anal inserts aim to prevent leakage rather than absorb it.

Clinical Vignette: A Continence Nurse's Experience

Linda, a continence nurse specialist at a pelvic health clinic, recently introduced silicone anal inserts to several patients as part of a broader accidental bowel leakage treatment approach.

One was a 54-year-old woman managing fecal incontinence for nearly a decade following a complicated vaginal delivery. She had tried dietary modification, pelvic floor therapy, and biofeedback with modest improvement. She wore pads daily and had declined sacral nerve stimulation, citing concerns about the procedure.

"She told me she just wanted something that would let her go to her daughter's wedding without worrying," Linda recalled.

After confirming no contraindications, Linda explained how the device worked and provided an evaluation kit so the patient could determine the most comfortable fit.

Two weeks later, the patient returned. She had worn the insert during several outings — a long car trip, dinner with friends. She described feeling more confident and less preoccupied with restroom proximity.

> "It's not a miracle," the patient said.
> "But it's the first time in years I've felt like I had some control."

Individual results vary, and not every patient will experience the same benefit. However, early experiences like these suggest silicone anal inserts may offer a useful addition to the fecal incontinence management toolkit for carefully selected patients.

Identifying Appropriate Candidates for Fecal Incontinence Devices

Silicone anal inserts are not appropriate for every patient with fecal incontinence. Thoughtful patient selection is essential to achieving good outcomes and avoiding complications.

May Be Appropriate	May Not Be Appropriate
Adults with FI affecting quality of life	Active inflammatory bowel disease
Persistent symptoms despite conservative measures	History of anal fissure, Grade III–IV internal hemorrhoids, or thrombosed external hemorrhoids within the past 6 months
Dissatisfaction with absorbent products	Recent anorectal/colorectal surgery (typically <4 weeks)
Preference for non-surgical management	Known silicone allergy
Capable of self-insertion/removal (or caregiver support)	Cognitive impairment limiting safe device management

Refer to **Information for Use (IFU)** for complete contraindications and warnings.

Clinical Conversation Points

When discussing silicone anal inserts with patients, consider:

- **Manual dexterity** — Can the patient (or a caregiver) comfortably insert and remove the device?
- **Expectations** — Manages symptoms but does not cure the underlying disease
- **Lifestyle goals** — When would the device be most useful? (travel, social events, work)
- **Trial approach** — Evaluation kits allow patients to find optimal fit before committing

Shared decision-making remains central to successful fecal incontinence management.

Practical Takeaways for Clinicians

Clinical Takeaways

- ✓ **Screen routinely.** Many patients will not volunteer FI symptoms. Ask directly, especially in high-risk populations (older adults, postpartum women, post-surgical patients, those with neurological conditions).[4]
- ✓ **Expand the conversation.** Let patients know device-based options exist beyond pads and surgery. Awareness itself can reduce feelings of hopelessness.
- ✓ **Position within the care continuum.** Silicone anal inserts may bridge the gap between conservative measures and invasive interventions and can be used as a complementary option alongside other therapies.
- ✓ **Encourage a trial approach.** Evaluation kit allow patients to test fit and comfort before committing to regular use.
- ✓ **Understand the regulatory status.** StaySure™ is FDA 510(k) cleared and prescription-only.[10]

Toward Comprehensive Continence Care

Fecal incontinence management is evolving. As awareness of the condition grows, clinicians are increasingly recognizing the need for a broader spectrum of treatment options.

Silicone anal inserts represent one evidence-informed addition to the conservative management toolkit.[1,8] They do not replace other therapies, nor do they cure the underlying causes of fecal incontinence. However, for patients who have struggled between behavioral measures and invasive interventions, they may provide a meaningful option.

For clinicians, familiarity with emerging device-based solutions supports more comprehensive patient counseling. When patients ask whether there is something between pads and surgery, it helps to have an informed answer.

> Silence should never be the standard of care, and neither should a one-size-fits-all approach to managing fecal incontinence.

Learn More

For clinicians: Request an evaluation kit or clinical materials at mnmedicaltechnologies.com.

For patients: Education and prescription ordering information available at StaySureToday.com.

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