



A Hidden Epidemic: Rethinking the Standard of Care for Fecal Incontinence

The Quiet Condition Affecting Millions

Ellen used to be a volunteer choir director and the go-to babysitter for her grandkids. Now, she barely leaves the house.

"I never thought I'd live like this," she says, describing the dread of accidents, the ruined upholstery, and the fear of losing control in public. "It's like my body betrayed me."

Ellen isn't the only one.

Fecal incontinence (FI) affects 18 million adults in the United States³ and 1 in 12 adults globally.¹ Yet it remains one of the least discussed and most stigmatized health issues in modern care.

Patients lose confidence. They lose independence. And eventually, many lose their place in the community.

It's time to change that narrative.

What Is Fecal Incontinence?

Fecal incontinence (FI) is defined as the inability to control bowel movements, resulting in involuntary leakage of stool.¹ It can range from occasional accidents to daily episodes that significantly interfere with quality of life. Causes may include nerve or muscle damage, chronic diarrhea, inflammatory bowel disease, or age-related decline.¹

The True Scope of the Problem

FI isn't rare. It's just rarely talked about. Unlike urinary incontinence (UI), which has received more mainstream attention and management pathways, FI is often underdiagnosed, undertreated, and deeply stigmatized.

The statistics tell a sobering story. Studies show that FI affects:

- 8% to 10% of community-dwelling adults²
- Up to 50% of residents in skilled nursing facilities³
- More than 15% of women over age 45, especially after childbirth or menopause⁴

And yet, only an estimated 10-30% of people with fecal incontinence ever disclose symptoms to a healthcare provider, with women significantly more likely to report than men.³

Why Providers Delay Action

So why does this care gap persist? While awareness around FI is growing, open conversations are still less common than they should be. Many patients won't bring up symptoms unless explicitly asked, often due to embarrassment, fear of judgment, or the belief that "nothing can be done."

Many patients don't speak up, and many providers don't ask.

Even among engaged providers, navigating this topic can be challenging. In one prospective study, just 3% of patients presented with FI as a primary concern. The remaining 97% only disclosed their symptoms when asked directly by their clinician.³

And when it comes to clinical documentation:

- Only 2.7% of women with reported FI symptoms had a corresponding diagnosis recorded⁵
- Over 90% of patients had never been asked about bowel leakage at all⁶

The hesitation doesn't stem from indifference — far from it. Many clinicians want to help but face real barriers, including:¹⁷

- Limited exposure to newer, non-invasive support options
- Discomfort initiating sensitive conversations
- Misconceptions about treatability, especially in older adults
- Workflow time constraints or unclear next steps for referral

Only 54% of primary care providers screen for FI.³

Still, even small delays can have serious downstream effects: worsening symptoms, emotional distress, and increased risk of preventable complications.¹⁷

When patients do disclose symptoms, some are still under the impression — or told — that few options exist beyond pads or surgery. Among providers who do screen, 40% believe conservative therapies lack efficacy.³ That perception can limit access to effective non-surgical solutions and prevent patients from exploring care that better supports dignity and independence.

These missed opportunities lead to real-world consequences, including skin breakdown, increased fall risk, depression, social withdrawal, and even premature long-term care placement.³

Acronym	Meaning
FI	Fecal Incontinence (bowel leakage)
UI	Urinary Incontinence (bladder leakage)
DI	Dual Incontinence (both FI + UI)

Nearly 1 in 3 adults over 50 with UI also experience FI, compounding care needs.⁶

Why Now? The Rising Need for Smarter FI Solutions

With the global population aged 60 years and older expected to double by 2050 (2.1 billion),⁷ and a growing emphasis on home-based care, addressing bowel health has become a care priority.

50% of nursing home residents have FI.¹²

Several converging trends make this issue more urgent than ever:

- **Aging populations:** As the U.S. population over 65 grows, so does the prevalence of incontinence-related issues.⁸
- **Home- and community-based care expansion:** More patients are aging in place, increasing the need for discreet, non-surgical management options.⁹
- **Caregiver burnout:** Family members and professional caregivers are struggling with the hygiene and emotional toll of unmanaged FI.¹⁰
- **Healthcare cost containment:** The economic burden of untreated incontinence is rising, driven by avoidable hospitalizations, skin injury, and long-term facility placement.¹¹

Unmanaged FI amplifies burdens across care settings, from skilled nursing facilities (SNFs) to private homes. In short, the need for dignified, intermediate care options has never been greater.

“It impacts your whole life, you have to constantly take into account that an FI episode can happen.”

— Female patient with fecal incontinence, age 83¹⁸

Beyond the Bathroom: The Full Toll of FI

The effects of fecal incontinence extend far beyond the bathroom. Many patients describe their lives as ruled by proximity to a bathroom, a fear of accidents, or anxiety over visible stains and odor.

These challenges compound over time, often unnoticed by clinicians, but deeply felt by patients.



Fiona’s Story

Fiona, a former educator, experienced escalating urgency and leakage after a hip fracture. Shopping trips, coffee with friends, and even short walks became stressful.

“I didn’t want to leave the house. I felt embarrassed and defeated. I didn’t feel like myself anymore.”

Skin and Physical Health Risks:

Frequent exposure to stool can increase the risk of:

- Skin breakdown and IAD (Incontinence-Associated Dermatitis), a form of MASD (Moisture-Associated Skin Damage), now recognized with specific ICD-10 coding^{13,20}
- Pressure injuries, especially in bedbound patients¹³
- Falls and fractures due to rushing to the bathroom³
- Recurrent urinary tract infections in dual incontinence patients³

These complications are especially prevalent in long-term care settings where incontinence care is reactive or inconsistent.

In addition to these physical risks, FI is associated with hospitalization and worse health outcomes among older adults.¹⁴ This underscores the importance of early intervention, not only for comfort and dignity but also to prevent costly acute events.

Emotional and Psychological Effects:

FI is not just a physical condition — it greatly impacts mental health and emotional well-being.

Studies show strong links between FI and depression, anxiety, and social withdrawal.¹⁵ In fact, among patients surveyed using the PROMIS incontinence tool, those with FI scored highest in anxiety, higher than those with urinary or dual incontinence.¹⁵

Patients describe feelings of:³

- Embarrassment, shame, and loss of control
- Hypervigilance and fear of public outings
- Disrupted sleep and reduced sexual intimacy
- A burdened sense of identity and isolation from loved ones

Lower bowel movement frequency, which can be both a contributor to and consequence of FI, is also associated with worse cognitive function.¹⁶ When patients live in fear of accidents, they may avoid physical activity or meaningful engagement, worsening cognitive and emotional outcomes.



FI in Men: Sten's Story

Sten, a retired engineer, developed FI after rectal cancer surgery. He and his wife Ingrid started carefully planning daily routines around managing symptoms. Sten says, "I never go anywhere without a plan and a spare change of clothes."

The emotional impact is just as real: "I've stopped biking and even skipped a few birthdays because I didn't want to be far from a toilet," he shares. "It's exhausting always being on alert."

Increased Caregiver Burden:

Most older adults with incontinence are supported by a caregiver, whether it's a family member, spouse, or home health aide. These caregivers face physical, emotional, and financial strain, often with little recognition or reprieve.¹⁰

Common caregiver burdens include:¹⁰

- Missed work, career sacrifices, and lost income
- Physical strain from cleaning, lifting, and laundry
- Emotional exhaustion, guilt, and helplessness
- Disrupted sleep and social isolation

When FI is properly managed, caregivers regain time, energy, and emotional resilience. This delays institutionalization, improves home care stability, and supports long-term quality of life for both patient and caregiver.¹⁰

Loss of Independence:

Fecal incontinence remains one of the leading contributors to nursing home placement in older adults.¹² More than half of nursing home residents live with urinary and/or fecal incontinence, and both are considered significant risk factors for institutionalization in the last decades of life.¹² For families and providers, the inability to manage hygiene discreetly, especially when paired with mobility limitations, dementia, or safety concerns like falls and infection, can force difficult care decisions.

Once institutionalized, residents often remain incontinent due to a complex mix of factors: cognitive decline, physical immobility, insufficient staffing, and limited access to effective toileting programs.¹²

FI Impacts Across the Care Continuum

At Home:

Dignity loss, caregiver stress

In Assisted Living Facilities:

Rising hygiene costs, staff time

In Long-Term Care:

Increased placement rates, behavioral health needs

Patients with frequent FI averaged 4.21 more healthcare visits per year than those without.⁵

Economic Impact of Untreated FI

In addition to being emotionally and physically disruptive, FI is also financially costly at every level. Patients may spend over \$1,000 annually on absorbent products, cleansing supplies, and barrier creams alone.³ But the broader economic burden reaches far beyond personal hygiene. Healthcare systems, employers, and caregivers all absorb the ripple effect through higher utilization, productivity loss, and premature institutionalization.³

Studies show that individuals with FI incur significantly higher direct and indirect costs than those without, especially in outpatient and home care settings:³

- FI adds approximately \$2,897 in annual direct medical costs per patient, even excluding hospitalizations and surgical procedures¹⁸
- A separate study estimated total annual cost per patient (including productivity loss) at \$4,110 (in 2010 US dollars), with \$1,549 of that due to lost work time³
- A Dutch study estimated the total annual cost of \$2,628 (in 2004 US dollars) per FI patient³

Beyond annual figures, systemic totals are also staggering:

- FI increases healthcare costs by 55% compared to patients without it, with U.S. estimates placing the total national burden near \$11 billion annually⁵
- 400 million dollars are spent annually in the U.S. on adult diapers, often not covered by insurance³
- Inpatient procedures for female FI cost an estimated \$24.5 million per year (2003 USD)³

Solutions that address FI proactively, especially those offering daily reliability without surgery, reduce both personal suffering and systemic cost burdens.

The Real Costs of FI

\$1,000+
annually in patient-paid
absorbent products³

\$2,897
higher direct costs
compared to non-FI patients⁵

\$4,110
average total yearly cost per
patient with FI (U.S.)³

\$11 billion+
in annual U.S. healthcare
costs attributed to FI⁵

Bridging the Gap in Care: A Call for Intermediate Solutions

Improving outcomes for patients with FI requires more than just empathy — it demands a shift in how we identify, manage, and talk about bowel leakage. Despite its serious implications, the care pathway for FI remains fragmented. Many patients are left cycling between basic containment strategies, like pads, diet changes, and pelvic floor therapy, and invasive interventions, such as nerve stimulation or surgery.

Too often, there's no clear next step when traditional first-line approaches aren't enough, and many patients aren't ready, or appropriate, for procedures. That's where the support gap lies.

To move forward, we need proactive, inclusive, and compassionate care that bridges this long-standing divide.

Here's what that shift must include:

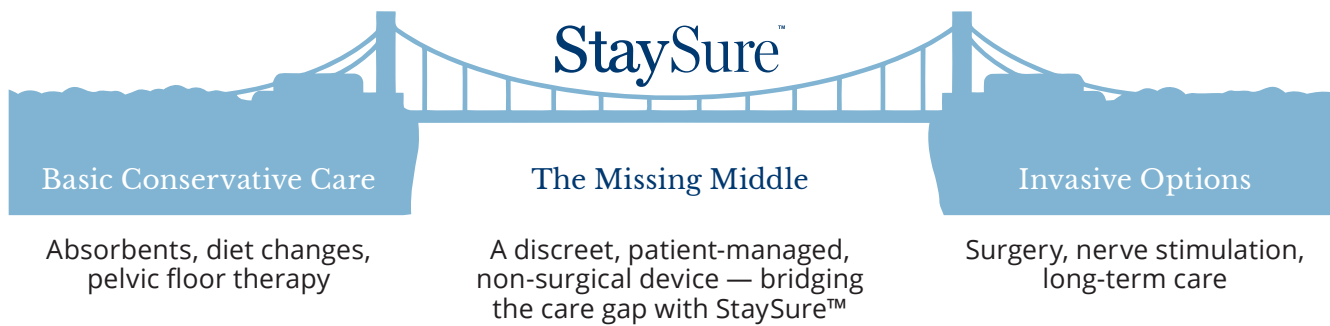
- **Normalizing bowel health conversations:** Empower providers to screen for incontinence routinely, just like they do for other common conditions.
- **Expanding conservative options beyond pads:** Offer patients a complete continuum of care, including medical and device-based solutions that fill the gap between lifestyle changes and surgery.
- **Restoring dignity and independence at home:** Adopt tools that reduce caregiver burden, support early intervention, and give patients the confidence to live fully.

Patients need real solutions, ones that preserve dignity, offer control, and fill the gap between absorbents and invasive procedures.

That's exactly what StaySure™ was designed to do.

Language matters, too. Terms like “fecal incontinence” may feel medical but can trigger shame. Alternatives like “accidental bowel leakage” (ABL) are preferred by patients and supported by the NIH as stigma-reducing language.⁷

The FI Management Gap



As a discreet, clinically informed, and non-surgical device, StaySure™ offers a next step within the conservative care spectrum — a bridge, not a leap — for patients who need more than pads, but not a procedure.

Introducing StaySure™: A Clinically Sound Middle Ground

StaySure™ is a clinically tested, FDA-cleared device designed to offer a discreet, non-surgical option for managing fecal incontinence and accidental bowel leakage.

Soft, flexible, and designed for all-day comfort, StaySure™ gently seals the rectum to help prevent accidents before they happen. It empowers patients to resume their routines, from morning walks to dinner with friends, without fear or embarrassment.

Unlike absorbents that react to leakage, StaySure™ is designed to prevent it.

A Proven Innovation, Now Available in the United States

In July 2025, StaySure™ received 510(k) clearance and is now available for use at home, in long-term care settings, and in clinical environments throughout the United States.

Prior to its U.S. launch, the device had been available in Europe since 2021 under the brand name Navina Insert, where it gained widespread clinical adoption. In post-market evaluations, the device demonstrated improvements in patient confidence, reduced leakage frequency, and enhanced quality of life, even in patients with dual incontinence or limited dexterity.

A recent clinical trial completed by Mayo Clinic further confirmed the safety and effectiveness of StaySure™ in reducing fecal incontinence episodes. Full results are pending publication and will be released when finalized.¹⁹

StaySure™ is backed by years of development, clinical insight, and real-world use across global care settings, now available to patients and providers in the U.S.

How It Works

StaySure™ is a soft, 100% silicone insert worn inside the rectum. Its gentle, anatomical design allows for 24-hour protection without surgery, bulky absorbents, or external devices. Patients can insert and remove it independently, and it remains secure during daily movement and activity.

Key Benefits:

- Immediate control without surgical intervention
- Comfortable 24-hour wear
- Anatomical design that conforms to the body
- Easy, hygienic self-insertion and removal
- No external visibility or dangling parts
- Allows patients to stay active, social, and independent



StaySure™ at a Glance

Prescription-only silicone insert

Designed to seal the rectum and prevent leakage

Single-patient use; up to 24 hours of protection

Conforms to movement without discomfort

Developed by industry experts with 100+ years of combined medical device experience

“Going out now is great. I can sit in a café and enjoy my coffee again without fear.”
— **Fiona**

Real-Life Impact Across Care Settings

StaySure™ marks a shift in how we view dignity, autonomy, and care in the FI journey. Closing the gap between containment and invasive interventions gives providers a meaningful way to act sooner and patients a powerful way to reclaim life.

“When I go swimming, the insert is my only choice, because it makes me feel completely safe.”
— Sten

Setting	How StaySure™ Supports Care
Primary Care	Initiates early, discreet treatment
Gastroenterology	Complements dietary and medical management plans
Urogynecology	Fills the gap between postpartum therapy and surgical routes
Colorectal	Offers a conservative, device-based option to manage chronic bowel leakage
Home Health	Enables safe, daily management at home
Skilled Nursing	Reduces reliance on absorbents and staff time
Long-Term Care	Helps people remain active, independent and at home longer

Who StaySure™ Helps



Fiona

Active retiree avoiding social outings



Sten

Rectal cancer survivor needing reliability during physical activity



Maria

Family caregiver overwhelmed by cleanup



Providers

Healthcare providers needing a practical middle-ground option

StaySure™

***Ready to Rethink
FI Care?***

Help your patients rejoin life on their own terms.
Refer them to StaySure™.

Visit StaySureToday.com
to request clinical info, starter kits, or support resources.

Redefining the Middle Ground in FI Care

As the clinical conversation about fecal incontinence evolves, so must the care options we offer. Most patients are looking for something practical. Something they can use. Something they can live with.

By expanding the middle of the treatment pathway, we can meet people where they are, offering choices that are less overwhelming and non-invasive, while aligning more with how patients prefer to manage their symptoms.

Devices like StaySure™ reflect this shift, prioritizing discretion, usability, and dignity so patients can take control without waiting until things get worse.

This is how we begin to redefine what good care looks like. Not by choosing between doing nothing and doing everything, but by supporting the space in between.

Because silence should never be the standard of care.

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