

Medtronic

It's time to explore
life-changing control



More hope for control

More than 21 million adults in the United States are living with chronic fecal incontinence (FI),¹⁻³ commonly referred to as bowel control issues.



This is more common than you think and we're here to help

It can feel frustrating and isolating. But you're not alone. Millions of people are living with bowel control issues – 1 in 12 adults in the United States alone.¹⁻³ That's more common than asthma or Alzheimer's disease.^{4,5} You may have tried diet changes, physical therapy, or medications – but the results just aren't what you hoped.

There is hope. Discover treatment options tailored to your needs.

Understanding your symptoms

Fecal incontinence is the uncontrolled loss of feces (liquid or solid) from the bowel. Someone with FI typically has one or more of the following symptoms:

Passive fecal incontinence

If you clean yourself well after having a bowel movement, but find feces on the tissue when you wipe the next time you use the bathroom, you may have passive fecal incontinence. When you have passive fecal incontinence, bowel leakage occurs without you knowing it.

Urge fecal incontinence

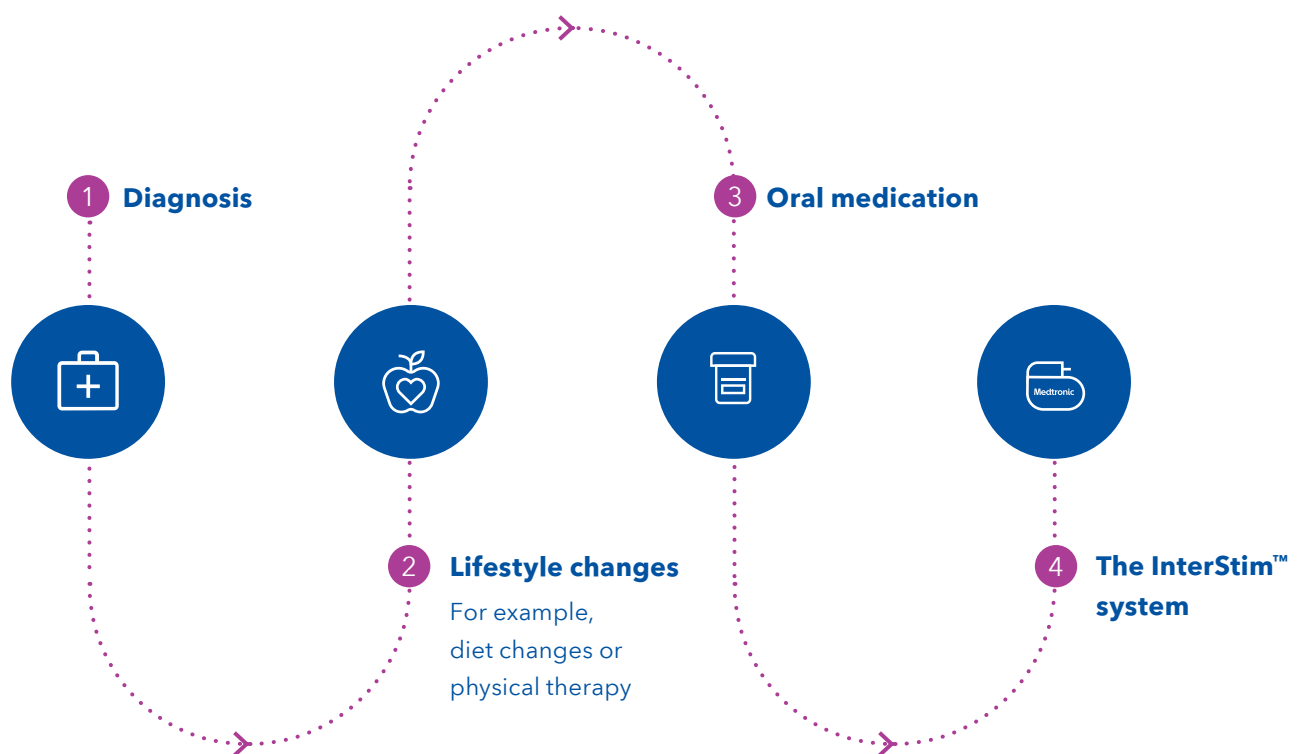
If you feel a strong sensation to have a bowel movement, but cannot stop it before reaching a toilet you may have urge fecal incontinence.

If other treatments don't deliver the results you expected, you have options.



Your path to relief with the InterStim™ system

Everyone experiences symptoms differently, and there are many ways to manage bowel control issues. Your journey to relief may include trying a few options before you find the one that brings back the life you've been missing. The steps below show the path people may take to find an option that works.



When you have tried lifestyle changes and oral medication without seeing the results you hoped for, don't give up. **The Medtronic InterStim™ system may help when other treatments have failed.**

The Medtronic InterStim™ system is unique because it targets the cause of your symptoms directly and allows you to try the therapy for a short period of time before making any lasting decisions. Often called the "test," this is your opportunity to find out if you would benefit from long-term therapy.

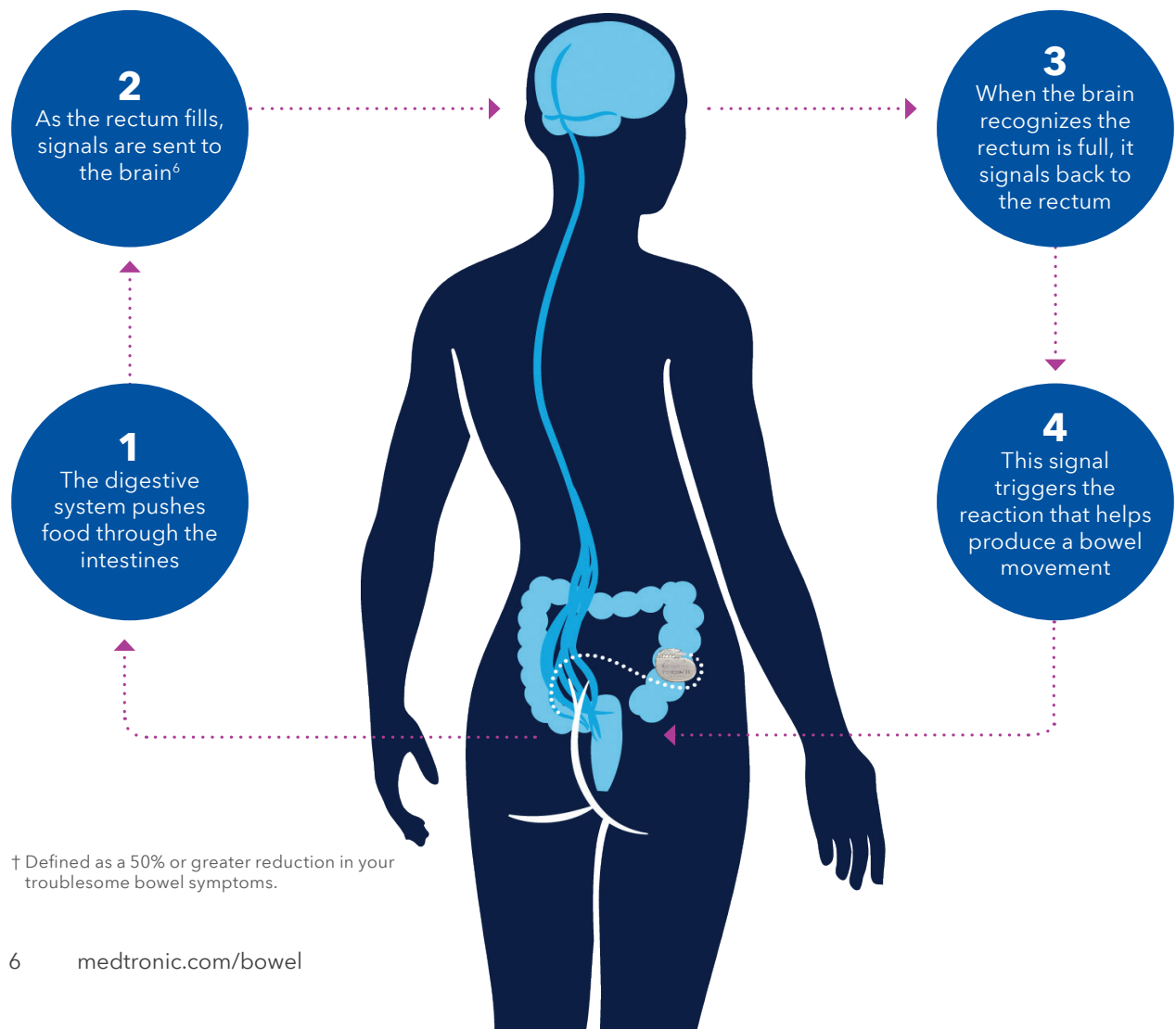
What is the InterStim™ system and how does it work?

A therapy that targets the cause, not only the symptoms

Research shows a miscommunication between the bowel and the brain may be a reason why people have bowel control issues.⁶⁻⁸ In other words, your bowels may get the message too often, too late, or not at all.

The Medtronic InterStim™ system uses gentle nerve stimulation to restore† bowel-brain communication and reduce your symptoms.^{9,10}

The InterStim™ system is placed entirely beneath the skin and is powered by a small neurostimulator that sits in the upper buttock. It's sometimes called sacral neuromodulation (SNM) because it works on the sacral nerves.



† Defined as a 50% or greater reduction in your troublesome bowel symptoms.



"I've been able to fully embrace the activities I love."

Judy

Found relief for bowel control issues with the InterStim™ system

More freedom. Less worry.

With Medtronic bowel control therapy, patients may experience fewer trips to the bathroom, fewer accidents, and more confidence.^{11,‡}

Not everyone who receives Medtronic bowel control therapy will experience the same results. Talk with your healthcare provider to determine if sacral neuromodulation is right for you.

Did you know?

The InterStim™ system is also proven to treat bladder control issues.¹¹⁻¹³ Ask your healthcare provider for more information.



‡ The most common device-related adverse events in SNM subjects were undesirable change in stimulation 10.2% (6/59), implant site pain 8.5% (5/59), lead migration/dislodgement 3.4% (2/59), and implant site infection 3.4% (2/590).

Get more control with the InterStim™ system¹¹⁻¹³

Medtronic bowel control therapy has been helping people regain control and improve their lives for 10 years. It is a safe, FDA-approved, and minimally invasive therapy.

400k+



people worldwide have chosen the Medtronic InterStim™ system for long-term relief.

89%



of people using Medtronic bowel control therapy experienced long-term success.¹¹



Significant quality of life improvements (lifestyle, ability to cope, embarrassment, and depression).¹¹

The most common device-related adverse events experienced during clinical studies included pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms.

Therapy outcomes

Medtronic bowel control therapy is considered successful when you have a 50% or greater improvement in one or more of your baseline symptoms. That means, for example, having half the number of bowel accidents you have today. While results differ from person to person, if you have a 50% or greater improvement during your test, you can likely expect the same results with long-term therapy.

Experience matters. Trust Medtronic.

Medtronic bowel control therapy delivers life-changing relief, and we have the experience to prove it.

Healthcare providers have been using the InterStim™ system to treat people with bowel control issues for 10 years.

Scientific studies prove again and again that the InterStim™ system provides meaningful results that improve the lives of people with chronic FI.¹¹



Say yes to the test

For most people, it takes one simple test and less than one week

The test for an InterStim™ system is like a trial run. It's your opportunity to see how your body responds to nerve stimulation with no *long-term commitment*. Within a week, you'll learn if stimulating your sacral nerve helps your brain and bowel communicate with each other to relieve your symptoms.† These results will help you and your healthcare provider decide whether to pursue long-term therapy.

†Defined as 50% or greater reduction in your troublesome bowel symptoms.



What patients are saying



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I was very excited for the screening test because I hoped this treatment would give me back more of my life.”

James, Living with bowel control issues



//

During my test, my accidents went from daily to almost none.”

Janet, Living with bowel control issues

Not all patients will experience similar results. Please talk to your healthcare provider about your condition and the risks and benefits of this therapy.

Here's how the test works



1

Get ready

Complete a symptom diary at least 3 days prior to your appointment so that your healthcare provider can use the information as a baseline for future comparison.



2

Get started

The simple test starts after a thin wire is inserted in your upper buttock and attached to a small, external device (worn discreetly under your clothes). This device delivers the therapy by gently stimulating the sacral nerve.



3

Test the therapy

Stop, start, or adjust the therapy with an easy-to-use programmer that resembles a smartphone. You should be able to go about most of your regular activities for the next 3-14 days.[†] Talk to your healthcare provider about specific activity limitations during your test.

[†]Test time frame may vary.



4

Record your bowel symptoms

Track your symptoms using the provided symptom diary so you and your healthcare provider can determine the success of your test. Insurance companies may also require this diary for reimbursement purposes.



5

Review results

Once your test is completed, meet with your healthcare provider to compare your test results to the symptoms you were experiencing prior to your test. If there is a 50% or greater improvement in your symptoms, your test is considered a success!



6

Schedule your outpatient procedure

You will then be able to schedule your outpatient procedure to place the long-term InterStim™ system of your choice.‡

Complications can occur with the test, including movement of the wire, technical problems with the device, and some temporary pain. Your healthcare provider will show you how to use the system and inform you of any activity restrictions and precautions related to the test.

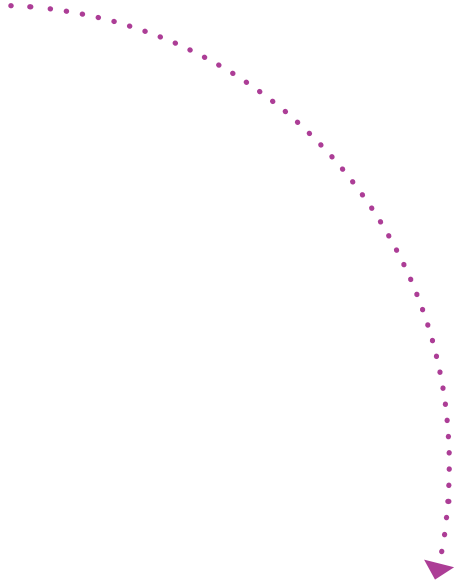
‡If your trial was inconclusive, your healthcare provider may suggest further testing or alternative treatment options.

What happens next?



Schedule your test with your healthcare provider.

1



2

Complete your symptom diary (enclosed) at least 3 days prior to your test appointment.



Bring your completed symptom diary to your test. Wear loose-fitting clothes. Discuss any additional recommended preparations with your healthcare provider.



Your healthcare provider will give you additional information and instructions on the day of your test.



It's time to step closer to control with the InterStim™ system.

Notes & references:

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- ¹¹ Hull T, Giese C, Wexner SD, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. *Dis Colon Rectum*. 2013; 56(2):234-45.
- ¹² Siegel S, Noblett K, Mangel J, et al. Five year follow-up results of a prospective, multicenter study in overactive bladder subjects treated with sacral neuromodulation. *Urology*. 2018; 199(1), 229-236.
- ¹³ Medtronic InterStim™ Therapy Clinical Summary (2018).

Important safety information

Medtronic Bowel Control Therapy delivered by the InterStim™ system treats chronic fecal incontinence (an accident or leaking involving stool). It should be used after you have tried other treatments such as medications and dietary modifications and they have not worked, or if you are not a candidate for them.

You must demonstrate an appropriate response to the evaluation to be a candidate. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an InterStim™ device.

This therapy is not intended for patients with a urinary blockage. Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 16; or for patients with neurological disease origins.

In addition to risks related to surgery, complications can include pain at the implant sites, new pain, infection, lead (thin wire) movement/migration, device problems, interactions with certain other devices or diagnostic equipment such as MRI, undesirable changes in urinary or bowel function, and uncomfortable stimulation (sometimes described as a jolting or shocking feeling).

This therapy is not for everyone. This treatment is prescribed by your doctor. Please talk to your doctor to decide whether this therapy is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients may benefit from the use of this treatment, results may vary. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

USA Rx Only. Rev 0517

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604, USA

medtronic.com/bowel

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