

A man and a woman are hiking outdoors. The man, on the left, has grey hair and is wearing a grey jacket. The woman, on the right, has blonde hair in a ponytail and is wearing a light blue jacket. They are both smiling and looking towards the right. The woman is holding a map and a wooden railing. The background shows a lush green landscape with trees and a distant view of a valley.

INTERSTIM™ THERAPY FOR BOWEL CONTROL

Patient Information Guide

Medtronic
Further. Together

YOUR BOWEL CONTROL MATTERS

Millions of people are suffering in silence from bladder and bowel control issues.^{1,2}

Solutions exist.

Bowel control problems are treatable conditions and symptoms are manageable. Contrary to preconceptions, faecal incontinence is not a normal part of aging or inevitable after giving birth. It is a medical condition for which it is important to seek medical advice.

**YOU DON'T HAVE TO DEAL
WITH THIS ON YOUR OWN,
YOU CAN TALK ABOUT IT.**

1. Damon, H. et al. Prevalence of anal incontinence in adults and impact on quality-of-life. *Gastroenterol. Clin. Biol.* 30, 37–43 (2006).
2. Mundet, L., Ribas, Y., Arco, S. & Clavé, P. Quality of life differences in female and male patients with fecal incontinence. *J. Neurogastroenterol. Motil.* 22, 94–101 (2016).



BOWEL SYMPTOMS

01.

WHAT IS FAECAL INCONTINENCE?

You are not alone.
Solutions exist.

02.

ABOUT SACRAL NEUROMODULATION

InterStim™ journey.

BOWEL CONTROL SYMPTOMS



FAECAL INCONTINENCE (FI)

Bowel control problems can be embarrassing and debilitating.

They can have a major negative impact on lifestyle as well as on both physical and psychological health leading to depression, loss of confidence, loss of self-esteem. You may have to cut back on your hobbies, stop working, feel trapped by a fear of leaking accidents, or feel the need to be close to the bathroom at all times.^{1,2}

What is faecal incontinence?

Faecal incontinence, prevents you from controlling your bowel movements. You may experience unexpected leaks, or use the bathroom very frequently. Some people experience a combination of these symptoms.

WITH FAECAL INCONTINENCE

You may:

- Have diarrhea
- Feel the urgent need to go to the toilet and/or not reach the toilet on time
- Have constipation
- Stain or soil your underwear

1. Damon, H. et al. Prevalence of anal incontinence in adults and impact on quality-of-life. *Gastroenterol. Clin. Biol.* 30, 37–43 (2006).
2. Mundet, L., Ribas, Y., Arco, S. & Clavé, P. Quality of life differences in female and male patients with fecal incontinence. *J. Neurogastroenterol. Motil.* 22, 94–101 (2016).



WHY DO I HAVE BOWEL CONTROL PROBLEMS?

Nerves carry information to and from the brain. Some nerves control the bowel and muscles that relate to defecation. When the communication system between these nerves and the brain is disturbed, a person may have bowel problems such as faecal incontinence or constipation.

YOU ARE NOT ALONE

Faecal incontinence is common
and affects 4.8-6.7% of adults.¹



4.8* - 6.7**%

of adults

*for solid stools
**for liquid stools

You can suffer from both
bladder and bowel problems.²

OVERACTIVE BLADDER (OAB)



17%

of adults suffer from
OAB in Europe.³

OAB & FAECAL INCONTINENCE

18%

of patients with OAB
may also have faecal
incontinence.⁴

1. Giebel et al. Prevalence of fecal incontinence: what can be expected? Int J Colorect Dis (1998) 13: 73–77.
2. Soligo M, et al. Double Incontinence in Urogynecologic practice: A new insight; AM J Obstet Gynecol 189: 438 443 (2003).
3. Milsom, et al. "How widespread are the symptoms of an overactive bladder and how are they managed?" A population-based prevalence study BJU Int. 2001 Jun; 87(9):760-6.
4. Markland AD et al. Associated factors and the impact of fecal incontinence in women with urge urinary incontinence: from the Urinary Incontinence Treatment Network's Behavior Enhances Drug Reduction of Incontinence study. Am J Obstet Gynecol. 2009 Apr;200(4):424.e1-8. doi: 10.1016/j.ajog.2008.11.023. Epub 2009 Feb 6.



YOU ARE NOT ALONE

FAECAL INCONTINENCE IS A CHRONIC
AND DEBILITATING CONDITION

ONLY **28.6%** OF ADULTS SPOKE TO
A PHYSICIAN ABOUT THIS CONDITION¹



QUALITY OF LIFE

Suffering from Accidental Bowel Leakage (ABL) can make everyday activities
a challenge and socially very difficult.¹

In a survey of **1096** women **≥ 45** years:

97% of patients expressed 'bother' about this condition.

A total of **39.2%** of women with ABL were
categorised as having severe impact on QoL.

29% of patients reported frequently feeling depressed.
Almost one-third of women with ABL agreed that they
felt they were fighting a losing battle.

1. Brown HW, Wexner SD, Segall MM, Brezoczky KL, Lukacz ES. Quality of life impact in women with accidental bowel leakage. Int J Clin Pract. 2012 Nov;66(11):1109-16.

SOLUTIONS EXIST

Even if the journey can be long, solutions are available, and each patient may be offered suitable therapies according to his/her symptoms.

If there is an underlying cause to the symptoms, this should be treated first.

First line treatments should be proposed by your doctor:

- Behavioural treatments: lifestyle changes, fluid and diet modifications, bowel retraining, pelvic floor exercises/physical therapy
- Medication: Your doctor may prescribe medications to help control the symptoms

If these treatments are not working or not well tolerated, other specialized options can be offered.

IT'S TIME FOR ANOTHER OPTION.

SACRAL NEUROMODULATION:

Sacral Neuromodulation Therapy with the InterStim™ System can help to restore normal bowel function. This therapy addresses the communication problem between the bowel and the brain that may be causing your symptoms.

SACRAL NEUROMODULATION



WHAT IS SACRAL NEUROMODULATION?

WHAT IS IT?

Medtronic Sacral Neuromodulation with the InterStim™ System uses a small implanted medical device to send mild electrical pulses to nerves that control your bowel. It helps to restore normal nerve activity so that you can defecate normally.¹



DID YOU KNOW...

That InterStim™ Therapy can also treat urinary incontinence alone or in combination with your bowel problems?

Ask for more information from your doctor.



InterStim™ II and Micro
Neurostimulator



THE CHOICE IS YOURS

Medtronic lets you and your doctor choose between the convenience of a recharge-free device and the long-lasting performance of a rechargeable system.



1. Gourcerol G. et al. How sacral nerve stimulation works in patients with faecal incontinence. Colorectal Dis. 13(8):e203-11 (2011).

WHAT IS SACRAL NEUROMODULATION?



HOW IT WORKS

Medtronic Bowel Control Therapy works with the sacral nerves, located near the tailbone.

The sacral nerves control the bowel and muscles related to defecation function.

If the brain and sacral nerves are miscommunicating, the nerves can't tell the bowel to function properly.

Sacral Neuromodulation helps the brain and the nerves to communicate so the bowel and related muscles can function properly.¹

It may help you resume normal activities and help you avoid frustrating or embarrassing experiences associated with faecal incontinence.

1. Gourcerol G. et al. How sacral nerve stimulation works in patients with faecal incontinence. Colorectal Dis. 13(8):e203-11 (2011)



PATIENT JOURNEY

Sacral neuromodulation with InterStim™ System: an adjustable, reversible and lasting results therapy

01. START WITH A TEST

With Medtronic Bowel Control Therapy's two-step process, you can test it out to see if it will work for you before making a long-term commitment. The testing period is called an "evaluation". The evaluation is temporary and generally lasts several days. It is used to measure the effectiveness of the InterStim™ Therapy in your daily life.

- Your doctor will tell you about the evaluation procedure and discuss the options for using either a temporary lead (a thin wire) or a long-term lead for the evaluation. Your doctor will help you to decide between:
 - A recharge-free system
 - A rechargeable system
- Before and during the evaluation, you'll be asked to track your symptoms to help determine how well Medtronic Bowel Control Therapy works for you

02. DECIDE TOGETHER, WHAT'S BEST FOR YOU

- If you experienced relief from your symptoms during the evaluation phase you may be a candidate for a permanent implant
- Together, you and your doctor will decide if the long-term therapy is the right choice. If it is, your evaluation device can be replaced with an implantable device called a neurostimulator



DID YOU KNOW...

That InterStim™ evaluation will indicate in only a few days if the Interstim™ Therapy is effective for you?

03. IMPLANT PHASE

If the evaluation phase was successful, your doctor may propose you the implant of an InterStim™ System.

The InterStim™ System consists of:

- An implantable neurostimulator which is like a pacemaker implanted under the skin
- A lead which is a thin wire that carries mild electrical pulses to the nerves controlling the bowel
- A hand-held patient programmer that enables you to adjust the level of the stimulation and allows you to turn your neurostimulator on or off
- Only in case of a rechargeable system A portable recharger that enables you to recharge the neurostimulator



04. LIFE AFTER THERAPY

Sacral Neuromodulation therapy may allow you to resume many daily activities.

- Minimal follow up required
 - once per year recommended
- The system can estimate the longevity of the battery so that a replacement can be pre-scheduled
- The system is eligible for full-body MRI*.

*Under certain conditions; refer to your doctor for details

LIVE WITHOUT LIMITS

The InterStim™ II system is the only recharge-free, long-term therapy³ that lets you get full-body MRI* scans if you need them.

Longevity:
The battery usually lasts 5-6 years until you need to have it replaced.¹



SMALL DEVICE, BIG INNOVATION

The InterStim™ Micro system is the smallest rechargeable system for SNM therapy that lets you get full-body MRI* scan if you need it.

Longevity:
Powered by an innovative battery, the InterStim™ Micro system delivers 15 years of results with just a quick weekly recharge.**

*Under certain conditions; see IFU for details.



RELAX AND RECHARGE

Recharging is easy and only takes 20 minutes, once a week.**

**Under standard patient therapy settings and implant depth.

CHOOSE A THERAPY WITH LONG LASTING RESULTS

SACRAL NEUROMODULATION FOR FAECAL INCONTINENCE



**90% PATIENTS
SATISFIED WITH SACRAL
NEUROMODULATION²**



**89% PATIENTS
ACHIEVED
SUCCESS AT 5 YEARS^{3, §}**



Smart programmer with the communicator
to manage your therapy discreetly with
a device that looks like a smartphone.

- Sacral Neuromodulation is a well-established therapy
- **325,000 patients** worldwide have received the InterStim™ System for bladder and bowel control
- The InterStim™ System has been available for over **25 years**, treating on average **50 patients** every day, for different indications worldwide^{§§}



1. Medtronic data on file (1-2V, 14Hz, 210uS, bipolar electrode config, and continuous stim)
 2. Van Wunnik BP, Govaert B, Leong R, Nieman FH, Baeten CG. Patient experience and satisfaction with sacral neuromodulation: results of a single-center sample survey. Dis Colon Rectum. 2011 Jan;54(1):95-100.
 3. Hull et al. Long-term Durability of Sacral Nerve Stimulation Therapy for Chronic Fecal Incontinence Dis Colon Rectum 2013; 56: 234-245 DOI: 10.1097/DCR.0b013e318276b24c.
- § Therapeutic success was defined as a 50% or greater improvement in weekly incontinence episodes per day.
- §§ Medtronic data on file

NOTES

Information contained herein does not replace the recommendations of your healthcare professional.



www.medtronic.com/manuals

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your healthcare professional.

Safety and effectiveness have not been established for:

- Pediatric use
- Pregnancy
- Uncorrected high-grade internal prolapse

Medtronic

Europe

Medtronic International Trading Sarl
Route du Molliau 31
Case postale
1131 Tolochenaz
Switzerland
Tel: +41 (0) 21 802 70 00
Fax: +41 (0) 21 802 79 00

Medtronic Limited

Building 9
Croxley Park
Hatters Lane
Watford, Hertfordshire
WD18 8WW
Tel: +44 (0) 1923 212213
Fax: +44 (0) 1923 241004

Medtronic Ireland Limited

Block G,
First Floor
Cherrywood Business Park
Loughlinstown
Dublin 18
Tel: +353 (0)1 511 1400
Fax: +353 (0)1 807 7220

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