Medtronic

InterStim™ Therapy for bladder control

Patient information guide



Your bladder control matters

Millions of people are suffering in silence from bladder and bowel control issues.[1]
Solutions exist.

Bladder control problems are treatable conditions and symptoms are manageable. Contrary to preconceptions, urinary 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.

Approximately

52%

of the bothered overactive bladder (OAB) patients initiated a conversation about their urinary symptoms with a healthcare provider.[2]

You don't have to deal with this on your own, you can talk about it.



Bladder symptoms

1 What is urinary incontinence? You are not alone. **Solutions exist.**

2 About the sacral neuromodulation InterStim™ journey.

1 Bladder control symptoms

Bladder control problems can be embarrassing. You may leak small or large volumes of urine, use the bathroom very frequently, or not be able to completely empty your bladder.

Learn more about the different types of bladder problems overleaf.



What is urinary incontinence?

Urinary incontinence is any involuntary or unwanted loss of urine. People with urinary incontinence use the bathroom very frequently and may leak urine.

There are different types:

Overactive bladder (OAB):
Characterised by an increased pressure or abnormal contractions of the bladder.

OAB consists of several symptoms and is defined by a sudden and irrepressible need to void which can't be postponed.

Sometimes the frequency of the voids increases and there is a need to go to the bathroom more often during the day or night. Bladder leakages may also occur. In most cases, there is no cause found, so we talk about idiopathic overactive bladder. The different symptoms of SUI and OAB described above can co-exist. In this case, it is called mixed incontinence.

Urinary retention
You may:

- Spend a long time on the toilet but produce only a weak, dribbling stream of urine
- Leak urine (also called overflow incontinence)
- Not have a sensation when your bladder is full
- Have to use a catheter to empty your bladder

Stress urinary incontinence (SUI):
Characterised by an involuntary loss of urine during effort: lifting heavy things, laughing, coughing, sneezing or doing exercise.

During these kind of activities, the pressure on the bladder increases and the urethra or urinary sphincter can't resist the pressure and will leak urine.

InterStim™ is not indicated for treatment of this condition.

Why do I have bladder control problems?

Nerves carry information to and from the brain. Some nerves control the bladder and muscles that relate to urination. When the communication system between these nerves and the brain is disturbed, a person may have bladder problems.

You are not alone

OAB is extremely common and disrupts the lives of more than 17% of people in Europe.[1]
Urinary incontinence causes distress and alters quality of life.[1]
It is not just women that suffer.

OAB affects both men and women

17% of women**[1] 16% of men**[1]

You can suffer from both bladder and bowel problems.[3]

Overactive bladder (OAB)

17%

of adults** suffer from OAB in Europe.[1]

Faecal incontinence

18%

of patients with OAB may also have faecal incontinence.[4]



You are not alone

OAB is a chronic and debilitating condition.



Quality of life

65% of men and 67% of women with an overactive bladder[1] reported that their symptoms influenced their daily life. This condition can make simple everyday activities a challenge and social life very difficult.[1]

Overactive bladder (OAB) has a multidimensional impact on quality of life:

Physical

38% were less physically active; 34% gained weight because they were unable to exercise.[5]

Psychological

OAB also negatively affects self-esteem and can be associated with anxiety and depression.[6]

Occupational

Absence from work, decrease of productivity.[7]

Social

Reduction in social interaction, limited travel, planned around toilet accessibility.[7]

Domestic

Requirements for specialised underwear, bedding and special precautions with clothing.[7]

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, bladder retraining, pelvic floor exercises/physical therapy.

Medication: Your doctor may prescribe medications to help control the symptoms of overactive bladder.

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

It’s time for another option.



2 Sacral neuromodulation

Sacral neuromodulation therapy with the InterStim™ System can help to restore normal bladder function.

This therapy addresses the communication problem between the bladder and the brain that may be causing your symptoms.

Did you know...

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

Ask for more information from your doctor.

What is sacral neuromodulation?

Medtronic sacral neuromodulation with the InterStim™ System uses a small implanted medical device to send mild electrical pulses to nerves that control your bladder. It helps to restore normal nerve activity so that you can urinate normally.[8]



InterStim X™

and InterStim™ Micro Neurostimulators



The choice is yours

Medtronic lets you and your doctor choose between the convenience of a recharge free or a rechargeable system.



How it works

InterStim™ Therapy works with the sacral nerves, located near the tailbone.

The sacral nerves control the bladder and muscles related to urinary function.

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

Sacral neuromodulation helps the brain and the nerves to communicate so the bladder and related muscles can function properly.[8]

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



Patient journey

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

01. Start with a test
With InterStim™ Therapy's two-step process, you can test 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
- Before and during the evaluation, you'll be asked to track your symptoms in a diary to help determine how well InterStim™ 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

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

The InterStim™ System consists of:
- An implantable neurostimulator, which is like a pacemaker implanted in buttock area under the skin
- A lead which is a thin wire that carries mild electrical pulses to the nerves controlling the bladder
- 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
- A portable charger that enables you to recharge the neurostimulator (only in case of a rechargeable system)

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*



Did you know...

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

Live without limits

The InterStim X™ System is the only recharge-free, long-term therapy[10] that lets you get full-body MRI* scans if you need them.

Longevity:
Powered by an innovative battery, the InterStim X™ System delivers more than 10 years of results.∏‡



Small device, big innovation

The InterStim™ Micro System is the smallest rechargeable system for SNM therapy that lets you get a 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.†



Relax and recharge

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

Choose a therapy with long-lasting results

Sacral neuromodulation is a well-established therapy.

375,000¥ 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.¥

91% would recommend to a friend in need.[9]

82% of patients achieved success at 5 years.[10]

84% had improved or greatly improved urinary symptoms.[10]



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



Information contained herein is not medical advice and should not be used as an alternative to speaking with your doctor. Discuss indications, contraindications, warnings, precautions, adverse events and any further information with your health care professional.

References

1. Milsom I et al. "How widespread are the symptoms of an overactive bladder and how are they managed?" A population-based prevalence study. BJU Int. 2 001 Jun; 87(9):760-6.
2. Irwin DE et al. "Symptom bother and health care-seeking behavior among individuals with overactive bladder" European urology 53 (2008) 1029-1039.
3. Soligo M et al. Double Incontinence in Urogynecologic practice: A new insight; AM J Obstet Gynecol 189: 438 – 443 (2003).
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.
5. Dmochowski RR, Newman DK. Impact of overactive bladder on women in the United States: results of a national survey. Curr Med Res Opin. 2007;23:65-76.
6. Milsom I et al. -Effect of Bothersome Overactive Bladder Symptoms on Health-related Quality Of life, Anxiety, Depression, and Treatment Seeking in the United States: Results From EpiLUTS. Urology.-2012; 80 : 90-96.
7. Tubaro A, Defining Overactive Bladder: Epidemiology and burden of disease. -Urology. -2004; 64 (Supp 6A): 2-6
8. Leng WW et al. How Sacral Nerve Stimulation Neuromodulation Works. Urologic Clinics of North America doi:10.1016/j.ucl.2004.09.004
9. Leong RK et al. Satisfaction and Patient Experience with Sacral Neuromodulation: Results of a Single Center Sample Survey; Journal of Urology. 2011; vol. 185, 588-592.
10. Siegel S et al. Five year follow up Results of a prospective, Multicentre Study of Patients with Overactive Bladder treated with Sacral Neuromodulation. Journal of Urology Vol, 199, 229-236, january 2018.

* Under certain conditions; refer to your doctor for details.

** Age >40

⎍ Under expected therapy settings and telemetry use.

‡ With low energy settings, your device may last up to 15 years.

† Under standard patient therapy settings and appropriate recharger placement.

¥ InterStim™ Implant Numbers, version 1.0, August-2022

Medtronic

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

medtronic.eu

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

medtronic.co.uk

Medtronic Ireland Limited
Ground Floor, Block 3090-3094
Lake Drive
Citywest Business Campus
Co. Dublin
Ireland
Tel: +353 (0)1 511 1400

medtronic.ie

UC202306985a-interstim-therapy-patient-information-guide-for-bl-en-we-8328122

© 2023 Medtronic. All Rights Reserved.