SACRAL
NEUROMODULATION
THERAPY WITH THE
MEDTRONIC
INTERSTIM™ SYSTEM
FOR BLADDER CONTROL
AND BOWEL CONTROL
OVERVIEW



PRESENTED BY LEVEL 1
NAME LEVEL 2
TITLE LEVEL 3





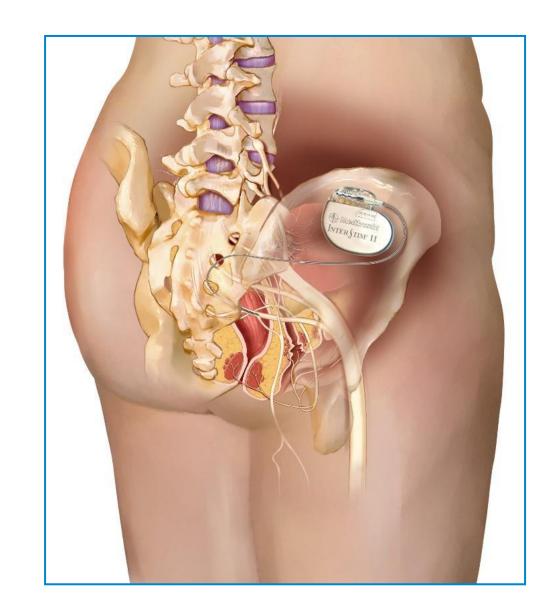


WELCOME TO MEDTRONIC SACRAL NEUROMODULATION



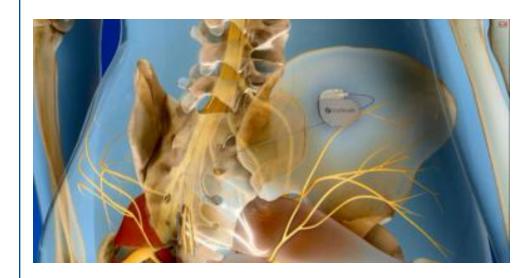
PRINCIPLE OF SACRAL NEUROMODULATION (SNM) (BLADDER OR PELVIC FLOOR PACEMAKER)

Medtronic SNM delivers mild electrical pulses to the **sacral nerve** via an implanted InterStim™ System neurostimulator and lead thereby modulating abnormal neuronal signals from various pelvic organs such as bowel and bladder or its sphincters.



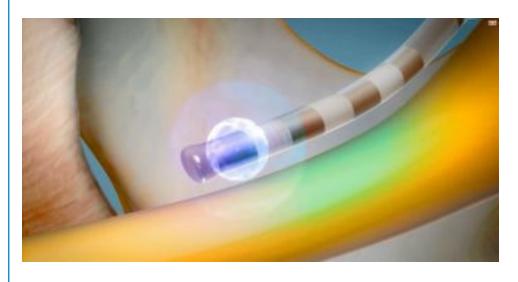
WHAT IS SACRAL NEUROMODULATION (SNM)?

MEDTRONIC SNM DELIVERS ELECTRICAL
STIMULATION TO THE SACRAL NERVE VIA AN
IMPLANTED INTERSTIM® SYSTEM
NEUROSTIMULATOR AND LEAD.



InterStim™ device and lead

THE SACRAL NERVE, IN PARTICULAR,
INFLUENCES PELVIC FLOOR BEHAVIOR AND IS
BELIEVED TO MODULATE NEURAL REFLEXES.¹



InterStim™ lead near sacral nerve

1. Buback D, et al. AORN J. 2001;73(1):176-190

HISTORY OF SNM WITH INTERSTIM™ THERAPY

1982 — 1° SNM implant (Tanagho & Schmidt) at University of California a San Francisco 1997 — FDA:
For Urgency Urinary
Incontinence (UUI)
treatment

2000 — CE Mark: For Faecal Incontinence treatment

ce

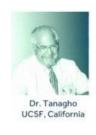
2006 —
InterStim™ II neurostimulator and patient
Programmer iCon™



2013 — Verify™ Evaluation system



2018 — Smart Programmer



1994 — CE Mark: For low urinary tract disease treatment

1999 — FDA:
For Urinary freaquency
(UF) and Urinary Retention
(UR) treatments

2002 — Tined Lead & N'Vision



2011 — FDA for Faecal Incontinence treatment





- **2019** — Verify New basic ner evaluation lead





TODAY OVER 300,000 PATIENTS HAVE BEEN IMPLANTED WORLDWIDE

HISTORY OF SNM WITH INTERSTIM™ THERAPY

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InterStim™ II neurostimulator and patient Programmer iCon™



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UCSF, California

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2002 —

2000 — CE Mark:

For Faecal Incontinence

treatment

Tined Lead & N'Vision



2011 —

FDA for Faecal Incontinence treatment



enhanced Verify programmer



2019 —

New basic evaluation lead





TODAY OVER 300,000 PATIENTS HAVE BEEN IMPLANTED WORLDWIDE

A PROVEN THERAPY WITH MORE THAN 25 YEARS OF EXPERIENCE

- Indications: Patients who have failed or could not tolerate more conservative treatments for:1
 - Overactive bladder (OAB) [a sudden urge to urinate]
 - OAB wet (urinary urge incontinence)
 - OAB dry (urgency-frequency) [frequent voidings: ≥ 8 × / day]
 - Non-obstructive urinary retention (NOUR) [→ need for self-catheterization]
 - Fecal Incontinence
- Endorsed by the 6th International Consultation on Incontinence (ICI) 2017²
- ≥ 25 years of SNM therapy with InterStim[™] system
- Proven permanent long-term therapy with 5 year follow-up^{3,4}



CAVEAT: SNM IS NOT INDICATED FOR THE TREATMENT OF STRESS URINARY INCONTINENCE (WHEN SNEEZING, COUGHING OR HEAVY LIFTING)

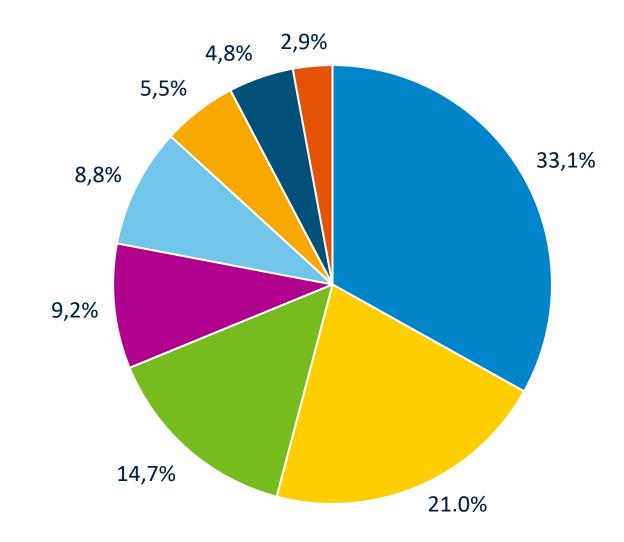
- 1. Noblett K, et al. Neuromodulation and female pelvic disorders. Curr Opin Urol. 2016;26(4):321-7.
- 2. Abrams P, et al. (Eds) Incontinence 6th Edition (2017). ICI-ICS. International Continence Society, Bristol UK, ISBN: 978-0956960733.
- 3. Siegel S, et al. Five-Year Followup Results of a Prospective, Multicenter Study of Patients with Overactive Bladder Treated with Sacral Neuromodulation. J Urol. 2018 Jan;199(1):229-236.
- 4. Hull T, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. Dis Colon Rectum. 2013;56(2):234-45.

SNM IS USED FOR MANY ETIOLOGIES

(FECAL INCONTINENCE)

Etiologies of FI (%)¹

- Idiopathic
- latrogenic
- Obstetric trauma
- Neurological disease
- Pelvic surgery
- Post ARR
- Spinal trauma/lesion
- Other



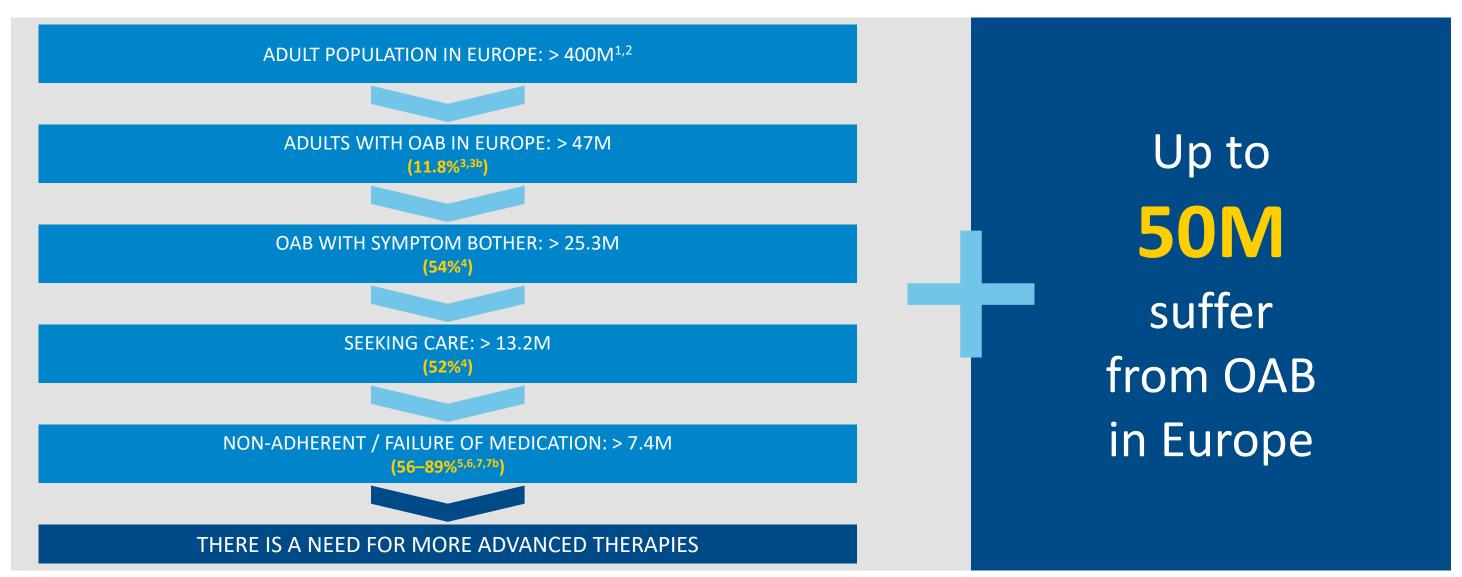
ARR: anterior rectum resection

1. Altomare DF, et al. European SNS Outcome Study Group. Long-term outcomes of sacral nerve stimulation for faecal incontinence. Br J Surg. 2015; 102(4):407-15

DISEASE PREVALENCE OF PELVIC FLOOR DYSFUNCTIONS



OAB IS A HIGHLY PREVALENT AND UNDERTREATED DISEASE

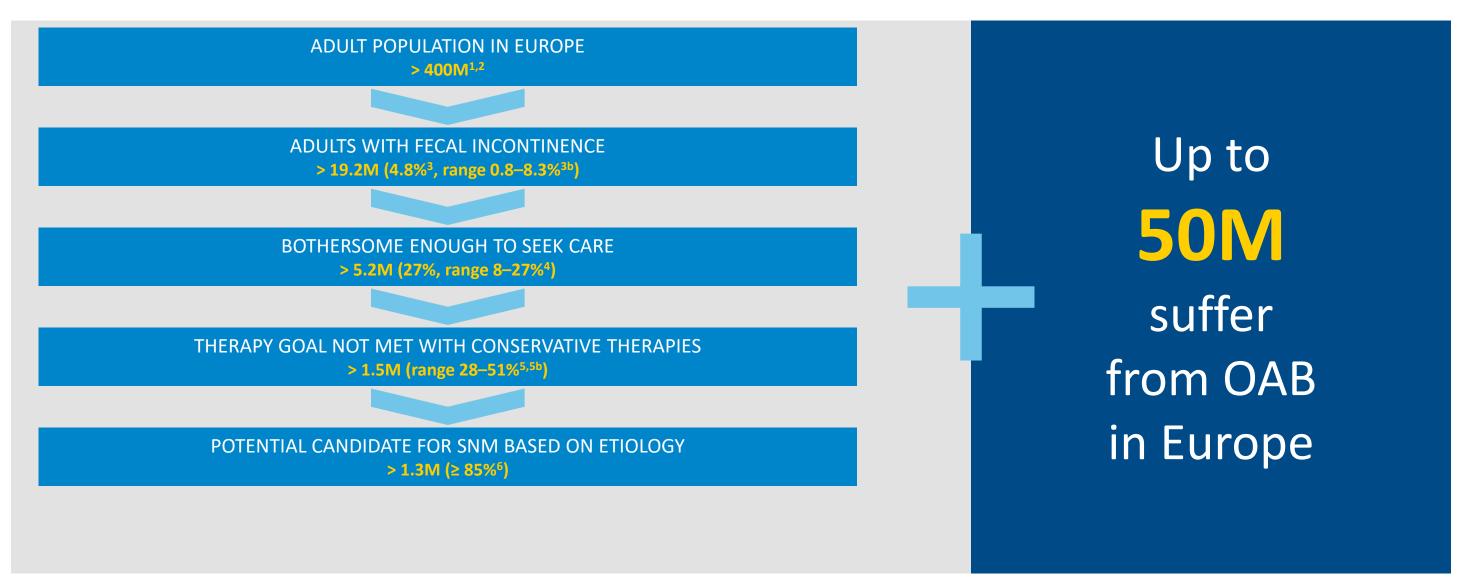


- 1. https://ec.europa.eu/eurostat/statistics-explained/index.php/Population and population change statistics;
- http://www.viewsoftheworld.net/?p=4201;
- 3. Irwin et al. Eur Urol. 50(6):1306-1314; 3b. Temml et al. Eur Urol. 2005;48(4):622-7.;

- 4. Irwin et al. Eur Urol. 2008; 53(5):1029-1037;
- Sussman et al. Int J Clin Pract. 2017; 71:3-4;
- 6. Chapple et al. Eur Urol 72(3):389-399;
- 7. Wagg et al. Can Urol Assoc J. 2015;9:(9-10):343-50; 7b. Yu et al. Value Health. 2005; 8(4):495-505.

FECAL INCONTINENCE

A HIGHLY PREVALENT AND UNDERTREATED DISEASE



 $^{1.} https://ec.europa.eu/eurostat/statistics-explained/index.php/Population_and_population_change_statistics;$

^{2.}http://www.viewsoftheworld.net/?p=4201;

^{3.} Giebel et al. Int J Colorect Dis. 1998 13: 73-77; 3b. Duelund-Jakobsen et al. Therap Adv Gastroenterol. 2016;9(1):86-97;

^{4.} Brown et al. Int J Clin Pract, November 2012, 66, 11, 1109–1116;

^{5.} Dudding et al. Colorectal Disease. 2011; 13, E187–E195; 5b. Norton et al. Aliment Pharmacol Ther. 2001;15(8):1147-54.;

^{6.} Bondurri et al. Tech Coloproctol. 2011; 15:159–164

OVERACTIVE BLADDER & FECAL INCONTINENCE IMPACT ON QUALITY OF LIFE & COMORBIDITIES



The negative impact of OAB

The annual incidence of comorbidities attributable to OAB is 310,000 for skin infections, 40,000 for falls, 12,000 for fractures, and 26,000 for depression in Germany.¹



Fecal incontinence

97% of patients with accidental bowel leakage express "bother" about this condition².

56% wish to get their normal life back before they had that condition. Due to embarrassment care-seeking remains low, ranging from 8% to 27%.²

^{1.} Klotz T et al. The economic costs of overactive bladder in Germany. Eur Urol. 2007 Jun;51(6):1654-62

^{2.} Brown et al. Quality of life impact in women with accidental bowel leakage. Int J Clin Pract. 2012 Nov;66(11):1109-16

PATIENT SELECTION

TEST STIMULATION IS THE ONLY RELIABLE PREDICTOR

During test stimulation patients should demonstrate at least a $50\%^1$ improvement in one the following symptoms — documented by their bladder or bowel diaries — to be a candidate for a permanent implant:

- Urge Incontinence
 - Number of leaking episodes per day
 - Number of pads per day
- Urgency-Frequency
 - Number of voids / day
 - Volume voided / void

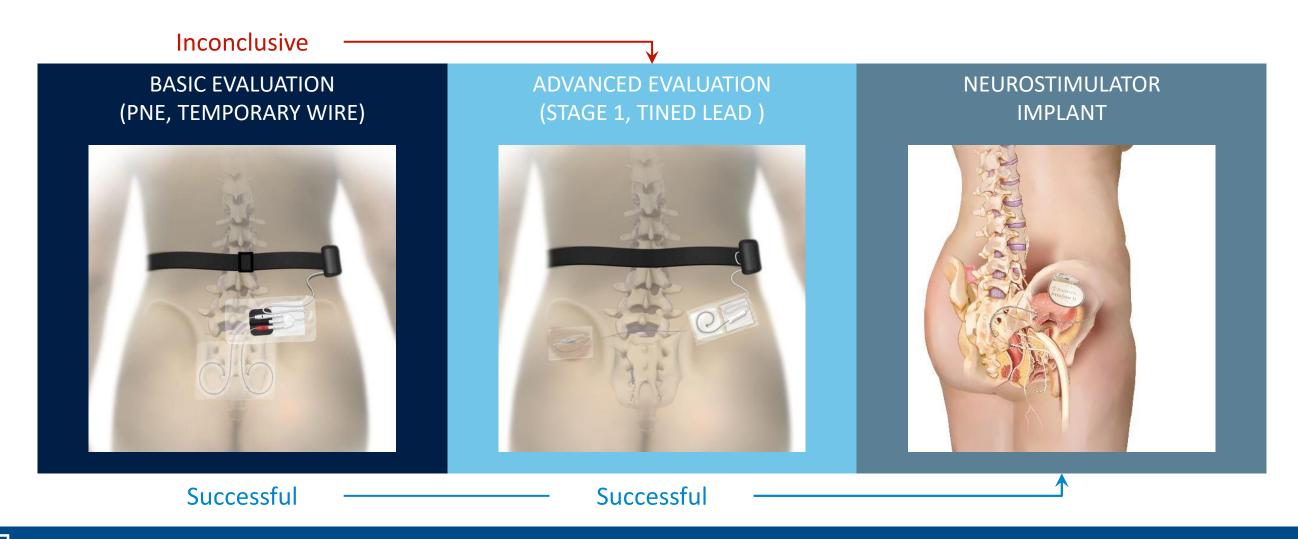
- Retention
 - Catheterized volume per catheterization
 - Number of catheterizations per day
- Fecal incontinence
 - Number of fecal incontinence episodes per week
 - Number of days with incontinence episodes per week
 - Ability to defer defecation

^{1.} El-Azab AS, et al. Sacral neuromodulation for female pelvic floor disorders. Arab J Urol. 2019; 18;17(1):14-22.

PROCEDURE AND PRODUCTS



EVALUATION (TEST STIMULATION)PROCEDURE FLOW





IF THE PNE TEST IS INCONCLUSIVE, AN ADVANCED EVALUATION SHOULD BE CONSIDERED

BASIC EVALUATION

ALSO KNOWN AS (PNE) TEST WITH TEMPORARY WIRE

THERAPY PATH	 Available as an initial evaluation option
	 With positive results, proceed directly to long-term therapy
	 With inconclusive results, the advanced evaluation is recommended
EVALUATION PERIOD	■ Up to 7 days
PROCEDURE	 Maybe performed as an out-patient procedure
ANESTHETIC	 Local anesthesia possible
TYPE OF LEAD	Flexible, thin wire
	 Only one electrode contact
FLUOROSCOPY	 May or may not be used, but recommended
PROGRAMS AVAILABLE	• 1
CONCLUSIONS	+ Simple minimally invasive procedure, Lead can be easily removed after evaluation
	 Significant lead dislodgement, test success rates may be up to 40% lower than with the advanced evaluation^{1, 2, 3}

^{1.} Bannowsky, et al. World J Urol. 2008; 26(6):623-6

^{2.} Borawsky, et al. Neurourol Urodyn. 2007; 26:14-18

^{3.} Altomare, et al. Colorectal Disease 2010, 13:198–202

ADVANCED EVALUATION

ALSO KNOWN AS "STAGE 1 / TEST WITH TINED LEAD"

THERAPY PATH	 Available as an initial evaluation option
	With positive results, proceed directly to long-term therapy (INS implant)
	With inconclusive results, consider other therapy options
EVALUATION PERIOD	■ Up to 28 days (NEW)
PROCEDURE	 Minimally invasive in-patient procedure
ANESTHETIC	 Monitored anesthesia care (MAC) or general anesthesia
TYPE OF LEAD	 Flexible lead with tines that anchor into place
	 Remains in place for long-term therapy after a positive evaluation
	 Four electrode contacts provide more programming options
FLUOROSCOPY	Mandatory
PROGRAMS AVAILABLE	4 individual & 7 standard programs as options
CONCLUSIONS	 More invasive than BASIC EVALUATION; shorter second procedure (stage II); less lead dislodgement; higher test success rates expected^{1,2,3,4}

^{1.} Bannowsky, et al. World J Urol. 2008; 26(6):623-6

^{2.} Borawsky, et al. Neurourol Urodyn. 2007; 26:14-18

^{3.} Altomare, et al. Colorectal Disease 2010, 13:198–202

^{4.} Rydningen, et al. Colorectal Dis. 2017; 19:274–282

VERIFY EVALUATION AND INTERSTIM IMPLANT SYSTEM COMPONENTS

THE ENHANCED EVALUATION SYSTEM



THE IMPLANT SYSTEM



VERIFY EVALUATION SYSTEM



Wireless, touch-screen, lightweight, hand-held device used to control the Verify ENS during advanced and basic evaluation.



Verify ENS

External Neurostimulator

— Small external device

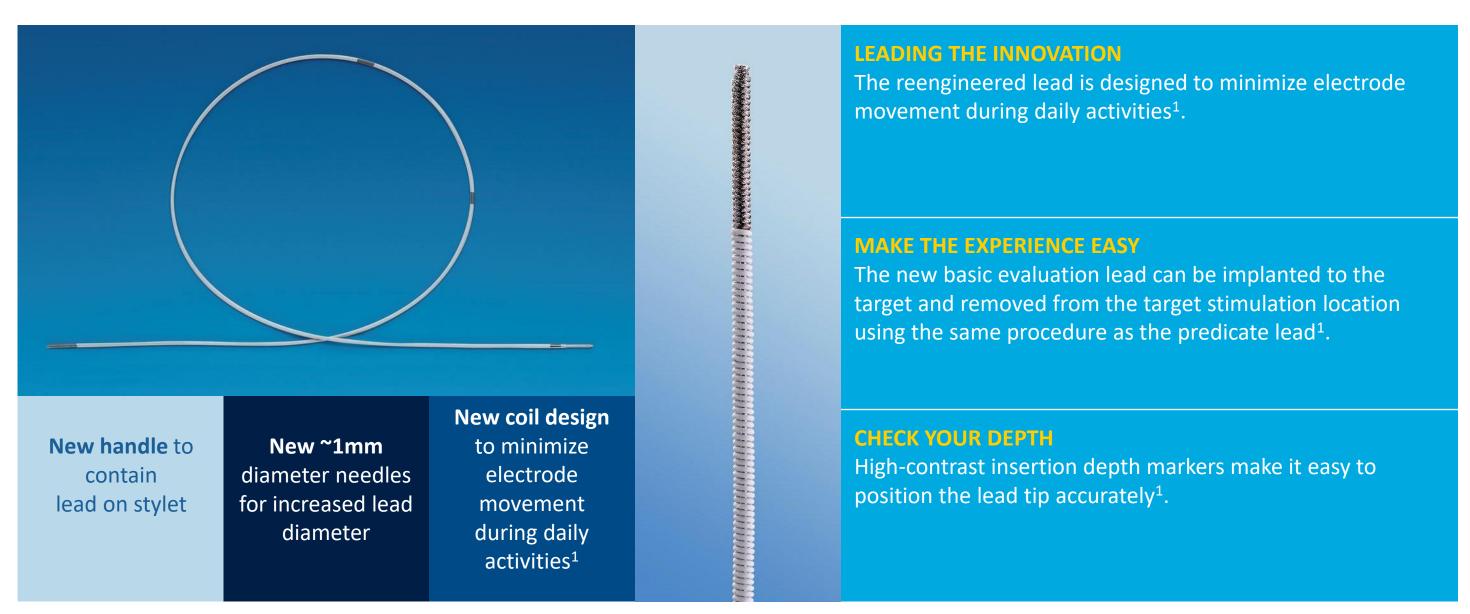




The external test battery is worn on a belt discreetly under clothing.

It is unobtrusive and allows patients to resume many normal activities.

NEW BASIC EVALUATION LEAD (PNE)



1. Medtronic data on file - Based on computational modeling and experimental data. (NDHF1534-172546)

TINED LEAD FOR ADVANCED EVALUATION



TINED LEAD KIT

The exclusive Medtronic tined lead

- One 4-electrode tined lead, 28cm, 33cm or 41cm long.
 Lead electrodes 3mm, spacing 3mm.
- Offers minimally invasive positioning with visual aid and radiopaque markers (fluoroscopy)
- Minimises surgical steps, which may reduce surgical and healing time
- Has tines designed to deploy as a fixation system
- Curved, soft stylet with steering capabilities allows lead placement close to the nerve^{1,2}

TECHNICAL SPECIFICATIONS.

Lead lengths: 28, 33 and 41cm

Lead shape: Straight

Lead diameter: 1.27 mm

Connector: In-line

Number of electrodes: 4

Electrode shape: Cylindrical/coiled

Electrode Length: 3 mm (4x)

Electrode Spacing: 3 mm

Number of conductor wires: 4

^{1.} Vaganée D, et al. Sacral neuromodulation using the standardized tined lead implantation technique with a curved vs a straight stylet: 2-year clinical outcomes and sensory responses to lead stimulation. BJU International. 2019;123(5A):E7-E13 2. Matzel KE, et al. Sacral Neuromodulation: Standardized Electrode Placement Technique. Neuromodulation Technology at the Neural Interface; 2017; 20 (8): 816-824.

INTERSTIM™ II NEUROSTIMULATOR



SPECIFICATIONS

Height: 44 mm Length: 51 mm Thickness: 7.7 mm

Weight: 22 g Volume: 14 cc

Expected battery life: 3-7 years^{3,4} Depends on parameter settings and amount of use

- Neurostimulator for use with a tined lead 3889 and InterStim™ smart programmer models TH90G02 (EU) and TH90G03 (UK / Ire).
- Programmable device that delivers stimulation through one lead.
 The stimulation settings are stored as a program. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination (up to 4 electrodes).
- More than 300,000 patients⁵ have received Sacral Neuromodulation Therapy worldwide since it became commercially available in 1994
- Sacral Neuromodulation Therapy provided by the InterStim™ System is reversible and has shown long-term efficacy and an established safety profile^{1,2}

^{1.} Siegel S, et al. Five-year Follow-up Results of a Prospective, Multicenter Study of Patients with Overactive Treated With Sacral Neuromodulation. Journal of Urology. 2018; 199(1):229-236.

^{2.}Hull T, et al. Long-term Durability of Sacral Nerve Stimulation Therapy for Chronic Fecal Incontinence. Dis Colon Rectum. 2013;56:234–245.

^{3.}Duchalais E, et al. Exhausted implanted pulse generator in sacral nerve stimulation for faecal incontinence: What next in daily practice for patients? Int J Colorectal Dis. 2016; 31(2):439-44

^{4.} Widmann B, et al. Success and Complication Rates After Sacral Neuromodulation for Fecal Incontinence and Constipation: A Single-center Follow-up Study. J Neurogastroenterol Motil. 2019;25(1):159-170.

^{5.} Medtronic data on file

SMART PROGRAMMER

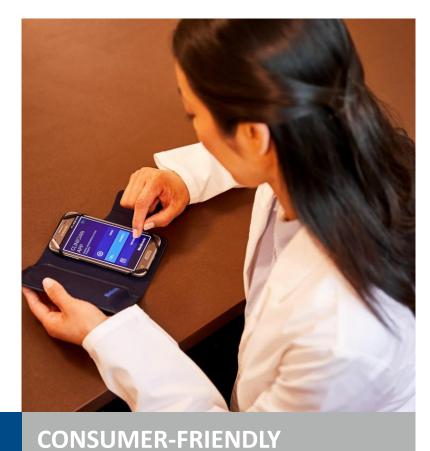
AN INTUITIVE EXPERIENCE FOR BOTH PATIENTS & CLINICIANS



CUTTING-EDGE PLATFORM Designed to support digital health solutions.



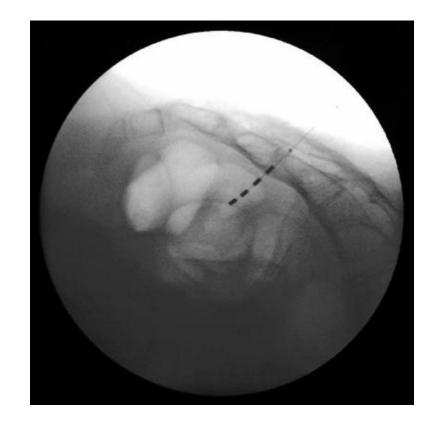
Powered by intuitive apps for both you and your patients, multiple devices have been streamlined into a single programmer.



TECHNOLOGY Based on a smartphone, the technology is instantly familiar to all the users

OPTIMIZED LEAD PLACEMENTWITH THE AID OF FLUOROSCOPY



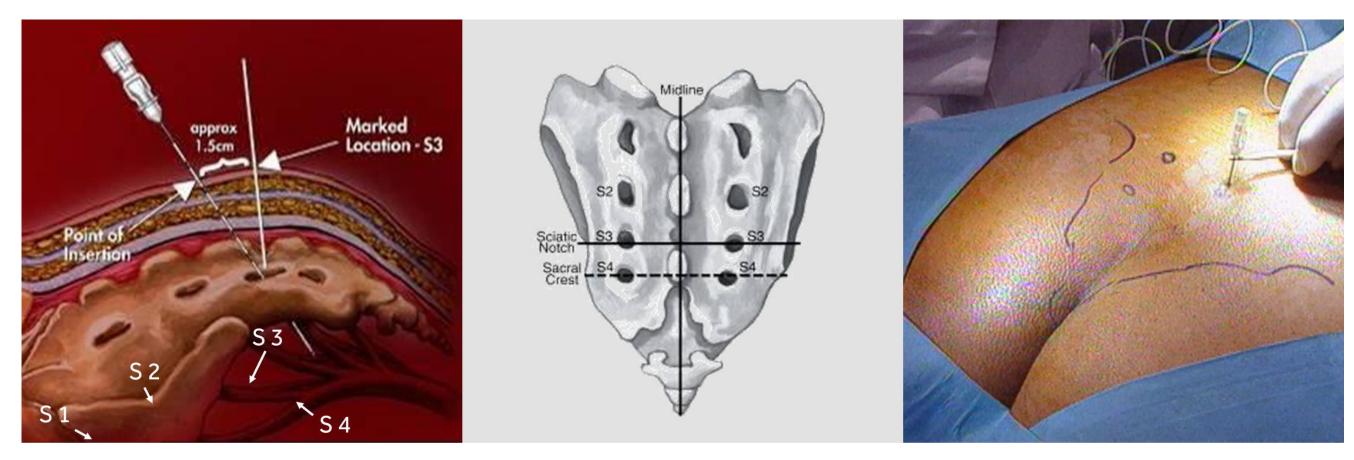


An optimally placed tined lead has a characteristic appearance on x-ray (AP and lateral view), where the lead occupies the most superior and medial position within the foramen and the contact points have a characteristic spacial orientation in each projection.^{1,2}

^{1.} Liberman D, et al. Sacral Neuromodulation in Urological Practice. Urology. 2017;99:14-22.

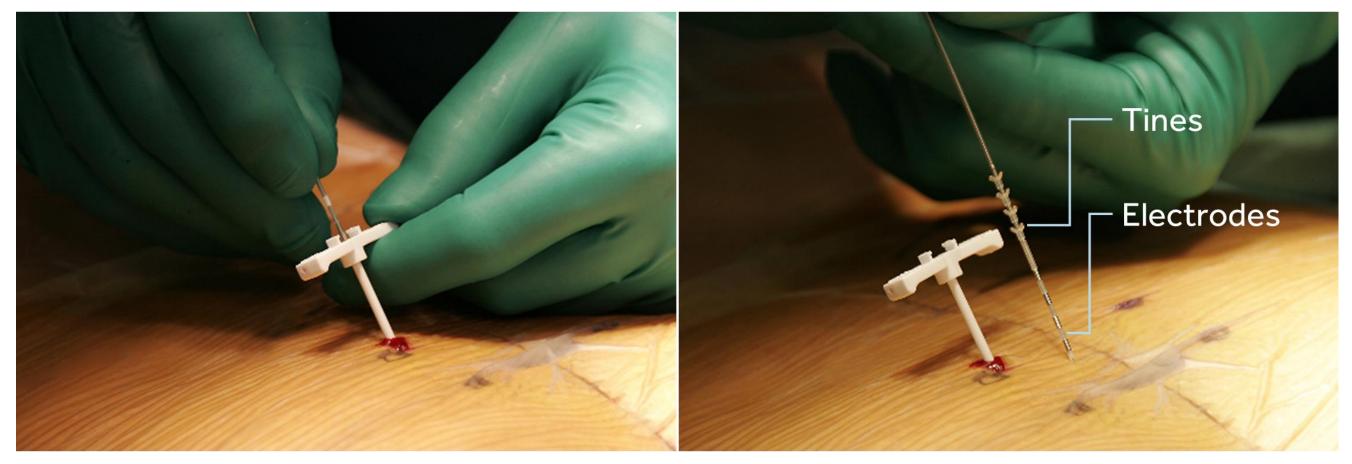
^{2.} Matzel KE. Sacral Neuromodulation: Standardized Electrode Placement Technique. Neuromodulation. 2017;20(8):816-824.

TESTING FOR MOTOR & SENSORY RESPONSES



- Using bony landmarks or fluoroscopy as a guide, insert an insulated foramen needle into the foramen with an approximate 60-degree insertion angle relative to
- Depth markings are located on the foramen needle in 1 cm increments, with a wider mark at 5 cm, to aid in needle placement.
- The needle should enter the foraminal canal perpendicular to the bony surface. (This will position the needle parallel to the nerve.)
- The nerve is positioned along the superior-medial side of the foramen.

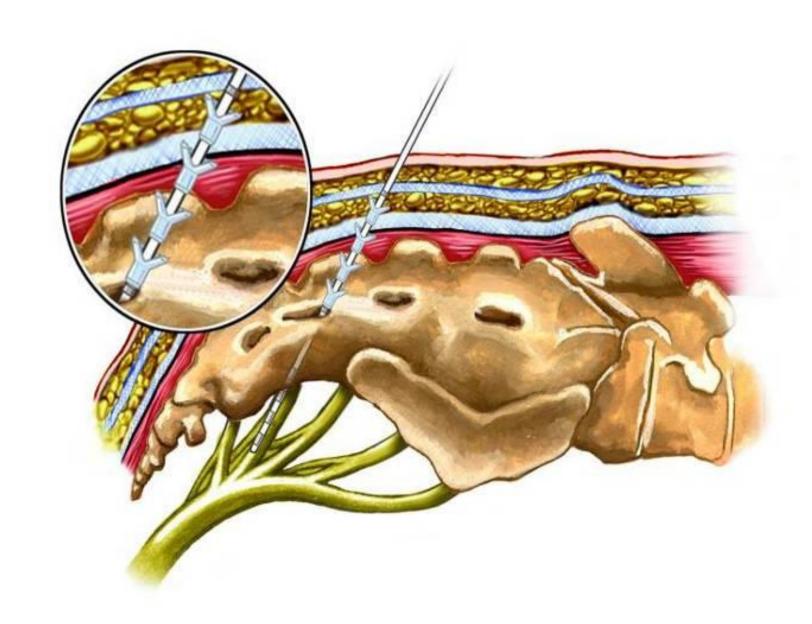
PERCUTANEOUS TINED LEAD — MINIMALLY INVASIVENESS



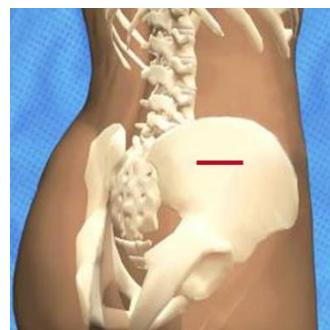
- Advance the introducer sheath until the radiopaque marker is approximately halfway through the foramen.
- Use fluoroscopy to confirm depth of the introducer sheath. Do not advance the tip of the dilator beyond the anterior surface of the sacrum.
- Insert the lead into the introducer sheath and advance the lead until visual marker band on the lead lines up
 with the top of the introducer sheath handle.
- The tip of the lead will be exiting the introducer

THE SIMPLEST WAY TO STIMULATE THE SACRAL NERVES

- Electrodes 2 and 3 are straddling the anterior edge of the sacrum).
- Use fluoroscopy to confirm lead placement .
- Test stimulate the various electrodes (0, 1, 2, 3) and observe responses.
- If necessary, reposition the lead within the foramen.



INTERSTIM™ NEUROSTIMULATOR IMPLANT



Create a subcutaneous pocket by blunt dissection

• Tunnel from the lead incision site to the neurostimulator pocket

buttock area.

to the anterior surface of

the muscle in the upper

- Insert the lead into the neurostimulator connector block until fully seated.
- Tighten the setscrew by turning clockwise until the torque wrench clicks





Place the neurostimulator in the pocket no deeper than 2.5 cm below the skin and should be parallel to the skin

LIVING WITH THE IMPLANT

- Often the neurostimulator is set to a sub-sensory threshold, so that the patients do not have a permanent perception of the stimulation
- The patient is able to adjust the amplitude of stimulation with the smart programmer or to switch the device off
- Typically 1–2 follow-up visits per year are sufficient.
- The battery life of the recharge-free device of Interstim II is typically about 5–7 years^{1,2}
- Some precautions have to be considered, similar to a heart pacemaker
- Typical age of an Interstim patient (at implant)
 - 57.0 years: urology³
 - 60.5 years: FI⁴



^{1.} Duchalais E, et al. Exhausted implanted pulse generator in sacral nerve stimulation for faecal incontinence: What next in daily practice for patients? Int J Colorectal Dis. 2016; 31(2):439-44.

^{2.} Widmann B, et al. Success and Complication Rates After Sacral Neuromodulation for Fecal Incontinence and Constipation: A Single-center Follow-up Study. J Neurogastroenterol Motil. 2019;25(1):159-170.

^{3.} Siegel S, et al. Five-Year Follow-up Results of a Prospective, Multicenter Study of Patients with Overactive Bladder Treated with Sacral Neuromodulation. J Urol. 2018 Jan;199(1):229-236

^{4.} Wexner SD, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg. 2010 Mar;251(3):441-9.

ADVANTAGES OF SNM

- Proven stable long-term results
- A holistic approach for various pelvic floor dysfunctions
 - Up to 60% of patients in a pelvic floor center may have a combination of bladder and bowel dysfunctions^{1,2}
- Established therapy
 - > 300,000 patients treated worldwide³
 - > 25 years clinical experience
- Reversible
 - In case of stimulation discomfort the neurostimulator can be switched off immediately
 - No irreversible complications to be expected

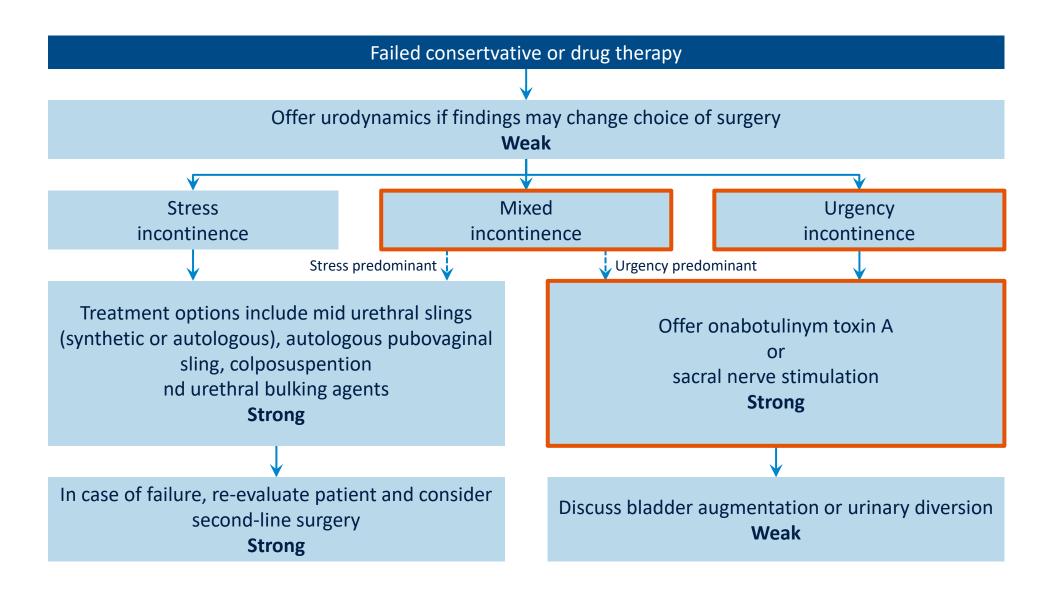
- 1. van Kerrebroeck PE, et al. Neurourology and Urodynamics. 2011;30:1403
- 2. Oerlemans DJ, et al. Sacral nerve stimulation for neuromodulation of the lower urinary tract. Neurourol Urodyn. 2008;27(1):28-33.
- 3. Medtronic data on file

GUIDELINES



WOMEN WITH URINARY INCONTINENCE

EAU GUIDELINES 2019¹

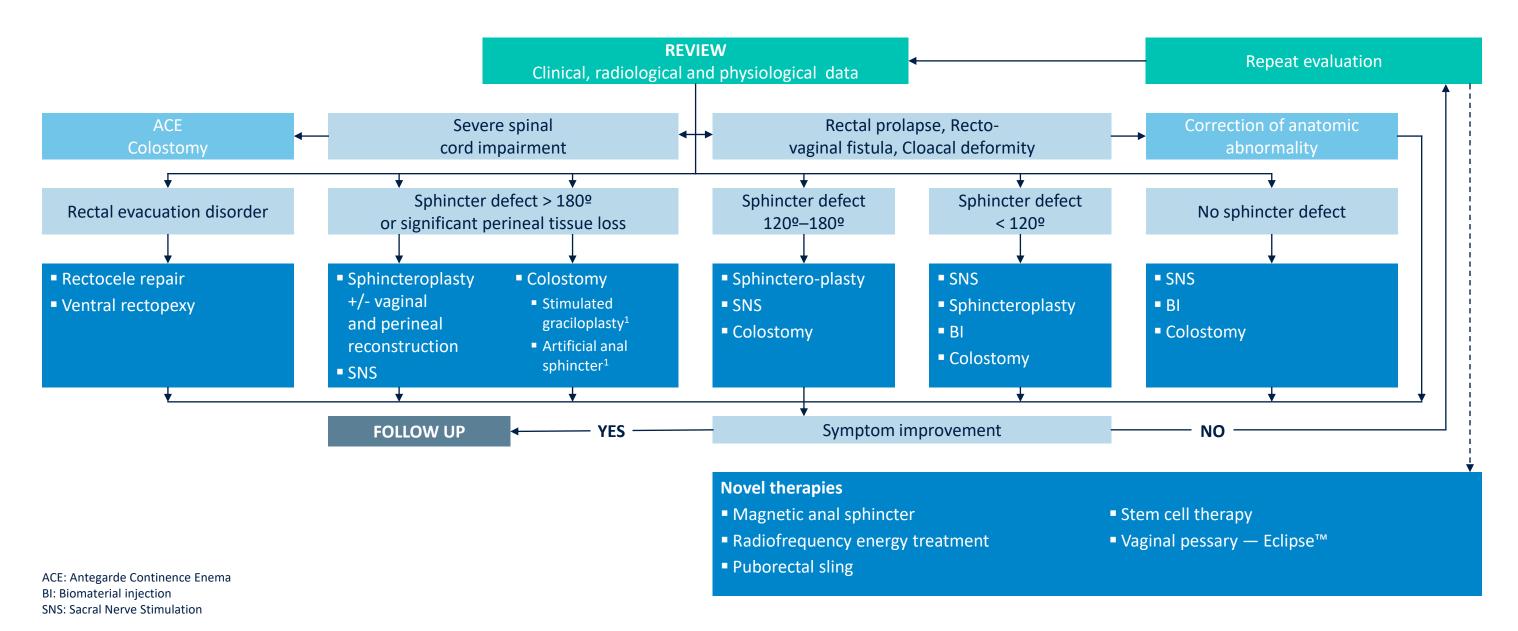


Failed Conservative / Medical Therapy: advanced therapies

1. Burkhard FC, et al. EAU Guidelines. Edn. presented at the EAU Annual Congress Copenhagen 2018. ISBN 978-94-92671-01-1. http://uroweb.org/guideline/urinary-incontinence/#4

ICI 2017

SURGICAL MANAGEMENT OF FECAL INCONTINENCE¹



1. Herold A, et al. Coloproctology, Springer 2017, DOI 10.1007/978-3-662-53210-2_9.

INTERSTIM™: THERAPY OF CHOICE FECAL INCONTINENCE

"Sacral neuromodulation has become the first line surgical treatment for fecal incontinence in people failing conservative therapies." 1

^{1.} Thaha MA, et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database Syst Rev. 2015; 24;(8):CD004464

WHY MEDTRONIC SACRAL NEUROMODULATION?



EXPERTISE

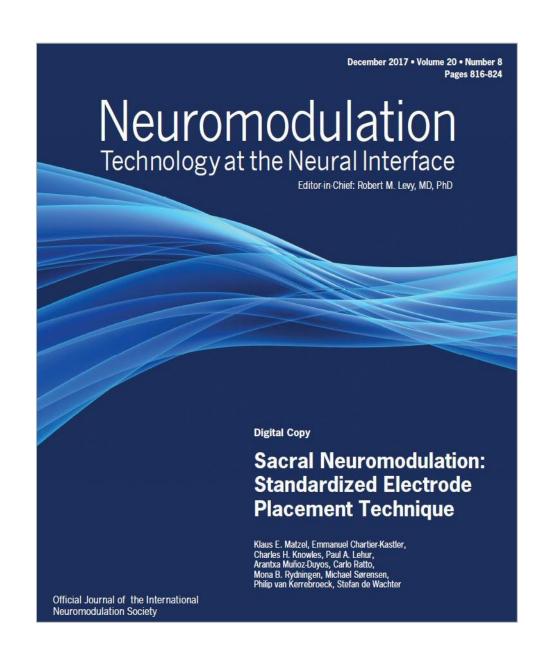




We provide expert support built on long-term knowledge and experience across the widest portfolio of neuromodulation therapies, enabling clinicians to deliver optimal therapies to their patients.

SCIENCE

- We are committed to invest in building scientific evidence to responsibly develop therapies and investigate new indications
 - Dedicated European Pelvic Health team to support physician initiated research programs and ...
 - Medtronic sponsored trials and therapy registries.



TECHNOLOGY



Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction Foundation

Overactive Bladder Clinical Care Pathway

Overactive Bladder Syndrome (OAB):

A clinical syndrome characterized by the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence in the absence of obvious pathology.

- We continuously innovate
 with technologies that
 bring values to hospitals
 and patients, to improve
 therapy outcomes, clinical
 decisions and patient
 comfort.
- Medtronic is committed to take the lead in Sacral Neuromodulation.

ECONOMIC VALUE

• In today's changing healthcare environment we are partnering with you, to demonstrate disease impact & therapy cost effectiveness to provide viable patient care.



Figure 11
Definitions used in cost-effectiveness analyses.

DEFINITIONS				
COST-EFFECTIVENESS ANALYSIS (CEA)	A comparison of the costs and effects (health outcomes) of two or more treatment options. The output of a CEA is often expresses as an incremental cost-effectiveness ratio (ICER). Calculating the cost-effectiveness of the			
WHAT IS AN ICER?		Cost-effectiveness is reported as an incremental cost-effectiveness ratio (ICER). An ICER is only meaningful with respect to a willingness-to-pay (WTP) threshold which is approximately €40,000 in Europe.		
	ICER =	Cost Treatment A-Cost Treatment B		
		QALYS Treatment A-QALYS Treatment B		
VHAT IS A QALY?	A QALY (quality adjusted life year) is a generic (i.e., not specific to any on disease) measure of effectiveness, that encompasses both the quality of life and the quantity of life (i.e., survival), providing a consistent and common measure that healthcare funders can use to facilitate their decisions for allocating constrained recourses to treatments.			

THERAPY DEVELOPMENT

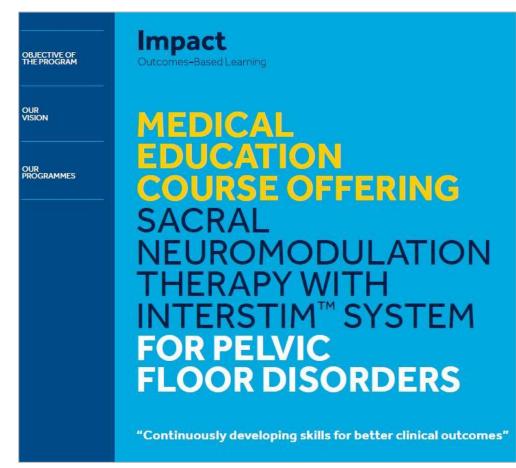
- We are committed to understand the needs of clinicians and patients to develop & create access
 to therapies and solutions that alleviate patient chronic disease symptoms.
 - Dedication to reaching patients and physicians where they are.
 - Engagement with a wide community of specialties, in a true Pelvic Floor Franchise.



EDUCATION

- We facilitate training & education on patient selection, surgical procedure and optimal patient management to perform optimized procedures and achieve the best possible clinical outcomes.
 - ECMT, European Continuing Medical Trainings:
 Basic and Advanced SNM courses for starting the practice and gaining knowledge.
 - Proctoring and mentoring opportunities targeted at physicians needs.
 - Centre of Excellence & Experienced Implanter Visits.





NETWORK

- We support and facilitate high level scientific exchange around the world amongst the medical community to share expertise and clinical evidence to raise the standard of care.
 - Support local and international events in collaboration with medical societies.
 - Medtronic global SNM forum and European pelvic floor expert meetings.



See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.



www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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