

Medtronic

InterStim[®] Therapy

FAMILY TECHNICAL BROCHURE

Make the
choice for **life**



...with InterStim Therapy



تهران جراح نوین

The InterStim® System

Model 3058
InterStim II
Neurostimulator,

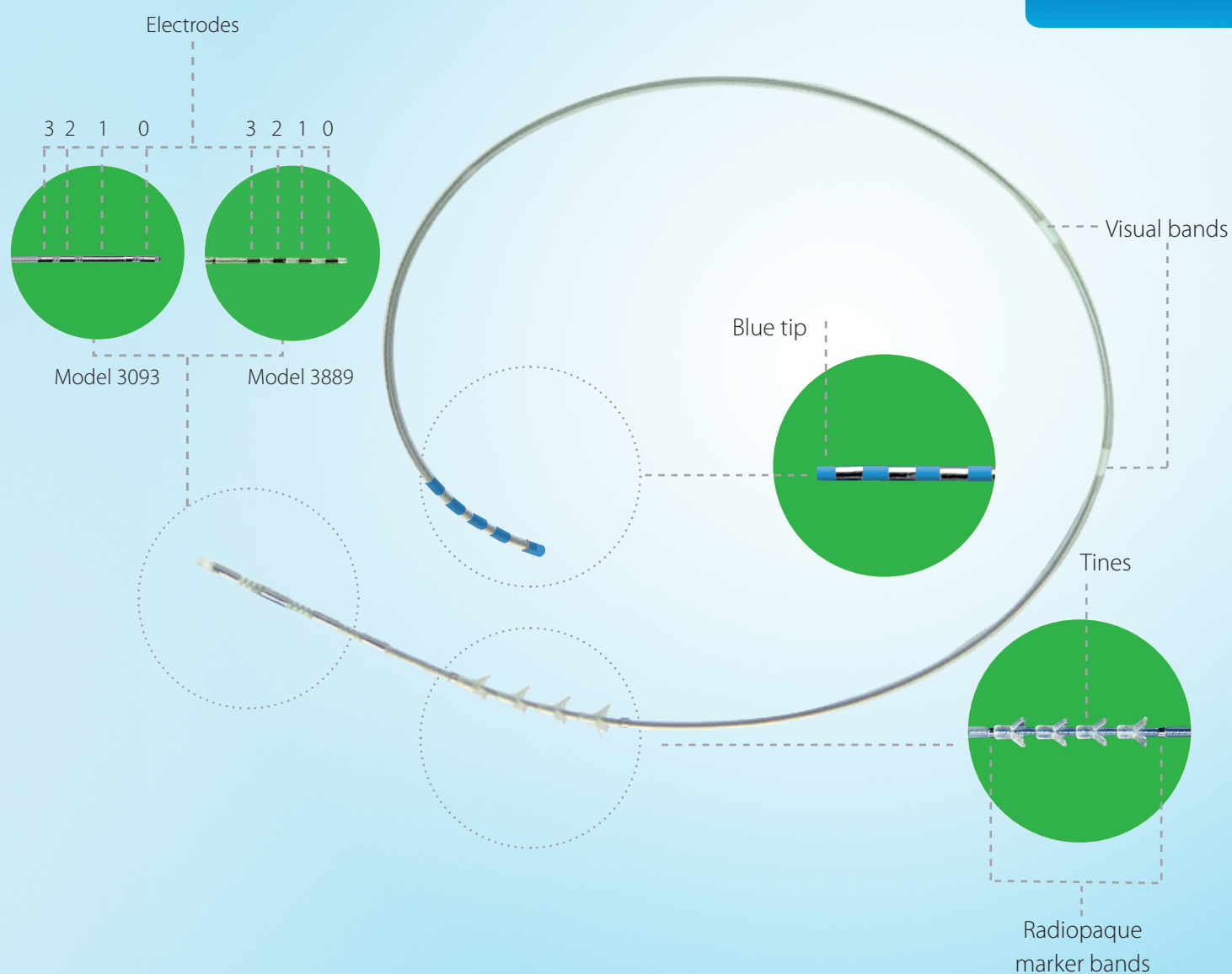
Direct connection with the lead
(no extension is required)



Neurostimulators

InterStim II Model 3058	
Volume	14 ml
Height	44 mm
Length	51 mm
Thickness	7.7 mm
Weight	22 g
Number of electrodes	4
Number of screws	1
Strain relief	Integrated into neurostimulator
Lead insertion indicator	Integrated into header
Torque wrench	Yes

Tined Lead Models 3093 and 3889



Tined Leads

	3093-28	3093-33	3093-41	3889-28	3889-33	3889-41
Length (cm)	28	33	41	28	33	41
Number of electrodes	4	4	4	4	4	4
Electrode length (mm)	3, 10, 3, 3	3, 10, 3, 3	3, 10, 3, 3	3, 3, 3, 3	3, 3, 3, 3	3, 3, 3, 3
Electrode spacing (mm)	1.5	1.5	1.5	3	3	3
Blue tip (Y/N)	Y	Y	Y	Y	Y	Y
Radiopaque Marker (Y/N)	Y	Y	Y	Y	Y	Y
Anchor type	Tined	Tined	Tined	Tined	Tined	Tined

The InterStim® Programmers

Model 3037



InterStim iCon® Patient Programmer

- Offers the patient the possibility to switch the stimulation configuration between 4 pre-set configurations
- Simplifies patient management and programming
 - improved graphics interface and feedback
 - logs therapy and program usage between visits
 - stores patient information and program history
- Supports both InterStim II 3058 and InterStim 3023 neurostimulator†

†InterStim II 3058 neurostimulator compatible only with the InterStim iCon programmer (3037).

InterStim 3023 neurostimulator compatible with both original patient programmer (3031A) and InterStim iCon programmer (3037).



InterStim® N'Vision® Clinician Programmer

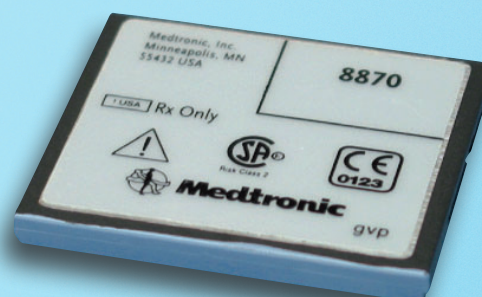
Model 8840

- Handheld and portable
- Stores approximately 100 programming sessions
- Compatible with N'Vision Report Link 8580 for printing
- Intuitive touch-screen interface
- Power saver screen display

InterStim N'Vision Software[‡]

Model 8870 NNB

- **Expedites and reduces programming time**
 - simplicity and clarity in user interface
 - adaptive reports reduce waste
 - facilitates and automates therapy evaluation via program libraries
- **Allows for more effective patient management**
 - provides summary of program and therapy usage data
 - special alerts flag common problems throughout course of therapy
 - transfers patient data with neurostimulator replacements



[‡] Can be used with InterStim II 3058, InterStim 3023 and InterStim TWIN 7427T neurostimulators.

Evaluation Procedures

Minimally Invasive Evaluation Phase



2 Ways to evaluate

Evaluation with tined lead - Advanced Evaluation

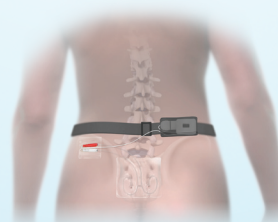
- Lead is placed next to the sacral nerves via a minimally invasive procedure under local or general anesthesia
- Lead is connected—via tunneling—to a percutaneous extension exiting the skin contralaterally to the future neurostimulator site
- Advanced Evaluation, if successful, allows patients to proceed directly to the second stage.
- Keeping the same lead in place for implant offers a higher reproducibility of the results
- The lead can be easily removed and the evaluation repeated if needed



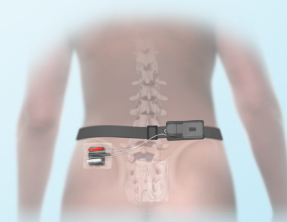
Advanced Evaluation

Basic Evaluation with temporary lead (PNE)

- Lead is placed next to the sacral nerves through a percutaneous procedure
- Lead is secured to the outside of the patient's sacral area
- If evaluation is inconclusive or unsuccessful, proceed to the Advanced Evaluation



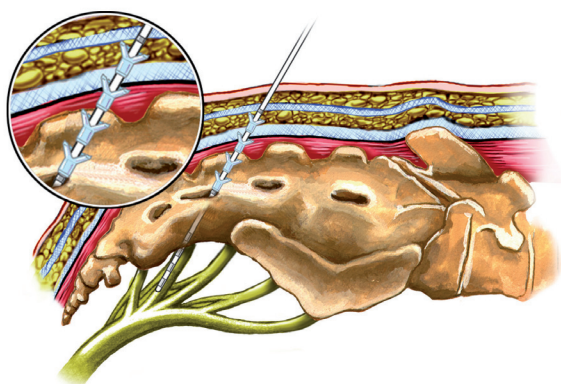
Basic Evaluation – Dual



Basic Evaluation with ground pad

Implant Procedure

InterStim® Tined Lead

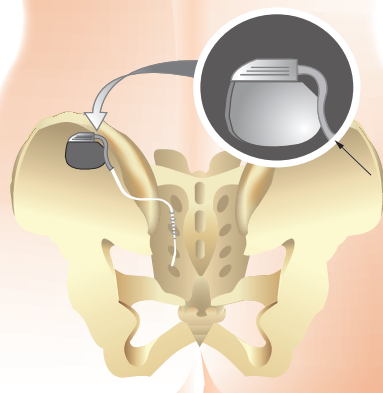


Model number 3093 or 3889

The Exclusive Medtronic Tined Lead¹⁻³

- Offers 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 and to allow easy removal under local anesthesia
- Allows for patient feedback with local anesthesia or conscious sedation

Permanent Implant



Implanted lead and neurostimulator model 3058

Minimally Invasive Implant Procedure

- The InterStim Therapy implant procedure directly follows a successful screening test
- The InterStim neurostimulator is typically implanted in the buttock⁴
- Lead is connected to the InterStim neurostimulator which is then placed in a pocket

Make the choice for Life
...with InterStim Therapy

Make the choice for **life**

...with InterStim® Therapy

- Predictable ^{[5],[6]}
- Adaptable ^{[5],[6]}
- Safe ^{[5],[6]}



InterStim Therapy Components

What is needed for an evaluation procedure?

Model#	Advanced Evaluation tined Lead
3093-xx or 3889-xx	Tined lead kit, -28 cm, 33 cm or 41 cm
355018	Lead introducer kit
3537	Controller Kit
3531	ENS Kit
3575	Test stimulation cable
357625 or 357664	Twist-lock-cable, available in 25 cm or 64 cm length

Model#	Basic Evaluation with temporary Lead (PNE)
309101	Test stimulation lead kit - 1 lead
3537	Controller Kit
3531	ENS Kit

What is needed for an implant procedure?

If evaluated with tined Lead

Model#	Implant with InterStim II
3037	Patient programmer (iCon®)
3058	InterStim II neurostimulator

If evaluated with temporary Lead (PNE)

Model#	Implant with InterStim II
3037	Patient programmer (iCon)
3058	InterStim II neurostimulator
3093-xx or 3889-xx	Tined lead kit, -28 cm, 33 cm or 41 cm
355018	Lead introducer kit
3537	Controller Kit
3531	ENS Kit
3575	Test Stimulation Cable

What accessories are needed / recommended?

Model#	Description
173866	Printer paper for programmer model 8840
8580	N'Vision® Report Link
8840	N'Vision Programmer
8870NNB	N'Vision InterStim application card
355002	Hex wrenches and screws

Model#	Description
041826	Self-adhesive ground pad - Box of 20
041828	Bulk 3.5 Needles (6 pk) 20 gauge
041829	Bulk 5.0 Needles (6pk) 20 gauge
357937 or 357975	Patient Cable without ground pad in 37cm or 75cm length
367637 or 367675	Patient Cable with ground pad in 37cm or 75 cm length
042294	Lead introducer
3550-80	Torque wrench kit
37094	Controller Cover

Refer to technical manual for complete list of indications, contraindications, warnings and precautions

References:

1. Chai TC, Mamo GJ. Modified techniques of S3 foramen localization and lead implantation in S3 neuromodulation. Urology 2001;58:786-90.
2. Spinelli M, Mamo GA, Arduini A, Gerber M, Giardiello G. Evolution of a minimally invasive procedure for sacral neuromodulation. In: Jonas U and Grunewald V, eds. New Perspectives in Sacral Nerve Stimulation. London, England: Martin Dunitz; 2002:217-22.
3. Spinelli M, Giardiello G, Arduini A, van den Hombergh U. New percutaneous technique of sacral nerve stimulation has high initial success rate: preliminary results. Eur Urol 2003;43:70-4.
4. Scheepens WA, Weil EHJ, van Koeveinge GA, et al. Buttock placement of the implantable pulse generator: a new implantation technique for sacral neuromodulation-a multicenter study. Eur Urol 2001;40:434-8.
5. Chartier-Kastler E. Sacral neuromodulation for treating the symptoms of overactive bladder syndrome and non-obstructive urinary retention: >10 years of clinical experience. BJU international 2008;101(4):417-23.
6. Van Voskuilen AC, et al. Long term results of Neuromodulation by Sacral Nerve Stimulation for Lower Urinary Tract Symptoms: A Retrospective Single Center Study. Eur Urol 2006;49(2): 366-72

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