PATIENT MANAGEMENT GUIDE

InterStim™ system for Sacral Neuromodulation
INITIAL TROUBLESHOOTING QUESTIONS

1. Do you have signs or symptoms of an infection?
2. Have you had a change in bladder or bowel function (constipation or diarrhea)?
3. Have there been changes with other known medical conditions (e.g., neurological disorder, IC flare, glucose change)?

Have there been any changes in your diet?

Yes

Refer to other sections in this guide for additional troubleshooting information.

Yes

Instruct patient to follow their provider’s recommendations for assessment and treatment.

No

Instruct patient to turn device on with the InterStim iCon™ Patient Programmer.

No

Is the neurostimulator on?

Yes

Some foods and fluids can cause changes in your bladder and bowel function.
Medications (e.g., antibiotics, diuretics, blood pressure, hormones) may cause changes in urinary and bowel symptoms, such as urgency-frequency or diarrhea.

Patient will need to schedule an office visit. You may decide to check impedances using the N’Vision™ Clinician Programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.

Have there been any changes to your medications or have you started any antibiotics?

Yes

1. Have you recently fallen or had trauma to your body?
2. Have you recently had any procedures or surgeries?

Yes

No

Refer to other sections in this guide for additional troubleshooting information.
Record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review Initial Session Details (Therapy Use, Program Use, etc.), review program settings, change to a different program, check impedances, and review Battery Capacity and Longevity using the N’Vision™ Clinician Programmer. Contact your Medtronic sales representative, if necessary.
Can’t Feel Stimulation

Ask
Initial Troubleshooting Questions

Symptom Return

Record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review Initial Session Details (Therapy Use, Program Use, etc.), review program settings (amplitude, cycling, etc.), change to a different program, check impedances, and review Battery Capacity and Longevity using the N’Vision Clinician Programmer. Contact your Medtronic sales representative, if necessary.

No Symptom Return

You may need to re-educate the patient on stimulation sensation. Patients do not need to feel stimulation for the InterStim™ system to be working.
**INTERMITTENT STIMULATION**

**Ask Initial Troubleshooting Questions**

**Is the stimulation positional?**

- **Yes**
  - Stimulation may fluctuate slightly due to positions or activities. Patients do not need to feel stimulation for the InterStim™ system to be working. If the intermittent stimulation is bothersome, instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to palpate for loose connections and check for positional sensitivity or check impedances using the N’Vision™ Clinician Programmer. Contact your Medtronic sales representative, if necessary.

- **No**
  - Stimulation may fluctuate slightly due to positions or activities. Patients do not need to feel stimulation for the InterStim™ system to be working. If the intermittent stimulation is bothersome, instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review program settings (SoftStart/Stop™, cycling, etc.) and check impedances using the N’Vision™ Clinician Programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.
I FEEL THE STIMULATION IN MY __________

Ask Initial Troubleshooting Questions

Symptom Return

Instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review Initial Session Details (Therapy Use, Program Use, etc.), review program settings (rate, pulse width, etc.), change to a different program, check impedances, and review Battery Capacity and Longevity using the N’Vision™ Clinician Programmer. Contact your Medtronic sales representative, if necessary.

No Symptom Return

You may need to re-educate the patient on stimulation location. Patients do not need to feel stimulation in a certain area for the InterStim™ system to be working. Focus on symptom relief. If the stimulation location is bothersome, patient may need to schedule an office visit. You may decide to review and adjust program settings (rate, pulse width, etc.).
Ask *Initial Troubleshooting Questions*

Instruct patient to adjust the stimulation amplitude to a comfortable level or change to a different program with the InterStim iCon™ Patient Programmer.

**Do you still feel uncomfortable stimulation?**

- **Yes**
  - Patient will need to schedule an office visit. You may decide to adjust the rate or pulse width to a comfortable level using the N’Vision™ Clinician Programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.

- **No**
  - Re-educate the patient on use of the InterStim iCon™ Patient Programmer.
PAIN IN THE INS POCKET

Ask Initial Troubleshooting Questions

Instruct patient to turn device off with the InterStim iCon™ Patient Programmer.

Do you still feel pain?

Yes

The pain is not likely related to stimulation. Rule out sources of non-stimulation pain (e.g., incision healing/pulling, seroma, skin staples, infection, falls/trauma). Instruct patient to follow their provider’s recommendations for assessment and treatment.

No

Patient will need to schedule an office visit. You may decide to change program settings using the N’Vision™ Clinician Programmer. If the electrode configuration is unipolar, program a bipolar configuration using the standard programs. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.
**SHOCKING/JOLTING SENSATION**

**Ask Initial Troubleshooting Questions**

Instruct patient to turn stimulation off with the InterStim iCon™ Patient Programmer.

**Do you still feel the shocking/jolting stimulation?**

**Yes**

The sensation is not likely related to stimulation. Instruct patient to follow their provider’s recommendations for assessment and treatment.

**No**

Patient will need to schedule an office visit. You may decide to adjust the rate or pulse width to a comfortable level using the N’Vision™ Clinician Programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.
PATIENTS WITH A PATIENT MANAGEMENT WORKSHEET

Review the Initial Troubleshooting Questions (pages 1-2), then instruct patient to:

1. Record symptoms using a Symptom Tracker for a minimum of three days and call back with results.
   a. If >50% improvement from baseline: Review patient expectations. Reassure patient that stimulation is on and working.
   b. If <50% improvement from baseline: Instruct patient to try the other program(s) in the InterStim iCon™ Patient Programmer.

2. If necessary, repeat Step 1 to evaluate other programs in the InterStim iCon™ Patient Programmer. Advise patient to evaluate each program for a minimum of three days and record symptoms using a Symptom Tracker.

3. If all four programs in the InterStim iCon™ Patient Programmer have been tried, schedule an office visit.

At appointment:

1. Review symptom tracker or voiding diary information and fill out Patient Management Worksheet.

2. Run impedance check and review Therapy Usage using the N’Vision™ Clinician Programmer.

3. Load other configurations (programs) using the N’Vision Clinician Programmer.

4. Advise patient to activate the first program in the InterStim iCon™ Patient Programmer for a minimum of three days.

Post-appointment, instruct patient to:

1. If necessary, repeat trying the other program(s) in the InterStim iCon™ Patient Programmer for a minimum of three days and record symptoms using a Symptom Tracker.

2. Schedule a follow-up office visit, if necessary.

Physicians can decide to reprogram, revise, or remove the neurostimulator at any time.
PATIENTS WITHOUT A PATIENT MANAGEMENT WORKSHEET

Review the Initial Troubleshooting Questions (pages 1-2), then instruct patient to:

1. Complete a three-day Symptom Tracker on current program.
2. Turn the device off for one week and then complete a three-day Symptom Tracker.
3. Schedule an office visit.

At appointment:

1. Collect the two Symptom Trackers, record on the Patient Management Worksheet, and compare results.
2. Run impedance check and review Therapy Usage using the N'Vision™ Clinician Programmer.
3. Load four programs into the InterStim iCon™ Patient Programmer.
4. Advise patient to activate the first program in the InterStim iCon™ Patient Programmer for a minimum of three days.

Post-appointment, instruct patient to:

1. If necessary, repeat trying the other program(s) in the InterStim iCon™ Patient Programmer for a minimum of three days and record symptoms using a Symptom Tracker.
2. Schedule an office visit, if necessary.

Physicians can decide to reprogram, revise, or remove the neurostimulator at any time.
Indications for Use:

**InterStim® Therapy for Urinary Control** is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to **InterStim Therapy for Urinary Control**:

**Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

**InterStim® Therapy for Bowel Control** is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

**Contraindications for Urinary Control and for Bowel Control:** Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

**Warnings/Precautions/Adverse Events:**

**For Urinary Control:** Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins such as multiple sclerosis.

**For Bowel Control:** Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

**For Urinary Control and for Bowel Control:** The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

USA Rx Only. Rev 0815

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