Medtronic

Neurological Division

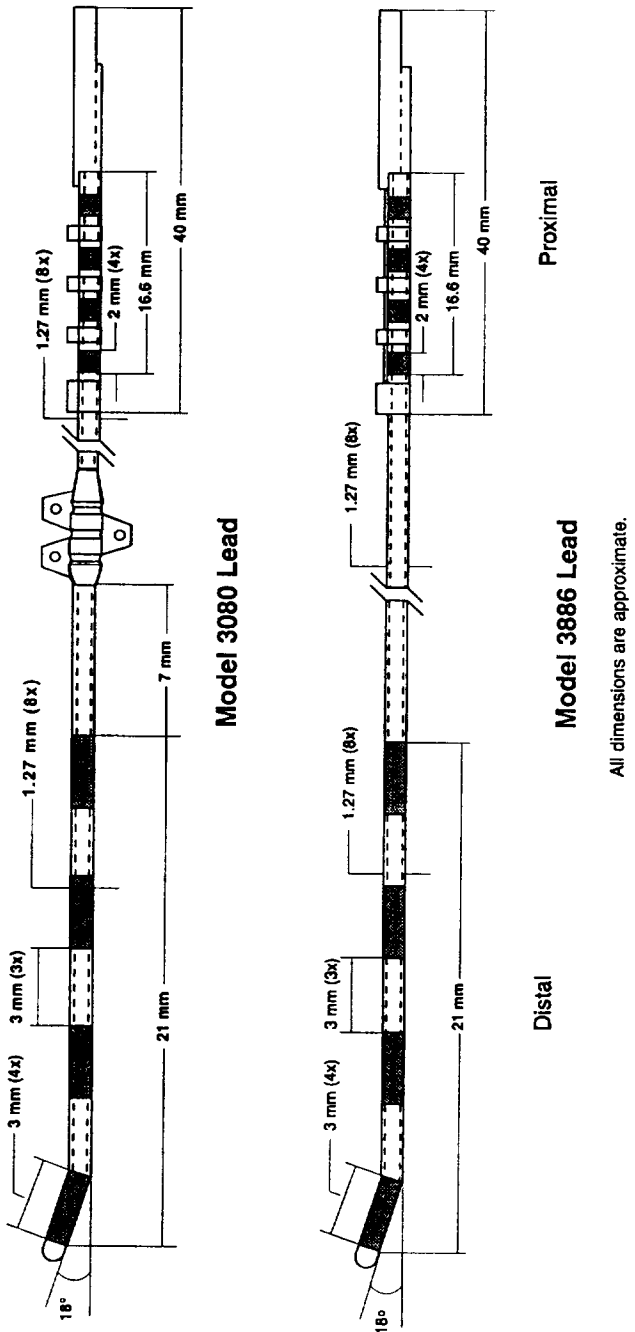
Physician and Hospital Staff Manual

InterStim System:

Model 3023 Quadripolar Neurostimulator

Model 3886 Lead
Model 3080 Lead

Model 3095 Extension



All dimensions are approximate.

Inside Front Cover–For Position Only–Do not print

Contents

⚠ Caution

Federal law (USA) restricts this device to sale by or on the order of a physician.

System Description

The Medtronic® InterStim® System uses sacral nerve stimulation (SNS) to deliver InterStim Therapy for Urinary Control. Electrical signals are transmitted from the Medtronic InterStim Model 3023 Neurostimulator (implantable pulse generator or IPG) to the sacral nerve via the Medtronic Model 3095 Extension and either the Model 3886 or 3080 Lead. These components comprise the implantable portion of the InterStim System (Figure 1).

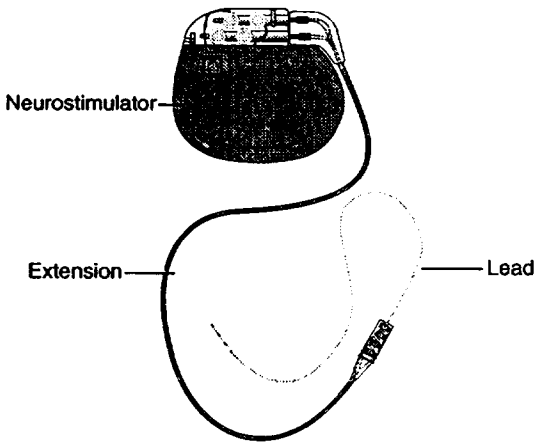


Figure 1. Neurostimulator, extension, and lead.

The InterStim Model 3023 Neurostimulator and Model 3095 Extension are packaged separately with technical manuals specific to those components. The Model 3886 and 3080 Leads are packaged with this system manual, which explains implantation of the leads, extension, and neurostimulator.

System Description

Both the Model 3886 and 3080 Sacral Nerve Stimulation (SNS) Leads are quadripolar in-line leads. The Model 3080 Lead features a pre-attached anchor proximal to electrode #3. This feature is the only difference between the two leads. Figure 2 shows the Model 3886 Lead.

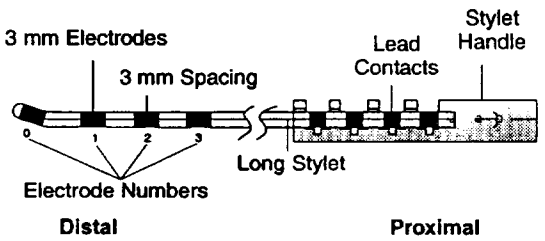


Figure 2. Model 3886 Lead.

Contents of Package

The Model 3886 or Model 3080 Lead Kit consists of the following items:

- One Model 3886 or Model 3080 Quadripolar Lead
- Stylets (short and long)
- One twist-lock screening cable
- One stainless-steel tunneling tool and tunneling tip
- PTFE (polytetrafluoroethylene) tubes
- One hex wrench
- One silicone rubber connector boot
- Silicone rubber anchors

The contents of the inner package are STERILE.

Indications

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

Contraindications

Patients are contraindicated for implantation of the InterStim System if:

- they have not demonstrated an appropriate response to test stimulation; or
- they are unable to operate the neurostimulator.

Precautions

⚠ Warning

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

Physician Training

Implanting Physicians — Implanting physicians should be trained on the implantation and use of the InterStim System.

Prescribing Physicians — Prescribing physicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the InterStim System.

Precautions

Storage and Sterilization

Resterilization Considerations — Refer to "Resterilization" for further information.

Storage Temperature — Store the lead between -30° F (-34° C) and 135° F (57° C). Temperatures outside this range can damage components.

System and Therapy

Case Damage — If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Component Failures — The InterStim System may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical shorts or open circuits and insulation breaches, cannot be predicted.

Components — The use of non-Medtronic components with the InterStim System may result in damage to Medtronic components, loss of stimulation, or patient injury.

Patient Management — To help ensure maximum benefits from the InterStim System, long-term, post-surgical management of patients is recommended.

Postural Changes — Postural changes or abrupt movements by patients may cause an increase or decrease in the perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable, "jolting," or "shocking," by some patients.

Implantation / Explantation

Component Disposal — If explanting an InterStim System component, please remember the following guidelines:

- Do not incinerate the neurostimulator; an explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

Connections — Wipe body fluids off the lead contacts before connecting, as contamination of connections can affect stimulation.

Excess Extension — Do not loop or coil extension on top of the neurostimulator's etched side. Wrap excess extension wire around the perimeter of the neurostimulator (Figure 3). This avoids any increase in the subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension.

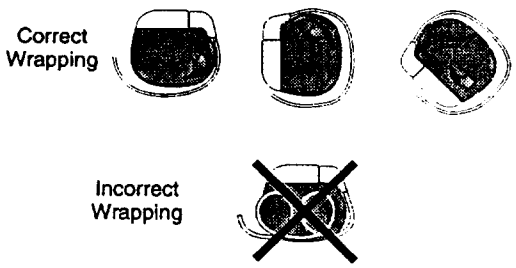


Figure 3. Wrap excess wire around the perimeter of the neurostimulator.

Precautions

Handling Components — Handle the implanted components of the InterStim System with extreme care. These components may be damaged by excessive traction or sharp instruments.

- Do not bend, kink, or stretch the lead body whether or not the stylet is in place. Do not bend or kink the stylet.
- Do not tie a suture directly to the lead body. Use an anchor supplied in the lead package.
- When handling the lead with forceps, use only rubber-tipped forceps.
- Be extremely careful when using sharp instruments around the lead to avoid nicking or damaging the lead body insulation.

Implant Considerations — Do not implant a component of the InterStim System when:

- the storage package has been pierced or altered; or if the component shows signs of damage; or
- the Use Before Date has expired.

Neurostimulator Implant Location — Place the neurostimulator with the etched identification side facing away from muscle. This helps to minimize the possibility of skeletal muscle stimulation that may be perceived as twitching or burning.

Medical Environment

Effects on Other Implanted Devices

The InterStim System may affect the operation of other implanted devices, such as cardiac pacemakers and implantable cardioverter defibrillators. Physical proximity may cause sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, evaluation of any potential interference problems and careful programming of each system may be necessary to optimize the patient's benefit from each device.

Effects with Other Therapies

Diathermy — It is not recommended to use diathermy directly over an implanted neurostimulator or lead, since internal components may be damaged.

Electrocautery — Electrocautery can cause temporary suppression of neurostimulator output and/or reprogramming of the neurostimulator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the neurostimulator and lead as possible.

External Defibrillators — Safety for use of external defibrillatory discharges on patients with InterStim Systems has not been established. Use of defibrillatory discharges in the vicinity of a neurostimulator can cause permanent damage to, or reprogramming of, the neurostimulator. Such reprogramming could cause the stimulation mode and all programmable parameters to reset to the nominal or preset state with the amplitude at zero and the output OFF.

If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the neurostimulator-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm the InterStim System function following any external defibrillation.

High Output Ultrasonics — Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted InterStim System. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Precautions

High Radiation Sources — High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, place lead shielding over the device to prevent radiation damage.

Effects from Diagnostic Procedures

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect the InterStim System operation. However, because of higher energy levels, sources such as transmitting antennas may interfere.

Magnetic Resonance Imaging — Patients with an implanted device should not be exposed to the electromagnetic fields produced by magnetic resonance imaging (MRI). Use of MRI may potentially result in dislodgment, heating, or induced voltages in the neurostimulator and/or lead. An induced voltage through the neurostimulator or lead may cause uncomfortable, "jolting," or "shocking," levels of stimulation.

Clinicians should carefully weigh the decision to use MRI in patients with an implanted InterStim System, and note the following:

- Magnetic and radio-frequency (RF) fields produced by MRI may change the neurostimulator settings, activate the device, and injure the patient.
- Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

Ultrasound Scanning — Ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulator or implanted lead if used directly over the neurostimulator or lead implant site.

Home or Occupational Environment

Control Magnet — The magnet provided to the patient for device activation and deactivation may damage televisions, computer disks, credit cards, and other items affected by strong magnetic fields.

Equipment Operation — During stimulation, patients should not operate potentially dangerous equipment such as power tools or automobiles.

Home Appliances — Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation.

Occupational Environments — Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough EMI to interfere with neurostimulator operation if approached too closely.

Theft Detectors and Screening Devices — Theft detectors found in public libraries, department stores, etc., and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch on or off. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation as they pass through these devices. For other indications, higher levels of stimulation have been described as uncomfortable, "jolting," or "shocking" by some patients as they pass through these devices.

Adverse Events*

The Medtronic® InterStim® System was implanted in 219 patients in the clinical study. These 219 patients were followed for 0 to 47 months with a mean follow-up time of 17.6 months.

Approximately 52% of patients experienced 201 adverse events related to InterStim Therapy. Of the 201 adverse events, 8% required no intervention, 38% required non-surgical intervention, and 54% required hospitalization or surgical intervention. None of these events resulted in permanent injury, however 9% were not resolved at the time of database closure.

Observed Adverse Events

The following therapy-related events were observed in the clinical trial (with the probability of adverse events in the first 12 months indicated in parentheses):

- Pain at neurostimulator site (15.3%)
- New pain (9.0%)
- Suspected lead migration (8.4%)
- Infection (6.1%)
- Transient electric shock (5.5%)
- Pain at lead site (5.4%)
- Adverse change in bowel function (3.0%)
- Technical problem (1.7%)
- Suspected device problem (1.6%)
- Change in menstrual cycle (1.0%)
- Adverse change in voiding function (0.6%)
- Persistent skin irritation (0.5%)
- Suspected nerve injury (0.5%)
- Device rejection (0.5%)
- Other** (9.5%)

* Although the clinical data was collected using the Itrel® II Sacral Nerve Stimulation (SNS) System, the InterStim® System has the same output characteristics as the Itrel® II SNS System. Therefore, the clinical study results are valid for both systems.

** Other adverse events included the following: change in sensation of stimulation (9), grand mal seizure when stimulation inactivated (1), hematoma or seroma (1), urinary hesitancy (1), neurostimulator turns on and off (2), lack of orgasm (1), lack of efficacy (2), numbness and tingling (3), foot/leg movement (6), strong anal sensation (1), unable to perceive stimulation (2), stress urinary incontinence (1), swollen feeling in abdomen (1), vaginal cramps (1), superficial connection (1), and possible skin perforation at neurostimulator (1).

Surgical Revision — Thirty-three percent of implanted patients required surgical intervention to resolve an adverse event. The leading events requiring revision surgery were pain at the neurostimulator site (13.7% of implanted patients) and suspected lead migration (7.8% of implanted patients).

The probability of 1 adverse event rquiring revision surgery was 29% at 12 months and 41% at 24 months. The probability of a second surgical intervention was 9.4% at 12 months and 14.3% at 24 months.

Seven implanted InterStim System patients had their systems explanted. Three were explanted due to pain at the neurostimulator or implant site, one due to new pain, one due to adverse change in bowel function, and two due to infection.

Potential Adverse Events

Potential adverse events that may occur, but were not reported in the clinical study, include permanent undesirable sensations.

Clinical Studies*

The Medtronic® InterStim® System was evaluated in a multicenter trial at study centers in the United States, Canada, and Europe for the indications of urge incontinence, urgency-frequency, and retention.

Patients Studied

Urge Incontinence Study** — One hundred eighty-four urge-incontinent patients were enrolled in the study (36 males). Mean age was 47 years (range 20 to 79 years). These 184 patients underwent at least one, and, in some cases, up to six test stimulation procedures. Of these 184 screened patients, 112 had a successful test stimulation result (experienced at least a 50% improvement in leaking variables). Of these 112 patients who were eligible for implantation, 100 (9 males) were implanted with the InterStim System. Fifty-eight patients (6 males) have data at six months follow-up and 38 patients (4 males) have data at twelve months follow-up.

Urgency-Frequency Study — Two-hundred twenty urgency-frequency patients were enrolled into the study (44 males). Mean age was 41 years (range 17 to 78 years). These 220 patients underwent one, and in some cases, up to six test stimulation procedures. Of the 220 screened patients, 80 had a successful test stimulation result (experienced at least a 50% reduction in urgency-frequency parameters). Of the 80 patients who were eligible for implantation, 64 (6 males) were implanted with the InterStim System. Forty-six patients (5 males) have data at six months follow-up and 33 patients (5 males) have data at twelve months follow-up.

* Although the clinical data was collected using the Itrel® II Sacral Nerve Stimulation (SNS) System, the InterStim® System has the same output characteristics as the Itrel® II SNS System. Therefore, the clinical study results are valid for both systems.

** The six- and twelve-month efficacy data for the urge-incontinent patient group is from the original study and has not been updated. However the safety data for all three patient groups was updated.

Retention Study — One hundred seventy-seven retention patients were enrolled into the study (46 males). Mean age was 43 years (range 17 to 81 years). These 177 patients underwent one, and in some cases, up to five test stimulation procedures. Of the 177 screened patients, 68 had a successful test stimulation result (experienced at least a 50% reduction in residual volume). Of the 68 patients who were eligible for implantation, 55 (7 males) were implanted with the InterStim System. Forty-seven patients (4 males) have data at six months follow-up and 38 patients (3 males) have data at twelve months follow-up.

Study Design and Methods

Design — The clinical study was a multicenter prospective randomized trial. All of the enrolled patients completed a test stimulation procedure of the sacral nerves. The test stimulation results were used to determine patient eligibility for randomization.

Patients were randomized into either an immediate implantation of the InterStim System (treatment arm) or six-month delay from implant (control arm). After completing the six-month delay arm, control group patients could elect to cross over to the treatment arm of the study. All implanted patients were followed at six-month intervals until completion of the study.

Methods — The effect of InterStim Therapy on dysfunctional voiding behavior was evaluated using a voiding diary as the primary outcome measure.

During the test stimulation period, voiding diary results completed at baseline and during the test stimulation were compared. If the results showed a minimum of 50% improvement in dysfunctional urinary symptoms, the patient was eligible for randomization.

Voiding diaries were completed at baseline and at six months for control group patients and at baseline, one, three, six, and twelve months post implant (and at six-month intervals thereafter) for the treatment group patients. Concomitant medical treatment, such as medications, was allowed in both the control and treatment arms of the study.

Efficacy Results

Voiding diary results showed statistically significant reductions in dysfunctional voiding symptoms in patients implanted with the InterStim System as compared to baseline. Table 1 through Table 3 show the percentage of patients who experienced a successful result (≥ 50% improvement in baseline symptoms) as recorded in voiding diaries at six and twelve months follow-up post implant. These results were obtained in patients refractory to conservative treatments.

Urge Incontinence Efficacy Results

As Table 1 indicates, 47% of implanted patients were dry at six months and an additional 28% reduced the frequency of leaking episodes by ≥ 50% for a total clinical success rate of 75% of implanted patients.*

Table 1. Six and Twelve Month Post Implant Results for Urge Incontinence (% of Patients with Successful Result).

	Six Months Post Implant (n = 58 patients)	Twelve Months Post Implant (n = 38 patients)
Any Leaking Episode		
Dry	47%	45%
≥ 50% Reduction	28%	34%
Total Clinical Success	75%	79%
Heavy Leaking Episodes		
Eliminated	77%	70%
≥ 50% Reduction	13%	10%
Total Clinical Success	90%	80%

* The six- and twelve-month efficacy data for the urge-incontinent patient group is from the original study and has not been updated. However the safety data for all three patient groups was updated.

Of patients who experienced heavy leaking episodes at baseline (soaked pad or clothing), 77% of patients eliminated heavy leaking episodes completely at six months and an additional 13% reduced the average severity of leaking (to less than two tablespoons) by ≥ 50% for a total clinical success rate of 90% of implanted patients. These results were sustained at twelve months.

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to:

- Physical functioning ($p = 0.001$)
- General health ($p < 0.0001$)
- Vitality ($p = 0.018$)

Urgency-Frequency Efficacy Results

As shown in Table 2, 34% of implanted patients had ≥ 50% reduction in the number of voiding episodes/day and another 14% decreased into the normal range (4 to 7 voids/day)*, 54% of implanted patients had ≥ 50% increase in the volume voided per void, and 83% of implanted patients demonstrated an improvement in the degree of urgency prior to void. These results were sustained at twelve months.

Table 2. Six and Twelve Month Post Implant Results for Urgency-frequency (% of Patients with Successful Result).

	Six Months Post Implant (n = 46 patients)	Twelve Months Post Implant (n = 33 patients)
≥ 50% Reduction in Voids/Day	34%	33%
Normal Number of Voids (4-7) in Voids/Day*	14%	31%
≥ 50% Increase in Volume Voided/Void	54%	61%
Improved Degree of Urgency Prior to Void**	83%	82%

* In patients with a baseline frequency of >7 voids per day.

** Success is defined as increased voided volumes with the same or reduced degree of urgency.

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to:

- Physical functioning ($p < 0.0001$)
- Role physical ($p = 0.01$)
- Bodily pain ($p = 0.01$)
- General health ($p = 0.003$)
- Vitality ($p = 0.01$)
- Social functioning ($p = 0.002$)
- Mental health ($p = 0.01$)

With respect to the three patient groups, urodynamic test results indicated that the InterStim Therapy does not adversely affect a patient's ability to void.

Additionally, patients implanted with the InterStim System perceived a significantly greater degree of improvement in General Health Status (SF-36 Health Survey) at six months as compared to control patients who did not receive the implant ($p < 0.0001$).

Retention Efficacy Results

As Table 3 indicates, 53% of the patients eliminated catheterization use completely at six months and an additional 19% reduced residual catheter volume by ≥ 50% for a total clinical success of 72% of implanted patients. These results were sustained at twelve months.

Table 3. Six and Twelve Month Post Implant Results for Retention (% of Patients with Successful Result).

	Six Months Post Implant (n = 47 patients)	Twelve Months Post Implant (n = 38 patients)
Residual Catheter Volume		
Eliminated Catheterization	53%	61%
≥ 50% Reduction	19%	16%
Total Clinical Success	72%	77%

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to bodily pain ($p = 0.03$).

Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. The InterStim Therapy is appropriate for patients who meet the following criteria:

- Patients have urge incontinence, urgency-frequency symptoms, or retention.
- Patients should have failed more conservative treatments.
- Patients should be suitable candidates for surgery.

Use in Specific Populations

The safety and effectiveness of this therapy has not been established for the following:

- Bilateral stimulation
- Patients with neurological disease origins, such as multiple sclerosis or diabetes
- Pregnancy or delivery
- Pediatric use (patients under the age of 16)

Medtronic

Neurological Division

INTERSTIM® THERAPY *Patient Manual*

InterStim® Therapy for Urinary Control

Medtronic

Neurological Division

Patient Manual

InterStim® Therapy for Urinary Control

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Inside Front Cover–For Position Only–Do not print

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Contents

Caution

Federal law (USA) restricts this device to sale by or on the order of a physician.

Introduction

This manual contains important information about your Medtronic® InterStim® System and how to use it. **Please read this entire manual before using your InterStim System.**

This manual covers the following topics:

- The parts of your InterStim System
- How your InterStim System is implanted
- How you can control your InterStim System
- Living with your InterStim System
- Answers to common patient questions
- A glossary of terms

Note: The terms *neurostimulator* and *IPG (implantable pulse generator)* are used interchangeably in this manual.

Introduction

If you have any questions after reading this manual, or if you have any problems with your InterStim System, talk to your doctor. He or she knows your medical history and can give you more information.

InterStim Therapy for Urinary Control

InterStim Therapy for Urinary Control is indicated for the treatment of urinary urge incontinence, urinary retention, and significant symptoms of urgency-frequency in patients who have failed or could not tolerate more conservative treatments. Your urinary function is controlled by your sacral nerves, which are located at the base of your spine in your lower back. The InterStim System stimulates your sacral nerves to manage the symptoms of your urinary control problem.

Introduction

The InterStim System is not the best treatment for your condition if

- You do not receive satisfactory symptom relief during your test stimulation, or
- You are unable to properly use the system.

⚠ Warning

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

Your InterStim System

Your InterStim® System consists of the following three parts:

- **Neurostimulator (Implantable Pulse Generator or IPG)**
  The neurostimulator, or IPG (Figure 1), produces the electrical pulse that stimulates your sacral nerve. A special battery and electronics, inside the neurostimulator, control the electrical stimulation. The neurostimulator connects to an extension, which connects to a lead, to carry the electrical pulse to your sacral nerve.

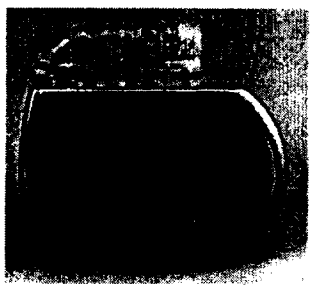


Figure 1. Neurostimulator (IPG).

- **Extension**
  The extension is a wire that carries the electrical pulse from your neurostimulator to your lead.

- **Lead**
  The lead is a wire that carries the electrical pulse from your neurostimulator and extension to your sacral nerve.

Devices Used to Control Your Neurostimulator

The following three devices are used to control your neurostimulator (Figure 2):

- **Physician Programmer**
  Your doctor uses the physician programmer to adjust your neurostimulator settings. The physician programmer is kept at your doctor's office or the hospital.

- **Patient Programmer**
  The patient programmer allows you to adjust some of the neurostimulator settings, within limits set by your doctor. You can set the amplitude (the strength or intensity of the electrical stimulation), and you can turn the neurostimulator on and off.

■ **Control Magnet**

The control magnet is a special magnet that allows you to turn your neurostimulator on and off. You will take the control magnet home with you. If necessary, your doctor can turn the circuit off that allows you to turn the neurostimulator on and off with the control magnet. However, if the circuit is turned off, you must use the patient programmer to control your neurostimulator.

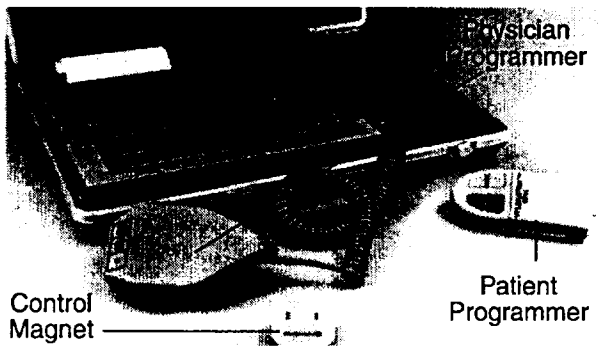


Figure 2. Devices used to control your neurostimulator.

Your InterStim System

You should have received a control magnet, patient programmer, or both, before leaving the hospital. Your doctor will decide which control devices you should have. If you do not have either device, do one of the following:

- Contact your doctor.
- Call or write Medtronic. Use the address or telephone number listed on the back cover of this manual.

How Your InterStim System Is Implanted

Your doctor will usually implant the InterStim® System during one operation. Typically, you will be under general anesthesia. Doctors usually implant the InterStim System in three parts: lead implant, extension implant, and neurostimulator (IPG) implant. The entire operation typically takes 2 to 3 hours.

You can expect up to three incisions to implant the InterStim System. The most likely incisions include the following:

- One incision in your lower back where the lead is implanted
- One incision at your side where the lead connects to the extension
- One incision in your right or left torso where the extension connects to the implanted neurostimulator

See Figure 3 for a diagram of the likely locations of implants in your body.

How Your InterStim System Is Implanted

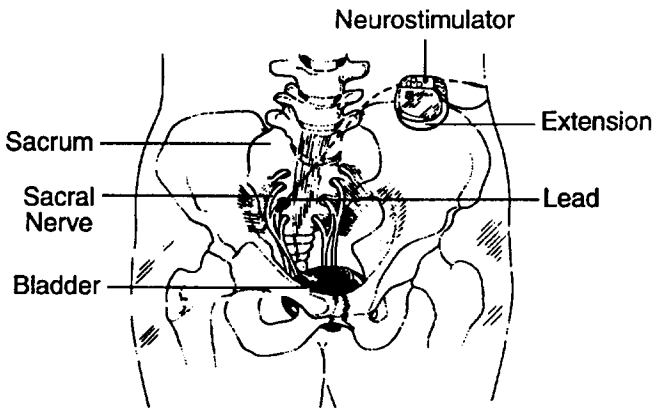


Figure 3. Your implanted InterStim® System.

Your doctor will discuss the surgery with you in detail and determine the best locations for the incisions and implants based on your medical history and individual anatomy.

6P

How Your InterStim System Is Implanted

Lead Implant

The doctor does the following to implant the lead:

1. Makes an incision in your lower back.
2. Places one end of the lead next to a sacral nerve. The doctor will test to make sure the lead is in a good location by one of your sacral nerves.
3. Places the main part of the lead under your skin, from your lower back to your side, above your hip bone.
4. Makes an incision in your side to connect the lead to the extension (if an extension is used).

Extension Implant

The doctor places the extension under your skin from your hip bone to your lower abdomen or other site that you and your doctor have decided upon. The extension connects to the lead at your side and to the neurostimulator.

How Your InterStim System Is Implanted

Neurostimulator Implant

The doctor does the following to implant the neurostimulator:

1. Makes a small incision (a pocket) in your lower abdomen or other site that you and your doctor have decided upon. The doctor will try to place the neurostimulator in an area you feel is most comfortable and looks the best.
2. Connects the neurostimulator to the extension. The doctor will test the system to make sure it is working the way it should.
3. Places the neurostimulator inside the pocket.

After implanting the InterStim System, your doctor programs the neurostimulator. He or she uses the physician programmer to program the best stimulation settings for you. Your doctor will need your input to program these settings for you.

Your doctor may also choose to program a SoftStart™/Stop stimulation. SoftStart/Stop is a feature that gradually increases the amplitude from zero (0) to the programmed amplitude when your neurostimulator is on. When you turn your neurostimulator off, the amplitude will gradually decrease to zero (0) before turning off.

Controlling Your InterStim System

There are times when you will need to control your neurostimulator. You can use either the patient programmer or the control magnet to control your neurostimulator.

Turning Off the Neurostimulator

You will need to turn your neurostimulator off when

- Driving a car, or operating other motor vehicles
- Using possibly harmful equipment, such as power tools

You can use the patient programmer or the control magnet to turn the neurostimulator off and on.

The neurostimulator has a circuit that allows only the system control devices to turn the neurostimulator on or off. Other household devices will not turn the neurostimulator on or off.

Controlling Your InterStim System

⚠ Warning

Do not use possibly harmful equipment (that is, cars, power tools, etc.) when your neurostimulator is on or programmed above zero volts.

A change in your body position may cause you to feel a sudden increase in stimulation (a jolt or shock). This can cause you to lose control of your car, other motor vehicles, or any equipment you are using.

To prevent this, you must turn your neurostimulator off (and decrease the programmed amplitude to zero) when driving a car, operating other motor vehicles, or using possibly harmful equipment, such as power tools.

Adjusting the Amplitude

At times you may need to adjust your stimulation by increasing or decreasing the amplitude. You can use the patient programmer to adjust the amplitude, but not the control magnet.

You may need to adjust the amplitude when

- The stimulation is too weak. Increase the amplitude until the stimulation is adequate.
- The stimulation is too strong. Decrease the amplitude until the stimulation feels comfortable.
- You want to change posture, such as going from a sitting position to lying down. Either increase or decrease the amplitude as necessary.

If you cannot adjust the amplitude so that stimulation is adequate and comfortable, contact your doctor to see if a new range, new electrode setting, or new cycling sequence might help.

Using Your Patient Programmer

The patient programmer (Figure 4) allows you to adjust the amplitude of electrical signals from your neurostimulator **within ranges set by your doctor.** You will also be able to turn your neurostimulator on or off.

Controlling Your InterStim System

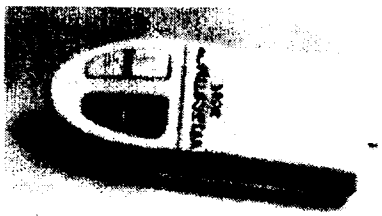


Figure 4. Patient Programmer (Model 3031 shown).

The patient programmer sends signals to your neurostimulator. The signals tell the neurostimulator to turn on or off, or to change the amplitude. To use the patient programmer, place the patient programmer over the implant site and press the programmer push buttons.

Detailed instructions on using the patient programmer are in the patient manual packaged with the patient programmer. Please read the patient manual before using the patient programmer.

Using Your Control Magnet

Your control magnet can turn your neurostimulator on or off, but it will not allow you to adjust the amplitude. When you use your control magnet to turn the neurostimulator on, the stimulation resumes at the level at which it was set before it was turned off.

If necessary, the ON/OFF feature can be disabled by your doctor. If the ON/OFF feature is disabled, the control magnet will not turn the neurostimulator on or off and you will have to use the patient programmer instead.

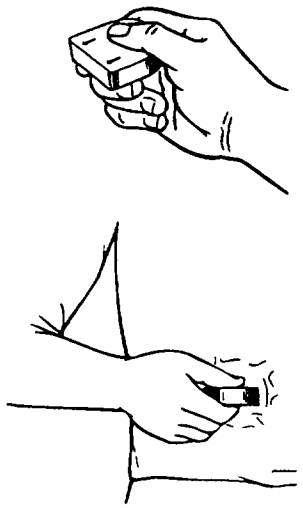
Your doctor should tell you about any special settings programmed into your neurostimulator.

> **Note:** Your implant site and the location of your neurostimulator may be different from the examples shown in the following instructions. Have your doctor show you how to center the control magnet over your implant site.

Controlling Your InterStim System

Turning the Neurostimulator On or Off

1. Grasp the control magnet with the flat end away from you.



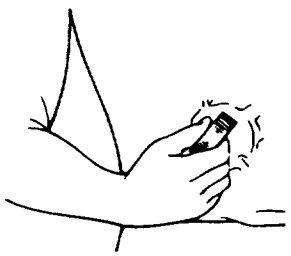
2. Center and hold the control magnet over your neurostimulator for 1 to 2 seconds.

3. Remove the control magnet.

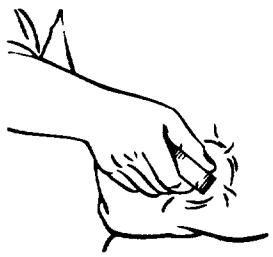
You can find out if your neurostimulator is on by reading the section "Checking to See If Your Neurostimulator Is On."

If the Control Magnet Fails to Turn the Neurostimulator On or Off

1. Repeat Steps 2 and 3 from the previous section, "Turning the Neurostimulator On or Off," while holding the control magnet against the neurostimulator in a slightly different position.
2. Try a "1 o'clock" or "4 o'clock" position.



1 o'clock position



4 o'clock position

Controlling Your InterStim System

Note: If your doctor has programmed the neurostimulator with the SoftStart™/Stop feature, after the control magnet turns stimulation on, the amplitude starts to gradually increase.

Allow a few seconds for SoftStart to slowly increase the amplitude to a level where you can feel it.

If your doctor has programmed the neurostimulator with the cycling feature and you use your control magnet (or patient programmer) to turn the neurostimulator off, your therapy will then stop. When you use the control magnet to turn the neurostimulator on again, your therapy always starts at the beginning of the ON cycle.

Carrying Your Control Magnet

Caution:

Do not place the control magnet in a pocket or purse on the side of your body where the neurostimulator is implanted. The control magnet can turn your neurostimulator on and off.

Caring for Your Control Magnet

Be careful not to drop your control magnet, because it may break if dropped on a hard surface. A broken control magnet will have less strength.

In an emergency, if you break or lose your control magnet, you can use any large magnet (such as a horseshoe magnet) until you can get a new control magnet.

If you have broken or lost your control magnet, contact your doctor or Medtronic, as soon as possible, to get a new control magnet. If you have a patient programmer, use it to program your neurostimulator until you have a new control magnet.

Controlling Your InterStim System

Avoiding Damage to Personal Items

Do not store the control magnet within 2 inches of a wrist watch, pocket watch, or clock. The control magnet will stop them.

The control magnet's magnetic field may damage the following items or erase information from them.

Avoid placing the control magnet within 6 inches of the following items:

- Items with a magnetic strip such as bank cards or credit cards
- Magnetic media such as video or audio cassette tapes or computer disks
- Home electronic items such as a personal computer, VCR, television, or camera

Medications

Your doctor will decide whether you need medications to treat your urinary voiding dysfunction in addition to your InterStim® System. It is important that you follow your doctor's instructions for taking the medication.

Activities and Exercise

On the advice of your doctor, and as you begin to feel better, you should be able to gradually resume your normal (before your implant) lifestyle. Such activities may include the following:

- Traveling
- Bathing, showering, and possibly swimming
- Sexual activity
- Returning to your job or work
- Hobbies or recreation, such as walking, hiking, gardening, bowling, golfing, fishing, or hunting

Living with Your InterStim System

It is important that you follow your doctor's advice. Ask your doctor about any particularly strenuous activities, such as lifting heavy objects.

Changes in Stimulation

Changes in stimulation may happen for many reasons, including

- Changes in body position
- Changes due to other electrical devices
- Changes due to the InterStim System
- Changes due to a low neurostimulator battery

Each of these is discussed as follows.

⚠ Warning

Do not use possibly harmful equipment (that is, cars, power tools, etc.) when your neurostimulator is on or programmed above zero volts.

A change in your body position may cause you to feel a sudden increase in stimulation (a jolt or shock). This can cause you to lose control of your car, other motor vehicles, or any equipment you are using.

To prevent this, you must turn your neurostimulator off (and decrease the programmed amplitude to zero) when driving a car, operating other motor vehicles, or using possibly harmful equipment, such as power tools.

Living with Your InterStim System

- **Stimulation changes due to body position**
  The lead of your InterStim System is implanted near a sacral nerve in your lower back. When you move your body, the position of the lead, relative to the nerve, may change slightly. If this happens, you may feel an increase or decrease in your stimulation. You may feel as if the neurostimulator is turning on or off; however, the neurostimulator is not actually turning on or off. You may even feel a burst (a jolt or shock) of stimulation when you move. When this happens, your neurostimulator amplitude is not changing. **The neurostimulator is still delivering the correct amount of energy.** The closeness of the lead to the sacral nerve makes it feel like more, or less, stimulation.

  Bursts of stimulation could cause you to lose control of your car, other motor vehicles, or equipment. This loss of control could hurt you or others. To help ensure your safety, turn your neurostimulator off when driving a car, operating other motor vehicles, or using possibly harmful

equipment, such as power tools. Turn it on again when you are done driving a car, operating other motor vehicles, or using possibly harmful equipment, such as power tools.

- **Stimulation changes due to other electrical devices**
  Your neurostimulator has built-in features to protect it from interference produced by other electrical devices. Most of the electrical devices you are around in a normal day will not harm your neurostimulator. Special circuits inside the neurostimulator protect it from extreme electrical stress.

  However, your InterStim System may interact with certain **strong** magnetic fields. This can increase stimulation to your sacral nerve. Also, in addition to your control magnet, some strong magnetic fields can turn your neurostimulator from on to off or off to on. See page 32 for a list of devices that have magnetic fields strong enough to turn your neurostimulator on or off.

Note: If your doctor has disabled the ON/OFF feature so that the control magnet will not turn the neurostimulator on or off, then strong magnetic fields will not turn your neurostimulator on or off. However, you could still feel a jolt when you pass by a theft detector or airport/security screening device.

Most household appliances, office machines, and personal radios **do not** produce magnetic fields strong enough to cause these problems. If you stay about an arm's length away from these devices, your neurostimulator will not be affected.

The following devices should **not** interfere with your InterStim System:

- Microwave ovens
- Televisions, AM/FM radios, stereos, cellular phones
- Tabletop appliances, such as toasters, blenders, electric can openers, food processors

- Hand-held items, such as hair dryers, shavers
- Appliances, such as washers, dryers, electric stoves
- Electric blankets and heating pads
- Vacuum cleaners, electric brooms
- Personal computers, electric typewriters, copiers, and fax machines

However, if you place devices with small permanent magnets (such as stereo speakers, radios, and telephones) **within inches** of your neurostimulator, the device could turn the neurostimulator on or off.

The devices listed below have enough magnetic energy to cause painful increases in stimulation if you are near them. When possible, it is best to avoid these devices:

- Theft detectors
- Airport/security screening devices

Living with Your InterStim System

The devices listed below have enough magnetic energy to turn your neurostimulator on or off if you are near them. Approach these devices carefully:

- Large stereo speakers with magnets
- Magnetic resonance imaging (MRI) equipment
- Manufacturing and heavy industrial equipment
- Electric arc welding equipment
- Electric induction heaters used in industry to bend plastic
- Electric steel furnaces
- Power lines
- Electric substations and power generators

If magnetic fields turning your neurostimulator on and off becomes a problem for you, ask your doctor to disable the ON/OFF feature. Keep in mind that if the ON/OFF feature is disabled, you will have to use the patient programmer to control your neurostimulator.

⚠ Warning

The following devices may increase your stimulation level as you pass through them:

- **Theft detectors with gateways through which you walk. These are often in places like public libraries and department stores.**
- **Airport/security screening systems.**

Use care when approaching these devices. If you feel unwanted bursts of stimulation (a jolt or shock) as you approach a device, you may want to show your InterStim Identification card (see "Your InterStim Identification Card" on page 43) to the appropriate people and ask them to let you bypass the device.

Living with Your InterStim System

If you think an electrical device or magnet is interfering with your neurostimulator:

1. Move away from the electrical device or magnet or, if possible, turn the electrical device off.
2. Using your patient programmer or control magnet, if necessary, turn your neurostimulator back to the desired on or off state.

When turned on, your neurostimulator will resume stimulation at the level at which it was set before it was turned off.

Carry your InterStim identification card at all times. Show your identification card to the appropriate people if you wish to bypass security devices or theft detectors.

- **Stimulation changes due to the InterStim System**
  When you turn your neurostimulator on, you may notice a brief tingling feeling. If you think your neurostimulator is on but your symptoms do not improve, contact your doctor and/or check to see if your neurostimulator is on (see the section "Checking to See If Your Neurostimulator Is On"). Your doctor may just need to change the neurostimulator to a different treatment setting. However, there may be a problem with the extension, lead, or neurostimulator. Your doctor should be able to find the cause of the problem and fix it.

- **Stimulation changes due to a low battery**
  Your doctor may be able to predict the life of your neurostimulator battery. As with all batteries, the neurostimulator battery will run down. As the neurostimulator battery runs down, the stimulation may be less helpful in managing your symptoms. These changes are normal and are no cause for concern. When you feel this change in stimulation, tell your doctor. Make an

appointment with your doctor to have your neurostimulator battery checked if you and your doctor have not already done so.

Caution:

If you have very low stimulation thresholds when your battery nears total depletion, you may feel more intense stimulation. Adjust your neurostimulator amplitude to the desired level or turn it off.

Medical Appointments

Follow-Up Appointments for Your InterStim System

It is important that you go to all of your follow-up appointments. These appointments allow your doctor to make sure your InterStim System is providing the desired treatment.

Please tell your doctor if your address changes. Also, if you change doctors, be sure to have your medical history sent to the new doctor.

Other Medical and Dental Procedures

Always tell any medical or dental personnel that you have an implanted InterStim System and present your InterStim identification card so they can take proper precautions. For example, you may be given a prescription for antibiotics prior to or following a medical or dental procedure to reduce the risk of infection of your implanted system.

With proper precautions, most medical procedures are unlikely to interfere with your InterStim System. However, some of the following procedures may affect your InterStim System implant:

- **X-rays**
  Diagnostic x-rays do not cause a problem. However, some x-ray procedures that require enclosure of the area where your neurostimulator is implanted may require adjustment of the x-ray equipment.

- **Ultrasound**
  Therapeutic ultrasound may cause mechanical damage to an implanted neurostimulator or lead and should not be used anywhere near the InterStim System implant sites.

- **Diathermy treatments**
  Diathermy treatments (sometimes used for muscle relaxation) may affect or damage parts of your InterStim System. It is not recommended to use diathermy directly over an implanted neurostimulator or lead, since internal components may be damaged.

- **Magnetic resonance imaging (MRI)**
  MRI is not recommended. Use of MRI on components of a neurostimulator system may result in movement or heating of the neurostimulator and/or the lead. It may cause uncomfortable, "jolting," or "shocking" levels of stimulation.

- **Pacemakers**
  If you have a pacemaker tell your doctor. The InterStim System may affect the pacemaker or therapy. If the two systems are implanted close to each other, the pacemaker may sense electrical activity from the InterStim System as heart activity and not deliver the appropriate pacing therapy. Before you are implanted, your doctor will evaluate any possible interference problem and determine if you can be implanted.

- **Heart defibrillators**
  Electrical shocks from defibrillators may reset the neurostimulator stimulation parameters and, therefore, necessitates reprogramming of the neurostimulator. The electrical shocks could also damage the neurostimulator and require replacement.

When to Call Your Doctor's Office

Call your doctor's office if

- You experience any pain, redness, or swelling at the incision site more than 6 weeks after surgery.
- You notice that the stimulation feels different or hurts. Turn the neurostimulator off first, then call.
- You are not getting enough stimulation.
- You feel stimulation in a different site than usual.
- The IPG battery light on the patient programmer is blinking, or if it has been blinking, and will no longer turn on after you press any key.

Your InterStim® Identification Card

After your implant, your doctor will give you a temporary identification card. This card has important information about your implant. You should carry this identification card at all times. In the event of an accident, the card will tell anyone taking care of you that you have an implanted medical device. The card supplies basic information about your InterStim System and identifies your doctor.

A few weeks after your implant, Medtronic will send you a permanent, plastic-coated identification card to replace the temporary one.

Your card is especially important if you travel by air, because airport security devices may interfere with your neurostimulator. Airport security devices may also detect the metal in your neurostimulator. Show your identification card to the appropriate airline people to bypass the security device.

Your InterStim Identification Card

If you lose your identification card at any time, contact:

Medtronic InterStim
Patient Registration Service
800 53rd Avenue NE
Minneapolis, MN 55421-1200
(612) 514-5000
(800) 510-6735

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Checking to See If Your Neurostimulator Is On

You can check to see if your neurostimulator is on by using the following test. Check with your doctor first if you don't know your stimulation amplitude.

1. Turn a small AM transistor radio on to the lowest setting on the tuning dial, about 540 kHz (but not on a station).
2. Adjust the volume to its loudest setting.
3. Hold the radio over the neurostimulator implant site. If the neurostimulator is on, and the neurostimulator amplitude is 1.5 volts or more, the radio should emit a strong ticking or clicking sound over the radio static. If your doctor has programmed your neurostimulator to cycle, the sound will cycle on and off.
4. If you don't hear any ticking or clicking from the radio, your neurostimulator may be off. Use your patient programmer or control magnet to try turning your neurostimulator on.
5. If you still do not hear ticking or clicking from the radio, contact your doctor.

Replacement Surgery

Because the neurostimulator battery is sealed inside the neurostimulator case, the battery cannot be replaced separately. Therefore, when it is time to replace the battery, your doctor will remove the entire neurostimulator and replace it with a new one. During replacement surgery, your doctor will also check your implanted extension and lead. If the extension and lead are working properly, your doctor will connect the new neurostimulator. If the extension and lead are not working as they should, your doctor may need to replace them also.

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Clinical Studies

In a clinical study*, 219 patients with dysfunctional voiding behavior (100 urge incontinence, 64 urgency-frequency, and 55 retention) were implanted with the Medtronic® InterStim® System. Results were measured 6, 12, and 18 months after implant.

Results for Urge Incontinence

Of the 58 implanted urge incontinent patients who were evaluated at 6 months, 47% of patients eliminated all leakage of urine and another 1 out of every 4 patients reduced the number of leaks by at least 50%.** A total of 3 out of every 4 implanted patients had a clinically successful result. In addition, 3 out of 4 patients who had heavy leaking eliminated these types of leaks. Data at 12 months (38 patients) and 18 months (21 patients) showed similar results.

* Although the clinical data was collected using the Itrel® II Sacral Nerve Stimulation (SNS) System, the InterStim System has the same output characteristics as the Itrel II SNS System. Therefore, the clinical study results are valid for both systems.

** The 6- and 12- month efficacy data for the urge-incontinent patient group is from the original study and has not been updated. However, the safety data for all three patient groups was updated.

Results for Urgency-Frequency

Of the 46 implanted urgency-frequency patients who were evaluated at 6 months, 34% reduced the number of voids per day by at least 50% and another 14% decreased the number of voids per day into the normal range (4 to 7)*. In addition, 54% of patients increased the amount of urine voided by at least 50%. Eighty-three percent of patients reported improvements in the degree of urgency prior to urination.** Similar results were obtained at 12 months (33 patients) and 18 months (24 patients).

* In patients with a baseline frequency of >7 voids per day.

** Success is defined as increased voided volumes with the same or reduced degree of urgency.

Results for Retention

Of the 47 implanted retention patients who were evaluated at 6 months, 53% eliminated use of catheterization. In addition, nearly 1 out of 5 patients reduced the amount of urine emptied from the bladder using a catheter by at least 50%. A total of approximately 3 out of every 4 implanted patients had a clinically successful result. Data at 12 months (38 patients) and 18 months (24 patients) showed similar results.

Adverse Events

In a clinical study*, a total of 219 patients were implanted with the Medtronic® InterStim® System.

Approximately 52% of patients experienced 201 adverse events related to InterStim Therapy. Of the 201 adverse events, 8% required no intervention, 38% required non-surgical intervention, and 54% required hospitalization or surgical intervention. None of these events resulted in permanent injury, however 9% were not resolved at the time of database closure.

Complications reported by patients are listed below. The probability of each adverse event in the first 12 months are indicated in parentheses.

- Pain at neurostimulator site (15.3%)
- New pain (9.0%)
- Suspected lead migration (8.4%)

* Although the clinical data was collected using the Itrel® II Sacral Nerve Stimulation (SNS) System, the InterStim System has the same output characteristics as the Itrel II SNS System. Therefore, the clinical study results are valid for both systems.

Adverse Events

- Infection (6.1%)
- Transient electric shock (5.5%)
- Pain at lead site (5.4%)
- Adverse change in bowel function (3.0%)
- Technical problem (1.7%)
- Suspected device problem (1.6%)
- Change in menstrual cycle (1.0%)
- Adverse change in voiding function (0.6%)
- Persistent skin irritation (0.5%)
- Suspected nerve injury (0.5%)
- Device rejection (0.5%)
- Other** (9.5%)

** Other adverse events included the following: change in sensation of stimulation (9), grand mal seizure when stimulation inactivated (1), hematoma or seroma (1), urinary hesitancy (1), neurostimulator turns ON and OFF (2), lack of orgasm (1), lack of efficacy (2), numbness and tingling (3), foot/leg movement (6), strong anal sensation (1), unable to perceive stimulation (2), stress urinary incontinence (1), swollen feeling in abdomen (1), vaginal cramps (1), superficial connection (1), and possible skin perforation at neurostimulator (1).

Adverse Events

Adverse events may be resolved with surgery, medical therapy (e.g., medications), or no treatment. Thirty-three percent of patients had additional surgery to resolve an adverse event.

Potential Adverse Events

Potential adverse events that may occur, but were not reported in the clinical study are permanent undesirable sensations. However, based on Medtronic's experience with similar devices, these events could possibly occur.

What is InterStim® Therapy?

InterStim Therapy for Urinary Control is InterStim Therapy for Urinary Control is indicated for the treatment of urinary urge incontinence, urinary retention, and significant symptoms of urgency-frequency in patients who have failed or could not tolerate more conservative treatments. The InterStim System sends electrical pulses to your sacral nerves. The sacral nerves control your bladder, bowel, and pelvic organs.

Will the InterStim® System cure my urinary control problem?

This therapy will not cure your voiding dysfunction. However, InterStim Therapy has been proven effective for managing symptoms of urinary urge incontinence, urinary retention, and urgency-frequency. The degree to which symptoms are relieved varies from patient to patient.

Common Questions

Will the InterStim® System limit my activities?

Generally, no. However, you should consult your doctor about performing any strenuous activities, such as lifting heavy objects.

Can stimulation be used during pregnancy?

The safety of InterStim Therapy for use during pregnancy or delivery has not been established. If you learn, or suspect, that you are pregnant, turn your neurostimulator off and call your doctor.

What does stimulation feel like?

The feeling of stimulation varies from patient to patient. You may feel a brief tingling when stimulation is first turned on. You may feel some level of stimulation whenever your neurostimulator is on. Some patients describe higher levels of stimulation as uncomfortable, "jolting," or "shocking."

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Will I be able to increase or decrease the strength of stimulation?

If your doctor has programmed a range of amplitude settings, you may adjust the settings (within the range set by your doctor) with your patient programmer. Otherwise, your doctor or a clinician uses the physician programmer to change the amplitude.

What should I do if the stimulation changes or becomes uncomfortable?

First, decrease the amplitude with your patient programmer. If the stimulation is still uncomfortable, turn the neurostimulator off with either your patient programmer or the control magnet and contact your doctor.

Common Questions

What does it mean if I can only feel the stimulation sometimes?

Your doctor may have programmed your stimulator output to cycle. This means that the neurostimulator turns off and on at regular intervals. As long as the system controls your symptoms, there is no cause for concern.

Is it normal for the stimulation feeling to increase or decrease when I change position?

Generally, the feeling of stimulation will be constant. However, abrupt movements or changes in posture could make it feel like it is increasing or decreasing. Some patients describe higher levels of stimulation as uncomfortable, "jolting," or "shocking." As long as the system controls your symptoms, this is no cause for concern. If your symptoms worsen or the feeling of stimulation stops entirely, contact your doctor.

What is a neurostimulator?

A neurostimulator, or implantable pulse generator, is the device that creates electrical pulses to send to the sacral nerves. The neurostimulator contains a special battery and electronics to create the pulses.

How large is the neurostimulator?

The neurostimulator is about 0.5 inches (10 mm) thick, 2.5 inches (60 mm) long, and 2 inches (55 mm) wide. The neurostimulator weighs 1.5 ounces (42 grams).

Will the neurostimulator show through my clothes?

Your doctor will implant the neurostimulator in a place that is most comfortable and looks the best. However, depending on your body build, the neurostimulator may show as a small bulge under the skin.

Does the neurostimulator make any noise?

No.

Common Questions

Should I void with the neurostimulator on or off?

Ask your doctor for specific instructions.

What happens if the neurostimulator stops working?

The stimulation will stop and your symptoms may return. If you can't determine the possible cause and correct the problem, contact your doctor.

How often should my doctor check the neurostimulator?

Generally, the neurostimulator should be checked about once every 6 months. However, your doctor may want to see you more or less often, depending on your situation.

Will I be able to turn the neurostimulator on and off?

Yes. You can use the patient programmer or control magnet provided with your system to turn your neurostimulator on and off.

How long will the neurostimulator battery last?

The battery life of the neurostimulator depends on how long you use it each day, and how strong the stimulation must be to manage your symptoms. Once your doctor determines your neurostimulator settings, he or she can give you a better estimate of your neurostimulator's battery life.

Can I check the status of the battery?

Yes. You can use the patient programmer to check the neurostimulator battery. See the patient manual packaged with the patient programmer for instructions.

Can the battery be recharged?

No.

Common Questions

How is the battery replaced?

Because the neurostimulator battery is sealed inside the neurostimulator case, the battery cannot be replaced separately. Therefore, when it is time to replace the battery, your doctor will remove the entire neurostimulator and replace it with a new one.

If the ON/OFF feature is disabled and I can't use the control magnet, why can I still use the patient programmer to control the neurostimulator?

There are two electric circuits that will turn the neurostimulator on or off. One circuit allows the control magnet to turn the neurostimulator on or off. The other circuit allows the patient programmer to turn the neurostimulator on or off. The circuit for the patient programmer still operates even if the circuit for the control magnet is disabled.

What if I have trouble turning my neurostimulator on?

First, wait at least 8 seconds after your last try to turn your neurostimulator on. When you try again, be sure you hold your patient programmer or control magnet directly over the implanted neurostimulator. If you still cannot turn your neurostimulator on, call your doctor or Medtronic at the telephone number listed on the back cover.

Will a microwave oven interfere with the neurostimulator?

No.

Will there be any problems when I pass through theft detectors and screening devices?

Theft detectors found in places like public libraries and stores, and airport/security screening systems may cause the neurostimulator to turn on or off. Some patients may feel a momentary increase in their stimulation. Some patients describe higher levels of stimulation as uncomfortable, "jolting," or "shocking."

Also, the security devices may detect the metal in your neurostimulator.

Will my neurostimulator be affected by the change to the year 2000?

No. Your neurostimulator is not affected by actual time. It is not synchronized in any way to clock or calendar time.

Whom should I contact in case I have a problem?

Your first call should be to your doctor. If you are unable to contact your doctor, please contact Medtronic at the telephone number listed on the back cover of this manual.

Glossary

amplitude. A measure of the electrical intensity or strength of a stimulating pulse, measured in volts.

hematoma. A localized collection of blood, usually clotted, in a tissue or organ.

interference. Anything that reduces the effectiveness of the neurostimulator or a programming transmission.

InterStim® Therapy for Urinary Control. A therapy that sends electrical pulses to your sacral nerves to manage symptoms of urinary urge incontinence, urinary retention, and urgency-frequency.

lead. An implantable thin wire with one or more electrodes at its tip. The lead delivers electrical stimulation to the sacral nerve.

neurostimulator. An implantable pulse generator (IPG) that produces electrical pulses to stimulate your sacral nerves.

retention. The partial or complete inability to initiate a void or an inability to completely void.

Glossary

sacral nerves. Nerves located near the base of the spinal cord in your lower back. Sacral nerves control your bladder, bowel, and pelvic organs.

sacral nerve stimulation (SNS). A therapy that sends electrical pulses to your sacral nerves to manage symptoms of urinary voiding dysfunctions.

seroma. A localized, fluid-filled mass in a tissue or organ.

SoftStart™/Stop Stimulation. A feature that allows stimulation to begin and end gradually. The SoftStart feature prevents a sudden burst of stimulation when the neurostimulator turns on. SoftStart does this by gradually increasing the amplitude of the stimulating pulses. The Stop feature also causes a gradual decrease of the amplitude (stimulation intensity) down to zero when the neurostimulator is turned off, or when the OFF cycle begins.

urge incontinence. The involuntary loss of urine associated with an abrupt, strong desire to void (urgency).

urgency-frequency. The frequent strong desire to void, but resulting in only small amounts of urine voided.

void. Elimination of waste products from the body, for example urinating.

voiding dysfunction. The inability to control the frequency, timing, and amount of urine when you feel the urge to void. Urinary voiding dysfunctions include urge incontinence, urgency-frequency, and retention.

Medtronic

When Life Depends on Medical Technology

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