



The Canadian
Continence
Foundation

Continence Facts

Sacral Nerve Stimulation – A Treatment Option for Certain Types of Bladder Control Problems

The concept of nerve stimulation has been used for different health problems over the years, including for severe body pain. Basically mild electric pulses are used to stimulate nerves.

Sacral nerve stimulation (or sacral nerve modulation) for the treatment of bladder control problems is relatively new, and approved for general use in Canada since 1994. The treatment involves a device implanted in your body, under the skin. This involves surgery. The device, placed in the lower abdomen or lower back area, delivers electrical pulses to the nerves in your pelvis that affect how your bladder works.

This fact sheet is intended to provide you with answers to some of the questions you may have about this treatment. If you are considering sacral nerve stimulation, you may want to take this sheet with you on your next visit to your doctor, and discuss it with him/her. If you both decide to further explore the treatment, be sure to consult with a doctor who has a particular expertise and experience with this treatment.

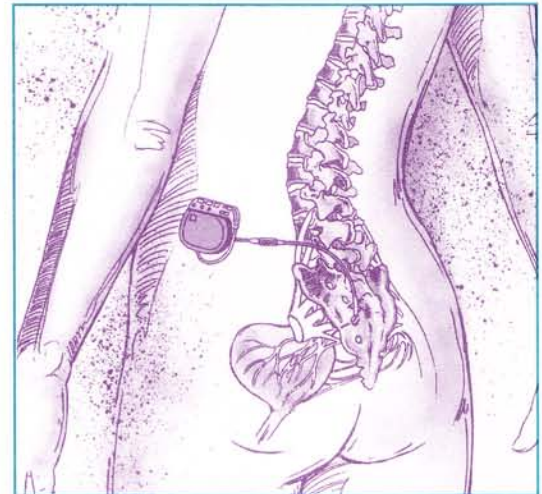
How do I know if I am a candidate for sacral nerve stimulation?

There are three types of bladder problems for which this treatment may help:

- Urge incontinence (an urgent need to go to the bathroom and not being able to get there in time);
- Severe urgency and/or frequency (either continuous urgent needs to go to the bathroom and/or frequent trips to the bathroom), either of which is having a significant impact on your quality of life;
- Urinary retention, (the bladder does not completely empty when you urinate, or you may not be able to urinate at all).

Generally, this treatment would only be considered if:

- You are a male or female adult over the age of 16;
- You have gone through a thorough discussion of the problem and its impact on your life with your healthcare professional, as well as testing to confirm the type and cause of the bladder problem;
- You have already tried, without success, other non-surgical treatments with an interested and knowledgeable healthcare professional. These would include: pelvic muscle exercises (Kegel) with or without the use of biofeedback and/or electrical stimulation, bladder retraining techniques, fluid/diet modifications, and medications;
- Your bladder is large enough to store at least 150mls of urine;



- You do not have a pacemaker for your heart and are not having MRI (Magnetic Resonance Imaging) tests;
- You are not pregnant.

What are the possible benefits of this treatment ?

This treatment has been shown, in some individuals, to achieve one or more of the following:

- Reduce urine leakage (or eliminate leakage);
- Reduce the number of urinary tract infections;
- Reduce the number of trips to the bathroom during the day or night;
- Reduce pain in the pelvic area;
- Improve bladder emptying.



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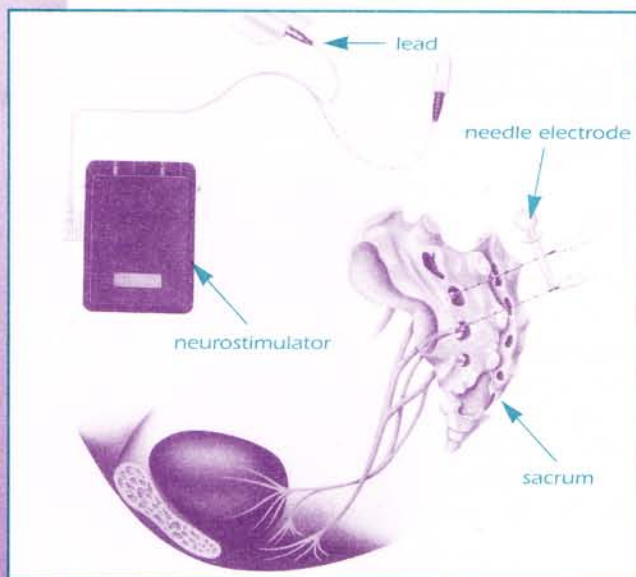
What is the procedure to put the device in my body?

Phase 1—The test phase

First, a test is done to see if you are likely to respond to the treatment. This is done after you have completed a diary for several days noting when and how much you have urinated during the day and night.

The test is an important procedure, for which you will be given a local anesthetic. Here is what will happen:

- Areas around certain nerves in your pelvis (called sacral nerves) will be reached with a needle electrode passed through the skin of your lower back, into existing holes in the *sacrum* (a bony plate near the end of your spine).



- An attempt will be made to stimulate certain nerves leading to the muscles and organs in your pelvis. If your doctor sees a good response to the stimulation, he/she will insert a temporary electrode (wire) through the needle and position it alongside the nerve.
- The needle will then be removed, leaving the wire in place. The wire will be secured to the skin of your back with plastic tape and covered with a surgical dressing.
- The wire will be connected by cables to a stimulator outside your body.

The above procedure will take approximately one half to one hour.

You will then return home. Using the control knobs on a stimulator installed outside your body, you will be able to adjust the amount of stimulation or turn the system ON and OFF.

The complete testing phase will probably take about a week. During this testing phase, you will be asked to complete a diary showing when and how much you urinate or leak during the day and night. You may feel a bit "funny", with a wire in your back. It will be important for the wire to remain in place, so your doctor may ask you to reduce your daily activities to some extent.

During this phase, be sure you know how to reach your doctor quickly, in case you have any concerns. You may experience one or more of the following:

- Skin irritation and wound infection from the temporary wire electrode in your sacrum;
- Pain or discomfort in your back, pelvis, buttocks, or lower extremities, and possible temporary sensations of mild electric shock;
- Movement of the wire, away from where it was originally placed.

There may be other complications. All possible complications and risks should be discussed with your doctor.

Following the test period of several days, you will be required to return to your doctor's office, where he/she will remove the temporary wire. Over at least one more week, you will be asked to complete another diary (including any use of catheters or pads), and to send this diary to your doctor.

If the test provided a real benefit for you, you may qualify for a permanent implant.

Phase 2 – The permanent implant

If you do qualify for the permanent implant, you will require general anesthesia. During surgery, an incision several inches long will be made in your lower back. A *lead* (thin wire with electrodes at its tip) will be inserted through your *sacrum* and positioned near a nerve. An extension wire will be attached between the *lead* and the *neurostimulator*, a small electronic device which looks like a heart pacemaker. This device will be implanted above your waist or over the buttock. The whole procedure will take approximately 2 – 3 hours. You will stay in the hospital for a few days to recover.

Prior to discharge, the device will be turned on.

Are there any possible complications, side effects or risks?

This treatment is a surgical procedure, and every surgical procedure carries risks.

All possible complications or risks should be discussed with your physician.

Approximately 3 of every 10 individuals receiving the permanent implant experience some problems directly related to the implant. These include:

- Pain in your back, pelvic area, buttocks or lower extremities. This is usually temporary. If it is ongoing, the implant may have to be relocated.
- Temporary injury occurring to a nerve during the surgical placement of the lead. This is not likely to significantly affect normal body function but may produce temporary feelings of electric shock. Injury to a nerve might also occur as a result of repeated electrical stimulation. There is presently no information on the long-term effect of this. There is no clinical evidence of any damage to the nerves to date.
- Improper functioning of the neurostimulator or electrodes after implantation. This may require reprogramming or a surgical procedure.
- Possible skin problems where the *neurostimulator*, the lead, or the extension were implanted. This could lead to infection, requiring treatment with antibiotics and possible removal or relocation of the neurostimulator, lead and/or extension. Removal or relocation would require a surgical procedure.
- An allergic or immune system response to the implant. The implant would then have to be removed.

It is important to understand that this is a relatively new procedure – there may be other risks which are not yet known and may arise. It is not yet known exactly what makes this treatment work for some individuals.

How does the implant work once I am out of the hospital? Can I live my life normally?

The implant stays in your body, as you will always need it to control your symptoms. You will be able to turn the stimulator ON and OFF, although it will usually just stay on. You should feel normal sensations to urinate and then be able to urinate normally. It is only in exceptional situations, for example, when you may be experiencing problems, that you may want to turn the stimulator off.

After a short recovery period, you should be able to return to your normal activities. However, depending on your physician's advice, you may have to turn your stimulator OFF or reduce the amplitude before starting certain activities, or stay away from some strenuous activities.

The implanted neurostimulator will usually require replacement every 5 to 7 years, requiring a minor surgical procedure. The procedure is usually performed in a hospital, and is carried out through the original incision in your abdomen.

Occasionally, an implanted neurostimulator may need "reprogramming". This would be done by the urologist who implanted the device.

If you must undergo Magnetic Resonance Imaging (MRI) testing for any reason, be sure to mention your implant to the doctor proposing the test, due to the potential effects of the MRI magnetic field on the stimulation system.

You should also discuss the MRI test with the doctor who implanted the device, and propose the two doctors consult together with you, to decide how to proceed.

It is possible for theft detectors found in public libraries, department stores, etc. and airport/security screening devices to cause the following:

- your neurostimulator to switch ON or OFF;
- a momentary increase in your perceived stimulation, if you are sensitive or you have a low tolerance for stimulation;
- set-off of the alarm systems through which you have passed.

You may want to request assistance to bypass the device, showing the individuals on the scene your implant identification card.

Who can do this surgery for me?

In general, a urologist will perform this surgery. However, not all urologists in Canada are trained to perform it. For more information on the doctors in your community who do perform this procedure, you can contact The Canadian Continence Foundation or the company currently distributing the implant in Canada, Medtronic of Canada (their phone number is 1-800-268-5346).





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Many thanks to
Dr. Jerzy Gajewski,
QE11 Health Science Center,
Halifax, Nova Scotia,
Dr. Magdy Hassouna,
Toronto Hospital,
Western Division,
Toronto, Ontario,
Dr. Sender Herschorn,
Sunnybrook Health
Science Center,
Toronto, Ontario,
and Ms. Nancy Jeffrey,
Stouffville, Ontario,
for their input and review
of this continence
fact sheet.

How many people have actually received this treatment in Canada? What has the success rate been?

As of mid-1998, approximately 100 Canadians had received this treatment in Canada. There is some information from a clinical study involving the United States, Canada and Europe. In this unpublished study, 86 individuals experiencing urge incontinence received the implant (79 women and 7 men). After 6 months, follow-up information was available for 58 of these individuals. At that time, 75% of the 58 individuals were experiencing significant improvements in leakage, with 47% completely dry. However, several also required surgical correction and some had to have the implant removed for various reasons (1). A smaller, more recent study among 18 individuals with urge incontinence who received the implant showed a significant reduction in the frequency of urination and leakage (2). All patients with the exception of one were still using the system 18 months after it was implanted. This second study used an updated device. It also looked at the perceived impact of the implant on the individuals' quality of life: the people involved in the study reported the greatest impact of the improvement in incontinence was on indoor and outdoor activities.

There is also a recent clinical study in which 20 individuals experiencing urinary retention (inability to completely empty the bladder) received this treatment. All individuals experienced some improvement in their ability to empty their bladders. Pelvic pain also improved. (3)

As of the publication date for this information sheet, published clinical studies among a large number of individuals only report results up to 6 months after the implant surgery, although some individuals have been monitored by their physicians for up to five years. There is unpublished information available which reports results up to 18 months after surgery (4). By the time you read this, there may be more published information available. You can discuss the latest published information with your physician.

Reimbursement

Funding for this implant has not yet been uniformly established in Canada; you may have to pay for it. Your doctor will be able to tell you what your costs will be. The amount may be significant for you. Your doctor may also be able to provide some information on whether or not the treatment is covered under provincial or private insurance health plans. For your private insurance, you may have to call your company with your policy number in hand to find out if your plan provides coverage.

Where can I get more information before making my decision?

Be sure to consult an interested and knowledgeable healthcare professional about all your options and the likelihood of success of each of them, before determining the one which is best for you.

Remember – this treatment should not be considered **unless** you have already tried without success, other available non-surgical treatments.

For this treatment, do not be shy to ask your doctor how many he/she has done in the past, and about his/her own success rate with this particular treatment.

Collect all the materials on this treatment and others you can from your doctor, from The Canadian Continence Foundation and from the internet.

Speak to a few people who have undergone sacral nerve stimulation for a similar problem to yours. (The Canadian Continence Foundation and your doctor may be able to put you in touch with some individuals). You may want to ask them if they were happy they received the treatment, what the impact has been on their day-to-day lives, and whether any complications arose.

It is important to be confident that you have all the information needed to make an informed decision with your healthcare professional.

References:

- (1) Medtronic unpublished clinical data on file, 1997.
- (2) Shaker, Hassan S. and Hassouna M.: Sacral Nerve Root Neuromodulation: An Effective Treatment for Refractory Urge Incontinence. *The Journal of Urology*, 159: 1516-1519, May 1998.
- (3) Shaker, Hassan S. and Hassouna M.: Sacral Root Neuromodulation in Idiopathic Nonobstructive Chronic Urinary Retention. *The Journal of Urology*, 159: 1476-1478, May 1998.
- (4) Medtronic unpublished clinical data on file, 1997.

For more information about incontinence contact

The Canadian Continence Foundation

P.O. Box 66524, Cavendish Mall P.O., Cote St. Luc, Quebec H4W 3J6
Tel. (514) 932-3535 ■ Fax (514) 932-3533 ■ General Information 1-800-265-9575
www.continence-fdn.ca

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This information sheet was made possible through an educational grant from Medtronic of Canada Inc.
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