

GENESIS
SPINAL CORD
STIMULATION
THERAPY

*Information for you and your physician about
spinal cord stimulation therapy.*

ANS

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COPING WITH CHRONIC PAIN



Coping with chronic pain is one of life's greatest challenges. While you struggle with simple daily tasks, those around you struggle to understand just how much you hurt and why your pain doesn't get better. In time, the pain can overwhelm every aspect of life. It can take away your hope of recovering, and greatly decrease the quality of life for you and your loved ones.

SPINAL CORD STIMULATION: A PROVEN THERAPY FOR PAIN

Over the last 20 years, thousands of people with severe chronic pain have been treated successfully with spinal cord stimulation (SCS).

SCS uses a small implanted device — called a neurostimulator — to generate low-level electrical impulses that change pain messages before they are sent to the brain. Areas where you usually feel pain are replaced with another sensation. Some patients describe the sensation (called paresthesia) as a tingling effect. For many, this is the first step toward reclaiming a better quality of life.

THE GENESIS NEUROSTIMULATION SYSTEM

The Genesis Neurostimulation System is an implanted pulse generator (IPG) used for spinal cord stimulation. Genesis is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome and intractable low back and leg pain. In addition to an appropriate diagnosis, certain physical and psychological factors make some patients better candidates than others for SCS therapy. Your doctor will carefully evaluate your medical history before prescribing spinal cord stimulation.

GENESIS COMPONENTS

The implanted components (leads and IPG) of the Genesis system are placed during a surgical procedure which, depending on the type of leads placed, can be brief and minimally invasive. The leads (1) are positioned in the space above the spinal cord (called the epidural space). The power source consists of a battery and related electronics that are housed in a single metal container, called an IPG. The IPG (2) is placed just under the skin in a practical location (e.g. the abdomen or just below the beltline and above the buttocks), which is acceptable to you and your physician. The leads are then connected to the IPG.



It is important to note that when the system's battery is depleted, a surgery must be performed to replace the IPG (battery). The Genesis IPG will provide you with a warning before the battery is totally depleted, at which time you should contact your physician to inform him your IPG battery is low. Battery life depends on the power output you require and how often you use the device.



(3) Genesis Programmer

An external device, called a programmer (3), is used to control the system, including turning the system on and off and increasing and decreasing the stimulation, which creates the sensation that replaces the pain.

When the power source is turned on, stimulation is sent to the electrodes on the leads which stimulate specific nerve fibers that affect the areas of your pain. The stimulation of these targeted nerves is intended to change how the brain perceives the pain signals. Instead of feeling pain, a different sensation is felt in areas that normally hurt. Most patients say this new sensation feels like tingling.

WHEN THE DEVICE SHOULD NOT BE USED

Genesis should not be used in patients with demand-type cardiac pacemakers. Patients that are unable to operate the system or fail to receive effective pain relief during trial stimulation should not be implanted with the system. Additionally, safety and effectiveness of spinal cord stimulation has not been established for pediatric use or during pregnancy.

POTENTIAL RISKS

Are there possible complications with the surgery?

As with any surgical procedure, there is a risk of infection and bleeding. There is also a possibility of injury to the spinal cord, which can result in spinal cord compression, temporary or permanent paralysis or cerebral spinal fluid (CSF) leakage. Additional risks include lack of benefit from the therapy, hematoma or a swelling containing blood, or bleeding in the epidural space which can result in stroke or paralysis. Although the risk of complications is low, you should ask your doctor about them.

Are there possible complications with spinal cord stimulation?

SCS is a pain therapy with a low risk of complications. Complications include the loss of effective stimulation and a resulting reduction in pain relief due to movement of the leads, changes in tissue around the electrodes and/or equipment failure, movement of the stimulation coverage, over-stimulation resulting in an uncomfortable or jolting sensation, loss of pain-relief over time, an allergic reaction to the system components, pain at the implant site and local skin erosion over the implant. The effect of spinal cord stimulation therapy on pregnancy and nursing mothers has not been studied. You should discuss risk factors and your concerns with your doctor.

BENEFITS OF THE SYSTEM

When successful, painful sensations are replaced with what some patients describe as a tingling sensation called paresthesia. SCS may help you resume a more active lifestyle.

Spinal cord stimulation is not a cure, so it is unlikely SCS will eliminate all of your pain. The goal of SCS is to decrease severe chronic pain to the point where you can increase your participation in daily activities. The degree of pain relief attained varies from person to person.

Many people are able to decrease or even discontinue pain medications, but spinal cord stimulation is part of an overall treatment plan to manage chronic pain. Therefore, there may be times when your pain increases, and you will need pain medications in addition to spinal cord stimulation.

WHAT TO EXPECT BEFORE, DURING AND AFTER THE SURGICAL PROCEDURE

What does spinal cord stimulation therapy involve?

Spinal cord stimulation requires a surgical procedure to implant the system components. During the procedure, one or more leads are placed in the epidural space (the space just above the spinal column). The leads contain electrodes that receive electrical signals from the IPG and deliver stimulation. The leads are then connected to an IPG placed just under the skin in a practical location (e.g. the abdomen or just below the beltline and above the buttocks). The surgical procedure is often performed in a hospital's outpatient department or at a day surgery center.

How long will it take before I feel better?

Recovery times vary among patients. Many say spinal cord stimulation makes a noticeable difference in controlling their pain from the time it is first turned on — placing a richer, fuller life within their reach.

Will spinal cord stimulation allow me to return to work?

Your physician will help you make this decision. Some patients, depending upon their condition and occupation, are able to return to work while using spinal cord stimulation.

Will I feel the electronic device under my skin?

Patients can feel the device, but once the incision heals, most patients say it is easy to forget the implanted device is there. You may experience some discomfort while the incision heals. This is perfectly normal and signals the healing process is underway.

Can you see the implanted device under my skin?

It depends on your body shape and size and where the implant is located. You and your doctor will together determine the most cosmetically acceptable and comfortable location for the implanted device.

Do I use the stimulator 24 hours a day?

You can use your spinal cord stimulation (SCS) system around the clock if necessary. Most patients get pain relief during the day, and turn off the system before bedtime. Other patients use their systems while sleeping. You and your doctor can determine the best schedule to control your pain.

Can I shower or swim with the stimulator?

Yes. Since the system components are implanted you can shower or swim without interrupting your therapy.

Is it safe to use household appliances or cellular equipment with my stimulator?

Yes. It is safe to use pagers, computers and standard household appliances, including microwave ovens, with your system. The effect of cellular phones on spinal cord stimulators is unknown and patients should avoid placing cellular phones directly over the device. Certain types of anti-theft devices, such as those used at department stores or airport security gates may cause an increase or decrease in stimulation, which can result in an uncomfortable or jolting sensation, while you pass through the device. This sensation is temporary, and should not harm your system. However, as a precaution, it is advised that the system be turned off before passing through these kind of devices.

Can I drive with the stimulator turned on?

No. Spinal cord stimulation should not be used while operating a motor vehicle or other heavy equipment. If you are driving, you will need to turn the stimulator off. However, you can ride as a passenger with the stimulator on.

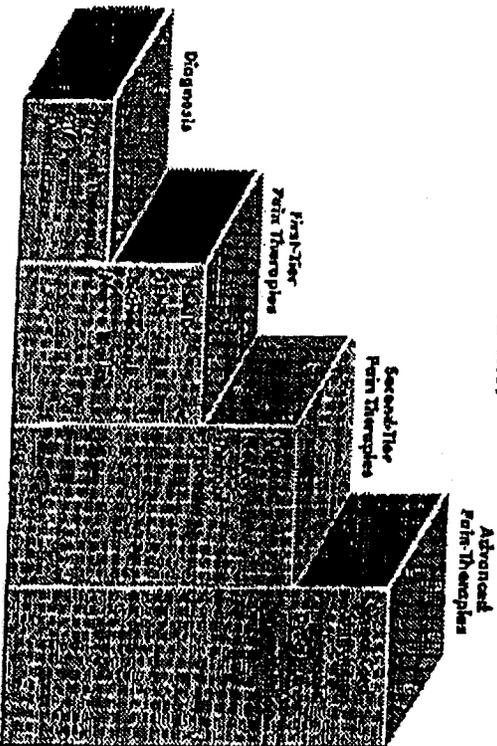
Can I travel with the stimulator?

Yes. Metal detectors and anti-theft devices may detect your spinal cord stimulation system, but a patient identification card will help to clear you through these checkpoints. Thousands of people have implanted medical devices, such as pacemakers, so the security personnel will know what to do. However, it is important to remember that certain types of anti-theft devices, such as those used at department stores or airport security gates may cause an increase or decrease in stimulation, which can result in an uncomfortable or jolting sensation, while you pass through the device.

ALTERNATIVE THERAPIES

Pain specialists recognize the complex nature of pain, and have created a strategy to help identify the best treatment for an individual patient. This strategy is called the chronic pain treatment continuum.

The Chronic Pain Treatment Continuum



The chronic pain treatment continuum is a "plan of attack" that helps you and your doctor decide on the best treatment for your pain. It also helps to ensure no potential solution for your pain is overlooked.

It is important to know that it is a generalized treatment strategy only, and that it can vary depending on your condition, your response to previous treatments and the recommendation of your pain physician.

After making an initial diagnosis, your doctor will take specific steps to treat your pain. The treatment continuum usually begins with less involved and less expensive therapies. If you have suffered with chronic pain for a year or more, you are probably

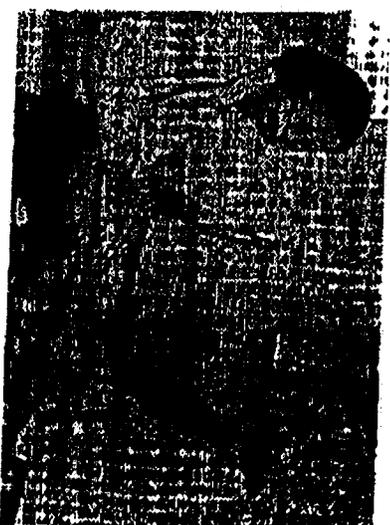
familiar with the initial therapies of the treatment continuum. These include pain medications, physical therapy, TENS and nerve blocks. Some of these treatments may have worked at first, but you may find they did not offer lasting pain relief.

If pain does not respond to these less aggressive therapies, pain specialists look at more advanced surgical approaches along the treatment continuum. These more advanced approaches include sympathectomy (severing the nerve pathway), radio frequency controlled spinal cord stimulators and totally implanted spinal cord stimulators (IPG).

ASK YOUR PHYSICIAN

You and your doctor should work together to evaluate your individual situation and the effectiveness of various treatment options (using the chronic pain treatment continuum).

Pain physicians have advanced training and knowledge in the diagnosis, treatment and rehabilitation of people with chronic pain. Pain specialists provide care at various levels. They may treat your pain directly by prescribing medications, recommending rehabilitation services, performing pain-relieving procedures and counseling you and your family.



The important thing to remember is there are treatments for chronic pain. Your physician and ANS are here to help. *Life gets better.*

"Off." You are advised to inform their health care professional that you cannot be exposed to diathermy treatment.

Operation of Machines, Equipment, and Vehicles — Do not drive, operate heavy machinery or power tools with the stimulator turned on. Postural changes or abrupt movements could cause overstimulation (jolting sensation) that might cause you to lose control of your vehicle or equipment.

Magnetic Resonance Imaging (MRI) — You should NOT be subjected to an MRI. The electromagnetic field generated by an MRI may dislodge implanted components, damage the device electronics, and induce voltage through the lead that could cause a jolting or shocking sensation.

Theft Detectors and Metal Screening Devices — Certain types of anti-theft devices such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are implanted with non-adjacent multiple leads and/or patients that are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. It is recommended that patients use caution when approaching such a device and request assistance to bypass the device. If they must proceed through the device the patient should turn off the stimulator and proceed with caution, ensuring to move through the detector quickly.

Lead Movement — Avoid bending, twisting, stretching, or lifting objects over five pounds, for six to eight weeks post-implantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in - overstimulation or ineffective stimulation.

Explosive or Flammable Gases — Do not use the programmer in an environment where explosive or flammable gasses are present.

Cardiac Pacemakers — Implanted neurostimulation systems may adversely affect the operation of implanted cardiac demand pacemakers.

Pediatric Use — Safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Pregnancy — Safety for use during pregnancy has not been established.

Cardioverter Defibrillators — Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Postural Changes — Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn your IPG off or lower the amplitude before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, the IPG should be turned off.

PRECAUTIONS

This section lists the actions you should be aware of and avoid to prevent situations that may cause uncomfortable sensations or damage to your neurostimulation system.

Keep the Programmer Dry — Do not use the programmer when engaging in activities that might cause the programmer to get wet, such as exposure to rain, swimming, bathing, etc. Your programmer is not waterproof and should be kept dry to avoid damage.

Handle the Programmer With Care — The programmer is a sensitive electronic device that can be damaged by rough handling, including dropping on the ground or being crushed.

Battery Care — Batteries can explode, leak or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Disconnecting the Wand — Do not pull directly on the cord to disconnect the wand from the programmer. Doing so can damage the cord and make the wand inoperable. To disconnect the wand, grasp the connector at the contoured finger grips and pull gently downward.

Medical Tests and Procedures — Before undergoing medical

tests or procedures, contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotripsy, therapeutic x-rays, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system.

Electromagnetic Interference (EMI) — Certain commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave programmers, linear power amplifiers, high-power amateur transmitters), and high-voltage power lines may generate sufficient EMI to interfere with neurostimulation operation if approached too closely. Use caution when approaching such devices and turn your IPG off if you feel any unusual sensations. Do not turn the IPG on again until you are away from the area of EMI interference.

Control of Your Programmer — Keep your programmer out of the hands of children in order to avoid the potential of damage or unauthorized change in stimulation parameters.

Physician Instructions — Always follow the programs and therapy instructions established for you by your physician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Unauthorized Programming Changes — Do not make unauthorized changes to physician established stimulation parameters. If you find yourself in an unfamiliar screen display, press the previous screen key.

Magnet Usage — The magnet provided with your Genesis system is a high powered magnet intended for use solely with the Genesis system. Keep it away from watches, credit cards, computer disks and other magnetic sensitive items to avoid damaging them. Always place the "Keeper Bar" on the magnet when not in use.

FCC Statement — FCC ID: PX 2001 — This device (Patient Programmer) complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

Cellular Phones — The effect of cellular phones on spinal cord stimulators is unknown and patients should avoid placing cellular phones directly over the device.

High Output Ultrasonics and Lithotripsy — The use of high output devices such as an electrohydraulic lithotripsy may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic Scanning Equipment — The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted device.

External Defibrillators — The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic Radiation — Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic x-rays, cobalt machines, and linear accelerators. If radiation therapy is required the area over the implanted IPG should be shielded with lead.

ADVERSE EFFECTS

The implantation of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with implantation, and/or use of a neurostimulation system:

- Undesirable changes in stimulation may occur over time. These changes in stimulation are possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections and/or lead failure.
- Placement of a lead in the epidural space is a surgical procedure that may expose the patient to risks of epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis.

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- Stimulation at high outputs may cause unpleasant sensations or motor disturbances (including movement). If unpleasant sensations occur, turn the IPG off immediately.
 - Battery failure and/or battery leakage may occur.
 - Radicular chest wall stimulation.
 - CSF leakage.
 - Persistent pain at the electrode or IPG site.
 - Seroma at the implant site.
 - Lead migration, which can result in changes in stimulation and subsequent reduction in pain relief.
 - Allergic or rejection response to implant materials.
 - Implant migration and/or local skin erosion.
 - Paralysis, weakness, clumsiness, numbness or pain below the level of implantation.

Caution: U.S. federal law restricts this device to sale and use by or on the order of a physician.

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