USER'S GUIDE

Neurostimulation has been shown to benefit patients with certain types of chronic intractable pain conditions. It uses a method of pain control that replaces areas of chronic pain with a more pleasant tingling or massaging sensation called paresthesia.

This manual will help you understand how to use and care for your Genesis Implantable Pulse Generator (IPG) and Programmer. Thoroughly review this manual before using your system and ask anyone involved in your care to also read it.

If you have questions beyond those addressed in this manual, or if an unusual situation arises, consult your physician. Your physician is familiar with your medical history and can give you more detailed information.

For assistance or questions about the system not covered in this manual call:

1 (800) 727-7846 or (972) 309-8000

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

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INDICATIONS FOR USE

The Genesis (IPG) Neurostimulation System 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.

CONTRAINDICATIONS

The system is contraindicated for patients with demand type cardiac pacemakers.

If you are unable to operate the system or fail to receive effective pain relief during trial stimulation you cannot be implanted with a SCS.

WARNINGS

This section lists the potential hazards associated with spinal cord stimulation that you must be aware of to avoid serious outcomes that may cause injury or death.

You should not use Spinal Cord Stimulation (SCS) if you are a poor surgical risk, have multiple illnesses or active general infections.

Diathermy Therapy – You cannot have any short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on your body if you have any part of a spinal cord stimulator implanted. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "On" or "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 over-stimulation (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 antitheft 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 lithotriptors, 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. **NOTE:** Changes or modifications to this product not authorized by ANS could void the FCC certification and negate your authority to operate this product.

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 lithotriptor 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.
- 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.