IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KATHLEEN M. FREED and RICHARD FREED,	:	
Plaintiffs,	:	
	:	**C.A. No.: 17-cv-01128-MAK**
v.	:	
	:	**TRIAL BY JURY TWELVE DEMANDED**
ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL S.C., INC., ABBOTT LABORATORIES, INC., and ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION,	:	
Defendants.	:	

FIRST AMENDED COMPLAINT

THE PARTIES

1. Plaintiffs Kathleen M. Freed ("Mrs. Freed") and Richard Freed are and were, at all times relevant hereto, residents of the State of Maryland.

2. St. Jude Medical, Inc. is a foreign corporation that sells its products and otherwise does business in the State of Delaware. It can be served by serving process on it pursuant to 10 *Del.C.* §3104 and/or by serving its registered agent at The Corporate Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

3. Defendant St. Jude Medical, S.C., Inc. is a foreign corporation that sells its products and otherwise does business in the State of Delaware. It can be served by serving process pursuant to 10 *Del.C.* §3104.

4. Defendant Abbott Laboratories, Inc. ("Abbott") is a Delaware corporation that sells its products and otherwise does business in the State of Delaware. It may be served by serving its

agent for service of process at The Corporate Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Upon information and belief, Abbott Laboratories purchased the assets and liabilities of St. Jude Medical, Inc. and/or St. Judge Medical S.C., Inc. and operates it as a wholly owned subsidiary. Abbott is a successor-in-interest to the liability alleged in this action.

5. Defendant Advanced Neuromodulation Systems, Inc. d/b/a St. Jude Medical Neuromodulation Division is a foreign corporation that sells its products and otherwise does business in the State of Delaware. It can be served by serving process pursuant to 10 *Del.C.* §3104.

6. Collectively the Defendants will be referred to hereafter as "St. Jude".

THE FDA APPROVAL PROCESS

7. At all times relevant hereto St. Jude designed, manufactured, marketed, distributed, and/or sold a Protégé 16-Channel IPG Spinal Cord Stimulator Catalogue Number 3789, Lot Number 4699346 (hereafter "the SCS device") for implantation in patients including those suffering from chronic lower back and lower extremity pain.

8. On November 21, 2001, the Federal Food and Drug Administration ("FDA") issued an approval for the commercial distribution of the Genesis and Eon Family of Neurostimulation (IPG) Systems manufactured by St. Jude Medical. Ex. A. The approval of the device (or family of devices) followed the submission of a premarket approval application (PMA) and review. In its approval letter, the FDA identified the components of the system as follows: "the Model 608 Pulse Generator, the Model 3580 Patient Programmer, the Model 1232 Programing Wand and the Model 1210 Patient Magnet". The letter also stated that the PMA approval was subject to "…the conditions described below and in the 'Conditions of Approval' enclosed". Finally, the approval letter stated that "…as soon as possible and before commercial distribution of your device, you

must submit an amendment to this PMA submission with copies of all approved labeling in final printed form".

9. The incorporated "Conditions of Approval" issued by the FDA contained the following relevant requirements. They state as follows:

> "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidents of anticipated adverse effects or device failures necessitate a labeling, manufacturing, or device modification."
>
> "ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness, the applicant shall submit 3 copies of a written report identified, as applicable, as an 'Adverse Reaction Report' or 'Device Defect Report' to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 within 10 days after the applicant received or has knowledge of information concerning:
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> ***
>
> (2) Any adverse reaction, side effect, injury, toxicity or sensitivity reaction that is attributable to the device and
>
> (a) has not been addressed by the device's labeling…'. [original underlining]
>
> REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting Requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, …, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggest that the device marketed by the manufacturer or importer:
>
> (1) May have caused or contributed to a death or serious injury; or
> (2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to occur." [original underlining]

10. According to the FDA's website the original PMA approval for the Genesis device (or family of devices) has been supplemented 109 times. None of those supplements relate to the system's IPG battery component or labeling for the IPG battery component.

11. On March 21, 2014, the FDA issued an approval for labeling modification in order to change the name of the Eon Mini IPG to the Protegé Model 3789, as well as to implement certain minor software modifications to sync the programmer with the new Protégé device and model number.

12. The Genesis and Eon family of neurostimulator devices has been the subject of multiple recall campaigns since 2001. On May 24, 2011, St. Jude initiated a recall for the Eon Mini Neurostimulation (IPG) System Model 3788. This recall addressed a defective battery as the cause for reports of the inability to communicate with or recharge the IPG. On December 19, 2011, St. Jude initiated a recall following 112 complaints of the Eon Mini IPG's losing its ability to communicate with or recharge the unit resulting in the loss of pain relief and subsequent explant. It was determined that the cause of the reports had to do, in part, with the positioning of the internal battery. On the same date—December 19, 2011—St. Jude initiated a second recall after receiving 110 complaints of "warmth or heating at the implantable pulse generator (IPG) implant site during charging for the Eon IPG and 116 reports of similar complaints for the Eon Mini IPG respectively". On September 4, 2012, St. Jude initiated a recall for the Eon Mini IPG manufactured in April 2012 that "...could potentially exhibit a sudden, brief surge in stimulation that would be felt by the patient as uncomfortable or painful". St. Jude identified the potential for the internal battery to come into contact with the internal microcontroller board. On July 26, 2012, St. Jude initiated three separate recalls relating to certain Eon devices after receiving reports in "a number of cases" in which "discomfort associated with heating around the device site while patients are using the charging system to charge their spinal cord stimulator". Three patients suffered burn injuries at the implant site.

13. 21 C.F.R. §807.65 exempts manufacturers of raw materials or components to be used in the assembly of a device "…because the Commissioner [of the FDA] has found that such regulation is not necessary for the protection of the public…". Upon information and belief the battery used in the SCS device is a component part manufactured by another and which is not subject to FDA regulation.

14. The FDA's approval letter to the Genesis and Eon family of neurostimulator devices [and therefore the SCS device] states that "The sole, distribution and use of this device are restricted to prescription use in accordance with 21 C.F.R. 801.109". Subsections (c) and (d) of §801.109 provide as follows:

> "(c) Labeling on or within the package from which the device is to dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, **and any relevant hazard**s, contraindications, side effects, **and precautions** under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it was intended, including all purposes for which it is advertised or represented….
> (d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration, **and any relevant hazards**, contraindications, side effects, **and precautions** under which practitioners licensed by law to employ the device can use the device safely and for the purpose for which it was intended, including all purposes for which it is advertised or represented…". [emphasis added].

21 C.F.R. §814.39(a) requires that a manufacturer of a medical device submit a supplemental PMA for any proposed labeling changes that affect the safety of the device. Subsection (d) of §814.39 further provides that after the FDA approves a PMA the applicant may put into effect any change in labeling "…to reflect newly acquired information that enhances the safety of the device…" before the supplement has been approved, including "labeling changes that add or strengthen a …warning, precaution, or information about an adverse reaction for which there is reasonable

evidence of a causal association". See 21 C.F.R. §814.39(d)(1) and (2)(i). These regulatory requirements were mandated by the Conditions of Approval for the Genesis and Eon family of devices, but there is no indication that St. Jude complied with or took action to supplement its labeling or notify patients such as Mrs. Freed of the specific hazards alleged in this Complaint.

15. Similarly, the Conditions of Approval issued by the FDA to St. Jude required compliance with 21 C.F.R. §814.82(a)(9) which calls for the submission of an Adverse Reaction Report or Device Defect Report to the FDA within ten days after St. Jude received or acquired knowledge of information concerning "...any adverse reaction..., injury, ...that is attributable to the device and...has not been addressed by the device's labeling...". There is no indication that St. Jude submitted any such report(s) before or after the SCS device was implanted into Mrs. Freed's body.

16. Once the SCS device was approved for commercial distribution through the PMA process, St. Jude became bound by the "good manufacturing practices" ("GMP") requirements found in 21 C.F.R. §820.1-820.198. §820.90(a) requires that each manufacturer "...establish and maintain procedures to control product that does not conform to specified requirements". §820.100(a)(3) requires each manufacturer to "[i]dentify the action(s) needed to correct and prevent reoccurrence of nonconforming product and other quality problems...". Mrs. Freed received a non-conforming SCS device as set forth below.

IMPLANTATION OF THE SCS DEVICE

17. Prior to October 17, 2014 Mrs. Freed suffered from chronic lower back and left lower extremity pain for which she had received both non-surgical and surgical treatment modalities with only modest overall relief of her pain.

18. On or about July 14, 2014 Mrs. Freed underwent a trial placement of a St. Jude spinal cord stimulator system. A representative from St. Jude was present during this procedure. The representative informed Mrs. Freed that she would be "very happy" with the SCS device. Plaintiffs relied upon this statement in deciding to proceed with the trial. On or about July 21, 2014 the St. Jude representative re-programmed the system to obtain better coverage of Mrs. Freed's left lower extremity pain. On or about July 23, 2014, Mrs. Freed's physician noted excellent relief of her pain and removed the trial leads. It was recommended that Mrs. Freed undergo surgery to permanently implant a St. Jude Spinal Cord Stimulator device for use in management of her chronic pain symptoms. Before deciding to proceed with permanent implantation of the SCS device Plaintiffs did their own research on the internet as to both the SCS device and other alternative devices. Based on what they read on St. Jude's website Plaintiffs were satisfied that the SCS device was safe and of good quality. Plaintiffs relied upon the information on St. Jude's website in deciding to proceed with the permanent implant.

19. On October 17, 2014, Mrs. Freed presented herself at the Christiana Hospital in Newark, Delaware where Dr. Kennedy Yalamanchili implanted the SCS device in her body. As part of this operative procedure Dr. Yalamanchili surgically implanted the neurostimulator and battery components in the soft tissues of Mrs. Freed's left buttocks. Again a St. Jude representative was present at the Hospital during the implantation procedure. At no time prior to this operative procedure was Mrs. Freed informed or warned of any defects, faults, or contraindications to the use of the SCS device.

20. In the months that followed the October 17, 2014 surgery a representative or representatives of St. Jude met regularly with Mrs. Freed and her physician(s) to assess the

performance of the SCS device. At no time was Mrs. Freed informed or warned of any defects, faults, or contraindications to the use of the SCS device.

21. On or about June 12, 2015 Mrs. Freed presented herself at the Christiana Hospital in Newark, Delaware for further exploratory and fusion surgery performed by Dr. Yalamanchili on her lumbar spine. Shortly after this surgery Dr. Yalamanchili prescribed the use of a bone growth stimulator to augment the healing process.

22. Soon thereafter Mrs. Freed began using the bone stimulator prescribed by Dr. Yalamanchili. When she did so she experienced discomfort in the area of the left buttocks where the neurostimulator and battery components of the SCS device had been implanted. This discomfort progressed to the point where the SCS device started giving off severely painful electrical shocks and a burning sensation throughout the left buttocks. Mrs. Freed immediately stopped using the SCS device and on August 5, 2015 presented herself at the Easton Hospital Emergency Room in Easton, Maryland for a complaint of persistent severe burning pain in her left buttocks. A representative of St. Jude was present and spoke with Mrs. Freed at the Emergency Room.

23. In consultation with Dr. Yalamanchili and a representative of St. Jude a medical decision was made to surgically remove the neurostimulator and battery components from Mrs. Freed's left buttocks. The surgery was performed by Dr. Yalamanchili on August 17, 2015 at the Upper Bay Surgery Center in Elkton, Maryland. A representative of St. Jude was present at the Surgery Center on the day of the surgery and immediately took possession of the explanted neurostimulator and battery components. Upon information and belief, St. Jude has transported those components to its Plano, Texas facility where they remain today.

COUNT I

BREACH OF EXPRESS WARRANTY

24. Plaintiffs incorporate the averments set forth in Paragraphs 1 through 23 above as if fully restated herein.

25. Through its marketing materials, its website, the statements of its representatives, and the published materials provided to Mrs. Freed and physicians such as Drs. Ganesh Balu and Kennedy Yalamanchili, St. Jude expressly affirmed as fact and/or promised that the SCS device was free of defects, designed for safe use in the management of chronic low back and lower extremity pain, safe for implantation in the human body, and in conformity with the sample or model that had been used on a trial basis before the permanent implantation.

26. These affirmations of fact and/or promises constituted express warranties within the meaning of 6 Del.C. §2-313.

27. Mrs. Freed relied upon those affirmations of fact and/or promises in deciding to have the SCS device implanted in her body.

28. St. Jude breached its express warranty by designing, manufacturing, distributing, and/or selling the SCS device which malfunctioned while implanted in Mrs. Freed's body.

29. As a direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed suffered severe and permanent bodily injuries.

30. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has experienced, and will continue to experience into the future, severe pain and suffering and emotional distress.

31. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has incurred, and will continue to incur into the future, the cost of medical care to treat her injuries.

COUNT II

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

32. Plaintiffs incorporate the averments set forth in Paragraphs 1 through 31 above as if fully restated herein.

33. Through its marketing materials, its website, the statements of its representatives, and the published materials provided to Mrs. Freed and her physicians, St. Jude impliedly warranted that the SCS device was of merchantable quality and fit for the ordinary purposes for which such devices are implanted in the human body within the meaning of 6 Del.C. §2-314.

34. Mrs. Freed relied upon their representations in deciding to have the SCS device implanted in her body.

35. St. Jude breached the implied warranty of merchantability by designing, manufacturing, distributing and/or selling the SCS device which was not safe or fit for use in Mrs. Freed's body as intended.

36. As a direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed suffered severe and permanent bodily injuries.

37. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has experienced, and will continue to experience in the future, severe pain and suffering and emotional distress.

38. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has incurred, and will continue to incur in the future, the cost of medical care to treat her injuries.

COUNT III

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

39. Plaintiffs incorporate the averments set forth in Paragraphs 1 through 38 above as if fully restated herein.

40. At all times relevant hereto St. Jude knew, or had reason to know, that the SCS device was to be used for the management of Mrs. Freed's chronic pain symptoms and that the SCS device would be implanted inside Mrs. Freed's body for that purpose.

41. Through its marketing materials, its website, the statements of its representatives, and the published materials provided to Mrs. Freed and her physicians, St. Jude impliedly warranted that the SCS device was of merchantable quality and fit for the ordinary purposes for which such devices are implanted in the human body within the meaning of 6 Del.C. §2-315.

42. Mrs. Freed relied upon their representations in deciding to have the SCS device implanted in her body.

43. St. Jude breached the implied warranty of fitness for a particular purpose by designing, manufacturing, distributing, and/or selling an SCS device that did not serve that particular purpose and which malfunctioned causing injury and additional pain to Mrs. Freed.

44. As a direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed suffered severe and permanent bodily injuries.

45. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has experienced, and will continue to experience in the future, severe pain and suffering and emotional distress.

46. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has incurred, and will continue to incur in the future, the cost of medical care to treat her injuries.

COUNT IV

MANUFACTURE OR SALE OF A DANGEROUS AND/OR ADULTERATED CHATTEL

47. Plaintiffs incorporate the averments set forth in Paragraphs 1 through 46 above as if fully restated herein.

48. 21 U.S.C. §351 defines a device as adulterated if it was not in all respects in conformity with the standard approved by the FDA.

49. As a manufacturer and/or seller of the SCS device St. Jude owed a duty to Mrs. Freed not to supply a chattel that it knew, or had reason to know, was adulterated or dangerous for use in the human body.

50. Upon information and belief St. Jude had manufactured and/or sold a variety of spinal cord stimulator devices with components including batteries that were defective and caused bodily injury to patients like Mrs. Freed who had them implanted in their bodies.

51. Upon information and belief St. Jude has conducted recall campaigns for various spinal cord stimulator devices and components including batteries it has manufactured and/or sold for implantation in the human body.

52. Upon information and belief, St. Jude manufactured and/or sold to Mrs. Freed an SCS device that was adulterated or otherwise nonconforming with the good manufacturing practices required by the FDA.

53. St. Jude knew or had reason to know that the SCS device implanted in Mrs. Freed's body was dangerous and had the capacity to harm Mrs. Freed and cause her bodily injury.

54. St. Jude breached its duty of care to Mrs. Freed by:

(a) Failing to inform or warn her of the SCS device's dangerous propensities;

(b) Failing to warn Mrs. Freed's physicians of the SCS device's dangerous propensities;

(c) Failing to inform or warn her of the relevant hazards and precautions as mandated by the FDA in 21 C.F.R. §801.109;

(d) Failing to update or change its labeling to inform or warn Mrs. Freed of the relevant hazards or precautions as mandated by 21 C.F.R. §814.39 and §814.82(a)(9);

(e) Failing to inform or warn Mrs. Freed and/or her physicians of ways to avoid harm or injury to her body after the SCS device had been implanted;

(f) Failing to inform or warn Mrs. Freed of the SCS device's incompatibility with the simultaneous use of a bone growth stimulator;

(g) Failing to comply with the good manufacturing practices as mandated by the FDA in 21 C.F.R. §820.1 *et seq.*;

(h) Manufacturing and selling to Mrs. Freed an SCS device that was adulterated within the meaning of 21 U.S.C. §351;

(i) Otherwise failing to act in accordance with its duty as further discovery may demonstrate.

55. As a direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed suffered severe and permanent bodily injuries.

56. As a further direct and proximate result of St. Jude's breach Plaintiff Kathleen M. Freed has experienced, and will continue to experience in the future, severe pain and suffering and emotional distress.

57. As a further direct and proximate result of St. Jude's Plaintiff Kathleen M. Freed has incurred, and will continue to incur into the future, the costs of medical care to treat her injuries.

COUNT V

LOSS OF CONSORTIUM

58. At all times relevant hereto Plaintiffs Kathleen M. Freed and Richard Freed were married.

59. As a direct and proximate result of St. Jude's conduct and his wife's injuries, Plaintiff Richard Freed has lost the consortium, society, aid, and comfort of his wife Kathleen M. Freed.

WHEREFORE, Plaintiffs demand judgment in their favor and against the Defendants, individually, jointly and severally, for the following:

(A) Compensatory damages for severe and permanent bodily injuries, pain and suffering, emotional distress, mental anguish, and the loss of enjoyment of life;

(B) Consequential damages for breach of warranty pursuant to 6 *Del.C.* §2-715(2);

(C) Loss of consortium;

(D) Past and future medical expenses;

(E) Attorneys' fees;

(F) Expert witness fees;

(G) Pre-and post-judgment interest;

(H) The costs of this action;

(I) Any other relief that the Court deems to be just and proper.

TYBOUT, REDFEARN & PELL

By: _____

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(302) 658-6901
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Attorneys for Plaintiffs

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Drew Johnson
Director, Regulatory Affairs
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Dr., Suite 100
Plano, Texas 75024

Re: P010032
Genesis Neurostimulation (IPG) System
Filed: May 29, 2001
Amended: June 11, 2001, August 13, 2001, September 10, 2001, September 17, 2001, September 17, 2001, October 5, 2001, October 11, 2001, October 18, 2001 and November 16, 2001

Dear Mr. Johnson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Genesis Neurostimulation (IPG) System. The System includes the following components: the Model 3608 pulse generator, the Model 3850 patient programmer, the Model 1232 programming wand and the Model 1210 patient magnet. This device 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 failed back surgery syndrome, intractable low back pain and leg pain. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

Expiration dating for this device has been established and approved at 2 years.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include

the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Kristen A. Bowsher, Ph.D. at (301) 594-1296.

Sincerely yours,

Daniel G. Schultz, M.D.
Deputy Director for Clinical
and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Last modified 8-21-01

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It

allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b)reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each

identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1)A mix-up of the device or its labeling with another article.

(2)Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of

information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

1. Summary Of Safety And Effectiveness Data

1.1 General Information

1.1.1 Device Generic Name

Totally Implanted Spinal Cord Stimulator for Pain Relief

1.1.2 Device Trade Name

Genesis Neurostimulation (IPG) System

1.1.3 Applicant's Name and Address

Advanced Neuromodulation Systems (ANS), Inc.
6501 Windcrest Drive, Suite 100
Plano, Texas 75024

1.1.4 PMA Number

P010032

1.1.5 Date of Notice of Approval to the Applicant

November 21, 2001

1.2 Indications for Use

ANS Genesis Neurostimulation (IPG) 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 the following: failed back surgery syndrome, intractable low back and leg pain.

1.3 Device Description

1.3.1 Genesis Neurostimulation System

The Genesis Neurostimulation (IPG) System consists of the following components: Model 3608 Implanted Pulse Generator (IPG), Model 3850 Patient Programmer, Model 1232 Programming Wand, and Model 1210 Patient Magnet.

The Genesis Neurostimulation (IPG) System is intended to be used with the following ANS' legally marketed components:

- percutaneous lead models 3143, 3146, 3153, 3156, 3183 and 3186
- surgical lead models 3222, 3240, 3244 and 3280
- extension models 3382, 3383, 3341, 3342 and 3343
- ANS TS8 test stimulation system.

The IPG is connected to a lead with four or eight electrodes, either directly or with a lead extension. The electrodes contact the patient along the spinal cord. The IPG is implanted in a subcutaneous pocket, and receives radio frequency (RF) programming signals from an external Patient

Programmer. The IPG decodes the RF signals and delivers stimulation pulses to the patient via a selected combination of output electrodes. The IPG is powered by a hermetically sealed battery enclosed within a hermetically sealed titanium case and uses an integrated circuit to generate electrical stimulation.

1.3.1.1 Implantable Pulse Generator (IPG)

The Model 3608 IPG is designed to produce a monophasic capacitively coupled rectangular output pulse. The IPG is current regulated and is capable of producing output stimulus in the following ranges: amplitude 0 to 25.5 mA, pulse width 52 to 507 µs, and frequency 2 to 200 Hz. The IPG is powered by an internal 3.7 volt lithium thionyl chloride battery. The IPG has the following specifications:

Dimensions: 50mm (1.96") X 54mm (2.11") X 14mm (0.54")
Weight: 53 grams (1.8 oz.)
Volume: 29 cm^3 (1.75 in^3)

1.3.1.2 Patient Programmer and Wand

The Model 3850 IPG Patient Programmer is a battery-operated device that is connected to the Model 1232 wand, which allows for two-way communication with the IPG for the purpose of programming the stimulation output parameters and receiving feedback from the IPG. The programmer communicates with the IPG by sending RF signals from the programmer wand to the implanted IPG. The stimulation RF output signals are programmed using a combination of amplitude, frequency pulse width and electrode polarity.. The programmer allows clinicians to set the output stimulation parameters that best provide pain relief for individual patients. It also allows the user to select individual pre-set stimulation parameters within clinician prescribed ranges. The Patient Programmer has the following specifications:

Dimensions: 6.8 cm (2.7") X 10.77 cm (4.2 ") X 2.6 cm (1.0")
Weight: 128 grams (4.6 oz)
Power: 3 AAA Alkaline Batteries

1.3.1.3 Magnet

The Genesis Model 1210 magnet allows the user to turn the IPG on and off at any time.

1.4 Contraindications, Warnings, and Precautions

1.4.1 Contraindications

The system is contraindicated 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 a SCS.

1.4.2 Warnings

Spinal cord stimulation (SCS) should not be used on patients that are poor surgical risks, those with multiple illnesses or active general infections.

Diathermy Therapy – Do not use short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and 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". All patients are advised to inform their health care professional that they should not be exposed to diathermy treatment.

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

Magnetic Resonance Imaging (MRI) – Patients with implanted neurostimulation systems should not be subjected to MRI. The electromagnetic field generated by a MRI may dislodge implanted components, damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Explosive or Flammable Gases – Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present. The operation of the patient programmer could cause them to ignite, causing severe burns, injury or death.

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 interfere with the operation of the device. 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 – Patients should be instructed to 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.

Operation of Machinery and Equipment – Patients should not operate potentially dangerous machinery, power tools, vehicles, climb ladders, etc., when the IPG is operating. Postural changes or abrupt movement could alter the perception of stimulation intensity and cause patients to fall or

lose control of equipment or vehicles, injure others, or bring injury upon themselves.

Postural Changes – Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting of arms over head, or exercising. If unpleasant sensations occur, the IPG should be turned off immediately.

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.

Device Components – The use of non-ANS components with this system may result in damage to the system and increased risk to the patient.

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

1.4.3 Precautions

GENERAL PRECAUTIONS

Physician Training – Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone sufficient surgical and device implantation training.

Patient Selection – It is extremely important to appropriately select patients for spinal cord stimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the stimulator.

Infection – It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of Two Systems – If two systems are implanted, ensure that at least 8 in. (20 cm) separates the implanted IPGs to minimize the possibility of interference during programming.

Implantation of Multiple Leads – If multiple leads are implanted, the leads should be routed to the IPG in adjacent tunnels. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

High Stimulation Outputs – Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.

Stimulation Parameters – Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs except under direct orders from their physician.

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

FCC Statement – FCC ID: PX2001 – This device (Patient Programmer) complies with part 15 of the FCC Rules. Operation is subject to the following conditions: (1) This device may cause interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

STERILIZATION AND STORAGE

Single-Use Device – The implanted components of the ANS Genesis IPG System are intended for a single-use only. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Storage Temperature – Store system components between -10°C (14°F) and 55°C (131°F) because temperatures outside this range can damage components.

Storage Humidity – Store components between 10% and 90% humidity.

HANDLING, IMPLEMENTATION, AND EXPLANTATION

Expiration Date – Do not implant a device if the use-before date has expired.

Care and Handling of Components – Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting or the use of sharp instruments may damage and cause failure of the component.

Package and Component Damage – Do not implant a device if the sterile package or components show signs of damage, the sterile seal is ruptured, or if contamination is suspected for any reason. Return to ANS for evaluation.

Exposure to Body Fluids or Saline – Exposure of the internal metal (i.e., contacts on the lead, the IPG or extension) to body fluids or saline can cause corrosion and affect stimulation. If this occurs, clean with sterile, de-ionized or distilled water and dry completely prior to lead connection and subsequent implantation.

System Testing – The operation of the system should always be tested after implantation and before the patient leaves the surgery suite to assure correct operation.

Component Disposal – Return all explanted components to ANS for safe disposal.

HOSPITAL AND MEDICAL ENVIRONMENTS

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.

Electrosurgery Devices – Electrosurgery devices should not be used in close proximity to an implanted neurostimulation IPG or lead(s). Contact between an active electrode and an implanted IPG, lead or extension can cause direct stimulation of the spinal cord and cause severe injury to the patient. If use of electrocautery is necessary turn the IPG off.

HOME AND OCCUPATIONAL ENVIRONMENTS

Electromagnetic Interference (EMI) – Certain 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 sufficient EMI to interfere with the neurostimulation system operation if approached too closely.

1.5 Alternative Practices and Procedures

Alternative practices to the use of totally implanted IPG for spinal cord stimulation to treat chronic pain of trunk and limbs include:

1. Non-surgical treatment options for chronic pain patients include:
    a. Oral medication
    b. Rehabilitative therapy
    c. Transcutaneous electrical nerve stimulation (TENS);
    d. Behavior modification
    e. Neurolysis (i.e.,Therapeutic nerve block, Cryoanalgesia RF Lesioning)
2. Surgical treatment options for chronic pain patients include:
    a. Sympathectomy- severing the nerve pathway
    b. Partially Implanted spinal cord stimulation (SCS) Systems – RF implantable spinal cord stimulators (the power source in this system is external).

c. Commercially available fully implanted SCS Systems.

1.6 Marketing History

The Genesis Neurostimulation (IPG) System for the treatment of chronic pain of trunk and limbs is currently approved for commercial distribution in Europe. The CE mark was received in 2000. No Genesis Neurostimulation (IPG) System has been withdrawn from marketing for reasons related to safety and effectiveness of the device.

1.7 Potential Adverse Effects of the Device on Health

1.7.1 Adverse Events

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.
- 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.
- Device Failure

1.8 Summary of Nonclinical Studies

Qualification testing was conducted to provide adequate data to support the intended use of the device system. Testing was largely based on commonly recognized test methods and standards, such as International Standards Organization (ISO), European Standards (EN), American Society and Materials (ASTM) and military standards.

1.8.1 IPG

1.8.1.1 Environmental Testing

The following testing was performed to simulate the environmental conditions the device may encounter during normal usage: operating pressure, operating temperature, ultrasonic energy, drop testing, vibration resistance and exposure to defibrillation. IPG function was verified after exposing the device to the following environmental conditions: a pressure

of 70 and 150 kPa for five minutes respectively per EN 45502-1 Section 25.1; operating temperatures of 29°C, 37°C, and 45°C while the IPG is submerged in a 0.9% saline solution; exposure of the IPG for one hour to ultrasonic energy per EN 45502-1 Section 22.1; dropping onto a stainless steel tray resting on a 2 inch thick hard maple wooden bench top from a distance of 8 inch in each of six axes; random vibration per EN 45502-1 Section 23 and exposure to a defibrillation source per EN 45502-1 Section 20.2. Testing demonstrated that the IPG operated according to specification after exposure to the above environmental conditions. Additionally the device was subjected to storage temperature extremes (-20°C to +55°C) and was tested for proper operation. Testing demonstrated that the device operates as expected and within specification over the operating temperature range of the device and after exposure to storage temperature extremes.

Environmental testing for the Genesis IPG was performed to demonstrate compliance to Environmental Storage, Shipping Sterilization, and Shelf Life Requirements. Testing was performed in accordance with the standard: ASTM D 4169 – 98 – "Standard Practice for Performance Testing of Shipping Containers and Systems". The test results met the standards requirements.

1.8.1.2 Surface Temperature Testing

Testing was performed per EN 45502-1 to ensure the surface temperature of the IPG would not be greater than 2°C above normal surrounding body temperature (37°C) when implanted and functioning under normal operation, or in any single-fault condition. The test results met the requirement.

1.8.1.3 Hermeticity

The IPG was tested for hermeticity as defined in MILSTD 883E. Results demonstrated that the welds for the battery, titanium can and feedthroughs did not leak when exposed to helium leak testing in accordance with MILSTD 883E.

1.8.1.4 Electrical Characterization

Characterization of the electrical design of the IPG was performed. The testing included variations in temperature, supply voltage, load resistance, output current, pulse width, and frequency. Characterization of the device's output along the Impedance /Current curve under loads from 300 to 2000 ohms was performed. Results verified that the IPG system performed in accordance with design specifications.

1.8.1.5 Header Adhesion Testing

Bonding of the IPG header to its titanium can and the bonding of the dip coating material to the titanium case were characterized. The test was designed to ensure the material bonds do not delaminate due to shear stresses between the materials caused by a force applied to one of the two materials. Header bonding was performed using titanium strip samples overlapped with header material strip samples. In addition to the strip samples, three sample IPG devices were assembled and tested to ensure there was no shorting path between the feed through leads and the IPG case. Results of the header bonding test exceeded the anticipated 44.2 PSI shear stress. Results of the dip-coating test demonstrate the shear

strength of the dip coating and the titanium is higher than the strength of the header bonding by a factor of 2 to 1. Results of the overall testing for the header demonstrate the method for bonding a header to the IPG can and dip coating the titanium case meet acceptance criteria and are adequate for its intended use.

1.8.2 Battery Testing

Design verification testing was divided into segments of non-destructive and destructive testing and was designed to simulate the conditions of usage, handling, shipping and storage.

Each battery sample was subjected to visual, dimensional, radiographic, electrical, and hermeticity evaluation before and after environmental testing to assure the acceptability of the battery. Other non-destructive tests included high pressure (90 psi), low pressure (equivalent to atmospheric pressure at 30,000 ft), mechanical shock and vibration, temperature cycling (-40 °C to 70 °C twice in 48 hours), high temperature storage at 60 degrees C, low temperature storage at -40 °C, and short circuit testing for four hours at 37 °C.

Destructive testing included slow dent/puncture, crush and battery capacity testing. Battery capacity testing included discharging the batteries at a constant rate to determine any changes due to battery chemistry and to determine the battery capacity. The batteries showed no evidence of loss of hermeticity or sudden electrical failure that was attributable to the design.

Non-destructive and destructive testing for the battery demonstrates that the battery is suitable and can reliably perform within the IPG.

Electrical characterization for the Elective Replacement Indicator (ERI) and the End of Service (EOS) was performed. Characterization testing included ERI voltage, minimum communication voltage and minimum operating voltage measured under minimum, nominal and maximum operating conditions as well as for 0, 100, and 200 Ohm source impedances. The device met acceptance criteria.

Testing demonstrating that the battery source impedance at which a false ERI could occur was performed. The worst case battery source impedance at which a false low battery indication occurred was 160 ohms, which is greater than the typical source impedance expected during normal operation of a lithium thionyl chloride battery of 10–50 ohms.

1.8.3 Programmer and Wand Testing

Software for the Genesis Neurostimulation (IPG) System was developed and meets the recommendations provided in the Food and Drug Administration (FDA) guidance document, entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Mechanical verification of the Patient Programmer/Wand design included size and weight measurements, operational environment testing for temperature/humidity, pressure, heat generation, vibration, and drop testing. The devices were tested in accordance with EN 45502-1 and IEC 60601-1. Test results demonstrated that the device meets functional requirements when operated in a worse case fault condition.

In addition to mechanical and software verification tests, testing of the ability of the packaging to protect the device during shipping and handling was performed. The packages were tested in accordance with ASTM shipping test D4169-98. Results of the testing show that all acceptance criteria were met. Testing of the programmer's capability to reliably communicate with the IPG device from specified distances and orientations was performed. Testing demonstrated the device operates as expected and exceeds all communication distance/alignment requirements. Temperature testing for the AAA battery pack and the wand was performed. The testing demonstrated that the temperature of these devices does not rise to unsafe levels.

1.8.4 Electromagnetic Compatibility (EMC) Testing

The Genesis Neurostimulation (IPG) System has been evaluated for effects on its functioning and /or programming by external sources of interference in accordance with all applicable sections of IEC 60601-1-2 "Medical Electrical Equipment - Part 1: General Requirements for Safety: Electromagnetic Compatibility- Requirements and Tests". Testing included radiated emissions, RF immunity, magnetic immunity, and electrostatic discharge.

The test results met the requirements of the applicable sections of the standard.

1.8.5 Hazard Analysis

A risk analysis was performed using the failure modes and effects analysis (FMEA) on the complete device and the critical components. A risk assessment was performed in accordance with EN1441. The hazard analysis was incorporated into the design and development processes to ensure that critical failure mode or potentially hazard situations have been identified and adequately eliminated or mitigated. The software risk assessment was conducted as part of the system risk assessment.

All potential faults were identified in the FMEA/Failure Analysis and in the Fault/Failure Tree. The full analysis consisting of the Risk Assessment, the Software Risk Assessment, the Unacceptable Risks Analysis, and the FMEA all conclude that through the appropriate design, as well as testing, the hazards or unacceptable risks have been mitigated to an acceptable level.

1.8.6 Reliability Testing

The Genesis Neurostimulation (IPG) System was tested and analyzed for reliability. The testing included accelerated life testing that estimated the expected real time longevity performance and failure rate of the device.

Results of the reliability prediction analysis document that the failure rate for the nominal mode 0.076% per month and the failure rate for worst case mode was 0.103% per month. The failure rates are lower than the design goal of 0.15% failures per month.

1.8.7 Sterilization and Shelf Life

The devices are EtO sterilized with a sterility assurance level (SAL) of 10^{-6}. Validation for the sterilization cycle was performed in accordance with ISO

11135. Validation of the Shelf Life Study for sterile package supports a 2 year shelf life for the Genesis Neurostimulation (IPG) System.

1.8.8 Biocompatibility

All the tissue contacting raw materials for the implantable components of the Genesis Neurostimulation (IPG) System have been tested with the exception of titanium that houses the IPG. Titanium has been historically used in implanted medical devices. The titanium material used in the manufacture of the IPG is in compliance with ASTM F67, " Standard Specification for Unalloyed Titanium for Surgical Implant Applications". Biocompatibility testing was performed in compliance with ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing".

The following testing has been conducted on the tissue contacting raw materials:

- Cytotoxicity (ISO elution method), Hemolysis (Extraction method)
- Systemic Toxicity (USP method, rat model), Acute Intracutaneous Reactivity (rabbit model)
- Muscle Implantation (7 day and 90 day)
- Ames Salmonella/ Mammalian Microsome Mutagenicity Assay
- Rabbit Pyrogen Study
- Delayed Contact Sensitization Study (Saline Extract)

The results of these tests showed that the raw materials used in the Genesis Neurostimulation (IPG) System are biocompatible and therefore, suitable for the intended use.

ANS performed biocompatibility tests on the finished device in accordance with ISO 10993 to determine the potential for *in vitro* cytotoxicity. The results from testing on the sterilized finished IPG product found the device to be non-toxic.

1.8.9 Packaging Qualification

Qualification testing for the packaged product consisted of environmental stress tests including extreme temperature/humidity conditions, extreme vibration, stacking and drop testing. Visual inspection and functional testing of sterile package seals, package materials and contents were performed. Functionality of each device was verified at the completion of the tests. The packaging met the test requirements

1.9 Summary of Clinical Studies

The clinical data summarized below consisted of available peer reviewed published literature for similar implantable spinal cord stimulation (SCS) systems. The Genesis Neurostimulation (IPG) System device is similar to the SCS systems reported in the published literature in intended use, target patient population, technology, device design and output characteristics. Three key studies which met specific inclusion and exclusion criteria were included in the effectiveness analysis. A total of 16 studies which met safety specific inclusion and exclusion criteria were included in the safety analysis. The effectiveness data represents a total of 116 patients that were implanted with SCS systems, while the safety data represents a total of 1253 patients that received SCS systems.

1.9.1 Objectives of Studies

Based on nonclinical studies that demonstrated the Genesis Neurostimulation (IPG) System has comparable output characteristics to the commercially available SCS systems reported in the literature, the primary objective was to provide clinical evidence of the effectiveness of the Genesis Neurostimulation (IPG) System, using literature articles, for the relief of failed back surgery syndrome, intractable low back, and limb pain.

Effectiveness was demonstrated by 1) a reduction of pain as demonstrated by a significant reduction in the Visual Analog Scale (VAS) score, 2) a 50% reduction in pain using either a 3 or 4 point scale in at least 30% of patients included in that study, 3) a significant difference in pain reduction as measured by a VAS score when compared to a control group, and/or 4) a significant reduction in pain medication.

Safety of the Genesis Neurostimulation (IPG) System was established using literature articles, for the relief of failed back surgery syndrome, intractable low back, and limb pain. This was accomplished by examining the incidence of complications of the SCS systems used in the published literature.

1.9.2 Effectiveness

Three (3) clinical literature studies were used to assess the effectiveness of the Genesis Neurostimulation (IPG) System (Ohnmeiss et al. 1996, Villavicencio et al. 2000 and Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis Neurostimulation (IPG) System.

- The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. A total of 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP, isometric lower extremity testing, and patient questionnaires. An intent to treat analysis was also performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, SCS was effective in improving intractable leg pain.

  In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Also, 3 patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

- The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome) CRPS I and II, 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

  In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

- A retrospective analysis by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

  In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were of 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" (Hassenbusch SJ et al. 1995) 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 $\pm$ 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

  In the Hassenbusch study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

The output of the Genesis Neurostimulation (IPG) System when used with percutaneous lead models 3143, 3146, 3153, 3156, 3183, and 3186, surgical lead models 3222, 3240, 3244 and 3280 and extension models 3382, 3383, 3341, 3342 and 3343 is within the range of the output parameters of the SCSs and associated leads reported in the retrospective literature evaluation. The Genesis

Neurostimulation (IPG) System and the associated leads may produce a greater output when compared with the devices reported in the literature. Instructions for use will ensure that energy output is adeqaute to achieve optimum effectiveness.

1.9.3 Safety

Sixteen (16) studies, as listed in the references, were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis (IPG) Neurostimulation System. The studies included a total of 1253 patients. The following complications were seen in the retrospective clinical evaluation: lead migration, infection, hematoma, paralysis, cerebral spinal fluid (CSF) leak, over/under stimulation, pain over the implant, allergic reaction, skin erosion, lead breakage, hardware malfunction, loose connection, other biologic reaction specific to an IPG, and battery failure.

Table 2 -Summary of Risks Identified In the Literature Review

Risks	# of Patients	# of Events	% of Patients
Lead Migration	1059	144	13.6
Infection	1253	37	3.0
Epidural Hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF Leak	1253	6	0.5
Over/Under Stim	1059	27	2.6
Intermittent Stim	1059	0	0
Pain over Implant	1059	12	1.1
Allergic Reaction	1059	2	0.2
Skin Erosion	1059	1	0.1
Lead Breakage	1059	182	17.2
Hardware Malfunction	1059	32	3.0
Loose Connection	1059	10	1.0
Battery Failure	911	17	1.9
Other	1059	24	2.3

The above table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include both IPG and RF Systems. FDA believes that the clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

1.10 Conclusion Drawn from the Studies

The nonclinical laboratory testing performed on the IPG, battery, programmer and programming wand demonstrate that the individual components, as well as the combined system, are reliable and that the probable benefits to health from the use of the device outweigh any probable injury or illness from such use. Further, the nonclinical laboratory studies conducted by the applicant, when considered with the clinical experience reported in the public literature on similar SCS systems, provides reasonable assurance that the Genesis Neurostimulation (IPG) System is safe and effective when used to treat chronic intractable pain of the

trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome or intractable low back and leg pain.

1.11 CDRH Decision

Prior to the ANS, Inc. submission of PMA number P010032, the Genesis Neurostimulation (IPG) System was the subject of a reclassification petition submitted by ANS, Inc. on June 16, 1999. Although the request to reclassify this device type from class III (premarket approval) to class II (special controls) was subsequently denied by the Agency, much of the data and information submitted in this PMA had been carefully evaluated by FDA during the review of the reclassification petition. In fact, on September 17, 1999, FDA consulted with the Neurological Devices Panel (the Panel) during which time the Panel reviewed many of the nonclinical studies, as well as the clinical literature, that ANS, Inc. included in PMA number P010032 as evidence of their device's safety and effectiveness. While FDA disagreed with the Panel's recommendation that the device be reclassified from class III to class II, FDA acknowledged that considerable valid scientific evidence existed in the public domain that the applicant could use to streamline the PMA process and support approval of a PMA.

Upon completion of the evaluation of the information submitted in this PMA, FDA has concluded that the Genesis Neurostimulation (IPG) System is sufficiently similar to the SCS systems reported in literature in regard to intended use, targeted patient population, technology, device design, and electrical output characteristics, that the literature can provide a basis upon which the performance of the Genesis Neurostimulation (IPG) System can be judged. FDA has also concluded that the available published clinical studies constitute valid scientific evidence for the purposes of determining safety and effectiveness. FDA has determined that this evidence, when combined with the nonclinical data included in the PMA, provides reasonable assurance of the safety and effectiveness of the Genesis Neurostimulation (IPG) System for treating chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome or intractable low back and leg pain. Furthermore, FDA inspections of the manufacturing facilities demonstrated that all sites involved in the manufacture of the Genesis Neurostimulation (IPG) System are in compliance with the Quality System Regulation.

In arriving at this conclusion, FDA has taken into consideration, as required under section 205 of the Food and Drug Administration Modernization Act of 1997, the least burdensome means to market, while maintaining the statutory threshold for approval of a PMA, i.e., reasonable assurance of safety and effectiveness.

1.12 Approval Specifications (To be completed by FDA)

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.

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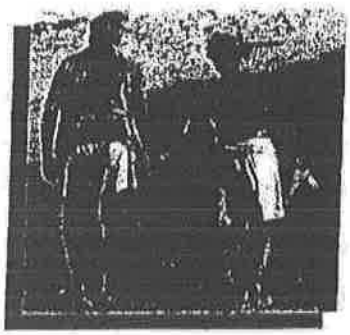
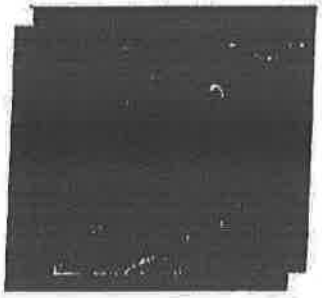
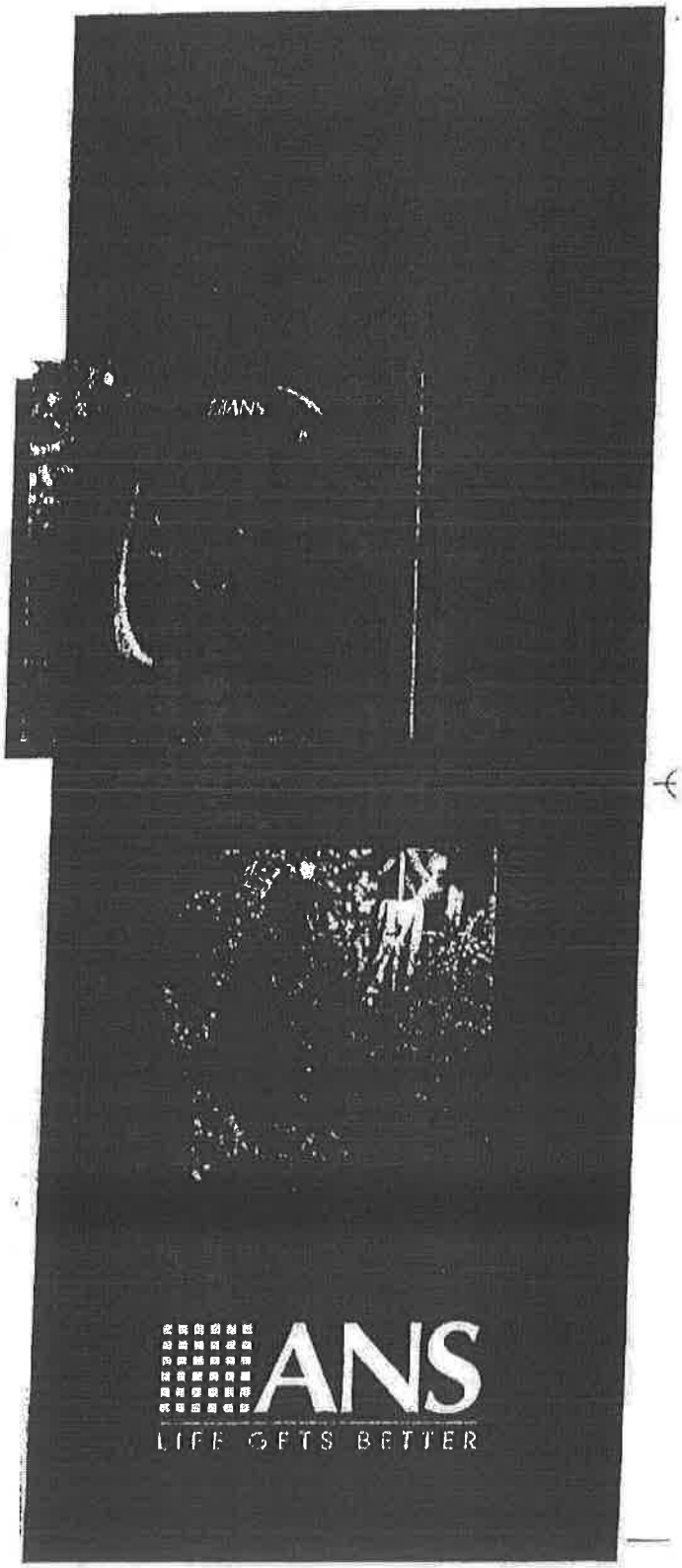
Genesis™

Neurostimulation System







Programmer User's Guide

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.

CONTENTS

PATIENT MANUAL

INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

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

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.

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.

PATIENT MANUAL

GENESIS (IPG) NEUROSTIMULATION SYSTEM CLINICAL SUMMARY

The safety and effectiveness of the Genesis (IPG) Neurostimulation System was determined based on available published clinical studies for similar totally implanted spinal cord stimulation systems. The ANS IPG device is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the Genesis (IPG) Neurostimulation System for use as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

EFFICACY EVALUATION

Three (3) clinical literature studies were used to assess the safety and effectiveness of the Genesis (IPG) Neurostimulation System (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis (IPG) Neuromodulation System.

The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP, isometric lower extremity testing, and patient questionnaires. An intent to treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, SCS was effective in improving intractable leg pain.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. 3 patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1to have the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome) CRPS I and II, 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period

period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain.. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis by Hassenbusch SJ et al. 1995 that included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were of 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" (Hassenbusch SJ et al. 1995) 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 + 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Sixteen (16) studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis (IPG) Neurostimulation System (all references in the Bibliography were used). The studies included a total of 1,253 patients.

SUMMARY OF RISKS IDENTIFIED IN THE RETROSPECTIVE CLINICAL STUDIES

Risks	*# of Patients*	*# of Events*	*% of Patients*
Lead Migration	1059	144	13.6
Infection	1253	37	3.0
Epidural Hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF Leak	1253	6	0.5
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Other	1059	24	2.3

The above table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

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Van de Kelft, E. and De La Porte, C. "Long-term pain relief during spinal cord stimulation. The effect of patient selection." Quality of Life Research 3(1994):21-27.

Villavicencio, A.T., J.C. Leveque, L. Rubin, K. Bulsara, and J.P. Gorecki. "Laminectomy versus percutaneous electrode placement for spinal cord stimulation." Neurosurgery 46(2000):399-406.

SYSTEM REGISTRATION

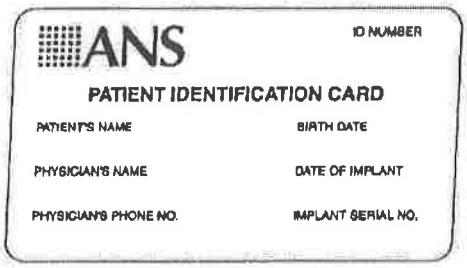
WHY SHOULD I REGISTER MY GENESIS NEUROSTIMULATION SYSTEM?

You will be sent a personal medical identification card. This small card:

- Identifies you as having an implanted medical device.
- Helps you pass through security systems like those in airports.
- Provides emergency information that allows your physician to be contacted.
- Activates the system warranty.

If you have questions about your card or system registration call ANS Customer Service at:

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



SERVICE INFORMATION

If your system needs service or repair, call ANS Customer Service toll-free at 1 (800) 727-7846 or (972) 309-8000 for instructions.

PATIENT ACCESSORIES AND ORDERING INFORMATION

To place an order, please contact ANS Customer Service toll-free at 1 (800) 727-7846 or (972) 309-8000.

Order Number	Product Description
1210	System Magnet
1232	Wand
1253	Battery Pack for AAA Batteries
1272	System Storage Case

PATIENT MANUAL

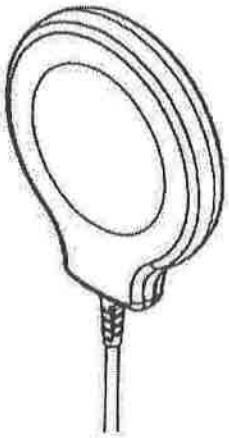
SYSTEM DESCRIPTION

The Genesis Neurostimulation System is an implanted pulse generator that delivers low-level electrical impulses to selected nerve fibers as a method of pain control that works well for certain types of chronic intractable pain. The electrical impulses are believed to stop pain messages from being transmitted to the brain and replaces areas of pain with a tingling or massaging sensation called paresthesia or stimulation.

The Genesis Neurostimulation System is intended to be used with ANS leads (3143, 3146, 3153, 3156, 3183, 3186, 3222, 3240, 3244, 3280) and extensions (3341, 3342, 3343, 3346, 3382, 3383, 3386).

THE GENESIS NEUROSTIMULATION SYSTEM CONSISTS OF FOUR PRIMARY COMPONENTS:

PATIENT PROGRAMMER
The Genesis Programmer enables full patient control through the selection of clinician prescribed programs for downloading to the IPG.



PROGRAMMING WAND
The wand provides two-way communication capability for uploading and downloading information between the IPG and the programmer.

IPG
The Genesis implanted pulse generator contains a battery and electronics for generating electrical impulses to the leads.

LEAD
The lead is a thin cable or small paddle that is implanted in the space above the spinal cord or near a selected nerve. Metal electrodes along the lead deliver low-level electrical impulses to the desired area.

DEFINITIONS

Amplitude — A measure of the strength of the stimulation signal generated by the IPG. Think of amplitude as the volume control on a radio. When you increase amplitude, the tingling sensation increases in strength. When you decrease amplitude, you feel less tingling.

MultiStim® Program — An optional stimulation program type comprised of two individual stim sets that provide stimulation to different body areas. The system activates each stim set automatically to provide overlapping stimulation coverage.

Paresthesia — The tingling or massaging sensation created by low-level electrical stimulation that can help mask the presence of certain types of chronic pain, also known as stimulation.

Program or Stimulation Program — A series of pre-defined stim sets programmed into the programmer that can be selected and used to meet changing pain requirements. The number of programs available is determined by your physician.

Programming — The selection and adjustment of stimulation parameters by your physician or clinical team. Once the best parameters for your pain control therapy are selected, they are stored in the programmer.

Stimulation Modes:

- **Continuous** — Provides constant stimulation until it is manually turned off or until 18 continuous hours of stimulation. The IPG will automatically turn off after 18 consecutive hours of stimulation to remind you to be conscious of battery usage and conserve the battery. Simply recommunicate with the IPG to resume stimulation and your IPG will provide stimulation for another 18 hours.
- **Cycle** — Automatically administers stimulation on and off times for controlled stimulation reducing battery usage time while maintaining optimal stimulation.
- **Bolus** — Allows for stimulation to be provided in set amounts of time. After stimulation elapses an automatic lock-out phase is entered. Upon completion of the lock-out period, the patient can bolus themselves again.

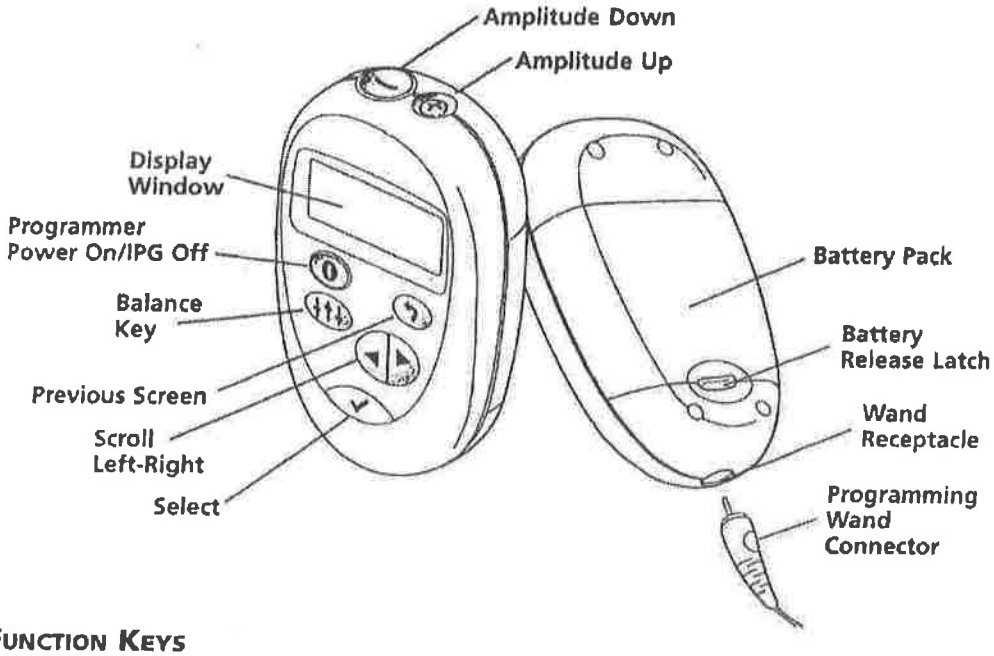
Stimulation Parameter — A setting that can be changed during programming by your physician or clinical team to optimize your stimulation therapy.

Stim or Stimulation — The massaging or tingling sensation known as paresthesia. It is created by low-level electrical stimulation that can help mask the presence of certain types of chronic pain.

Stim Set or Stimulation Set — A combination of stimulation parameters created by your physician or clinical team and programmed into your programmer to provide paresthesia to a specific anatomic location.

Single Program — A single set of stimulation parameters that can be designated to a specific stimulation mode for delivery of the selected therapy.

THE GENESIS PROGRAMMER



FUNCTION KEYS

Amplitude Down Key — Used to decrease the amplitude.

Amplitude Up Key — Used to increase the amplitude.

Programmer Power On/IPG Off Key — Used to turn the programmer power on and the IPG off. The programmer will automatically turn off after 1 minute of inactivity.

Previous Screen Key — Used to return the display to the previous screen or cancel the last screen action.

Scroll Keys — Used to move from one program to another on your display screen. You can also scroll from the Program to Menu Modes. Within the menu, you scroll across the choices displayed on the screen.

FUNCTION KEYS (CONTINUED)

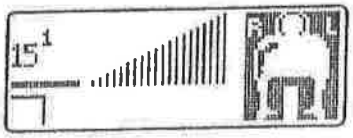
Balance or Stim-Set Balance Key — Used to make individual amplitude adjustments to selected stim sets.

NOTE: If amplitude is not active, an "invalid" symbol will be displayed when the Balance key is pressed.

Select Key — Used to select and activate menu changes. Also used to start the program that is shown on the display window. Pressing the Select key activates that program.

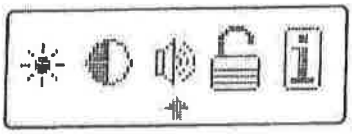
DISPLAY SCREENS AND INDICATORS

Operational Display Screen — The display window that is shown when the programmer is in the Stimulation (operation) mode (see page 13).



Program Selection Screen — The display window that is shown when the programmer is in the Program Selection mode (see page 19).

Menu — The display window that provides information and control of the display characteristics, sound qualities, and wand placement. It also provides information about your system (see page 25).

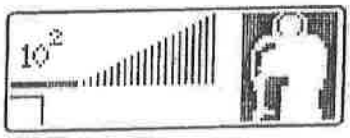


Stimulation (Stim) Diagram or Map — A map or diagram showing the areas of stimulation (paresthesia coverage) as a result of a selected program.

NOTE: This is an optional setting that may not be included as part of your therapy as determined by your physician. If this is the case, and a stimulation diagram is not included, the graphic to the right will be displayed.

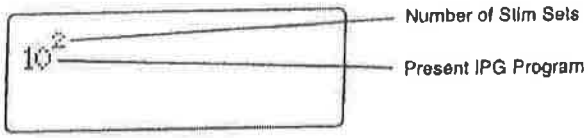
THE OPERATIONAL DISPLAY SCREEN

Your programmer's display screen is comprised of five components to assist you with its operation.

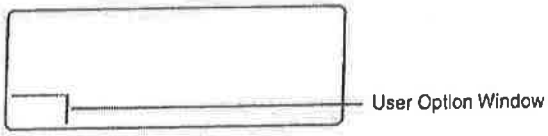


When any key is pressed, the display will "light-up." After 10 seconds the light will turn off. After 1 minute of inactivity the Programmer will automatically turn off. Press any key except the Power key to "light-up" the display screen.

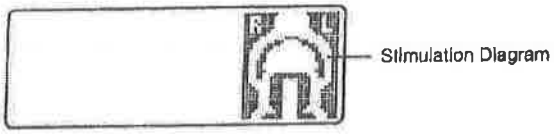
Program Number — The screen displays the present program number and number of stim sets in IPG.



User's Option Window — Shows current operational mode. **P** indicates program selection mode. **M** indicates menu selection mode. A blank user option window indicates normal stimulation operational mode.

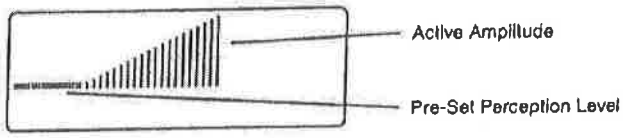


Stimulation Diagram — Graphically shows the area of stimulation coverage for a given program.

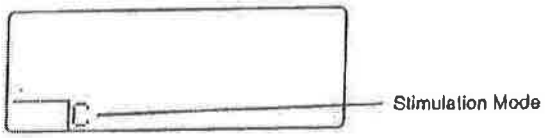


NOTE: If stimulation diagrams were not included as part of the therapy, then the following symbol will be displayed.

Active Amplitude — Graphically shows the current amplitude setting.



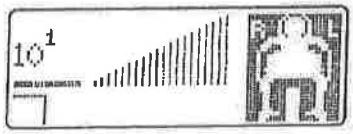
Stimulation Mode — Shows the stimulation mode (Continuous, Bolus, or Cycle). See stimulation mode section for specifics.



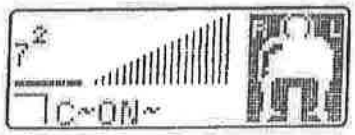
Stimulation Modes

The Genesis Neurostimulation System provides several delivery modes for patient therapy. These modes are Continuous, Cycle and Bolus mode. Each mode is described below.

Continuous Mode — This mode provides continuous stimulation to the patient. When the system is turned on, therapy is delivered until the system is manually turned off. Continuous mode does not display a visual prompt.



Cycle Mode — Cycling allows the physician to set selected time intervals for on and off times. This allows cycling of the therapy for battery conservation and stimulation refinement. Two screens will be displayed in this mode, either "Cycle On" mode or "Cycle Off" mode. The visual prompt for the cycle mode is "C." Samples of both are displayed below. Cycle times over one minute will display countdown times in On and Off phases.

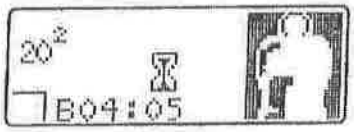


Cycle On

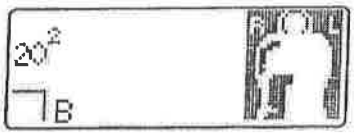
Cycle Off

Bolus Mode — Bolus mode allows the IPG to have predetermined on and lock-out (off) periods. This enables activation for a physician prescribed duration. Upon completion, the system will enter a preset lock-out period during which no stimulation is available. Stimulation can be activated again when the lock-out period is complete. There are three potential screens when the IPG is on. The visual prompt for the Bolus mode is "B."

Bolus On



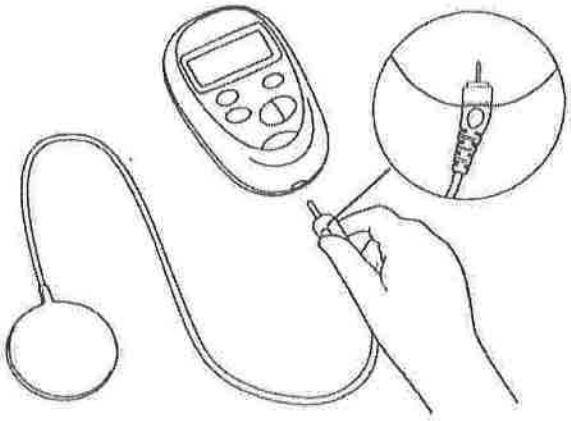
Bolus Lock Out



Bolus Ready

STARTING YOUR GENESIS SYSTEM

1. Plug the programming wand into the programmer. Grasp the wand plug and gently insert the pin into the opening in the bottom of the programmer. The plastic end should extend partly into the case, and you should feel a slight snap when the wand is properly connected.

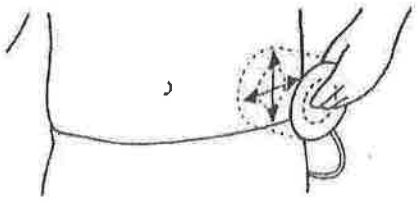


2. Turn on the programmer by pressing the red colored Programmer Power On/IPG Off Key ⏻.

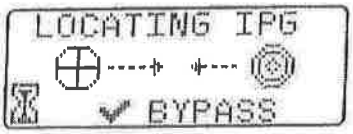
NOTE: The diagnostic screen shows for approximately two seconds.

POSITIONING THE WAND

1. Position the wand directly over the IPG to establish communication with the IPG.



NOTE: An audible tone will sound signifying active communication. This will last for 18 seconds or when the IPG is located, whichever is first.



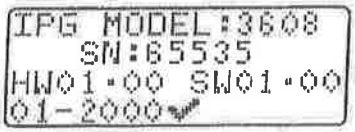
NOTE: Once communication is established, do not move the wand. Successful use of the Genesis Programmer is dependent upon wand position.

NOTE: IPG/Programmer communication can be interrupted by "electrical noise." For good communication, ensure you are away from electrical equipment (e.g., computer monitors).

2. Programmer/IPG communication is now being established.

NOTE: The program information presently stored and used in the IPG is being uploaded to the Programmer.

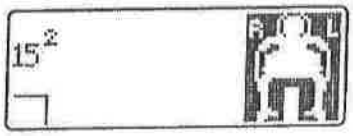
3. The IPG information screen is now displayed.



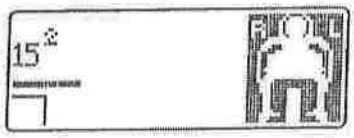
NOTE: Removal of the wand from the IPG site will discontinue IPG communications.

TO BEGIN STIMULATION

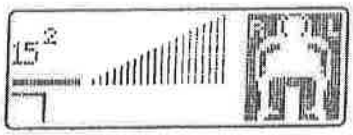
Immediately after the information screen is displayed, the operational screen (shown below) will appear. This screen indicates that the IPG is in the Off state, no stimulation is being provided and the device must be turned on for stimulation.



1. Push the Amplitude Up key ⊕ once. The amplitude will automatically advance to a preprogrammed perception level as indicated by the horizontal bar under the program number. This may take a few seconds to occur.



2. Press the Amplitude Up key ⊕ repeatedly or press and hold until stimulation is felt at a comfortable level. As the level of stimulation increases, the bars on the display rise. **You should feel increased stimulation.**



3. Reduce your level of stimulation by pressing the Amplitude Down key ⊖. You may adjust the stimulation level at any time by simply pushing the amplitude up or down keys. Their distinctive shape allows you to identify them without having to look at the programmer.

INTRODUCTION TO PROGRAM SELECTION* *(Optional Features)*

As part of your SCS therapy, your physician may have entered several stimulation programs into your programmer to utilize the Patient-Controlled Stimulation (PC-Stim®) feature. Each of these programs can include up to two stim sets that may change the quality of your sensation and/or the area of the body stimulated.

** This is an **optional feature** for specific pain conditions and **may not be included** as part of your therapy. Your physician will let you know if your therapy includes multiple stimulation programs.*

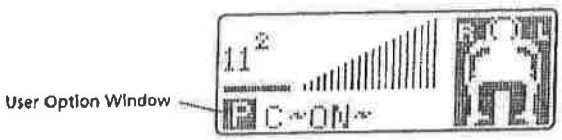
PROGRAM SELECTION

1. Press the Scroll keys ◄► until **P** is displayed in the User Option Window.

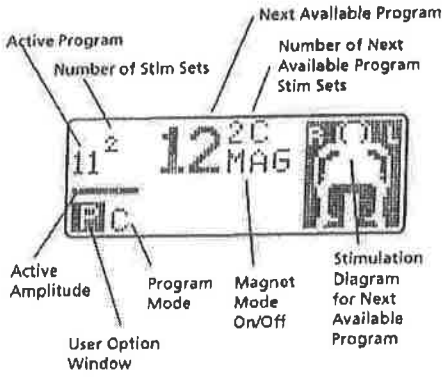
NOTE: If multiple programs are not loaded in the programmer, the **P** *will not be displayed.*

NOTE: The + and – keys are active during program review and if pressed will return the display to the Operational Display Screen and cause the amplitude to change as requested.

THE OPERATIONAL DISPLAY SCREEN



2. Press the Select key ✓ and the Program Selection Screen is displayed.



3. Press the Scroll keys to view other available programs and corresponding stimulation diagrams (if available).

THE PROGRAM SELECTION SCREEN

NOTE: If stimulation diagrams were not included as part of your therapy as determined by your physician, then the graphic below will be displayed.

4. Press the Select key to select the desired program. The display will return to the Operational Display Screen.

NOTE: When you change programs the amplitude will automatically be turned off.

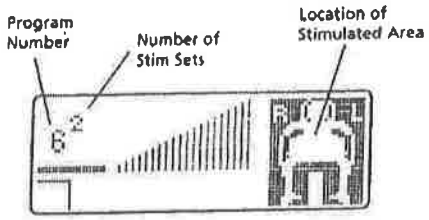
5. Press the Amplitude Up key to begin stimulation.

USING THE BALANCE CONTROL

The Balance Control allows you to adjust the amplitude of single and MultiStim programs to reach your optimal stimulation level. In either program type you may need more or less stimulation than your prescribed settings allow. The balance key enables you to manually bypass the pre-established settings. The balance key also allows you to adjust multiple stim sets within a MultiStim program, ensuring comfort for all areas covered.

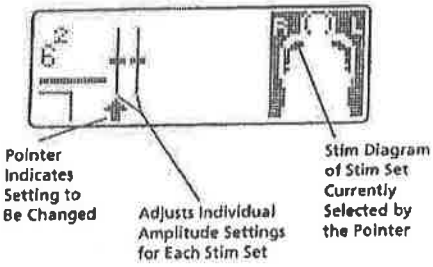
1. Press the Amplitude Up key ⊕ to begin stimulation.

A MULTISTIM PROGRAM

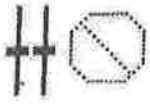


2. Push the Balance key ⊕⊕⊕.

TO FINE-TUNE AMPLITUDE BALANCE WITHIN A PROGRAM:

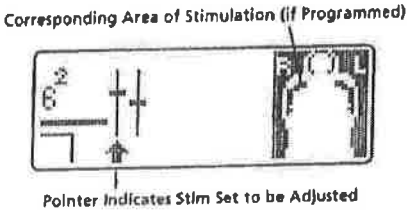


NOTE: If the amplitude is at zero, the screen below will be displayed. Increase the amplitude to adjust.



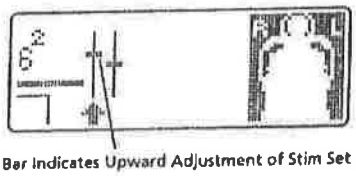
NOTE: A stimulation diagram will only appear when it has been entered by your clinician.

3. Press the Scroll keys to scroll through individual stim sets.



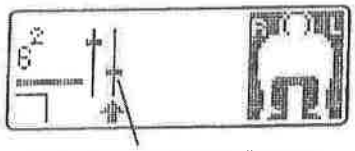
NOTE: Only one stim set adjustment bar will be displayed for a single type program.

4. Adjust the Amplitude by pressing the Amplitude Up key or Amplitude Down key.

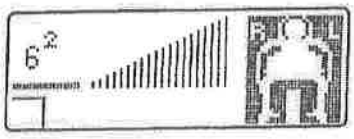


NOTE: This will only change the amplitude of the indicated stim set.

5. Repeat steps 1-4 for other stim set, if desired.



6. Press the Select key to activate the changes. **You may readjust individual stim sets as often as you like.** When you restart your system or load a new program, all stim set values revert back to the pre-set values established by your doctor.



NOTE: You may cancel any changes by pressing the Previous Screen key prior to pressing select.

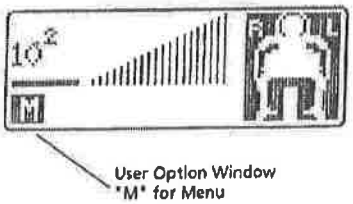
FINE-TUNING YOUR SYSTEM

The Menu Display Screen allows the fine-tuning of the visual display, sound volume and review of authorization and device status.

ENTERING THE MENU DISPLAY SCREEN

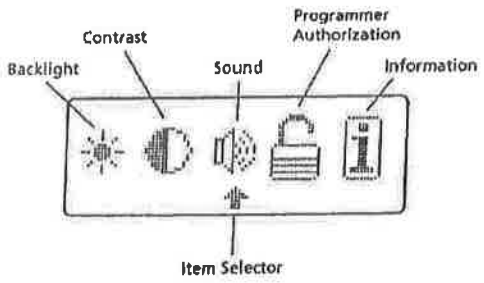
1. From the Operational Display Screen, press the Scroll keys ◀▶ until an M is displayed in the User Option Window.

THE OPERATIONAL DISPLAY SCREEN



2. Press the Select key ✓ and the Menu Screen will display.

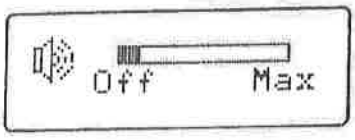
THE MENU SCREEN



NOTE: The amplitude level will remain constant while reviewing or changing all menu preferences.

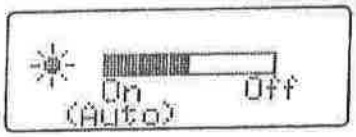
To Change or Adjust a Menu Preference:

1. Press the Scroll keys to highlight the desired preference, then press the Select key.

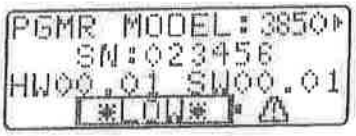


Sound — Press the Scroll keys to change the volume or turn sound off.

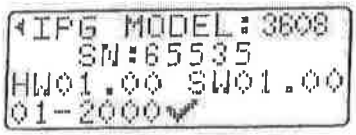
Contrast — Press the Scroll keys to change the display contrast.



BackLighting — Press the Scroll keys to change the backlighting of display.



Programmer Information — Displays information about the programmer.



IPG Information — Displays information about the IPG.

Programmer Authorization — Displays information about Genesis programmer and IPG authorization.

2. Press the Scroll keys to change preferences.
3. Upon completion of desired change, use the Select key to save the new setting.

NOTE: You may cancel any changes by pressing the Previous Screen key prior to pressing select.

NOTE: Use of the Amplitude Up key and Amplitude Down key will return you to the Operational Display Screen in addition to making the amplitude change.

PARTIALLY AUTHORIZED PROGRAMMERS

Your Genesis Programmer is specifically authorized to work with your IPG. It is fully capable of accessing and downloading all programs and stimulation parameters. If your programmer is not available, your physician can use another programmer to adjust the stimulation parameters in your IPG. When this occurs the screen below will be displayed on your programmer.

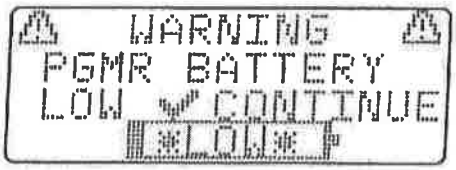
This shows that the program stored in the IPG does not match any of the programs stored in the programmer and was adjusted by another programmer. If the program is effective, have your physician or representative store the program in your Genesis Programmer.

NOTE: If you change programs without saving the "X" program, the "X" program will be lost.

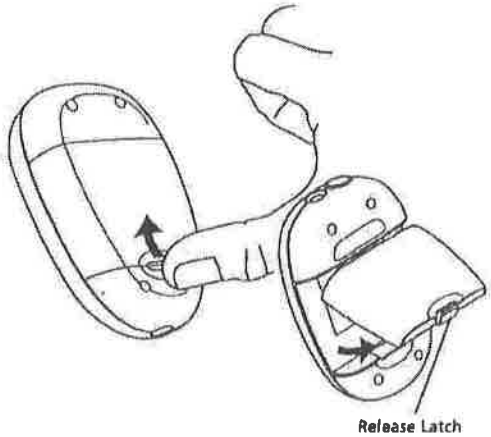
PROGRAMMER BATTERY INFORMATION

The programmer is powered by three AAA alkaline batteries contained in the battery pack.

When the battery power is low, an audio alarm will sound and this screen will be displayed. You should replace your AAA batteries.



BATTERY REMOVAL AND INSTALLATION

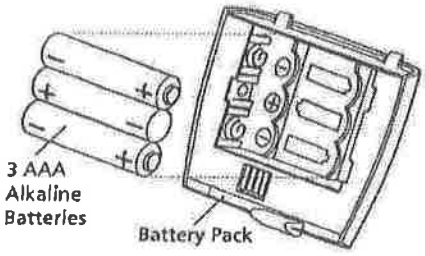


1. Ensure the programmer power is Off.
2. Push and hold the battery release latch on the bottom rear of the battery compartment.
3. Lift the battery pack from the programmer.

THE PROGRAMMER BATTERY PACK

The Genesis Programmer comes with three AAA batteries and a battery pack that fits into the programmer battery compartment.

1. Insert the batteries into the battery pack. Be sure to line up the + and – signs on the batteries with the signs in the battery compartment. The AAA batteries included with your Programmer are not rechargeable.

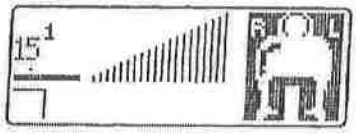


NOTE: If needed, additional AAA alkaline batteries can be obtained from retail stores.

TO END STIMULATION

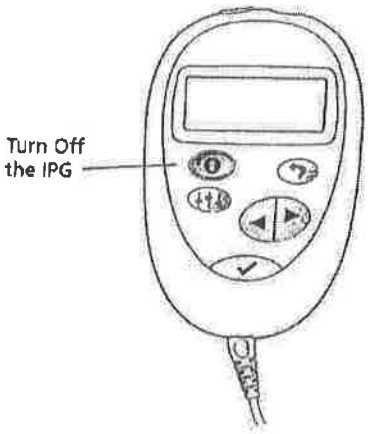
Your Genesis system can be turned off with the programmer or a magnet. To use the magnet refer to the next section. There are two methods to end stimulation with the Genesis programmer, both require you to establish communication with the IPG.

1. Ensure communication with the IPG. *(See Starting Your Genesis System on page 18.)*
2. Push the Amplitude Down key to reduce the level of stimulation until it is not felt.



OR

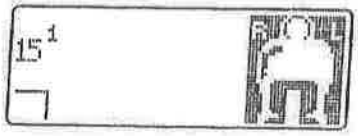
1. Turn off the IPG by pressing the Programmer Power On/IPG Off Key.



NOTE: *If you need to end stimulation immediately, press the Programmer Power On/IPG Off Key to turn the IPG off.*

NOTE: *The patient programmer will turn off automatically after 60 seconds of inactivity. There is no manual way to turn off the programmer once it is powered on except by removing the battery pack which is not recommended during normal operation.*

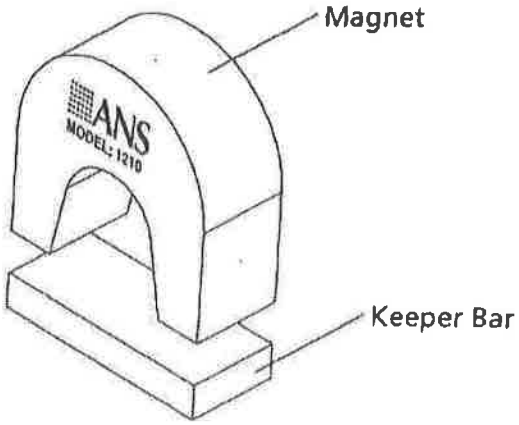
The programmer will display that stimulation is off.

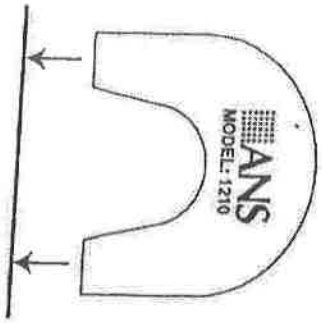


USING YOUR MAGNET

The Genesis system is provided with a magnet that is able to turn the IPG off at any time. The magnet can also be used to turn on the IPG when your physician activates the magnet mode. The IPG can be placed in two magnet modes, either magnet "Off" or magnet "On/Off." When selected, the magnet "On/Off" mode will be displayed as [MAG] in the Program Selection window. To use your magnet follow these steps:

1. Take the keeper bar off the magnet.





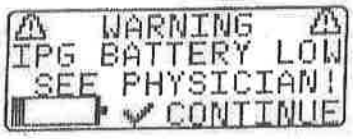
2. Place the magnet directly over the IPG.
3. Hold in place for 2 seconds.
4. Remove the magnet, replace the keeper bar and store the magnet.

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

GENESIS SYSTEM END OF LIFE

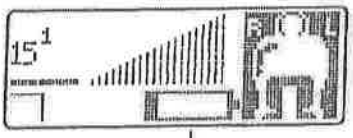
The Genesis IPG will provide you with warning before the battery is totally depleted and the system needs replacing. Battery life depends on the power output you require and the amount of time you use the device.

1. The Genesis system will display the screen below on the programmer when the IPG battery is low.



When you encounter this warning screen:

2. Press the Select key ✓ to continue with normal stimulation and contact your physician to inform him your IPG battery is low.
3. Upon continuing stimulation, a low battery icon will appear on your user's option screen to remind you to call your physician.



Low Battery Icon

CARING FOR YOUR PROGRAMMER

PROGRAMMER SYSTEM CARE

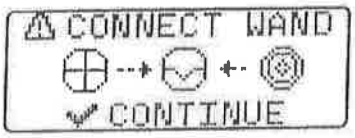
The programmer should be handled with care. It is a sensitive electronic device that can be damaged by rough handling, including dropping it on the floor.

- The programmer and wand are not waterproof; therefore limit activity that might cause them to get wet.
- Clean your programmer by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not submerge the programmer or wand in liquids or use a cloth that is saturated. Do not use alcohol, cleaning solutions or solvents to clean the programmer or wand.
- Do not allow the connector that plugs into the programmer to get wet. Do not pull on the wand cable to disconnect it from the programmer. Instead, grasp the connector where it plugs into the programmer and gently pull until it releases from the receptacle.
- Do not expose programmer to prolonged direct sunlight or extreme temperatures [below 14° F (–10° C) or above 131° F (55° C)].

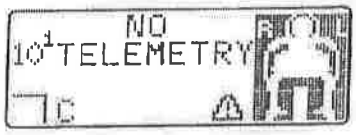
TROUBLESHOOTING

Diagnostic Messages

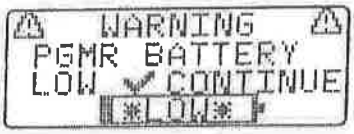
The programmer contains an automatic diagnostic program that continuously performs a system check during operation. If a malfunction or abnormal condition is detected relating to the programmer, IPG, or wand, a diagnostic screen is displayed and advises you of the situation and what to do next. The following are the common diagnostic screens:



Wand Connection Error — Check connection of the wand to programmer.



No Telemetry — IPG location was interrupted by pressing the Select key . No communication is established in this mode. Let the Programmer turn off and recommunicate with the IPG.



Programmer Batteries Low — Replace the batteries in the Programmer (see page 26).

IPG Battery Low — Press the Select key and call your physician to notify him of a low IPG battery (see page 31).

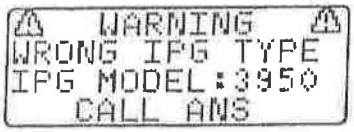
Diagnostic Error — Call ANS Customer Service for instructions.

System Error — Call ANS Customer Service for instructions.

Bad Program — Select another program or have your physician edit the present program.

IPG Communication Error — Reposition wand and press the Select key ✓.

NOTE: *IPG/Programmer communication can be interrupted by "electrical noise." For good communication, ensure you are away from electrical equipment (e.g., computer monitors).*



Wrong IPG Type — Call ANS Customer Service for instructions.

Changes In The Stimulation Sensation

During the recovery or healing period (which is usually 4-6 weeks), changes in the stimulation sensation can occur that may cause it to be perceived as more or less intense. Situations that may cause this include:

- Shifting your body position, such as lying down or leaning back in a chair, may cause the stimulation sensation to be more intense.
- Changing physical posture, such as leaning forward or arching your back, may cause the stimulation sensation to be less intense.
- Standing or walking may cause the stimulation sensation to be less intense.
- Straining to cough, or when having a bowel movement.
- Lifting an object heavier than a gallon of milk (8 pounds). Remember that lifting is to be avoided during the recovery period.

To decrease the possibility of experiencing uncomfortable stimulation, ANS recommends turning the amplitude down or the IPG off before assuming these positions.

After the recovery period, changes in stimulation should decrease with changes in posture or physical positions. However, changes can still occur when coughing, straining with a bowel movement or lifting an object. It is important to follow your physician's guidelines for physical activities and lifting.

If your stimulation pattern changes from your painful areas, or it becomes uncomfortable beyond your ability to control it by adjusting the amplitude, turn the IPG off and contact your physician.

What To Do If Something Seems Wrong

If you suspect that something may be wrong with your IPG, the following steps may help solve the problem:

1. Use your programmer to establish communication with your IPG.
2. Inspect the display screen for a diagnostic message.
3. Ensure the IPG is not in the cycle or bolus "Off" state (see page 16).
4. Check that the amplitude is adjusted to the correct and comfortable level.
5. If you still do not achieve the best results, call your physician's office. If the programmer does not operate, call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES

Problem/Symptom	Possible Cause	Possible Corrective Action
Uncomfortable Stimulation	Positional or inadvertent programming changes	Decrease amplitude. If unable to correct, turn IPG off and call physician's office.
No Stimulation	Amplitude set too low	Increase amplitude until comfortable stimulation is achieved.
	IPG in "off" phase	Check to see if the IPG is in Cycle or Bolus "off" phase. Wait until phase is completed. (See page 16.)
	Power is off	Check to see that IPG power is on.
	Depleted IPG battery	Call physician's office.
	Inadvertent programming change	Call physician's office.
	Program load error	Attempt to reload a new program. Call physician if ineffective.
	Implant Damage	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES *(continued)*

Problem/Symptom	Possible Cause	Possible Corrective Action
Intermittent Stimulation	Positional sensitivity	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust satisfactorily.
	Implantable system damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
Ineffective Stimulation	Positional changes	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES *(continued)*

Problem/Symptom	Possible Cause	Possible Corrective Action
Changes in Stimulation Coverage	Positional changes	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust satisfactorily.
No Control of IPG with Programmer	Wand positioned incorrectly	Reposition wand over the IPG.
	Wand not inserted properly	Reinsert wand.
	Noisy electrical environment	Move to another area and try again.
	Wand damaged	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
No Programmer Power	Depleted batteries	Replace Programmer batteries with new AAA batteries.
	Battery pack or AAA batteries not inserted properly	Reinsert battery pack or AAA batteries.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
No Programmer Display	Power is off due to automatic time out	Push the Programmer Power On/IPG Off Key .
	Depleted batteries	Replace Programmer batteries with new AAA batteries.

LIMITED WARRANTY

General Warning

A. Advanced Neuromodulation Systems, Inc. Genesis Neurostimulation Systems are comprised of implantable components, programmers and patient accessories. The patient accessories include wands, batteries and system magnet. The implantable components include leads/lead kits, IPG kits, extensions and accessories. Upon being implanted, these components must withstand exposure to an extremely hostile and unpredictable environment in the human body. The implanted components may fail during or following implantation into the body for any one or a number of reasons, including, but not limited to: medical complications, body rejection phenomena, lead breakage, or improper handling, implantation or use, or insulation breach.

B. Advanced Neuromodulation Systems, Inc. makes no representations or warranties that failure or cessation of function of any component, or the system, will not occur; that the body will not react adversely to implantation; or that medical complications will not develop.

Limited Warranty

A. LIMITATION OF WARRANTY

Advanced Neuromodulation Systems, Inc., 6501 Windcrest Dr., Ste. 100, Plano, TX 75024, warrants the Advanced Neuromodulation Systems, Inc.'s Genesis Neurostimulation System to be free from defects in material or workmanship within one (1) year from the date of implantation or ownership, subject to the terms and conditions contained in this warranty. Only patient-customers who receive an Advanced Neuromodulation Systems Genesis Neurostimulation System and return a properly completed warranty registration card to Advanced Neuromodulation Systems, Inc. within 60 days from the date of surgery may enforce this limited warranty.

B. THIS LIMITED WRITTEN WARRANTY CONTAINS THE FINAL, COMPLETE AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR ADVANCED NEURO-MODULATION SYSTEMS, INC. GENESIS NEURO-STIMULATION SYSTEMS, AND IT APPLIES IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES OR REPRESENTATIONS ON BEHALF OF ADVANCED NEUROMODULATION SYSTEMS, INC. This limitation may not apply to you because some states and countries prohibit the limitation or exclusion of implied warranties. You may have other rights under state law not specifically addressed in this limited warranty.

THIS LIMITED WARRANTY FOR THE GENESIS NEUROSTIMULATION SYSTEM DOES NOT APPLY TO:

1. Any damage caused by misuse, neglect, accident, modification, improper application, or from other than normal and ordinary use.
2. Any damage caused by any repair or attempted repair by one other than an authorized Advanced Neuromodulation Systems-trained technician.

3. Any damage resulting from failure to clean or use in accordance with the Operating Instructions and/or Services Manual furnished by Advanced Neuromodulation Systems.

C. LIMITATION OF DAMAGES

ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS LIABILITY FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF, OR IN CONNECTION WITH, THE USE OR PERFORMANCE OF THE SYSTEM, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT, WARRANTY OR OTHERWISE. This limitation of liability applies to all warranty claims. No waiver or amendment of this limited warranty shall be valid unless in writing signed by Advanced Neuromodulation Systems, Inc. Some states, and countries, do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

IMPLANTABLE COMPONENTS

A. Subject to Sections I and II and paragraph III(B), if any of the implantable components should fail to function due to a defect in material or workmanship during the warranty period, Advanced Neuromodulation Systems, Inc. will, at its option:

1. Replace the implantable component with an equivalent, or functionally equivalent, implantable component at no charge to the patient-consumer; or
2. Issue a credit to the patient-consumer for a replacement Advanced Neuromodulation System implantable component, the credit being equal to the net invoice price for the replaced implantable component.

B. For repair, replacement or credit under this limited warranty:

1. The implantable component must be implanted prior to the expiration date indicated on the component's packaging, and
2. If the implantable component is explanted, the patient-consumer, his or her authorized representative, physician or hospital, must return the component to Advanced Neuromodulation Systems. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a Return Merchandise Authorization number obtained from Customer Service to Advanced Neuromodulation Systems, Inc. within 30 days after explantation. If the implantable component is not explanted, the component's serial number or lot number must be provided within 30 days after discovery of the defect.
3. Upon Advanced Neuromodulation Systems Inc.'s receipt of the product, the returned implantable component shall become the exclusive property of Advanced Neuromodulation Systems, Inc.

PROGRAMMERS AND PATIENT ACCESSORIES

A. Subject to Sections I, II and paragraph IV(B), if any System programmer or patient accessory fails to function due to a defect in material or workmanship during the warranty period, Advanced Neuromodulation Systems, Inc. will, at its option:

1. Repair any defective part of the programmer or accessory at no charge to the patient-consumer; or
2. Replace the programmer or accessory with an equivalent, or functionally equivalent, programmer or accessory at no charge to the patient-consumer; or
3. Issue a credit to the patient-consumer for a replacement Advanced Neuromodulation Systems programmer or accessory in an amount equal to the net invoice price for the defective programmer or accessory.

B. For repair, replacement or credit under this limited warranty:

1. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a Return Merchandise Authorization number obtained from Customer Service to Advanced Neuromodulation Systems, Inc. within 30 days after discovery of the defect.
2. Upon Advanced Neuromodulation Systems, Inc.'s receipt of the product, the returned component shall become the exclusive property of Advanced Neuromodulation Systems, Inc

CUSTOMER SERVICE INFORMATION

ORDERING INFORMATION / ASSISTANCE

For questions or requests for assistance contact:

U.S.A. and Others:
ANS Customer Service
6501 Windcrest Drive, Suite 100
Plano, TX 75024

Tel: (800) 727-7846
(972) 309-8000
Fax: (972) 309-8150

Europe:
ANS European Representative
12 Squirrel Rise, Marlow Bottom
Buckinghamshire
SL7 3PN United Kingdom

NOTES

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ANS
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100 / Plano, Texas 75024
(800) 727-7846 / (972) 309-8000 / www.ans-medical.com

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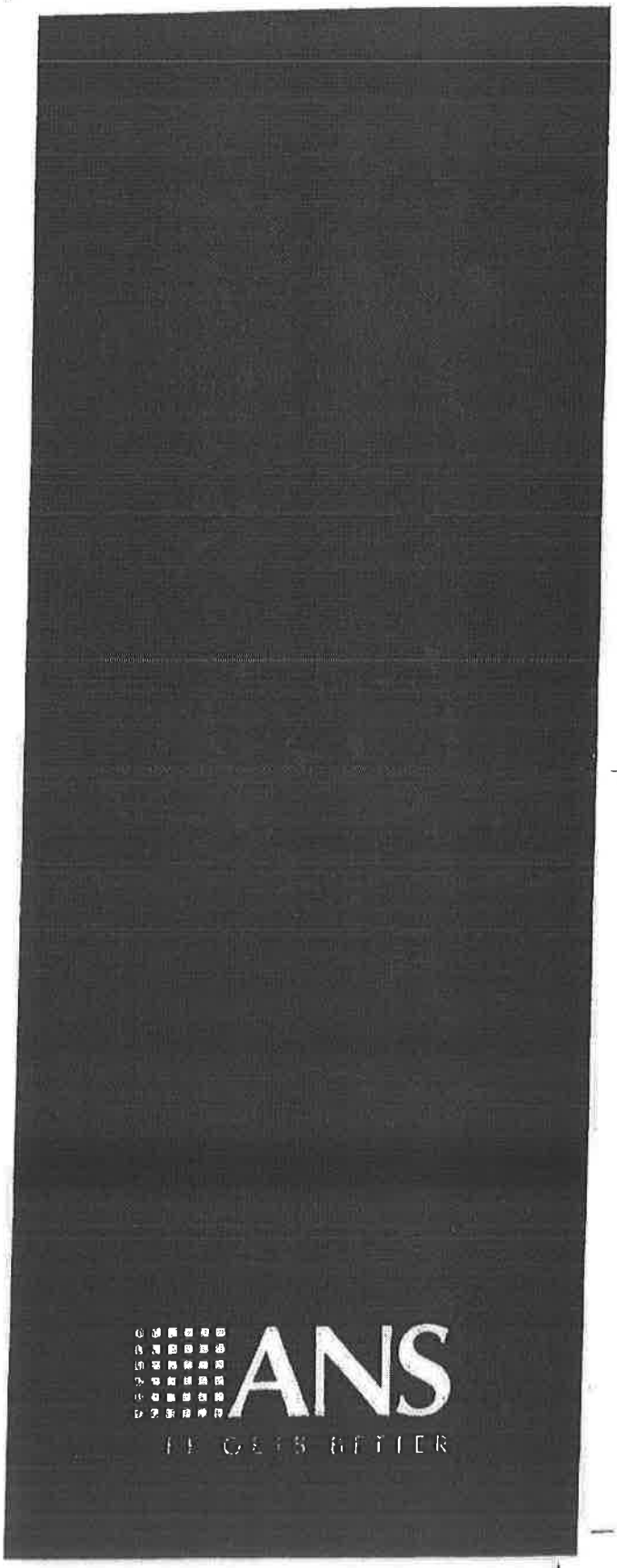
NOV 01

Genesis™ Neurostimulation System



Clinician's Manual

ABOUT THIS MANUAL

This manual is intended to explain the operation of the ANS Genesis™ System. It includes information about system components, the implant procedure, and device programming. The system includes the following components:

3608	8-Channel Implantable Pulse Generator
3143	Quattrode® Percutaneous Lead Kit, 30cm, 3/4 Spacing
3146	Quattrode® Percutaneous Lead Kit, 60cm, 3/4 Spacing
3153	Quattrode® Percutaneous Lead Kit, 30cm, 3/6 Spacing
3156	Quattrode® Percutaneous Lead Kit, 60cm, 3/6 Spacing
3183	Octrode® Percutaneous Lead Kit, 30cm
3186	Octrode® Percutaneous Lead Kit, 60cm
3222	Lamitrode® 22 Surgical Lead Kit, 60cm
3240	Lamitrode® 4 Surgical Lead Kit, 60cm
3244	Lamitrode® 44 Surgical Lead Kit, 60cm
3280	Lamitrode® 8 Surgical Lead Kit, 60cm
3382	Extension, 20cm
3383	Extension, 30cm
3386	Extension, 60cm
3341	Dual Extension, 10cm
3342	Dual Extension, 20cm
3343	Dual Extension, 30cm
3346	Dual Extension, 60cm
3810	PainDoc® Computerized Support System
3850	Genesis Programmer
1210	Patient Magnet
1232	Programmer Wand
1253	Battery Pack for AAA Batteries
1272	System Storage Case

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

CONTENTS PAGE

CONTENTS *(Continued)* **PAGE**

THE GENESIS IPG SYSTEM

The Genesis™ System is a multi-programmable implantable neurostimulation system designed to deliver low-intensity, electrical impulses to nerve structures. The system consists of an implantable pulse generator (IPG), an implanted lead(s) and a patient programmer.

The electrical impulses travel to the leads, which are connected to the IPG, and are delivered to selected nerve fibers in order to provide therapeutic stimulation. The patient programmer enables the patient to adjust current stimulation parameters and select new programs for customized therapy.

SYMBOLS AND DEFINITIONS

The following symbols are used in this manual or on the product package:

⚠	Notice for the reader to pay special attention to the details which follow
SN	Denotes serial number
⧗	Denotes expiration date
⊗	Denotes for single use only
LOT	Denotes batch code
	Denotes date of manufacture
LATEX FREE	Denotes latex free

CONTENTS OF PACKAGE

ANS neurostimulation devices, leads, and accessories have been sterilized using ethylene (EtO) oxide gas before shipment and are supplied in sterile packaging to permit direct introduction into the operative field. The Programmer is supplied unsterile. An expiration date (or use-before date) is marked on the label of each package.

The package contents of the Genesis IPG Kits are as follows:

MODEL 3608	
1 each	IPG
2 each	Connector Strain Reliefs
1 each	Torque Wrench
1 each	Tunneling Tool
1 each	Clinician Manual
1 each	Registration Card

The package contents of the Patient Programmer Kit are as follows:

MODEL 3850			
1 each	Genesis Programmer	1 each	Carrying Case
1 each	Battery Pack	1 each	Patient Manual
3 each	AAA Batteries	1 each	Patient Video
1 each	Programming Wand	1 each	Patient Information Packet
1 each	Registration Card	1 each	Magnet

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.

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

⚠ WARNINGS

Spinal Cord Stimulation (SCS) should not be used on patients that are poor surgical risks, those with multiple illnesses or active general infections.

Diathermy Therapy – Do not use short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. 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." All patients are advised to inform their health care professional that they should not be exposed to diathermy treatment.

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

Magnetic Resonance Imaging (MRI) – Patients with implanted neurostimulation systems should not be subjected to MRI. The electromagnetic field generated by an MRI may dislodge implanted components, damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Explosive or Flammable Gases – Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present. The operation of the patient programmer could cause them to ignite, causing severe burns, injury or death.

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 – Patients should be instructed to 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.

⚠ WARNINGS *(Continued)*

Operation of Machinery and Equipment – Patients should not operate potentially dangerous machinery, power tools, vehicles, climb ladders, etc., when the IPG is operating. Postural changes or abrupt movement could alter the perception of stimulation intensity and cause patients to fall or lose control of equipment or vehicles, injure others, or bring injury upon themselves.

Postural Changes – Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting of arms over head, or exercising. If unpleasant sensations occur, the IPG should be turned off immediately.

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.

Device Components – The use of non-ANS components with this system may result in damage to the system and increased risk to the patient.

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

PRECAUTIONS

General Precautions

Physician Training – Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient Selection – It is extremely important to appropriately select patients for spinal cord stimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the stimulator.

Infection – It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of Two Systems – If two systems are implanted, ensure that at least 8 in. (20 cm) separates the implanted IPGs to minimize the possibility of interference during programming.

Implantation of Multiple Leads – If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

High Stimulation Outputs – Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.

Stimulation Parameters – Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs except under direct orders from their physician.

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

FCC Statement – FCC ID: PX2001 – 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.

Sterilization and Storage

Single-Use Device – The implanted components of the ANS Genesis IPG System are intended for a single-use only. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Storage Temperature – Store system components between -10°C (14°F) and 55°C (131°F) because temperatures outside this range can damage components.

Storage Humidity – Store components between 10% and 90% humidity.

Handling, Implementation, and Explantation

Expiration Date – Do not implant a device if the use-before date has expired.

Care and Handling of Components – Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting or the use of sharp instruments may damage and cause failure of the component.

Package and Component Damage – Do not implant a device if the sterile package or components show signs of damage, the sterile seal is ruptured, or if contamination is suspected for any reason. Return to ANS for evaluation.

Exposure to Body Fluids or Saline – Prior to connection, exposure of the metal contacts, on the connection end of the lead or extension, to body fluids or saline can lead to corrosion. If this occurs, clean with sterile, deionized or distilled water and dry completely prior to lead connection and subsequent implantation.

System Testing – The operation of the system should always be tested after implantation and before the patient leaves the surgery suite to assure correct operation.

Component Disposal – Return all explanted components to ANS for safe disposal.

Hospital and Medical Environments

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.

Electrosurgery Devices – Electrosurgery devices should not be used in close proximity to an implanted neurostimulation IPG or lead(s). Contact between an active electrode and an implanted IPG, lead or extension can cause direct stimulation of the spinal cord and cause severe injury to the patient. If use of electrocautery is necessary turn the IPG off.

Home and Occupational Environments

Electromagnetic Interference (EMI) – Certain 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 sufficient EMI to interfere with the neurostimulation system operation if approached too closely.

PROGRAMMING

The ANS Genesis System can be programmed manually with the Genesis Programmer. Manual programming with the Genesis Programmer is discussed on page 40.

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.
- 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.

GENESIS (IPG) NEUROSTIMULATION SYSTEM CLINICAL SUMMARY

The safety and effectiveness of the Genesis (IPG) Neurostimulation System was determined based on available published clinical studies for similar totally implanted spinal cord stimulation systems. The ANS IPG device is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the Genesis (IPG) Neurostimulation System for use as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to assess the safety and effectiveness of the Genesis (IPG) Neurostimulation System (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis (IPG) Neuromodulation System.

The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP, isometric lower extremity testing, and patient questionnaires. An intent to treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, SCS was effective in improving intractable leg pain.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1to have the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome) CRPS I and II, 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis by Hassenbusch SJ et al. 1995 that included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were of 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" (Hassenbusch SJ et al. 1995) 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 + 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Sixteen (16) studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis (IPG) Neurostimulation System (all references in the Bibliography were used). The studies included a total of 1253 patients.

SUMMARY OF RISKS IDENTIFIED IN THE RETROSPECTIVE CLINICAL STUDIES

Risks	# of Patients	# of Events	% of Patients
Lead Migration	1059	144	13.6
Infection	1253	37	3.0
Epidural Hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF Leak	1253	6	0.5
Over/Under Stim	1059	27	2.6
Intermittent Stim	1059	0	0
Pain over Implant	1059	12	1.1
Allergic Reaction	1059	2	0.2
Skin Erosion	1059	1	0.1
Lead Breakage	1059	182	17.2
Hardware Malfunction	1059	32	3.0
Loose Connection	1059	10	1.0
Battery Failure	911	17	1.9
Other	1059	24	2.3

The above table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

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INDIVIDUALIZATION OF TREATMENT

Best results are obtained when the patient is fully informed about the therapy risks and benefits, implantation procedure, follow-up requirements, and self-care responsibilities. Spinal cord stimulation is appropriate for patients who meet the following criteria:

- Patients with chronic pain of the trunk or limbs, whose pain is physiological in origin and of the type treatable with spinal cord stimulation.
- Patients who are able to operate the device.
- Patients who are suitable candidates for surgery and free of active general infections.

Before a spinal cord stimulation system is implanted, the following conditions should be met:

- Patients have undergone a successful trial screening period.
- Patients have demonstrated a willingness to participate in the treatment protocol.

USE IN SPECIFIC POPULATIONS

The safety and efficacy of this device has not been established for uses not covered in the "Indications for Use" section of this manual or in patients who are:

- Pregnant or nursing
- Pediatric

PATIENT COUNSELING INFORMATION

The patient should be given simple and practical instructions regarding the operation and care of the SCS system. Guidelines should also be given about how posture and activity can affect stimulation as well as under what circumstances the physician should be contacted regarding device problems. Other patient instructions should include:

- Never operate the stimulator while driving a vehicle, operating power tools, or engaging in any other potentially hazardous activity. Postural changes or abrupt movement could alter the perception of stimulation intensity and cause patients to lose their balance or lose control of the equipment or vehicle.
- 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. Caution should be exercised when approaching such a device and assistance should be requested to bypass the device by presenting their Patient ID Card. 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.

- 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 pattern (especially with leads in the cervical area) resulting in ineffective stimulation.
- Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting of arms over head, or exercising.
- Inspect the implant site frequently and contact the physician if redness, swelling or painful sensation occurs.
- If unpleasant stimulation sensations occur, the system should be immediately turned off.
- Amplitude and program selection are the only parameters that should be changed as a matter of everyday usage. Other parameter changes should be made only with permission of the physician.
- As amplitude, frequency, or pulse width is increased IPG battery life will be reduced.

SYSTEM DESCRIPTION

The Genesis IPG System consists of three primary components: the IPG, lead(s), and programmer.

The Genesis Neurostimulation System is intended to be used with ANS leads (3143, 3146, 3153, 3156, 3183, 3186, 3222, 3240, 3244, 3280) and extensions (3341, 3342, 3343, 3346, 3382, 3383, 3386).

IMPLANTABLE PULSE GENERATOR (IPG)

The Genesis IPG is an 8-channel multi-programmable system designed to be connected to one lead of 4 or 8 electrodes or one extension capable of dual leads (see Appendix C). It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant current electrical stimulation. Stimulation programs can be delivered as either single stimulation or MultiStim® programs depending on the patient's needs.

The IPG is insulated on all sides except the side with markings. This allows the IPG to be used as an anode to facilitate unipolar stimulation. Ensure that the marked side is implanted up, away from any muscle.

In addition to the IPG, Genesis kits contain the following:

- **Connector Strain Relief(s)** (Model #1109) – Placed over the lead and inserted into the IPG connector assembly to function as a strain relief for the lead at the juncture where it exits the IPG connection
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel for routing the lead to the IPG site

LEADS

The leads are available in two configurations: percutaneous or surgical. Each lead consists of a variety of platinum iridium electrodes on the distal end connected by individually insulated wires to platinum iridium contact bands on the proximal end. The insulated wires are covered by a biocompatible polyurethane.

Percutaneous leads are designed for introduction into the epidural space using a special needle. The lead assembly consists of 4 or 8 cylindrical electrodes spaced at precise intervals. Percutaneous leads are supplied with a stylet to aid in positioning. Surgical leads are designed to be placed via a small incision or mini-laminotomy procedure. These leads consist of 4 or 8 plate-type electrodes, embedded in a silicone paddle. Lead specifications are listed in Appendix B on pages 57 and 58.

In addition to the lead, ANS percutaneous lead kits contain the following:

- **Guide Wire** (Model #1102) – Used to establish an appropriate pathway for the lead in the epidural space. The guide wire is 50 cm (20") in length
- **Trial Cable** (Model #3008) – Used to connect the lead to a test stimulator for intra-operative testing or for an extended trial procedure
- **Lead Anchor(s)** (Model #1105, #1106)– Made of silicone and used to secure the lead(s) to connective tissue for stability
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel to route the lead(s) to the IPG site
- **Epidural Needle** (Model #1114, #1115, #1116) – Special 14-gauge needle designed for insertion of the percutaneous leads into the epidural space
- **Introde-AK™ Lead Introducer** (Model #1103) – Radiopaque sheath designed to facilitate the insertion of the percutaneous lead to the epidural space and placement at the appropriate site
- **Lead Stylet(s)** (Model #1121, #1122, #1123, #1124) – Inserted in the lead body to assist in steering and positioning
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension

In addition to a lead, the ANS surgical lead kits contain the following:

- **Lead Anchor(s)** (Model #1105, #1106) – Made of silicone and used to secure the lead(s) for stability
- **Trial Cable** (Model #3008) – Used to connect the lead to test stimulator for intra-operative testing or an extended trial procedure
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel for routing the lead(s) to the IPG site
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension

PROGRAMMER

The Genesis Programmer controls the creation and adjustment of all programming parameters. Powered by three AAA batteries, the programmer communicates through the use of radio-frequency signals from the programmer wand to the implanted IPG. The programmer allows clinicians programming capability.

It also provides the IPG patient with Patient-Controlled Stimulation (PC-Stim®), empowering them to choose between several prescribed programs within the programmer memory.

X-Ray Identification

X-Ray identification allows the identification of the manufacturer and IPG model number. With standard x-ray procedures, the code inside the connector block is visible. For the ANS Genesis Model 3608, the code is ANS AXX, where "XX" designates the year of manufacture.

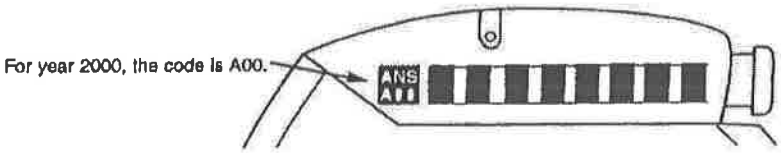

FIGURE 1

STERILIZATION INFORMATION

ANS pulse generator, leads, and accessories have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the operative field. The patient programmer is supplied unsterile. An expiration date (or use-before date) is marked on the label of each package.

CAUTION: ANS implantable components are intended for single use only. Do not resterilize.

SUGGESTED IMPLANT GUIDELINES

The physician should carefully review the following suggested guidelines for implantation of a Genesis IPG System. If a multiple-lead system is being implanted, repeat the appropriate steps for each lead.

Percutaneous Lead Placement

Percutaneous leads are designed for introduction into the dorsal epidural space using a special needle, guide wire and the optional Introde-AK (Introde) lead introducer. Each percutaneous lead is packaged with the accessories required to place the lead percutaneously (see Appendix A for specifications).

Implantation of a percutaneous lead should always be done with the aid of fluoroscopy. The physician should externally measure and determine the length of lead required to extend from the appropriate spinal level to the predetermined location of the implanted IPG. The appropriate vertebral level for needle entry should be identified and marked (Figure 2) to allow approximately 20 cm of the lead to lie in the epidural space. This will facilitate stabilization of the lead and electrodes following implantation. Typical entry levels for lead target sites include:

ANS
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100 / Plano, Texas 75024
(800) 727-7846 / (972) 309-8000 / www.ans-medical.com

0115-01-A

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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

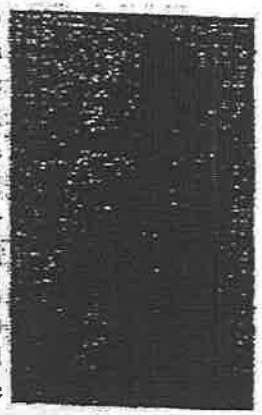
Over the last 20 years, thousands of people with severe chronic pain have been treated successfully with spinal cord stimulation (SCS).

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

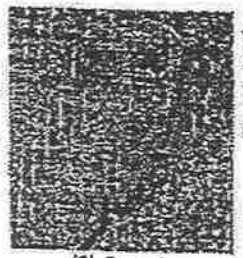
The Genesis Neurostimulation System is an implanted pulse generator (IPG) used for spinal cord stimulation. Genesis is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back 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.

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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.

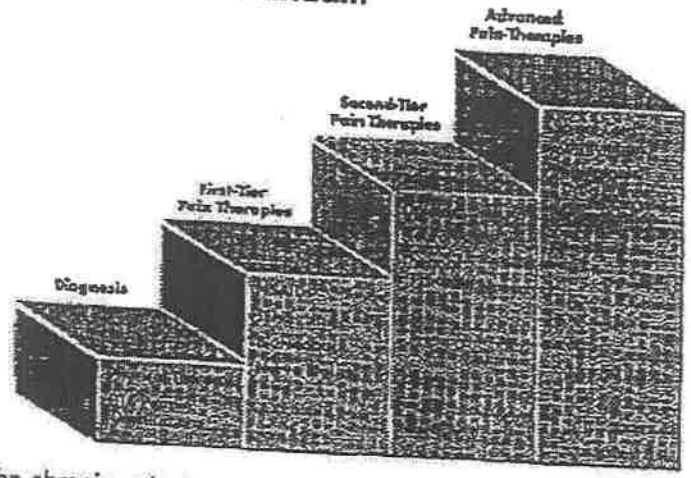
Can I travel with the stimulator?

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.

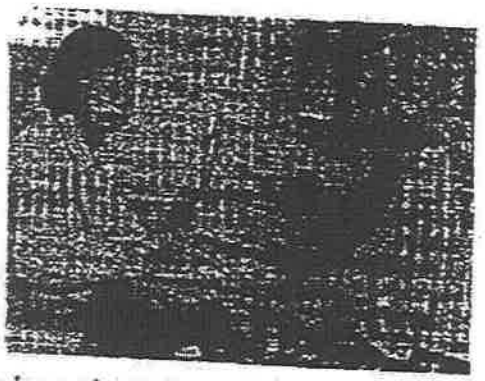
It is important to know that it is a generalized treatment strategy only, and that it can vary depending on your condition, your response to previous treatments and the recommendation of your pain physician

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 sympathec-tomy (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.*

NOTES

INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

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 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.

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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.

FCCStatement — 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.

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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.

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

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EXHIBIT 4