IMTHERA

aura® 6000

THN Sleep Therapy® System

Implant Manual

CE 0344 2012

Explanation of symbols on product or package labeling

REF	Model number
SN	Serial number
	Manufacturing date
	Manufacturer
	Use by
	Caution: Consult instructions for use
	Consult instructions for use
	Do not reuse
	Do not use if package damaged
	Storage temperature
STERILE EO	Sterilization: ethylene-oxide gas
IPG	Implantable pulse generator
LEAD	Lead length
	Non-pyrogenic
CE	Conformite Europeene (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0344) and R&TTE Directive 1995/5/EC
	Operating Instructions

IMTHERA

Manufacturer

ImThera Medical, Inc.
12555 High Bluff Drive, #310
San Diego, CA 92130 USA

Authorized Representative in the European Community

Cormedics Medizintechnik GmbH
Bahnhofstrasse 32
82041 Deisenhofen Germany

LIMITED WARRANTY

ImThera Medical, Inc., (referred to as ImThera) warrants to the patient who receives an aura6000 System (referred to as "aura6000") that the aura6000 will be free from defects in workmanship and materials for a period of one year from the date of surgical implant. This warranty applies only to the patient who has the implanted device and no other person or entity. If the aura6000 fails to function within normal ranges within one year after the date it is implanted, ImThera will repair or replace the aura6000 component with a functionally equivalent device made by ImThera. No other relief whatsoever is available under this limited warranty. The limited warranty for a repaired or replacement aura6000 will last only for one year from the date of surgical implant of the original aura6000. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration form must be completed and returned to ImThera within 30 days of surgery.
2. The device must be implanted before the "use before" date.
3. Failure of the device must be confirmed by ImThera.
4. The device must be returned to ImThera (or ImThera's authorized agent) within 30 days after it fails to function within normal ranges. That device becomes ImThera's property.
5. This limited warranty does not include failures to function within normal ranges caused by:
   a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as "Acts of God";
   b) accident, misuse, abuse, negligence, or the customer's failure to operate the aura6000 in accordance with manufacturer's instructions;
   c) unauthorized attempts to repair, maintain, or modify the aura6000 by the patient or any unauthorized third party; or
   d) attaching equipment to the aura6000 that is not supplied or expressly authorized by ImThera.

This limited warranty is the only warranty that applies to the aura6000, and ImThera expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose. Under this limited warranty, ImThera will be responsible only for repair or replacement of the aura6000 with a functionally equivalent device made by ImThera and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the aura6000, whether the claim is based on warranty, contract, tort or any other theory.

Any translation of this Limited Warrant is done for local requirements and/or convenience only. In the event of a dispute between the English and any non-English versions, the English version of this Limited Warranty shall govern.

Interference Type / Description	How to Minimize Effects
EMI	
Conductive current—current introduced by something touching the body, e.g. electrocautery, defibrillation.	Turn the device off. Keep the IPG/lead out of the conductive path. In surgery, use only bipolar electrocautery. Do not place external defibrillator paddles over the IPG.
Induced/coupled current—current introduced by an electric or magnetic field where the energy travels through the air (no physical contact).	Lead wires will act as an antenna to electric fields, and lead loops will act to "pickup" magnetic fields. The electric/magnetic field strength decreases with distance, so move away from EMI sources to reduce EMI effects.
Radiated energy—energy traveling through the air, e.g. x-rays, radioactive materials.	High dose radiation can temporarily or permanently damage an IPG or lead. If possible, avoid placing the IPG/lead directly in the radiation beam. This type of damage to the device may not be immediately detectable.
Mechanical	
Mechanical interference—pressure waves generated by vibrating or ultrasonic transducers.	Avoid placing the IPG/lead directly in the path of the pressure beam. The beam may damage the device, or the device may inadvertently concentrate therapeutic ultrasound and cause harm.

CONTENTS

APPENDIX A: ELECTROMAGNETIC INTERFERENCE AND MECHANICAL ENERGY

Electromagnetic interference (EMI) is a field (electrical, magnetic or both) that can be produced by various types of electrical devices found in the home, work or medical environment. There are three types of EMI—conductive current, induced/coupled current and radiated energy—which can occur alone or in combination and potentially produce enough interference to:

- turn the IPG on or off;
- change the stimulation parameters;
- temporarily change the IPG output;
- cause a shocking/jolting sensation to the patient;
- induce/conduct excessive current in the lead causing tissue damage; or
- damage the IPG or lead.

In addition, certain mechanical devices, e.g. ultrasound, may produce mechanical energy that is strong enough to be a source of interference.

Whenever possible, the device should first be deactivated, or care should be taken to monitor the functioning of the device during the initial stages of, and after exposure to, any procedure that produces EMI or mechanical energy.

SPECIFICATIONS AND TECHNICAL DATA

IPG Characteristics	
Case	Titanium
Header	Epoxy
Dimensions	45 x 32 x 8 mm
Weight	16 g
Lead connector	Ring type, 6 contact
Retention strength	> 10 N
Radiopaque marking	AURA 6000
Telemetry type	MICS 400 MHz
Storage temperature	-10 to 55 °C
Battery	Lithium-ion secondary cell
Capacity	50 mA·h
Charging	Inductive coupling
Estimated Lifetime (to EOL)	15 years
Stimulation Parameters	
Waveform	Biphasic, charge-balanced with cathodic phase pulse 4x amplitude and ¼ duration of the anodic phase.
Output current amplitude	0 to 3000 µA
Pulse frequency	1 to 100 Hz
Pulse width	50 to 1000 µsec
Lead Characteristics	
Electrode type	Self-sizing cuff
Electrode pattern	6 contacts, 50º radial spacing
Electrode cuff inner diameter	2.5 mm
Connector	1.5 mm diameter, 2.3 mm contact spacing
Overall length	25 cm
Material	Stainless steel, silicone, platinum-iridium, polyurethane
Storage temperature	-10 to 55 °C

Declaration of Conformity

ImThera Medical declares that this product is in conformity with the essential requirements of Directive 1995/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices. For additional information, contact ImThera Technical Services.

ABOUT THIS MANUAL

This manual provides information about the implantable pulse generator (IPG) and lead components of the *aura6000*® targeted hypoglossal neurostimulation (THN™) Sleep Therapy System.

Refer to the information packaged with the other system components for contraindications, warnings, precautions, adverse events and other additional information associated with the use of those devices.

DEVICE DESCRIPTION

The *aura6000* IPG and lead are part of the THN Sleep Therapy® System for the treatment of obstructive sleep apnea (OSA). Other components include the handheld remote control and charger (RCC or remote; model 500.0100), charging antenna (antenna; model 500.0300), and *aura6000* clinical manager (aCM; model 700.0100) software.

PACKAGE CONTENTS

Model	**100.0100**	**300.0100**
IPG	1	-
Torque Wrench	1	1
Suture Sleeve	1	1
Lead	-	1
Instructions for use	1	1
Product registration form	1	1
Temporary Patient ID card	1	-

INDICATIONS

The *aura6000* System is indicated for use in patients who cannot or will not tolerate positive airway pressure (PAP) therapy for the treatment of obstructive sleep apnea. The *aura6000* System is for use by or on the order of a physician.

CONTRAINDICATIONS

Implantation of the *aura6000* System is contraindicated in individuals with any of the following:

- Central sleep apnea

Performing any of the following procedures is contraindicated in patients implanted with an *aura6000* System:

Diathermy—Shortwave, microwave, and/or therapeutic ultrasound (all now referred to as diathermy) energy can be transferred through the stimulation system, causing damage to the implant and tissue damage resulting in severe injury or death. Diathermy can also damage the neurostimulation system components resulting in loss of therapy and requiring additional surgery for explantation and replacement. Advise your patient to inform all their healthcare professionals that they must not be exposed to diathermy treatment. Injury to the patient or damage to the system components can occur during diathermy treatment: i) whether the system is on or off; ii) wherever diathermy is used on the body (not just over the system component); and iii) whether diathermy delivers heat or not.

CUSTOMER SERVICE INFORMATION

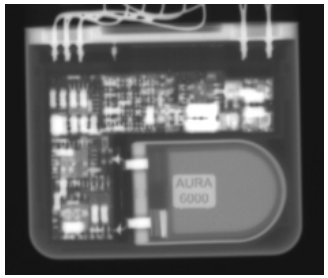
Technical Service

Contact your local ImThera representative for technical support. For additional support, ImThera Medical Technical Service may be reached at +1-858-259-2980 between 9:00am and 5:00pm Pacific Time or via email at support@ImTheraMedical.com.

Product Registration Information

A product registration form is packaged with each ImThera Medical IPG and lead. The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory, or IPG to gain quick access to pertinent data from ImThera. Complete the registration form and: i) return one copy to ImThera Medical; ii) keep one copy for your records; and iii) provide one copy to the patient.

Customer Service Department
ImThera Medical, Inc.
12555 High Bluff Drive, Suite 310
San Diego, CA 92130 USA



Radiopaque Identification

A radiopaque identifier is visible on standard x-ray, and identifies the IPG as the ImThera model 100.0100.

Rechargeable System Information

The *aura*6000 IPG has a rechargeable battery. At typical stimulation settings and usage, IPGs will require charging at least twice a week, and possibly daily. More frequent charging may be required at higher stimulation settings or when the system is used for more hours of therapy per day. Charging sessions may range from 30 minutes to 2.5 hours. Patients should be instructed to charge the IPG until the RCC beeps, signaling the full replenishment of the IPG battery.

Over time the IPG battery will lose its ability to recover to full capacity. This may result in more frequent charging sessions. The IPG will need replacement when stimulation can no longer be maintained with acceptable charging intervals.

Never suture directly to the lead.

Figure 6

15. Close and dress all incisions.

    Caution: Do not use surgical staples to close the IPG pocket. The staples may heat when the IPG is charged.

16. Complete the product registration form and return it to ImThera Medical.

IPG Replacement

1. Surgically open the IPG pocket and withdraw the IPG.
2. Use the torque wrench provided with the replacement IPG to unscrew the setscrew in the old IPG, and then gently pull the lead out of the old IPG header.
3. Follow steps 5 through 15 of "IPG Placement" to complete the surgical procedure.
4. If possible, use the aCM to place the old IPG into shelf mode and return it to ImThera Medical for analysis and disposal. See the aCM Operator's Manual for instructions on placing an IPG into shelf mode.

WARNINGS

Magnetic Resonance Imaging (MRI)—Implanted patients should not be subjected to MRI. MRI exposure may result in dislodgement of implanted components, heating of the IPG, lead and/or electrode(s) which may in turn cause tissue damage, damage to the device electronics, and/or voltage induction through the lead and IPG.

Implant Damage—Severe burns may result if the IPG case is pierced and tissue is exposed to battery chemicals. Never implant a damaged IPG.

Interaction with Cardiac Devices—When a patient's medical condition requires both this device and an implanted cardiac device (e.g. pacemaker, defibrillator), clinicians involved with both devices should discuss the possible interactions between the devices before surgery. Interactions could include:

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The cardiac device may sense the neurostimulator pulses and respond inappropriately.

Electromagnetic Interference (EMI)—The IPG contains features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the IPG, however strong EMI sources can cause:

- Serious patient injury or death—The lead can act as an antenna that "picks up" EMI and delivers excess current causing nerve or tissue damage.
- IPG operational changes or system damage—EMI can cause a loss of, or change in, stimulation requiring reprogramming or surgical replacement.
- Unexpected stimulation—EMI can cause a transient increase in, or interruption of, stimulation which could be perceived as a tingling or shocking.

PRECAUTIONS

Clinician Training

Prescribing Clinicians—Prescribing clinicians should be experienced in the diagnosis and treatment of the condition for which the system is being prescribed and should be familiar with the use of neurostimulation systems.

Patient Selection—The safety and effectiveness of this neurostimulation system has not been established for pediatric use.

Implanting Physicians—Implanting physicians should be experienced in cranial nerve anatomy and surgical techniques, and should review this manual before surgery.

Storage, Sterilization, Implantation and Disposal

Storage—All system components must be stored within the storage conditions listed on their package.

Sterilization—The products have been sterilized according to the process indicated on the package label. This device is for single use only and is not intended to be resterilized.

Component Handling—Handle the implantable components of this system with extreme care. In particular:

- Never sharply bend or kink the lead body or cuff electrode.
- Do not tie suture(s) directly on the lead.
- Always provide a strain relief loop to minimize tension on the electrode cuff.
- Avoid handling the lead with sharp instruments.
- Use caution when using sharps near the lead and IPG.

Component Packaging—Do not implant a system component if any of the following have occurred:

- the sterile package has been pierced or altered;
- the component shows signs of damage; or
- the use-by date has passed.

13. Gently pull the lead back toward the electrode cuff and create an S-shaped section of lead near the neck incision as shown in Figure 5.

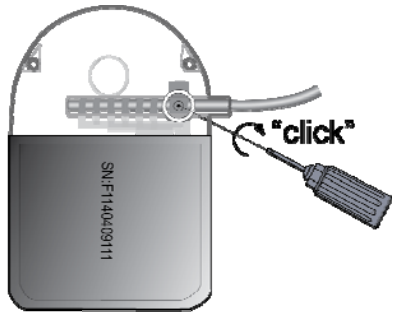


Figure 4

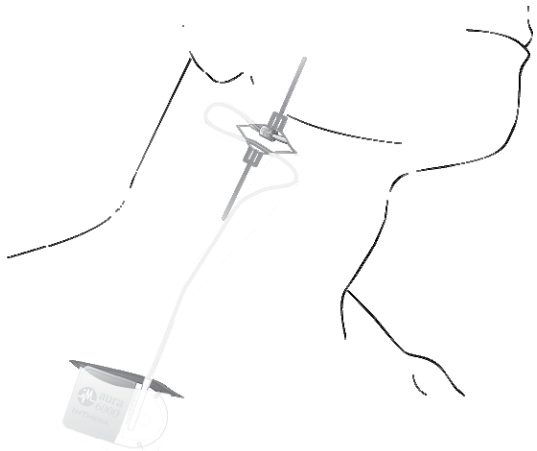


Figure 5

14. Place the suture sleeve around the lead approximately 4-5 cm from the cuff, then secure the lead to the tissue by first tying a 2-0 non-absorbable braided suture to the tissue approximately 1-2 cm ventral to the electrode cuff (Figure 6a), and then tying the tails of the suture around the center groove of the suture sleeve (Figure 6b).

9. Use the aCM programmer to verify that acceptable impedances exist for all electrode contacts. See the aCM Operator's Manual for instructions on operating the aCM.

Impedance (Ω)	Interpretation/Action
< 200	Low. Troubleshoot, see below
200 - 3000	OK.
> 3000	High. Troubleshoot, see below.

For low impedance: inspect the fit of the electrode cuff to ensure that it has sufficient contact with the nerve and reposition the cuff as necessary. If an acceptable motor response is obtained at an acceptable amplitude, then a low impedance is OK.

For high impedance: i) ensure that the IPG is in the IPG pocket or otherwise making tissue contact; ii) ensure that the lead is properly inserted into the IPG (see Figure 2); iii) confirm that there is no visible blood or tissue on the lead terminal bands; iv) confirm that there is no air gap/bubble between the electrode contact and nerve by flushing the incision with saline.

If the issue persists, then explant and replace the lead; and failing that explant and replace the IPG.

10. Use the aCM to verify that noticeable and acceptable muscle movements occur when stimulated.

Stimulation Level (μA)	Interpretation/Action
< 500	Optimal.
500-2500	Acceptable. Confirm that the electrode cuff is around the nerve (not a tendon or other nearby structure).
> 2500	Recheck impedances, and reposition the electrode cuff as necessary until movements can be seen at lower stimulation levels.

11. Remove the IPG from the pocket and use the torque wrench provided to tighten the setscrew until it "clicks" (Figure 4). Do not tighten the setscrew any further after the clicking sound.

12. Tie the IPG sutures to stabilize the IPG within the IPG pocket.

IPG Implant Location—Select an IPG implant location that is:

- on the opposite side of the body from another active implanted device to minimize the potential of interaction between the devices;
- away from bony structures and areas of restriction/pressure to minimize the potential for discomfort and skin erosion;
- accessible to the patient for proper operation of the RCC and charging coil; and
- close enough for the lead to reach the IPG with a strain relief loop.

Also take into account: i) the patient's cosmetic needs; and ii) possible future cardiac needs (e.g. pacemaker, defibrillator). Implanting a neurostimulator on the patient's right side allows for possible future placement of cardiac devices on the patient's left side.

Disposal—If possible, return any explanted devices to ImThera for analysis and disposal. Do not autoclave the returned devices or expose them to ultrasonic cleaners. Devices that are not returned should be disposed of according to local environmental regulations. The IPG contains a battery. Never incinerate or cremate the IPG because it may explode.

Medical Devices/Therapies—The following medical therapies or procedures may interfere with stimulation or may cause permanent damage to the system, particularly if used in close proximity to the device. See Appendix A for more information.

- electrocautery: Do not use monopolar cautery.
- internal or external defibrillation
- radiation therapy
- lithotripsy
- high-output ultrasound
- magnetic stimulation, TENS, FES, or any other form of electrical stimulation

Patient Information

Clinicians should convey the following information to patients implanted with the *aura6000* System.

Patient Identification Card—Tell the patient to carry the *aura6000* patient identification card at all times.

Post-operative activities—Following implantation, patients should avoid:

- disturbing the implant location, lifting heavy objects, and making extreme head or neck movements to avoid changing the position of the electrode cuff on the nerve; and
- activities that could damage the IPG or lead by mechanical force or direct impact.

Twiddling—Patients should never attempt to change the orientation, invert or otherwise manipulate the IPG. Doing this may damage the lead or flip the IPG and make it impossible to charge or communicate with the IPG, and may require surgery to correct.

Regular IPG Charging—Patients must charge the IPG on a regular basis to keep the IPG from overdischarging. Overdischarging may permanently damage the IPG. Direct patients to the *aura6000* User's Manual for information on the IPG charging requirements and procedure.

Wound Contact—Do not place charging antenna on an unhealed wound. The remote and antenna are not sterile.

Heat Due to Charging—While charging, the remote, antenna, and/or IPG may become warm. If heating occurs, patients should stop charging until the heat dissipates or try charging more frequently for a shorter duration; and if heating persists, contact their doctor. Patients should not charge while sleeping.

Device Failure—Tell the patient that, if the device stops working, they should turn off the IPG and contact their doctor so that the device can be evaluated.

Hospital or Medical Environment—Instruct the patient to always inform any other health care personnel that they have an implanted medical device before undergoing any medical procedure or exam. See Appendix A for more information.

Home or Work Environment—ImThera Medical neurostimulators should not be affected by normal operation of equipment such as household appliances, machine shop tools, microwave ovens, cell phones, or AM/FM radios. Nonetheless, tell the patient that if they suspect interference with any electrical device to avoid using the system near that

Note: The setscrew may move during transit and it may be necessary to retract the setscrew slightly to permit the lead to enter the header.

Caution: Use only ¼ turns to retract the setscrew.

Caution: Do not tighten the setscrew yet.

7. Prepare to secure the IPG in the pocket as follows:

   a. Determine where the IPG anchor holes will lay within the IPG pocket.

   b. Place and tie a 2-0 non absorbable braided suture in the deep fascia at the inferior IPG anchor hole location leaving long suture tails (see Figure 3). Cut the needle from the suture.

   c. Repeat step 7b at the superior IPG anchor hole.

   d. Thread the inferior and superior sutures through the inferior and superior IPG anchor holes respectively (see Figure 3).

   Note: Do not tie the suture to the IPG until the impedance and motor thresholds have been tested according to steps 9 and 10.

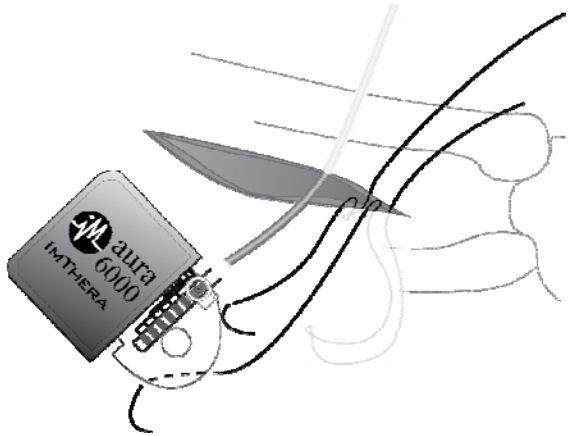


Figure 3

8. Place the IPG into the IPG pocket (metal portion first) with the ImThera logo facing outward as shown in Figure 5. Ensure that the lead is not sharply bent.

IPG Placement

1. Select the site for the IPG pocket. See the Precautions section of this manual for important information on selecting the IPG pocket site.
2. Make a ~5 cm medio-lateral incision (equal to the width of the IPG).
3. Create a subcutaneous pocket. Make the pocket just large enough to contain the IPG, and so that the incision will not be over the IPG.

   Caution: Ensure that the IPG is placed no deeper than 1 cm (ideally 5-7 mm) below the skin and is parallel to the skin. Charging may be inefficient or unsuccessful if the IPG is too deep or not parallel to the skin.
4. Use a shunt passer, or other suitable method, to tunnel the proximal end of the lead to the IPG pocket.
5. Use sterile gauze to wipe any visible blood or tissue from the metal contact bands on the proximal end of the lead.

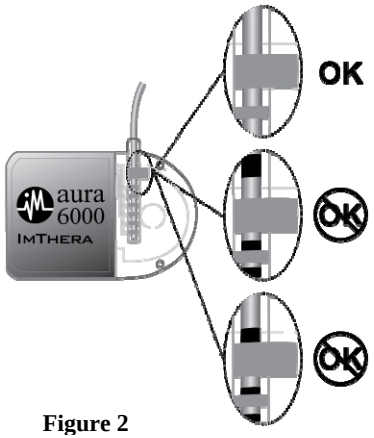


Figure 2

6. Holding the lead 5 mm from its proximal end, insert the lead into the IPG header. Continue to insert in 5mm increments until the lead is fully seated. You will feel the lead bottom out in the header and see that the proximal end of the most distal band on the lead is within the setscrew block (Figure 2).

device. Avoid prolonged exposure to RFID sources. RFID sources may not necessarily be located near the door of a building.

Handling—The remote and charging antenna are sensitive medical devices and should be handled with care. Dropping the devices on hard surfaces or in water, or other rough handling, may permanently damage them.

Cleaning—The remote and charging antenna may be cleaned using a damp cloth. Do not submerge or use abrasive cleansers.

Component Disposal—Never dispose of batteries in fire. Dispose of used batteries in accordance with local regulations.

Adverse Effects

Potential adverse events from hypoglossal nerve stimulation may include but are not limited to the following. These events may result in hospitalization, prolongation of hospitalization, unanticipated surgery, tracheotomy, revision or replacement of system components, or death.

Medical/Surgical Complications—Infection; bleeding, hematoma, or seroma; scarring; excessive fibrotic tissue growth around the implanted device; temporary or permanent hypoglossal or other nerve damage resulting in paresis, paralysis or other dysfunction including difficulty or inability to swallow or speak; complications from anesthesia or extended procedure time; heart attack; persistent pain at the implant site; allergic or immune system response to the implanted materials; and component migration or erosion through the skin can occur.

Device Complications—Lead migration, dislodgement, disconnection, fracture, insulation breakage or erosion; failure of IPG component, battery, software or telemetry; and IPG migration or flipping can occur.

Stimulation Complications—Paresthesia or tingling; loss of therapeutic effect; extrahypoglossal stimulation; and worsening of OSA condition can occur.

SURGICAL GUIDELINES

Pre-Operative

1. Charge the IPG before opening the shelf box. For charging instructions, see the *aura6000* User's Manual.
2. Before opening the IPG sterile package, verify that the IPG is operable by using the aCM to interrogate the IPG and read the IPG battery charge level. See the aCM Operator's Manual for instructions on how to operate the aCM.
3. Confirm that the RCC-to-IPG RF range will be sufficient to communicate with the IPG without placing the RCC into the sterile field. Place the RCC in a sterile bag if the RCC needs to enter the sterile field to communicate with the IPG.

Lead Placement

1. Determine on which side of the body the IPG (and lead) will be placed, and prep that side of the neck and infraclavicular region for surgery.

   Caution: If possible, place the IPG contralateral to any other active implanted device to minimize the potential of interaction between the devices.
2. Make a 5-6 cm incision approximately ~2 cm below the mandibular body and centered over the lesser cornu of the hyoid bone.
3. Use blunt dissection to expose a 1.5 – 2.0 cm length of hypoglossal nerve distal to the ansa cervicalis branch and proximal to the first branch innervating the tongue muscles (usually the styloglossus branch of the hypoglossal nerve) leaving the perineural tissues intact. Take care not to disrupt the blood vessels or lymphatics surrounding the hypoglossal nerve.
4. Place the electrode cuff ventrolateral to the exposed nerve such that the lead cable exits posteriorly.
5. Position the electrode cuff around the nerve as follows:
   a. [Optional] Instruct an assistant to use a vein retractor to gently lift the hypoglossal nerve.
   b. Position forceps #1 ventromedial to the nerve, then advance its angled tip laterally beneath the nerve to grasp the red thread on the medial edge of the electrode cuff (Figure 1a).
   c. Use forceps #2 to grasp the blue thread on the lateral edge of the electrode cuff and spread the electrode cuff open (Figure 1b).

   d. Use forceps #1 to pull the cuff under the nerve to the medial side (Figure 1c) and release forceps #2 (blue thread) when the lateral edge of the cuff reaches the nerve.
   e. Allow the electrode cuff to completely furl around the nerve (Figure 1d).

      Note: Ensure that the cuff flap with the red thread is on the outside of the cuff, and not against the hypoglossal nerve which would preclude the electrodes from contacting the nerve.
   f. Cut and remove both the red and blue threads from the cuff (Figure 1e).
   g. Rotate the cuff so that the lead cable is on the superficial side of the nerve.

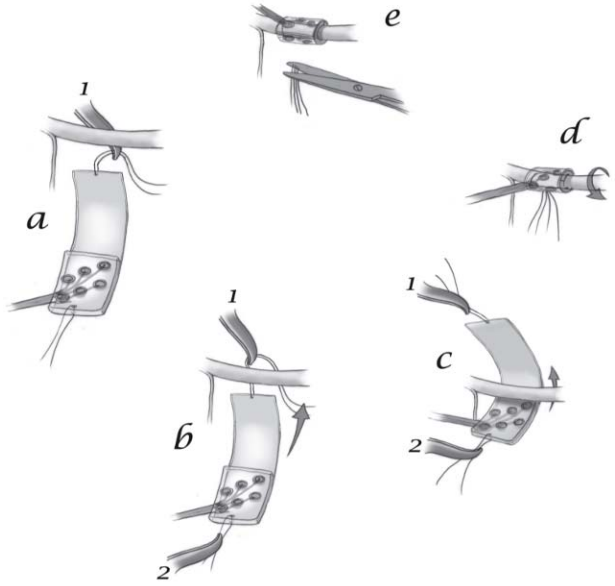


Figure 1