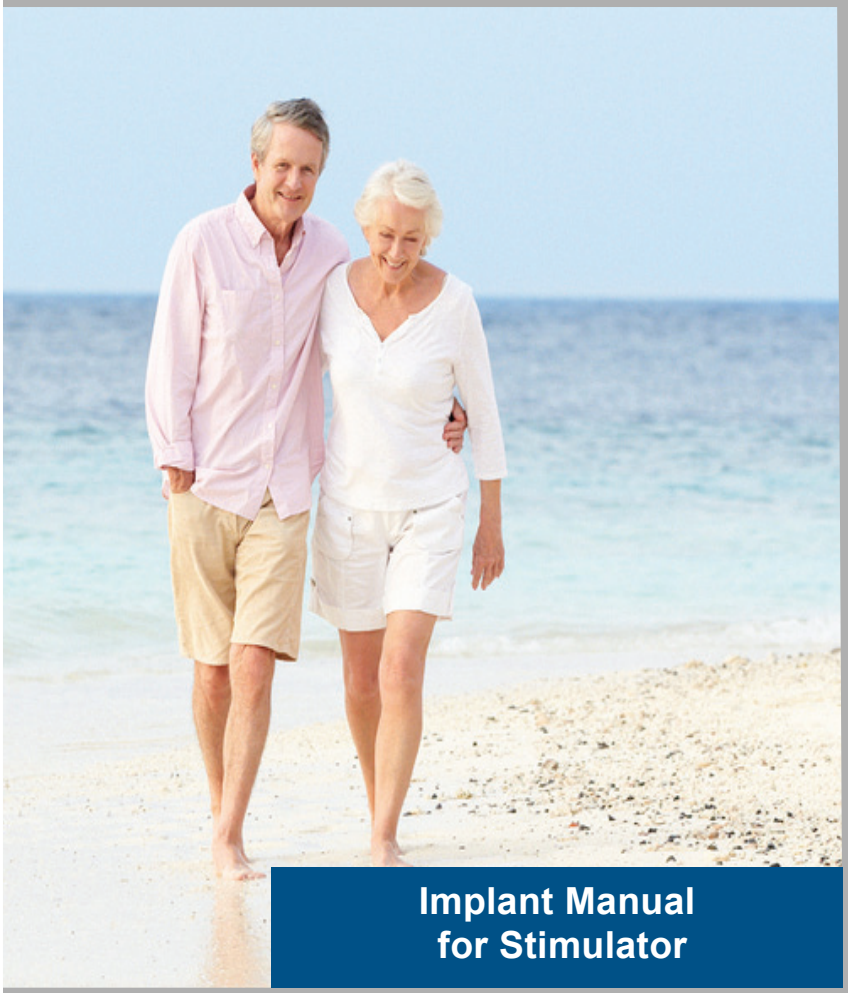
algovita™



Algovita™ Spinal Cord Stimulation System

Stimulator Models 2408 and 2412

For IPG replacement

Implant Manual for Stimulator

ALGOSTIM, LLC

℞ Only

CE 0123 20XX

Algovita™ is a trademark of QIG Group, LLC

CoreGuard™ is a trademark of Greatbatch, Inc.

Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, and related information.

FCC Information (US Only)

The following is communications regulation information about the Algovita Implantable Pulse Generator (IPG).

2408 and 2412 IPG FCC ID: 2ABU824082412

These devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) These devices must accept any interference received including interference that may cause undesired operation.

Important: Changes and modifications to these products not authorized by Algostim, LLC could void the FCC certification and negate your authority to operate these products.

Contents

Explanation of Symbols Used on Packaging

Symbol	Explanation
CE 0123 20XX	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC.
Rx Only	Caution: Federal Law (USA) restricts this device to sale on or by the order of a physician.
	Consult instructions for use
	Caution
SN	Serial number
REF	Catalog number
MODEL	Model number
EC REP	Authorized representative in Europe
	Use by date
	Distributed by
	Manufacturer
	Temperature limit
	Keep dry
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Do not reuse

Symbol	Explanation
	Keep away from sunlight
	Do not use if package is damaged
	Phone
	Recycle
	Contents
	IPG: 3 connector ports with 8 channels each
	IPG: 2 connector ports with 12 channels each

Component Description

The Algovita™ Stimulator Model 2408 or 2412 (*Figure 1*) is part of the Algovita Spinal Cord Stimulation (SCS) System, a rechargeable, 24-electrode, SCS system for the treatment of chronic pain.

Figure 1. Algovita Stimulator Model 2408 and Model 2412

The Algovita Stimulator is the implantable pulse generator (IPG) for the Algovita SCS System. In addition to the IPG, the implanted components of the SCS system consist of percutaneous leads or paddle leads with optional extensions.

During the intraoperative test, an external pulse generator (EPG) is used in place of the IPG. The clinician programs the IPG and the EPG using a Clinician Programmer. The patient adjusts the system using either of 2 patient programmers.

Algovita IPGs are 24-channel rechargeable IPGs. Each channel allows the system 1 active electrode. The channels are distributed over 2 or 3 connector ports, depending on the IPG model.

- Algovita Stimulator Model 2408 (3x8 channel)—Three connector ports accommodate 1 to 3 percutaneous leads, with each lead allowing up to 8 active electrodes.
- Algovita Stimulator Model 2412 (2x12 channel)—Two connector ports accommodate 1 or 2 percutaneous or paddle leads, with each lead allowing up to 12 active electrodes.

The IPG delivers stimulation using independent current distribution, a technology that allows variable amounts of current to be delivered to each active electrode.

The IPG battery is a deep discharge recovery battery with CoreGuard™ technology. Even if the patient allows the battery to completely discharge, the battery can be recharged with the Algovita Programmer Charger.

Package Contents

- Stimulator Model 2408 (3x8) or Model 2412 (2x12)
- Torque wrench
- Port plugs (3 for Model 2408, 2 for Model 2412)
- Product literature
- Temporary patient ID card
- Implant registration form and business reply envelope

Component Sterilization

The implantable and surgical accessory components were sterilized with ethylene oxide prior to shipment. The SCS system sterile components are intended for single use only and must not be resterilized.

> **Caution:** Do not resterilize a system component or reimplant an explanted system component because of risk of infection or malfunction.

About this IPG Replacement Manual

This manual provides the instructions for the replacement of an Algovita Stimulator Model 2408 or 2412. For complete instructions on implanting an IPG as part of a system implant, refer to the system manual packaged in the lead kit.

Implant Procedure

Implanting clinicians should be thoroughly familiar with this manual and all other product labeling.

> **Caution:** Do not place the charging paddle on an unhealed wound. The charging paddle is not sterile. Contact with an unhealed wound may result in an infection.

Preparing for Surgery

Before opening the sterile pack, verify the following on the sterile pack label:

- IPG—Model number and use-by date

Preoperative IPG Preparation

Cautions:

- To allow the surgical wound to heal before another charge is needed, charge the IPG in its shelf carton before implanting.
- To assure maximum IPG battery life, make sure the IPG and its packaging are at room temperature before charging the IPG.
- Charging at temperatures above 35°C (95°F) can impair charging paddle operation.
- Do not implant the IPG if it has been dropped onto a hard surface.
- 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 a component, which may cause component failure.

Before implanting an IPG, verify that the IPG is fully charged, verify IPG function, and determine the IPG implant site. A fully charged IPG allows the wound to heal before a recharge is needed.

Verify that the IPG is functioning by using the Clinician Programmer to read the IPG battery charge level. (Refer to the Clinician Programming Manual for instructions on how to read the battery charge level.)

To charge the IPG and verify that the IPG is functioning:

1. If the Programmer Charger needs charging, connect the power cord and AC power adapter to the Programmer Charger, and plug the AC power adapter into a wall outlet.

   Note: To determine if the Programmer Charger needs charging, see the Patient System Manual.

2. Connect the charging paddle to the Programmer Charger.
3. Turn the Programmer Charger on by sliding and holding the power on/off button on the side of the Programmer Charger.
4. Lift the flap on the top of the IPG shelf carton and place the charging paddle on the window over the IPG (*Figure 2)*.

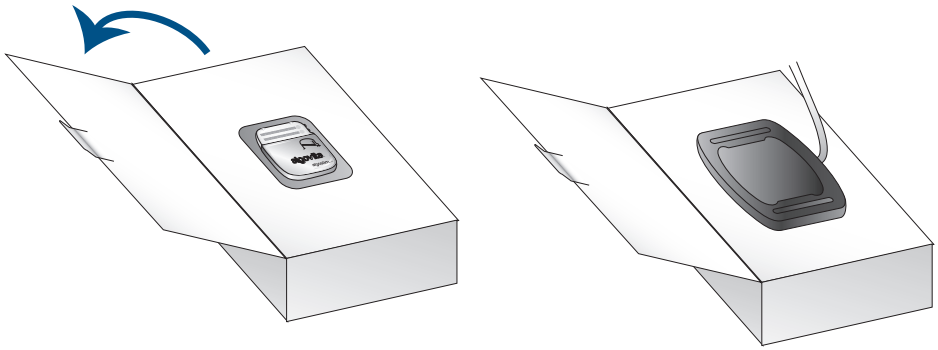


Figure 2. Preoperatively check the IPG

5. When the Notification screen appears, select Cancel (*Figure 3*).

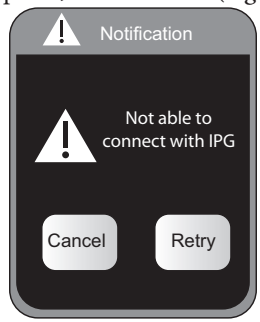


Figure 3. Notification screen

6. When the Main screen appears, select  (*Figure 4*).

Figure 4. Main screen

7. While the IPG is charging, the Charge Status screen is displayed (*Figure 5*).

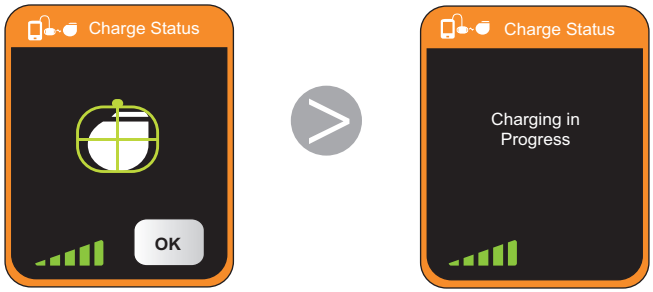


Figure 5. Charging in progress.

8. When the Charge Status screen shows that charging is complete, select OK (*Figure 6*).

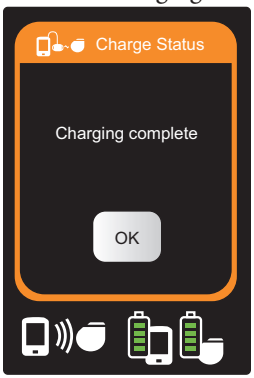


Figure 6. IPG charging complete

Explanting the IPG

1. Turn off the IPG.
2. Place the patient in a position that will allow access to the IPG.
3. Use standard sterile technique to prepare and drape the patient.
4. Administer prophylactic antibiotics according to an infection control protocol.

   Caution: To help prevent infection, use prophylactic antibiotics. An infection may require the removal of the entire SCS system.
5. Using standard surgical technique, open the IPG pocket.
6. Remove the IPG from the pocket.
7. Use the Algovita torque wrench to unscrew the setscrews.
8. Remove the leads or extensions from the IPG header.
9. Return the explanted IPG components to Algovita as instructed in the *Returning Explanted Components on page 18*.

Connecting the Leads or Extensions to the New IPG

1. Prepare the lead or extension for connection to the new IPG.
   a. Wipe the lead or extension contacts dry with sterile gauze.

      Note: Wipe gloves dry before drying or cleaning components.

   b. If the contacts came in contact with body fluids or saline, thoroughly clean the contacts with sterile deionized or sterile water, then dry them completely.

      Caution: Before connecting a lead or extension to the IPG, wipe off any body fluids and dry the connections. Fluids in the connections may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

   c. Inspect the lead or extension for any evidence of damage or corrosion. Explant and replace any damaged or corroded component.
2. Fully insert each lead into the appropriate connector port.

   Caution: Do not use saline or other ionic fluids at connections. Ionic fluids in the connection may cause in a short circuit.

   a. Grasp the lead or extension in the middle of the contacts.

b. Slowly insert the lead or extension into the appropriate connector port (*Figure 7*), stopping when the lead or extension begins to meet resistance or your fingers touch the connector port.

Figure 7. Insert the lead or extension into the connector port.

c. Grasp the lead or extension near the setscrew ring (*Figure 8*).

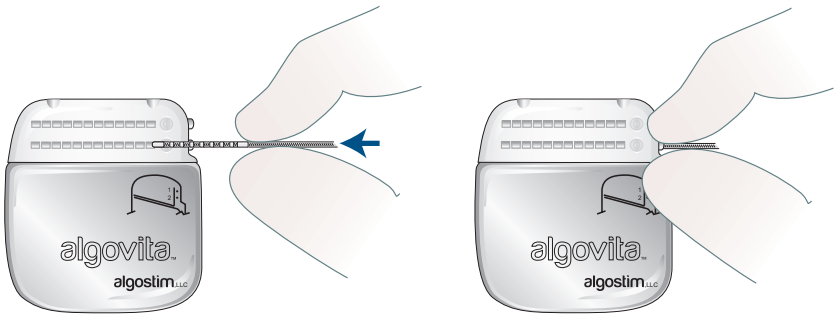


Figure 8. Grasp near setscrew ring.

d. Using a steady force, continue inserting the lead or extension into the connector port.

e. When the lead is fully inserted, you will see the end of the lead move to the back of the connector port and feel it stop against the back of the connector port. The setscrew ring will be aligned with the setscrew.

f. Repeat the insertion steps for additional leads or extensions.

3. Insert a port plug into any connector port not being used for this implant (*Figure 9*).

Figure 9. Insert a port plug into any unused port.

4. Using the torque wrench provided in the IPG package, tighten each lead, extension, and port plug.

   Cautions:

   » Use only the torque wrench that is part of the Algovita SCS System. Using another torque wrench may damage the lead, and may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

   » The torque wrench is single use only. Do not resterilize the torque wrench because of risk of infection or device malfunction.

   a. Fully insert the torque wrench into the grommet in the IPG header until it stops in the setscrew socket.

      Caution: Make sure the torque wrench is fully inserted into the grommet before tightening because the setscrew may be damaged, resulting in intermittent stimulation or loss of stimulation.

   b. Turn the torque wrench clockwise until it clicks once *(Figure 10)*. If you continue to turn, the wrench will continue to click, but the additional turns do not tighten the setscrew further.

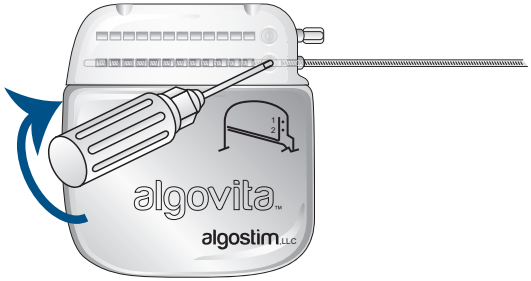


Figure 10. Tightening the setscrews.

Checking System Integrity

1. To ensure the leads or extensions have been properly connected to the IPG and to rule out a short or open circuit, use the Clinician Programmer to program the basic stimulation parameters, check the battery charge level, and check the electrode impedances.
2. If the system integrity test results are not acceptable, check the connections made in *Connecting the Leads or Extensions to the New IPG on page 13*.

Implanting the New IPG

1. Making sure of the following, place the IPG into the subcutaneous pocket (*Figure 11*):
   - » IPG is parallel to the skin and the Algovita logo is facing outward
   - » Lead or extension is loosely coiled behind the IPG with no sharp bends in the coils
   - » IPG is placed no deeper than 1.5 cm below the skin

   Caution: Ensure that the IPG is placed deep enough to avoid dehiscence or erosion. Also ensure that the IPG is placed no deeper than 1.5 cm (0.59 in) below the skin and is parallel to the skin. If the IPG is too deep or is not parallel to the skin, communication with the programmers and recharge connection may be inefficient or unsuccessful.

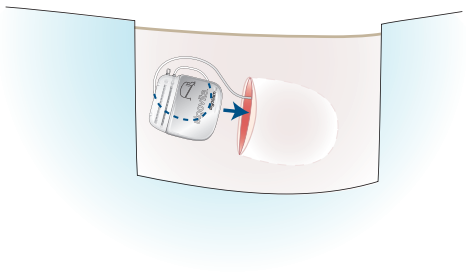


Figure 11. Place the IPG in the pocket.

2. Secure the IPG in the pocket with a suture through each suture hole in the header.

Completing the Implant Procedure

1. Close and dress all wounds.
2. Complete the implant registration form and return the documents to Algostim, LLC in the business reply envelope supplied in the packaging.
3. Fill out the temporary patient identification card.

Patient Counseling Information

Provide the patient with the appropriate information applicable to the SCS surgical procedure.

SCS System Implant: IPG Replacement

- Provide your patient with postoperative care cautions that include the following:
  - » Not drive any vehicles or operate any other dangerous equipment (for example, power tools) with stimulation on
  - » Not engage in rigorous physical activity such as twisting, bending, or climbing
  - » Not stretch or reach the arms above the head
  - » Not lift objects weighing more than 5 pounds (2 kilograms)
  - » Not to place the charging paddle on an unhealed wound

- Keep metal objects away from charging paddle
- Call your office:
  - If patient notices redness around an incision, at any signs of bleeding, pus-like drainage, persistent drainage, redness, excessive swelling, or excessive pain
  - At any signs or symptoms of extreme nausea or persistent headache
  - At any signs of sudden severe pain, leg weakness, spasm, loss of bladder and/or bowel function
  - If patient notices redness at the charging site
  - If patient is not receiving adequate pain relief

Registration Form and Temporary Patient ID Card

At the time of implantation, complete the implant registration form in the product package and return it to Algostim, LLC. Registration initiates the system warranty.

A temporary patient identification card is packaged with the IPG. A permanent identification card will be mailed to the patient when Algostim, LLC receives the implant registration form.

Returning Explanted Components

Return explanted leads, extensions, IPGs, and anchors to Algostim, LLC. The IPG should be explanted before cremation. The cremation process may cause the IPG battery to explode. Do not autoclave the components or expose them to ultrasonic cleaning. Dispose of unreturned components according to local environmental regulations.

Algostim Customer Service

If you have any questions about an Algovita SCS System, call Algostim Customer Services at XXX-XXX-XXXX. Algostim Customer Service is available 24 hours a day, 7 days a week.

Specifications

Table 1. Operating Values for Stimulator Model 2408 and 2412	
Programmable parameter	**Operating range and resolution[a]**
Number of programs	1 to 10
Number of pulses per sub-program	1 to 4
Electrode configuration	2 to 24 electrodes and IPG can as anode, cathode, or off
Amplitude	0 to 15 mA per channel (IPG pulse maximum 30 mA) (Max 17 V)
Pulse width	20 to 1500 µs (20 µs resolution)
Frequency	2 to 2000 Hz (64 frequency options)
Ramp on/off	Off, On: 1, 2, 4, or 8 second duration

a. The Algovita SCS System includes programmable coverage areas with each individual electrode contact limited to 15 mA. A programming interlock is enforced to limit the coverage area output current to 30 mA or less.

Table 2. Component Materials for Stimulator Model 2408 and 2412		
Components	**Material**	**Material Contacts Human Tissue**
IPG		
Case	Titanium	Yes
Header	Polysulfone	Yes
	Polyurethane	Yes
	Silicone	Yes
	Silicone rubber	Yes
Setscrews	Titanium	Yes
Torque wrench		
Handle	Polyether ether ketone	Yes
Shaft	Stainless steel	Yes
Port plugs	Polyurethane	Yes

Table 3. Specifications for Stimulator Model 2408 and 2412	
Description	**Value**
Connector	
Type	3-Octapolar in-line 2.54 mm (0.100 in) spacing – Model 2408 2-Dodecapolar in-line 2.54 mm (0.100 in) spacing – Model 2412
Diameter	1.4 mm (0.05 in)
Height	55.0 mm (2.2 in)
Length	58.0 mm (2.3 in)
Thickness	
Case	9.5 mm (0.4 in)
Weight	40.0 g (1.4 oz)
Volume	20.5 cm^3 – 2408, 19.5 cm^3 –2412 (1.25 in^3 – 2408, 1.19 in^3 – 2412)
Battery life	10 years
Power source	Lithium ion rechargeable battery – fully recoverable battery
Storage temperature	–35° to 55°C (-31° to 131°F)
Radiopaque Identification (ID) code	ALG24
Lead retention strength	Meets EN45502-1 requirements

Wireless Information

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (ie, transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Algovita SCS System Component Compatibility

Only Algovita SCS System components should be used as part of an implanted Algovita SCS System.

Table 4. Algovita SCS System Component Compatibility

	Stimulator Model 2408 (3x8)	Extension Model 5208 (1x8)	Stimulator Model 2412 (2x12)	Extension Model 5212 (1x12)	Trial Stimulator Model 4300	Clinician Programmer Model 4500	Programmer Charger Model 4200	Pocket Programmer Model 4100
3x8 For Placing 1–3 8-electrode Leads								
Percutaneous Lead Models 1081-xx[1], 1084-xx, 1086-xx	■	■			■	■	■	■
Trial Lead Models 1081-xxT, 1084-xxT (Percutaneous)		■			■	■	■	■
2x12 For Placing 1–2 12-electrode Leads								
Percutaneous Lead Models 1121-xx, 1124-xx, 1126-xx			■	■	■	■	■	■
Paddle Lead Model 3000-xx (3-4-3-2)			■	■	■	■	■	■
Paddle Lead Model 3101-xx (2x6)			■	■	■	■	■	■
Trial Lead Models 1121-xxT, 1124-xxT (Percutaneous)				■	■	■	■	■

1. Denotes length





algovita™

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Part Number
1006977
0300-000021-05
Revision 5

March 2014