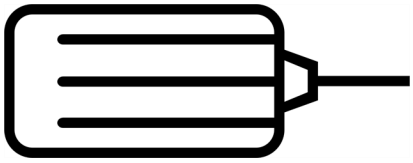
LivaNova
Health innovation that matters

PHYSICIAN'S MANUAL

LivaNova® Accessory Pack Model 502



October 2023

NOTE: This "Directions for Use" contains information on the LivaNova Model 502. Physicians should refer to the generator / lead physician's manual for important prescribing and safety information.

℞

CE 0344

The year of authorization to affix the CE mark:

Model 502	2003

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1.0. Description

The Accessory Pack Model 502 contains components for the implantation procedure. These components are replacements for items that may become unusable during routine surgery. The components in the accessory pack can also be used to aid in revision, replacement, or removal surgery.

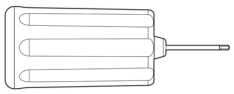
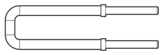
NOTE: For system compatibility, see the indication specific physician's manual.

1.1. Intended Use

The items in the accessory pack are supplied as replacements for system components.

1.2. Package Contents

Figure 1. Accessory Pack Components

1 Hex Screwdriver	1 Single-pin Test Resistor
	
4 Tie-downs	**1 Dual-pin Test Resistor**
	

1.3. Product Specifications

The specifications and product information for the implantable tie-downs is shown below.

Table 1. Product Specifications - Tie-Downs

Component*	Material / Dimensions
Tie Down	**Relaxed Radius**: 0.04 in. (1.0 mm)
	Material: Radio-opaque silicone

* No component of the system is made with natural rubber latex.

1.4. Sterilization

The accessory pack has been sterilized with hydrogen peroxide (H_2O_2 or HP) gas plasma and is supplied in a sterile pack to permit direct introduction into the operating field.

NOTE: Either ethylene oxide (EO/EtO) gas or HP gas plasma may have been used on sterile devices previously distributed.

A use by date and method of sterilization is marked on each package. A sterilization process indicator is located on the inner sterile pack and is only used as an internal manufacturing process aid.

2.0. Precautions ⚠

2.1. General

Use Sterile Technique

Always use **sterile technique** to open the accessory pack.

Non-pyrogenic

The implantable components of the accessory pack are non-pyrogenic.

2.2. Sterilization

Do Not Re-Sterilize

Do not resterilize any product. The sterility, functionality, and reliability cannot be ensured, and infections may occur. Return any opened devices to LivaNova. See "Return Product Form" on page 6.

Single Use Only


The accessory pack is a single-use-only device. Never resterilize or reuse it.

2.3. Storage

Temperature

Store between -20 °C (-4 °F) – +55 °C (+131 °F).

Liquids and Moisture

Do not store any components of the system where they may be exposed to water or other liquids. Moisture can damage the seal integrity of the package materials.

2.4. Handling

Use By Date

Do not implant or use a sterile device if the use by date has expired. This can adversely affect the device's longevity and sterility.

Sterile Device Integrity

Do not implant or use a sterile device if the integrity of the outer or inner sterile barrier has been pierced or altered.

3.0. Directions for Use

Directions for opening the accessory pack and using its components are provided below. Additional information about individual components can be found in the generator / lead physician's manual.

3.1. How to Open the Sterile Pack

Before any sterile pack is opened, examine it carefully for evidence of damage or compromised sterility. If the outer or inner sterile barrier has been opened or damaged, LivaNova cannot guarantee sterility of the contents, and it should not be used. An opened or damaged product should be returned to LivaNova.

⚠ CAUTION: Do not open the sales pack if it has been exposed to extreme temperatures or if there is evidence of external damage or damage to the package seal. Instead, return it unopened to LivaNova.

⚠ CAUTION: Do not implant or use a sterile device if the device has been dropped. Dropped devices may have damaged internal components.

To open the sterile pack, complete the following steps:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to lift out the sterile inner tray.
3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.
4. To remove the hex screwdriver, a resistor assembly, or tie-downs, push down on one end of the item and grasp the opposite (raised) end.

3.2. How to Use the Components

3.2.1. Tie-Downs

Use the tie-downs to secure the lead to fascia during implantation and to help form the strain-relief bend and loop that provide the slack necessary for neck movement. The four tie-downs in the accessory pack are in addition to the four tie-downs provided in the lead package. The tie-downs in the accessory pack are provided for use in the event that the tie-downs supplied with the lead become unusable during the surgical procedure.

ⓘ NOTE: For details on the use and placement of the tie-downs, see the indication specific physician's manual.

3.2.2. Test Resistor Assembly

Use the appropriate test resistor assembly (single-pin or dual-pin) to test the generator during the optional Generator Diagnostics.

NOTE: For details on diagnostic tests, see the indication specific physician's manual.

3.2.3. Hex Screwdriver

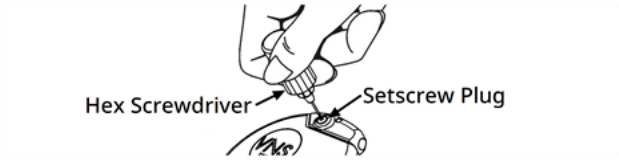
Use the hex screwdriver to loosen, retract (back out), and tighten setscrews, and to allow the escape of back pressure created by the insertion of the lead connector pin into the generator receptacle. See "Hex Screwdriver Position" below.

NOTE: For details, see the indication specific physician's manual.

CAUTION: When you use the hex screwdriver, grasp it by the handle only. Do not grasp any other portion of the hex screwdriver during use as this may affect its proper function.

CAUTION: When you use the hex screwdriver to tighten a setscrew, turn the screwdriver clockwise until a click (ratchet sound) is heard, and always push down to ensure that the hex screwdriver is fully inserted into setscrew.

Figure 2. Hex Screwdriver Position



3.3. Return Product Form

A Returned Product Form is used for the return of any system component. Call first for a Return Goods Authorization (RGA) number, available from "Technical Support" on the next page. Before device components are returned, disinfect them with Betadine®, Cidex® soak, or other similar disinfectant, and double seal them in a pouch or other container properly labeled with a biohazard warning.

Return Product Forms are posted at www.livanova.com.

Contacts and Resources

For information and support in use of the system or any of its accessories, contact LivaNova.

Contacts

	LivaNova USA, Inc. 100 Cyberonics Blvd Houston, Texas 77058 USA	LivaNova Belgium NV Ikaroslaan 83 B-1930 Zaventem BELGIUM	LivaNova Switzerland Rue de Grand-Pont 12 CH-1003 Lausanne SWITZERLAND
Tel:	+1 281 228 7200 (Worldwide)	+32 2 720 95 93	
Toll free:	+1 800 332 1375 (US/Canada)		
Fax:	+1 281 218 9332	+32 2 720 60 53	
Website:	www.livanova.com	www.livanova.com	www.livanova.com

Technical Support

Available 24 hours per day	
Toll free:	+1 866 882 8804 (US/Canada)
Tel:	+1 281 228 7330 (Worldwide)
Tel:	+32 2 790 27 73 (Europe/EMMEA)

Regulatory Authority Websites

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

US	https://www.fda.gov
Australia	https://www.tga.gov.au/
Canada	https://www.canada.ca/en/health-canada.html
UK	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EU	https://ec.europa.eu/growth/sectors/medical-devices/contacts_en