



VNS Therapy[®] Accessory Pack Model 502



Directions for Use

For Healthcare Professionals

June 2017

Worldwide Version

Rx Only



Note: This “Directions for Use” contains information on the LivaNova[®] Model 502 accessory pack. It is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all sections of the physician’s manuals for the VNS Therapy System and its component parts, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes. A copy of this VNS Therapy manual is posted at www.livanova.com.

1. DESCRIPTION

The VNS Therapy® System, used for vagus nerve stimulation (VNS), consists of an implantable VNS Therapy pulse generator, implantable VNS Therapy lead, and an external programming system used to change stimulation settings.

The VNS Therapy Accessory Pack Model 502 contains replacement components for the VNS Therapy System. These components are replacements for items that may become unusable during routine surgery. The hex screwdriver can also be used during an explantation of a pulse generator.

1.1. Intended Use

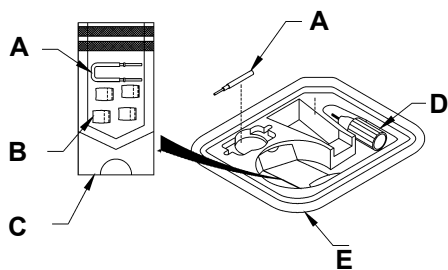
The items in the accessory pack are supplied as replacements for VNS Therapy System components.

1.2. Package Contents

Each accessory pack contains the following items, as shown in Figure 1:

- 1 Tyvek® pouch containing:
 - ◆ 4 tie-downs
 - ◆ 1 resistor assembly (dual-pin)
- 1 resistor assembly (single-pin)
- 1 hex screwdriver
- Documentation

Figure 1. VNS Therapy Accessory Pack Contents



- | | |
|-------------------------------------|------------------------------|
| A VNS Pulse Generator Test Resistor | D Hex Screwdriver |
| B Tie-Down (4) | E VNS Therapy Accessory Pack |
| C Sealed Tyvek Pouch | |

2. PRECAUTIONS

Follow these precautions when using the accessory pack and its components:

- ⚠ Always open the accessory pack using **sterile technique**.

- ⚠ Always verify that the accessory pack's expiration (use-before) date has not passed; if it has passed, do not use any of the components.

- ⊘ **Never resterilize or reuse items in the accessory pack.** Once the pack is opened, discard all unused components.

3. STERILIZATION

Refer to the exterior package label to ascertain the method of sterilization. The sterilization method is indicated by the hydrogen peroxide gas plasma (H₂O₂) sterility symbol or the ethylene oxide (EO) sterility symbol, as described in Section 2 of these directions.

The accessory pack has been sterilized using H₂O₂ or EO and is supplied in a sterile package to permit direct introduction into the operating field. A sterilization process indicator is included in the package. The accessory pack should be used only if the color of the indicator is in the range of gold to bronze (in the case of product sterilized with H₂O₂)—or gray to green (in the case of product sterilized with EO). An expiration (use-before) date is indicated on the package.

The implantable components of the accessory pack are nonpyrogenic.

- ⚠ Do not use items in the pack if the following occurs:
 - ◆ The outer or inner package has been pierced or altered, because this could have rendered it nonsterile.
 - ◆ The expiration (use-before) date has passed, because this can adversely affect the device's sterility.
 - ◆ The color of the sterilization process indicator within the inner package is not in the range of gold to bronze for product sterilized by H₂O₂.
 - ◆ The color of the sterilization process indicator within the inner package is not in the range of gray to green for product sterilized by EO.

- ⚠ Do not resterilize or reuse any items in the Accessory Pack.

4. STORAGE AND HANDLING

Follow these guidelines for storing and handling the accessory pack and its components:

- ⚠ Store the unopened accessory pack between -20°C (-4°F) and +55°C (+131°F).
- ⚠ Do not store the accessory pack where it is exposed to water or moisture, because water and moisture can damage the seal integrity of the package materials.
- ⚠ Do not use items in the pack if the expiration (use-before) date has passed.

- ⚠** Leave the package unopened and return it to LivaNova® if the outer or inner package has been pierced, altered, or exposed to extreme temperatures, water, or moisture, because any of these could have rendered the package nonsterile.

5. 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 pulse generator physician's manual and the lead physician's manual.

- ⚠** If the inner or outer package has been opened, damaged, or altered, do not use any of the items. Instead, return the accessory pack and *all* its components to LivaNova.

To open the package, do the following:

1. Grasp the tab, and peel back the outer cover.
2. Observing sterile technique, 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. Remove the hex screwdriver or single-pin resistor assembly by pushing down on one end of the item and grasping the opposite (raised) end.
5. If necessary, remove the tie-downs and dual-pin resistor assembly from the small Tyvek pouch by slowly peeling open the pouch at the end clearly marked, using sterile technique.

5.1. Using Items in the VNS Therapy Accessory Pack

5.1.1. Tie-downs

Tie-downs are used 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.

For specific instructions on the use and placement of the tie-downs, refer to the lead physician's manual.

5.1.2. Resistor Assembly

The resistor assembly is used for testing the pulse generator during the Pre-Implant (pulse generator) Test. For specific instructions on using the resistor assemblies, refer to the pulse generator physician's manual.

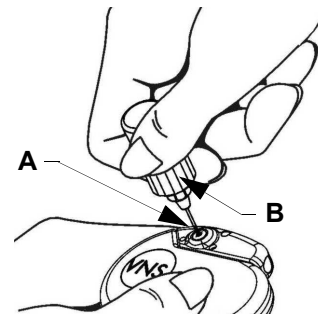
5.1.3. Hex Screwdriver

The hex screwdriver is used to loosen, retract (back out), and tighten the setscrew(s) and to allow the escape of back pressure created by inserting the lead connector pin(s) into the lead receptacle(s) of the pulse generator.

- ⚠** When using the hex screwdriver to tighten a setscrew, turn the screwdriver clockwise until a click (ratcheting) is heard, and always push down to ensure that the hex screwdriver is fully inserted into setscrew.

- ⚠** When using the hex screwdriver, grasp it by the handle only as shown in Figure 2. Do not grasp any other portion of the hex screwdriver during use as this may affect its proper function.

Figure 2. Using the Hex Screwdriver



A Setscrew Plug

B Hex Screwdriver

5.2. Returned Product Form

A *Returned Product Report* form is included in the accessory pack. It is used for the return of any VNS Therapy System component.

Please call first for a *Return Goods Authorization (RGA) number*, available from Technical Support (see phone numbers under "Information and Support").

6. PRODUCT SPECIFICATIONS

The specifications and product information for the implantable tie-downs included in the accessory pack are presented in Table 1.

Table 1. Product Specifications

Component*	Description
Tie-downs	
Relaxed Radius	.04 in (1.0 mm)
Material	Radiopaque silicone

*No component of the VNS Therapy System is made with natural rubber latex.

7. INFORMATION AND SUPPORT

If there are questions regarding use of the VNS Therapy System or any of its accessories, contact LivaNova:



LivaNova USA, Inc.

100 Cyberonics Boulevard
Houston, Texas 77058 USA

Telephone: +1 (281) 228-7200
 1 (800) 332-1375 (US and Canada)
Fax: +1 (281) 218-9332



LivaNova Belgium NV

Ikaroslaan 83
1930 Zaventem, BELGIUM

Telephone: +32 2 720 95 93
Fax: +32 2 720 60 53

For 24-hour Clinical and Technical support, call:

Telephone: 1 (866) 882-8804 (US and Canada)
 +1 (281) 228-7330 (Worldwide)

Internet

www.livanova.com

© Copyright 1998 - 2017 LivaNova, PLC, London, UK
All rights reserved.

LivaNova, NCP, Demipulse, Demipulse Duo, Perennia, VNS Therapy, AspireHC, PerenniaFLEX, PerenniaDURA and AspireSR are registered United States trademarks of LivaNova, Inc. Pulse and Pulse Duo are trademarks of LivaNova USA, Inc. Corresponding foreign trademarks may also be registered or pending.

The year of authorization to affix the CE mark: 2003