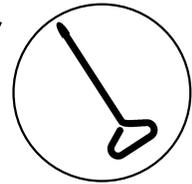




LivaNova[®] Tunneler Model 402



Directions for Use

For Healthcare Professionals

June 2017

Rx Only



Non-U.S. Version

Note: This "Directions for Use" contains information on the LivaNova[®] Model 402 Tunneler. Physicians should refer to the LivaNova Pulse Generator physician's manual for important prescribing and safety information.

1. DESCRIPTION

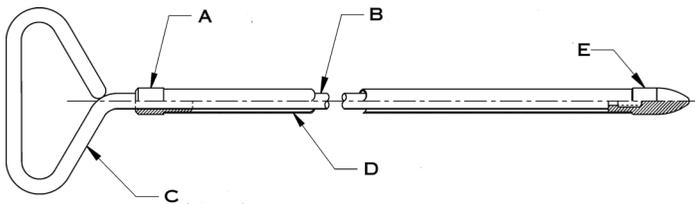
The VNS Therapy® System, used for vagus nerve stimulation (VNS), consists of an implantable Pulse Generator and Lead, and an external programming system used to change stimulation settings.

The LivaNova® Tunneler, Model 402 is designed for use during implantation of a LivaNova dual-pin or single-pin Lead.¹ It is recommended for subcutaneous tunneling of the Lead connector(s) from the neck to the chest. The Tunneler, supplied sterile, is a single-use-only device.

The Tunneler consists of four basic components: a stainless steel shaft, two fluorocarbon polymer sleeves, and a stainless steel bullet tip.

Figure 1 shows a diagram of the assembled device with the larger diameter sleeve to be used with a dual-pin Lead.

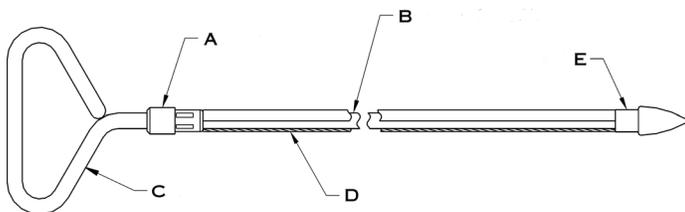
Figure 1. Assembled Tunneler with Larger Diameter Sleeve



- A Retainer
- B Stainless Steel Shaft
- C Shaft Handle
- D Sleeve
- E Bullet Tip

Figure 2 shows a diagram of the assembled device with the smaller diameter sleeve to be used with a single-pin Lead.

Figure 2. Assembled Tunneler with Smaller Diameter Sleeve



- A Retainer
- B Stainless Steel Shaft
- C Shaft Handle
- D Sleeve
- E Bullet Tip

Dimensions of the LivaNova Tunneler were optimized to minimize risk of damage to Lead connector(s) that may occur with the use of general-purpose tunnelers.

Component dimensions are shown in Table 1.

Table 1. Tunneler Dimensions

Component	Dimension (Nominal)		
Stainless steel shaft	length	13.4 in	34 cm
Large-diameter fluorocarbon polymer sleeve (dual-pin Lead)	length	11 in	28 cm
	inside diameter	0.25 in	6.4 mm
	outside diameter	0.31 in	7.9 mm
Small-diameter fluorocarbon polymer sleeve (single-pin Lead)	length	10.45 in	26.5 cm
	inside diameter	0.135 in	3.4 mm
	outside diameter	0.185 in	4.7 mm
Stainless steel bullet tip	outside diameter	0.31 in	7.9 mm

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

2. INTENDED USE

The Tunneler is intended for use only to aid in routing, or directing, the Lead from the neck incision to the chest incision. Precautions

- The Tunneler is a single-use-only device. **Never resterilize or reuse it.**
- Replacements for Tunnelers should be available in the event of compromised sterility or damage induced during surgery.
- Care should be taken **not to injure** any arteries, veins, or nerves during the tunneling procedure.
- Always tunnel **from the neck incision to the chest incision** to reduce the risk of damaging one of the major arteries or veins in the neck.

3. STORAGE AND HANDLING

- Store the Tunneler between -20°C (-4°F) and +55°C (+131°F).
- Do not store the Tunneler where it is exposed to water or other liquids, because moisture can damage the seal integrity of the package materials.

Before opening the sterile package, examine it carefully for evidence of damage or compromised sterility. If the outer package has been opened or damaged, LivaNova cannot guarantee sterility of the Tunneler and it should not be used. An opened or damaged product should be returned to LivaNova.

To open the Tunneler package, do the following:

1. All single-pin and dual-pin Leads referred to in this "Directions for Use" are manufactured by LivaNova, Inc.

1. Grasp the tray's tab that has the peel illustration and peel back the outer cover.
2. Using 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.

Make sure to remove all four pieces in the package:

- 1 Shaft
- 1 Bullet tip
- 1 Large-diameter sleeve (for use with a dual-pin Lead)
- 1 Small-diameter sleeve (for use with a single-pin Lead)

4. DIRECTIONS FOR USE

The following directions cover the use of the Tunneler. Placement of the Lead electrodes around the nerve is described in the Lead physician's manual. Implantation of the Pulse Generator is described in the Pulse Generator physician's manual.

4.1. Sterilization

Reference 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 Tunneler 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 Tunneler 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.

If the package has been exposed to extreme temperatures or moisture, or if there is any indication of external damage, the package should be left unopened and returned to LivaNova with a *Returned Product Form*. Call first for a *Return Goods Authorization (RGA)* number, available from Technical Support (see "Information and Support" on page 4).

 **Do not use** the Tunneler 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 process indicator within the inner package is not in the range of gold to bronze for product sterilized by H₂O₂.
- ◆ The color of the process indicator within the inner package is not in the range of gray to green for product sterilized by EO.

 **Do not resterilize** the Tunneler because sterility, functionality, and reliability cannot be ensured, and infections may occur. Return any opened packages that have not been used to LivaNova.

 The Tunneler is a single-use-only device. **Never resterilize or reuse it.**

4.2. Assemble the Tunneler

The Tunneler must be assembled at the time of surgery. To do so, follow these steps:

1. Using sterile technique, remove the four Tunneler components from the inner tray, and place them into the sterile field.
2. Select the appropriate sleeve.
 - ◆ The *larger* diameter sleeve is used when implanting a dual-pin Lead (used with a dual-receptacle Pulse Generator).
 - ◆ The *smaller* diameter sleeve is used when implanting a single-pin Lead (used with a single-receptacle Pulse Generator).
3. Slide the appropriate sleeve over the shaft until it fits up against the retainer at the handle end of the shaft.
4. Carefully screw the bullet tip onto the shaft (see Figure 1 and Figure 2).

 Do not over-tighten the bullet tip. Doing so could damage the bullet tip threads.

4.3. Pass the Tunneler and Lead

After the chest and neck incisions are made, and before the electrodes are inserted around the left cervical vagus nerve, the Tunneler can be inserted and passed from the neck incision to the chest incision. (If necessary, the Tunneler can be manually shaped to help direct it through the body.)

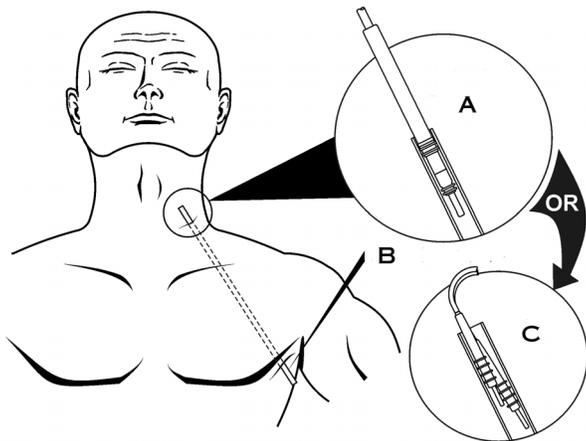
 Do not manually shape the Tunneler **more than 25 degrees**, because doing so may cause the sleeve to bend or kink.

To pass the Tunneler, do the following:

1. Place the bullet-tip end of the Tunneler through the neck incision and tunnel subcutaneously toward the chest incision, exerting force on the handle end and directing the Tunneler as necessary.
2. After the bullet tip has passed from one incision site to the other, unscrew the bullet and withdraw the shaft from the sleeve, leaving the sleeve extended through both incisions (see Figure 3).

Figure 3. Position of Sleeve and Lead Connector(s)

Insert the Lead into the sleeve at the neck incision until secure



A Single-Pin Lead

B Tunneler Sleeve

C Dual-Pin Lead

3. With the sleeve in place between the two incisions, carefully insert the Lead connector(s) inside the end of the sleeve at the neck incision.

For a *dual-pin* Lead, the second connector will form a slight compression fit between the first Lead connector tubing and the inside of the sleeve (see Figure 3).

4. Carefully pull the sleeve, along with the Lead connector(s), from the chest incision end until the lead connector(s) completely exit(s) the chest incision.
5. Remove the Lead connector(s) from the sleeve, leaving the electrode array at the neck incision site.
6. Discard the Tunneler after use.

5. INFORMATION AND SUPPORT

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

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