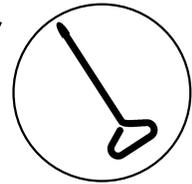




# **LivaNova<sup>®</sup> Tunneler Model 402**



## **Directions for Use**

*For Healthcare Professionals*

**June 2017**

*U.S. Version*

### **Rx Only**

**Note:** This “Directions for Use” contains information on the LivaNova<sup>®</sup> Model 402 Tunneler. A copy of this manual is posted at [www.livanova.com](http://www.livanova.com)

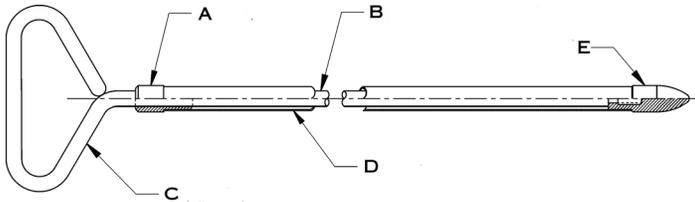
## 1. DESCRIPTION

The LivaNova® Tunneler, Model 402 is designed for subcutaneous tunneling.

The Tunneler, supplied sterile, is a single-use-only device. It 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 an assembled device. Component dimensions are shown in Table 1.

**Figure 1. Assembled Tunneler**



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

**Table 1. Tunneler Dimensions**

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

## 3. 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.

## 4. 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. 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
- 1 Small-diameter sleeve

## 5. DIRECTIONS FOR USE

### 5.1. Sterilization

Reference the exterior package label to ascertain the method of sterilization. The sterilization method is indicated by the hydrogen peroxide gas plasma (H<sub>2</sub>O<sub>2</sub>) sterility symbol or the ethylene oxide (EO) sterility symbol, as described in Section 2 of these directions.

The Tunneler has been sterilized using H<sub>2</sub>O<sub>2</sub> 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 H<sub>2</sub>O<sub>2</sub>)—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 "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" on page 3).



**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 H<sub>2</sub>O<sub>2</sub>.
- ◆ 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.**

## 5.2. 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. Slide the appropriate sleeve, if needed, over the shaft until it fits up against the retainer at the handle end of the shaft.
3. Carefully screw the bullet tip onto the shaft (see Figure 1).



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

## 5.3. Pass the Tunneler

The Tunneler can be passed subcutaneously to manipulate tissue. If necessary, the Tunneler can be manually shaped to help direct it through the body.



If a sleeve is used, 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 incision and tunnel subcutaneously, exerting force on the handle end and directing the Tunneler as necessary.
2. If a sleeve is used, 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.
3. Discard the entire Tunneler assembly, including unused portions, after use.

## 6. INFORMATION AND SUPPORT

If there are questions regarding use of the Tunneler, contact LivaNova:

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**For 24-hour support, call:**

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

### Internet

[www.livanova.com](http://www.livanova.com)

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