

PHYSICIAN'S MANUAL

LivaNova® Tunneler Model 402



April 2022

 NOTE: This "Directions for Use" contains information on the LivaNova Model 402. Physicians should refer to the generator / lead physician's manual for important prescribing and safety information.

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1.0. Description

The LivaNova Tunner Model 402 is designed for subcutaneous tunneling. The tunneler, supplied sterile, is a single-use-only device.

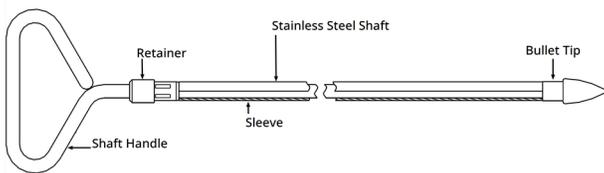
1.1. Intended Use

The tunneler is intended for use only to manipulate tissue.

1.2. Package Contents

The package contains one tunneler. The tunneler consists of four basic components: a stainless steel shaft, two fluorocarbon polymer sleeves (1 small diameter for single pin leads and 1 large diameter for dual-pin leads), and a stainless steel bullet tip.

Figure 1. Assembled Tunner



1.3. Product Specifications

Table 1. Tunner Product Specifications

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

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

1.4. Sterilization

The tunneler 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

Replacements

Replacements for tunnelers should be available in the event of compromised sterility or damage induced during surgery.

Avoid Injury

Take care to not cause injury during the tunneling procedure (e.g., arteries, veins, nerves).

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 tunneler is a single-use-only device. Never resterilize or reuse it.

2.3. Storage

Temperature

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

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

The following directions cover the use of the tunneler. Placement of the lead electrodes around the nerve and implantation of the generator is described in the VNS Therapy 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. Remove all four pieces in the package (shaft, bullet tip, large-diameter sleeve, small-diameter sleeve).

3.2. Assemble the Tunneler

The tunneler must be assembled at the time of surgery. To assemble the tunneler, follow these steps:

1. Use sterile technique to remove all four components from the inner tray, and place them into the sterile field.
2. Slide the appropriate sleeve 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.

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

3.3. 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.

 CAUTION: 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. Exert force on the handle end and direct 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. Leave the sleeve extended through both incisions.
3. Discard the entire tunneler assembly and unused portions after use.

3.4. 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 [page 7](#). 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

Tel:	+1 281 228 7200 (Worldwide)
Toll free:	+1 800 332 1375 (US/Canada)
Fax:	+1 281 218 9332
Website:	www.livanova.com

Technical Support

Available 24 hours per day	
Toll free:	+1 866 882 8804 (US/Canada)
Tel:	+1 281 228 7330 (Worldwide)

Regulatory Authority Websites

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

US	https://www.fda.gov
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