LivaNova
Health innovation that matters

PHYSICIAN'S MANUAL

LivaNova® Tunneler Model 402

October 2023

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.

℞

CE 0344

The year of authorization to affix the CE mark:

Model 402	2005

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1.0. Description

The LivaNova Tunneler Model 402 is designed for use during implantation of a LivaNova dual-pin lead or single-pin lead. It is recommended for subcutaneous tunneling of the lead connector or connectors from the neck to the chest. The tunneler, supplied sterile, is a single-use-only device.

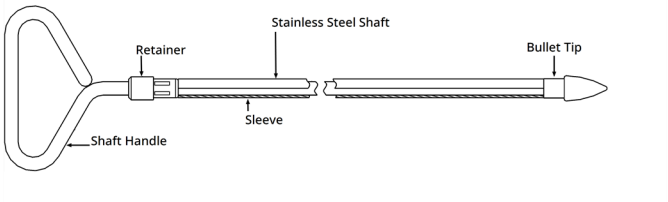
1.1. Intended Use

The tunneler is intended for use only to aid in routing, or directing, the lead from the neck incision to the chest incision.

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 Tunneler



1.3. Product Specifications

Table 1. Tunneler 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

Table 1. Tunneler Product Specifications (continued)

Component*	Dimension (Nominal)†		
Stainless steel bullet tip	outside diameter	0.31 in.	7.9 mm

* No component of the system is made with natural rubber latex.
† Dimensions of the LivaNovaTunneler were optimized to minimize risk of damage to the lead connector that may occur with the use of general-purpose tunnelers.

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).

Tunnel Direction

Always tunnel from the **neck incision to the chest incision** to reduce the risk of damage to one of the major arteries or veins in the neck.

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 7.

Single Use Only


The tunneler 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

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. Select the appropriate sleeve.
    - The smaller diameter sleeve is used when a single-pin lead is implanted (used with single-receptacle generator).
    - The larger diameter sleeve is used when a dual-pin lead is implanted (used with a dual-receptacle 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.

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

3.3. Pass the Tunneler

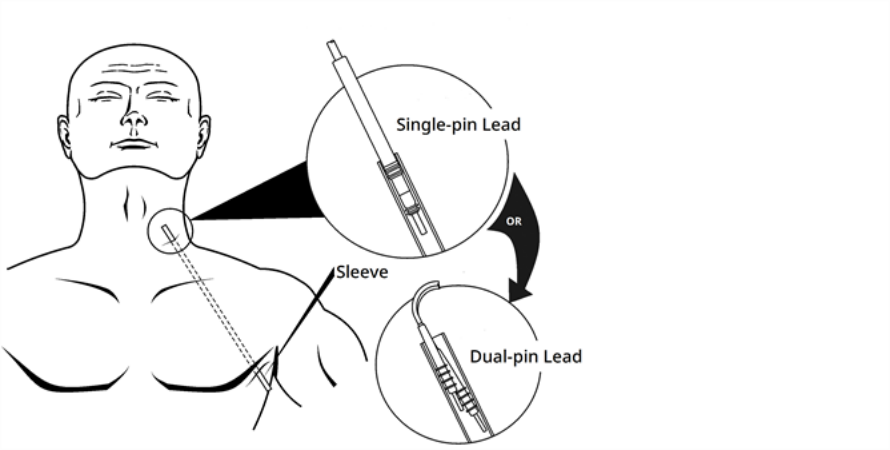
After the chest and neck incisions are made, and before the electrodes are inserted around the cervical vagus nerve, the tunneler can be inserted and passed from the neck incision to the chest incision. (If necessary, the tunneler can be manually shaped to help direct it through the body.)

⚠ 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 neck incision and tunnel subcutaneously toward the chest incision. 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.

   Figure 2. Position of Sleeve and Lead Connectors



   ⓘ NOTE: Insert the lead into the sleeve at the neck.

3. With the sleeve in place between the two incisions, carefully insert the lead connector 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 tube and the inside of the sleeve.
4. Carefully pull the sleeve, along with the lead connector, from the chest incision end until the lead connector completely exits the chest incision.
5. Remove the lead connector from the sleeve and leave the electrode array at the neck incision site.
6. 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 8. 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.

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