9. INSPECTION PRIOR TO USE

Prior to use, verify that the use by date has not been exceeded and the Tunneler and sterile packaging have not been damaged. Verify that the tube size is suitable for the specific procedure which it is intended. Do not use past use by date or if sterile package is damaged.

⚠ Do not continue to use the Tunneler if the sterility is compromised.

10. DIRECTIONS FOR USE

The following directions cover the use of the Tunneler:

10.1 PREPARE THE TUNNELER

To open the Tunneler packaging, do the following:

1. Break tamper evident sticker on sales package and remove the sterile packaged Tunneler. The sterile package is configured as a pouch in pouch with a tray and retainer.
2. Open the outer pouch.
3. Using sterile technique, remove the sterile inner pouch.
4. Open the inner pouch and remove the tray.
5. Carefully take off the retainer and remove the three Tunneler components without dropping them. If the device is dropped, do not use the device and discard.

10.2 ASSEMBLE THE TUNNELER

The Tunneler must be assembled prior to being used. To do so, follow the steps below:

1. Slide the tube over the shaft.
2. Screw the tip onto the shaft.

⚠ Do not over tighten the tip. Doing so could make it difficult to remove.

10.3 USING THE TUNNELER

Follow standard surgical practice to create entrance and exit incisions for the Tunneler. The Tunneler can be inserted and passed from one incision to the other. If necessary, the Tunneler can be manually shaped to help direct it between incision sites.

To pass the Tunneler, do the following:

1. Place the tip end of the Tunneler through an incision exerting force on the handle and directing the Tunneler as necessary.
2. After the tip has exited the other incision, unscrew the tip and withdraw the shaft, leaving the tube extending through both incisions.
3. Insert the lead into the tube until it is held by the tube for IS-1 style connectors or pass through the tube if the size allows.
4. Pull the tube from the exiting incision until the other end of the tube and lead are exposed.
5. Remove the tube from the lead at the exiting incision being careful not to stretch the lead body.
6. Dispose of used product and packaging in accordance with hospital, administration and/or local government policy.

11. INFORMATION AND SUPPORT

If there are questions regarding the use of the Tunneler or any serious injuries occur resulting from the use of the device, please contact:

MicroTransponder, Inc.
2802 Flintrock Trace
Suite 226
Austin, TX 78738
USA

Internet: www.vivistim.com/ifu
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MicroTransponder®

MicroTransponder Tunneler: Model 6001

Instructions For Use

1. DESCRIPTION

The MicroTransponder Tunneler Model 6001 is designed for creating pathways between incision sites.

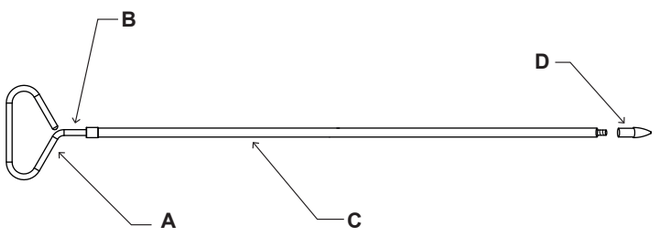
The Tunneler is provided sterile using an ethylene oxide (EO) process and consists of three components: a shaft with a formed handle, a tube and a tip.

2. SPECIFICATIONS

The materials and substances to which patients can be exposed are stainless steel and polyether block amide.

Discuss allergies or other intolerances related to the materials with the patient before the procedure. Stainless steel contains nickel. Nickel is used in mixtures of metals and is a known allergen.

Assembled Tunneler



A Handle

B Shaft

C Tube

D Tip

The Tube is compatible with IS-1 style connector leads.
Tube Inner Diameter (ID): 3.4mm
Tube Length: 274mm

3. SYMBOLS AND DEFINITIONS

Do not use if package is damaged

Consult instructions for use

Manufacturing Date

Caution

STERILE EO — Sterilized using ethylene oxide

Storage Conditions

Use by date

Manufacturer

Rx only — Prescription Only Device

LOT — Lot

Keep Dry

Double Sterile

Single Use

Do not resterilize

Open here

4. INTENDED USE

The Tunneler is a general use accessory intended for creating pathways between incision sites.

5. WARNINGS

Care should be taken not to injure any nerves, arteries, or veins during the tunneling procedure.

6. PRECAUTIONS

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

Do not resterilize the Tunneler because functionality and sterility cannot be ensured and infections may occur.

Extra Tunnelers should be available in case sterility is compromised or if the Tunneler is damaged or dropped during surgery.

Use the Tunneler prior to the ¨Use by¨ date specified on the package.

7. ADVERSE EVENTS

The complications that may result from the tunneling procedure include, but are not limited to:

- allergic reaction
- hematoma
- hemorrhage
- infection
- nerve irritation, nerve impingement or nerve damage
- pyrogenic reaction
- tissue damage

8. STORAGE

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.