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Document Information

Document Number: MM-17-004Z-X-02

Device Name: Mainstay Tunneler

Document/Label Type: Instructions for Use

Country: US

Language: English

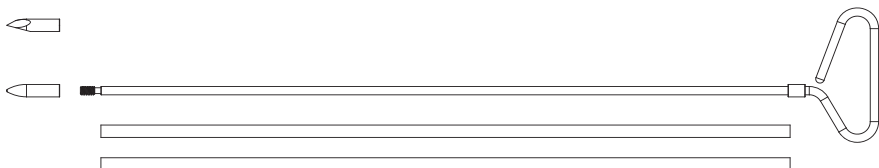
Revision: A

Filename: MM-17-004Z-X-02_Mainstay Tunneler IFU (US) - English_Rev A, 11-21-2024.pdf



Mainstay Tunneler: Model TUN1

Instructions For Use



Rx only

MM-17-004Z-X-02

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1. DESCRIPTION

The Mainstay Tunner Model TUN1 is designed for use during implanta- tion of Mainstay Medical leads. It is recommended for subcutaneous tun- neling between incisions in the back.

The Tunner consists of five components: a stainless steel shaft with a formed handle, two Pebax (7233 Clear) sleeves and two stainless steel tips.

2. SYMBOLS AND DEFINITIONS



Do not re-sterilize



Do not reuse



Do not use if package is damaged



Consult Instructions for Use



Date of manufacture



Caution



Sterilized using ethylene oxide



Temperature Limit

Rx only By prescription only



Catalogue number



Outside diameter



Length



Lot Number



Quantity



Keep away from sunlight



Keep Dry



Manufacturer



Use-by date

3. INTENDED USE

The Tunneler is intended for use to route lead(s) between incisions in the back.

4. 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. Return any open packages that have not been used to the manufacturer.



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



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

5. STORAGE AND HANDLING

Store the Tunneler between -29°C and 60°C.



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.

Prior to opening the sterile package, examine it carefully for damage or compromised sterility. If the outer package has been opened or damaged, sterility of the Tunneler cannot be guaranteed and should not be used. If the package has evidence of exposure to extreme temperatures or moisture, or if there is any indication of external damage, the package should be left unopened and returned to the manufacturer.

To open the Tunneler package, do the following:

1. Carefully break tamper evident sticker on sales package and remove the sterile packaged Tunneler. The sterile package is configured as a tray in pouch.
2. Open the outer pouch.
3. Using sterile technique, remove the sterile inner tray.
4. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.

Make sure to remove all five pieces from the tray (1 shaft, 2 sleeves and 2 tips).

6. DIRECTIONS FOR USE

The following directions cover the use of the Tunneler.



Do not use the Tunneler if the following occurs:

- The outer or inner package has been pierced or altered, because this can render it nonsterile.
- The stainless steel shaft or tips show any visible corrosion.
- The expiration (use-by) data has passed, because this can adversely affect the component's sterility.
- Do not resterilize the Tunneler because functionality and sterility cannot be ensured and infections may occur. Return any open packages that have not been used to the manufacturer.



6.1 Assemble the Tunneler

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

1. Using sterile technique, remove the five Tunneler components from the inner tray and place them into the sterile field.
2. Slide one of the sleeves over the shaft.
3. Carefully screw the appropriate tip onto the shaft.



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

6.2 Using the Tunneler

After the incisions have been made and the lead(s) have been implanted, 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 through the back.



Do not shape the Tunneler more than 25 degrees, because it may cause the sleeve to kink or become difficult to remove.

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.



Take care if tunneling towards an incision near lead; impact between the tunneler and the lead may cause damage to the lead.

2. After the tip has passed from an incision to the other, unscrew the tip and withdraw the shaft, leaving the sleeve extending through both incisions.
3. Carefully insert the lead(s) into the sleeve until visible at the opposite incision.
4. Carefully remove the sleeve from the lead(s) at the exiting incision.
5. When the Tunneler is no longer needed, discard the Tunneler.

7. INFORMATION AND SUPPORT

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

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2024-06