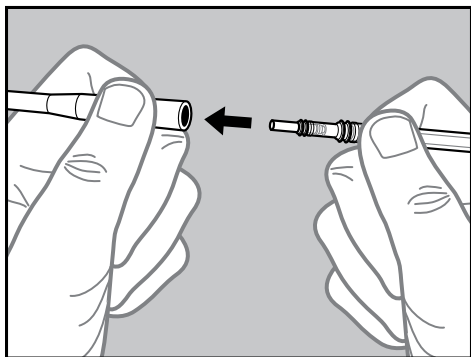


Traverser™

Pacemaker Tunneling Tool



Directions for Use

This device is intended for one time use only. Read instructions prior to use.

Indications

For use to tunnel a pacemaker lead with an IS-1 connector from the venous insertion site of the implanted pacing lead to a signal generator pocket not immediately adjacent to that location.

Precautions

- This device is **ONLY** indicated for use with a **male IS-1 pacemaker lead connector**. Use with any other connector may result in damage to the pacemaker lead.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- It is important to pass the device within the subcutaneous tissue of the chest wall such that it **does NOT penetrate the muscle layer or the skin surface**.

Suggested Instructions for Use:

NOTE: The Pacemaker Tunneling Tool is available in three model lengths. A device should be selected of sufficient length to span the distance between insertion site and the signal generator pocket.

1. After all pacemaker lead measurements are complete and satisfactory, firmly secure the lead at its insertion site by suturing it to the underlying muscle layer. A small stress relieving loop may be added to the lead.
2. Create a pocket for the signal generator where desired, or open an existing pocket.
3. Measure the distance between the point of lead insertion and the pocket and select the appropriate Pacemaker Tunneling Tool.
4. Open package and place contents on sterile field.
5. The Pacemaker Tunneling Tool's curve can be customized by hand. If necessary, adjust the device to better fit the geometry of the chest wall prior to use.
6. Insert the IS-1 connector of the pacemaker lead into the opening of the Pacemaker Tunneling Tool until it can go no further.
7. Anaesthetize the projected tunnel path with an appropriate local anesthetic delivered by a long needle.
8. Advance the tapered tip of the Pacemaker Tunneling Tool through the subcutaneous tissue between the pacemaker lead insertion site and the surgical pocket. The tunnel should be as deep as possible to avoid late lead erosion, but above the muscle layer.
9. When the tip of the Pacemaker Tunneling Tool appears within the pocket, grasp it manually or with a clamp and pull it until the pacemaker lead is in the pocket.
10. Gently disengage the IS-1 connector from the Pacemaker Tunneling Tool.
11. Connect the pacemaker lead to the appropriate port of the signal generator.

Manufactured in U.S.A. for

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