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Intended Purpose/Indications for Use

The ReActiv8 Release Tool (REF EXT1) is designed for use during the removal of the ReActiv8 leads.

Precautions and Handling

The Release Tool is a single-use device. Do not re-sterilize or reuse it. Do not use if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Do not use the tool if the expiration or "use-by" date has expired.

This product contains up to 0.13% Cobalt.

Directions for Use

The procedure described below is recommended to remove implanted peripheral lead components. Fluoroscopic imaging capabilities may facilitate the procedure.

1. Disconnect leads from system components and dissect any fibrotic tissue to expose the proximal body of the lead. Perform any small fascial incisions as required to assist during dilation.
2. Advance the sheath down the lead, maintaining alignment, up to beginning of the proximal tine. A twisting motion with minimal axial force may assist sheath advancement past any proximal lead electrodes. The sheath will stop at the proximal tine.
3. Insert the dilator over the lead and fully inserted sheath and advance it up to and over as much of the proximal tine(s) as possible. Take care not to use excessive axial force or push dilator and lead into other tissues, instead carefully using a twisting motion to advance the dilator along the lead and sheath.
4. Insert the trephine over the dilator, sheath, and lead. Use careful twisting motions to advance the trephine cutter while maintaining position of the dilator. A depth mark on the dilator will be seen when the trephine tip is aligned at the end of the dilator.
5. Use a gentle reciprocal rotation of the trephine with minimal axial load to incise any encapsulating tissue. Maintain axial alignment with the lead, periodically giving the lead a gentle tug to determine if it has been released. If released, the lead, dilator, and sheath should all pull out of the trephine cutter.
6. Once the leads have been removed, inspect them carefully to confirm that all portions of the lead and any tines have been removed.



Information and Support

If there are questions regarding the use of the ReActiv8 Release Tool, please contact:

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For label symbol definitions, refer to:
www.mainstaymedical.com/symbols

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