

Isolater Isolation Pen



6.3.2

INDICATION FOR USE

The Isolator™ pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or ASB3 in Ablation mode. The Isolator™ pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

PRODUCT HIGHLIGHTS

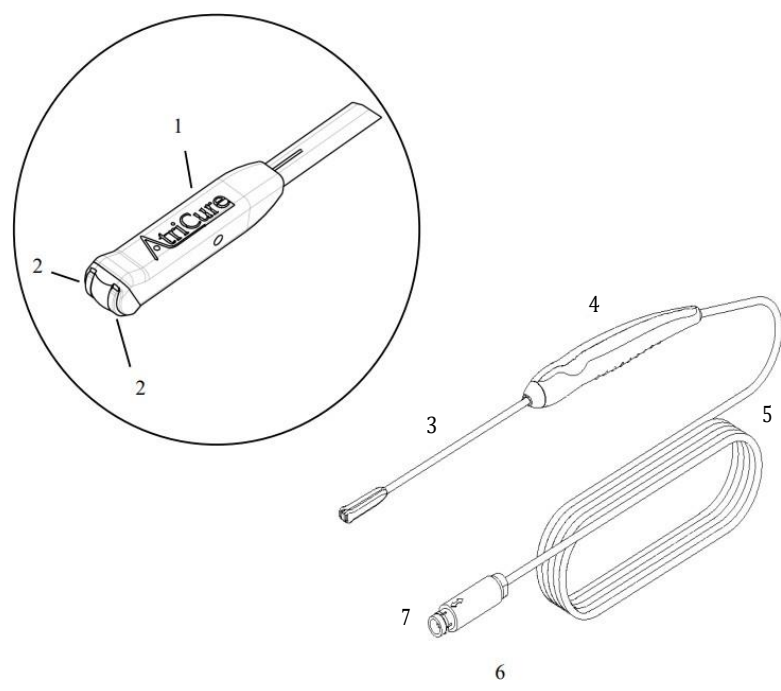
- The Isolator Transpolar Pen creates reliable transmural lesions at predictable depths.
- Bipolar pen offered to both ablate cardiac tissue and evaluate conduction block.
 - Pace. Sense. Stimulate. High Frequency Stimulate. Ablate. All with the same device.
 - Semi-rigid shaft provides stable contact with target epicardium yielding desired pressure when creating lesion.
 - “Pen-Point” accuracy delivers predictable energy for creating connecting lesions—where you want them, when you want them.
 - Toggle to locate and ablate triggers without repositioning.

The Isolator Transpolar Pen is supplied as a STERILE clamp and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

The other components (ASU and ASB3) are not sterile and may be reused

Features	Details MAX3	Details MAX5
Electrodes	6.3.1 Bipolar copper electrodes with a nickel-gold plating covering all exposed surfaces	
	Arc: 10mm Width: 6.9 mm Thickness: 5.8 mm Spacing between the electrodes: 3 mm Width: 1 mm	
Shaft	malleable, 18.5 cm in length	Malleable, 29.7 cm in length

PRODUCT ILLUSTRATION



- 1. Distal Jaw
- 2. Electrodes
- 3. Malleable Shaft
- 4. Handle
- 5. Cable
- 6. Connector
- 7. Alignment Arrow