

Isolator Synergy Clamp



INDICATION FOR USE

2.
- The AtriCure Bipolar (Transpolar) System is indicated for ablation and coagulation of soft tissue in general, ENT, thoracic, urological, gynecological surgical procedures and ablation of cardiac tissue during surgery including pulmonary vein isolation and atrial connecting lesions for the Maze procedure for the treatment of cardiac arrhythmias, including atrial fibrillation.

PRODUCT HIGHLIGHTS

- 6.1.2
- The Synergy™ Ablation Clamps feature two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanisms.

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- The Synergy Ablation Clamp requires the use of the AtriCure Switch Box (ASB3) and Ablation Sensing Unit (ASU3).

The RF-Clamp (OLL2) is the only Bipolar clamp that has FDA approval for the treatment of Atrial Fibrillation; no other bipolar clamp has this approval. To ensure that the RF energy is delivered uniformly across the cardiac tissue ablation zone, the clamp has a unique parallel jaw closing system. Each jaw contains two sets of gold-plated pulsating electrodes that ensure ablation takes place in the deepest part of the tissue first.

The clamp continuously monitors tissue impedance directly and adjusts the power multiple times per second. These unique and advanced features ensure that each ablation is transmural, delivered safely and is tissue specific thus maximizing the ability to promote better clinical outcomes.

The Synergy Ablation System 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	OLL2	OSL2
Electrodes	2 pairs of Beryllium-Copper electrodes with a Nickel/Gold plating covering all exposed surfaces	2 pairs of Beryllium-Copper electrodes with a Nickel/Gold plating covering all exposed surfaces
Shaft	6.1.1 Stiff stainless-steel shaft	Rigid stainless-steel shaft
Lengths of jaws	65 mm 6.1.3	55 mm
Closing Force	10 lbf (Max force spike is 25 lbf)	10 lbf (Max force spike is 25 lbf)
Closure	The opposing clamping surfaces will touch at a minimum of one point with a maximum gap of 0.020" (0.51mm) along the length of the jaws	The opposing clamping surfaces will touch at a minimum of one point with a maximum gap of 0.020" (0.51mm) along the length of the jaws

UNIQUE LESION FORMATION

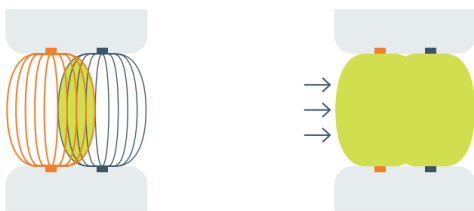
A lesion is only as strong as its weakest link, or gap. Traditional radio frequency creates a lesion from the surface toward the middle, resulting in an hourglass-shaped lesion. AtriCure’s Isolator Synergy Bipolar clamp uses dual electrodes with alternating and overlapping fields to form a lesion from the middle to the surface. The result is a more robust and wider column-shaped lesion with transmuraliity.

FIGURE 1. CONVENTIONAL BIPOLAR



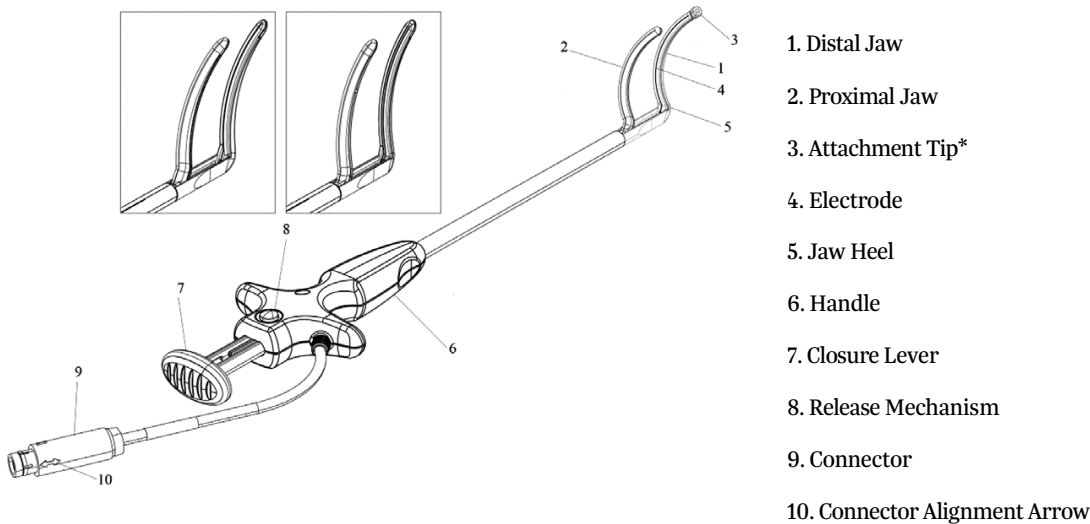
With conventional bipolar (one pair of electrodes), electrical signals can escape through the weakness in the lesion.

FIGURE 2. ISOLATOR SYNERGY CLAMP



The Synergy clamp uses two pairs of electrodes, creating a more robust lesion.

PRODUCT ILLUSTRATION



*Only on devices packaged with GLIDEPATH Tape Instrument Guide