

# LASER ENERGY



The Ablation Science Behind Laser Energy and How the HeartLight X3 Catheter is Used to Create RAPID, Contiguous, Transmural Lesions

## OVERVIEW

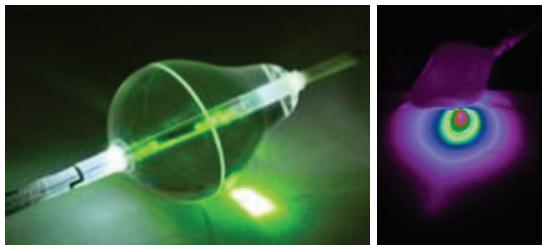
### Catheter Information

The HeartLight X3 Catheter has a glass fiber optic that runs the length of the catheter which transmits the 980nm near-infrared laser energy. The laser energy exits the shaft of the catheter perpendicularly and projects a 30° arc ablative footprint. The position of the energy is adjustable distally, proximally, and rotationally over 360° in both the clock and counter-clock direction.



### Laser Energy

Laser energy generates heat within the myocardial tissue as it is absorbed. It is titratable from 5.5–15 Watts and the energy density is uniform across the 30° arc. The 980nm laser was chosen for its specific absorption characteristics with myocardial tissue. The laser fiber does not need to be in contact with the tissue to create a lesion — the compliant balloon pushes the blood out of the way to expose the tissue for ablation.



### RAPID Mode Ablation

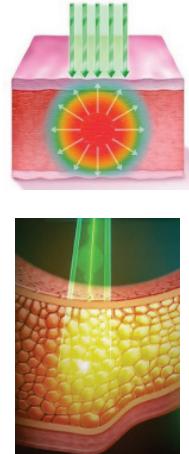
During RAPID mode the laser fiber is driven by a motor allowing for contiguous lesion creation. The motor rotates the fiber at 2.25° per second, eliminating the need for manual overlap. Time exposure of the laser energy to the myocardial tissue is controlled and optimized to create transmural lesions. The laser energy can be applied for a continuous 360 degrees.



## LESION DATA

### Lesion Creation

Laser energy creates a lesion by optically penetrating the tissue. It is directed forward and subsurface, with the focal point of heat about 2mm below the surface. As the tissue absorbs the photon energy it produces a vibrational excited state in molecules. By absorbing this energy the tissue is heated which is then conducted to the surrounding tissue, creating a transmural lesion. The fluid circulating within the balloon helps cool the tissue interface, enabling heat generation within the tissue instead of at the surface like an RF catheter.



### Dosing

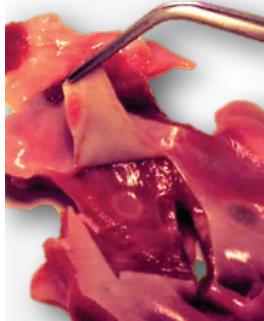
The laser energy can be titrated from 5.5–15 Watts based on the thickness of the tissue you are ablating, and the level of tissue contact or exposure. Lesions are created using lower wattages than other modalities such as RF due to the ability to optically penetrate the tissue and begin lesion creation about 2mm below the surface. With RF, about 90% of the power is absorbed within the first 1–1.5mm of tissue. RF is limited by the surface area of the tip, the force to generate and maintain contact, and the depth of penetration.

### Power (Watts)      Time (sec)

<b>5.5W</b>	30s
<b>7.0W</b>	30s
<b>8.5W</b>	30s
<b>8.5W</b>	20s
<b>10W</b>	20s
<b>12W</b>	20s
<b>13W RAPID</b>	continuous
<b>15W RAPID</b>	continuous

## LASER BENEFITS

### Safety



Laser energy also has benefits when it comes to safety. The lower max temperatures seen during ablation decrease the risk of charring and steam pops. During creation of a laser lesion, the endothelial layer is preserved by the "cooling" effects of the fluid filled balloon and the lesion focal point ~2mm below the surface. Preservation of this membrane decreases the risk of thromboembolism.

### Edema & Stenosis Data

With laser, several studies have shown less edema and PV stenosis post-procedure as compared to RF.<sup>1,2</sup> A 24.1% increase was seen in average PV wall thickness with RF as compared to 1.2% with laser. A 12.1% decrease in median PV luminal area was seen after RF ablation whereas the luminal area increased by 0.36% with laser. It was also noted that significantly more energy was required for vein isolation when using RF compared to laser (11,124 Joules vs 5,687 Joules). The 5,687 Joules of delivered energy was from solely the point-by-point method of the second-generation laser balloon. With the addition of RAPID mode in the new HeartLight X3, the motor driven system moves at 2.25° per second which has the potential to reduce the amount of laser energy delivered to the range of 2,196 Joules for a vein isolation based on a sweep of 380° to ensure lesion overlap.

## Modality Comparison Chart

	<b>Source</b>	<b>Energy Source Contact</b>	<b>Considerations</b>	<b>Impact</b>
<b>Laser</b>	980nm near infrared diode laser	Not required	RAPID vs Manual mode based on visual confirmation of tissue exposure, energy titration based on anatomical location	Visual confirmation and ultra compliant balloon allows for stable, effective contact allowing laser energy to penetrate the myocardium in a uniform manner
<b>CRYO</b>	Liquid Nitrogen	Yes	Vein size and shape, anatomical variation, confirmation of occlusion via fluoro + contrast and/or ICE	Static balloon size and shape could lead to gaps; Lack of titratable energy could lead to non-uniform lesions based on anatomical variances and vein size
<b>RF</b>	Radiofrequency Energy (Watts)	Yes	Stability, catheter angle of approach, energy and time, 3D map/algorithm-based approach	Potential for gap formation due to catheter movement and instability from contractility and respiration; Additional challenges with power delivery and complete lesion formation in these scenarios

1. Gao X, et al. Left atrial thickness and acute thermal injury in patients undergoing ablation for atrial fibrillation: laser versus radiofrequency energies. J Cardiovasc Electrophysiol. 2021; 1-9. <https://doi.org/10.1111/jce.15011>

2. Dukkipati SR, et al. Pulmonary Vein Isolation Using the Visually Guided Laser Balloon: A Prospective, Multicenter, and Randomized Comparison to Standard Radiofrequency Ablation. J Am Coll Cardiol. 2015 Sep 22;66(12):1350-60. doi: 10.1016/j.jacc.2015.07.036.

CAUTION: Federal Law (USA) restricts device to sale by or on the order of physician. The HeartLight X3 Endoscopic Ablation System is indicated for the treatment of drugrefractory recurrent symptomatic paroxysmal atrial fibrillation. Refer to device operating manual for detailed information regarding the procedure, indications contraindications, warnings, precautions, and potential complications / adverse events and other important information. For further information, please consult the CardioFocus® website at: [www.cardiofocus.com](http://www.cardiofocus.com).