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HEARTLIGHT® ENDOSCOPIC ABLATION SYSTEM: QUICK REFERENCE

About the HeartLight System

- The HeartLight® Endoscopic Ablation System is a FDA-approved, visually guided laser balloon technology that enables controlled and consistent pulmonary vein isolation (PVI). PVI is a first-line treatment option for symptomatic drug-refractory atrial fibrillation (AF).
- HeartLight is the first and only PVI technology that combines four unique features: laser energy, visual guidance, titratable energy and a universal balloon design.
- HeartLight is the first balloon-based ablation technology to complete a successful clinical trial in comparison to a gold standard, radiofrequency (RF) catheter ablation technique.
- More than 5,000 patients worldwide have been treated with HeartLight.
- HeartLight is developed and manufactured by CardioFocus, Inc., Marlborough, MA.

Indication

- In the U.S., the HeartLight System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal AF.

Approval

- U.S. FDA approval April 2016 and now commercially available in the U.S.
- Received CE Mark in 2009 and is commercially available in Europe.
- Japan PMDA approval June 2017 and is now commercially available in Japan.
- HeartLight Excalibur Balloon™ approved in EU (2017) and US (2018)

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How It Works

- The HeartLight System provides physicians with the capacity to see within the heart and, for the first time, visually direct the application of laser energy to achieve durable PVI.
- HeartLight also allows full rotational and axial energy positioning capabilities. Energy is applied in a series of continuous 30° arcs, and can be freely directed to any area, creating precisely tailored lesion sets.
- The Endoscope allows the electrophysiologist (EP) to visually see the pulmonary veins (PVs) they are ablating unlike older or alternative solutions that rely on x-ray or mapping support for guidance.
- Ultra-compliant, universal balloon easily accommodates PVs with varying anatomies and sizes, providing the clinician maximum procedural flexibility.
- Focused laser energy enables precise ablation, optimized for variations in anatomy.
- Ability to titrate energy as needed for an individual patient's cardiac anatomy and varied thickness of the PVs.

Clinical Outcomes

- Results from the U.S. pivotal trial, which randomized 353 patients to HeartLight or RF ablation, showed that the majority of patients (61%) having a single ablation procedure using the HeartLight System experienced freedom from paroxysmal AF at 12 months.[1]
- HeartLight has also shown high rates of success in single-center non-randomized published studies from experienced centers showing 71-93 % freedom from AF recurrence after one year follow up[2,3,4]
- A short learning curve means promising practical findings with HeartLight: physicians largely new to the HeartLight technique can equal their performance with RF devices by using the HeartLight System.

[1] Dukkipati, S.R., et. al., J Am Coll Cardiol 2015;66:1350–60.

[2] Sediva, L., et al. Visually guided laser ablation: a single-centre long-term experience. Europace. 2014 Dec;16(12):1746-51.
[3] Osca, J., et al. Electrical Isolation of Pulmonary Veins Using Laser Catheter in the Treatment of Paroxysmal and Persistent Atrial Fibrillation. One-Year Results. Revista Espanola de Cardiologia (English Edition) 69, no. 5: 488-93. (2016).
[4] Koopman, P., et al. Pulmonary Vein Isolation using Laser Balloon as Compared to Standard Radiofrequency Catheter Ablation. IAF Poster. (2017).