

# UNDERSTANDING THE FDA-APPROVED HEARTLIGHT® SYSTEM & ATRIAL FIBRILLATION



## U.S. Media Fact Sheet

**The HeartLight Endoscopic Ablation System** is a revolutionary catheter ablation technology designed for the treatment of atrial fibrillation (AF), the most common heart arrhythmia. The HeartLight System's direct visualization, titratable laser energy, and universal balloon design make it a new standard for pulmonary vein isolation (PVI) procedures. PVI is a first-line treatment option for symptomatic drug-refractory AF.

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.<sup>1</sup> This eliminates total reliance on maps and other surrogate visualization methods.

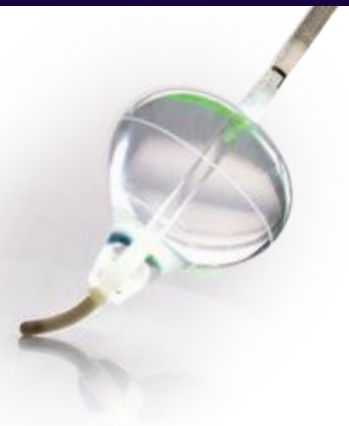
In the U.S., the HeartLight System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal AF. HeartLight is developed and manufactured by CardioFocus®, Inc. ([www.cardiofocus.com](http://www.cardiofocus.com)).

## OVER 5,000 PATIENTS WORLDWIDE HAVE BEEN TREATED WITH HEARTLIGHT

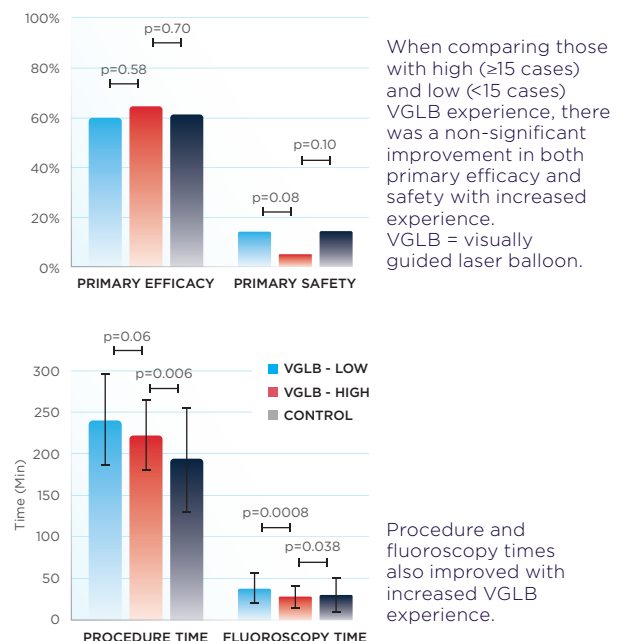
- ▶ Received CE Mark in 2009 and commercially available in Europe
- ▶ U.S. FDA approval April 2016 and commercially available in the U.S.
- ▶ Japanese PMDA approval June 2017 and now commercially available in Japan

## BENEFITS OF CATHETER ABLATION TREATMENT WITH HEARTLIGHT

- ▶ The U.S. pivotal trial of HeartLight demonstrates that a majority (61%) experienced freedom from AF at 12 months.<sup>2</sup> HeartLight is also the first balloon-based ablation technology to complete a successful clinical trial in comparison to a gold standard, radiofrequency (RF) catheter ablation technique.
- ▶ HeartLight-treated patients experience high rates of success, with single-center non-randomized published studies from experienced centers showing 71-93% freedom from paroxysmal AF recurrence after one year follow up.<sup>1,3-5</sup>
- ▶ A short learning curve means promising practical findings with HeartLight: Physicians quickly become proficient with the HeartLight system. Exploratory analysis showed that physicians performing 15 or more HeartLight procedures achieved outcomes that compare to a standard RF catheter technique.<sup>2</sup> (Figure 1)



**Figure 1. HeartLight Operator Learning Curve<sup>3</sup>**



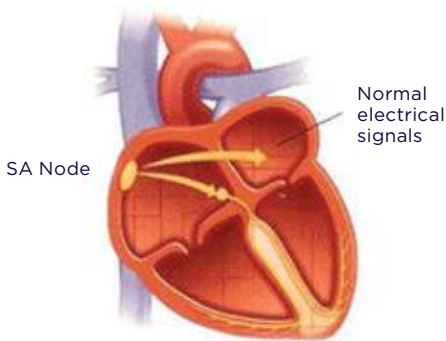
## FOUR KEY FEATURES LEADING TO POSITIVE CLINICAL OUTCOMES

- ▶ Focused laser energy enables precise ablation, optimized for variations in anatomy. 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.
- ▶ Ability to titrate energy as needed for an individual patient's cardiac anatomy and varied thickness of the PVs.

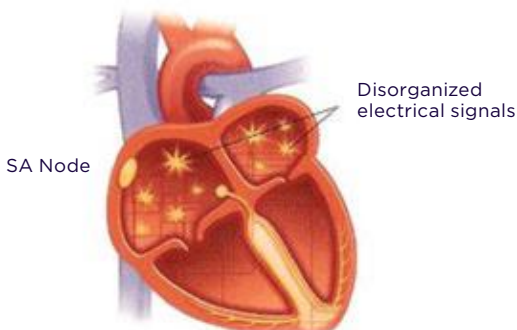
## ABOUT ATRIAL FIBRILLATION (AF)

Atrial fibrillation (AF), the most common cardiac arrhythmia, is the rapid and uncontrolled beating of the atria, the upper chambers of the heart. AF is believed to be a progressive disease. Initially it is “paroxysmal”—consisting of isolated, self-terminating episodes. Over time these episodes tend to become more frequent and longer in duration. Eventually, the continued presence of AF provokes changes or “remodeling” in the atrial tissue that make the tissue more susceptible and better able to maintain the arrhythmia. At this point, it will become “persistent,” requiring electrical or chemical cardioversion to restore normal sinus rhythm. Finally, it becomes long-standing persistent or permanent when it can no longer be terminated by cardioversion.<sup>6</sup>

### NORMAL CONDUCTION



### ATRIAL FIBRILLATION



## MOST COMMON AF SYMPTOMS<sup>7</sup>

- ▶ Heart palpitations (feeling the heart is racing or fluttering)
- ▶ Weakness, fatigue, shortness of breath
- ▶ Dizziness, sweating, anxiety
- ▶ Chest pain, pressure, or discomfort

## THE MOST SERIOUS RISK FROM AF

If left untreated, AF can permanently damage the heart and lead to other medical problems, including:<sup>8</sup>

- ▶ Stroke
- ▶ Heart failure
- ▶ Chronic fatigue
- ▶ Additional heart rhythm problems

## CAUSES OF AF<sup>8</sup>

Sometimes the cause of AF is unknown, however other times, it is the result of damage to the heart's electrical system from various conditions, such as long-standing, uncontrolled high blood pressure or coronary artery disease. AF is also the most common complication after heart surgery.

## ALTERNATIVE TREATMENT OPTIONS

Because of the risk of stroke, patients typically require lifelong treatment with anticoagulants, also known as blood thinners. These medications put users at higher risk of suffering bleeding events. There are also other medications, referred to as "anti-arrhythmics" that can be given to patients with atrial fibrillation. In many cases, however, these medications are not enough to keep atrial fibrillation under control and may have serious side effects.

## PREVALENCE OF AF

AF affects nearly 2.3 million people in the United States,<sup>9</sup> and the numbers are climbing along with the growing elderly population. Catheter-based treatment of AF has created a global market in excess of \$1.5 billion, currently growing at approximately 15% annually, making it one of the largest and highest-growth medical device market opportunities.<sup>10</sup> The global AF market is projected to amount to \$2 billion in 2017.<sup>10</sup>

### More information:

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**CardioFocus Website:** <http://www.cardiofocus.com/>

### References:

1. Dukkkipati, S.R., et al., The durability of pulmonary vein isolation using the visually guided laser balloon catheter: Multicenter results of pulmonary vein remapping studies. *HeartRhythm*. 2012.01.019. 2. Dukkkipati, S.R., et al., *J Am Coll Cardiol* 2015;66:1350–60. 3. Sediva, L., et al. Visually guided laser ablation: a single-centre long term experience. *Europace*. 2014 Dec;16(12):1746–51. 4. 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). 5. Koopman, P., et al. Pulmonary Vein Isolation using Laser Balloon as Compared to Standard Radiofrequency Catheter Ablation. IAF Poster. (2017). 6. U.S. Opportunities in the Management of Atrial Fibrillation. Health Resource International, October 2002. 7. The Mayo Clinic, Atrial Fibrillation Symptoms and Causes [<http://www.mayoclinic.org/diseases-conditions/atrialfibrillation/symptoms-causes/dxc-20164936>]. 8. American Heart Association. [http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Why-Atrial-Fibrillation-AF-or-AFib-Matters\\_UCM\\_423776\\_Article.jsp#.V6jgFTXl\\_Zs](http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Why-Atrial-Fibrillation-AF-or-AFib-Matters_UCM_423776_Article.jsp#.V6jgFTXl_Zs). 9. Go AS, et al. Prevalence of diagnosed atrial fibrillation in adults. *JAMA*. 2001;285:2370–2375. 10. CardioFocus Data on File.

### Brief Statement

#### CardioFocus® HeartLight® Endoscopic Ablation System

**Indication:** The HeartLight Endoscopic Ablation System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

**Contraindications:** The HeartLight System should not be used: 1. In patients who have had a ventriculotomy or atriotomy within the preceding four weeks as the recent surgery may increase the risk of perforation; 2. In patients with prosthetic valves as the catheter may damage the prosthesis; 3. In patients with an active systemic infection as this may increase the risk for cardiac infection; 4. In patients with unstable angina; 5. In patients with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt following transeptal puncture; 6. In the ventricle because of the danger of catheter entrapment in the chordae tendineae; 7. In patients with conditions where the manipulation of the catheter within the heart would be unsafe (for example, presence of intracardiac thrombus and myxoma); 8. In patients with one or more pulmonary vein stents.

**Warnings:** Only adequately trained personnel in a fully equipped electrophysiology laboratory should perform cardiac ablation procedures. This device should be used only by physicians fully trained in cardiac electrophysiology procedures. Prospective physician operators of the HeartLight Endoscopic Ablation System must complete specific training provided by CardioFocus prior to the first clinical procedure.

Operation Manual / Instructions for Use – Do not attempt to use the HeartLight System before reading and completely understanding the HeartLight Endoscopic Ablation System Operation and Maintenance Manual.

**Potential Complications:** Adverse reaction to anesthesia, air embolism, anemia, anxiety, aspiration pneumonia, atrio-esophageal fistula, esophageal ulceration, esophageal tear, arteriovenous (AV) fistula, back pain, bleeding from puncture site, blood clot/thromboembolic event/deep vein thrombosis, blurred vision or vision changes, bradycardia, bronchitis, bruise, cardiac perforation/tamponade/tear, cardiopulmonary arrest, chest pain/ discomfort/pressure, complete heart block, coronary artery spasm, dissection thrombosis, cough, death, diarrhea, dizziness/vertigo, dysphagia, esophago-mediastinal fistula, fatigue, fever, headache, hematoma, hemothorax, hemorrhage, hemoptysis, hypertension/ hypotension, incision site pain/tenderness, infection, major bleeding, myocardial infarction, nausea/vomiting, nerve injury, neurological deficits, pain or severe coughing during energy delivery, pericardial effusion, pericarditis, phrenic nerve damage leading to diaphragmatic paralysis, phrenic nerve palsy, pneumothorax, pleural effusion, pseudo-aneurysms, pulmonary edema, pulmonary vein stenosis/occlusion, pyrogenic reaction, scarring, sepsis, shortness of breath, stroke/transient ischemic attack (TIA)/ cerebrovascular accident, tachyarrhythmia, ulceration, urinary infection, wound healing difficulties, valvular damage, vascular complication requiring surgery, vascular damage/tear, vasovagal reactions.

Refer to the 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 call CardioFocus at 844-527-3723.

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

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