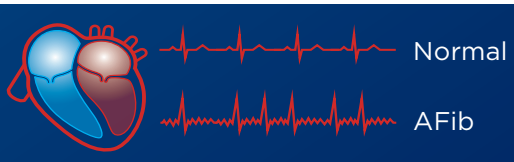
HEARTLIGHT® X3 ENDOSCOPIC ABLATION SYSTEM ▶

AN EFFECTIVE TREATMENT FOR PAROXYSMAL ATRIAL FIBRILLATION

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of physician. The HeartLight X3 Endoscopic Ablation System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation (PAF).

ATRIAL FIBRILLATION (AFIB), the most common cardiac arrhythmia, is the rapid and irregular beating of the atria, the upper chambers of the heart.

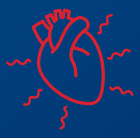


EVERY YEAR, IN THE U.S., AFIB AFFECTS

3-6 million people[1]

- **>750,000** hospitalizations[2]
- **$6 billion** in medical costs[3]

MOST COMMON AFIB SYMPTOMS INCLUDE[4]:



Heart palpitations

- Weakness
- Fatigue
- Shortness of breath

- Dizziness
- Sweating
- Anxiety

- Chest pain
- Pressure or discomfort

Serious risks associated with AFib include: stroke, heart failure, chronic fatigue, additional heart rhythm problems[5].

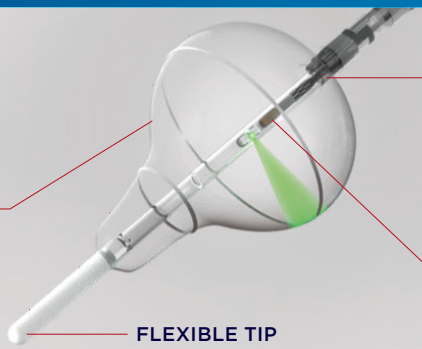
THE FDA-APPROVED HEARTLIGHT X3 ENDOSCOPIC ABLATION SYSTEM is a proven technology that uses a camera enabled "laser balloon" to treat AFib. Patient outcomes include:

71.9%
Freedom from AFib at 12 months in Pivotal Trial[6]

1 Hour
Overall procedures times were 73.7 minutes for HeartLight X3 compared to 206 minutes from the historical control study for original HeartLight.[7]

>10,000
Treated with HeartLight worldwide

HEARTLIGHT X3 LASER BALLOON™



ENDOSCOPE
To deliver a real-time view of the inside of the heart

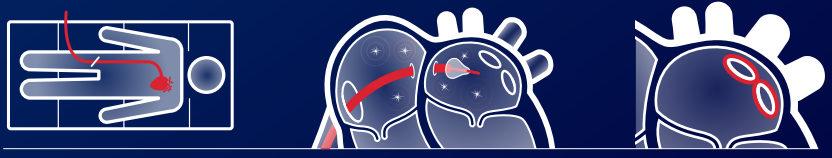
COMPLIANT BALLOON
Excalibur balloon design adapts to the vein's specific shape

LASER ENERGY SOURCE

FLEXIBLE TIP

HOW IT WORKS:

Minimally invasive procedure is performed while the patient is under general anesthesia.



STEP 1: Catheter is inserted through a vein in the leg and advanced through the heart

STEP 2: Customizable laser energy is used to create lines of scar tissue outside the pulmonary vein

STEP 3: The scar tissue blocks the electrical signals that cause AFib

TIME:
Procedure typically takes approximately 1 hour to complete

RECOVERY:
Usually rapid – patients can go home on the same or next day

RESULTS:
Most patients can have their AFib addressed with a single procedure*

**However, there can be situations where an additional treatment may be recommended.*

For more information please visit:
www.cardiofocus.com

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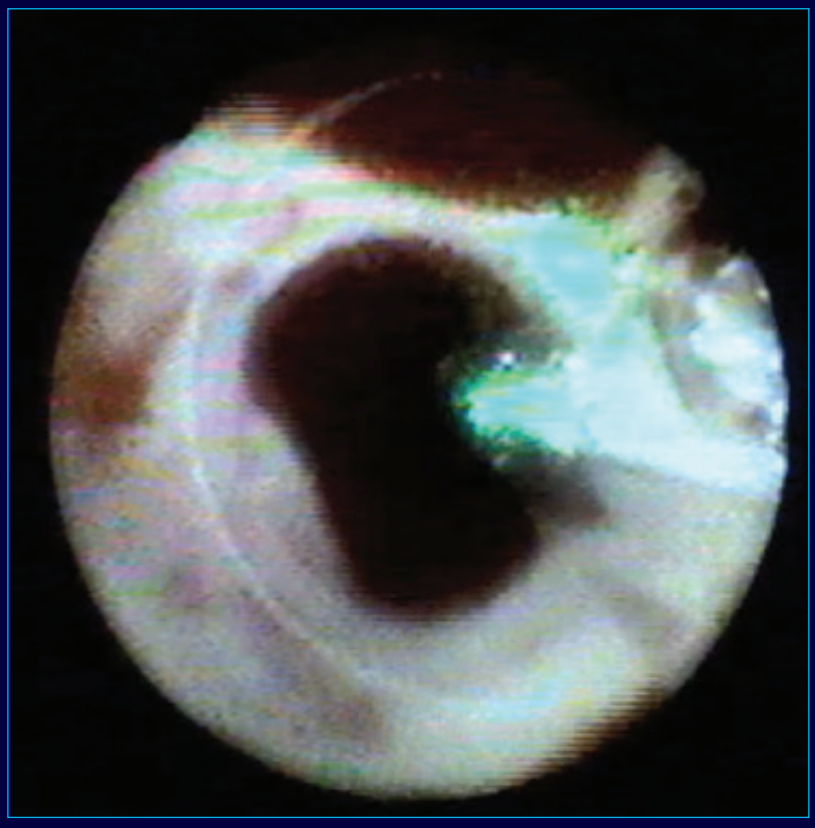
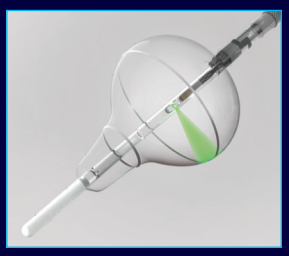
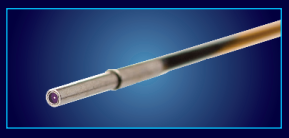
AN INSIDE LOOK AT HEARTLIGHT TECHNOLOGY.



Camera view of the inside of the heart



Balloon Catheter



Endoscope (camera)

HeartLight Console

References:

1. Circulation Research Volume 127, Issue 1, 19 June 2020; Pages 4-20. Epidemiology of Atrial Fibrillation in the 21st Century. Novel Methods and New Insights. https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.120.316340. **2.** Agency for Healthcare Research and Quality. Weighted national estimates. HCUP National Inpatient Sample [online]. 2012. [cited 2015 Feb 9]. Available from: http://hcupnet.ahrq.gov/HCUPnet.jsp. **3.** MozAfibibfarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29–e322. **4.** The Mayo Clinic, Atrial Fibrillation Symptoms and Causes [http://www.mayoclinic.org/diseases-conditions/atrialfibrillation/symptoms-causes/dxc-20164936]. **5.** American Heart Association. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Why-Atrial-Fibrillation-AFIBIB-or-AFIBIBib-Matters_UCM_423776_Article.jsp#. V6jgFTXl_Zs). **6.** For chronic efficacy, a participant was considered to be a treatment failure when a symptomatic episode of AF one (1) minute or more was reported or had cardiac surgery, left-side heart ablation or an implantable ICD for AF or did not have all clinically relevant pulmonary veins isolated or experienced ablation-induced left atrial flutter or was prescribed any Class I, II or III AAD prescribed for AF at any time during the 9-12 months post-ablation index procedure. **7.** Total procedure time excluding the protocol-required 30-minute wait period. X3 operators were experienced with HeartLight, whereas the majority of operators in the historical control study were new to HeartLight.

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 transseptal 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.*

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