



HeartLight[®] Endoscopic Ablation Catheter, Endoscope and Balloon Fill Media

Instructions for Use

Package Insert

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

The following are trademarks or registered trademarks of CardioFocus in the United States and possibly in other countries: CardioFocus, HeartLight[®]

Explanation of symbols

Refer to the package labels to see which of the following symbols apply to this product



For single use only



Do not attempt to operate the device prior to completely reading and understanding the applicable instructions for use



Use by



Serial number



Sterilized using ethylene oxide



Catalog Number



Do not resterilize



Do not use if package is open or damaged



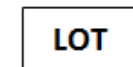
Keep dry



Keep away from heat, store at room temperature



Manufactured by



Lot number



Package Contains 1 Item



Date of Manufacture



CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.



Consult instructions for use



Fragile: Handle with care



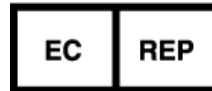
Product documentation



Temperature limitation



Open here





1. Description

These instructions for use are intended for the HeartLight[®] Catheter, Endoscope and Balloon Fill Media. The HeartLight[®] Catheter is a sterile, single-use, disposable device that delivers infrared laser energy to create a rise in tissue temperature resulting in thermal ablation of the target tissue.

The HeartLight[®] Catheter is comprised of the following basic elements and features:

- a multi-lumen Catheter
- an inflatable, compliant Balloon at the distal end. The Balloon is inflated with a sterile Balloon Fill Media, Deuterium Oxide (D₂O) admixture (packaged separately)
- the Lesion Generator that delivers light energy
- two optical fibers for illuminating the tissue with white light to permit visualization by the Endoscope
- Endoscope (packaged separately) is a 2F, 145cm usable length, reusable device compatible with the HeartLight[®] Catheter.

Use only the CardioFocus HeartLight[®] Catheter with the HeartLight[®] Console.

For details about the HeartLight[®] Console and how to use it as an integrated system with the Catheter to perform ablation procedures, refer to the HeartLight[®] Endoscopic Ablation System Operation and Maintenance Manual 06-3617.

1.1 Contents of package

The product is supplied sterile. The package contains all-inclusive product documentation and one of the following items (each packaged separately):

- HeartLight[®] Catheter
- Endoscope
- Balloon Fill Media (D₂O)

2. Indications for Use

The HeartLight[®] Endoscopic Ablation System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. The HeartLight[®] System consists of the HeartLight[®] Catheter, the Endoscope, Balloon Fill Media and the HeartLight[®] Console.

The HeartLight[®] Catheter is a single-use disposable device to be used in the treatment of atrial fibrillation. It is introduced percutaneously in the setting of an Electrophysiology or Catheterization Laboratory.

The Endoscope is a 2F, 145cm usable length, reusable device compatible with the HeartLight[®] Catheter. The Endoscope is inserted into the Catheter allowing direct visualization and confirmation of cardiac tissue contact when used in conjunction with the Catheter, Balloon Fill Media and the Console. The Endoscope is intended only for use with the HeartLight[®] Catheter. The Endoscope is supplied sterile in a labeled, sealed Tyvek pouch. It is intended to be reused up to ten (10) times and can be sterilized by the STERRAD[®] NX process. Please refer to: **Appendix A: Endoscope Cleaning & Sterilization (06-3915)** for sterilization, cleaning and re-sterilization instructions. Hospitals should track the number of re-sterilizations per Endoscope using the card supplied with each new Endoscope and reproduced for reference in **Appendix B: Endoscope Sterilization Tracking Card (06-3823)**.



Balloon Fill Media is a single use sterile disposable liquid composed of heavy water (deuterium oxide) and sodium diatrizoate (contrast) supplied in 95ml glass bottles. Balloon Fill Media is used to inflate the balloon of the HeartLight[®] Catheter. The Balloon Fill Media is transparent to the 980nm laser light emitted by the Catheter. Sodium diatrizoate renders the Balloon Fill Media visible under fluoroscopic imaging. Under normal use, the Balloon Fill Media is retained in the fluid pathways of the Catheter and is not administered to the patient. The Balloon Fill Media is intended only for use with the HeartLight[®] Catheter and Endoscope. Balloon Fill Media is provided as sterile bottles with crimp-sealed septums.

3. Contraindications

The HeartLight catheter should not be used:

- In patients who have had a ventriculotomy or atriotomy within the preceding four weeks as the recent surgery may increase the risk of perforation;
- In patients with prosthetic valves as the catheter may damage the prosthesis;
- In patients with an active systemic infection as this may increase the risk for cardiac infection;
- In patients with unstable angina;
- In patients with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt following transseptal puncture;
- In the ventricle because of the danger of catheter entrapment in the chordae tendineae;
- In patients with conditions where the manipulation of the catheter within the heart would be unsafe (for example, presence of intracardiac thrombus and myxoma);
- In patients with one or more pulmonary vein stents.

4. Warnings

▲ Training - 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. Personnel must be trained in the safe use of lasers. It is strongly recommended that prior to first use by new clinician operators, that operator either (1) attends a clinical case conducted by a trained clinical user or (2) has a trained clinical user attend their first clinical case. Non-clinical nurses or technicians operating the Console should attend a training program conducted by CardioFocus personnel or its representative prior to first clinical use.

▲ 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 06-3617.

▲ The Catheter and Balloon Fill Media are for single use only and should not be re-sterilized. Adverse patient reactions may result from reuse of the device.

▲ Monitor patients closely - Monitor patients closely for adverse events following left side ablative procedures.

▲ Medical risks from the procedure should be explained to the patient and be included in the written informed consent.



-
- ▲ **Minimize x-ray exposure – Minimize x-ray exposure to patient and clinical staff. Excessive x-ray exposure can result in acute radiation injury and increase risk for somatic and genetic effects due to x-ray beam intensity and fluoroscopic imaging exposure time.**

 - ▲ **Avoid eye or skin exposure to direct or scattered radiation.**

 - ▲ **Pregnancy – Careful consideration should be given to the use of this device in pregnant women because of the risk associated with x-ray exposure.**

 - ▲ **Personal Protective Equipment (PPE) – Users should follow all proper precautions for the safe conduct of standard electrophysiology cases as required at their institution including personal protection from patient bodily fluids contact and x-ray exposure.**

 - ▲ **Use of controls, adjustments, or performance of procedures other than those specified in this operation manual may result in hazardous radiation exposure. Follow all safety precautions and adhere to all warnings to ensure safe operation.**

 - ▲ **Do not modify the Catheter, console, or accessories in any way since this may result in damage to the device and/or serious injury to the patient and/or medical personnel.**

 - ▲ **Therapeutic application requires adequate experience in the use of diode laser systems and optical fiber delivery devices.**

 - ▲ **Do not use a Lesion Generator that is kinked or otherwise damaged. Use of such a Lesion Generator may result in injury to the patient or medical personnel from unintended laser emission.**

 - ▲ **The aiming beam passes through the same optical fiber as the therapeutic beam. If the aiming beam is not visible at the distal end of the Catheter, if its intensity is reduced, or if the beam is visible at locations other than the distal end, the Lesion Generator may be damaged and should be replaced.**

 - ▲ **Do not bend or kink the Catheter. Improper use of the Catheter can cause a malfunction and laser energy to be emitted at points other than the Catheter tip. Unintended laser emission can cause serious injury to the patient and/or medical personnel. Use of such a Catheter may result in injury to the patient or medical personnel from unintended laser emission.**

 - ▲ **Do not energize the Class 4 ablation laser while the Balloon is outside the patient’s body. Do not turn on the illumination light when looking directly at the Catheter Balloon. Do not look directly into any light source on the Console.**

 - ▲ **Withdrawing or advancing the Lesion Generator through a tight Catheter bend can damage the Lesion Generator.**

 - ▲ **Do not use excessive force when advancing or removing the Catheter. Use caution during device placement to avoid adverse events.**

 - ▲ **When advancing the catheter, use the fluoroscopy to observe the distal tip of the catheter. Do not advance the catheter if the tip is bent.**



-
- ▲ Observe the endoscopic image during Balloon inflation. If circumferential tissue contact is seen prior to full inflation, retract the Balloon slightly to avoid inflation within the vein.
 - ▲ Under no circumstances should energy be delivered more than 0.5cm distal to the vein ostium.
 - ▲ Energy should not be delivered within 3mm of a side branch. If such delivery cannot be avoided, review pre procedure CT or MRI images and/or obtain an angiogram and insure that the path of the energy will not pass through the side branch.
 - ▲ Do not deliver laser energy into stagnant blood. Delivery into stagnant blood can cause coagulum formation. Laser energy can be delivered into moving blood. Only use 5.5W 30 seconds when delivering energy into moving blood. Determination of whether blood is moving is made based on the endoscopic image. Moving blood is evidenced by motion of the boundary between tissue and blood relative to a fixed point on the Balloon surface consistent with the cardiac cycle.
 - ▲ Do not deliver laser energy into folds which may appear in the Balloon. Folds in the Balloon may contain stagnant blood. Delivery into stagnant blood can cause coagulum formation.
 - ▲ The Console is in the ready state when Press Footswitch is displayed. To avoid unintended laser emission DO NOT press the footswitch before the Catheter is properly positioned.
 - ▲ Energy should NOT be delivered beyond the distal white line found on the Balloon.
 - ▲ Stop delivering energy if the audible tone is active and aiming beams do not flash.
 - ▲ Warning: In clinical studies the recommended overlap of successive energy deliveries was about 30% to 50%. The risk of additional energy deliveries in the same location, especially in a short period of time where energy delivery could create a cumulative effect, is unknown and should be avoided.
 - ▲ Stop delivering energy if the live image is frozen.
 - ▲ Verify continuous fluid flow at the drip chamber during energy delivery. Failure to provide proper flow may result in patient injury due to overheated balloon, or damage to the Lesion Generator.
 - ▲ Do not leave an un-inflated Balloon in the circulatory system for more than one (1) hour. There is a risk of thrombus formation in the folds of the un-inflated Balloon.
 - ▲ If excessive resistance is felt while retracting the balloon into the sheath, stop and advance the balloon half a centimeter and retract again. Do not continue to pull on the catheter if excessive resistance is felt.

5. Clinical Summary

Study Title: Pivotal Clinical Study of the CardioFocus Endoscopic Ablation System – Adaptive Contact (EAS-AC) or HeartLight® for the Treatment of Symptomatic Atrial Fibrillation

Number of Centers: 19 Centers in the United States



Number of Participants: 366 enrolled and 353 Randomized Participants

5.1 Study purpose

The primary purpose of the HeartLight (HL) study was to demonstrate the safety and effectiveness of the CardioFocus HeartLight[®] System in the treatment of symptomatic drug refractory paroxysmal AF by creating electrical isolation of the pulmonary veins. The study was designed to provide objective, scientific evidence to support the indication for use statement in Section 2.

5.2 Study Design

The HeartLight (HL) study was a prospective, randomized, controlled, open-label, multi-center U.S. investigation. In this study, the investigational device was the HeartLight System and the control device was the ThermoCool ablation catheter (P030031/S011) that received FDA approval for the treatment of paroxysmal AF. This study was sponsored by CardioFocus, Inc. and conducted at nineteen (19) clinical study sites throughout the United States. The study was conducted from early 2012 to last participant follow-up in November 2014. The first participant was enrolled March 12, 2012 and the last participant was enrolled October 11, 2013.

A core lab was utilized during the study to evaluate and assess the transtelephonic event monitor (TTM) tracings and 24-hour Holter recordings.

A safety monitoring committee (Clinical Oversight Committee) comprised of an independent Medical Monitor and two other independent members (one physician and one statistician), was utilized to ensure ongoing monitoring of participant safety throughout the enrollment and ablation phase of the study. The Clinical Oversight Committee reviewed all serious adverse events (SAEs) throughout the conduct of the study.

5.3. Inclusion and Exclusion Criteria

Enrollment in the HL study was limited to patients who met the following inclusion criteria:

- Be 18 - 75 years of age.
- Diagnosed with symptomatic paroxysmal atrial fibrillation (AF) where paroxysmal atrial fibrillation is defined as AF with self-terminating episodes lasting no longer than 7 days.
- Failure (resistance or intolerance) of at least one (1) specified Class I, II or III antiarrhythmic drugs (AAD) as evidenced by recurrent symptomatic atrial fibrillation or intolerable side-effects due to AAD.
- Have at least two (2) symptomatic episodes of AF, (attacks lasting \geq 1 minute) in the six months prior to enrollment.
- Have at least one documented episode of AF in the past twelve months prior to enrollment where documentation of atrial fibrillation episode includes electrocardiogram (ECG), transtelephonic monitor (TTM), Holter monitor (HM), other event recorder, or telemetry strip.
- Understands the nature of the study procedure and provides written informed consent approved by the Local Ethics Committee (EC) or Institutional Review Board (IRB) of the respective clinical site.
- Willing to comply with specified pre-, post- and follow-up testing, evaluations and requirements.
- Expected to remain available (geographically stable) for at least 12 months after enrollment.

Patients were not permitted to enroll in the HL study if they met any of the following exclusion criteria:

- Any pulmonary vein with an average diameter > 35 mm.
- Atrial fibrillation secondary to a reversible cause or of non-cardiac origin.
- More than four (4) electrical cardioversions in the year prior to enrollment but not including cardioversions performed within 24 hours of arrhythmia onset.
- Documented left atrial thrombus on imaging (e.g., transesophageal echocardiogram, angiogram).
- Cannot be removed from anti-arrhythmic drugs for reasons other than AF which includes participants with Wolff-Parkinson-White (WPW) Syndrome and participants with a history of ventricular tachycardia (VT).
- NYHA functional Class III or Class IV heart failure.
- Unstable angina.
- Left ventricular ejection fraction < 30%.
- History of any valvular cardiac surgical procedure.
- Coronary artery bypass graft (CABG) procedure within 6 months prior to enrollment.
- Any other cardiac surgery within three months prior to enrollment.
- Awaiting cardiac transplantation or other cardiac surgery within the next year.
- Left atrial size > 50 mm as measured in the parasternal antero-posterior view.
- Previous left heart ablation procedure, either by surgery or percutaneous catheter, for atrial fibrillation or atrial flutter.
- Myocardial infarction (MI) within 60 days prior to enrollment.
- Uncontrolled bleeding, diathesis, coagulopathy or pro-coagulant state.
- Active systemic infection or sepsis.
- Diagnosed with atrial myxoma (soft tumor).
- Presence of an implantable cardioverter/defibrillator (ICD).
- History of a documented thromboembolic event such as stroke or transient ischemic neurological attack (TIA) in the three months prior to enrollment.
- Significant gastrointestinal (GI) or genitourinary bleed within three months prior to enrollment.
- Significant pulmonary disease, malfunction of lungs or respiratory systems or history of primary pulmonary hypertension.
- Currently enrolled in another investigational device or drug trial that has not completed the required follow-up period and would conflict with this study.
- Previously enrolled in this Study.
- Woman of childbearing potential who is pregnant, lactating or not using adequate birth control.
- Other co-morbid condition(s) that could limit the participant's ability to participate in the study or to comply with follow-up requirements, or impact the scientific integrity of the study.
- Any condition in the opinion of the Investigator that would compromise the participant's safety in the Study or whose condition poses an inordinately high procedural risk such as known contraindication to contrast media.

5.4. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1, 3, 6 and 12 month post procedure. Adverse events were recorded at all visits. Table 1 lists the protocol-required baseline, procedural, and follow-up assessments for all participants.

Table 1. Study Schedule



Study Activities	Prior to Randomization ¹	After Randomization and Prior to Treatment	Treatment	Pre-Discharge ²	1 Month ± 2 week	Weekly Until Study Failure	3 Months ± 1 month	6 Months ± 1 month	12-months ± 1 month
Informed Consent, Eligibility Assessments, Medical History	X								
Physical Exam	X			X	X		X	X	X
Pregnancy test for women, if applicable	X	or X							
12-lead ECG	X			X	X		X	X	X
TTE within 6 months of enrollment	X			X					
CT or MRI for PV assessment	X	or X					X		X ³
NIH Stroke Scale (NIHSS) Assessment ⁴	X	or X		X					X
24-Hour Holter (3 lead) until Failure or End of Study								X	X
Issue event recorder before 3 month visit					X		X		
Weekly & Symptomatic Event Monitoring (1 minute) - begin end Blanking Period						X			
Anticoagulation Therapy ⁵				X	X		X	X	X
Adverse Events			X	X	X		X	X	X

¹ No study-related assessment shall be conducted until study participant has completed an informed consent form.

² All study participants will be contacted within one week after discharge to assess for any possible adverse effects.

³ 12 month CT only required if one or more PV's had a greater than 50% narrowing at 3-months.

⁴ Performed by a neurologist or individual certified in NIHSS testing.

⁵ Oral anticoagulation therapy should be continued for 12-months unless participant develops a contraindication or is at a minimal risk for stroke. If the participant has no conventional risk factors for stroke, anticoagulation therapy may be discontinued during the Study at the discretion of the Investigator. Participants should receive anti-coagulation therapy in accordance with the ACC/AHA/ESC 2006 Guidelines for the management of Patients with Atrial Fibrillation, as periodically updated or follow the 2012 HRS Expert Consensus Statement, in particular Section 6.6. Use of any FDA approved anti-coagulant including Coumadin, Pradaxa (dabigatran) or Xarelto (rivaroxaban) is permitted.

5.5. Study Endpoints

5.5.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint was freedom from protocol-defined treatment failure, which included documented symptomatic AF occurrence of at least 60 seconds occurring after the 90-day blanking period.

Ablation-induced left atrial flutter or atrial tachycardia (atypical AFL or AT) occurring after the 90-day blanking period was considered a treatment failure. When AFL or AT was identified in follow-up but could not be classified as definitively right-sided flutter, it was considered left sided atrial flutter and

therefore the participant was considered a study failure. Treatment failure was also defined as any participant that did not have all clinically relevant (a PV less than 10mm in greatest diameter may not be clinically relevant) PVs isolated. Any Class I, II or III antiarrhythmic drug (AAD) prescribed for AF during the 9-12 months post-procedure was also considered a treatment failure. Any participant that had cardiac surgery, left heart ablation or an implantable ICD for AF during follow-up before the 12-month visit was considered a treatment failure.

5.5.2 Secondary Effectiveness Endpoints

Pre-specified additional comparisons between the two groups included the following secondary endpoints in a hierarchical order:

Ranking	Secondary Endpoint
1	PVs reconnected during procedure
2	Rate of Chronic Durable PV Isolation
3	Success on Previously Ineffective AAD
4	Success in Isolating all Attempted PVs Acutely
5	Recurrence of Asymptomatic Atrial Fibrillation
6	Technical (Acute) Success

5.5.3 Primary Safety Endpoint

The primary safety endpoint was a composite of the following Primary Adverse Events (PAEs) through 12 months.

- Transient ischemic attack (within 1 month of treatment)
- Cerebrovascular accident including stroke caused by air embolism
- Major bleeding that requires transfusion (within 1 week of treatment)
- Cardiac perforation, tamponade or clinically significant pericardial effusion (within 1 month of treatment)
- Pulmonary vein stenosis (> 50% diameter decrease) (during the 12-month evaluation period)
- Myocardial infarction (Q-wave only – within 1 week of treatment)
- Diaphragmatic paralysis (that persists after blanking period)
- Atrio-esophageal fistula (within 6 months of treatment)
- Death (during the 12-month evaluation period and cause possibly related to device or procedure or if unknown)
- Atrial fibrillation or flutter that requires cardioversion

All adverse events that met the PAE definition were included in the PAE rate for the study because no distinction was made between procedure or device-relatedness in the definition of PAE, with the exception of death.

5.6. Study success criteria

Study success is achieved when the following criteria are met:

- The protocol-defined primary effectiveness endpoint and primary safety endpoint are met by demonstrating non-inferiority of the HeartLight System to the control device. A non-inferiority margin of 15% for effectiveness and 8% for safety were utilized in the HeartLight study analyses; and
- The lower bound of the one-sided 95% confidence interval for the HL group primary effectiveness success rate exceeds 32%.

5.7 Accountability of PMA Cohort

At the time of database lock, of 366 patients enrolled in the PMA study, 89.3% (327) patients were available for analysis at the completion of the study, the 12-month post-procedure visit.

Participant disposition is given in Table 2 below for the 366 enrolled participants. There were a total of 353 participants randomized to the two treatment groups (178 HL, 175 controls). There were a total of 342 participants (170 HL, 172 controls) in the safety population. All 342 participants in the safety population were eligible for the primary effectiveness endpoint analysis (i.e., the MITT population), and 334 participants (167 HL, 167 Control) in whom the primary effectiveness endpoint was evaluable.

Table 2. Participant Disposition

Pivotal Cohort ¹	366	
Enrollment Failure Analysis Population	13/366 (3.6%)	
Screen failures	11/366 (3.0%)	
Withdrawal prior to Randomization	2/366 (0.5%)	
	HeartLight	Control
ITT Population²	178	175
Treatment not initiated	8/178 (4.5%)	3/175 (1.7%)
Safety Population³	170/178 (95.5%)	172/175 (98.3%)
Treatment not received	0/170 (0.0%)	0/172 (0.0%)
MITT Population⁴	170/178 (95.5%)	172/175 (98.3%)
Evaluable for Primary Endpoint Analysis	167/170 (98.2%)	167/172 (97.1%)
Completed study ⁵	165/170 (97.1%)	162/172 (94.2%)
Early Withdrawal; Primary Reason:	5/170 (2.9%)	10/172 (5.8%)
Investigator Decision	0/5 (0.0%)	0/10 (0.0%)
Participant withdrew consent	1/5 (20.0%)	5/10 (50.0%)
Participant Lost-to-follow-up	1/5 (20.0%)	4/10 (40.0%)
Adverse Event	1/5 (20.0%)	1/10 (10.0%)
Death	1/5 (20.0%)	0/10 (0.0%)
Other	1/5 (20.0%)	0/10 (0.0%)

¹ All participants who signed the Informed Consent (i.e. enrolled).

² Consists of participants who are randomized into the study.

³ Consists of participants who are randomized and for whom treatment was initiated (i.e., treatment catheter is inserted in the vasculature).

⁴ Consists of participants who are randomized and received treatment (i.e. energy is delivered by the treatment catheter) in at least one vein.

⁵ Completed study is defined as those participants who did not withdraw from the study early.

The following definitions were used to classify analysis populations.

Enrollment Failure Analysis Population

Participants who enrolled in the study (executed informed consent) and were not randomized. This population was not included in the safety or effectiveness analyses, but reported on separately.

Intent to Treat Population (ITT)

The ITT population was defined as all participants randomized into the study. All available data, regardless of specific time windows, was included in any ITT analysis. Participants were analyzed according to the investigational treatment assigned regardless of the subsequent sequence of events.

Primary Safety Analysis Population (Safety Population)

The primary analysis population for the safety endpoint included enrolled participants in whom treatment was initiated. Treatment was considered to be initiated when the treatment catheter was inserted into the



vasculature.

Primary Effectiveness Analysis Population (MITT)

The primary analysis population for the effectiveness endpoint included enrolled participants who received treatment. Participants were considered to have received treatment when energy was delivered with the treatment catheter. This analysis population was labeled the Modified Intent-to-Treat (MITT) population.

5.8 Study Population Demographics and Baseline Parameters

The HL study population consisted of mostly non-Hispanic white ethnic background (96.2%), had a mean age of 59.9 years with 66.4% being male. The baseline characteristics were comparable between the randomized groups, as summarized in tables 9 through 11 below.

Table 3. Baseline Demographics

		HeartLight (n=170)	Control (n=172)	Difference [95% CI]
Gender	Male	118 (69.4%)	109 (63.4%)	6.04 [-3.95, 16.03]
	Female	52 (30.6%)	63 (36.6%)	
Age (years)	Mean ± SD (n)	59.7±10.4 (170)	60.1±8.9 (172)	-0.42 [-2.49, 1.64]
	Median (Min, Max)	62 (26,75)	62 (29,75)	
Race	White	164 (96.5%)	168 (97.7%)	-1.20 [-4.78, 2.37]
	Black/African American	5 (2.9%)	0 (0.0%)	2.94 [0.40, 5.48]
	Asian	1 (0.6%)	2 (1.2%)	-0.57 [-2.55, 1.40]
	American Indian/ Alaska Native	0 (0.0%)	0 (0.0%)	N/A
	Native Hawaiian/ Pacific Islander	0 (0.0%)	2 (1.2%)	-1.16 [-2.76, 0.44]
Ethnicity	Hispanic or Latino	0 (0.0%)	3 (1.7%)	-1.74 [-3.70, 0.21]
	Not Hispanic or Latino	170 (100.0%)	169 (98.3%)	

Table 4. AF Related Medical History

AF Related Medical History		HeartLight (n=170)	Control (n=172)	Difference [95% CI]
Duration of AF Symptoms (Years)	Mean ± SD	4.8±5.9 (170)	5.3±6.6 (172)	-0.49 [-1.82, 0.85]
	Median (Min, Max)	2 (0, 40)	3 (0, 40)	
Duration of AF Symptoms (Years)	≤ 1 year	62/170 (36.5%)	51/172 (29.7%)	6.82 [-3.13, 16.77]
	> 1 year	108/170 (63.5%)	121/172 (70.3%)	
Previous Catheter Ablation for Atrial Fibrillation		0/170 (0.0%)	0/172 (0.0%)	N/A
History of Atrial Flutter		42/170 (24.7%)	41/172 (23.8%)	0.87 [-8.22, 9.96]
Previous Catheter Ablation for Atrial Flutter		15/170 (8.8%)	15/172 (8.7%)	0.10 [-5.89, 6.10]
Implantable cardioverter/ defibrillator (ICD)		0/170 (0.0%)	0/172 (0.0%)	N/A



AF Related Medical History	HeartLight (n=170)	Control (n=172)	Difference [95% CI]
Previous Cardioversions	55/170 (32.4%)	45/172 (26.2%)	6.19 [-3.43, 15.81]
Number of failed AADs	1.8 +/- 0.78	1.9 +/- 0.89	-0.13 [-0.31, 0.05]
Failed AADs			
Class I	84 (49.4%)	101 (58.7%)	
Class II	86 (50.6%)	81 (47.1%)	
Class III	98 (57.6%)	99 (57.6%)	
Failure of Class II AAD only	20 (11.8%)	16 (9.3%)	2.5 [-4.0, 9.1]

Table 5. Other Medical History

Other Medical History	HeartLight (n=170)	Control (n=172)	Difference [95% CI]
Myocardial Infarction	7/170 (4.1%)	7/172 (4.1%)	0.05 [-4.15, 4.25]
Hypertension	101/170 (59.4%)	100/172 (58.1%)	1.27 [-9.16, 11.71]
Coronary Artery Disease	36/170 (21.2%)	35/172 (20.3%)	0.83 [-7.77, 9.43]
Coronary Artery Bypass Grafting	5/170 (2.9%)	7/172 (4.1%)	-1.13 [-5.02, 2.77]
Previous Cardiac Surgery	0/170 (0.0%)	1/172 (0.6%)	-0.58 [-1.72, 0.55]
Prior Cardiac Valvular Surgery	0/170 (0.0%)	0/172 (0.0%)	N/A
Diabetes	26/170 (15.3%)	17/172 (9.9%)	5.41 [-1.60, 12.42]
Heart Failure	9/170 (5.3%)	4/172 (2.3%)	2.97 [-1.08, 7.02]
Stroke or TIA	11/170 (6.5%)	13/172 (7.6%)	-1.09 [-6.50, 4.32]

Baseline echocardiography measurements of left atrial (LA) diameter for the two groups were 3.97±0.56 cm and 4.00±0.55 cm for the HeartLight and Control groups, respectively. Baseline ejection fraction measurements for the groups were 60.6%±7.4% and 60.2%±7.4% for HeartLight and Control groups, respectively.

5.9 Procedural Data

Table 6 below summarizes the procedural data. Fluoroscopy, LA, and procedure times were longer in the HL group compared to the control group. Ancillary ablations beyond PV isolation were performed more frequently in the control group with cavo-tricuspid isthmus (CTI) ablation being performed in a similar proportion of subjects between the two groups.

Table 6. Procedural Characteristics¹

Characteristic		HeartLight (n=170)	Control (n=172)	Difference [95% CI]
Duration of Overall Procedure ² (mins)	Mean ± SD (n)	236.0±52.8 (168)	193.0±63.6 (171)	43.09 [30.61, 55.58]
	Median (Min, Max)	233.0 (90.0, 458.0)	188.0 (77.0, 468.0)	
LA Time ³ (mins)	Mean ± SD (n)	173.8±46.6 (168)	151.2±56.2 (171)	22.57 [11.55, 33.59]
	Median (Min, Max)	164.5 (60.0, 389.0)	144.0 (58.0, 374.0)	
Overall Fluoroscopy Time (mins)	Mean ± SD (n)	35.6±18.2 (167)	29.7±21.0 (172)	5.86 [1.67, 10.04]
	Median (Min, Max)	35.0 (3.8, 123.6)	24.8 (1.0, 135.0)	
Number of Veins attempted	Mean ± SD (n)	3.9±0.4 (170)	3.9±0.5 (172)	0.05 [-0.05, 0.14]
	Median (Min, Max)	4.0 (1.0, 5.0)	4.0 (1.0, 5.0)	
Laser or RF time (mins)	Mean ± SD (n)	54.8±16.5	50.4±23.8	---
	Median (Min, Max)	52.7 (10.4, 124.5)	48.9 (6.0, 119.0)	---
Ancillary ablations		23 (13.5%)	58 (33.7%)	-20.19 [-28.93, -11.45]
<i>CTI line</i>		21 (12.4%)	25 (14.5%)	
<i>LA roof line</i>		0	20 (11.6%)	
<i>Mitral isthmus line</i>		1 (0.6%)	3 (1.7%)	
<i>LA septal line</i>		0	5 (2.9%)	
<i>Intercava line</i>		1 (0.6%)	1 (0.6%)	
<i>Other</i>		1 (0.6%)	21 (12.2%)	

¹ All parameters are evaluated on a per-participant basis unless otherwise specified.

² Defined as the time from the initial leg puncture to the time at conclusion of the last 30 minute wait period

³ Defined as the time from the insertion of the ablation catheter to the time at conclusion of the last 30 minute wait period.

In the HL group, a mean of 40.1 +/- 19.8 laser applications were delivered to isolate a PV. The average number of laser applications for a given PV with each ablation setting is summarized in Figure 1 below.

Figure 1. Average number of laser applications with each ablation setting

LS = left superior PV; LI = left inferior PV; RS = right superior PV; RI = right inferior PV; RM = right middle PV; LC = left common PV

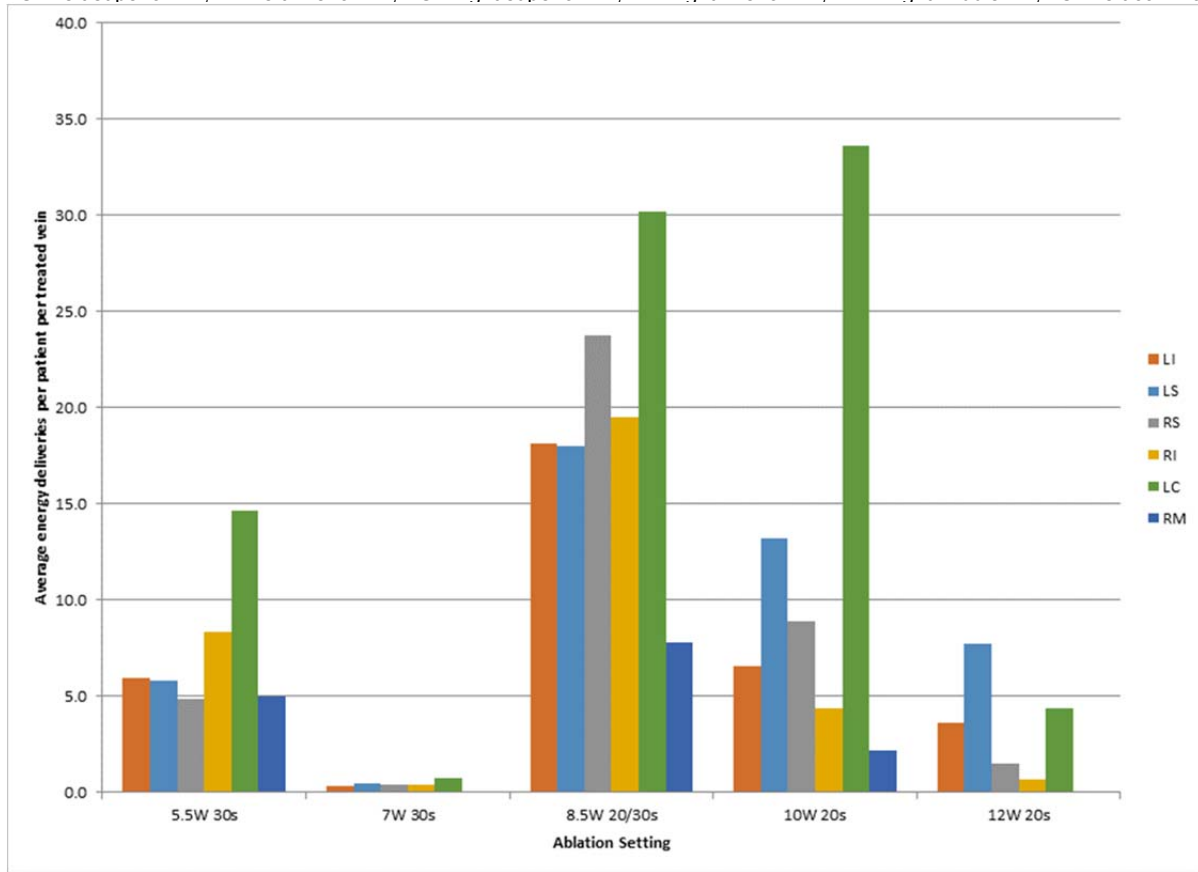


Table 7 below presents the average power, number of laser applications and laser time delivered to a given PV in the HL group.

Table 7. Average power, number of laser applications and Laser Time for a given PV

Characteristic		LS	LI	RS	RI	LC	RM
Power (W)	Mean ± SD	9.25±0.98	8.65±1.01	8.66±0.94	8.05±1.08	7.91±1.21	8.84±1.02
Number of laser applications	Mean ± SD	45.2±22.2	34.6±10.6	39.4±13.8	33.4±11.8	83.6±56.7	15.0±4.5
Laser Time (min)	Mean ± SD	16.0±8.5	12.4±4.0	13.9±5.4	12.5±5.0	30.2±20.9	5.8±2.4

LS = left superior PV; LI = left inferior PV; RS = right superior PV; RI = right inferior PV; RM = right middle PV; LC = left common PV.

5.10 Safety and Effectiveness Results

Primary Effectiveness Endpoint

As shown in the Table 8 below, the HL group and the control group had similar primary effectiveness success rate – 61.1% vs. 61.7%, and the results met the pre-specified noninferiority margin of 15%. In addition, the lower bound of the one-sided confidence interval for the HL group (54.5%) exceeded the pre-specified threshold of 32%, meeting the second study success criterion.

Table 8. Primary Effectiveness Endpoint-Non-Inferiority Analysis

	HeartLight (n=170)	Control (n=172)	Difference (HeartLight- Control)	p-value
Number of Participants Evaluated ¹	167	167		
Primary Effectiveness Endpoint Successes	61.08% (102)	61.68% (103)	-0.60	0.003 ²
Lower Bound of 95% Confidence Interval ³	54.5% ⁴	55.1%	-9.28 ⁵	

¹ Consists of participants who completed the 12-month follow-up or were identified as a failure prior to early withdrawal.

² Calculated using the Farrington-Manning method for non-inferiority.

³ Lower bound of the 1-sided 95% confidence interval is presented.

⁴ Study success is declared if the lower bound is greater than the pre-specified threshold rate of 32%.

⁵ Study success is declared if the lower bound is greater than the pre-specified non-inferiority margin of -15%.

As shown in Table 9 below, the reasons for primary effectiveness failure were well balanced between the study groups, with most subjects failing the primary effectiveness endpoint due to symptomatic AF lasting \geq 1 minute after the 90-day blanking period.

Table 9. Reasons for Primary Effectiveness Failure

	HeartLight (n=170)	Control (n=172)
Number of Participants Evaluated	167	167
Number of Participants who are primary effectiveness endpoint failures	65 (38.2%)	64 (37.2%)
Reason for Failure¹:		
Did not have all clinically relevant² PVs isolated acutely using randomized treatment device	10 (15.4%)	7 (10.9%)
Symptomatic AF lasting \geq1 minute after the 90-day blanking period, documented by³:	34 (52.3%)	40 (62.5%)
TTM (core lab)	28 (82.4%)	29 (72.5%)
24-hour Holter (core lab)	6 (17.6%)	8 (20.0%)
12-lead ECG (not core lab)	12 (35.3%)	11 (27.5%)
Other: Holter, mobile, pacemaker, telemetry (not core lab)	5 (14.7%)	7 (17.5%)
Any Class I, II or III AAD prescribed for AF at any time during the 9-12 months post-ablation index procedure	7 (10.8%)	3 (4.7%)
Ablation-induced left atrial flutter after the 90-day blanking period⁴	8 (12.3%)	7 (10.9%)
Additional Intervention for AF⁵	5 (7.7%)	7 (10.9%)
Other⁶	1 (1.5%)	0 (0.0%)

¹ Participants may have more than one reason for failure but the first occurrence of failure is classified as the primary reason. If multiple reasons for failure occurred on the same day then the reason for failure will be determined hierarchically in the order presented.



² Defined as excluding PVs with no potentials and small PVs (<10 mm) unless ablation was attempted

³ Symptomatic AFib can be documented by more than one method; therefore the percentages may not add up to 100%

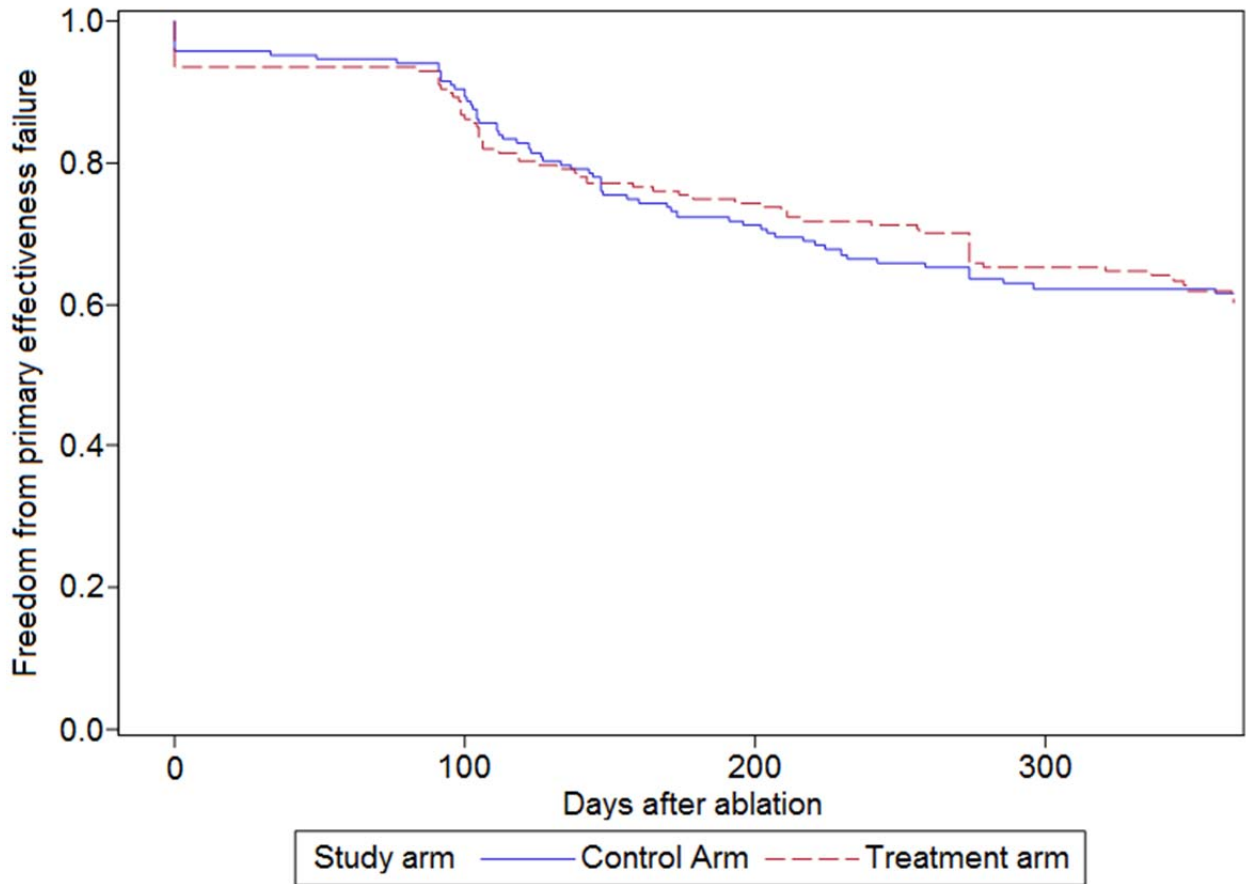
⁴ If atrial flutter or atrial tachycardia cannot be classified as definitively right-sided flutter, it must be classified as left-atrial flutter.

⁵ Cardiac surgery, left-sided heart ablation and Implantable ICD for AF. Because the protocol allows for the Control participants to have a repeat left-sided heart ablation performed within 80 days of the index procedure, these procedures are not included here as reasons for failure unless there was no documented symptomatic episode of AF.

⁶ Right-sided flutter ablation during index procedure without history of flutter or flutter seen during index procedure and/or left-sided procedure using non-randomized treatment device during index procedure.

Figure 2 below presents the Kaplan-Meier curve for each of the treatment groups for freedom from primary effectiveness failure and shows similar pattern in time to primary effectiveness failure between the treatment groups. The curve made an initial drop for both groups at day 0, representing acute procedure failures. A second drop occurred at day 90 representing recurrence of atrial tachyarrhythmia soon after the 90-day blanking period. A third drop occurred at day 270, representing the time point at which being on an AAD for AF counts toward a treatment failure.

Figure 2. KM Curves of Primary Effectiveness Endpoint



Secondary Effectiveness Endpoints

Table 10 below summarizes the secondary effectiveness results. The two groups showed similar results in all but one secondary effectiveness endpoint. While both groups had a very high acute success rate, the HeartLight group had a statistically significantly lower incidence of PV reconnection during the procedure at 2.7%, compared to 5.7% in the control group.



Table 10. Secondary Effectiveness Endpoints

	HeartLight (n=170)	Control (n=172)	P Value⁷
Secondary Effectiveness Endpoints			
Evaluated on a per-participant basis			
Success in isolating all attempted PVs acutely ¹	94.1% (160/170)	97.1% (167/172)	N/A
Chronic Durable PV Isolation (per participant) ²	13.6% (3/22)	16.7% (3/18)	N/A
Recurrence of Asymptomatic AF ³	12.6% (21/167)	14.4% (24/167)	N/A
Evaluated on a per-vein basis			
PVs reconnected during procedure ⁴	2.71% (18/664)	5.72% (38/664)	0.006
Technical (Acute) Success ⁵	97.3% (649/667)	97.9% (658/672)	N/A
Chronic Durable PV Isolation (per vein) ⁶	52.7% (49/93)	46.4% (32/69)	0.511

¹ Success in isolating all attempted PVs acutely is defined as the percentage of participants that have all attempted pulmonary veins isolated during the index procedure.

² Chronic durable PV isolation on a per-participant basis is calculated as the number of participants requiring a 2nd procedure with all PVs isolated acutely during index procedure that remain isolated at start of 2nd procedure / number of participants requiring a 2nd procedure with all PVs isolated acutely during index procedure (not tested for statistical significance).

³ Percentage of participants with asymptomatic AF that lasts one minute or more outside the 90-day blanking period, independent of any reports of symptomatic AF.

⁴ Percentage of attempted PVs that reconnect during the index procedure.

⁵ Technical Success is defined as the number of clinically relevant pulmonary veins successfully isolated / number of clinically relevant veins *100.

⁶ Chronic durable PV isolation on a per-vein basis is calculated as # of PVs isolated acutely during index procedure that remain isolated at start of 2nd procedure / # of PVs isolated acutely during index procedure*100.

⁷ A hierarchical closed test procedure was used to account for multiple testing and Control the maximum overall Type I error rate. Endpoints were tested in the order described in the study design section, each tested at a significance level of p <0.05. The test procedure was stopped the first time statistical significance was not achieved. Secondary effectiveness endpoints were calculated using a t-test.

Primary Safety Endpoint – Primary Adverse Events

Table 11 summarizes the primary safety endpoint results. The PAE rate was 11.8% in the HL group vs. 14.5% in the control group. The difference in the PAE rate between the two groups was 2.8%. The upper 95% confidence interval of 3.5% was less than the pre-specified non-inferiority margin of 8%, demonstrating success in the primary safety endpoint.



Table 11. Primary Safety Endpoint¹ Non-Inferiority Analysis

	HeartLight (n=170)	Control (n=172)	Difference (HeartLight-Control) [95% Confidence Interval ²]	p-value
Percent (Number) of Participants with a PAE³	11.76% (20)	14.53% (25)	-2.77 [3.45]	0.002 ⁴

¹ Primary safety endpoint is the composite of Primary Adverse Events (PAEs) through 12 months.

² Upper bound of the 1-sided 95% confidence interval is presented. Study success is declared if the upper bound does not exceed the pre-specified non-inferiority margin of 8%.

³ Each participant is only counted once in the overall percentage of participants with a PAE.

⁴ Calculated using the Farrington-Manning method for non-inferiority.

Table 12 below summarizes the PAEs. The two groups were comparable in all PAEs but two, namely phrenic nerve injury resulting in diaphragmatic paralysis and PV stenosis. As has been reported with other balloon-based PV isolation technologies, phrenic nerve injury resulting in diaphragmatic paralysis was more frequent with HL ablation compared to conventional open irrigated RF ablation (3.5% vs. 0.6%). However, PV stenosis was more frequent in the control group treated with conventional open irrigated RF ablation compared to the HL group (2.9% vs 0).

Table 12. Primary Adverse Events (PAEs)

	HeartLight (n=170)		Control (n=172)	
	Number of events	x (%) of participants ¹	Number of events	x (%) of participants ¹
Transient ischemic attack (within 1 month of treatment)	0	0 (0.0%)	0	0 (0.0%)
Cerebrovascular accident including stroke caused by air embolism	2	2 (1.2%)	1	1 (0.6%)
Major bleeding requiring transfusion (within 1 week of treatment)	0	0 (0.0%)	1	1 (0.6%)
Cardiac perforation, tamponade or clinically significant pericardial effusion (within 1 month of treatment)	2	2 (1.2%)	3	3 (1.7%)
Pulmonary Vein Stenosis > 50% ² (during the 12-month evaluation period)	0	0 (0.0%)	5	5 (2.9%)
Myocardial infarction (Q-wave only within 1 week of treatment)	0	0 (0.0%)	0	0 (0.0%)
Diaphragmatic paralysis (that persists after the blanking period)	6	6 (3.5%)	1	1 (0.6%)
Atrio-esophageal fistula (within 6 months of treatment)	0	0 (0.0%)	0	0 (0.0%)
Death (during the 12-month evaluation period and cause possibly related to device or procedure or if unknown)	0	0 (0.0%)	0	0 (0.0%)
Atrial Fibrillation or flutter requiring cardioversion	14	14 (8.2%)	16	16 (9.3%)
Number of participants experienced at least one Primary Adverse Event	--	20	--	25

¹ A participant is counted only once within each Primary Adverse Event Name category however, could be counted multiple times across different Primary Adverse Event Name categories.

² Based on change in PV size.

5.11 Additional Safety Information from HL Study



Serious Adverse Events

Serious adverse events (SAEs) that occurred in the HL group and control group are presented in Table 13 below. A total of 26 SAEs in 23 study subjects were reported by investigators during the 12-month follow-up period. The overall proportion of subjects with one or more SAE appeared to be slightly higher in the HL group than that in the control group (8.2% vs. 5.2%). Of note, not all primary AEs were SAEs. For example, two events of phrenic nerve injury leading to diaphragmatic paralysis (one in each study group) were considered non-serious by investigational sites, but were classified as PAEs.

Table 13. All Serious Adverse Events (SAEs)¹

Adverse Event Name	HeartLight (n=170)	Control (n=172)
Cardiac Perforation	0 (0.0%)	1 (0.6%)
Cardiac Tamponade	2 (1.2%)	2 (1.2%)
Cerebrovascular Event -- Other	0 (0.0%)	1 (0.6%)
Cerebrovascular Event -- Stroke	1 (0.6%)	0 (0.0%)
Chest Pain/Discomfort	2 (1.2%)	2 (1.2%)
Diaphragmatic paralysis	1 (0.6%)	0 (0.0%)
Hemorrhage	1 (0.6%)	0 (0.0%)
Other: Fall	1 (0.6%)	0 (0.0%)
Other: Methicillin Susp. SA infected PPM and RA & RV leads	0 (0.0%)	1 (0.6%)
Other: Moderate drop in Hemoglobin	1 (0.6%)	0 (0.0%)
Other: Pulmonary Emboli - Multiple	1 (0.6%)	0 (0.0%)
Pericardial effusion	1 (0.6%)	1 (0.6%)
Pericarditis	0 (0.0%)	2 (1.2%)
Phrenic nerve damage leading to diaphragmatic paralysis	4 (2.4%)	0 (0.0%)
Pseudoaneurysm	1 (0.6%)	0 (0.0%)
Total	14 (8.2%)	9 (5.2%)

¹ Defined as events that place the participant's health in jeopardy and that occur despite following all labeling precautions and instructions for use and where all attempts at correction by medical intervention do not resolve the event. A participant is counted only once within each Adverse Event Name category however, could be counted multiple times across different Adverse Event Name categories.

Death Summary

One subject in the HL group expired during the 12 month follow-up period. The subject was a 66 year old female with a past medical history significant for hypertension, cerebrovascular accident, NYHA Class II heart failure, pulmonary hypertension, and AF/atrial flutter. She underwent an acutely successful PV isolation procedure using the HL system without immediate complications. One month post procedure, atrial tachyarrhythmia recurred and required multiple DC cardioversion. This was followed by acute on chronic diastolic heart failure with right heart catheterization revealing increased right-sided pressure and severe pulmonary hypertension that required maximal medical therapy. Four months post the index procedure, a repeat ablation procedure using an approved RF ablation catheter was performed for AF and atrial flutter without immediate complications. Post procedure, the subject was evaluated and treated for NYHA Class III/IV heart failure. Approximately 7 months after the index procedure and approximately 3 months after the RF ablation procedure, the subject fell at home and was found dead by her family. No clear reason for death was documented. Family declined autopsy. The event was adjudicated by the independent Clinical Oversight Committee as not related to the study device or the index ablation procedure but related to pre-existing pulmonary hypertension.

Phrenic Nerve Injury



Phrenic nerve injury resulting in diaphragmatic paralysis occurred in 6 subjects (3.5%) in the HL group and one subject (0.6%) in the control group. All 7 occurrences of diaphragmatic paralysis were classified as primary AEs because they had persisted for at least 3 months. Of the 6 cases of diaphragmatic paralysis in the HL group, 3 resolved by 12 months post the index procedure, 3 persisted at 12 months, with 2 resolving at 17 months and 23 months, respectively. The single diaphragmatic paralysis in the control group was persistent at 12 months. Among the 6 HL subjects who had phrenic nerve injury, 5 were women. The power setting in these 6 subjects was 8.5 W or 10 W. All 6 subjects had one or more associated symptoms/signs including shortness of breath (n = 5), decreased lung sounds (n = 2), respiratory failure requiring re-intubation (n = 1), hypoxia with confusion (n = 1), inability to extubate (n = 1) and wheezing (n = 1) during the period in which hemi-diaphragmatic abnormalities were noted.

PV stenosis

CT or MR imaging was performed at baseline and 3 month post ablation to screen for PV stenosis. Subjects with PV narrowing of > 50% on 3 month CT/MRI underwent repeat PV imaging at 12 month. Table 13 below summarizes PV narrowing and stenosis detected in the HL study. On a per-vein basis, the rate of PV narrowing of 20%-50% was similar between the two groups. No PV stenosis was detected in the HL group. However, 5 subjects in the control group had a single PV with > 50% narrowing. None of these 5 subjects had PV stenosis related symptoms or required therapeutic intervention.

Table 14. Pulmonary Vein Narrowing and Stenosis on a Per-Vein Basis

	3-month FU ¹			12-month FU ²		
	HL (n=622)	Control (n=632)	Difference (HL-Control) [95% Confidence Interval]	HL (n=3)	Control (n=12)	Difference (HL-Control) [95% Confidence Interval]
PV Narrowing (>20 to <= 50% decrease from baseline)	136 (21.9%)	156 (24.7%)	-2.82 [-7.49, 1.86]	2 (66.7%)	3 (25.0%)	41.67 [-17.03, 100.00]
PV Stenosis (>50% decrease from baseline)	0 (0.0%)	5 (0.8%)	-0.79 [-1.48, -0.10]	0 (0.0%)	3 (25.0%)	-25.00 [-49.50, -0.50]

¹ Includes veins attempted during the Index Procedure and imaged at 3 months.

² Only those veins that showed >50% decrease at 3 months are required to be imaged at 12 months.

Stroke

There were two (2) strokes (1.2%) in the HL group (one occurred prior to discharge and the other a week after discharge) and one stroke (0.6%) in the control group that occurred prior to discharge. Both strokes in the HL group were considered embolic in nature with one stroke being acute cerebellar infarct resulting in left hemiparesis and ataxia, and the other being sub-acute infarcts resulting visual changes. The stroke in the control group was a small infarct at the right caudal nucleus, resulting in left sided weakness with tremors. Both strokes from the HL group recovered completely, and the control subject with stroke had minor residual effects by the conclusion of study follow-up.

5.12 Additional Analyses

Effect of Operator Experience

An analysis was conducted to examine learning curve by individual operator's life-time HL procedure experience. This *post-hoc* analysis was conducted to examine the effects of learning curve on HeartLight ablation procedure metrics. There were 30 primary operators that performed at least one randomized HL procedure that were included in this analysis. All 30 operators had extensive experience with standard radiofrequency ablation and limited experience with the HeartLight System. Each procedure where an operator was a Primary Operator (conducted more than half of a HL procedure) counted towards the total number of lifetime HL procedures, regardless of study protocol or where (study center) that case was performed. By the end of the pivotal clinical study, only half (15/30) of the operators had performed more than 3 randomized HeartLight procedures and only 17% (5/30) had performed 15 or more lifetime HL procedures. The five operators with ≥15 lifetime procedures of experience with HeartLight (HeartLight-High; 40 procedures) were compared to the 25 operators with <15 lifetime procedures of experience (HeartLight-Low; 130 procedures). Fifteen procedures was selected as an experience threshold for experience because it has been previously used to determine the HeartLight learning curve¹.

Figures 3 and 4 below summarize the operator learning curve effect on procedure and fluoroscopy times, and primary endpoints. There was a small increase in the primary effectiveness success rate from 59.4% (HeartLight-Low) to 65.0% (HeartLight-High) with increased experience. There was also a trend toward more improved safety and shorter procedure time with more experience. The PAE rate was 13.8% in HeartLight-Low vs. 5.0% in the HeartLight-High groups. Procedure time was 241.0±55.0 min in HeartLight-Low vs. 222.0±42.0 min in HeartLight-high groups. Fluoroscopy time appeared shortened with more experience (38.4±18.6 min in HeartLight Low group vs. 27.3±13.4 min in HeartLight High group). Compared to the control group, the primary effectiveness success was slightly greater in the HeartLight-

¹ Dukkupati SR, Kuck KH, Neuzil P et al. Pulmonary vein isolation using a visually guided laser balloon catheter: the first 200-patient multicenter clinical experience. *Circ Arrhythm Electrophysiol* 2013;6:467-72.

High group (65.0% vs. 61.7%) and the PAE rate appeared to be lower (5.0% vs. 14.5%). The overall procedure time still appeared to be shorter in Controls (222±42.0 min vs. 193±63.6 min) but fluoroscopy time appeared to be shorter (27.3±13.4 min vs. 29.7±21.0 min) in the HeartLight-High group. These data suggested a learning curve with the use of the HL system for PV isolation.

Figure 3. Operator Learning Curve Effect on Primary Endpoints

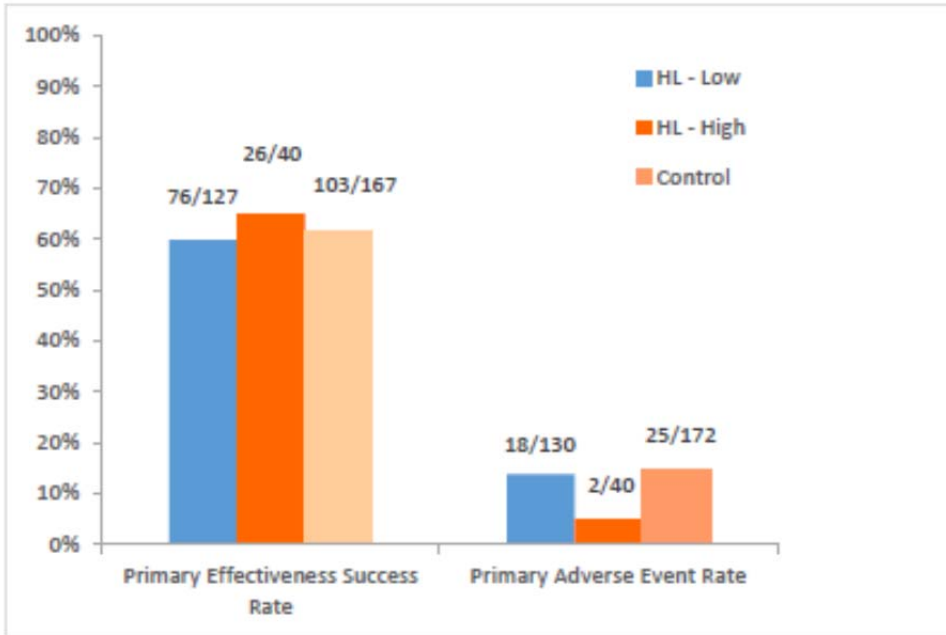
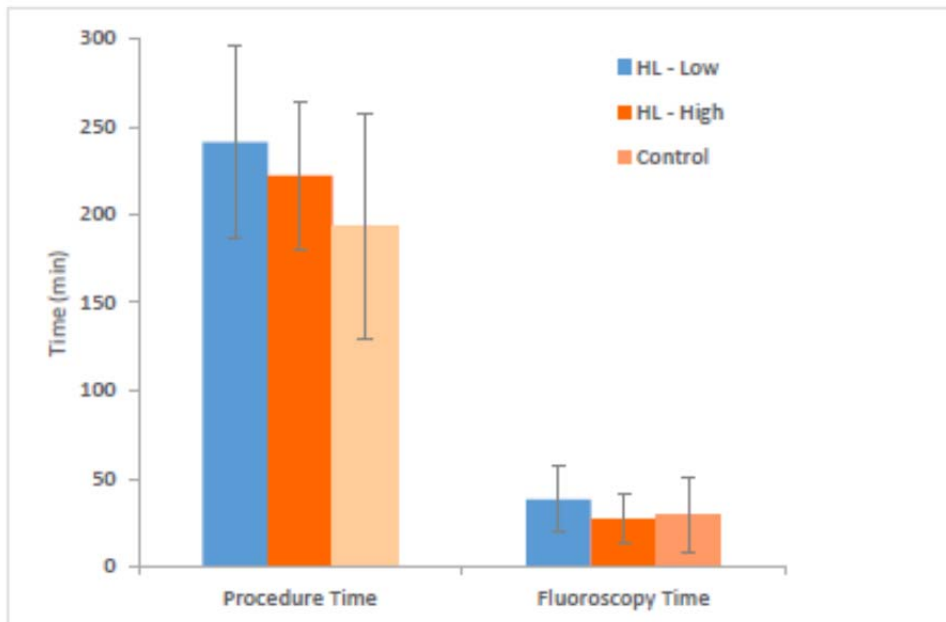


Figure 4. Operator Learning Curve Effect on Procedure and Fluoroscopy Times



5.13 Gender Analysis

A gender analysis was performed to assess the differences in primary effectiveness and safety



endpoints between female and male subjects. There was no gender discrepancy in primary effectiveness success. However, the PAE rate excluding cardioversion (or major complication rate) appeared to be greater in female HL subjects (11.5% or 6/52) than in male HL subjects (2.5% or 3/118). The greater major complication rate in female HL subjects was primarily driven by a higher incidence of phrenic nerve injury resulting in diaphragmatic paralysis (9.6% or 5/52).

It should be noted that this study was not powered to determine gender-specific safety profile of the HL system. Although women were well represented in the study (33.7% female), the number of female subjects enrolled was small (52 subjects in the HL group). Therefore, no firm conclusion could be made regarding the safety profile of the HL system in women. Moreover, there is no known anatomical or clinical reason for gender disparity in the risk of phrenic nerve injury associated ablation using the HL System. A post approval study that enrolls a large number of female subjects will be conducted to further evaluate the safety profile of the HL System including the risk of phrenic nerve injury in women and to update the device labeling.

5.14 Study Conclusion

In conclusion, the results of the study demonstrate that there is a reasonable assurance of safety and effectiveness to support the use of the HeartLight catheter for the treatment of symptomatic drug refractory paroxysmal AF.

6. Adverse Events

Potential adverse events associated with cardiac catheter ablation procedures include, but are not limited to, the following conditions:

- Adverse reaction to anesthesia
- Air Embolism
- Anemia
- Anxiety
- Aspiration Pneumonia
- Atrio-esophageal fistula, esophageal ulceration, or esophageal tear
- Arteriovenous (AV) fistula
- Back pain
- Bleeding from puncture site
- Blood Clot / Thrombotic / 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 / ecchymosis
- Hemothorax
- Hemorrhage
- Hemoptysis
- Hypertension/ hypotension
- Incision site pain or 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

7. Sterilization/"Use By" Date

- The Catheter and Endoscope have been sterilized with ethylene oxide gas.
- The Balloon Fill Media is sterile by aseptic processing.
- Use the Catheter, Endoscope and Balloon Fill Media prior to the "Use by" date shown on the package label.
- Do not use the device if the package is open or damaged.

8. Instructions for Use

8.1 HEARTLIGHT® CATHETER Preparation

For detailed instructions on preparation and proper connection of the HeartLight® Catheter to the HeartLight® Console, please refer to the HeartLight® Endoscopic Ablation System Operation and Maintenance Manual 06-3617

1. Using a 50-60cc syringe and needle (≤ 18 gauge), aseptically transfer Balloon Fill Media from the rubber stoppered glass vials into the syringe.

△ **Caution: Use only CardioFocus supplied Balloon Fill Media.**

2. Set up a sterile compatible deflectable sheath capable of 180 degree deflection with an inner diameter (ID) of $\geq 12F$, a usable length of 75cm and an overall length of not more than 94cm. Consult IFU included with sheath's packaging.

3. Deliver the sterile Catheter and Endoscope to the sterile field. The Gowned Sterile Technician (GST) will hand the proximal ends of Catheter back to the Non-Sterile Technician (NST) for connection to the Console.

4. Un-cap both illumination fiber connectors on the Catheter and immediately connect them to the illumination adapters taking care not to allow the optical connectors' face to contact anything.

△ **Caution: Do not use if Catheter package is opened or damaged.**

△ **Caution: Use prior to the "Use Before" date on the package.**

8.2 COOLING LOOP SET-UP

1. Clip the burette into the two C-shaped clips on the front of the Console.

2. Open the pump head by using the lever on the right side of the pump head.

3. Insert the rubber tube into the pump head and then carefully close the pump head. Make sure the rubber tube is not pinched by the pump head jaws.

4. Press the Balloon Fill Media tube into the bubble detector.
5. Aseptically attach the Balloon Fill Media filled syringe to the end of the burette feed tube.
6. Fill the burette with Balloon Fill Media using the filled syringe.
7. Always be sure to monitor and maintain Balloon Fill Media level slightly above the level sensor located in the center of the C-shaped clip on the front of the console throughout the entire procedure. Both burette dip tubes must stay submerged beneath the liquid level at all times.

8.3 PURGE COOLING LOOP

1. Hold the shaft of the Catheter near the Balloon with the distal tip pointing downward.
2. Select the 'Purge' control located in the Balloon tab. This will allow the pump to run and Balloon to inflate while disregarding any air present at the bubble detector.
3. Purge the Balloon and cooling lines to remove all bubbles.
4. Select 'Stop' on the Balloon tab with the Balloon partially inflated.

8.4 ENDOSCOPE INSTALLATION

1. Straighten the Catheter to enable proper seating of the Endoscope.
2. Pull out the Endoscope fitting on the Catheter handle, and lock it into the extended position by rotating it one half turn.
3. Remove the cap on the Endoscope fitting, and dispose of cap.
4. Insert the Endoscope through the Endoscope fitting and into the Catheter. Securely connect the luer on the Endoscope to the Endoscope fitting.
5. Rotate the Endoscope fitting one half turn to unlock it from the extended position.
6. Pass the proximal end of the Endoscope to the NST for connection to the camera. An image will appear on the Console display.
7. Select the 'Purge' control in the Balloon tab to inflate the Balloon. Remove any remaining air bubbles.

8.5 CONNECT LESION GENERATOR

1. The GST should pass the Lesion Generator's optical connector to the NST.
2. The NST will un-cap the Lesion Generator's connector. The NST should take care not to allow optical connector face to come in contact with anything.
3. The NST should disconnect the dust cap and immediately insert the Lesion Generator connector into the console output port taking care not to allow the face of the connector to touch the output port. Turn the knurled nut clockwise until tight.

△ **Caution: Do not contaminate the proximal face of the Lesion Generator connector. Be sure to insert the Lesion Generator by carefully holding the connector at an angle, tipping the connector into the output port and inserting the connector into the output port.**

8.6 ENTER CATHETER SERIAL NUMBER

1. Select the field under the 'Catheter Serial Number' label in the Catheter Preparation Screen. *Enter Catheter Serial Number Dialog Box* will be displayed.
2. Enter the Catheter serial number (12-XXXX-XXXX).
3. Press 'Save' when serial number is correctly entered.

❖ **Note: If it is necessary to disconnect the Lesion Generator, it may be reconnected within 24 hours. After 24 hours the Catheter serial number is invalid.**

8.7 FINAL CATHETER PURGING

1. Select the 'Purge' button on the Balloon tab. Purge all remaining air from the Catheter as follows: The physician or GST should hold the Balloon distal end down and tap to allow any air to flow out of the Balloon. Allow all air to flow out of the return line. Tap the tubing lines and Catheter handle as necessary to allow all air to be purged from that part of the system. Select the 'Deflate' button and allow the Balloon to deflate and then select the 'Purge' button again and check for air bubbles. Repeat as necessary until all air is purged from the system.
2. Select 'Run/Inflate' in Balloon Tab, and select Balloon Size '1'.
3. Inspect the Balloon and all of the Catheter's flow paths for any signs of leakage. If leakage is due to a loose fitting, tighten the fitting and confirm Catheter is leak free before use. If there is any sign of leakage from the Balloon do not use that Catheter.

△ **Caution: Verify that the Balloon cooling lines have been fully purged of air before insertion into vasculature.**

8.8 HEARTLIGHT[®] ENDOSCOPIC ABLATION PROCEDURE

8.8.1 PATIENT PREPARATION

The standard procedures for EP studies will be followed.

1. Perform a transseptal puncture using standard techniques. At the option of the physician an additional transseptal puncture may be performed to provide access for other catheters into the left atrium.
2. It is recommended to administer heparin to achieve a therapeutic ACT per standard of care and to maintain this level of anticoagulation from the time of transseptal puncture and throughout the ablation procedure until the Catheter and sheath are withdrawn into the right atrium.
3. Introduce the sheath into the left atrium in accordance with the sheath's Instructions for Use.
4. Pre-ablation mapping may be performed at the discretion of the physician.

8.8.2 PROCEDURE



The CardioFocus HeartLight[®] Catheter must be used with the HeartLight[®] Console. Please refer to the HeartLight[®] Endoscopic Ablation System with Adaptive Contact Operation and Maintenance Manual 06-3617 for recommended procedural steps.

1. Prepare a Catheter for the first vein to be treated. Insert the Catheter into the sterile compatible deflectable sheath as described in the sheath's Instructions for Use.

❖ **Note: Make sure that the Lesion Generator is positioned inside the Balloon, before insertion of the Catheter into the sheath. The Lesion Generator should remain in this portion of the Catheter during insertion into the sheath, during manipulation in the atrium and during removal from the sheath. The Lesion Generator should not be made to traverse a tight bend in the catheter. Malfunction of the Lesion Generator may result.**

2. Select 'Live Vein' then designate vein name on the Console Operations Screen.

3. Advance the sheath and Catheter tip into the ostium of the pulmonary vein under fluoroscopic or ICE guidance.

4. Advance the Catheter using fluoroscopy to observe the distal tip of the catheter. Do not advance the Catheter if the Balloon tip is bent.

5. For initial inflation at the ostium of a given vein, select Balloon size '1' in the Balloon tab. Select 'Inflate/Run' to start inflating the Balloon. Inflate the Balloon such that the distal tip of the Balloon is just inside the pulmonary vein ostium.

△ **Caution: Do not attempt to inflate the Balloon when located within the sheath.**

6. Advance the inflated Balloon until it occludes the pulmonary vein ostium. Manipulation of Catheter position and adjustment of the Balloon size controls may be used to optimize contact. Use the endoscopic image to determine when contact is optimized. Do not use excessive force when advancing or positioning the Catheter.

7. Orient endoscopic image:

a. A 'Z' shaped radiopaque orientation marker, Z-Marker, is located on the proximal neck of the Balloon (see **Figure 5: Distal Tip Configuration**). This Z-Marker allows the user to determine the rotational orientation of the Balloon relative to the patient anatomy.

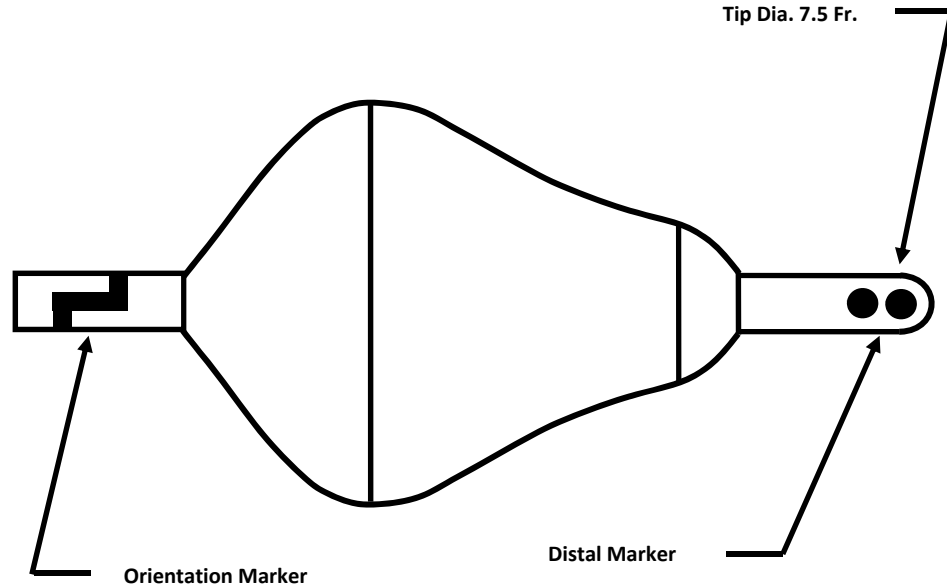


Figure 5: Distal Tip Configuration

b. Figure 6 below illustrates typical radiographic AP views of the Balloon and orientation marker for the LSPV. **Error! Reference source not found.** Views A-D show how the Z-Marker will appear depending on its orientation to the anatomy. Interpretation of the Z-Marker orientation for other pulmonary veins follows the same strategy.

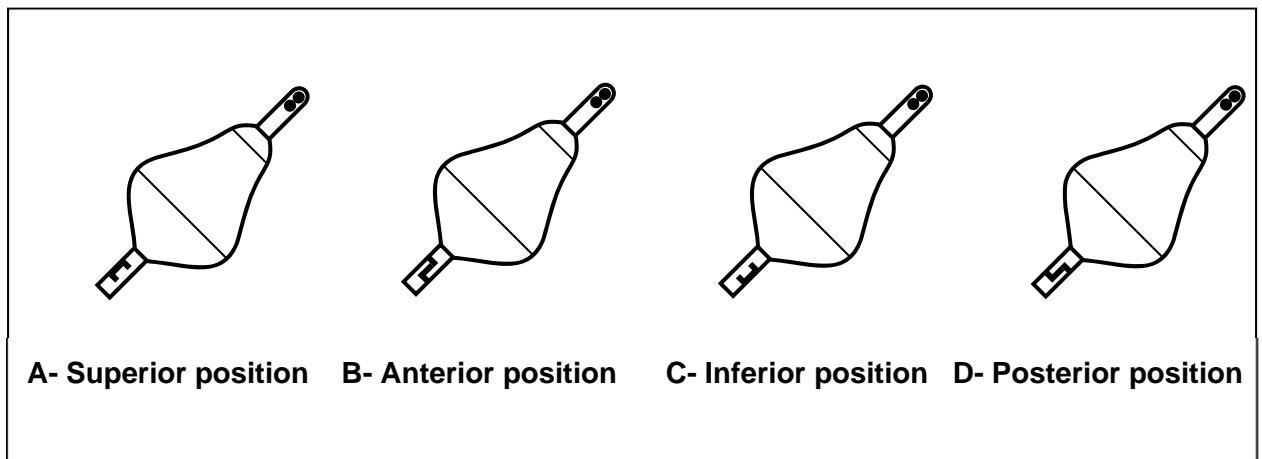


Figure 6: Typical Radiographic AP Views of Z-Marker with Balloon in LSPV

c. If desired, using the orientation marker as a guide, adjust the endoscopic image by rotating the proximal Endoscope fitting relative to the camera so the superior, anterior, inferior and posterior directions are displayed in typical convention on the display. **Figure 7: LSPV Endoscopic Views** shows the corresponding examples of endoscopic views for each of the LSPV-AP angiographic views.

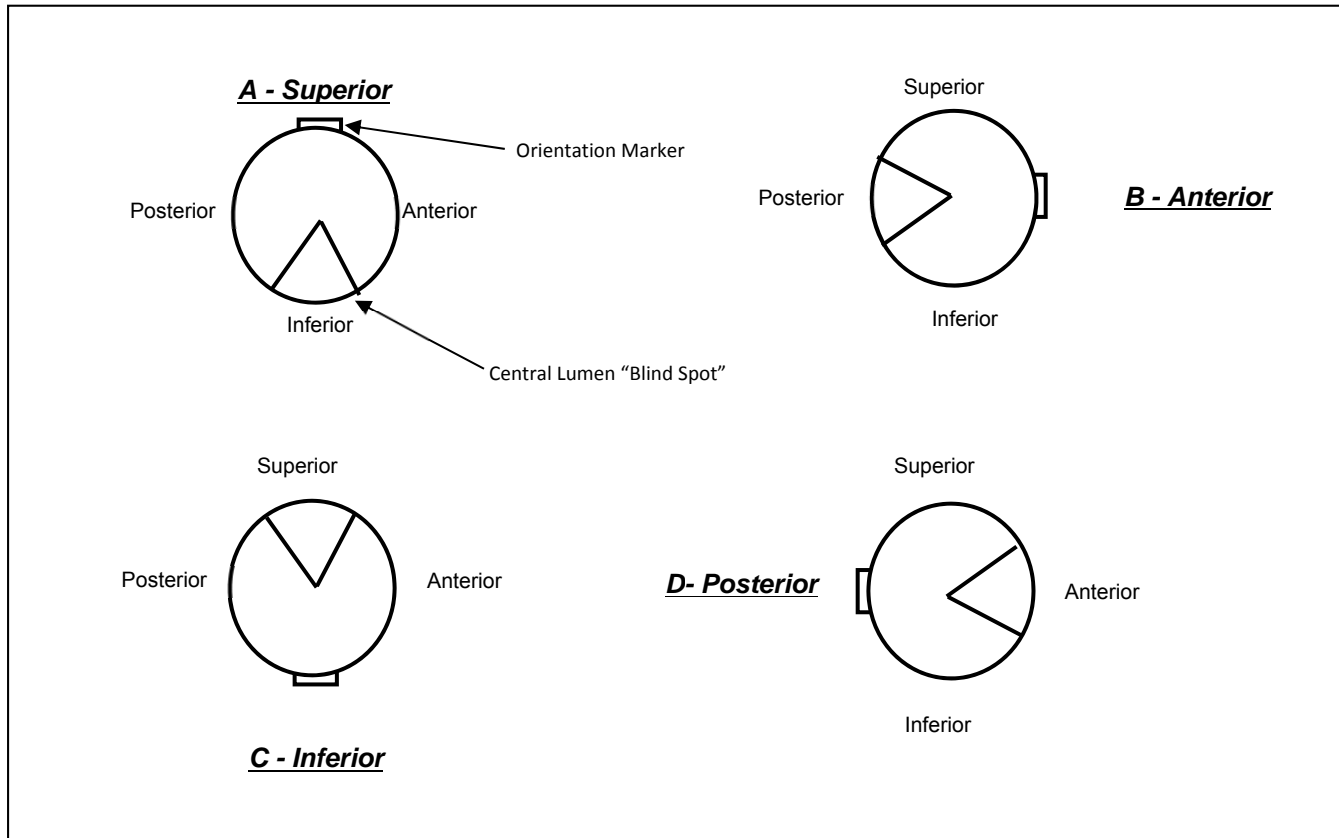


Figure 7: LSPV Endoscopic Views

❖ **Note: The orientation marker which is located on the catheter shaft is not visible in the endoscopic view but is always positioned opposite the central lumen "blind spot".**

❖ **Note: Adjustment to the endoscopic image on the flat panel display is not essential but is recommended as a guide prior to performing ablations in a particular vein.**

8. Observe ICE and/or fluoroscopic images to insure that the maximum diameter of the Balloon is proximal to the pulmonary vein ostium.

9. Phrenic nerve pacing is recommended to avoid injury to the phrenic nerve. One method for conducting pacing is as follows: Pace from the superior vena cava (SVC) once the Balloon is inflated near the RSPV (and if desired, RIPV) to assess the location of the phrenic nerve by observing any "capture" at the target energy delivery site. It is recommended that pacing be conducted at high output to ensure capture of the phrenic nerve.

10. When pacing prior to energy delivery, the site of diaphragmatic stimulation (and therefore the approximate phrenic nerve location) can be compared via fluoroscopy or ICE with the target energy delivery site. Do not deliver energy to any area where there is phrenic nerve capture.

11. When concomitant phrenic nerve pacing is used, monitoring of the phrenic nerve during energy delivery by palpation of the strength of diaphragmatic excursion or other methods is recommended. Energy delivery to the RSPV (or RIPV) must be discontinued if movement of the diaphragm slows or changes during energy delivery.

12. Advance the Lesion Generator. Turn on the aiming beams. Rotate and determine a plan for energy deliveries that will create a circumferential lesion. Energy should be delivered fully into 'tissue' or into 'tissue and moving blood' (5.5W dose only), but never into stagnant blood. Energy should be delivered as proximal (antral) as contact allows. Energy should be delivered in an overlapping fashion to avoid gaps between lesions.

13. The Lesion Generator will need to be moved proximally in order to visualize tissue contact and the possibility of stagnant or moving blood, which may lie behind the Lesion Generator. When delivering lesions behind the Lesion Generator, lower doses should be used (5.5W) to avoid inadvertently delivering energy into blood at higher doses.

14. Determine the desired dosage. When operating the Console, select values to control the delivery of energy; power and duration. The power parameter refers to the output power that the console delivers through the catheter to the target tissue. It is measured as watts (W). Duration of the therapy is pre-selected for each dose level.

15. 8.5W for 20 seconds should be used as a starting dose in most situations. Power levels may be reduced or increased based on physician judgment. In general, less energy should be used:

- when the Lesion Generator position is more distal
- when the Balloon size is smaller
- when the aiming beam spot size appears smaller

16. The available dosages are listed in the Table 15 below. Please see the section of Procedural Data in the Clinical Summary for ablation settings used in the HeartLight clinical study.

Table 15: Available Ablation Settings. The Console Displays a Power and Time Combination from One of the Selections Below

Power (Watts)	Time (seconds)	Recommendations
5.5W	30s	Tissue and moving blood. Use when any possibility of moving blood exists
5.5W	30s	Tissue only When user desires lower dose, for example, to avoid excessive esophageal temperature rises
7.0W	30s	Tissue only
8.5W	20s	Tissue only Recommended starting dosage
8.5W	30s	Tissue only Areas of possible thicker tissue
10W	20s	Tissue only Areas of possible thicker tissue
12W	20s	Tissue only Areas of possible thicker tissue

17. If there is any doubt about the presence of moving blood or the location relative to the distal white



line, consider lowering the power to 5.5W for 30 seconds.

18. Ensure that circumferential tissue contact exists via the endoscopic image and that the aiming beam is targeted at the desired lesion location.

19. If desired, a reference snapshot may be captured prior to treating a vein. To collect a snapshot, select the 'Snapshot' tab, then select 'Reference'. A reference snapshot may be captured at any time during the procedure.

20. Select 'Laser Enable'. 'Laser Standby' will flash for 2 seconds then 'Laser Ready' and 'Press Footswitch' will be displayed in the Message Area.

21. With the Lesion Generator aiming at a properly selected ablation site, depress the footswitch to deliver energy. When energy is being delivered the following will occur:

- an audible tone sounds
- the message area counts down energy delivery time remaining
- the red and green aiming beams flash on and off
- 'Laser Active' is displayed in the Message Area

22. During energy delivery, monitor the appearance of the tissue being ablated in the endoscopic view. If the tissue begins to darken discontinue energy delivery.

23. During energy delivery, it is recommended to monitor esophageal temperature with a probe. If the temperature exceeds 38.5 °C, the operator should immediately stop energy delivery.

24. When the countdown timer reaches zero, release the footswitch and ensure that the screen returns the Console to the 'Laser Ready' state. The Console is now ready for another energy delivery.

25. A snapshot is automatically captured at the beginning of each energy delivery. This enables the use of the 'Overlay Feature' which may be used to help locate subsequent energy deliveries. To use the Overlay Feature:

- confirm that the 'Overlay' button is selected in the Overlay tab.
- adjust the 'Opacity' using the slider until both the active spot, and the spot from the previous snapshot are visible.
- position the aiming beam in the desired location overlapping the previous energy delivery location.

❖ **Note: If the message, "Last snapshot not displayed" is visible in the Message Area, be aware that you are not using the previous energy delivery as a reference. This older snapshot may not be optimal.**

26. Observe the aiming beam during energy delivery. If the spot appears distorted at any point, terminate the energy delivery, and replace the Catheter.

❖ **Note: If the Catheter is rotated and/or the Endoscope is rotated relative to the camera, the snapshot overlay may need to be moved or rotated to correctly align the live image with the most recently captured Energy Delivery snapshot using the Snapshot Overlay Position controls.**

27. Continue ablation in the targeted vein until a circumferential lesion set has been created.



28. If desired, review the vein snapshots prior to moving to the next vein: Select 'Overlay' tab, and set opacity to 100%. Select the 'Review' tab. Selecting one of the arrows will display all of the snapshots in sequential or reverse sequential order. Selecting 'Reference Only' will display the reference snapshots only. Selecting the 'Energy Delivery Only' will display only the snapshots associated with an energy delivery.

29. Deliver more lesions as deemed necessary to complete a circumferential lesion set.

30. Deflate the Balloon and retract into sheath with Catheter tip extended beyond the tip of the sheath, guide the Catheter to the next pulmonary vein.

❖ **Note: It is important to correctly label each vein prior to delivering energy and taking snapshots. The snapshot review feature uses the vein label to sort the snapshots.**

31. Repeat steps 2-30 until all pulmonary veins have been targeted and treated.

32. Deflate the Balloon while observing the endoscopic image to determine when the Balloon is fully deflated. The Balloon will deflate in less than 60 seconds. Once it is fully deflated, retract the Balloon into the sheath and withdraw the Catheter from the sheath.

33. Post-ablation mapping may be performed at the discretion of the physician.

32. If the Endoscope will be reprocessed, remove Endoscope from the catheter. See **Appendix A: Endoscope Cleaning & Sterilization** for instructions.

- straighten the Catheter
- uncouple the luer from the Endoscope fitting at the back end of the Catheter handle
- gently pull the Endoscope out of the Catheter
- coil the Endoscope into a loop no smaller than 15cm (6") diameter

9. Specifications

Table 16. Specifications

Outer Catheter diameter	4 mm (12 Fr)
Recommended Introducer sheath	≥ 12F ID 180° deflectable sheath 75cm usable length; ≤94cm overall length
Storage Parameters	Greater than 0°C (32°F)
Laser type	Diode
Laser class	Class 3R Red and Green Aiming Beam Lasers Class 4 980nm Therapy Laser
Therapy beam	980nm ±15 nm
Maximum output power	63W Overall (40W for HeartLight® application)
Maximum output at distal end of Catheter	12W
Beam divergence	Approximately 30 degrees full angle
Emission aperture	Rectangular emission at the distal end of the HeartLight® Catheter
Energy monitoring	Internal energy detector
Aiming beams	15 mW red diode laser with a wavelength of 648-668 nm 40 mW green diode laser with a wavelength of 530-534 nm

10. Storage

- Store the Catheter and in a cool dry place. Recommended storage temperature is from 5 to 30 °C (41 – 86 °F).
- The Balloon Fill Media should be stored in a cool, dry place protected from direct sunlight and freezing temperatures.
- Between uses, store the Endoscope in a clean, dry environment. To prevent damage, minimize contact between the device and other equipment.

11. Disposal

- Used products are contaminated and must be handled and disposed as contaminated hospital waste according to local and national regulations and hospital guidelines.
- Remember to remove the endoscope from the catheter for reprocessing prior to disposal.

12. Limited Warranty

LIMITED WARRANTY: The purchaser must comply with the terms and conditions in this document for this Limited Warranty to apply.

CARDIOFOCUS WARRANTS THAT THE PRODUCT(S) HAS (HAVE) BEEN MANUFACTURED AND RELEASED FOR USE IN ACCORDANCE WITH ITS SPECIFICATIONS AND TESTED USING ITS ESTABLISHED TEST METHODS.

CARDIOFOCUS DOES NOT WARRANT THE SUITABILITY OF A DEVICE FOR ANY SPECIFIC PATIENT, SINCE FITNESS FOR USE IS A MEDICAL DECISION.

CARDIOFOCUS WILL NOT BE RESPONSIBLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, DIRECT, INDIRECT, OR OTHER LIABILITIES, LOSSES, DAMAGES, OR COSTS PURSUANT TO OR AS A RESULT OF THIS WARRANTY.

THIS WARRANTY REPRESENTS THE ENTIRE OBLIGATION OF CARDIOFOCUS AND IS MADE IN LIEU OF ANY OTHER WARRANTIES WHETHER EXPRESSED OR IMPLIED, INCLUDING MERCHANTABILITY.

THE REMEDIES SET FORTH IN THIS WARRANTY WILL BE THE ONLY REMEDIES AVAILABLE TO ANY PERSON. NO PERSON HAS ANY AUTHORITY TO BIND CARDIOFOCUS TO ANY WARRANTY OR REPRESENTATION EXCEPT THOSE SPECIFICALLY CONTAINED HEREIN.

WITHOUT LIMITING THE FOREGOING, CARDIOFOCUS OR ITS AFFILIATED COMPANIES, SHALL NOT BE LIABLE FOR ANY SPECIAL, DIRECT, INCIDENTAL, CONSEQUENTIAL, OR OTHER DAMAGES, ARISING OUT OF THE REUSE OF ANY PRODUCT(S) LABELED FOR SINGLE USE OR WHERE REUSE IS PROHIBITED BY APPLICABLE LAW, AS WELL AS ANY REPROCESSING OR RESTERILIZATION OF THE PRODUCT(S) DESCRIBED HEREIN.

Some states do not allow the exclusion of incidental or consequential damages, so some of the preceding limitations or exclusions may not apply to you.

Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond CardioFocus control may directly affect the device and the results obtained from its use.



The purchaser must inspect the device upon receipt. If the device is received in a damaged condition, CardioFocus will replace it at no charge to the purchaser if the damage is reported to CardioFocus within fifteen (15) days of receipt of the device and it is promptly returned to CardioFocus. All devices returned to CardioFocus become the property of CardioFocus. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Descriptions and specifications appearing in CardioFocus printed matter, including this publication, are informational only and meant solely to generally describe the product at the time of manufacture and are not made or given as a warranty of the prescribed product in any way.

LIMITATION OF REMEDIES

The sole and exclusive remedy provided by CardioFocus under its limited warranty set forth above is exclusively limited to the repair or replacement of this device, at CardioFocus' sole and entire discretion.

13. Service

CardioFocus employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of CardioFocus products. CardioFocus also maintains a professional staff to provide technical consultation to product users. For more information, contact your local CardioFocus representative.

TECHNICAL SUPPORT CONTACT INFORMATION

For technical support contact CardioFocus:

Main Number 1-508-658-7200
Fax: 1-508-480-0600



Appendix A:

ENDOSCOPE CLEANING & STERILIZATION

❖ Please refer to the package insert (06-3915) contained in the Endoscope package for complete Endoscope cleaning and sterilization instructions.

1. WARNINGS:

▲ This section only applies to Endoscopes CardioFocus Part# 18-1447. Do not reprocess any other CardioFocus products. These instructions are valid only when the device is arranged within the package as prescribed. Any other configuration could result in inadequate sterilization.

▲ Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.

▲ The device must be cleaned prior to sterilization, or inadequate sterilization may result.

▲ Inspect the device for visible damage, such as kinks, prior to use. Do not use the device if it is damaged or the Endoscope image is not clear.

▲ Use only packaging approved for use in the Sterrad NX system.

▲ The following Sterrad process has been validated; however, the sterility assurance level for any given sterilization cycle is dependent on the actual conditions selected by the user and the correct calibration of the user's sterilization equipment and instrumentation. Because these factors are not within the control of CardioFocus, Inc., the user is responsible for the sterility assurance level.

▲ Sterilization is not a substitute for cleaning. The Endoscope must be thoroughly cleaned prior to sterilization.

▲ The Endoscope is only validated for Sterrad NX sterilization. Do not use any other sterilization methods.

▲ The adequacy of any sterilization procedure must be tested. It is critical that appropriate process parameters be validated for each facility's sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

▲ These storage guidelines are not provided as a means to maintain sterile devices within the tray.

2. CAUTIONS:

△ The Endoscope is fragile and must be handled with care. To prevent damage (i.e. kinking), do not coil the Endoscope into a loop smaller than 6" (15 cm). Avoid optical fiber (both ends of Endoscope) contact with hard surfaces.

△ Handle the Endoscope as if it has been contaminated with blood and follow appropriate hospital guidelines for handling.

△ Do not use metallic brushes, scrub pads, or other abrasive cleaning aids when reprocessing the device. These can cause permanent damage.

△ Do not use harsh chemicals (such as chlorine or caustic soda) or organic or ammoniated acids or solvents (such as acetone) when reprocessing the device. These can cause permanent damage.

△ Do not clean more than three (3) Endoscopes in the same cleaning basin.

3. LIMITATIONS ON REPROCESSING

- These reprocessing instructions are provided in accordance with ANSI ST 81 and ISO 17664.



- While these instructions have been validated by the manufacturer as being capable of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing (as actually performed, using equipment, materials, and personnel in the reprocessing facility) achieves the desired result. This normally requires validation and routine monitoring of the process. .
- The Endoscope may be processed up to ten (10) times.
- An enclosed Tracking Card, 06-3823 can be found in each Endoscope (18-1447) box
- Refer to and fill out the Tracking Card for endoscope reprocessing status.
- Use only the Sterrad sterilization method specified for reprocessing. Other sterilization methods have not been validated and might significantly reduce the performance of the device or result in inadequate sterilization.
- Damage incurred by improper processing will not be covered by the warranty.

4. INSTRUCTIONS FOR REPROCESSING

4.1 Point of Use:

- Upon completion of the clinical procedure, carefully remove the Endoscope from the catheter.
- Rinse the entire Endoscope under running water for at least one minute to remove major debris.
- Wipe the Endoscope with a water dampened soft cloth.
- Place the endoscope into a container and cover with a towel moistened with clean tap water.

4.2 Preparation for Decontamination:

- Reprocess the device as soon as reasonably practical following use.
- Cleaning should be performed before blood and debris are dry.

4.3 Cleaning – Manual:

- Prepare enzymatic detergent² in accordance with the manufacturer's instructions.
- Submerge Endoscope (no more than 3) in a clean basin (minimum 8" x 8") with enzymatic detergent, making sure all surfaces are free of bubbles by gently agitating the device(s).
- Soak the Endoscope (no more than 3) for a minimum of 5 minutes. Wipe the device with a soft clean cloth while submerged to remove visible soil and debris.
- Submerge the Endoscope (no more than 3) in a basin of clean tap water for at least 1 minute.
- Submerge Endoscope (no more than 3) in a clean basin (minimum 8" x 8") with a neutral pH detergent, making sure all surfaces are free of bubbles by gently agitating the devices(s).
- Soak the Endoscope (no more than 3) for at least 4 minutes. Wipe each device at least once with a soft clean cloth while submerged.
- Submerge the Endoscope (no more than 3) in a basin of clean non-pyrogenic deionized water for at least 1 minute. Repeat two (2) additional times.
- Clean the Endoscope ends with 70% isopropyl alcohol using a clean cotton tip, non-plastic applicator or a clean soft, lint-free cloth.

4.4 Drying:

- Dry the Endoscope with a soft, lint free cloth.

4.5 Maintenance, inspection, and testing:

² Enzol®, a trademark of Advanced Sterilization Products, was used in the validation.



-
- Visually verify, under fluorescent lighting, that the Endoscope and cloth are clean. If soil is visible, repeat cleaning.
 - Visually inspect the Endoscope fiber ends for any residue or hazing. Repeat cleaning if residue visible.

4.6 Packaging:

- Coil device in a coil no smaller than 6" (15cm) and place in a" pouch approved for STERRAD[®] NX sterilization.

4.7 Sterilization:

- Sterilize the device within the pouch in accordance with the following Sterrad NX sterilization parameters:
 - Standard 28 minute Cycle


4.8 Storage:

- Between uses, store the device in a clean, dry environment.
- To prevent damage, minimize contact between the device and other equipment.



Appendix B:

ENDOSCOPE STERILIZATION TRACKING CARD

		HEARTLIGHT[®] Endoscope REF 18-1447	
Endoscope Tracking Card			
Hospital			
Endoscope Serial Number	<i>(AFFIX UDI LABEL HERE)</i>		
Refer to Instructions for Use for Reprocessing Information			
Reprocess No.	Date Reprocessed	Initials	
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
		Date Removed from Service	
<small>06-3823 Rev. B</small>			
Notes: 1) Printed Card Dimensions shall be 5 inch x 7 inch			