CLINICAL COMPENDIUM

The HeartLight® Endoscopic Ablation System

CardioFocus com

HeartLight
Isolate with Laser Focus

TABLE OF CONTENTS

Published results summarized in this compendium may include references to both onlabel and off-label usage of the 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

CAUTION:

Federal Law (USA) restricts this device to sale by or on the order of physician

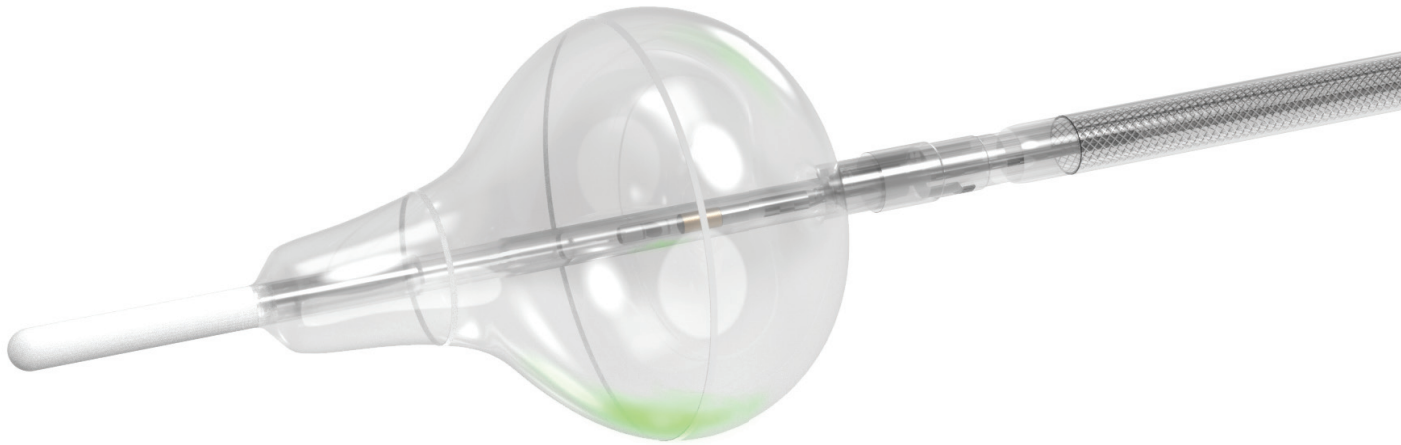
INTRODUCTION

The HeartLight System has been successfully used worldwide in more than 16,000 patients and featured in more than 200 peer-reviewed publications and abstracts The clinical data demonstrates that:

- Efficacy of the HeartLight System compares well to other atrial fibrillation (AF) ablation modalities.
- The quality and durability of lesions produced by the HeartLight System are highly reproducible and well suited for establishing chronic pulmonary vein isolation (PVI)
- HeartLight allows for targeted and flexible energy titration strategies that accommodate significant variability in pulmonary vein (PV) tissue thickness
- HeartLight is able to address wide-ranging PV variant anatomies, allowing for high rates of PV isolation without separate touch-ups required
- HeartLight represents a paradigm in ablation of cardiac arrhythmias as it enables direct visualization and continuous titratable laser energy on a universal, ultra-compliant balloon platform

KEY FEATURES

- Direct visualization via a 2F endoscope enables real time visualization of anatomy, tissue contact, and lesion placement
- The ultra-compliant balloon, along with the ability to adjust the sizing, conforms to variant pulmonary vein anatomy Veins varying in size from 7-41mm[*1] have been successfully treated with the HeartLight catheter
- RAPID mode energy delivery allows for continuous, motor driven, high-speed lesion creation, with the ability to isolate veins in as few as 3 minutes[*]
- Laser energy creates lesions by optically penetrating the tissue, with the focal point about 2mm[*] below the endocardial surface This allows for less energy usage, lower max temperatures decreasing the risks of char and thromboembolisms, and less edema and PV stenosis



* Data on file with CardioFocus

1. Borge R. Successful Treatment of a 41 mm Left Common Pulmonary Vein Using the Second-Generation Visually Guided Laser Balloon [abstract taken from Abstracts from the 26th Annual International Atrial Fibrillation Symposium. J Cardiovasc Electrophysiol. 2021 May;32(5):1467-1515.

COMPARATIVE STUDIES

Efficacy of the HeartLight System compares well to other atrial fibrillation (AF) ablation modalities

Pivotal study of a novel motor-driven endoscopic ablation system

Schmidt, B, et al. Circ Arrhythm Electrophysiol. 2021.

- This non-inferiority study evaluated the acute safety, performance and chronic efficacy of the latest generation X3 endoscopic ablation system with the introduction of a new ablation mode (RAPID) for continuous lesion deployment
- The study was prospective and historically controlled (comparison to original Pivotal HeartLight study) and a total of 60 patients were enrolled at 2 centers
- The primary end point was ablation time (time from insertion of the X3 catheter to the end of the last 30-minute wait period)
- Except one, all PVs were treated with RAPID mode Acute PV isolation was achieved in 98 7% of these. The ablation time was significantly shorter with X3 than in the original HeartLight study (77.3±25.8 versus 173.8±46.6 min). Procedure time and fluoroscopy time were also significantly shorter (103.7±32.3 versus 236.0±52.8 min; 6.9±3.5 versus 35.6±18.2). PV isolation after the first circular lesion was achieved in 91 6% of PVs (Times include a 30-minute wait period)
- The 6-month and 12-month atrial fibrillation–free rates for X3 compare favorably with the rates reported for HeartLight, 89 5% versus 75 0% and 71 9% versus 61 1%, respectively
- Only two strokes and one late pericardial effusion were noted in the treatment group; none were deemed device related

Key Takeaways

The X3 System now offers a RAPID ablation mode that clinically and statistically reduced ablation and procedure time This study showed that RAPID mode was applicable in virtually all PVs, leading to a high rate of first pass isolation. Given these promising changes, the HeartLight System has evolved from point-by-point therapy toward the opportunity for "single shot device" isolation

Pulmonary vein isolation using the visually guided laser balloon: a prospective, multicenter and randomized comparison to standard radiofrequency ablation

Dukkipati SR, et al. JACC. 2015.

- In this study, 353 patients with a history of paroxysmal AF (PAF) (178 HeartLight, 175 Irrigated Radiofrequency [RF]) were randomized across 19 highly experienced RF clinical sites
- Efficacy was defined as freedom from treatment failure which included: documented symptomatic AF, ablation-induced LA flutter or atrial tachycardia, failure to isolate all PVs, use of any anti-arrhythmic drug or additional intervention for AF
- Despite minimal prior experience, the efficacy and safety with HeartLight proved to be noninferior (similar) to RF. Efficacy rates were 61.1% for HeartLight and 61.7% for RF. Primary adverse event rate was 11 8% for HeartLight and 14 5% for RF
- HeartLight demonstrated a statistically significant lower rate of reconnection in comparison to RF
- When analyzing results of physicians who had performed a minimum of 15 procedures, HeartLight outcomes start to appear even more favorable
- The results also compare well to the US Pivotal Trial with the CryoBalloon, which demonstrated 1-year efficacy of 49.7% in the STOP AF study

Key Takeaways

In a randomized clinical trial, HeartLight demonstrated excellent efficacy and safety despite a significant difference in physician experience with the two modalities under evaluation.

Rapid pulmonary vein isolation utilizing the third-generation laser balloon – the PhoeniX registry

Christian-H. Heeger, et al. IJC Heart & Vasculature 2020

- In this study, 15 consecutive patients (40% PAF and 60% PeAF) were prospectively enrolled and treated using LB3 (3rd generation laser balloon - X3) These patients were compared to the last 15 consecutive patients (100% PeAF) treated by LB2 (2nd generation laser balloon)
- A total 59/59 PVs (100%) were successfully isolated. Fifty-six of 59 PVs (95%) proved PVI after the first application of a circular lesion around the PVs
- The median procedure time significantly declined from LB2 (91 (86, 105) min) to LB3 (77 (68, 87) min), p < 0 001
- The median left atrial dwelling time significantly decreased from LB2 (72 (62, 84) min) to LB3 (45 (38, 52) min), p < 0 0001
- The total laser time decreased from LB2 (1920 (1765, 2193) sec) to LB3 (1077 (896, 1165) sec), p < 0 00001
- The total rate of periprocedural complications for the LB3 was 6 7% (1/15 patients) and was similar to the LB2 group One (6 7%) pericardial tamponade, not related to LB3 handling, requiring epicardial puncture was detected at the end of the procedure after successful PVI It was drained by percutaneous puncture No operation was necessary and the patient recovered without any sequelae

Key Takeaways

With 100% successful PVI without the necessity of RF touch-up, the LB3 was highly effective Procedure time, LA dwelling time, and total laser time significantly decreased compared to the LB2 The LB3 offers the opportunity of real single shot applications, achieving this in 1/3 of PVs

Wide area circumferential ablation for pulmonary vein isolation using radiofrequency versus laser balloon ablation

Jamario Skeete, et al. Journal of Arrhythmia 2022

- In this retrospective multicenter study, the procedural performance of LB-WACA and point-by-point RF-WACA strategies for isolation of ipsilateral PVs in patients with persistent AF were assessed
- 204 consecutive patients were studied (LB-WACA: n = 103; RF-WACA: n = 101) All operators were experienced in the ablation technique performed (RF-WACA— Four operators, LBA-WACA— four operators)
- In all patients, acute electrical isolation was achieved during the index procedure. The rate of first-pass PV isolation was higher in patients treated with LB-WACA compared to RF-WACA (88 3% vs 75 2%)
- Procedure time (118 vs 143 min) and LA dwell time (78 vs 109 min) were shorter when using LB3 in comparison with the LB2 catheters About 43% of PVs were ablated using only the LB3's RAPID mode
- Ten patients required supplemental ablation to complete electrical isolation of WACA lesion sets in the LB group; 7/103 (6 8%) via laser balloon and 3/103 (2 9%) via RF
- In the LB group, there were 25 (24.2%) patients with any AFT (atypical atrial flutters or tachycardia)/ AF events, consisting of 5 (4 9%) patients with AFT and 23 (22 3%) with AF recurrences In the RFA group, there were 41 (40 6%) patients with AFT/AF events, including 19 (18 8%) with AFT, and 36 (35 3%) with AF recurrences

Key Takeaways

The LB ablation strategy was associated with higher long-term freedom from AFT/AT after a single catheter ablation procedure and a significantly higher likelihood of achieving first-pass isolation of all target PVs when performing WACA. These findings highlight the potential added role of LBA as an alternative approach for WACA PVI in patients with persistent AF

META-ANALYSIS

Laser balloon ablation for AF: a systematic review and meta-analysis

Reynolds M., et al. Journal of Cardiovascular Electrophysiology. 2018.

- This study used previously published data from 17 studies which included 1188 patients from approximately 40 different centers in eight countries
- Overall, 80% of the patients had paroxysmal AF (the other 20% persistent)
- 89.3% of pulmonary veins were isolated with first encirclement while 98.8% were successfully isolated by procedure end
- 12-month success for patients with only paroxysmal AF was 74 3% while all AF types combined was 72 9%
- The most common complication was phrenic nerve injury with an incidence rate of 2 6% (only 0 2% persisted through the end of study follow-up)
- The average procedure time was 183 minutes with centers observing a >60-minute decline from their earliest to their most recent groups of patients

Key Takeaways

The laser balloon system is an effective option for achieving pulmonary vein isolation with a low rate of major adverse events and reported freedom from recurrent arrhythmia in the range of 70-75% at 12-months On average, centers observed a greater than 60-minute decline in procedure time from their earliest to their most recent group of patients

LONG-TERM RESULTS – SINGLE CENTER EVALUATIONS

Long-term results with the HeartLight System have shown consistently to be durable

Acute and long-term results with the 3rd generation visually guided laser balloon ablation system for PV isolation

Funasako M. et al. Journal of Interventional Cardiac Electrophysiology. 2023

- This study of 110 paroxysmal and persistent AF patients evaluated the safety and efficacy of the third-generation laser balloon (X3)
- Ablation was performed using the continuous 13W RAPID mode where stable tissue contact was obtained and resorting to manual point-by-point mode when needed
- The RAPID mode was applied to 418/420 (99 5%) PVs and 138/420 (32 8%) PVs were treated only with the RAPID mode
- 91.1% (380/417) of veins were isolated on the first circumferential lesion set. All the veins were isolated only with X3 and no vein required an RF touch-up
- Mean procedure time from the first groin puncture to the sheath extraction from the LA was 77.0 ± 22 7 min The mean left atrial treatment time (LA dwell time) was 61 9 ± 22 0 min
- Mean fluoroscopy time was 3.7 ± 3.2 min
- In 88 3% of the PVs, RAPID mode was used in most (> 50%) or all of the ablation lesion sets
- At 1 year, SVT-free survival rate was 93 7% in paroxysmal AF patients and 81 1% in persistent AF patients
- Sixteen out of 19 PVs (84.2%) in the recurrent AF patients confirmed durable PV isolation

Key Takeaways

The X3 laser balloon is safe and effective for both paroxysmal and persistent AF patients The combination of laser energy and continuous RAPID delivery provide quick and durable PV isolation without serious complications The clinical results demonstrate high SVT-free survival rates

Pulmonary vein isolation by visually guided laser balloon ablation: single-center 5-year follow-up results

Koopman et al. Journal of Interventional Cardiac Electrophysiology (2023)

- In this observational report, 152 patients (598 PVs) treated with the first-generation laser balloon between 2014-2016 were analyzed
- Acute isolation was achieved in 98.2% of veins, with first-pass isolation in 92.5%
- Skin-to-skin time averaged 129 minutes
- Peri-procedural complications were reported in 15 patients, with minor vascular access complications being the most frequently reported
- At median follow-up of 51 months, 74 3% of patients remained free from AF (78 8% for paroxysmal, 65 3% for persistent)
- Freedom of AF at 1, 2, 3, and 4 years follow-up was 88 2%, 82 2%, 78 9%, and 74 8%, respectively
- In those patients whose recurrence led to an additional procedure, only 46 9% had PV reconnections

Key Takeaways

Ablation with the first-generation laser balloon demonstrated high isolation rates with good long-term freedom from AF after performing PVI only Complication rates were low and procedure times were reasonable

Visually guided laser ablation: a single-centre long-term experience

Sediva L, et al. Europace. 2014.

- In this study, 194 patients with a history of PAF or persistent AF (PsAF) were treated with HeartLight and followed for up to four (4) years to assess rates of freedom from AF
- Recurrence of AF was defined as any documented AF episode of greater than 30 seconds
- Follow-up demonstrated high and durable rates of AF freedom with 82% PAF patients free of AF at one year, 76% free at two years, 76% free at three years and 75% free at four years
- Patients with PsAF demonstrated 75% freedom from AF at one year Additional follow-up on PsAF patients was not yet available as these patients were addressed much later in this clinical evaluation
- Over the course of the site's experience, both procedure and fluoroscopy times improved substantially with mean procedure times of 150 minutes and mean fluoroscopy times of 13 minutes in its most recent cohort of patients

Key Takeaways

In a large consecutive series of patients with long-term follow, HeartLight demonstrated impressive long-term results out to four years

LESION QUALITY

The quality and durability of lesions produced by the HeartLight System are highly reproducible and well suited for establishing chronic PVI

Validation of lesion durability following pulmonary vein isolation using the new third-generation laser balloon catheter in patients with recurrent atrial fibrillation

Tohoku S. et al. Journal of Cardiology 2021

- This article assesses lesion durability as well as gap localization using the second generation (EAS2) and third generation (EAS3) laser balloon in patients with recurrent atrial fibrillation (AF)
- A total of 34 (EAS3 : N = 13, EAS2: N = 21) out of 225 patients (EAS3 : N = 125, EAS2: N = 100) underwent a second ablation for symptomatic atrial arrhythmia recurrences 11 9 ± 9 3 months after the initial procedure
- 68 9% (91/132) of PVs were persistently isolated, with a higher rate in the EAS3 cohort (82 0%) vs the EAS2 cohort (61 0%)
- On a per vein basis, the durable isolation rates in EAS3 were: RSPV 76 9%, RIPV 76 9%, LSPV 90 9%, LIPV 100% and LCPV 0%
- The need for focal energy reduction was a predictor of PV reconnection, highlighting the importance of optimal antral contact and visualization

Key Takeaways

The technical innovation of RAPID mode ablation with EAS3 resulted in a higher lesion durability compared to standard point-by-point ablation of EAS2

Left atrial thickness and acute thermal injury in patients undergoing ablation for atrial fibrillation: Laser versus radiofrequency energies

Gao X. et al. J Cardiovasc Electrophysiol. 2021.

- In this study, 27 (15 laser/12 radiofrequency) patients with paroxysmal or persistent atrial fibrillation were evaluated for acute tissue changes post ablation using intracardiac echocardiography (ICE)
- ICE images of the PV and antral tissue were taken immediately before ablation and at least 30 minutes post ablation after confirming isolation
- Average percent increase in thickness of all veins was greater in RF (24 1%) than laser (1 2%)
- Median percent change in wall thickness post ablation per transverse plane was greater in RF (9 5%) than laser (0 4%)
- Median percent change in PV luminal area per transverse plane was (−12.1%) for RF and (0.36%) for laser – a negative number indicated a decreasing vein diameter
- Significantly more energy was delivered per patient by RF (11,124 J) for PVI when compared with laser (5,687 J)

Key Takeaways

Acute tissue changes that occur immediately after ablation are different between the two energy sources. Compared with laser, RF shows markedly more thickening post-ablation with significant regional variations

A RAndomized Trail to compare the acute reconnection after pulmonary vein ISolation with Laser-BalloOn versus radiofreqency Ablation: RATISBONA trail

Ücer E, et al. Journal of Cardiovascular Electrophysiology. 2018.

- In this study, 50 paroxysmal atrial fibrillation (AF) patients were randomized 1:1 to pulmonary vein (PV) isolation (PVI) with either visually guided laser balloon (VGLB) or radiofrequency (RF) ablation
- This is the first randomized study comparing the acute PV reconnection rate after PVI with VGLB versus RF ablation using an adenosine provocation test (APT)
- Each PV underwent an APT at least 20 minutes after isolation, looking at the acute PV reconnection rate between the two ablation methods
- Significantly fewer PVs were reconnected during the APT in the VGLB group than in the RF group [10 PVs (10 8%) vs 29 PVs (30 9%); p = 0 001]
- The rates of reconnection seen in both arms of this study, VGLB and RF, were consistent with previous studies
- VGLB demonstrated a statistically significant higher rate of first pass isolation after the first encirclement in comparison to RF [78 PVs (80 4%) vs 46 PVs (47 9%); p < 0 001]

Key Takeaways

Although tissue injury caused by laser energy and RF are both thermally mediated, there are differences. VGLB creates deep transmural ablation lesions, resulting in lower acute PV reconnection. The acute PV reconnection rate is significantly less with VGLB than with RF, suggesting ablation with VGLB is more durable in the acute phase than RF.

The durability of pulmonary vein isolation using the visually guided laser balloon catheter: multicenter results of pulmonary vein remapping studies

Dukkipati SR, et al. Heart Rhythm Society. 2012.

- This study consisted of a multicenter evaluation of HeartLight's PV isolation durability 56 patients were evaluated with PVs acutely and chronically assessed
- 98% (202 of 206) PVs were acutely isolated and 86% (162 of 189) PVs remained isolated during remapping at an average of 105 days in the 52 patients who underwent remapping As part of the remapping procedure, un-isolated PVs could be re-isolated
- Using powers higher than 5 5W / 30 seconds was associated with a lower reconnection rate during follow-up
- For those operators who had performed at least 10 procedures, the rate of persistent PVs isolated at the time of remapping was 89 4%
- The drug-free rate of freedom from AF or atrial tachycardia in the 52 patients that underwent remapping at an average of 12 months was 71 2%

Key Takeaways

In this multicenter PV isolation remapping study, HeartLight demonstrated impressive lesion durability and AF freedom at one year

* According to the HeartLight Endoscopic Ablation System Instructions For Use (IFU), if the esophageal temperature exceeds 38 5°C, the operator should immediately stop energy delivery Furthermore, when delivering energy into moving blood only use 5 5W for 30 seconds Do not deliver energy into stagnant blood

DOSING / ABLATION STRATEGY

HeartLight allows for targeted and flexible energy titration strategies that accommodate significant variability in pulmonary vein (PV) tissue thickness.

Single-sweep pulmonary vein isolation using the new third-generation laser balloon — evolution in ablation style using endoscopic ablation system

Tohoku S. et al. J Cardiovasc Electrophysiol. 2021.

- This study sought to determine the feasibility of single-sweep PVI using the new contiguous circumferential RAPID ablation mode. Single-sweep PVI is defined as successful PVI with a single RAPID mode energy application
- One hundred AF patients (66% paroxysmal AF) were analyzed
- A total of 379 of 383 PVs (99%) were isolated with X3 Of these, 362 (95%) were isolated on the first pass
- True single-sweep isolation was achieved in 214/245 veins where this was attempted as the primary approach (56% of the overall cohort)
    - In 10 of these PVs, manual spot ablation was used because of esophageal temperature rise (n = 5) and unstable occlusion view (n = 5) The remainder (214/245, 87 3%) were successfully isolated with single-sweep PVI
- In 357 PVs (93%), isolation was accomplished solely via RAPID mode, without the need for manual spot lesions
- There were no acute thromboembolic events (stroke or transient ischemic attack), pericardial effusions/tamponades, and no adverse events associated with potential esophageal injury were detected A single transient phrenic nerve palsy was observed
- The mean total procedure and fluoroscopy times were 43.0 ± 10 and 4.0 ± 2 min, respectively

Key Takeaways

The new X3 EAS allows for single-shot fashioned ablation in terms of single-sweep PVI in over 50% of PVs. The new RAPID ablation mode leads to an improved rate of first-pass isolation associated with very short procedure times, without compromising safety

ADDRESSING ANATOMIC VARIABILITY

HeartLight is able to address highly variable wide-ranging pulmonary vein (PV) variant anatomies, allowing for high rates of PV isolation without separate touch ups required

Acute and long-term results with the 3rd generation visually guided laser balloon ablation system for PV isolation

Funasako M. et al. Journal of Interventional Cardiac Electrophysiology. 2023

- This study provided a discussion on the utility of the compliant balloon for various anatomical conditions
- The laser balloon enables operators to adjust the expandable compliant balloon to fit various PV sizes from 8 to 41mm via a live endoscopic view
- In this study, 20 common veins were all successfully treated only with X3
- An advantage of X3 is the compliant balloon that sits well around the PV antrum, creating stable tissue contact for the use of RAPID mode continuous ablation even in small veins, common PV trunks, and veins with small or early branches

Key Takeaways

X3 is the only single-sweep device for left common veins compared to other balloon techniques that require multiple segment applications per vein. The study showed high flexibility of the X3 system against anatomical anomalies without any RF touch-up ablation

An international two-centre experience with the third generation laser balloon system: safety, efficiency, and efficacy

Martignani et al., Europace (2023)

- In this two-center analysis, 163 patients having undergone ablation with the third-generation X3 Laser Balloon were reviewed
- A total of 655 PVs were identified
- 41 patients had anatomic variations: 19 with a LCPV or RCPV and 23 with supernumerary RPVs
- 44% of veins were isolated using RAPID mode exclusively; 59 4% utilized RAPID mode over at least 90% of the vein, and 64% were able to cover at least 80% of their area with RAPID mode

Key Takeaways

The X3 Laser Balloon achieves good tissue contact and effective isolation consistently even with variable and challenging anatomies

Impact of pulmonary vein anatomy assessed by cardiac magnetic resonance imaging on endoscopic pulmonary vein isolation in consecutive patients

Metzner A, et al. Europace. 2011.

- In this study, the impact of variant PV anatomy on outcomes with the HeartLight System was evaluated in 51 patients with a history of paroxysmal AF
- A total of 195 PVs were assessed by pre-interventional cardiac magnetic resonance imaging (CMRI)
- PV anatomy was found to be widely variable in terms of: number of PVs; separate vs common anatomy; PV diameter; round vs oval PV shape; level of first PV branching; and the level of insertion of the right inferior PV into the left atrium
- PV isolation was achieved exclusively with the HeartLight System in 192 of 195 (98%) PVs Isolation was achieved irrespective of variable PV anatomy

Key Takeaways

Study validates the HeartLight system's universal balloon design, demonstrating that a single balloon can be used in highly variable PV anatomies, achieving a very high rate of isolation without the requirement of additional 'touch ups'

CardioFocus, Inc
500 Nickerson Road
Marlborough, Massachusetts 01752
T: (508) 658-7200
information@cardiofocus com