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SINGLE SHOT CHAMPION

CLINICAL DATA SUMMARY

FARAPULSE™
Pulsed Field Ablation System

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SINGLE SHOT CHAMPION Clinical Trial Results

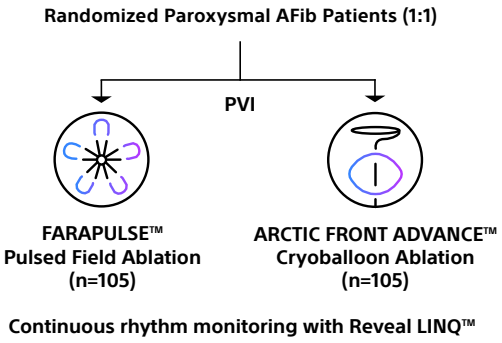
Reichlin, T et. al, 2025
Single Shot Pulmonary Vein Isolation: Comparison of Cryoballoon vs Pulsed Field Ablation in Patients with Symptomatic Paroxysmal Atrial Fibrillation – A Multi-Center Non-Inferiority Design Clinical Trial (The SINGLE SHOT CHAMPION Trial)
NCT05534581

OBJECTIVE

The Single Shot Champion trial was a randomized clinical trial that directly compared the safety and effectiveness of the FARAPULSE™ Pulsed Field Ablation System (PFA) versus Medtronic Arctic Front Advance™ Cryoballoon (CBA) to treat symptomatic, drug refractory paroxysmal atrial fibrillation (PAF) with continuous rhythm monitoring.

SINGLE SHOT CHAMPION TRIAL DESIGN

- Investigator-initiated, multi-center, patient-blinded non-inferiority trial with blinded endpoint adjudication.
- 210 patients with symptomatic, drug refractory PAF were randomized 1:1 and underwent PVI with either PFA or CBA. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.
- Ablation effectiveness was assessed with continuous rhythm monitoring (Medtronic Reveal LINQ™).
- No repeat ablations were allowed during the 3-month blanking period and AADs were discontinued after the blanking period.



SAFETY

The primary safety endpoint was a composite of cardiac tamponade requiring pericardiocentesis, persistent phrenic nerve palsy lasting >24 hours, serious vascular complications requiring intervention, stroke/transient ischemic attack, atria-esophageal fistula, or death within 30 days after ablation.

- The primary safety endpoint occurred in 1 (1.0%) FARAPULSE patient (ischemic stroke/TIA) and in 2 (1.9%) Arctic Front patients (cardiac tamponade requiring drainage).

THE OVERALL MAJOR ADVERSE EVENT RATES WERE **LOW**

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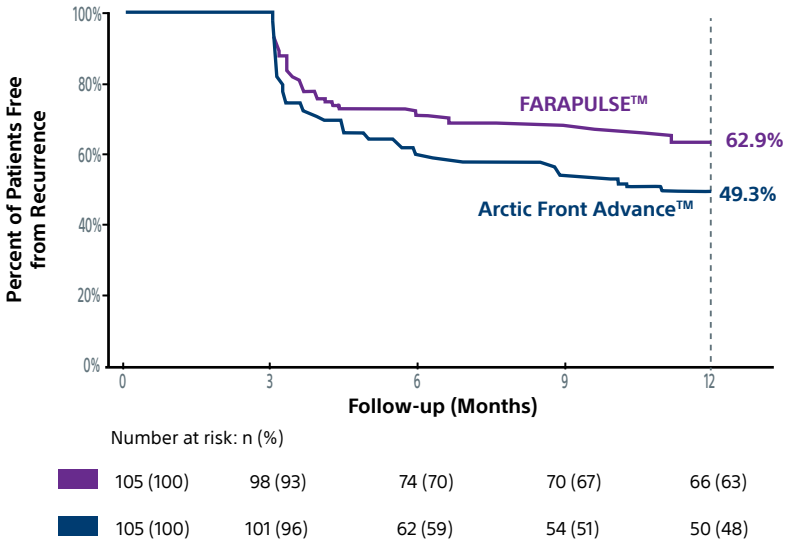
EFFICACY

Primary Efficacy Endpoint

The primary endpoint was the first recurrence of atrial tachyarrhythmia (AF/AFL/AT), (AA recurrence) after the blanking period (days 91-365) lasting >30 seconds. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.

- At 12 months, FARAPULSE demonstrated superiority in freedom from AA recurrence (62.9%) compared to Arctic Front Advance (49.4%), (p<0.001 for non-inferiority, p=0.046 for superiority).



Number at risk: n (%)

FARAPULSE™	105 (100)	98 (93)	74 (70)	70 (67)	66 (63)
Arctic Front Advance™	105 (100)	101 (96)	62 (59)	54 (51)	50 (48)

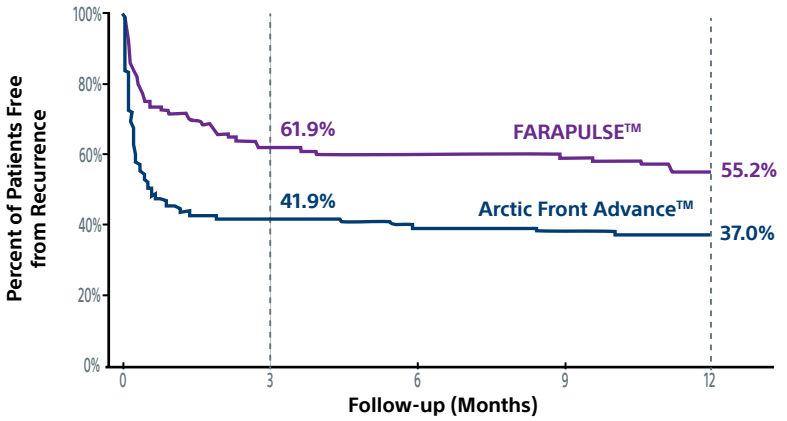
FARAPULSE
SIGNIFICANTLY REDUCED AA RECURRENCE

FARAPULSE treatment resulted in a 13.6% reduction in AA recurrence (p=0.046) at 12 months vs Arctic Front Advance

Secondary Efficacy Endpoints

Additional secondary endpoints included the first recurrence of atrial tachyarrhythmia (AF/AFL/AT) during days 1-90 and days 1-365; atrial arrhythmia burden (% time in atrial arrhythmia) during days 1-90 and days 91-365.

- There was a 20% reduction in atrial arrhythmia recurrence during the 3-month blanking period (days 1-90). The recurrence-free rate for FARAPULSE was 61.9% and 41.9% for Arctic Front Advance (95% CI, -33.2 to -6.8%).
- At 12 months, inclusive of the blanking period (days 1-365), there was an 18.2% reduction in atrial arrhythmia recurrence. The recurrence-free rate for FARAPULSE was 55.2% and 37.0% for Arctic Front Advance (95% CI< -31.5% to -4.9%).



Number at risk: n (%)

FARAPULSE™	105 (100)	65 (62)	63 (60)	62 (59)	58 (55)
Arctic Front Advance™	105 (100)	44 (42)	41 (39)	38 (36)	37 (35)

FARAPULSE showed an **EVEN GREATER REDUCTION** in AA recurrence vs Arctic Front Advance **DURING THE BLANKING PERIOD**

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ADDITIONAL ENDPOINTS

Clinical Interventions and Quality of Life (QoL)

- There were no significant differences in the number of hospitalizations or cardioversions for AA recurrence or repeat ablations between patients treated with PFA or CBA.
- There was no significant health-related QoL difference at 3 and 12 months between patients treated with FARAPULSE vs Arctic Front Advance.

PROCEDURAL CHARACTERISTICS

- The FARAPULSE ablation procedure time (54.8 ± 22.7 min) and catheter LA dwell time (36.1 ± 16.6 min) were 18 minutes and 15 minutes shorter than Arctic Front Advance (73.2 ± 26.7 min and 51.5 ± 20.0 min, respectively).
- Troponin levels were significantly higher in the FARAPULSE group signaling that FARAWAVE created larger, possibly more antral lesions vs Arctic Front (1920 ± 954 vs 1114 ± 419; difference 823; 95% CI 612-1034).

	FARAPULSE™ (n=105)	Arctic Front Advance™ (n=105)
Procedure time (min)	54.8 ± 22.7	73.2 ± 26.7
LA dwell time (min)	36.1 ± 16.6	51.5 ± 20.0
Fluoroscopy time (min)	14.6 ± 7.2	15.1 ± 7.9
Increase in hsTroponin on day 1 (ng/L)	1920 ± 954	1114 ± 419
Total # of applications	36 (32-40)	5 (5-7)
CTI ablation (%)	14 (13.3)	12 (11.4)

CONCLUSIONS

- Single Shot Champion was a randomized study where patients treated with FARAPULSE or Arctic Front Advance were monitored with a continuous monitoring device eliminating sampling error, giving a more comprehensive assessment of ablation efficacy.
- This study also had a stringent primary efficacy endpoint of first recurrence of atrial arrhythmia after the blanking period lasting >30 seconds.
- The SINGLE SHOT CHAMPION trial, using a stringent monitoring strategy and endpoint definition, demonstrated that significantly more patients treated with FARAPULSE (62.9%) were recurrence-free, compared to those treated with Arctic Front Advance (49.3%), (p=0.046), resulting in a 13.6% reduction in AA recurrence at 12 months.
- Additionally, there was a significant reduction in AA recurrence during the blanking period in patients treated with FARAPULSE (recurrence-free rate 61.9%) vs Arctic Front Advance (recurrence-free rate 41.9%), (95% CI, -33.2 to -6.8%).
- When the blanking period was included, there was an 18.2% reduction in AA recurrence of FARAPULSE vs Arctic Front Advance at 12 months (95% CI, -31.5% to -4.9%).
- There were no significant differences in the primary safety endpoint, clinical interventions or QoL between patients treated with FARAPULSE or Arctic Front Advance.
- FARAPULSE procedures were 18 minutes shorter on average than Arctic Front Advance and Troponin levels post-ablation were significantly higher.

FARAPULSE vs ARCTIC FRONT ADVANCE

- **FARAPULSE SIGNIFICANTLY REDUCED AA RECURRENCE:**
  - 13.6% post-blanking (day 91-365)
  - 20% during the blanking period (day 1-90)
  - 18.2% throughout the full 12 months (day 1-365)
- There was **no significant difference** in major adverse event rates, clinical interventions or QoL.

SINGLE SHOT CHAMPION was supported by an unrestricted research grant from BSC.

Reference:
Reichlin, Tobias, et al. (in press). "Pulsed Field or Cryoballoon Ablation for Paroxysmal Atrial Fibrillation." *New England Journal of Medicine*.

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FARAWAVE™ / FARAWAVE™ NAV Pulsed Field Ablation Catheters

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance.

INDICATIONS FOR USE The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF).

Intended Patient Population The FARAPULSE PFA System is intended for adult patients who are age 18 or older who have drug-refractory, recurrent, symptomatic PAF.

CONTRAINDICATIONS The FARAWAVE Catheter is contraindicated for use: in patients with active systemic infection; in patients with a mechanical prosthetic heart valve through which the catheter must pass; in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation; in patients with a bleeding disorder, or who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation; in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach; in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels); via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch.

WARNINGS If the visibility of the EP catheter is compromised for any reason, the user should stop and not resume ablation therapy until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures. Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. Device specific physician in-service training is made available by the manufacturer. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications. Carefully read all equipment and ancillary device instructions required for the procedure prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications.Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury. Before using, inspect the FARAWAVE Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed. Electromagnetic Interference (EMI) from any source during normal operation may adversely affect the visualization and tracking of the catheter during the procedure, which can cause patient injuries such as perforation, heart block and injury to adjacent structures. Use of the FARAWAVE Catheter with generators other than a compatible BSC PFA Generator can lead to unexpected energy delivery resulting in either insufficient ablation treatment or over-delivery of energy leading to possible patient hazardous events such as thrombus formation, tissue damage, etc.Patients undergoing ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker. When the catheter is in the patient, the patient and/or the catheter connector should not come in contact with grounded metal surfaces to minimize the potential for electrical shock. Ensure that the cable/catheter connection remains dry throughout the procedure in order to prevent electric shock or other patient injuries as well as to prevent loss of device function. Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the catheter. In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes. Care must be taken to ensure that any equipment used in connection with the FARAWAVE Catheter be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock. Do not directly touch the patient when ablation energy is being delivered to prevent the risk of electric shock. Stimulation of cardiac tissues caused by pacing stimulus and/or ablation energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. Warnings for patients with implantable pacemakers (PPMs) and Implantable Cardioverter Defibrillators (ICDs): PPMs, ICDs, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures.Do not apply ablation energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function. Temporarily reprogram the pacemaker or defibrillator per the manufacturer guidelines during ablation. The device could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters. Program the ICD Tachy therapy to "Off" to prevent inappropriate shock and/or possible damage to the device from the ablation procedure. Remember to turn Tachy Therapy to "On" once ablation is complete. Have temporary external sources of pacing and defibrillation available. Perform a complete analysis of the implanted device function after ablation. Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement. Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function. Ablation in contact with any other electrodes alters the function of the catheter and can lead to embolism. At no time should a FARAWAVE Catheter be advanced, withdrawn, rotated, deployed or undeployed when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter. Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is over torqued and/or positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. Do not use the FARAWAVE Catheter in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of a PFA Generator and the ablation system may adversely impact the image quality. This can also lead to loss of visibility during ablation which can cause patient injuries such as perforation, heart block and injury to adjacent structures. Catheter ablation procedures present the potential for significant radiation exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the radiation beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Due to radiation exposure during catheter ablation, the safety and effectiveness of this device has not yet been established in pregnant and/or nursing women and pediatric patients. There are no data to support the safety and effectiveness of this device in the pediatric population. Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible. Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. Excessive curves or kinking of the catheter may damage internal wires and components, including the flush lumen. This damage may affect mechanical and electrical performance leading to patient injury. Do not attempt to bend, kink, or shape the patient-contact portions or flush lumen of the FARAWAVE Catheter. Doing so could cause electrical or mechanical catheter failure resulting in patient injury. Kinking of the flush lumen may compromise flow through the device leading to potential thrombus formation and embolism. Use both fluoroscopy, or other visualization techniques such as echocardiography, and electrograms to monitor the advancement and navigation of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade. Do not rely solely on electromagnetic navigation system display to monitor catheter location. The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury. Do not deliver ablation energy with the catheter outside the target site. Ablation Generators can deliver significant electrical energy and may cause patient injury such as arrhythmia and heart block. Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system. Patients undergoing left-sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, and/or embolism. Patients undergoing an ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding/hemorrhage and/or embolism. Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution. The FARAWAVE Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death. Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism. If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a Transesophageal Echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage. Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion. Do not wipe this catheter with organic solvents such as alcohol or immerse the handle and/or cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient. Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures. The safety and/or efficacy of epicardial use of the FARAWAVE Catheter has not been evaluated in a clinical trial. Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair. Do not leave the FARAWAVE Catheter in the patient for more than four (4) hours. Failure to remove the device before four hours after first insertion could result in formation of thrombus with attendant stroke risks. Use of the FARAWAVE Catheter with delivery devices other than the FARADRIVE Sheath can result in poor access to endocardial locations, inefficient ablation delivery and inadequate procedural outcomes. Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes). The FARAWAVE Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury can be fatal. Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury. When positioning on cardiac structures, the guidewire should be retracted to prevent cardiac perforation or tissue damage. Ensure the tip of the device is not against tissue prior to advancing or retracting the guidewire to prevent cardiac perforation or tissue damage. The risk of igniting flammable gases or other materials is potential outcome of ablation procedures. Precautions must be taken to restrict flammable materials from the electrosurgical suite. Take care when manipulating the guidewire to prevent cardiac or vessel trauma. To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue. Minimize catheter exchanges and always advance and withdraw components through the valve slowly to minimize the vacuum created during withdrawal and to reduce the risk of air embolism. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements. Instruct users with co-implanted devices to refer to ancillary device labeling as well as the manufacturer of the ancillary device for recommended compatibility and settings. When ablating in proximity to metallic devices, arcing may occur which could lead to bubble formation, cardiac trauma, and/or damage to the devices. Use caution when advancing, retracting or otherwise manipulating system components to avoid damaging tissue or vessels or interfering with previously implanted medical devices. When advancing or undeploying the FARAWAVE catheter, do not retract the guidewi-

re simultaneously. If resistance is felt during retraction of the guidewire, do not continue to retract the guidewire until cause of resistance is determined as this may result in cardiac trauma. If resistance is felt, it may be necessary to advance guidewire under imaging guidance before continuing to retract. Ensure that the guidewire is not contacting ablation electrodes prior to starting ablation to prevent inappropriate energy delivery. Always un-deploy the catheter and withdraw the catheter into the sheath before removing the catheter from the Left Atrium (LA). Deploying the catheter in the septal puncture site or crossing the septum while the catheter is unsheathed or deployed may cause serious atrial septal defects or other cardiac and vessel trauma. Use visualization (such as fluoroscopy) to verify undeployment. Avoid deploying the catheter in constrained parts of the anatomy to prevent cardiac trauma or damage to the device. Prior to starting ablation verify that the catheter has been positioned and deployed correctly to prevent inappropriate application of ablation energy. Do not deploy the ca theter while the distal end is inside the sheath as it could lead to catheter damage which may result in patient harm. Intracardiac potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the Operational Instructions section, regardless of absence of intracardiac signal. Potential biohazard after use. Handle and dispose of in accordance with applicable regulations.

PRECAUTIONS Do not attempt to use with devices, including guidewires, larger than the delivery lumen diameter specified on the package label. Care must be taken to ensure all luer fittings are secure to prevent leaking. It is essential that a cardiac defibrillator with paddles connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation. There is limited data to support the safety and effectiveness of this device in patients older than 75 years. Catheter deployment and undeployment should occur under imaging guidance. Catheter may be fully deployed undeployed even though the slider switch is not fully engaged. Failure to monitor deployment may result in catheter damage and need for catheter exchange. Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible. Do not apply excessive force to the deployment mechanism when deploying the catheter as doing so may damage the catheter. Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly. Do not place the distal end of the catheter near a magnet. Magnetization of the catheter may result in degradation of magnetic tracking precision. Such degradation may be manifested by an unstable or complete loss of rendering of the position and/or orientation of the catheter by a magnetic tracking system. If this occurs, the catheter should be replaced.

POTENTIAL ADVERSE EVENTS Potential adverse events associated with use of the FARAWAVE Catheter includes, but are not limited to: Pain or discomfort, for example: Angina • Chest pain • Non-cardiovascular pain • Cardiac arrest • Death • Electric shock • Hypotension • Infection/inflammation/exposure to biohazardous material • Edema/heart failure/pleural effusion • Hemolysis • Renal failure/insufficiency • Respiratory distress/insufficiency/dyspnea • Arrhythmia (new or exacerbated) • Conduction pathway injury (heart block, nodal injury, etc.) • Nerve injury, for example: Phrenic nerve injury • Vagal nerve injury • Gastrointestinal disorders • Vessel trauma, including: Perforation • Dissection • Coronary artery injury • Vasospasm • Occlusion • Hemothorax • Cardiac trauma, for example: Cardiac perforation/cardiac tamponade/pericardial effusion • Valvular damage • Stiff left atrial syndrome • Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury • Pulmonary injury • Catheter entrapment • Physical trauma • Fistula, for example: Atrio-esophageal fistula • Bronchopericardial fistula • PV stenosis and its symptoms, for example: Cough • Shortness of breath, fatigue • Hemoptysis • Surgical and access complications, for example: Hematoma/seroma • AV fistula • Bleeding • Pseudoaneurysm • Pneumothorax • Residual atrial septal defect • Thrombus/thrombosis • Muscle spasm • Injury due to embolism/thromboembolism/air embolism/foreign body embolism • Cerebrovascular Accident (CVA)/stroke
• Transient Ischemic Attack (TIA) • Myocardial infarction • Neurological impairment and its symptoms, for example: Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment • Pulmonary embolism • Asymptomatic cerebral embolism • Procedural related side effects, for example: Allergic reaction (including anaphylaxis) • Genitourinary complication • Side effects related to medication or anesthesia • Radiation injury/tissue burn • Vasovagal response • Fluid volume overload. The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a pacemaker, and in rare cases, may result in death. 97316630 A.1

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