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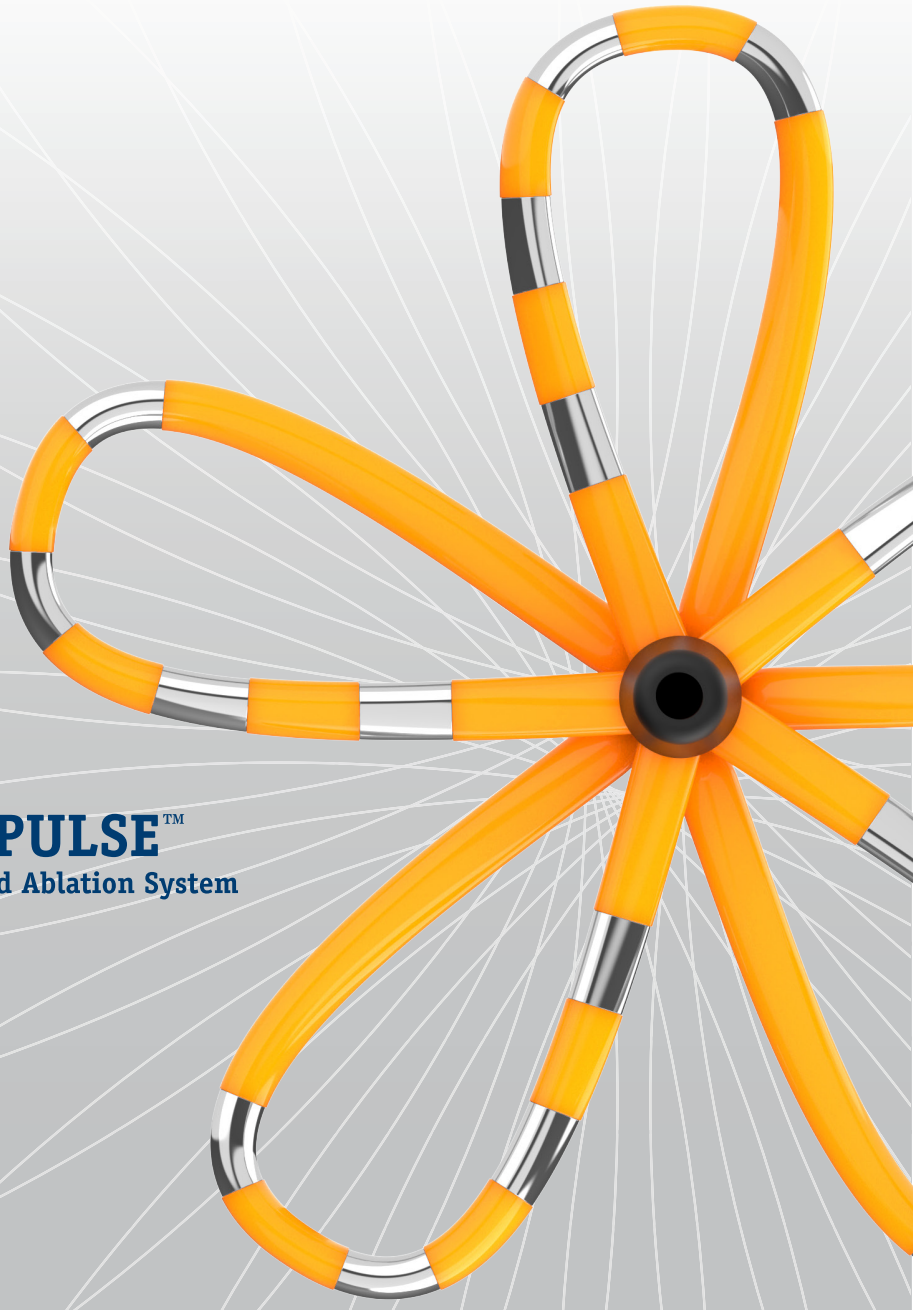
MANIFEST-17K
Multicenter Registry



FARAPULSE™
Pulsed Field Ablation System

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Multi-National Survey on the Safety of the Post-Approval Clinical Use of Pulsed Field Ablation in 17,000+ Patients (MANIFEST-17K)

OBJECTIVE[1]

- To assess if FARAPULSE™ Pulsed Field Ablation is:
  - Tissue-selective and spares the esophagus, pulmonary veins and phrenic nerve.
  - Associated with any unusual adverse events that would only be apparent after thousands of ablation procedures.

MANIFEST-17K REGISTRY DESIGN

- Retrospective observational study of the real-world commercial use of FARAPULSE Pulsed Field ablation.
- Center level data was collected from 106 centers (91.4% of all commercial centers using FARAPULSE) and 413 operators.
- The data expands beyond the previously published MANIFEST-PF registry to include a total of 17,642 (35% PersAF) patients.
- The initial MANIFEST-PF sites contributed 7,878 patients and the MANIFEST-17K sites contributed data from 9,764 patients.
- The results from MANIFEST-17K reflect a 2-year window of patients treated (3/2021-3/2023).

SAFETY

- The 3 adverse events classified as related to pulsed field energy delivery were transient phrenic nerve paresis (0.06%), coronary spasm (0.14%), and hemolysis/renal failure (0.03%). The remaining events (mortality, stroke, pericardial tamponade, TIA, and vascular access complications) were classified as non-PF energy related.

MAJOR ADVERSE EVENTS*

- The major adverse event rate was 0.98% with the most common complication being pericardial tamponade (0.36%).
- There were no reports of esophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury.
- **Mortality**
  - The mortality rate was 0.03% (n=5). Two deaths were procedure related (cardiac tamponade and post-procedure cardiogenic shock in a patient with cardiomyopathy and decompensated heart failure). The remaining 3 were not related to the ablation procedure.
- **Stroke**
  - The root cause analysis of the 22 (0.12%) stroke events was completed on 16 patients and showed that catheter exchanges, sheath management, ACT < 300, interruption of anticoagulation and uncontrolled hypertension accounted for 9 events, while 7 had no definitive cause.
- **Pericardial Tamponade**
  - The pericardial tamponade rate was 0.36%, that number improved significantly from the initial MANIFEST-PF registry (0.97%).
- **Coronary Spasm**
  - The rate of coronary spasm was 0.14% with a majority (88%) being proximity related occurring with off-label use of FARAWAVE during mitral isthmus (MI) or cavotriscupid isthmus (CTI) ablation. There were also 3 reports of generalized spasm (0.02%).
- **Hemolysis**
  - The rate of hemolysis was 0.03% and occurred in 5 persistent AF patients receiving complex lesion sets (PVI, PWI, MI, CTI)* with a large number of PF lesions (143 ± 27). Transient hemodialysis was used for all patients resulting in significant improvement of renal function at the time of discharge. Renal function normalized for all 5 patients in follow-up.

    *Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE™ PFA Catheter with the FARAPULSE PFA System.
- **Vascular Access**
  - Major vascular access complication rates requiring intervention (0.3%) were significantly lower in sites with routine use of vascular ultrasound. (0.17% in sites routinely using ultrasound versus 0.50% in sites not routinely using ultrasound).

    *Due to the retrospective nature of the registry, the adverse event rate was not reported at a pre-specified timepoint.

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MINOR ADVERSE EVENTS*

- The minor adverse event rate was 3.21% with the most common complication being vascular access site complication (2.2%).
- There were 11 (0.06%) cases of transient phrenic nerve palsy with all cases resolving prior to hospital discharge.

*Due to the retrospective nature of the registry, the adverse event rate was not reported at a pre-specified timepoint.

LEARNING CURVE

- Comparing the MANIFEST-PF[2] registry of the first 1,758 patients treated with FARAPULSE to the MANIFEST-17K registry, there was:
  - A significant decrease in rates of pericardial tamponade and minor vascular complications.
  - Improvements in stroke and transient phrenic nerve paresis rates.

Complication Rates Improved Between Initial Device Use and Continued Device Use

	MANIFEST-PF[2] (Previously Published, Initial Device Use) (n = 1,758)	MANIFEST-17K (n= 17,642)
Pericardial Tamponade*	0.97%	0.36%
Stroke	0.39%	0.12%
Transient Phrenic Nerve Paresis	0.46%	0.06%
Minor Vascular Complications*	3.28%	2.20%

**Significant Improvement ($p<0.05$)*

CONCLUSIONS

- This data expands beyond the initial 24 centers involved in the MANIFEST registry, showing that the low rate of safety events continues as the technology is adopted by additional centers.
- The major adverse event rate was <1% with no reports of esophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury.
- One of the goals of this registry was to look for any unusual adverse events that would only occur after thousands of procedures. Two rare events were noted, coronary spasm and hemolysis.
  - The rate of coronary spasm was 0.14% with a majority (88%) being proximity related occurring with off-label use of the catheter during mitral isthmus MI or CTI ablation. There were 3 reports of generalized spasm (0.02%) which is lower than the cited thermal (RFA/CBA) rate of 0.19%.
  - Hemolysis resulting in acute renal failure was rare (<1 in 1000) and were managed with hydration and associated with a high number of lesions applied.
- Evidence of learning curve at both the physician/site level and the EP community was seen in the significant decrease in rates of pericardial tamponade and minor vascular complications and improvements in stroke and transient phrenic nerve paresis rates from the initial MANIFEST-PF registry to MANIFEST-17K.

1. Reddy & Ekanem, et al. Multi-National Survey on the Safety of the Post-Approval Clinical Use of Pulsed Field Ablation in 17,000+ Patients (MANIFEST-17K). AHA 2023.

2. Ekanem, Emmanuel, et al. "Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF)." Europace 24.8 (2022): 1256-1266.

FARAWAVE™ Pulsed Field Ablation Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, 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, neither the patient nor the catheter connector should be allowed to 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 of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade. 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. 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 guidewire 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 catheter while the distal end is inside the sheath as it could lead to catheter damage which may result in patient harm. PV 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 PV 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 or 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.

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, • 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, • Hemolysis, • 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 permanent device such as a pacemaker, and in rare cases, may result in death. 97173260 (Rev. A)

FARADRIVE™ Steerable Sheath

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE / INDICATIONS FOR USE The FARADRIVE Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS Use of the FARADRIVE Sheath is contraindicated for use: in patients with active systemic infection; 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 mechanical prosthetic heart valve through which the catheter must pass; via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch; 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).

WARNINGS 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. Do not attempt to use the FARADRIVE Sheath prior to reading these instructions for use. All instructions should be understood and followed carefully. Observe all contraindications, warnings, and precautions noted in this user manual. Failure to do so may result in patient 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 FARADRIVE Sheath for any defects or physical damage that may cause patient and/or user injury if the sheath is used. Do not use defective or damaged devices. Replace damaged device(s) if necessary. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures and for selected patients undergoing right-sided 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 postprocedure according to the institution's standards to minimize bleeding and thrombotic complications. 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. Prior to inserting the device into the patient, pre-assemble the FARADRIVE Sheath and Dilator to remove residual air; failure to do so may result in air embolus. To minimize the risk of air embolism, observe and remove any air prior to introducing the sheath and during the procedure. Infusion through the flush line should only occur after all air has been removed. Always maintain a constant sterile, heparinized saline infusion to prevent coagulation within the sheath which may result in embolism. If constant infusion is interrupted, aspirate and flush the sheath with heparinized saline to minimize the potential for thrombus formation that may result in patient injury. Prevent any obstruction of the flush line to ensure effective heparinized saline flush. Introducing catheters and sheaths into the circulatory system entails the risk of air emboli. Air embolism can occlude blood vessels resulting in serious consequences such as tissue infarction and/or end organ failure. Always advance/withdraw the FARADRIVE Sheath slowly. Always advance/withdraw catheters slowly through the FARADRIVE Sheath valve and minimize catheter exchanges. At no time should components be advanced, retracted, or otherwise manipulated when resistance is met without first determining the cause. Use fluoroscopy or additional imaging modalities to assess system integrity and catheter position as needed and take remedial action as necessary. 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. Advancement or withdrawal of catheters should be followed with appropriate aspiration and flushing. Following insertion of catheter into the hemostatic valve aspirate via the side-port until air bubbles are no longer seen to prevent air embolism from occurring. Do not use with cardiovascular catheters less than 7F, as an air embolism or patient injury can occur. To minimize the risk of air embolism, do not flush or aspirate the FARADRIVE Sheath with the dilator present as doing so may damage the valve leading to patient injury. Monitor the spontaneously-breathing patient for risk factors which may lead to negative left atrial pressures. Negative left atrial pressure may increase the risk of air ingress through the hemostasis valve particularly during insertion and removal of the catheter. Such risk factors may include, among others, pre-existing low left atrial pressure (e.g., noted at time of transseptal puncture), hypovolemia, airway collapse, deep breathing, snoring, or apnea, and may be more prevalent under sedation. Use additional caution when using drugs with respiratory depressive effects in such patients. Do not use if kinked or damaged, as this may result in patient injury. Do not kink flush lumen; flow through the device lumen could be diminished or compromised resulting in embolism or other patient injury. Take care to minimize damage to the femoral vein and access site upon insertion, manipulation, or withdrawal of the FARADRIVE Sheath. Complications associated with femoral vein catheterization include hematoma and thrombosis. Air ingress may be recognized by the visual presence of air bubbles in the side port tubing, shaft, or by an audible sucking sound emanating from the hemostasis valve. Imaging modalities employed during the procedure, such as fluoroscopy or intracardiac echocardiography, may also demonstrate the presence of air. If air embolism is suspected, begin appropriate management immediately as indicated by treatment guidelines or consensus statements. To minimize unintended back-bleeding through the side port, make sure the stopcock is in a closed position to the FARADRIVE Sheath at all times unless aspirating or flushing. The Transseptal Procedure (TSP) presents a potential risk for perforation/tamponade; echocardiography and/or fluoroscopic images should be used to guide the transseptal puncture and a real-time arterial blood pressure monitor should be applied. TSP may induce an air embolus; use proper aspiration and flushing techniques to minimize air embolus. 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. The FARADRIVE Sheath should not be used when in the presence of active Magnetic Resonance (MR). Use of the FARADRIVE Sheath in the presence of active MR could lead to patient injuries such as perforation, heart block and injury to adjacent structures. Cardiac catheterization 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. Cardiac catheterization 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 cardiac 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. Do not leave the FARADRIVE Sheath 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. To avoid patient injury, manipulate the sheath carefully when performing the transseptal puncture especially if the patient has any of the following conditions: Enlarged aortic root. Marked right atrial enlargement. Small left atrium. Marked skeletal deformity or distortion of the thoracic configuration (e.g., scoliosis). 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.

ADVERSE EVENTS Potential adverse events associated with use of the FARADRIVE Sheath includes, but are not limited to: • Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain, • Cardiac arrest, • Death, • Hypotension, • Infection/inflammation/exposure to biohazardous material, • Edema/heart failure/pleural effusion, • Respiratory distress/insufficiency/dyspnea, • Arrhythmia (new or exacerbated), Conduction pathway injury (heart block, nodal injury, etc.), • 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, • Surgical and access complications, for example: Hematoma/seroma, AV fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect, • Thrombus/thrombosis, • 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, Renal failure/insufficiency, 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 permanent device such as a pacemaker, and in rare cases, may result in death. 97162573 (Rev. A)

FARASTAR™ Pulsed Field Ablation Generator

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, 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. The FARASTAR PFA Generator is part of the FARAPULSE PFA System.

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

CONTRAINDICATIONS The FARAPULSE PFA System 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 To avoid the risk of electric shock, the FARASTAR PFA Generator must always be connected to a supply mains with protective earth. The Equipotential ground provides a direct connection between the chassis of the FARASTAR PFA Generator and the equalization bus of the electrical installation. It is not a protective earth connection point. The conductive parts of electrodes and associated connectors for system applied parts, including the neutral electrode, should not come into contact with any other conductive parts including earth ground. Electric shock can occur if this happens. The FARASTAR PFA Generator must only be used with equipment and accessories listed in this manual or patient injury or death may occur. Use of the FARASTAR PFA Generator with devices other than the FARAWAVE PFA Catheter 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. Use only with equipment and cabling that are listed in this manual or tested during installation of the equipment. Use with untested equipment or cables could result in increased EM emission or decreased EM immunity. Before using, inspect the FARASTAR PFA Generator for any defects or physical damage. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed. The FARASTAR PFA Generator must be installed by a qualified/trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support. 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. The FARASTAR PFA Generator User's Manual is a fundamental part of the FARASTAR PFA Generator and should accompany it at all times. Users must refer to this manual for correct and complete information on the use of the FARASTAR PFA Generator. The FARASTAR RSM includes its own User's Manual. See this manual for specifics regarding the usage of the FARASTAR RSM. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result in patient or user harm. The FARASTAR PFA Generator internally produces voltages that are high enough to be potentially fatal. There are no user serviceable parts in the FARASTAR PFA Generator and it should not be opened. Maintenance should only be carried out by trained authorized personnel. Do not attempt to service the FARASTAR PFA Generator while in use with a patient. 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 PFA 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 may occur, and the resulting myocardial injury can be fatal. Direct patient contact should be avoided during ablation delivery as this may result in a mild electrical sensation and/or electric shock to the user. Do not touch the FARASTAR PFA Generator console and the patient simultaneously as this may cause excessive leakage currents on the patient which could lead to arrhythmias. Ensure that any additional equipment used with the FARAPULSE PFA System has been certified to IEC 60601-1. Use of non-certified equipment can increase the risk of patient harm due to failure of protective isolation barriers that could place hazardous voltages on the patient or operator or cause excessive leakage currents that may increase the risk of cardiac arrhythmias. Do not use a power bar or extension cord when connecting the FARASTAR PFA Generator and accessories (FARASTAR RSM) to the hospital AC source as this could cause an increase in leakage currents. Ensure the FARASTAR PFA Generator and FARASTAR RSM are plugged into separate AC mains connections. Do not use a power bar to connect any combination of FARASTAR PFA Generator or FARASTAR RSM together to an AC mains supply as doing this could cause an increase in leakage currents. Ensure that equipment is used at 120V/60Hz. Ablation with the FARASTAR PFA Generator may result in Ventricular Fibrillation. It is essential that a cardiac defibrillator with paddles or patches connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation. The FARASTAR stimulator outputs are primarily used to synchronize energy delivery and are not meant to replace the functions of the primary cardiac stimulator used by the Electrophysiology Lab, delay in arrhythmia treatment and/or arrhythmia may occur. Always have external sources of pacing and defibrillation available during ablation. Catheter electrodes are subjected to potentially harmful electrical energy. During preparation of the system do not deliver energy. If the user comes into contact with the catheter electrodes during delivery, electric shock can occur. 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.

PRECAUTIONS Ensure prior to use that the FARASTAR PFA Generator is connected to the proper mains power supply. This equipment is intended for use in hospitals except near active High Frequency (HF) surgical equipment (including diathermy and electrocautery equipment), or Radiofrequency (RF) shielded room of a Medical Electrical (ME) system for Magnetic Resonance Imaging (MRI) where the intensity of Electromagnetic Interference (EMI) is high. Do not use the FARASTAR PFA Generator no closer than 30 cm (12 inches) to any Wireless Power Transfer (WPT) and 5G cellular devices, otherwise electromagnetic interference from those devices could result in degradation of the performance of this equipment. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). Perform pulsed field ablation procedures only within environmental parameters as outlined in section 10.2. It is the user's responsibility to ensure that the equipment used with the system meets all local applicable electrical safety standards. Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. For purpose of disconnection, the mains connection is on the back of the console. Do not connect any device to the fiber optic port. Do not use the FARASTAR PFA Generator if a malfunction is suspected. Contact Boston Scientific if a malfunction is suspected. Do not use the FARASTAR PFA Generator in oxygen rich environment or in the presence of flammable gases or explosive gas mixtures. Ensure that the mains power supply cord is not damaged before plugging it into an electrical mains power supply. Replace the power supply cord if any damage is noticed. In the event of an external defibrillation pulse is delivered to the patient, the FARASTAR PFA Generator may become unresponsive and will require a reboot of the system. Avoid intentional or accidental liquid spills on the FARASTAR PFA Generator. Do not place cups or containers of liquid on the generator. Do not handle the generator with wet hands or gloves. Do not use the generator near irrigation equipment. Store the FARASTAR PFA Generator away from direct sunlight, heat sources or dust. Do not expose the LCD display of the generator to direct sunlight for long time periods. Ensure that the vents on the back of the generator are unobstructed. Avoid moving the generator when powered on. During transport, avoid jarring the device. Do not scratch the LCD display of the FARASTAR PFA Generator. Before cleaning the generator, ensure that it is powered OFF and disconnect the mains cord from the device. Clean the FARASTAR PFA Generator and the FARASTAR RSM by wiping down surfaces using a non-abrasive cloth with a mild detergent solution (not containing enzymes, abrasives, bleach, or alkali) or isopropyl alcohol. For the screen, use a standard screen cleaner. Do not position the FARASTAR PFA Generator in such a manner that it is difficult to access or unplug in the event of an emergency. To maintain system isolation, only Classified Medical Electrical Equipment may be connected to the FARAPULSE PFA System. The FARASTAR RSM must be used to pass ECG and/or EGM signals to the EP Recording System, during use of the FARAPULSE PFA System, to avoid potentially damaging the EP Recording System components. Disconnect all patient inputs from the Mapping System prior to pulsed field ablation. Leaving patient inputs connected during pulsed field ablation delivery may damage the Mapping System.

ADVERSE EVENTS Any potential clinical complications are in large part expected to be related to the accessories and/or therapeutic catheter that are used with the generator, rather than the generator itself. In order to identify potential adverse events, the user is instructed to read the pertinent instructions for use associated with the catheters and accessories that will be employed during the ablation procedure. Potential adverse events associated with use of the FARASTAR PFA Generator include, 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, • 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, • 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/laceration, • Fistula, for example: Atrio-esophageal fistula, Bronchopericardial fistula, • PV stenosis and its symptoms, for example: Cough, Shortness of breath, fatigue, Hemoptysis, • Thrombus/thrombosis, • Muscle spasm, • Injury due to embolism/thromboembolism/air embolism/foreign body embolism, Cerebrovascular Accident (CVA)/stroke, Transient Ischemia 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, • Hemolysis. The potential adverse events may be related to the PFA generator, 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 permanent device such as a pacemaker, and in rare cases, may result in death. 97172186 (Rev. A)

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EP-1742205-AA