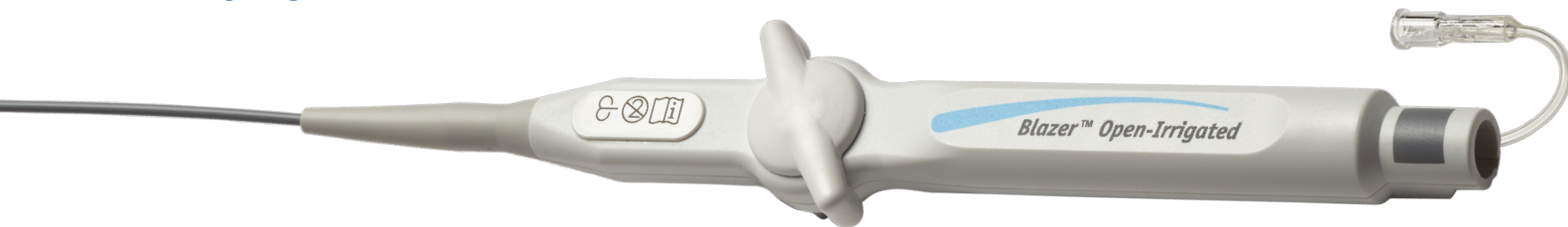


# BLAZER™ OPEN-IRRIGATED

## ABLATION CATHETER



### Ordering Information

Electrode Configuration: Quadripolar

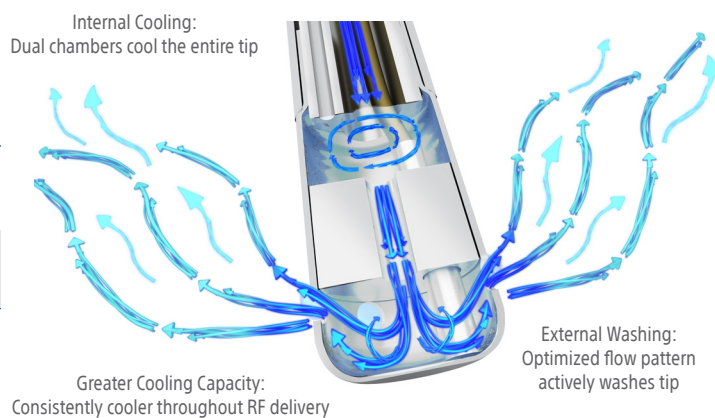
Electrode Spacing: 2.5mm

Model Number	Shaft Size	Tip Size	Curve Style	Shaft Length
M004 9620 0	7.5F	7F/4mm	Standard	110cm
M004 9620K2 0	7.5F	7F/4mm	Large	110cm
M004 9620K2E 0	7.5F	7F/4mm	Large/Extra Long	115cm
M004 9620N4 0	7.5F	7F/4mm	Asymmetric	110cm

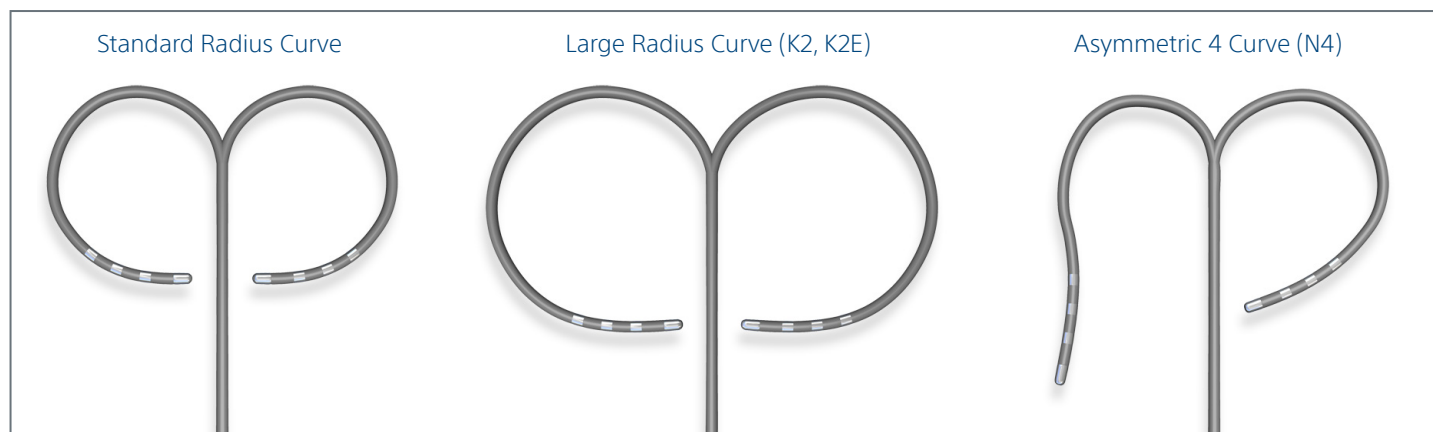
### Accessories

Model Number M004 671 0 Cable, BLAZER™ OPEN-IRRIGATED Catheter to MAESTRO 4000™ Generator

Model Number M004 117 0 METRIQ™ Irrigation Tubing Set



### Bidirectional Curve Options



Catheter configurations are illustrative representations only and may not reflect actual performance.

# BLAZER™ OPEN-IRRIGATED ABLATION CATHETER

**WARNING** Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

## BLAZER™ Open-Irrigated Ablation Catheter

**INDICATIONS FOR USE** The BLAZER OI Catheter, when used with a compatible Radiofrequency Controller and Irrigation Pump, is indicated for: • Cardiac electrophysiological mapping • Delivering diagnostic pacing stimuli • RF ablation of sustained or recurrent type 1 atrial flutter in patients age 18 years or older • Treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system

**CONTRAINDICATIONS** The BLAZER OI 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 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 who are hemodynamically unstable; • 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; • via retrograde transaortic approach in patients with a prosthetic aortic valve; Do not use this device: • with a long sheath or a short introducer < 8F • in the coronary vasculature

**WARNINGS** • If the visibility of the EP catheters are 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 and in the techniques of open-irrigated radiofrequency powered catheter mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. • 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 with 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 directions. Failure to do so may result in patient complications. • Before using, inspect the BLAZER OI 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. • Using the BLAZER OI Catheter at lower than the prescribed flow rates specified in the Operational Instruction may increase the potential for thrombus, coagulum, and char that may result in embolism. • 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. • Start the initial RF application at low power and carefully follow the power titration and the correlating flow rate procedures as specified in the instructions for use. A drop in impedance may be an indicator of lesion creation. Too rapid an increase in power during ablation, increasing power with a decrease in impedance, ablating at high power (> 30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or embolism. • Collateral tissue damage is a possibility when using the catheter at the upper power setting (50 W) or durations longer than 60 seconds or with a decrease in impedance without moving the catheter tip. Power should be increased to > 30 W only if lower energies do not achieve the intended result. • The BLAZER OI Catheter is not intended to be used with an RF Controller output setting exceeding 50 watts or 290 Vpk. The safety and performance of the BLAZER OI Catheter at powers exceeding 50 watts has not been evaluated in a clinical trial. Exceeding recommended power settings or using flow rates lower than recommended settings may increase the risk of patient injury. • Patients who have had a prior atrial flutter ablation procedure may be at greater risk for perforation and/or pericardial effusion with the use of this catheter system. • Patients undergoing septal accessory pathway, Atrioventricular (AV) node reentry tachycardia, and/or atrial flutter ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker. • Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. • During energy delivery, the patient should not 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 electrical shock or other patient injuries as well as to prevent loss of device function. • Electrodes and stimulating devices can provide paths of high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes as far away as possible from the ablation site and the Dispersive Pad. Protective impedances may reduce the risk of burns and permit continuous monitoring of the Electrocardiogram (ECG) during energy delivery. • Before use, ensure irrigation ports are patent and jetting by infusing heparinized normal saline through the catheter tubing. Patency of irrigation ports is important to maintain cooling function and minimize risks of coagulum, fibrin, thrombus and char that may result in embolism as well as perforation caused by steam pop. • Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the dilator or catheter. • Do not continue using the catheter if the irrigation ports are occluded or the catheter is not functioning properly. • Due to the design of the BLAZER OI Catheter tip, the velocity of fluid exiting the irrigation ports may change based on rate and pressure of flushing. As long as there is fluid exiting each port, regardless of the velocity, the catheter is functioning as designed and may be used. However, if any irrigation port has no flow (or extremely low flow compared to adjacent ports) despite attempts to flush the irrigation port, do not insert the catheter in the patient as there may be potential risk of embolism. • Patients undergoing a long irrigated 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. • 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 BSC catheters be type CF, be defibrillation proof, and 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 insert or withdraw the BLAZER OI ablation catheter without straightening the catheter tip (returning the steering lever to neutral position) in order to prevent entanglement/entrapment within the valve and/or other device that may result in myocardial trauma and/or may require additional medical/surgical intervention. • Stimulation of cardiac tissues caused by pacing stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. • Maximum Catheter Rated Voltage: 290 Vpk. • 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 instructions for use prior to performing ablation procedures. • Do not apply RF 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 Tach 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 dislodgment. • Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function. • Do not ablate from within the coronary artery as the resulting myocardial injury can be fatal. Adequate visualization techniques, such as fluoroscopy or intracardiac echocardiography, are necessary during the transaortic approach to avoid placement of the ablation catheter in the coronary vasculature. • During RF ablation, care must be taken not to deliver RF energy on or near the coronary artery even on the right side of the heart, as the resulting myocardial injury can be fatal. • Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation that may result in embolism. • At no time should a BLAZER OI Catheter be advanced or withdrawn 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 tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. • Do not use the BLAZER OI ablation system in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of an RF Controller 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. • In the event of a suspected failure of the integrity of fluid flow through the Blazer OI Catheter or if there is a rapid temperature rise of > 15 °C noted on the RF Controller, the procedure should be stopped, and the catheter withdrawn to reduce the risk of steam pop that could result in adverse events including perforation, embolism or injury to adjacent structures. Both the catheter and the Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of air embolism. • 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. • Excessive curves or kinking of the catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury. • Manual bending and/or twisting of the distal curve can damage the steering mechanism and cooling lumens and may cause catheter failure and patient injury. • Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to catheter failure and patient injury. • Use both fluoroscopy or other visualization technique 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. • Do not deliver RF energy with the catheter outside the target site. RF Controllers can deliver significant electrical energy and may cause patient injury. • In the event of a generator cut-off (impedance or temperature), the catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation. • Verify effective contact between the patient and the Dispersive Pad whenever the patient is repositioned as patient movement may disrupt Dispersive Pad contact resulting in patient injury and/or extended procedure times. • Always verify that the tubing set, catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and catheter 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, embolism and/or atrial esophageal fistula. • 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 BLAZER OI Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death. • The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. • 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. • Do not deliver RF energy when the tip electrode is withdrawn or partially withdrawn into a sheath, to minimize the risk of char or coagulum formation. • 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 cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient. • Irrigation flow during RF ablation may distort distal tip electrogram recordings due to the signal conductivity of the external cooling solution. Careful monitoring of additional intracardiac electrograms during RF application is recommended to reduce the possibility of inadvertent injury to adjacent structures if appropriate. Higher power coupled with higher flow rates may exacerbate the distortion of the EGM signal recordings. • 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 BLAZER OI Catheter has not been evaluated in a clinical trial. • The Transseptal Puncture (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 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. • 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) • Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

**PRECAUTIONS** • The BLAZER OI Catheter is designed for use with a compatible RF Controller, Irrigation Pump and Irrigation Tubing Set that meets the catheter flow rate requirements, a compatible Mapping System, and compatible Connection Box. • Use only sterile saline and gauze pad to clean the tip. • Verify the RF Controller is in the control mode which will deliver the amount of power specified by the power setting unless the measured temperature exceeds the temperature setting. Temperature controlled RF delivery may be affected by the cooling effects of the saline irrigation of the electrode. For example, the INTELLAGEN RF Cardiac Ablation Controller has these settings in the power control mode. • Equipment/accessories carrying high frequency alternating current may cause direct coupled interference and therefore, may disrupt the operation of the RF Controller. It may be necessary to take risk control measures, such as re-orienting, relocating, or shielding the interfering equipment/accessories. • Use only Dispersive Pads which meet or exceed IEC 60601-2-2 requirements and follow the Dispersive Pad manufacturer's instructions for use. The use of Dispersive Pads which meet ANSI/AAMI requirements (HF18) is recommended. • Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the Dispersive Pad

or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. • The Blazer OI Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than one and one-half (1½) full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall, before resuming rotation of the handle and catheter shaft. • Electrophysiology catheters and systems are intended for use only in radiation shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines. • The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite. • Adequate filtering must be used to allow continuous monitoring of the surface Electrocardiogram (ECG) during RF power applications.

**POTENTIAL ADVERSE EVENTS** Potential adverse events associated with use of the BLAZER OI catheter include, but are not limited to: • Pain or discomfort, for example: • Angina • Chest pain • Non-cardiovascular pain • Cardiac arrest • Death • Electric shock • Hypertension • Hypotension • Infection/inflammation (including pericarditis and pleuritis)/exposure to biohazardous material • Edema/heart failure/pleural effusion • 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 • Respiratory distress/insufficiency/failure/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 • Bronchopercutaneous 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 • Thrombosis • Injury due to embolism/thromboembolism/air embolism/foreign body embolism • Cerebrovascular Accident (CVA)/stroke • Transient Ischemic Attack (TIA) • Myocardial infarction • Neurological impairments and its symptoms, for example: • Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment • Pulmonary embolism • Asymptomatic cerebral embolism

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.

**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. 91128722 (Rev AE.3)

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**Cardiology**

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