POLARx™ Cryoablation System
POLAR ICE Registry Results

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OBJECTIVE

- Post-market clinical follow-up study to evaluate the safety and effectiveness of the POLARx™ Cryoablation Balloon for pulmonary vein isolation (PVI) to treat paroxysmal atrial fibrillation (PAF) using real-world data.

METHODS

- Prospective, non-randomized, multicenter international registry (NCT04250714).
- 399 patients were enrolled across 19 centers between August 2020 and May 2021.

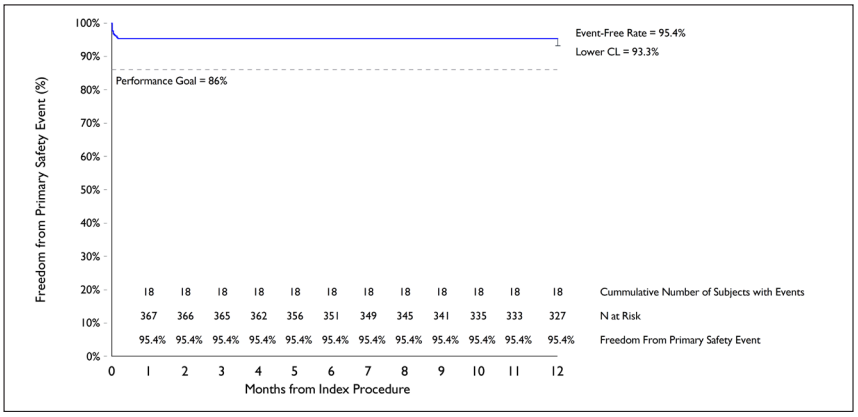
PROCEDURAL CHARACTERISTICS[1]

- Data on 372 de novo PVI procedures (n = 2190 ablations) were collected.
- Acute PV isolation occurred in 96.8% of PVs.
- The procedure time was 68.2 ± 24.6, left atrial dwell time was 46.6 ± 18.3 minutes and the fluoroscopy time was 15.6 ± 9.6 minutes.
- Grade 3 or 4 occlusion was achieved in 98.2% of PVs with a 71.2% rate of single-shot isolation.
- The average nadir ablation temperature was -56.3 ± 6.5°C.

SAFETY[2]

- The safety endpoint event rate was 4.6% (**Figure 1**). Endpoint events included serious vascular access complications (2.6%), cardiac tamponade/perforation (0.5%), thromboembolism/air embolism (0.5%), myocardial infarction (0.3%), persistent gastroparesis/vagus nerve injury (0.3%) persistent phrenic nerve injury (0.3%), and stroke/cerebrovascular accident (0.3%).

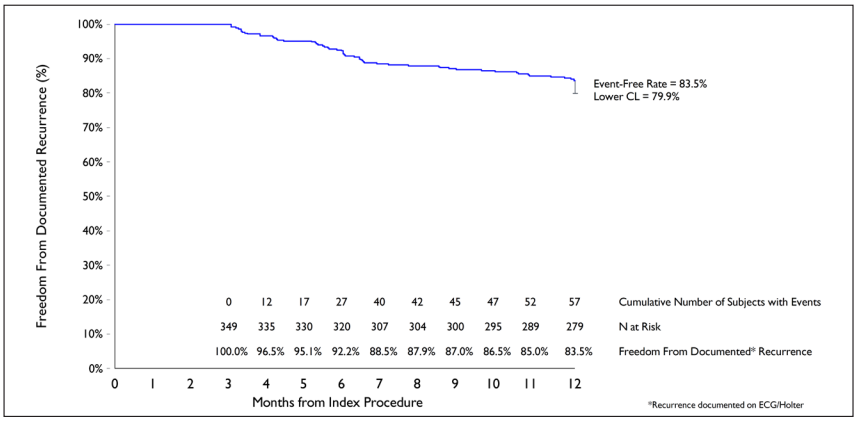
Figure 1. Freedom from Primary Safety Event



EFFICACY[2]

- The 12-month freedom from any arrhythmia was 83.5% and freedom from atrial fibrillation 88.1% (**Figures 2, 3**).

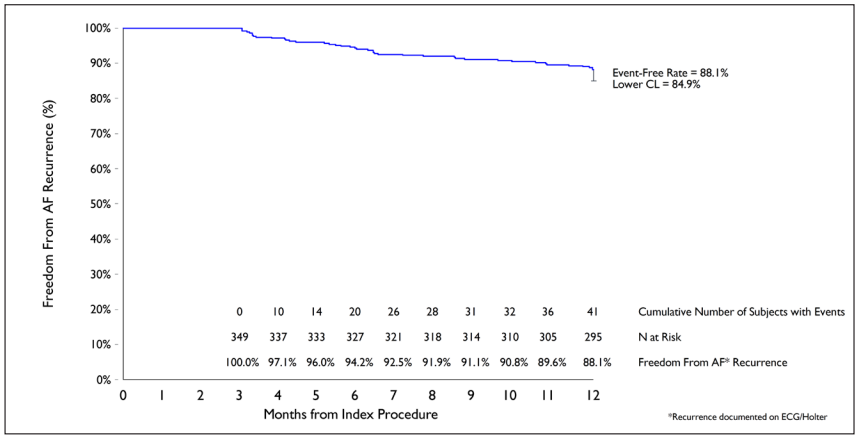
Figure 2. Freedom from Documented Arrythmia Recurrence



83.5%
Arrhythmia Recurrence Free

EFFICACY (*cont.*)

Figure 3. Freedom from AF Recurrence



88.1%
AF Recurrence Free

- Redo procedures were conducted on 19 patients. In 14/19 patients reconnection of at least one PV could be identified (RSPV n=8, RIPV n=12, LSPV n=9, LIPV n=11).
- Freedom from any arrhythmia was associated with lower nadir temperature (p=0.008) and longer time to thaw (p=0.05) during the index procedure.

CONCLUSION

- In the POLAR ICE real-world registry there was a low safety event rate (4.6%).
- The one-year arrhythmia recurrence free rates were 83.5%, with an AF recurrence free rate of 88.1%.
- Lower nadir temperatures and a longer thawing time were acute predictors of long-term clinical success.

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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.

POLARx™ FIT Cryoablation Balloon Catheter INTENDED USE The Boston Scientific Cardiac Cryoablation System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of paroxysmal atrial fibrillation. The POLARx FIT Cryoablation Balloon Catheter is a single use, flexible, over-the-wire balloon catheter intended to ablate cardiac tissue. **INDICATIONS FOR USE** The Boston Scientific Cardiac Cryoablation System using the POLARx FIT Cryoablation Balloon Catheter is indicated for the treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation (PAF). **CONTRAINDICATIONS** Use of the POLARx FIT Catheter is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolic event. In patients with a prosthetic heart valve (mechanical or tissue). In the ventricle of the heart where the device may become entrapped in a valve or chordae structures. In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARx FIT Catheter may dislodge or damage the stent. In patients with cryoglobulinemia as the cryoablation application may lead to vascular injury. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum. In patients with an interatrial baffle or path as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device. **WARNINGS** Introducing catheters and sheaths into the circulatory system increases the risk of air emboli. Always advance/ retract components slowly and use proper flushing techniques to minimize risk of air embolism. Avoid proximity to all heart valves whenever possible. Manipulation of the POLARx FIT Catheter across a heart valve structure may result in entanglement and damage to the valve. Use of N2 O as a refrigerant during the cryoablation procedure increases the risk of a gas embolism if the integrity of the POLARx FIT Catheter balloon is disrupted. Replace the POLARx FIT Catheter if there is any concern the POLARx FIT Catheter balloon has been damaged. Do not use the POLARx FIT Catheter without a POLARMAP Mapping Catheter fully inserted into the guidewire lumen, past the POLARx FIT Catheter balloon. An absent or partially inserted POLARMAP Mapping Catheter may not provide sufficient mechanical support for POLARx FIT Catheter balloon inflation and cryoablation operations and may result in POLARx FIT Catheter damage and N2 O leakage. Administer appropriate peri-procedural anticoagulation therapy per standard of care for patients undergoing cardiac cryoablation procedures. Administer anticoagulation therapy during and post-procedure according to local institution standards to minimize bleeding and thrombotic complications. Electrophysiology procedures, including ablation, may introduce arrhythmias. Always deflate the POLARx FIT Catheter and retract into the POLARSHEATH Sheath before pulling back across the septum. Crossing the septum with the POLARx FIT Catheter balloon exposed, inflated or inflating within the septum may cause endocardial damage. Do not use the POLARx FIT Catheter if it is not working properly. A POLARx FIT Catheter failing to function properly should be removed and replaced before continuing with the procedure. Do not inflate the balloon while housed in the POLARSHEATH Sheath. Always verify that the POLARx FIT Catheter balloon is outside the POLARSHEATH Sheath before inflation to prevent POLARx FIT Catheter damage. Do not inflate the balloon while the POLARx FIT Catheter is positioned inside the PV. Always inflate the POLARx FIT Catheter balloon while the POLARx FIT Catheter is positioned in the LA and then position it in the PV ostium. Inflating the POLARx FIT Catheter balloon in the PV may result in vascular injury. Always deflate and extend the POLARx FIT Catheter balloon prior to retraction of the balloon back into the POLARSHEATH Sheath. Do not use the POLARx FIT Catheter if any part of the POLARx FIT Catheter shaft appears to be kinked or damaged. If the POLARx FIT Catheter shaft appears kinked while in the body, remove the POLARx FIT Catheter and replace with a new POLARx FIT Catheter before continuing with the procedure. When using the POLARx FIT Catheter, catheter manipulation must be carefully performed in order to avoid cardiac damage, perforation, or tamponade. Do not advance the POLARx FIT Catheter with an exposed lumen; always advance the POLARx FIT Catheter over the POLARMAP Mapping Catheter, with the POLARMAP Mapping Catheter distal to the POLARx FIT Catheter balloon. Do not use excessive force to advance or withdraw the POLARx FIT Catheter when resistance is encountered. The steerability feature of the POLARx FIT Catheter is designed to operate in a single plane of motion. Attempts to deflect the distal section in other planes (e.g. perpendicular to normal steering plane, etc.) may result in damage to the steering mechanism and impaired ability to position the POLARx FIT Catheter as desired by the operator. Do not pull or move the POLARx FIT Catheter, POLARSHEATH Sheath, attached cables, or SMARTFREEZE Console while the POLARx FIT Catheter balloon is frozen as this may lead to tissue damage. Catheter ablation procedures near or in the PV may cause narrowing or stenosis. Avoid ablation in the tubular portion of the PV. Implantable pacemaker (PM) and cardioverter/defibrillator (ICDs) leads may be displaced during an EP procedure. See PM/ICD technical manual for additional instructions.5 Black (K) ΔE ≤5.0 BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, POLARx FIT, US, 51594697-01A. To prevent occlusion of the refrigerant line, over-pressurization and potential POLARx FIT Catheter failure when using the POLARx FIT Catheter in combination with the POLARSHEATH Sheath, avoid applying simultaneous high torque (twisting) and tensile stress (pulling) on the POLARx FIT Catheter while the catheter is engaged in the POLARSHEATH Sheath and the POLARx FIT Catheter is deflected. Cryoablations may cause collateral injury to the esophagus and in rare instances atrio-esophageal fistulas. Temperature monitoring with a probe placed within the esophagus may mitigate this risk. Cryoablations may cause collateral phrenic nerve injury. Stop cryoablation immediately if phrenic nerve impairment is observed. Continuous phrenic nerve pacing, and diaphragm movement monitoring should be performed to mitigate this risk. The POLARx FIT Catheter contains pressurized gas during operation. Failure of the POLARx FIT Catheter balloon to operate properly may result in a release of gas into the circulatory system and potential gas emboli. Use caution when manipulating the POLARx FIT Catheter around other intracardiac devices. Entanglement may prevent removing the devices from the cardiac chamber and require surgical intervention. Significant x-ray exposure during an electrophysiology procedure may result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps taken to minimize this exposure. **PRECAUTIONS** Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARx FIT Catheter and SMARTFREEZE Console. The POLARx FIT Catheter shall only be used with the SMARTFREEZE Console. Use only the POLARMAP Mapping Catheter with the POLARx FIT Catheter. Use only the POLARSHEATH Sheath with the POLARx FIT Catheter. If necessary, use only 0.081 cm (0.032 in.) or 0.089 cm (0.035 in.) guidewires with the POLARx FIT Catheter. Use of other guidewire sizes may damage the POLARx FIT Catheter. It is the user's responsibility to ensure that the equipment used with the POLARx FIT Catheter meets all local applicable electrical safety requirements. Perform cryoablation procedures only within environmental parameters as outlined in Section 11.8, Specifications. Do not immerse the POLARx FIT Catheter handle or Cryo-Cable in fluids; electrical performance could be affected. Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely. Always straighten the POLARx FIT Catheter prior to insertion or withdrawal from the body. Flush the guidewire lumen initially and then frequently throughout the cryoablation procedure to prevent coagulum formation. If contrast is used, flush the lumen thoroughly after each contrast injection. Do not physically scrub or twist the POLARx FIT Catheter balloon surface as damage to the POLARx FIT Catheter balloon may impact balloon shape or integrity. Do not apply excessive torque to the POLARx FIT Catheter during the procedure as it may adversely affect the cryoablation function. Do not apply excessive torque to the steering lever as doing so may damage the POLARx FIT Catheter deflection mechanism. Do not apply excessive force to the POLARx FIT Catheter extension slider switch (slider switch) during cryoablation or while the POLARx FIT Catheter balloon temperature is below freezing as doing so may damage the catheter. Properly scavenge and dispose of the N2 O with appropriate hospital systems. Do not outgas in the operating room. Dispose of the POLARx FIT Catheter per local regulatory and biohazard standards. **ADVERSE EVENTS** Potential adverse events associated with manipulation of the POLARx FIT Catheter within the left atrium and pulmonary veins may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury, Cardiac arrest, Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material, Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/ thromboembolism/air embolism/foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment, and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment, Speech impairment, Pulmonary embolism, Asymptomatic cerebral embolism, Nerve injury, for example: Phrenic nerve injury. Vagal nerve Injury, Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain7 Black (K) ΔE ≤5.0. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency. Vasovagal response, PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis, Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97085860 (Rev. A)

SMARTFREEZE™ Cryoablation System Console INTENDED USE/INDICATIONS FOR USE The Boston Scientific Cardiac Cryoablation System is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of patients with drug refractory recurrent symptomatic paroxysmal atrial fibrillation (PAF). The SMARTFREEZE Console is intended to be used with POLARx Cryoablation Balloon Catheters only. **Intended Use Environment** The SMARTFREEZE Console is intended to be used in facilities equipped for interventional cardiac electrophysiology procedures. **CONTRAINDICATIONS** Use of the Boston Scientific Cardiac Cryoablation System is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolic event. In the ventricle of the heart where the device may become entrapped in the valve or chordae structures. In patients with a prosthetic heart valve (mechanical or tissue). In patients with a recent ventriculotomy or atriotomy because this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the catheter may dislodge or damage the stent. In patients with cryoglobulinemia as the application of cryogenic energy may lead to vascular injury. In conditions where insertion into or manipulation in the atria is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or any other surgical intervention in or adjacent to the intra-atrial septum. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hyper-coagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. In patients previously implanted with a percutaneous Left Atrial Appendage Occlusion device. **WARNINGS** To avoid the risk of electric shock, the SMARTFREEZE Console must always be connected to a supply mains with protective earth. This Console must only be used with Boston Scientific equipment and accessories listed in this manual or patient injury or death may occur. Do not modify the SMARTFREEZE Console in any way. Doing so may affect performance and/ or patient safety. The Equipotential ground provides a direct connection between the chassis of the SMARTFREEZE Console and the equalization bus of the electrical installation. It is not a protective earth connection point. The SMARTFREEZE Console must be installed by a qualified/ trained Boston Scientific representative. For assistance with installation, please contact your local Boston Scientific representative or Technical Support. There are no user serviceable parts in the SMARTFREEZE Console. Do not attempt to service the SMARTFREEZE Console while in use with a patient. Do not touch the SMARTFREEZE Console and the patient simultaneously as this may cause patient harm. Standard of care methods for evaluating phrenic nerve function and determining when intervention is needed should always be applied during right pulmonary vein ablations. The DMS is not intended as a substitute for such standard of care methods. Read and follow IFUs for POLARx Catheter, POLARx FIT Catheter, and cryoablation system components prior to use. Observe all contraindications, warnings, and precautions. Failure to do so may result in patient harm or device malfunction. **PRECAUTIONS** Electrophysiology procedures, including ablation, may introduce arrhythmias. It is the user's responsibility to ensure that the equipment used with the System meets all local applicable electrical safety standards. Perform cryoablation procedures only within environmental parameters as outlined in Section 14.1.1. Cryoablation procedures should only be performed in a fully equipped facility. Use only isolated equipment (IEC 60601-1 Type CF equipment or equivalent) with this equipment and accessories. Use of accessories, transducers and cables other than those specified or provided by Boston Scientific could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not connect any device to the Ethernet port. Only connect an external monitor that is compliant to IEC 60601-1:2012 or any local equivalent standards. Do not use a power bar or extension cord. When connecting an external monitor to the SMARTFREEZE Console, an evaluation of IEC 60601-1:2012 requirements should be performed. 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. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio- frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12in) to any part of the SMARTFREEZE Console, including cables specified by Boston Scientific. Otherwise, degradation of the performance of this equipment could result. Only connect portable flash drives to USB ports for extraction of procedural data. Connection of a USB flash drive could result in previously unidentified risks to Patient, Operators or third parties. It is the hospital's responsibility to identify, analyze, evaluate and control these risks. IEC 80001-1:2010 provides guidance on this matter. Properly scavenge and dispose of the N2O with appropriate hospital systems. Do not outgas in the operating room. Only physicians thoroughly trained in electrophysiology procedures should operate the System. Do not use a power bar or extension cord when connecting the SMARTFREEZE Console to the hospital AC source (wall outlet). In order to maintain the device cybersecurity, firmware, and software (including off the shelf applications) of the SMARTFREEZE Console and accessories cannot be updated by the user. Contact your local Boston Scientific representative to schedule approved updates including security patches. In order to maintain the device cybersecurity, do not attempt to connect the SMARTFREEZE Console to the internet or hospital network in any way. Post installation, there are no specific security actions that the user or user facility are expected to take/implement to ensure secure use of this device. Patient data is stored on the console and should be purged prior to system decommissioning. Contact your local Boston Scientific representative to schedule this service. **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 system, rather than the system 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. As with other ablation systems, the SMARTFREEZE Console can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following: Procedural related side effects: Allergic reaction (including anaphylaxis), Genitourinary complication, Side effects related to medication and/or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. Arrhythmia (new or exacerbated), Conduction pathway injury (Heart block, nodal injury, etc.). Nerve injury, for example: Phrenic nerve injury, Vagal nerve injury. Injury due to embolism/ thromboembolism/air embolism/gas 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, headaches, motor impairment, sensory impairment, and speech impairment. Pulmonary embolism, Asymptomatic cerebral embolism. Electric shock, Injury related to tissue damage and/ or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Cardiac trauma, for example: Cardiac perforation/cardiac tamponade/pericardial effusion, Valvular damage, Stiff left atrial syndrome. 97085857 (Rev. A)

POLARx™ Cryoablation System

POLAR ICE Registry Results

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POLARSHEATH™ Steerable Sheath 12F INTENDED USE The POLARSHEATH Sheath is intended to facilitate the placement of diagnostic and/or therapeutic intracardiac devices during percutaneous catheter ablation procedures. The sheath deflection facilitates catheter positioning. **INDICATIONS FOR USE** The POLARSHEATH steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart. **CONTRAINDICATIONS** Use of the POLARSHEATH Sheath is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients where vascular access is unobtainable, or the femoral vein is known to be obstructed. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In the ventricle of the heart where the device may become entrapped in a valve or chordae structures. In patients with a prosthetic heart valve (mechanical or tissue). In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARSHEATH Sheath may dislodge or damage the stent. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a sheath in the cardiac chambers is deemed unsafe. **WARNINGS** 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 POLARSHEATH Sheath slowly. Always advance/withdraw catheters slowly through the POLARSHEATH Sheath valve and minimize catheter exchanges. 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. Administer anticoagulation therapy during and post-procedure according to institution standards to minimize bleeding and thrombotic complications. To minimize potential for air ingress, avoid actions that may induce strong negative pressure (vacuum) or create a leak pathway. Do not aspirate via the side port if the sheath lumen is occupied (i.e., by the dilator or components of the cryoablation catheter) as the aspiration may draw air across the sheath valve into the POLARSHEATH Sheath. Do not aspirate via the side port while the cryoablation balloon catheter is being introduced into the POLARSHEATH Sheath as this risks air ingress. Using high pressure flushing with heparinized saline, ensure that egress of heparinized saline from the hemostatic valve is observed during the introduction of the catheter. Avoid compromising the seal of the valve on the body of the cryoablation balloon catheter or holding open any portion of the valve membrane, such as by placing an introducer across the valve, as this may damage the valve and create a pathway for air to enter the POLARSHEATH Sheath. Do not push the introducer sleeve of the POLARx through the hemostasis valve. The POLARSHEATH Sheath has undergone evaluation with Boston Scientific cryoablation balloon catheters to ensure compatibility. The use of other diagnostic and ablation catheters has not been evaluated and Boston Scientific does NOT recommend their use. The potential for blood leakage and air emboli may be increased if catheters with diameter less than 11F are used within the POLARSHEATH Sheath. 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 the POLARSHEATH Sheath if any part of the catheter shaft appears to be kinked or damaged. If the catheter appears kinked while in the body, remove the device and replace with a new catheter. Do not navigate the POLARSHEATH Sheath through a prosthetic valve (mechanical or tissue). Avoid proximity to all valves whenever possible. Manipulation of the catheter across these structures may result in entanglement and damage to the valve. Take care to minimize damage to the femoral vein and access site upon insertion, manipulation, or withdrawal of the POLARSHEATH Sheath. Complications associated with femoral vein catheterization include hematoma and thrombosis. Regular flushing of the POLARSHEATH Sheath and dilator lumen is recommended to prevent blood stagnation, clots, emboli, and serious patient injury. Prevent any obstruction of the side port to ensure continuity of the saline flush. Rapid removal of the catheters may damage the valve membrane, resulting in blood flow and/or air ingress through the valve. Air ingress may be recognized by the visual presence of air bubbles in the side port tubing 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. Ensure there is no significant blood leakage through the hemostatic valve during the procedure. Connecting POLARSHEATH Sheath to a continuous drip provides forward flow, which can minimize back-bleeding. To minimize unintended back-bleeding through the side port, make sure the stopcock is in a closed position to the POLARSHEATH Sheath at all times unless aspirating or flushing. The POLARSHEATH Sheath and the dilator have not been tested for compatibility with transseptal needles and should not be used as the guiding catheter for a needle in a transseptal puncture procedure. Do not use the POLARSHEATH Sheath if the package is open and/or the sterile barrier is broken. Use prior to the Use By date as labeled on the POLARSHEATH Sheath package label. **PRECAUTIONS** Cardiac catheterization procedures should be performed only in a fully equipped facility. The POLARSHEATH Sheath and its accessories are to be used only by physicians, or under the supervision of physicians, trained in cardiac electrophysiology procedures in properly equipped facilities. **ADVERSE EVENTS** Potential adverse events associated with cannulation of the peripheral vasculature and intracardiac placement of the POLARSHEATH Sheath and dilator may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury. Cardiac arrest. Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material. Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/ thromboembolism/air embolism/foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment. Speech impairment, Pulmonary embolism, Asymptomatic cerebral embolism. Nerve injury, for example: Phrenic nerve injury, Vagal nerve Injury. Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis. Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97078815 (Rev. A)

POLARMAP™ Circular Mapping Catheter INTENDED USE The POLARMAP Catheter is intended to obtain electrograms and provide pacing in cardiac structures in the atrial regions of the heart. **INDICATIONS FOR USE** The POLARMAP Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. **CONTRAINDICATIONS** Use of the POLARMAP Catheter is contraindicated as follows: In patients with an active systemic infection as this may increase the risk for endocarditis and sepsis. In patients with a myxoma or an intracardiac thrombus as the POLARMAP Catheter could precipitate an embolic event. In patients with a prosthetic heart valve (mechanical or tissue). In the ventricle of the heart where the POLARMAP Catheter may become entrapped in a valve or chordae structures. In patients with a recent ventriculotomy or atriotomy as this may increase the risk of cardiac perforation or embolic event. In patients with pulmonary vein stents as the POLARMAP Catheter may dislodge or damage the stent. In patients with an interatrial baffle or patch as the transseptal puncture could fail to close. In patients with hypercoagulopathy or an inability to tolerate anticoagulation therapy during an electrophysiology procedure. In conditions where insertion into or manipulation in the atrium is unsafe as this may increase the risk of perforation or systemic embolic event. In patients with intra-atrial septal patch or other surgical intervention in or adjacent to the intra-atrial septum. In patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe. **WARNINGS** Introducing catheters into the circulatory system entails risk of air embolism. Always advance and withdraw the POLARMAP Catheter slowly. Minimize catheter exchanges and follow with proper flushing. 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. Administer anticoagulation therapy during and post-procedure according to institution's standards to minimize bleeding and thrombotic complications. Catheter procedures may introduce life threatening arrhythmias. Do not use the POLARMAP Catheter if any part of the catheter shaft appears to be kinked or damaged. If the catheter appears kinked while in the body, remove the device and replace with a new catheter. POLARMAP Catheter placement and manipulation should be performed under fluoroscopy. Exercise care and attention when manipulating the POLARMAP Catheter within the heart. Do not apply excessive force or torque to the POLARMAP Catheter, especially if resistance is encountered. Always rotate the POLARMAP Catheter clockwise. Inappropriate catheter manipulation may result in cardiac injury such as perforation or tamponade or device damage. Avoid positioning the POLARMAP Catheter around the chordae tendineae as this increases the likelihood of entrapment within the heart. Do not navigate the POLARMAP Catheter through a prosthetic valve (mechanical or tissue). Avoid proximity to all valves whenever possible. Manipulation of the POLARMAP Catheter across these structures may result in entanglement and damage to the valve. Do not allow the patient to contact grounded equipment that might produce electrical current leakage during ablation or Direct Current CardioVersion (DCCV). This may result in induced arrhythmias that could result in patient death. Do not connect the POLARMAP Catheter to a radiofrequency (RF) generator or use it to deliver RF energy. This may result in patient harm or device malfunction. Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the POLARMAP Catheter, or patient injury or death may occur. Do not allow leakage current from any devices connected to the patient to exceed 10µA under any circumstances. Use caution when manipulating the POLARMAP Catheter in patients with intracardiac devices (catheters, implants, wires, etc.). Entanglement with intracardiac devices may require surgical intervention. Significant x-ray exposure during an EP procedure may result in acute radiation injury, as well as increased risk for somatic and genetic effects, to both patients and laboratory staff. Take appropriate precautionary measures to minimize radiation exposure to patients and laboratory staff. **PRECAUTIONS** Do not change the equipment configuration or modify the equipment or applied parts in any way. Doing so may cause the system to behave unreliably and affect the patient adversely. It is the user's responsibility to ensure that the equipment used with the POLARMAP Catheter meets all local applicable electrical safety requirements. Disconnect the POLARMAP Catheter from the EP Electrical Cable prior to cardioversion or defibrillation. Failure to do so may result in damage to any connected EP recording system or equipment. Do not attempt to preshape the POLARMAP Catheter shaft or electrode loop. Do not scrub the catheter or electrode surface. Do not apply organic solvents such as alcohol. If using the POLARx Catheter, loosen the Tuohy valve prior to removal of the POLARMAP Catheter to prevent damage to the POLARMAP Catheter. Do not immerse the POLARMAP Catheter handle or cable connector in fluids; electrical performance could be affected. **ADVERSE EVENTS** Potential adverse events associated with manipulation of the POLARMAP Catheter within the left atrium and pulmonary veins may include the following conditions: Arrhythmia (new or exacerbated), Conduction pathway injury. Cardiac arrest. Cardiac trauma, for example: Cardiac perforation/tamponade/effusion, Valvular damage, Stiff left atrial syndrome. Death, Edema/heart failure/pleural effusion, GI disorders, Hypertension, Hypotension, Infection/inflammation/exposure to biohazardous material. Injury related to tissue damage and/or adjacent structures, for example: Esophageal injury, Pulmonary injury, Catheter entrapment, Physical trauma. Injury due to embolism/thromboembolism/air embolism/foreign body embolism: CVA/stroke, TIA, MI. Neurological impairment and its symptoms, for example: Cognitive changes, Visual disturbances, Headache, Motor impairment, Sensory impairment; Pulmonary embolism, Asymptomatic cerebral embolism. Nerve injury, for example: Phrenic nerve injury, Vagal nerve Injury. Pain or discomfort, for example: Angina, Chest pain, Non-cardiovascular pain. Procedural related side effects, for example: Allergic reaction (including anaphylaxis), GU complications, Side effects related to medication or anesthesia, Radiation injury/tissue burn, Renal failure/insufficiency, Vasovagal response. PV Stenosis and its symptoms, for example: Cough, SOB, Fatigue, Hemoptysis. Respiratory distress/insufficiency/dyspnea. Surgical and access complications, for example: Hematoma/seroma, AV Fistula, Bleeding, Pseudoaneurysm, Pneumothorax, Residual atrial septal defect. Thrombus/thrombosis, Vessel Trauma, including: Perforation, Dissection, Coronary artery injury, Vasospasm, Occlusion, Hemothorax. 97078813 (Rev A)

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1. Martin CA, Tilz RRR, Anic A, et al. Acute procedural efficacy and safety of a novel cryoballoon for the treatment of paroxysmal atrial fibrillation: results from the POLAR ICE study. *J Cardiovasc Electrophysiol*. 2023;34:833-840.
2. Luik, et al. Long-term success rates of a stable, low pressure cryoballoon for the treatment of paroxysmal atrial fibrillation: results of the prospective, international, multicenter POLAR-ICE study. Presented at: ESC 2023; August 2023; Amsterdam, NL.

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