Boston Scientific
Advancing science for life™

OPAL HDx™
Mapping System

Full-spectrum mapping
at the leading edge of PFA

OPAL HDx™
Mapping System

Power your practice with the full spectrum of cardiac mapping

OPAL HDx™ Mapping System is designed to enhance the transformational potential of pulsed field ablation.

OPAL HDx Mapping System provides integrated mapping for both RF and pulsed field ablation procedures — while providing enhanced, leading-edge workflows with the FARAPULSE™ Pulsed Field Ablation System. Offering a complete range of mapping solutions, OPAL HDx allows you to choose the treatment modality that best meets your case needs.

More than a name. A transformation.

Inspired by the precious gem that shares its name, OPAL HDx represents a rich spectrum of possibilities.

Future-ready, comprehensive capabilities

Only OPAL HDx™ enables PFA mapping via the included FARAVIEW™ Software Module. When paired with the FARAWAVE™ NAV Pulsed Field Ablation Catheter, the system provides seamless integration with the FARAPULSE™ Pulsed Field Ablation System, which results in simplicity, consistency and efficiency across procedures.

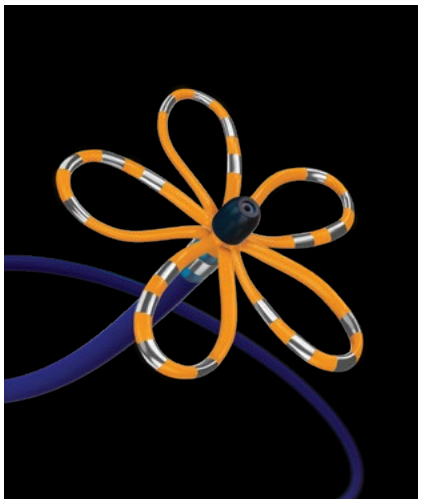
With its unrivaled mapping and suite of tools supporting rapid, precise identification of ablation targets, OPAL HDx is built to handle a broad range of arrhythmia cases.

Optimize versatility without compromising capabilities.

Empower your practice with the convergence of leading-edge PFA technologies from Boston Scientific.

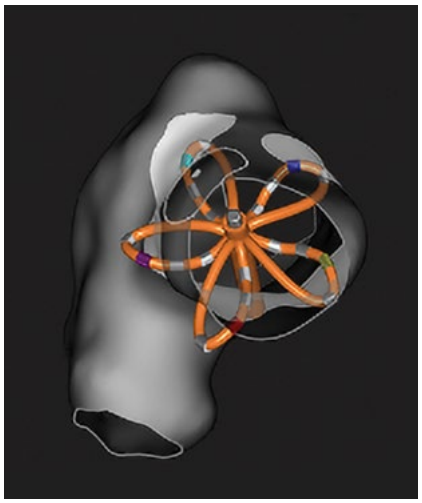
FARAVIEW: Built for FARAPULSE mapping

The FARAVIEW™ Software Module on OPAL HDx™ gives physicians enhanced ability to visualize and confirm pulsed field ablations:



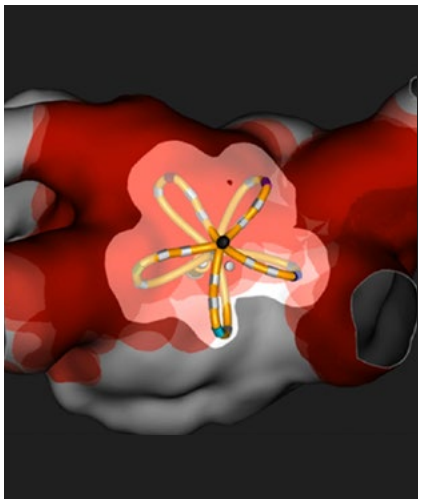
Single-catheter solution

Map and ablate with a single magnetically tracked PFA catheter. The FARAWAVE™ NAV Pulsed Field Ablation Catheter is designed to minimize catheter exchanges.



Dynamic visualization

Visualize pulsed field delivery and fine-tune your ablation strategy by visualizing catheter shape, rotation, and transitions in real-time.



Automatic field tagging

Visualize field volume, see the intersection of field with anatomy, and automatically tag areas where PFA is delivered.

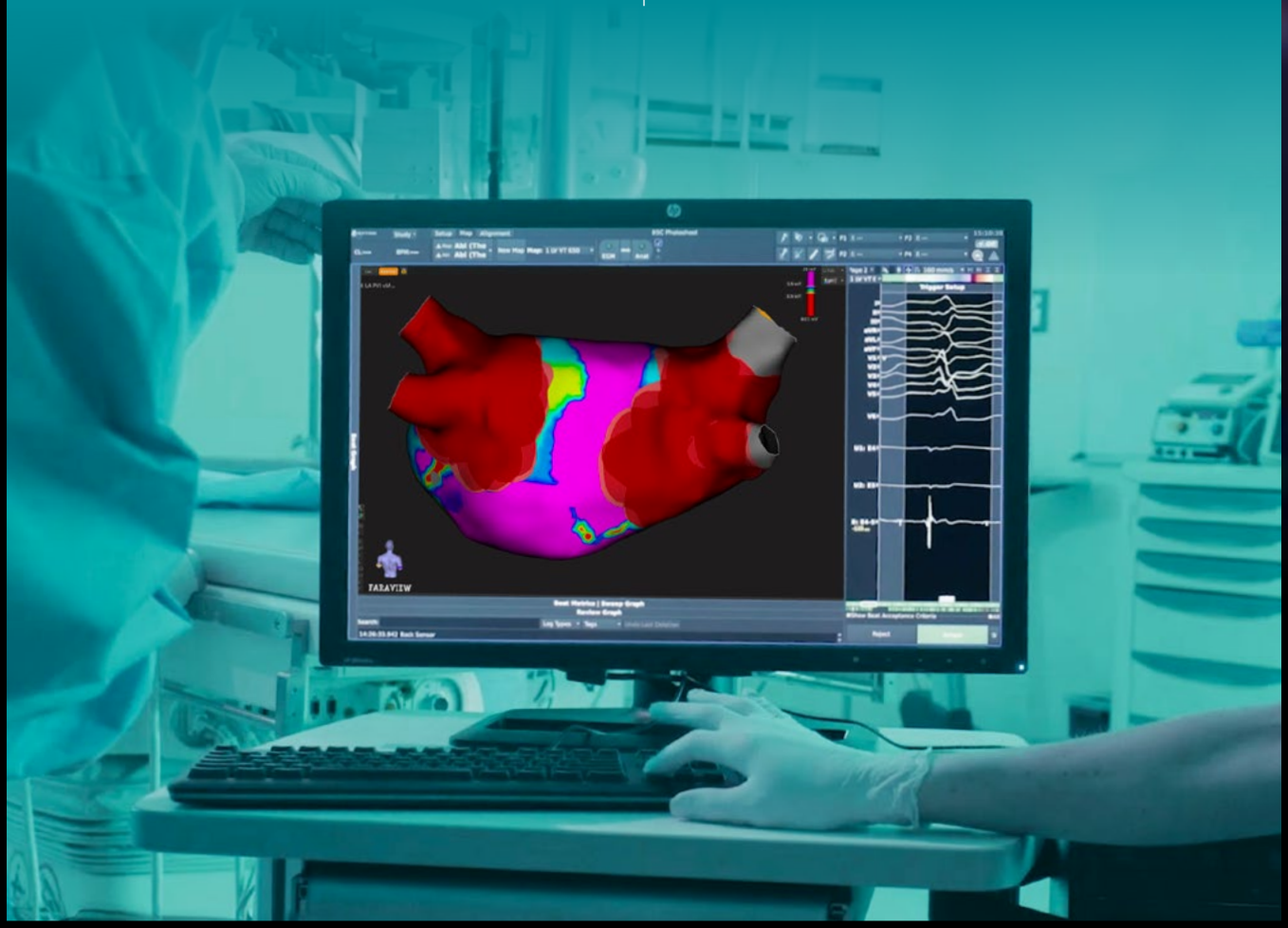
Harness the power of FARAVIEW on OPAL HDx™, the full-spectrum comprehensive mapping system.

Clinical leadership in PFA technology

Integrated with **FARAPULSE**™, OPAL HDx provides access to one of the most widely used PFA systems:

Proven PFA durability[1]

The most clinically proven PFA system worldwide



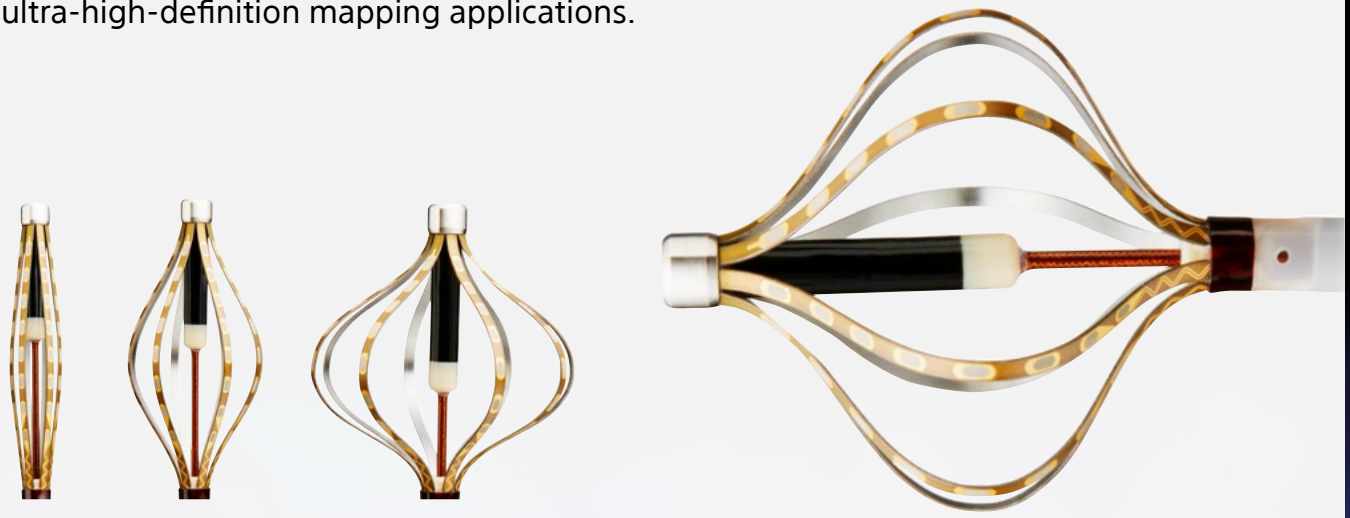
1. Della Rocca DG, Marcon L, Magnocavallo M, et al., Pulsed electric field, cryoballoon, and radiofrequency for paroxysmal atrial fibrillation ablation: a propensity score-matched comparison. EP *Europace*. 2024;Jan26(1) euae016. doi.org/10.1093/europace/euae016.

The brilliance of a single-catheter solution

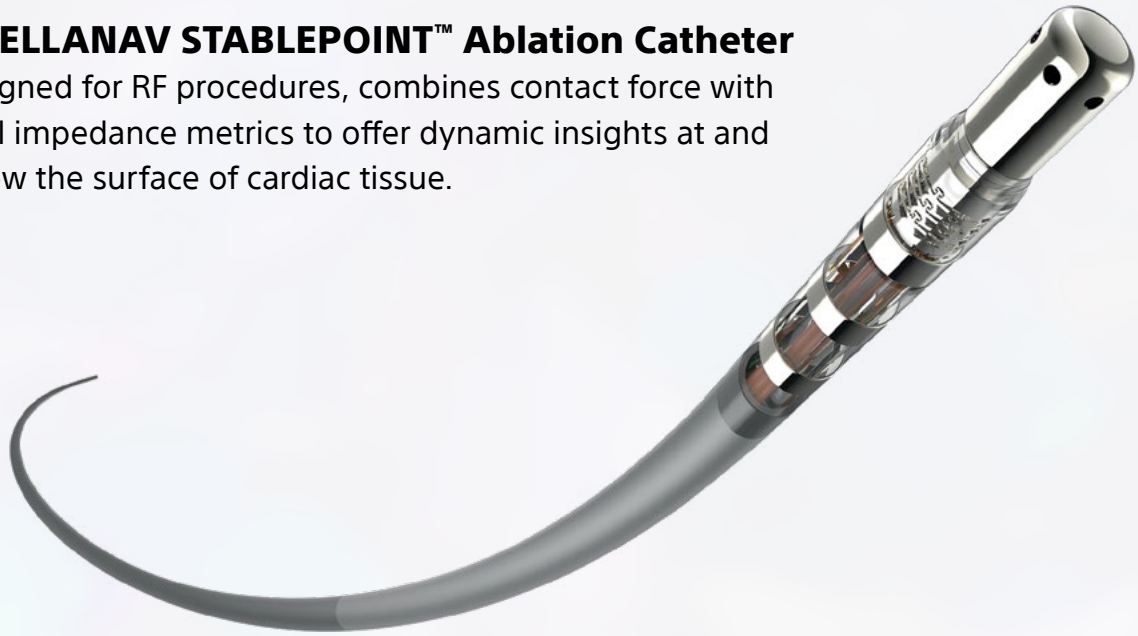
FARAWAVE™ NAV PFA Catheter is designed to deliver fully integrated PFA mapping and ablation technology, collect geometry and confirm workflows without the need for additional mapping catheters or catheter exchange.

With the flexibility to choose from a spectrum of catheters.

INTELLAMAP ORION™ Mapping Catheter
brings unprecedented resolution and accuracy for ultra-high-definition mapping applications.

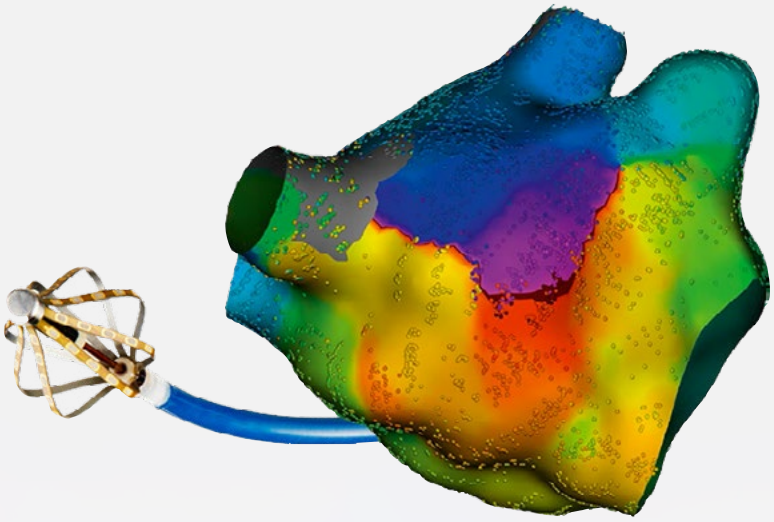


INTELLANAV STABLEPOINT™ Ablation Catheter
designed for RF procedures, combines contact force with local impedance metrics to offer dynamic insights at and below the surface of cardiac tissue.



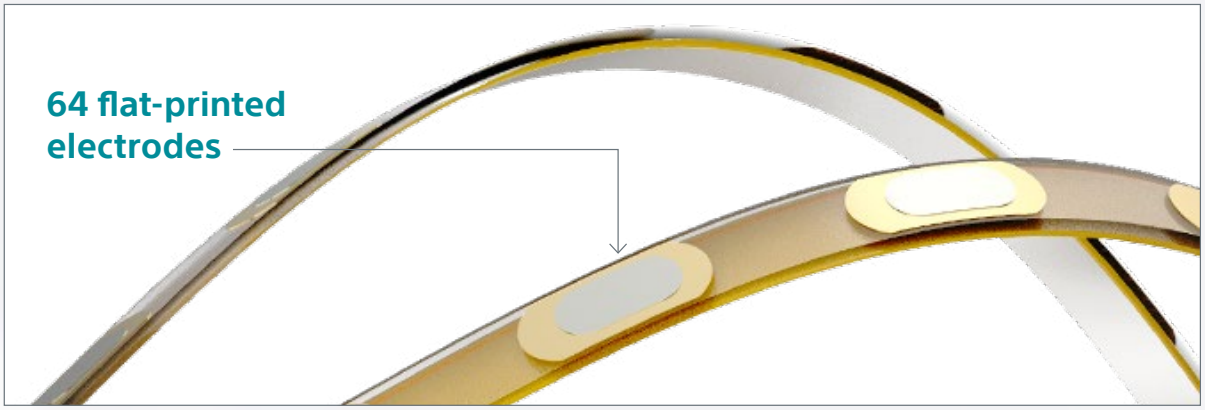
Conventional mapping capabilities

The OPAL HDx™ mapping toolset captures and annotates high-fidelity EGM signals, providing a more complete understanding of the electrical circuit.



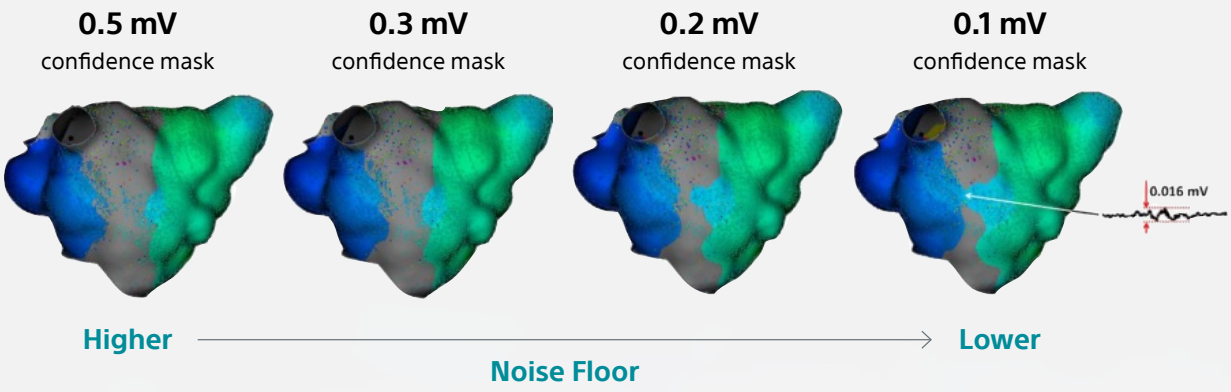
Precise localization of even the most complex arrhythmias

The multi-spline design and small electrodes of the INTELLANAV ORION™ Mapping Catheter support greater EGM signal capture and map resolution. The mapping catheter's small 0.4 sq mm flat electrodes offer improved near-field signal quality by capturing signals only near the point of contact with the tissue.



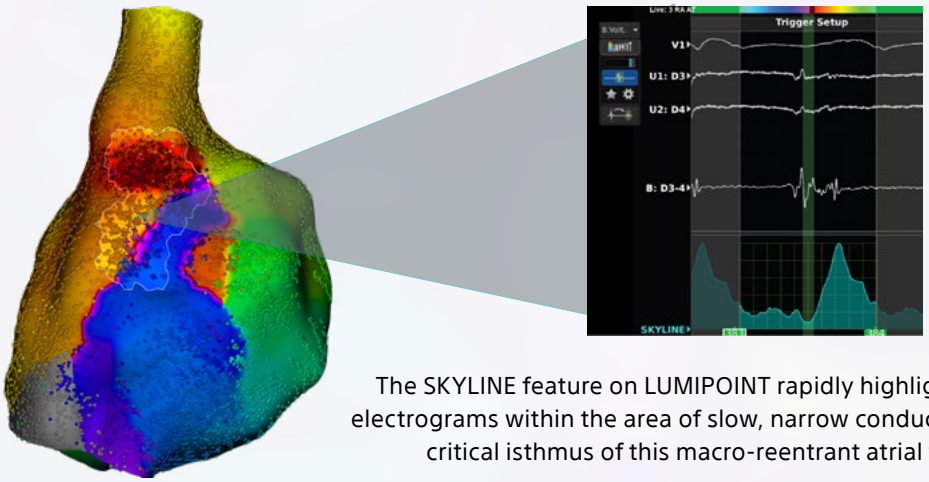
Better visualization

With its low noise floor, the OPAL HDx Mapping System better visualizes propagation even in diseased or heavily scarred tissue. It reveals gaps or isthmuses even in low voltage or scarred areas.



Rapid identification of areas of clinical interest

OPAL HDx employs four Beat Triggers and seven Beat Acceptance Criteria to ensure that only beats from the rhythm of interest are captured. With the system's LUMIPOINT™ Software Module, physicians can classify EGMs by zone of activation and across cycle length, use rapid late potential reannotation, and pinpoint potential critical isthmuses.



The SKYLINE feature on LUMIPOINT rapidly highlights fractionated electrograms within the area of slow, narrow conduction, revealing the critical isthmus of this macro-reentrant atrial tachycardia.

AT activation map of critical isthmus courtesy of Connor Haugh, MD, Catholic Medical Center

Supporting your lab's performance

OPAL HDx reflects our focus on innovation in the treatment of arrhythmia, and we're committed to providing the support your team needs to achieve optimal outcomes. You'll find:

- An expanded field force of cardiac mappers
- World-class educational resources
- Comprehensive 24-hour technical support and collaborative service plans offered through the ExpertCare Program
- An evolving portfolio of EP solutions

Helping you stay at the forefront of advances in electrophysiology, now and into the future.

OPAL HDx™
Mapping System

OPAL HDx™ Mapping System

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. The Boston Scientific Mapping System brand name has changed from RHYTHMIA HDx Mapping System to OPAL HDx Mapping System. Any reference to OPAL HDx Mapping system or Boston Scientific Mapping System in this document is equivalent to RHYTHMIA HDx Mapping System. **INTENDED USE** The OPAL HDx Mapping System (the system) is a 3D mapping and navigation system used in EP procedures. The SiS and related accessories provide data connection pathways for external input/output devices (e.g. catheters and recording systems) and serve as the data conduit to the system workstation and software. **INDICATIONS FOR USE** The OPAL HDx Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen. **CONTRAINDICATIONS** There are no known contraindications. **WARNINGS** • To ensure correct clinical decisions, use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify mapping results and catheter position. Always compare the anatomical map to the patient's expected anatomy. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury. • Do not use the system to route life-sustaining pacing signals. Only diagnostic stimulation signals (e.g. induction) may be routed through the system. Using the system to route life-sustaining pacing may result in prolonged bradycardia. • Diagnosis and treatment of cardiac arrhythmias using the system in conjunction with ablation and other medical devices may pose a risk of adverse events. Adverse events (e.g. cardiac perforation, new arrhythmias, exacerbation of existing arrhythmias) may require additional intervention. • Do not condition an INTELLAMAP ORION mapping catheter when it is in contact with the patient, either external or indwelling. Conditioning when in contact with a patient may lead to patient injury, including new arrhythmias or exacerbation of existing arrhythmias. • Avoid increasing power or duration of RF application beyond your standard of care to target a specific change in local impedance. Doing so may result in damage to adjacent structures, perforation caused by steam pop, arrhythmias, and/or embolism. The change in local impedance during RF delivery should not be used independent of established clinical indicators of RF tissue response (e.g. temperature limit, irrigation flow rate, power level, RF duration). Select ablation settings and limits (e.g. temperature limit, irrigation flow rate, power level, RF duration) in accordance with the compatible catheter Instructions for Use. Increases in contact force, ablation duration, or power in pursuit of a specific change in local impedance are not recommended. • Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority. • All devices that are connected to system hardware must independently meet IEC 60601-1 requirements as well as any other relevant safety standards. The combined hardware configuration must also meet IEC 60601-1 safety standards. The use of system hardware with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user. • System hardware must be connected solely to a functional, properly-tested supply main with protective ground (earth). Do not use extension cords or adapters for ungrounded outlets. The use of a faulty or ungrounded supply main increases the risk of electrical shock and system malfunction. • Do not connect more than one ablation catheter simultaneously to the Ablation System when used with OPAL HDx Mapping System. Doing so may lead to harm to the patient • The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system's normal operation and reduce the quality of catheter localization, and signals. • Do not operate the localization generator within 200 mm of an implanted CIED (cardiac implantable electronic device.) Doing so may affect CIED pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort. • The OPAL HDx Mapping System (the system) is intended for use with other medical devices in an EP laboratory. Carefully read the instructions for use (IFU) documents for every medical device that will be used during a study, prior to each study. Observe all contraindications, warnings, and cautions. Failure to do so may result in user harm, patient illness, injury, or death. • Carefully read this entire document and all other product IFUs before beginning the mapping study. Be sure to fully understand and consistently follow all warnings, cautions, and instructions. Failure to properly follow the instructions may cause equipment damage, system malfunction, or harm to the patient or user. • Always use the controls on the external stimulator to start or stop stimulation. The system only routes externally generated-and-controlled stimulation signals to the selected electrode and channel. • During EP procedures, do not use the OPAL HDx Mapping System as an ECG monitoring device. To prevent delays in treatment of life-threatening arrhythmias, the system must always be used in conjunction with an ECG recording/monitoring device. • Do not use the OPAL HDx Mapping System and its accessories in an oxygen rich environment or near flammable anesthetics. • Carefully read respective RF ablation generator IFUs before beginning the mapping study. Do not exceed power limits set by the manufacturer. • To reduce the risk of electric shock or equipment damage, do not clean system hardware when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. • To reduce the risk of electric shock, assure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. • To reduce the risk of electric shock during defibrillation, assure that the exposed connector tips on the ECG output box are enclosed at all times by the non-conductive protective cover that is built onto the ECG output boxes. Do not use the ECG output box if the protective cover is damaged. Only IEC 60601 compliance-certified stimulators should be used with the OPAL HDx Mapping System. • The OPAL HDx Mapping System is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measure such as re-orienting or relocating the OPAL HDx Mapping System or shielding the location. • When a catheter localization error is encountered, use fluoroscopy or other visualization techniques to verify catheter location. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury. • To ensure correct clinical decisions, Field Tags should be used in conjunction with conventional verification techniques (e.g. assessing electrograms, pacing maneuvers, fluoroscopy/ echocardiography etc.) for the diagnosis and treatment of cardiac arrhythmias. To prevent patient injuries such as perforation, heart block, and injury to adjacent structures, do not rely solely on the Field Tag visualization to make clinical decisions. **PRECAUTIONS** • Use care when attaching the body surface electrodes to lead connectors. To minimize the risk of electric shock, make sure that electrodes and lead connectors do not contact one another or contact ground. • Properly prepare the skin prior to attaching the electrodes to prevent receiving low quality signals from body surface electrodes. Do not use excessive gel as this may lead to signal crossover between electrodes. • To minimize signal interference, route the surface ECG cables across the torso instead of alongside it. • The localization generator may interfere with implanted CIEDs (cardiac implantable electronic device). When mapping a patient with such a device, consider interrogating the device pre – and post-procedure. This will identify any changes in programmed parameters which could then be corrected before transferring the patient from the procedure room. Consult the CIED manufacturer instructions for additional information. • If it becomes necessary to interrogate or program an implanted CIED while using the system, temporarily turn off the localization generator by using the on-screen button located on the annotating and editing maps toolbar. • Confirm catheter proximity to sheath using tools such as fluoroscopy or intracardiac echo. • RF Catheter Sheath detection is to be used with compatible Agilis™ and Direx™ sheaths. The performance of sheath detection with other sheaths has not been tested. Refer to the Instructions for Use for the catheter for information on compatible sheaths for that catheter family. • Carefully inspect all system components prior to using system hardware. Do not use any component that shows evidence of being damaged or defective. • Do not drop system components or subject them to extreme shock. Dropping components or forcefully hitting them against hard objects may damage components and cause system malfunction. Contact Boston Scientific Support for device repair or replacement. • To minimize the risk of dropping and damaging equipment, use care when inserting/ removing components. If needed, use two people to attach or remove devices such as the localization generator. • Do not use the OPAL HDx system 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. • Do not position the signal station (SiS) in a manner that would make it difficult to disconnect the power supply from the power mains. Disconnect the power cord if the SiS needs to be isolated from the power mains. • Connect the equipotential port on the rear panel of the SiS to an equipotential receipt box prior to using system hardware to minimize the risk of electric shock. This connection should remain connected at all times. • Use only the SiS power supply and power supply cable provided by Boston Scientific with the system. Using another power supply or power supply cable may damage the SiS. • Do not connect or disconnect the SiS power supply while the unit is turned on. This will minimize the risk of equipment damage. • Disconnect SiS from its power supply prior to cleaning in order to minimize the risk of electric shock. • Do not place containers of water or other liquids directly on or near the SiS or other system components. This reduces the risk of electric shock and/or damage to the SiS. • Do not block the air vent on the SiS during use. Blocking the air vent can cause the SiS to overheat, which may affect system operation. • Do not use SiS stacked or adjacent to other devices or equipment. • Always use two hands to carry the SiS. • Only place the SiS and SiS-related accessories on flat, stable surfaces. This will minimize the risk of dropped or toppled equipment. • Disconnect all patient inputs from the SiS prior to pulsed field ablation. If available, accessories which automatically disconnect patient inputs prior to pulsed field ablation may be utilized. Leaving patient inputs connected during pulsed field ablation delivery may damage the SiS. • In the event that routing of the stimulation signal through the mapping system software fails, direct stimulation may be required. Connect the stimulator jumper cables to any single pair of the direct stimulation ports located above input ports M, A, B, or ABL. The direct stimulation ports above input ports M, A, and B connect an external stimulator to channels 61 and 62 of the connected breakout box. The direct stimulation ports above the ABL port connect to channels 1 and 2 of the ablation catheter. • Use only ECG cables provided with the SiS by Boston Scientific. The ECG trunk is part of the SiS's defibrillation protection. • The localization generator may interfere with other systems that use magnetic-field based technology. Consult the supplier of these systems before using them in the presence of the magnetic localization system. • Use only the equipment, supplies, and accessories supplied or recommended by Boston Scientific for use with the OPAL HDx Mapping System. The use of other equipment, supplies and accessories may cause equipment damage or system malfunction. • Do not connect or disconnect the localization generator from the SiS while the unit is turned on. This will minimize the risk of equipment damage. • Manually disabling the localization generator disables all catheter visualization and localization capabilities, including impedance tracking. • Do not immerse system components in water, cleaning solutions, or liquid. Prevent fluids from entering air vents. Ensure connectors stay dry. Failure to follow cleaning guidelines may cause equipment damage or system malfunction, and may also void any warranties or service agreements. • To avoid equipment damage and malfunction, do not attempt to sterilize equipment that is provided non-sterile. • To avoid equipment damage and malfunction, do not insert anything (e.g., cotton swabs or pins) into cable connectors or equipment ports or openings. • Do not attempt to clean system components during system operation. Cleaning equipment during use increases the risk of electrical shock, system malfunction, and device drop. • Use a frequent back-up routine to archive cases that are no longer needed for immediate access. This will reduce the risk of data loss. • To reduce catheter configuration mistakes, when connecting catheters to the system, always verify the signals by reviewing the signal display and recording system to ensure correct configuration of catheter electrodes to displayed channels. • Imported geometrical shells should only be used as a reference, for example to identify anatomical features in advance of mapping. Use other visualization tools, such as fluoroscopy or echocardiography to verify catheter location. • During the mapping procedure, do not disconnect the localization generator from the signal station. • The software monitors location reference back patch (back patch) and ECG electrode connections during a study. If the color-coded patch quality indicators on the patient alignment (user interface) turn from green to red (indicating a poor quality connection), adjust or replace the problem patch(es). • The ECG cables (one trunk cable, chest leads set, and limb leads set) are provided nonsterile. They can be reused with multiple patients. Always clean and disinfect the ECG cables consistent with facility protocol prior to reuse. • Do not enter patient identifiable data into any open fields that are not dedicated to patient information, or as part of file names being imported into the OPAL HDx Mapping System. • Please refer to the Instructions for Use for the compatible catheter prior to enabling the display of DIRECTSENSE technology during RF energy application. • Sheath detection is enabled for FARAWAVE Catheters with compatible FARADRIVE Sheath. The performance of sheath detection with other sheaths has not been tested. Refer to the Instructions for Use for the catheter for information on compatible sheaths for that catheter family. • DIRECTSENSE local impedance is not an indicator of contact force. • The OPAL HDx Mapping System should only be connected to a secure network. • Do not place containers of water or other liquids directly on or near the workstation or other system components. This reduces the risk of electric shock and/or damage to the workstation. • Use only a flat, stable surface to hold or transport the workstation and workstation-related accessories. This will minimize the risk of dropped or toppled equipment. • Use only the ECG cables supplied by Boston Scientific for use with the system. ECG cables provided by Boston Scientific are designed and tested to protect the SiS from defibrillation energy. Using other ECG cables may cause damage to the system hardware. • Inspect all external connections and cables before using the SiS and secure any connections that are loose. Loose connections may impact the accuracy of mapping results. • Do not use excessive force when connecting or disconnecting cable connectors. Excessive force can damage the connectors, which may cause system malfunction. • Do not kink or bend cables. Kinks and sharp bends can damage the cables, which may cause system malfunction. • Store unused system cables in a clean, dry, and secure location consistent with storage guidelines to minimize the risk of damage. For specific storage guidelines, see Section 19 in the IFU. • Direct stimulation is not compatible with the FARAWAVE catheter. The FARAWAVE catheter does not utilize electrodes 61 & 62. If direct stimulation is required, another catheter should be used. • Do not use ungrounded electrical outlets to power any system components. Do not use extension cords or adapters for ungrounded outlets. Using ungrounded outlets, extension cords, or adapters may cause equipment damage, system failure or malfunction. • Avoid exposing system hardware to excessive moisture, heat or cold. Using the system in environmental conditions that exceed recommendations may affect system operation. • When connecting or disconnecting system cables, protect the cable connectors from water or moisture. Wet connectors may affect system operation. • Do not immerse any cable connectors in water or liquid. Immersion in water or liquid may damage connectors, which may cause system malfunction. • Always follow guidelines for equipment storage and transport. Storage or transport in extreme environmental conditions can damage system components. • Do not place cables used with the system hardware within 30 mm of the localization generator cable. Inaccurate tracking or "noisy" signals may occur if these cables are within 30 mm distance between each other, particularly if they are parallel. • Do not coil the localization generator cable. Doing so can disturb the magnetic field of the localization generator, which may lead to inaccurate tracking. • Do not use the magnetic localization system in the presence of other magnetic fields or large ferrous metal objects. Doing so may lead to inaccurate tracking • Do not connect or disconnect the localization generator from the SiS while the unit is turned on. This will minimize the risk of equipment damage. • The localization generator may interfere with fluoroscopy or other imaging modalities. Consult the supplier of these systems before using them in the presence of the magnetic localization system. • Do not use the ECG cables or any other cables or system components if they are soiled or contaminated with infectious, or potentially infectious, materials. Using soiled or contaminated items increases the risk of patients acquiring serious infections or contaminating other patients or users. Soiled or contaminated cables and equipment must be removed from use and either cleaned according to established facility protocol procedures or replaced. • Always clean multiple-use equipment according to established facility protocol prior to each reuse • Do not use disinfectants such as glutaraldehyde or hydrogen peroxide to clean system components. • Do not use solvents such as acetone to clean system components. • Do not attempt to repair, modify, or open any part of system hardware. Repair attempts by untrained, unauthorized individuals may cause user injury, equipment damage, or system malfunction. Contact Boston Scientific Support for device repair or replacement. • All external and accessible surfaces of this system should be cleaned and disinfected per the 51933747. Include any common detachable cables (power cord, video cables, accessories, etc.). Do not dispose of by incineration, burial or placement into common waste stream. System should be safely disposed of in accordance with hospital, administrative, and/or local government policy. **POTENTIAL ADVERSE EVENTS** Any potential clinical complications are in large part expected to be related to the accessory diagnostic or ablation catheters that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read pertinent Instructions for Use documents associated with the catheters and ablation generators that will be employed during a mapping session. As with other mapping systems, the OPAL HDx Mapping System 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: **Arrhythmias** Due to the programmed electrical stimulation performed during EP diagnostic procedures and catheter manipulations, patients undergoing EP procedures are at potential risk of arrhythmia. The patient may experience discomfort from the rapid pacing and/or the initiation of an arrhythmia. While the system has no active role in RF ablation, a risk does exist that the effectiveness of an RF ablation procedure could be suboptimal and cause the targeted arrhythmia to reoccur. **Misinterpretation of data Localization** Poor catheter localization may lead to clinical data misinterpretation and the potential of resultant patient injury. To ensure correct clinical decisions, the physician must use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify 3-D mapping results and catheter position. **Incorrect Force Measurements** Incorrect force measurement displayed or misinterpretation of the force displayed may lead to the user to apply more force than desired during mapping or ablating. User must observe any system messages displayed. If the user applies more force than desired during mapping or ablating, myocardial perforation, myocardial contusion, or myocardial injury could result. **Electrical Hazards** With any electrical system there is a potential risk of electrical shock to the user, patient, and service representative. 97291991 Rev A.1

IntellaMap Orion™ High Resolution Mapping Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE** The IntellaMap Orion Catheter is intended for electroanatomical mapping, intracardiac stimulation (pacing), and recording of electrical potentials when used in conjunction with a commercially available recording and/or stimulation system. The device is intended for use in adult (not pediatric) patients, with the exclusion of pregnant and/or nursing patients. **INDICATIONS FOR USE** The IntellaMap Orion Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. **CONTRAINDICATIONS** The IntellaMap Orion Catheter should not be used: • in patients who are not candidates for transvascular catheter procedures; • in patients with active systemic infection; • in patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside; • 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 hypercoagulable state or who cannot tolerate heparin or an acceptable alternative to achieve adequate anticoagulation therapy; • 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; • via transseptal approach in patients with intraatrial baffle or foramen ovale patches; • via retrograde transaortic approach in patients with a prosthetic aortic valve; • in pediatric patients. • in pregnant and/or nursing patients. • for radiofrequency (RF) ablation; • near or inside an MRI machine. • Do not use this device: • with a long sheath or a short introducer < 8.5 F • in the coronary vasculature. **WARNINGS** • Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of catheter mapping and RF powered ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. • Before using, inspect the IntellaMap Orion 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. • If a broken, fractured, or open spline is identified during the manipulation of the IntellaMap Orion Catheter, remove the catheter immediately and replace it to reduce the risk of embolism and/or pericardial effusion, perforation, or tamponade. • In order to reduce the risk of clot formation: • maintain an Activated Clotting Time (ACT) of greater than 300 seconds at all times during use of the catheter, and • continuously flush the electrode array with saline via the irrigation port at the proximal end. • If the visibility of the IntellaMap Orion Catheter is compromised for any reason, the user should stop and not resume mapping until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures. • Contents are supplied STERILE using an Ethylene Oxide (EO) process and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, call your Boston Scientific representative. • Before insertion, ensure that the IntellaMap Orion Catheter passes smoothly through the guiding sheath without the use of excessive force to avoid catheter entrapment/entanglement and reduce the risk of a delay or interruption in the procedure. • In order to prevent catheter vascular entrapment, use a sheath that is long enough to extend past the • inferior vena cavae (IVC) and always keep the IntellaMap Orion Catheter inside the sheath when advancing or withdrawing the catheter in the vessel(s). • 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. • 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. • 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. • When using the IntellaMap Orion Catheter with a steerable guiding introducer sheath, ensure under fluoroscopy that the guiding introducer sheath distal end is straight or in neutral position, and, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath to avoid catheter entrapment/entanglement and reduce the risk of damage to cardiac tissue and/or structure. • Do not advance or retract the catheter through a sheath when deployed or articulated. Doing so may compromise the physical integrity of the catheter and cause patient injury. • The use of this device in conjunction with RF ablation, as part of the diagnosis and treatment of arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion. • Always fully undeploy the catheter basket prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment. Inadvertent damage to cardiac tissue/structure during withdrawal of the catheter basket may result in embolism, perforation, tamponade and in rare cases, death. • Fibrin may accumulate in or on the sheath/catheter basket assembly during the procedure, which could result in embolism. • Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array to reduce risk of 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, 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. • Always move the articulation control level to its neutral position to straighten the catheter prior to removal from the patient in order to prevent entanglement/ entrapment within cardiac valves and/or other devices that may result in valvular injury, 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. • Warnings for patients with implantable pacemakers and Implantable Cardioverter/Defibrillators (ICDs): • Follow manufacturer guidelines for device programming prior to procedure. Temporary programming changes, such as changing to non-tracking mode or disabling tachy therapy, may be necessary prior to pacing maneuvers, arrhythmia induction or RF energy delivery. • Have temporary external sources of pacing and defibrillation available. • Fluoroscopic guidance or appropriate imaging and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment. • Perform a complete analysis of the implanted device and leads (sensing, impedance, thresholds) post procedure to confirm lead integrity and device function. • Restore permanent device programming post procedure, if applicable. • Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter, as this may alter the function of the catheter and may lead to thrombus, coagulum, or char formation that may result in embolism. • To avoid causing cardiac damage, perforation, or tamponade, do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or undeployment, stop and evaluate device location under fluoroscopy. • 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 overtorqued 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. • Catheter mapping and 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. Careful consideration must therefore be given for this use of the device in pregnant women and/or prepubescent children. • Excessive curves or kinking of the catheter may damage internal wires and components This damage may affect catheter performance and may cause patient injury. • Manual bending and/or twisting of the distal curve and/or basket can damage the electrodes or electronic circuit, steering mechanism, and irrigation lumens and may cause 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 and for undeployment and removal of the catheter to avoid conduction pathway injury, cardiac perforation or tamponade. • 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 extreme caution must be taken. • 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 the IntellaMap Orion 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 for the patient. • 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. • Pre-procedural anticoagulation therapy is at the discretion of the physician. Administer appropriate levels of peri-procedural and post procedural anticoagulation therapy for patients undergoing right and left-sided and ransseptal 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. 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. • Patients undergoing long procedures have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding from all causes /hemorrhage and/or embolism. • The safety and/or efficacy of epicardial use of the IntellaMap Orion 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 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. • 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 has occurred in relation to the device should be reported to BSC and the competent authority of the Member State in which the user and/or patient is established. **PRECAUTIONS** • When pacing, verify desired waveform is observed. • Remove and replace the catheter in case of any observed malfunction. • Use only sterile saline and gauze pad to clean the tip. • Electrophysiology catheters and systems are intended for use only in radiation shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines. • If artifact/noise is visible on electrograms, assess all associated connections and cables first. If artifact/noise persists, it may be necessary to inspect/replace the catheter. **POTENTIAL ADVERSE EVENTS** Potential adverse events related to the mapping, the ablation catheter(s), and/or the interventional procedure 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 materials • 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 • Injury related to tissue damage (for example: catheter entrapment/entanglement, physical trauma, and other events that may require surgical intervention) • Lead dislodgement • Arrhythmia (new or exacerbated) • Conduction pathway injury (for example: heart block, injury to sinus or AV node, 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 • Fistula (for example, atrio-esophageal 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 or hemorrhage • Pseudoaneurysm • Pneumothorax • Residual atrial septal defect • Thrombosis • 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 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. 91078319 AC.3

INTELLANAV STABLEPOINT™ 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 INTELLANAV STABLEPOINT 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 typical 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. **INDICATIONS FOR USE** The IntellaMap Orion Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. **CONTRAINDICATIONS** The INTELLANAV STABLEPOINT 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 < 8.5 F. • in the coronary vasculature. **WARNINGS** •• If the visibility of the EP catheters 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 and in the techniques of open-irrigated RF 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 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 directions. Failure to do so may result in patient complications. • Before using, inspect the INTELLANAV STABLEPOINT 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 INTELLANAV STABLEPOINT Catheter at lower than the prescribed flow rates specified in the Operational Instructions 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. • Carefully follow the power and the correlating flow rate procedures as specified in the Operational Instructions. Performing ablation with high power, insufficient flow rate, excessive contact force and/or excessive RF duration without moving the tip of the ablation catheter may lead to perforation, arrhythmias, damage to adjacent structures, and/or embolism. (Continued on page 14)

INTELLANAV STABLEPOINT™ Ablation (Continued from page 13)

• Avoid increasing power or duration of RF application beyond your standard of care to target a specific change in local impedance. Doing so may result in damage to adjacent structures, perforation caused by steam pop, arrhythmias, and/or embolism. • The INTELLANAV STABLEPOINT Catheter is not intended to be used with an RF Controller output setting exceeding 50 Watts or 133 Vpk. The safety and performance of the INTELLANAV STABLEPOINT 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. • 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 electric 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 INTELLANAV STABLEPOINT 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 jetting out of 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. • 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, 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 INTELLANAV STABLEPOINT 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: 133 Vpk. • Warnings for patients with implantable pacemakers and Implantable Cardioverter/Defibrillators (ICDs): • Pacemakers, implantable cardioverter/defibrillators, and leads can be adversely affected by radiofrequency energy. It is important to refer to the device manufacturer's instruction 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 pacemaker per the manufacturer guidelines during RF ablation to a non-tracking pacing mode if pacing is likely to be required during the ablation. • The pacemaker 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. • Deactivate ICDs as they could discharge and injure the patient or be damaged by the ablation procedure. • 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. • Remember to reactivate the pulse generator after turning off the RF ablation equipment. • Do not ablate from within the coronary artery as the resulting myocardial injury can be fatal. Adequate visualization techniques, such as fluorosocopy 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 INTELLANAV STABLEPOINT 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 overtorqued 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 INTELLANAV STABLEPOINT 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. • Do not use the INTELLANAV STABLEPOINT ablation system and its accessories in an in an oxygen rich environment or near flammable anesthetics. • 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 catheter or the tubing set 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 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. • 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 cooling lumen. This damage may affect steering performance or force accuracy and may cause patient injury. • Excessive manipulation of the distal tip and spring region may cause permanent damage to the contact force elements resulting in inaccurate force readings. • 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 use excessive force to advance or withdraw the catheter. The firmness of the tip dictates that care shall be taken to prevent perforation of the heart during catheter manipulation. If the force-sensing feature is active, evaluate applied force to avoid applying excessive loads. • Local impedance is affected by many factors including tissue conductivity, contact force, catheter orientation (focal/drag) power, duration, irrigation flow, tissue changes, and electrode char/thrombus/steam pop. • During RF, due to tissue heating, local impedance may not represent catheter proximity or stability nor relative position of the catheter tip-to-tissue, as it is when RF is OFF. • 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 RF Controller 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 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. • 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 INTELLANAV STABLEPOINT 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 INTELLANAV STABLEPOINT 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 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. • 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 INTELLANAV STABLEPOINT 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. • The contact force reading is for information only and is not intended to replace standard handling precautions. • The local impedance reading is for information only and is not intended to replace standard handling precautions. • The catheter must be warmed up prior to use. If the catheter has not reached a steady state condition prior to use, there is a potential for measurement drift to occur, which could result in an inaccurate force reading. • Ensure catheter tip is not in contact with myocardial wall or other device when zeroing the contact force reading. Failure to do so could result in inaccurate force reading. • Always zero the contact force reading following insertion into the patient or moving the catheter from one heart chamber to another. • To ensure proper function of the contact force reading, ensure the tip electrode and distal ring electrode are outside of a sheath. • To ensure proper function of the local impedance reading, ensure the tip electrode and all three ring electrodes are outside of a sheath. • When applying high force during mapping and RF application, the user should monitor the contact force visualization on the RHYTHMIA Mapping System screen to ensure the force does not exceed the operating range. • Do not place the distal end of the catheter near magnets. Magnetization of the catheter may result in degradation of magnetic tracking precision. Such degradation may be manifested by an unstable or complete loss of rendering of the position and/or orientation of the catheter by a magnetic tracking system. If this occurs, the catheter should be replaced. • Electromagnetic Interference (EMI) produced by the INTELLANAV STABLEPOINT Catheter when used in conjunction with the RF Controller during normal operation may adversely affect the performance of other equipment. • Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the electrode will not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the elec-trode. • 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 MAESTRO 4000 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 that 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. • The INTELLANAV STABLEPOINT 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 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. • Do not use the INTELLANAV STABLEPOINT ablation system and its accessories 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. **ADVERSE EVENTS** Potential adverse events associated with use of the INTELLANAV STABLEPOINT Catheter include, but are not limited to: • Pain or discomfort, for example: • Angina • Chest pain • Non-cardiovascular pain • Cardiac arrest • Death • Hypertension • Hypotension • Infection/inflammation/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 • 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 • 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. The potential adverse events may be related to the diagnostic mapping catheter(s) and/or the interventional ablation device(s) and/or the 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. Refer to the RF Controller, Irrigation Pump, and other ancillary device instructions for additional potential adverse events related to their use with the INTELLANAV STABLEPOINT Catheter. 97183419 B.3

FARAWAVE™/FARAWAVE NAV Pulsed Field Ablation Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE** The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non -conductive to prevent cardiac arrhythmia initiation or maintenance. **INDICATIONS FOR USE** The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF). **INTENDED PATIENT POPULATION** The FARAPULSE PFA System is intended for adult patients who are age 18 or older who have drug-refractory, recurrent, symptomatic PAF. **CONTRAINDICATIONS** The FARAWAVE Catheter is contraindicated for use: • in patients with active systemic infection • in patients with a mechanical prosthetic heart valve through which the catheter must pass • in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation • in patients with a bleeding disorder, or who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation; • in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach • in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels) • via transseptal approach in patients with an intra -atrial baffle or a foramen ovale patch. **WARNINGS** • If the visibility of the EP catheter is compromised for any reason, the user should stop and not resume ablation therapy until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures. • Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and in the specific approach to be used, in a fully -equipped electrophysiology lab. Device specific physician in-service training is made available by the manufacturer. • Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left -sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications. • Carefully read all equipment and ancillary device instructions required for the procedure prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications. • Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury. • Before using, inspect the FARAWAVE Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed. • Electromagnetic Interference (EMI) from any source during normal operation may adversely affect the visualization and tracking of the catheter during the procedure, which can cause patient injuries such as perforation, heart block and injury to adjacent structures. • Use of the FARAWAVE Catheter with generators other than a compatible BSC PFA Generator can lead to unexpected energy delivery resulting in either insufficient ablation treatment or over-delivery of energy leading to possible patient hazardous events such as thrombus formation, tissue damage, etc. • Patients undergoing ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker. • When the catheter is in the patient, the patient and/or the catheter connector should not come in contact with grounded metal surfaces to minimize the potential for electrical shock. • Ensure that the cable/catheter connection remains dry throughout the procedure in order to prevent electric shock or other patient injuries as well as to prevent loss of device function. • Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the catheter. • In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. • Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes. • Care must be taken to ensure that any equipment used in connection with the FARAWAVE Catheter be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock. • Do not directly touch the patient when ablation energy is being delivered to prevent the risk of electric shock. • Stimulation of cardiac tissues caused by pacing stimulus and/or ablation energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. • Warnings for patients with implantable pacemakers (PPMs) and Implantable Cardioverter Defibrillators (ICDs): • PPMs, ICDs, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures. • Do not apply ablation energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function. • Temporarily reprogram the pacemaker or defibrillator per the manufacturer guidelines during ablation. The device could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters. • Program the ICD Tachy therapy to "Off" to prevent inappropriate shock and/or possible damage to the device from the ablation procedure. Remember to turn Tachy Therapy to "On" once ablation is complete. • Have temporary external sources of pacing and defibrillation available. • Perform a complete analysis of the implanted device function after ablation. • Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement. • Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function. • Ablation in contact with any other electrodes alters the function of the catheter and can lead to embolism. • At no time should a FARAWAVE Catheter be advanced, withdrawn, rotated, deployed or undeployed when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter. • Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is over torqued and/or positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. • Do not use the FARAWAVE Catheter in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of a PFA Generator and the ablation system may adversely impact the image quality. This can also lead to loss of visibility during ablation which can cause patient injuries such as perforation, heart block and injury to adjacent structures. • Catheter ablation procedures present the potential for significant radiation exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the radiation beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Due to radiation exposure during catheter ablation, the safety and effectiveness of this device has not yet been established in pregnant and/or nursing women and pediatric patients. • There are no data to support the safety and effectiveness of this device in the pediatric population. • Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible. • Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. • Excessive curves or kinking of the catheter may damage internal wires and components, including the flush lumen. This damage may affect mechanical and electrical performance leading to patient injury. • Do not attempt to bend, kink, or shape the patient-contact portions or flush lumen of the FARAWAVE Catheter. Doing so could cause electrical or mechanical catheter failure resulting in patient injury. Kinking of the flush lumen may compromise flow through the device leading to potential thrombus formation and embolism. • Use both fluoroscopy, or other visualization techniques such as echocardiography, and electrograms to monitor the advancement and navigation of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade. Do not rely solely on electromagnetic navigation system display to monitor catheter location. • The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury. • Do not deliver ablation energy with the catheter outside the target site. Ablation Generators can deliver significant electrical energy and may cause patient injury such as arrhythmia and heart block. • Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system. • Patients undergoing left-sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, and/or embolism. • Patients undergoing an ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding/ hemorrhage and/or embolism. • Patients with hemodynamic instability or cardiogenic shock are at increased risk for life -threatening adverse events and ablation must be done with extreme caution. • The FARAWAVE Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death. • Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism. • If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a Transesophageal Echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage. • Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre -flush and maintain lumen patency with heparinized intravenous infusion. • Do not wipe this catheter with organic solvents such as alcohol or immerse the handle and/or cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient. • Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right -sided procedures. • The safety and/or efficacy of epicardial use of the FARAWAVE Catheter has not been evaluated in a clinical trial. • Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair. • Do not leave the FARAWAVE Catheter in the patient for more than four (4) hours. Failure to remove the device before four hours after first insertion could result in formation of thrombus with attendant stroke risks. • Use of the FARAWAVE Catheter with delivery devices other than the FARADRIVE Sheath can result in poor access to endocardial locations, inefficient ablation delivery and inadequate procedural outcomes. • Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes). • The FARAWAVE Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury can be fatal. • Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury. • When positioning on cardiac structures, the guidewire should be retracted to prevent cardiac perforation or tissue damage. Ensure the tip of the device is not against tissue prior to advancing or retracting the guidewire to prevent cardiac perforation or tissue damage. • The risk of igniting flammable gases or other materials is potential outcome of ablation procedures. Precautions must be taken to restrict flammable materials from the electrosurgical suite. • Take care when manipulating the guidewire to prevent cardiac or vessel trauma. • To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue. • Minimize catheter exchanges and always advance and withdraw components through the valve slowly to minimize the vacuum created during withdrawal and to reduce the risk of air embolism. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements. • Instruct users with co-implanted devices to refer to ancillary device labeling as well as the manufacturer of the ancillary device for recommended compatibility and settings. When ablating in proximity to metallic devices, arcing may occur which could lead to bubble formation, cardiac trauma, and/or damage to the devices. • Use caution when advancing, retracting or otherwise manipulating system components to avoid damaging tissue or vessels or interfering with previously implanted medical devices. • When advancing or undeploying the FARAWAVE catheter, do not retract the 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 ca use 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. • Intracardiac potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the Operational Instructions section, regardless of absence of intracardiac signal. • Potential biohazard after use. Handle and dispose of in accordance with applicable regulations **PRECAUTIONS** • Do not attempt to use with devices, including guidewires, larger than the delivery lumen diameter specified on the package label. • Care must be taken to ensure all luer fittings are secure to prevent leaking. • It is essential that a cardiac defibrillator with paddles connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation. • There is limited data to support the safety and effectiveness of this device in patients older than 75 years. • Catheter deployment and undeployment should occur under imaging guidance. Catheter may be fully deployed undeployed even though the slider switch is not fully engaged. Failure to monitor deployment may result in catheter damage and need for catheter exchange. • Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible. • Do not apply excessive force to the deployment mechanism when deploying the catheter as doing so may damage the catheter. • Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly. • Do not place the distal end of the catheter near a magnet. Magnetization of the catheter may result in degradation of magnetic tracking precision. Such degradation may be manifested by an unstable or complete loss of rendering of the position and/or orientation of the catheter by a magnetic tracking system. If this occurs, the catheter should be replaced. **ADVERSE EVENTS** Potential adverse events associated with use of the FARAWAVE Catheter includes, but are not limited to: • Pain or discomfort, for example: • Angina • Chest pain • Non-cardiovascular pain • Cardiac arrest • Death • Electric shock • Hypotension • Infection/inflammation/exposure to biohazardous material • Edema/heart failure/pleural effusion • Hemolysis • Renal failure/insufficiency • Respiratory distress/insufficiency/dyspnea • Arrhythmia (new or exacerbated) • Conduction pathway injury (heart block, nodal injury, etc.) • Nerve injury, for example: • Phrenic nerve injury • Vagal nerve injury • Gastrointestinal disorders • Vessel trauma, including: • Perforation • Dissection • Coronary artery injury • Vasospasm • Occlusion • Hemothorax • Cardiac trauma, for example: • Cardiac perforation/cardiac tamponade/pericardial effusion • Valvular damage • Stiff left atrial syndrome • Injury related to tissue damage and/or adjacent structures, for example: • Esophageal injury • Pulmonary injury • Catheter entrapment • Physical trauma • Fistula, for example: • Atrio-esophageal fistula • Bronchopericardial fistula • PV stenosis and its symptoms, for example: • Cough • Shortness of breath, fatigue • Hemoptysis • Surgical and access complications, for example: • Hematoma/seroma • AV fistula • Bleeding • Pseudoaneurysm • Pneumothorax • Residual atrial septal defect • Thrombus/thrombosis • Muscle spasm • Injury due to embolism/thromboembolism/air embolism/foreign body embolism • Cerebrovascular Accident (CVA)/stroke • Transient Ischemic Attack (TIA) • Myocardial infarction • Neurological impairment and its symptoms, for example: • Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment • Pulmonary embolism • Asymptomatic cerebral embolism • Procedural related side effects, for example: • Allergic reaction (including anaphylaxis) • Genitourinary complication • Side effects related to medication or anesthesia • Radiation injury/ tissue burn • Vasovagal response • Fluid volume overload The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death. EP-1995411-AA

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