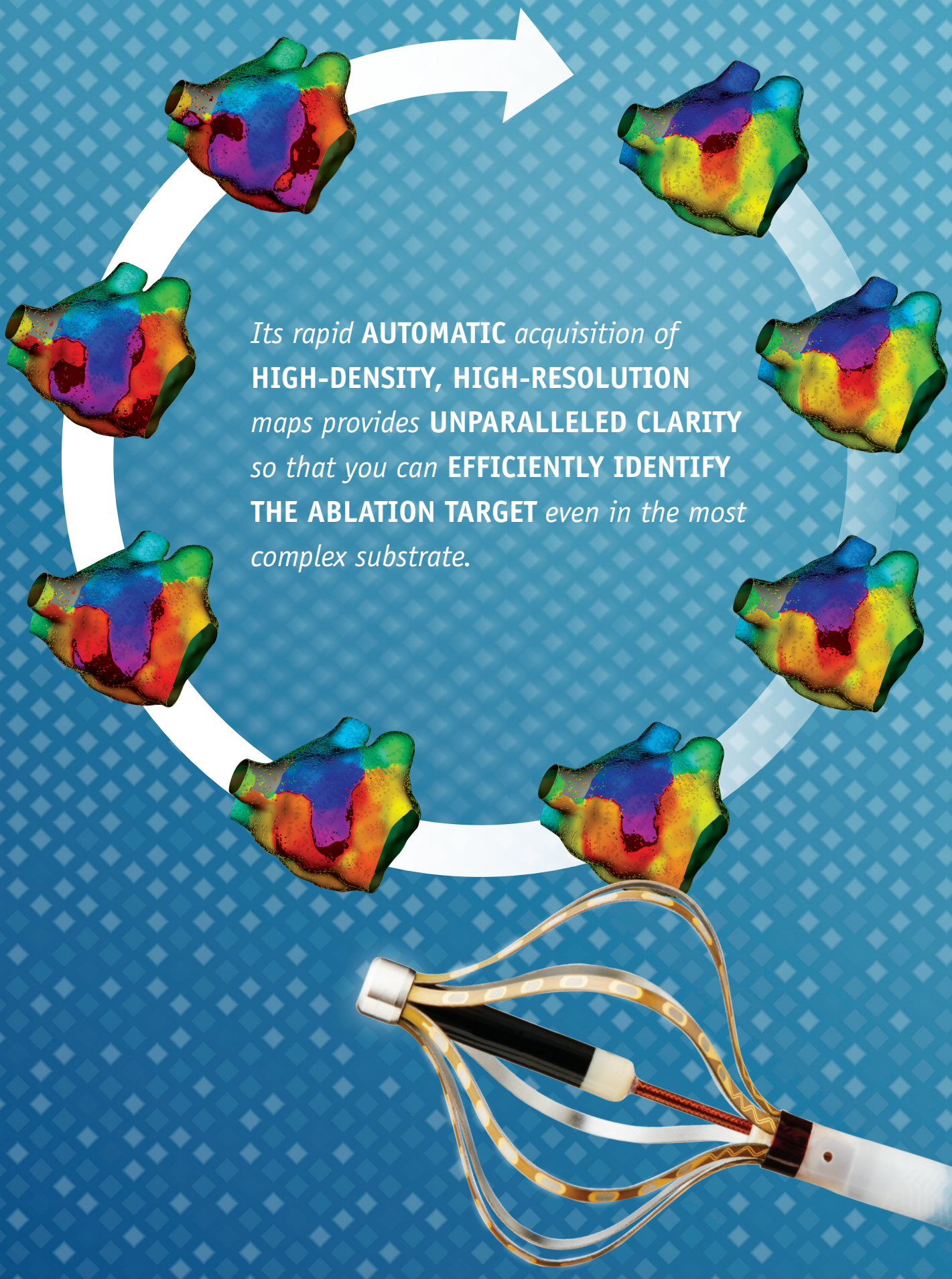
Boston Scientific
Advancing science for life™

RHYTHMIA HDx™
MAPPING SYSTEM

CLARITY
for any level of complexity

THE RHYTHMIA HDx™ MAPPING SYSTEM SETS THE STANDARD OF PERFORMANCE IN HIGH-DEFINITION MAPPING.

RHYTHMIA HDx
MAPPING SYSTEM



Its rapid **AUTOMATIC** *acquisition of* **HIGH-DENSITY, HIGH-RESOLUTION** *maps provides* **UNPARALLELED CLARITY** *so that you can* **EFFICIENTLY IDENTIFY THE ABLATION TARGET** *even in the most complex substrate.*

THE RHYTHMIA HDx™ MAPPING SYSTEM WAS BUILT FROM THE GROUND UP FOR HIGH-DEFINITION MAPPING.

HD CATHETER

"THE HIGH NUMBERS OF ELECTRODES PROVIDE *comprehensive and accurate electrical information to enable insight into underlying AT mechanisms and activation patterns that have rarely been available in this detail before."*

– Schaeffer et al.,[1] 2016

HD HARDWARE

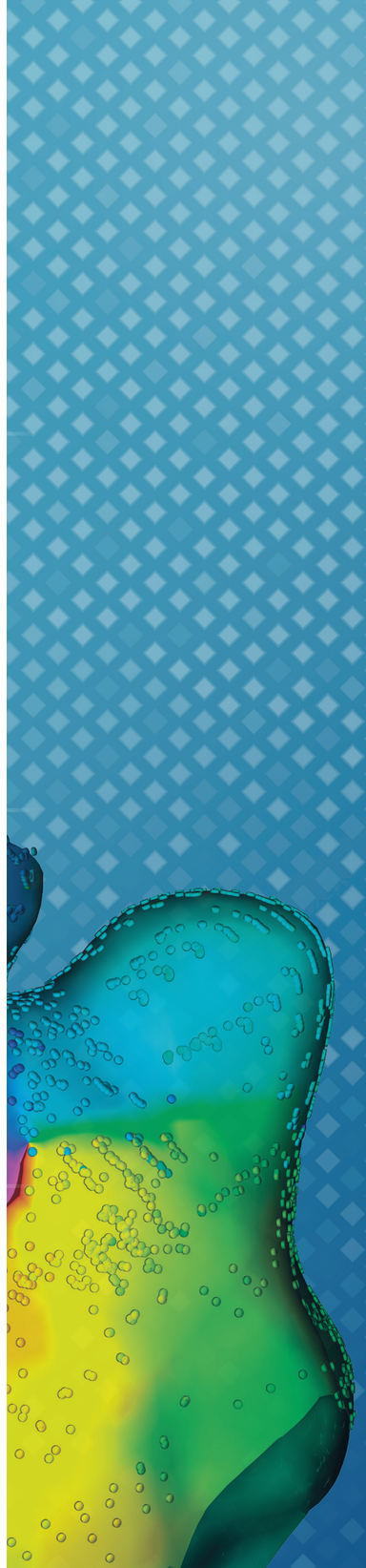
"THIS SYSTEM IS FOR THE FIRST TIME ABLE TO DISPLAY LOW-VOLTAGE CRITICAL ISTHMUSES, *which are far below the current scar cutoff of classically available systems."*

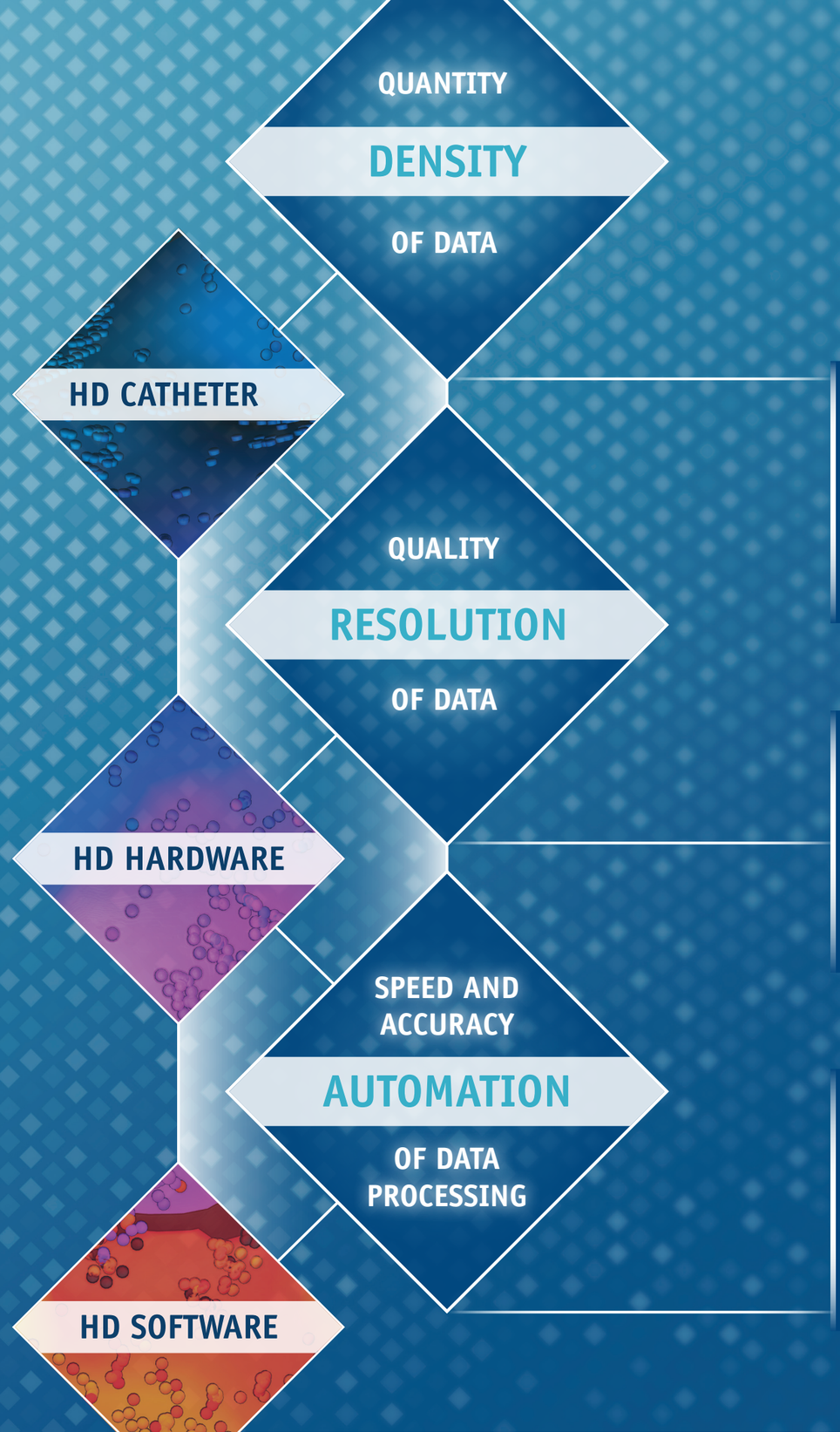
– Lațcu et al.,[2,3] 2017

HD SOFTWARE

"THE COMBINATION OF INCREASED SAMPLING DENSITY, MAPPING RESOLUTION AND A NOVEL ALGORITHM *to improve the accuracy of activation timing resulted in the ability to construct activation maps with better characterization of the circuit as compared to standard mapping technologies."*

– Anter et al.,[3,4] 2016





Only the combination of a high-resolution mapping **CATHETER,** *advanced noise-filtering* **HARDWARE** *and intelligent* **SOFTWARE** *working together can achieve the* **DENSITY, RESOLUTION** *and* **AUTOMATION** *required for true high-definition mapping.*

The INTELLAMAP ORION™ has **64 ELECTRODES** *that were shown to generate maps with 5x higher point densities*[5,6] *than competitive automated mapping systems.*

RHYTHMIA HDx™ has **NO POINT LIMITATION.**

ORION's **0.4 mm², 2.5 mm** *spaced,* **IRIDIUM-OXIDE** *coated,* **FLAT** *electrode design produces sharp, high-quality, high-resolution signals.*

RHYTHMIA HDx™ **0.01mV NOISE FLOOR** *reveals signals that cannot be visualized with standard-definition mapping systems.*

Continuous mapping leverages **4 ROBUST TRIGGERS** *and* **7 BEAT ACCEPTANCE CRITERIA** *to ensure that only beats from the rhythm of interest are accepted into the map, at* **SPEEDS GREATER THAN 1,000 POINTS/MINUTE.**[7]

RHYTHMIA HDx Intelligent Annotation Algorithm was shown to deliver **99.98%** *annotation* **ACCURACY.**[3,8]

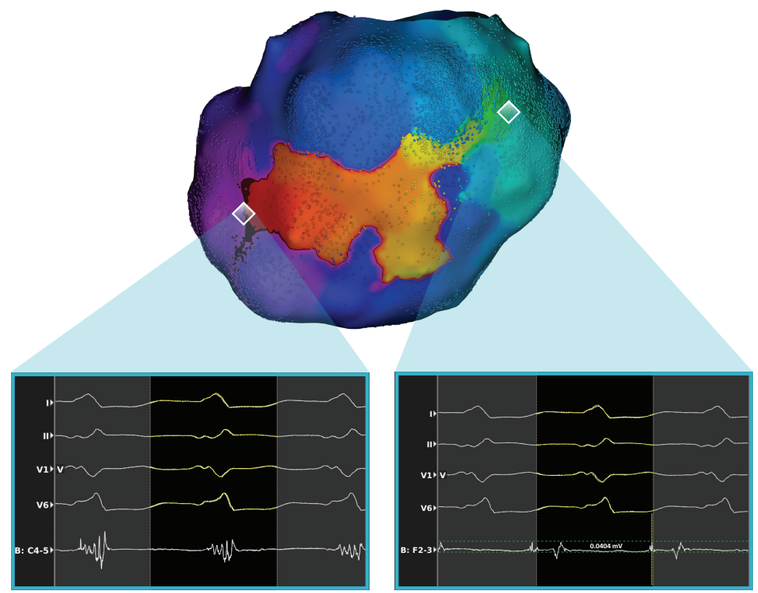
HD CATHETER

HD HARDWARE

HD SOFTWARE

1

DIAGNOSE WITH COMPLETE DATA

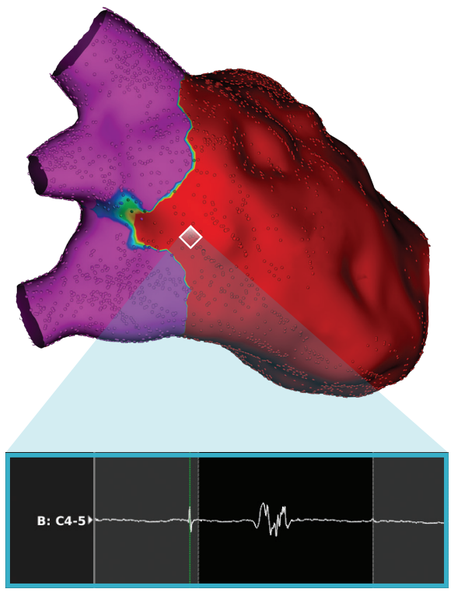


Ischemic VT activation map of a low-voltage critical isthmus. Courtesy of Frédéric Sacher, MD, CHU Bordeaux.

- Reduce the amount of interpolation between annotated points to more efficiently identify areas of interest
- Clearly visualize propagation of complex arrhythmia circuits
- Characterize complex substrates, including critical isthmuses, low-voltage regions of interest, scar and scar boundaries

2

DEVELOP A TARGETED ABLATION STRATEGY

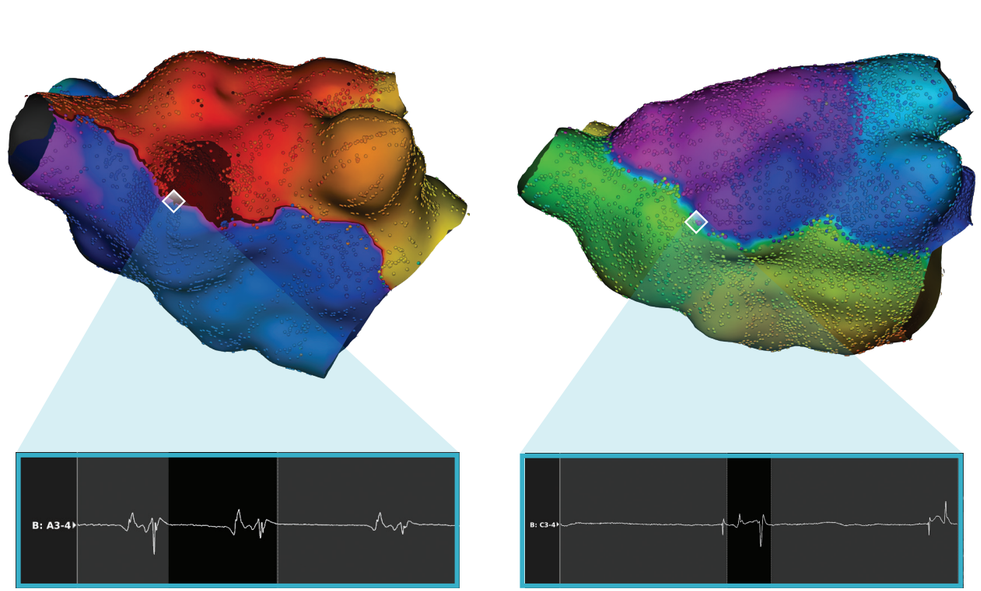


Redo AF activation map revealing a low-voltage gap in a previous PVI line.
Courtesy of Jamie Kim, MD, Catholic Medical Center.

- Uncover channels and small gaps in previously ablated lesion sets
- Clearly visualize low amplitude and complex fractionated electrograms that are not visible with standard-definition systems
- Precisely identify the ablation target so that you can limit ablation time

3

EFFICIENTLY CONFIRM PROCEDURAL ENDPOINTS



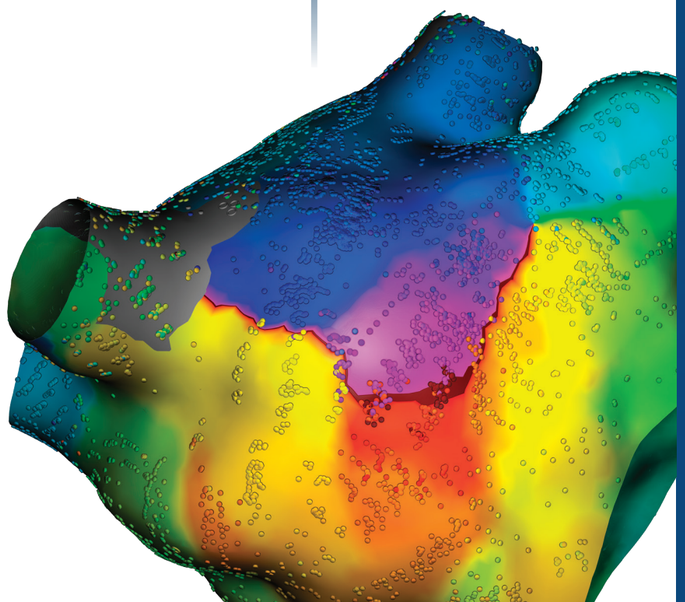
LA activation map revealing a gap in previous anterior ablation line. vMap post-ablation confirms bidirectional block.
Courtesy of Vivek Reddy, MD, Mount Sinai Medical Center.

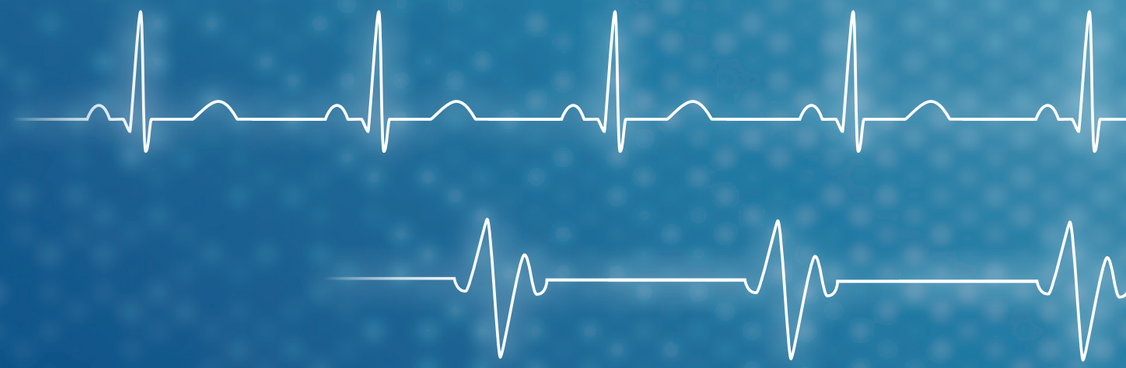
- Remap areas of interest at speeds >1,000 points/minute[7]
- Rapidly assess lesion integrity through post-ablation vMaps™

THE BETTER YOU CAN SEE IT,

the better you can treat it.

The RHYTHMIA HDx™ Mapping System provides map clarity that cannot be achieved through standard-definition mapping technologies.





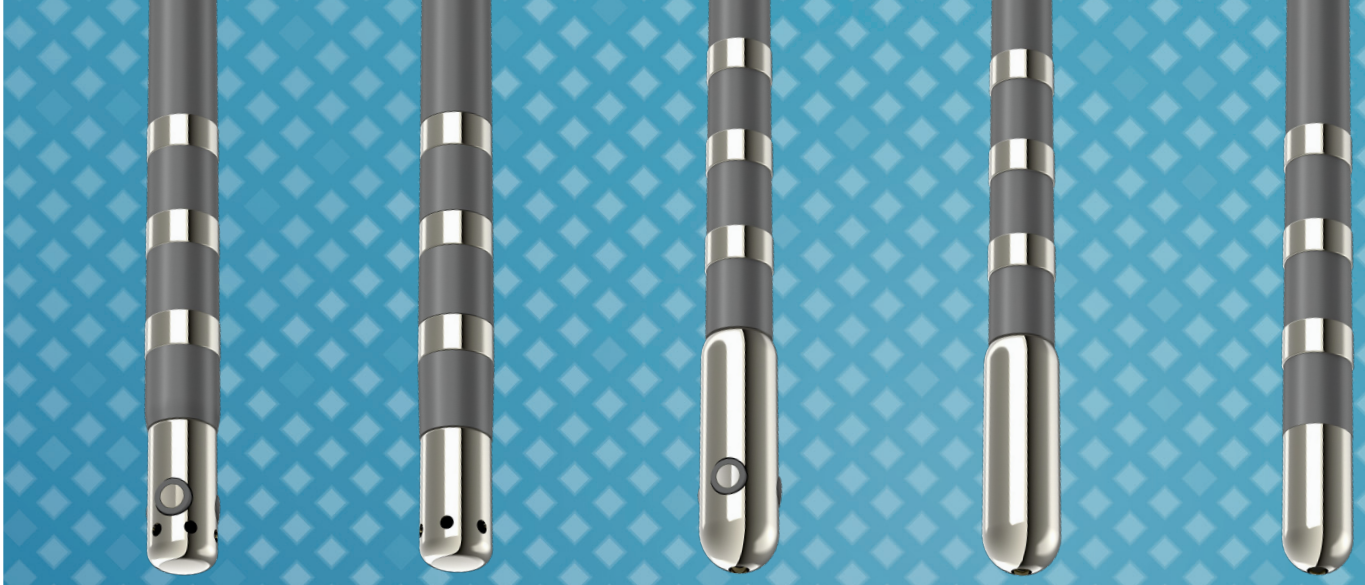
RHYTHMIA HDx™ HYBRID LOCALIZATION PROVIDES YOU THE FLEXIBILITY TO WORK WITH YOUR CHOICE OF CATHETERS.

NAVIGATIONAL ACCURACY OF ≤1 mm

For optimal accuracy and efficiency, magnetic tracking supports mapping with the Boston Scientific INTELLAMAP™ and INTELLANAV™ catheters[9]

NAVIGATIONAL ACCURACY OF ≤2 mm

Impedance tracking supports mapping and visualization of non-navigation-enabled catheters for flexibility of choice[9]



INTELLANAV MIFI™ OI
ABLATION CATHETER

INTELLANAV™ OI
ABLATION CATHETER

INTELLANAV MIFI™ XP
ABLATION CATHETER

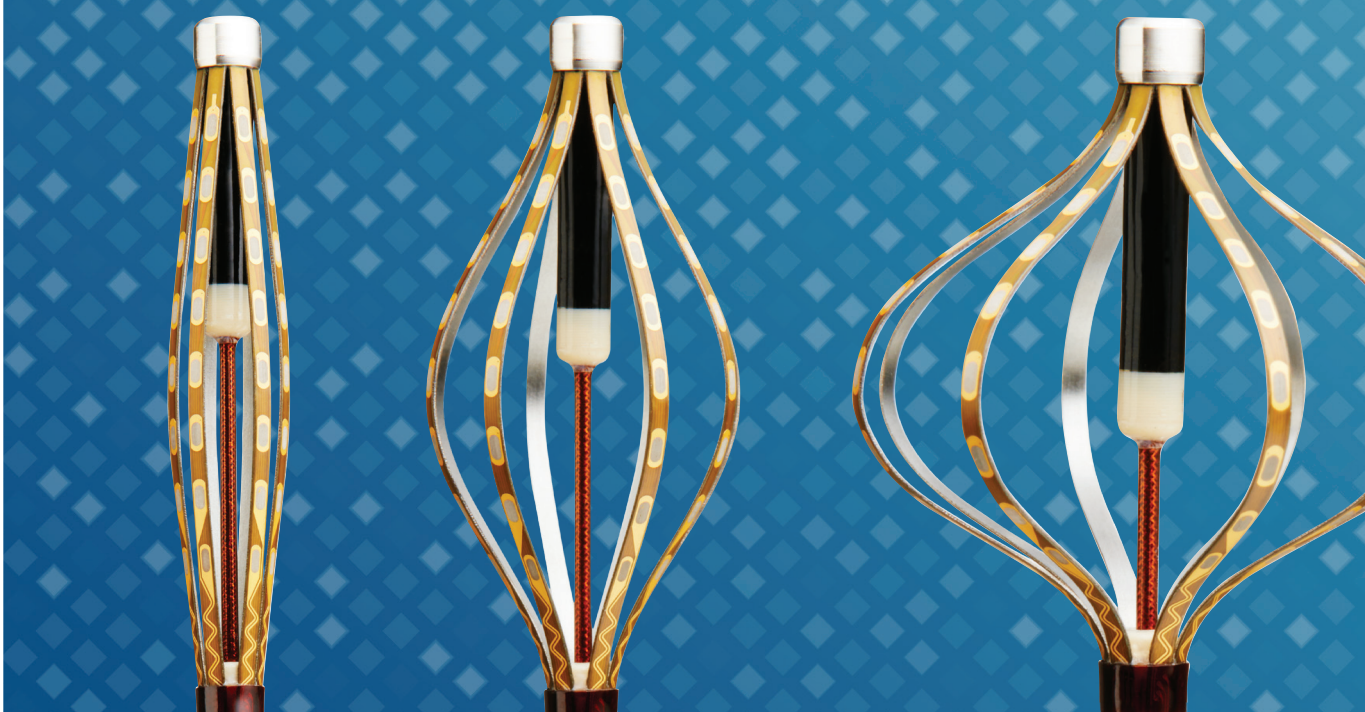
INTELLANAV™ XP
ABLATION CATHETER

INTELLANAV™ ST
ABLATION CATHETER

Boston Scientific offers a full portfolio of INTELLANAV™ Ablation Catheters.

FOR THE HIGHEST LEVEL OF ACCURACY, *use the INTELLAMAP ORION™ Mapping Catheter plus an INTELLANAV Ablation Catheter for high-definition mapping and optimal tracking accuracy.*

INTELLAMAP ORION™
MAPPING CATHETER



RHYTHMIA HDx™ Mapping System

INTENDED FOR USE The RHYTHMIA 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 RHYTHMIA 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 radio frequency (RF) 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 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. • 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. • 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 Rhythmia HDx Mapping System. • 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.

CAUTIONS • 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 cardiac implantable electronic devices (CIEDs). 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. • Sheath detection is to be used with compatible Agilis™, Zurpaz™, 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.

POTENTIAL ADVERSE EVENTS Any potential clinical complications are in large part expected to be related to the accessory diagnostic and/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 RHYTHMIA 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** 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. **Electrical Hazards** With any electrical system there is a potential risk of electrical shock to the user, patient, and service representative. 92106607 Rev. F.3

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

1. Schaeffer B, Hoffmann BA, Meyer C, et al. Characterization, mapping and ablation of complex atrial tachycardia: Initial experience with a novel method of ultra high-density 3D mapping. *J Cardiovasc Electrophysiol*. 2016 Oct;27(10):1139-1150.
2. Laţcu DG, Bun SS, Viera F, et al. Selection of critical isthmus in scar-related atrial tachycardia using a new automated ultrahigh resolution mapping system. *Circ Arrhythm Electrophysiol*. 2017 Jan;10(1). pii: e004510.
3. Study performed using Rhythmia™ Mapping System. Product specifications that deliver density, resolution, and automation remain consistent with Rhythmia HDx.
4. Anter E, McElderry TH, Contreras-Valdes FM, et al. Evaluation of a novel high-resolution mapping technology for ablation of recurrent scar-related atrial tachycardias. *Heart Rhythm*. 2016 Oct;13(10):2048-55.
5. Based on approximate mapping speed of 95 pts / minute in the right atrium in 5 swine USING THE ST. JUDE MEDICAL PRECISION ENSITE MAPPING SYSTEM. Ptaszek LM, et al. Rapid High-Density Automated Electroanatomical Mapping Using Multiple Catheter Types. Poster Session PO097 APHRS 2015.
6. Based on approximate mapping speed of 491 pts / minute in the right atrium in 5 swine USING THE BOSTON SCIENTIFIC RHYTHMIA MAPPING & NAVIGATION SYSTEM. Ptaszek LM, et al. Rapid Acquisition of High-Resolution Electroanatomical Maps Using a Novel Multielectrode Mapping System. JICE. Nov 2012.
7. Based on a minimum of 5 clinical publications to date demonstrating mapping speeds > 1,000 points / minute.
8. Mantziari L, Butcher C, Kontogeorgis A, et al. Utility of a novel rapid high-resolution mapping system in the catheter ablation of arrhythmias: An initial human experience of mapping the atria and the left ventricle. *JACC: Clin Electrophysiol*. 2015 Oct;1(5):411-20.
9. Data on File.

INTELLAMAP ORION™ HIGH RESOLUTION MAPPING CATHETER

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

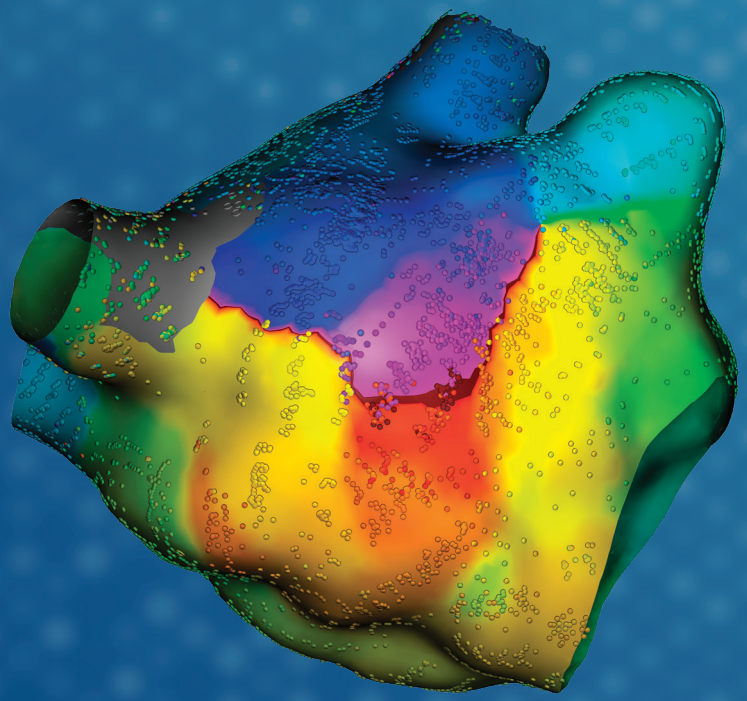
WARNINGS: • Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of catheter mapping and RF powered ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. • Before using, inspect 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

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.



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