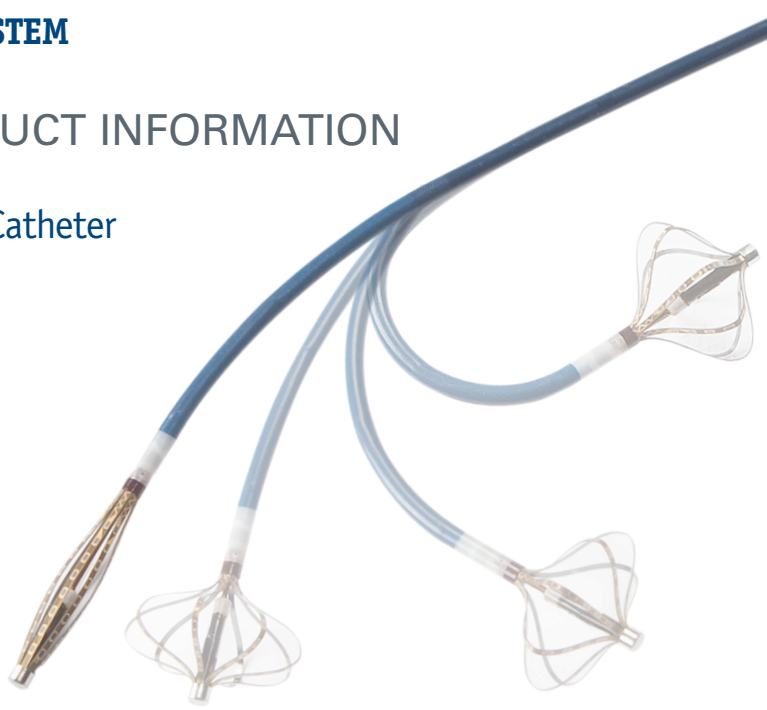
Boston Scientific
Advancing science for life™

RHYTHMIA HDx™ MAPPING SYSTEM

RHYTHMIA HDx DISPOSABLE PRODUCT INFORMATION

INTELLAMAP ORION™ High-Resolution Mapping Catheter



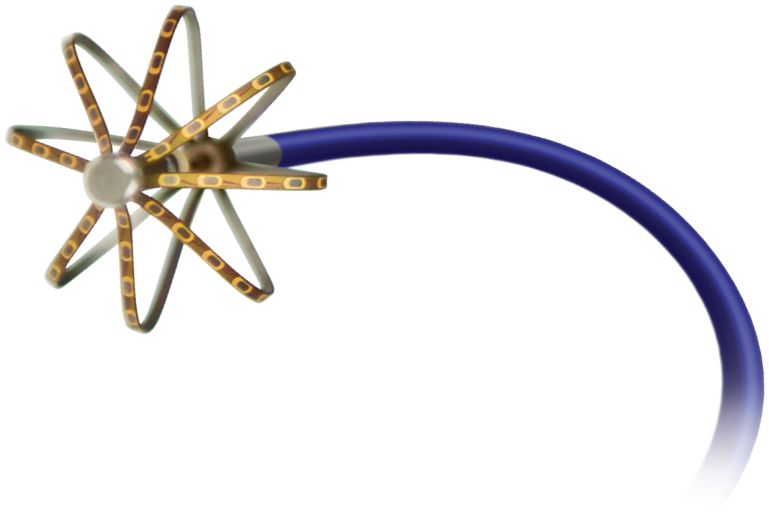
EGM Clarity

Description
64 Flat, Printed Electrodes
2.5mm Inter-electrode Spacing
0.4mm² Electrode Area

Mapping Versatility

Description
8.5F, bidirectional shaft steerability
Variable basket deployment diameter (3-22mm), for use in various anatomical structures
Compatible with most commercially available 8.5F fixed and steerable sheaths

Approved for use in all chambers of the heart



Safety in Design

Description
8 smooth, flexible splines
Flushing port designed to prevent clot formation

Location Reference Patch Kit

Description
Enables magnetic- and impedance-based tracking of catheters with the RHYTHMIA HDx system

Sold in Boxes of 5 kits / 1 kit contains:
1 Location Reference Back Patch 10 ECG Electrodes

RHYTHMIA HDx™ DISPOSABLE PRODUCT INFORMATION

INTELLAMAP ORION™ High-Resolution Mapping Catheter

UPN	Order Number	Useable Length	OD (F)	Number of Electrodes
M004 RC64S 0	RC64S	115cm	8.5	64

Umbilical Cables

UPN	Order Number	Useable Length
M004 RAUMBILICAL2 0	RAUMBILICAL2	78 in

Location Reference Patch Kit

UPN	Order Number	Order Quantity
M004 RAPATCH1 1	RAPATCH1	5 Kits per Box

RHYTHMIA HDx™ Mapping System from Boston Scientific 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 its accessories are indicated for catheter-based atrial and ventricular mapping. The system enables 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** 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. 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. Use only Maestro™ or EP-Shuttle RF ablation generators with the system. Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. 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. 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. 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. **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 directions 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. 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. (Rev AB)

INTELLAMAP ORION™ High-Resolution Mapping Catheter from Boston Scientific INDICATIONS FOR USE The IntellaMap Orion High-Resolution Mapping Catheter is indicated for electro-physiological 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. Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy. Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside. Patients with active systemic infection. Pediatric patients. Pregnant and/or nursing patients. Patients with any other condition where catheter manipulation may not be safe. The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation. The IntellaMap Orion Catheter should not be used inside an MRI machine. **WARNINGS** Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid. This catheter is intended for single patient use only. Do not reuse or re-sterilize. Resterilization may damage the device and reuse may increase the risk of cross contamination. Do not use the catheter to deliver ablation therapy. Do not expose the catheter to alcohol or other cleaning solvents. Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy. Do not advance or retract the catheter through a sheath when deployed or articulated. In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 sec. at all times during use of the catheter, and continuously flush the electrode array with saline via the irrigation port at the proximal end. Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated. **PRECAUTIONS** Store in a cool, dry place. Do not use if the sterile package is open or damaged. Do not use the device if the use-by-date has passed. 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. Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment. Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient. Only use guiding sheaths with curves that allow passage of the catheter without using excessive force. When used with a steerable guiding introducer sheath: Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. Do not articulate the sheath while the catheter array is inside the articulating section. Do not deploy or articulate the catheter while the distal end is inside a sheath. Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter. To prevent entanglement, use care when using the catheter in the proximity of other catheters. When pacing, verify desired waveform is observed. 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. Remove the catheter in case of any observed malfunction. Federal Law (U.S.A.) restricts the sale of this device by or on the order of a physician only. **POTENTIAL ADVERSE EVENTS** Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism and death. Complications reported included also (in alphabetical order): air embolism, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding and vasovagal reactions. (Rev A)

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.

Boston Scientific
Advancing science for life™

Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

EP-338909-AB MAY2017