Boston Scientific
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INTELLANAV™ ST ABLATION CATHETER

Ordering Information: **INTELLANAV ST**

Electrode Configuration: Quadripolar Electrode Spacing: 2.5mm

Model Number	Shaft Size	Tip Size	Curve Style	Shaft Length
M004 R5031TH 0	7F	7F/4mm	Standard	110cm
M004 R5031THK2 0	7F	7F/4mm	Large	110cm

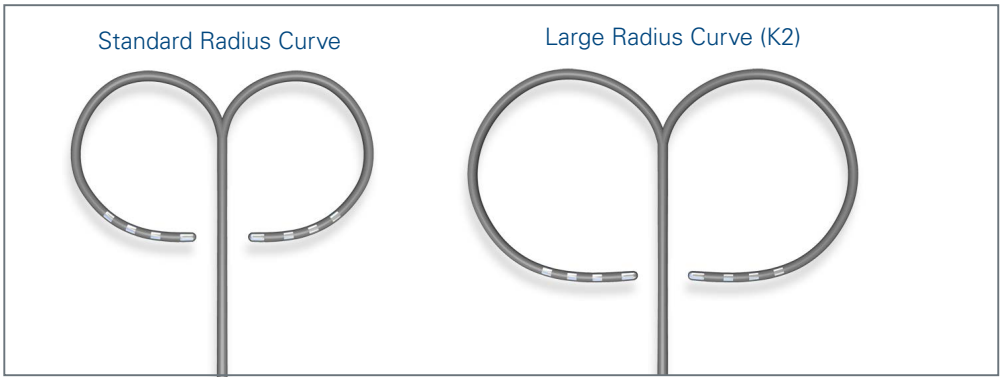
RHYTHMIA™ MAPPING SYSTEM Accessories

Model Number	Description
M004 RARC01 0	INTELLANAV Ablation Catheter Cable 6 Ft
M004 RA6250 0	INTELLANAV Connection Box - MAESTRO
M004 RARC20 0	INTELLANAV SIU Adapter Cable
M004 5441S 0	Octapolar Dx Cable

RHYTHMIA HDx™ MAPPING SYSTEM Accessories

Model Number	Description
M004 RARC01 0	INTELLANAV Ablation Catheter Cable 6 Ft
M004 RA6201US 0	RHYTHMIA HDx Connection Box - MAESTRO

Bidirectional Curve Options



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

INTELLANAV™ ST Ablation Catheter
INDICATIONS FOR USE: The Boston Scientific Corporation IntellaNav™ ST Catheter, when used with a compatible radiofrequency controller, is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia The IntellaNav ST Catheter, when used with a compatible radiofrequency controller, is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia. **CONTRAINDICATIONS:** The IntellaNav ST Catheter is intended to treat patients 18 years or older that have cardiac arrhythmias. The use of the device is contraindicated in patients: with active systemic infection, who have had a ventriculotomy or atriotomy within the preceding eight weeks, via the transeptal approach in patients with left atrial thrombus of myxoma, or interatrial baffle or patch, via the retrograde transaortic approach in patients with aortic valve replacement, who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach. **WARNINGS:** Before operating the device, read these warnings carefully: Peri-procedural anticoagulation therapy is at the discretion of the physician; however, patients with a history of thromboembolic events may require the therapeutic anticoagulation therapy, pre-, during and post ablation to reduce the incidence of major complications.Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should be given to pregnant patients. Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a. Retain temporary external sources of pacing available during ablation, b. Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing, c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, d. Perform complete pacing system analysis on all patients after ablation. Implanted cardioverter / defibrillators should be deactivated during delivery of RF power. 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 positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues. Maximum IntellaNav™ ST Catheter Rated Voltage: 178 Vrms (251 Vpk). In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. 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 thrombus in the left atrial appendage based on an individual patient-centered medical assessment of peri-procedural stroke risk. Do not pass the IntellaNav ST Catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve. 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. There are no data to support the safety and effectiveness of this device in the pediatric population. 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. **PRECAUTIONS:** Observe these precautions, before using the device: 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. The IntellaNav ST Catheters are intended for use with the BSC RF Controllers and accessories only. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. The catheter impedance LED display of the RF Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum. Adequate signal filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECGs) during RF power applications. Do not increase power before checking for obvious defects or misapplication. Electromagnetic interference (EMI) produced by the RF Controller during the delivery of RF power may adversely affect the performance of other equipment. **ADVERSE EVENTS:** The following potential adverse events (in alphabetical order) may be associated with cardiac catheterization and cardiac ablation procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery. These include but are not limited to: Allergic reaction (including anaphylaxis), Angina, Arrhythmias (new or exacerbation of existing arrhythmias), Atrioventricular node damage (transient or permanent), Cardiac or respiratory arrest, Catheter entrapment or entanglement, Chest pain or discomfort, Complete heart block (transient or permanent), Complications of sedative agents (e.g. aspiration pneumonia), Death, Damage to vessel intima or cardia ultrastructures, Electric shock, Embolism, venous, arterial (i.e., air, cerebrovascular accident, myocardial infarction, pulmonary embolism), Fistula (arterial, venous or atrio-esophageal), Gastroparesis, Hematoma or ecchymosis, Hemoptysis, Hemorrhage, Hemothorax, Hypertension, Hypotension, Infection, Myocardial infarction, Nerve palsy or weakness, Pain, Perforation, Pericardial or pleural effusion, Pericarditis or pleuritis, Phrenic or intercostal nerve damage, Pleurisy, Pneumothorax, Pseudoaneurysm, Pulmonary edema, Radiation exposure, Sinus or AV node injury, Skin burn (defibrillator, cardioverter or radiation), Stenosis-pulmonary vein, Stroke or cerebral vascular event, Tamponade, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasospasm, Vasovagal reaction, Vessel occlusion and Visual blurring. (Rev A)

RHYTHMIA™ INTELLANAV Connection Box
INTENDED USE: The IntellaNav Connection Box is an accessory to the Rhythmia Mapping System. It is intended for use during mapping and ablation procedures. The connection box routes intracardiac signals, sensed by the IntellaNav catheter, to the Rhythmia Mapping System's Signal Station. It is designed to be used with the RF generator designated by its device label. **INDICATIONS FOR USE:** The Rhythmia 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:** None known. **WARNINGS:** The IntellaNav Connection Box is intended for use with the Rhythmia Mapping System and other medical devices in an electrophysiology laboratory. Prior to each use, carefully read all device Instructions for Use. Always observe all contraindications, warnings, and cautions. Failure to do so may result in user harm or patient illness, injury, or death. Use the IntellaNav Connection Box with only compatible Maestro and Stockert (EP-Shuttle) RF generators. Do not use other RF generators for which compatibility is not demonstrated. Do not apply RF energy larger than 150W to ablation catheters that are connected to a Maestro RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to a Stockert (EPShuttle) RF generator and the Rhythmia Mapping System. **CAUTIONS:** Do not use excessive force when connecting or disconnecting cable connectors. Excessive force can damage the connectors, which may cause device malfunction. To avoid equipment damage and malfunction, do not insert anything (e.g., cotton swabs or pins) into cable connectors or equipment sockets or openings. Follow established guidelines for cleaning the device. Never immerse components in water, cleaning solutions, or liquid. Ensure that connectors remain dry. Failure to follow cleaning guidelines may cause equipment damage, and void any warranties or service agreements. Never clean the device during system operation. Cleaning equipment during use increases the risk of electrical shock and device malfunction. To avoid equipment damage and malfunction, do not attempt to sterilize the IntellaNav Connection Box. Always clean and disinfect the device according to established guidelines for cleaning the device. Do not use glutaraldehyde or hydrogen peroxide to clean the device. Do not use acetone. Do not use the device if it is 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 replaced or cleaned according to established facility protocol components. (Rev A)

RHYTHMIA HDx™ Ablation Connection Box
INTENDED USE: The RHYTHMIA HDx™ Ablation Connection Box is intended for use with the Maestro™ family of generators and associated catheters during mapping and ablation procedures. **CONTRAINDICATIONS:** There are no Known contraindications. **WARNINGS:** Use only Maestro RF Generators with the ablation connection box. Do not use with other RF generators. Compatibility with other RF generators has not been demonstrated. **POTENTIAL ADVERSE EVENTS:** Any potential clinical complications are in large part expected to be related to the RF generator and/or ablation catheters that are used with the ablation system, rather than the ablation connection box itself. In order to identify potential adverse events, the user is instructed to read pertinent directions for use documents associated with the catheters and RF generators that will be employed during an EP procedure. The RHYTHMIA HDx Ablation Connection Box can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the device, 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 device 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 A)

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

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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