Boston Scientific
Advancing science for life™

INTELLANAV™ OPEN-IRRIGATED
ABLATION CATHETER

Ordering Information

Electrode Configuration: Quadripolar

Electrode Spacing: 2.5mm

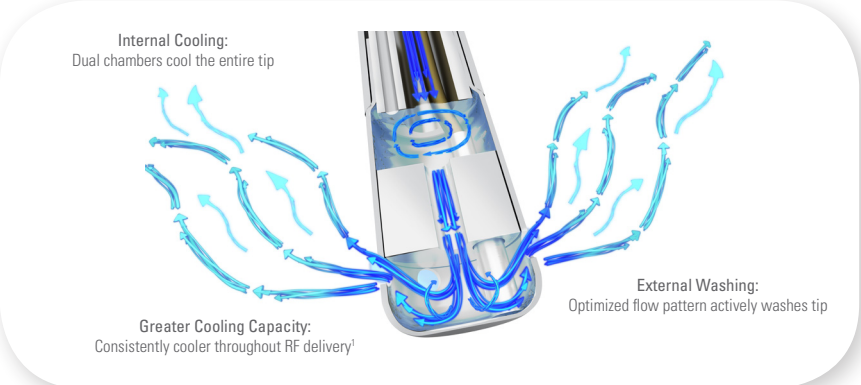
Model Number	Shaft Size	Tip Size	Curve Style	Shaft Length
M004 R9620 0	7.5F	7F/4mm	Standard	110cm
M004 R9620K2 0	7.5F	7F/4mm	Large	110cm
M004 R9620N4 0	7.5F	7F/4mm	Asymmetric	110cm

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
M004 117 0	METRIQ™ Irrigation Tubing Set

RHYTHMIA HDx™ MAPPING SYSTEM Accessories

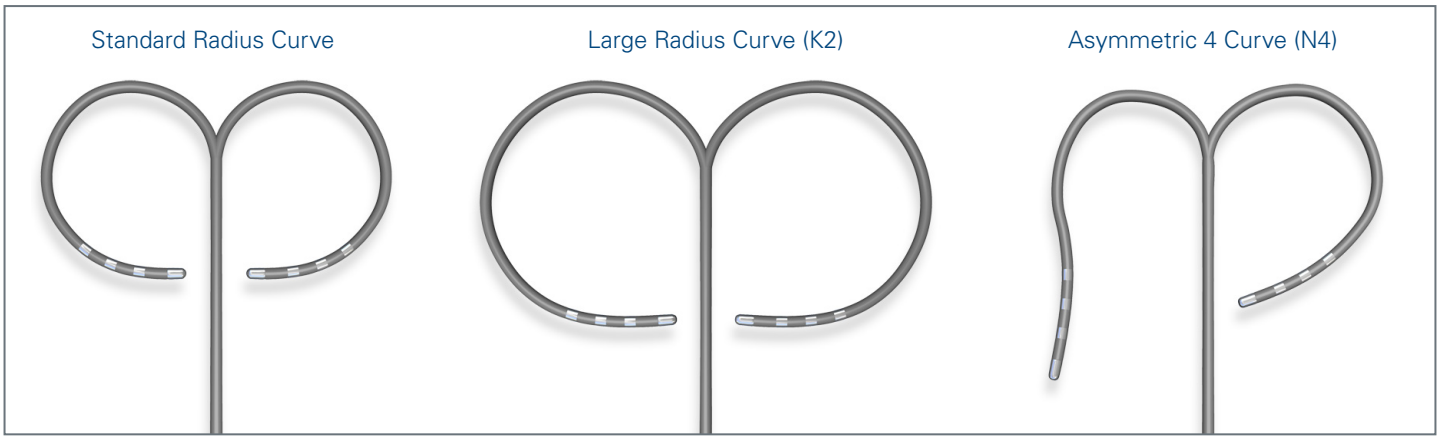
Model Number	Description
M004 RARC01 0	INTELLANAV Ablation Catheter Cable 6 Ft
M004 RA6201US 0	RHYTHMIA HDx Connection Box - MAESTRO
M004 117 0	METRIQ™ Irrigation Tubing Set



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

INTELLANAV™ OPEN-IRRIGATED ABLATION CATHETER

Bidirectional Curve Options



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

[1]Data on file.

INTELLANAV™ OPEN-IRRIGATED Ablation Catheter
INDICATIONS FOR USE: The IntellaNav™ OI Catheter, when used with a compatible Radiofrequency (RF) Controller and Irrigation Pump, is indicated for: Cardiac electrophysiological mapping, Delivering diagnostic pacing stimuli, RF ablation of sustained or recurrent type 1 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. **CONTRAINDICATIONS:** The IntellaNav OI Catheter is contraindicated for use in patients: With active systemic infection; With a mechanical prosthetic heart valve through which the catheter must pass; Unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation; Who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach; Who are hemodynamically unstable; Who have myxoma or an intracardiac thrombus; Who have had a ventriculotomy or atriotomy within the preceding eight weeks. Who have had a Patent Foramen Ovale (PFO) occlusion device. **WARNINGS:** 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. Note: The IntellaNav OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System. Catheter ablation procedures present the potential for significant x-ray 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 x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children. Start the initial RF application at low power and carefully follow the power titration and the correlating flow rate procedures as specified in the instructions for use.Patients undergoing an atrial flutter ablation are at risk for complete Atrioventricular AV block which requires the implantation of a temporary and/or permanent pacemaker. There are no data to support the safety and effectiveness of this device in the pediatric population. Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. 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. In the event of a suspected failure of the integrity of fluid flow through the IntellaNav OI Catheter or if there is a rapid temperature rise of greater than 15 degrees C noted on the RF Controller, the procedure should be stopped, and the IntellaNav OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the IntellaNav OI Catheter and the Irrigation Tubing Set should be replaced. 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. Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to IntellaNav OI Catheter failure and/or patient injury. In the event of RF Controller cut-off (impedance or temperature), the IntellaNav OI 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. 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. Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution. This IntellaNav OI 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. If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter 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. **PRECAUTIONS:** The IntellaNav OI Catheter is not intended to be used with a RF generator output setting exceeding 50 W or 200 Volts peak. The IntellaNav™ OI Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. The IntellaNav OI Catheter contains Bis (2-ethyhexyl) phthalate (DEHP). BSC has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BSC has not assessed the residual patient risk associated with phthalates which may be contained in non-BSC ancillary devices required for use in conjunction with the IntellaNav OI Catheter. **POTENTIAL ADVERSE EVENTS:** Potential adverse events which may be associated with catheterization and ablation include: Allergic reaction (including anaphylaxis),Angina, Arrhythmias (new or exacerbation of existing arrhythmias), Cardiac perforation, Cardiac/respiratory arrest, Catheter entrapment, Cerebrovascular accident (CVA), Chest discomfort, Conduction pathway injury,Complete heart block (transient/permanent), Complications of sedative agents/anesthesia, Congestive heart failure, Death, Edema, Effusion (pericardial/pleural), Embolism (venous/arterial) (e.g., air embolism, cerebrovascular accident, Myocardial Infarction (MI), pulmonary embolism), Esophageal Injury, Exacerbation of existing conditions, Fistula (arterial-venous/atrio-esophageal), Fluid volume overload, Gastroparesis/Gastrointestinal (GI) events, Hematoma, Hemorrhage, Hemothorax, Hypertension, Hypotension, Inadvertent injury to adjacent structures, Infection, Lead dislodgement, Myocardial infarction, Nerve injury (phrenic/vagus), Pericarditis, Pleuritis, Pneumothorax, Pseudoaneurysm, Pulmonary/pedal edema,Pulmonary vein stenosis, Radiation exposure, Renal insufficiency/failure, Residual Atrial Septal Defects(ASD), Skin burns (radiation/defibrillator/cardioverter),Tamponade, Transient ischemic attack (TIA), Thrombosis,Valvular damage, Vasospasm,Vasovagal reactions,Vessel trauma (perforation/dissection/rupture). 91164701 (Rev. 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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health autority product registrations. Information not intended for use or distribution in France.

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