Boston Scientific
Advancing science for life™

INTELLANAV MIFI™ OPEN-IRRIGATED
ABLATION CATHETER

Ordering Information: **INTELLANAV MIFI OI** Electrode Configuration: Quadripolar Electrode Spacing: 2.5mm

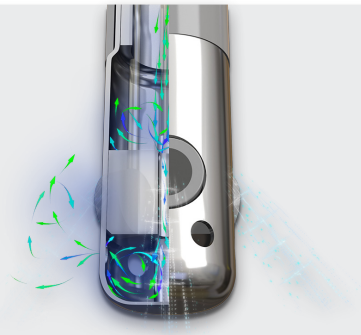
Model Number	Shaft Size	Tip Size	Curve Style	Shaft Length
M004 PMR9620 0	7.5F	7.5F/4.5mm	Standard	110cm
M004 PMR9620K2 0	7.5F	7.5F/4.5mm	Large	110cm
M004 PMR9620N4 0	7.5F	7.5F/4.5mm	Asymmetric	110cm

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



Confident Navigation

Unparalleled Clarity
Truth with multi-dimensional ablation technology.

Total Tip Cooling™
Designed for effective power delivery and reduced potential of char, coagulum and thrombus.

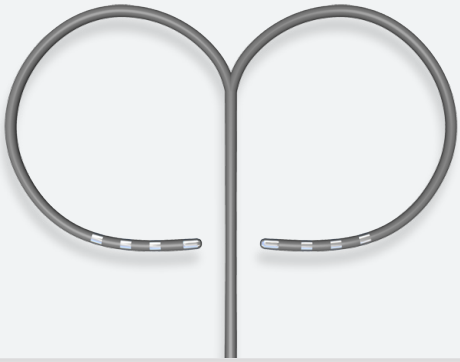
Catheter configurations are illustrative representations only and may not reflect actual performance.

INTELLANAV MIFI™ OPEN-IRRIGATED
ABLATION CATHETER

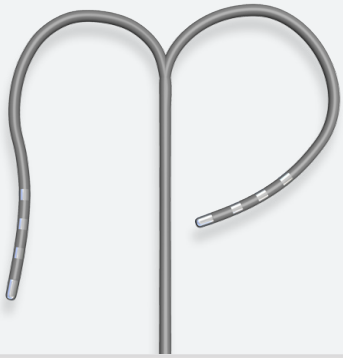
Bidirectional Curve Options

Standard Radius Curve

Large Radius Curve (K2)



Asymmetric 4 Curve (N4)



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NTELLANAV MIFI™ OPEN-IRRIGATED ABLATION CATHETER INTENDED USE/INDICATIONS FOR USE The IntellaNav MiFi™ OI 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 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 MiFi 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** Note: The IntellaNav MiFi OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System. Using the IntellaNav MiFi OI Catheter at lower than prescribed flow rate may increase the potential for thrombus, coagulum, and char that may result in embolism. Collateral tissue damage is a possibility when using the catheter at the upper power setting (50 W) or durations longer than 60 seconds or with a decrease in impedance without moving the catheter tip. Power should be increased to >30 W only if lower energies do not achieve the intended result. 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. Because the long term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children. In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. 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): Temporarily adjust tachytherapy settings of an ICD per the manufacturer guidelines during RF ablation as the device could reset or deliver inappropriate defibrillation therapy resulting in patient injury. The ICD could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reactivate the ICD's preoperative pacing, sensing, and therapy parameters after the ablation procedure. Temporarily reprogram the pacemaker per the manufacturer guidelines during RF ablation to a nontracking 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. Have temporary external sources of pacing and defibrillation available. 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. Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment. 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 tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. In the event of a suspected failure of the integrity of fluid flow through the IntellaNav MiFi OI Catheter or if there is a rapid temperature rise of greater than 15 °C noted on the RF Controller, the procedure should be stopped, and the IntellaNav MiFi OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the IntellaNav MiFi OI 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 the 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. 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 MiFi 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** 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. Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely. **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). 92164033 (Rev. B)

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 authority product registrations. Information not intended for use or distribution in France.

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