INTELLATIP MIFI™ XP Ablation Catheter
INDICATIONS FOR USE: The BSC IntellaTip MiFi™ XP Catheter is indicated for use with the BSC Maestro 3000® Controller, and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures. **CONTRAINDICATIONS:** Do not use this device: in patients with active systemic infection; via the transseptal approach in patients with left atrial thrombus or myxoma; via the retrograde approach in patients with aortic valve replacement. **WARNINGS:** Before operating the device, read these warnings carefully: Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anti-coagulation therapy, 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 therefore be given to pregnant women and pre-pubescent children. 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. Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use. Maximum IntellaTip MiFi XP Catheter Rated Voltage: 178 Vrms (251 Vpk) No modification of this equipment is allowed. 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 atrial flutter 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. Do not pass the IntellaTip MiFi XP 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. **PRECAUTIONS:** Observe these precautions, before using the device: Do not attempt to operate the Controller before thoroughly reading the appropriate BSC high power Cardiac Ablation Controller & Accessories Operator's Manuals. The IntellaTip MiFi XP Catheters are intended for use with the BSC Controller and accessories only. The IntellaTip MiFi XP Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than one and one-half times the full rotation (540 degrees). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall before resuming rotation of the handle and catheter shaft. 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. Excessive bending or kinking of the catheter shaft may damage internal wires. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury. Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in the techniques of RF Powered catheter mapping and ablation in a fully-equipped electrophysiology laboratory. Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block. Adequate filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECG) during RF power applications. When using the IntellaTip MiFi XP Catheter, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller. Placement of the DIP electrodes on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces. Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Regularly inspect and test re-usable cables and accessories. **ADVERSE EVENTS:** Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to: allergic reaction (including anaphylaxis), angina, arrhythmias , arterial or pulmonary embolism, arterial-venous fistula, atrioventricular node damage (transient/permanent), back pain and/or groin pain, cardiac perforation, cardiac respiratory arrest, catheter entrapment, complete heart block (transient/permanent), cerebral vascular accident, chest pain/discomfort, complications of sedative agents (e.g. aspiration pneumonia), death effusion (pericardial/pleural), hematoma/bruising, hemoptysis, hemorrhage, hemothorax, hypotension, infection, myocardial infarction, nerve palsy or weakness, pericarditis, phrenic nerve damage/diaphragmatic paralysis, pleurisy, pneumothorax, pulmonary edema, pseudoaneurysm, radiation exposure, sinoatrial node damage, skin burn (defibrillator/cardioverter/radiation), tamponade, transient ischemic attack (TIA), valvular damage, vasovagal reactions, visual blurring. 92289667 (Rev. A)

INTELLATIP MIFI™ OPEN-IRRIGATED Ablation Catheter
INDICATIONS FOR USE: The IntellaTip 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 IntellaTip 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 IntellaTip MiFi OI Catheter is not designed to be compatible with the Maestro 3000™ Cardiac Ablation System. Using the IntellaTip MiFi OI Catheter at lower than prescribed flow rate may increase the potential for thrombus, coagulum, and char that may result in embolism. 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 prepubescent 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 pre-operative 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. 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. 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 IntellaTip 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:** The IntellaTip MiFi 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 IntellaTip MiFi OI Catheter. 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). 92096509 (Rev. B)

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

1. Avitall B, Horbal P, Vance D, et al. Determinants of atrial lesion maturation during radio frequency ablation using localized tissue electrograms. J Innov Cardiac Rhythm Manage. 2014;5:1574-1585.
2. Avitall B, Horbal P, Vance D, et al. Maximal electrogram attenuation recorded from mini electrodes embedded on 4.5-mm irrigated and 8-mm nonirrigated catheters signifies lesion maturation. J Cardiovasc Electrophysiol. 2015 Feb;26(2):192-202.
3. Lo LW, Lin YJ, Chang HY, et al. A novel map and ablate technology to identify the arrhythmogenic atrial substrate. Poster session presented at Heart Rhythm Society; 2012 May; Boston, MA. IA02-8 (Right atrial canine model utilizing EnSite™ NavX™, n=9).
4. Maddox W. The IntellaTip MiFi XP Ablation Catheter: Thoughts from a young electrophysiologist. Presented at Boston Scientific National Sales Meeting; 2013 January; Orlando FL. EP-222201-AA.

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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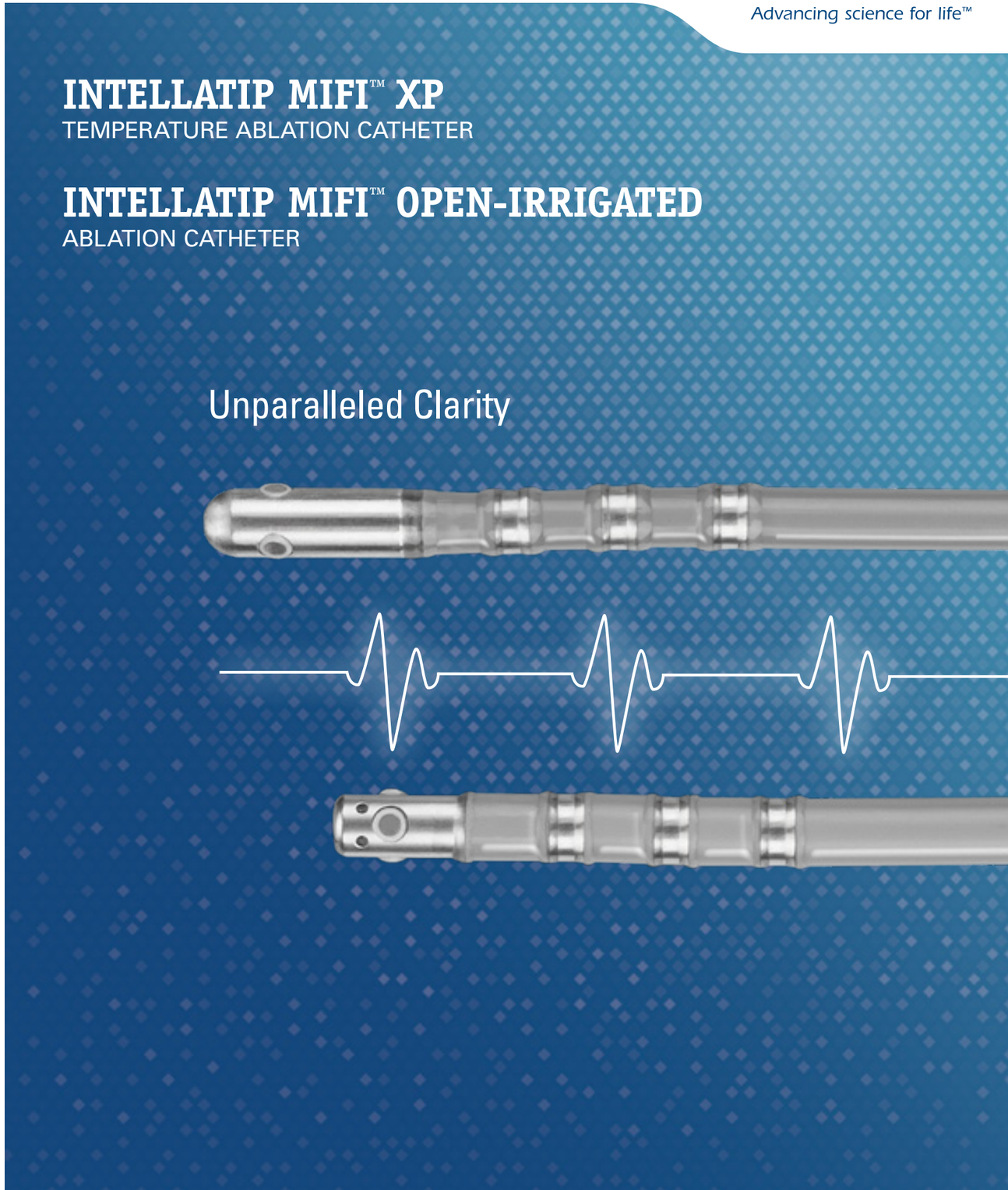
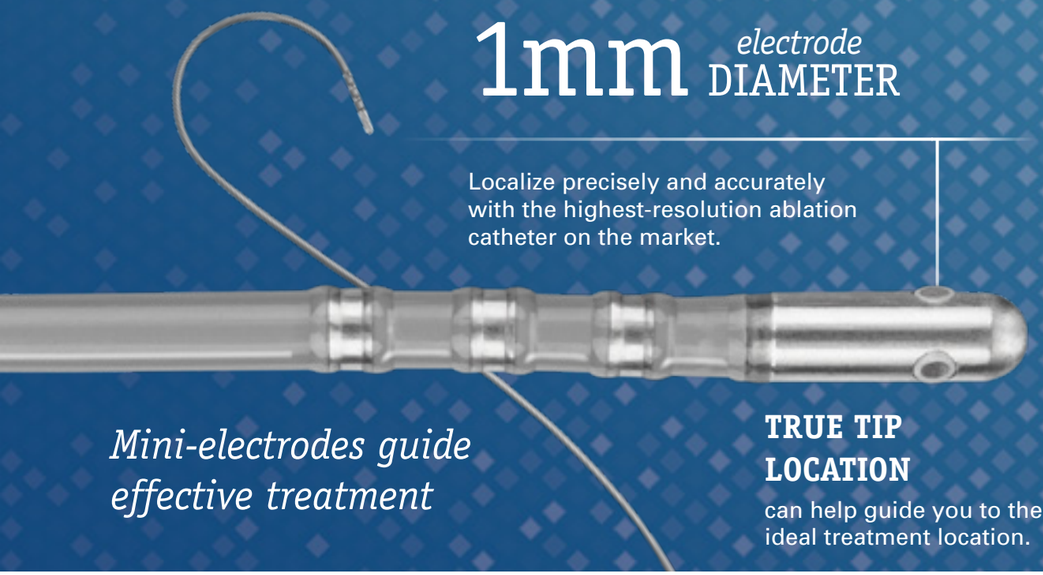
INTELLATIP MIFI™ XP
TEMPERATURE ABLATION CATHETER

INTELLATIP MIFI™ OPEN-IRRIGATED
ABLATION CATHETER

Unparalleled Clarity



INTELLATIP MIFI™ XP
TEMPERATURE ABLATION CATHETER



1mm *electrode* DIAMETER

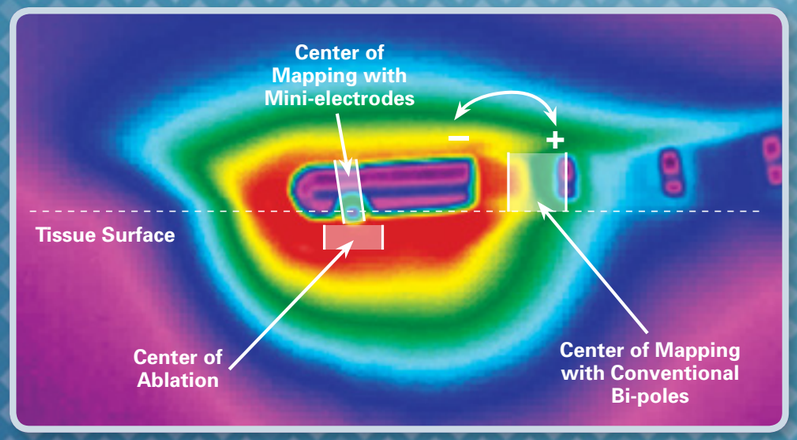
Localize precisely and accurately with the highest-resolution ablation catheter on the market.

Mini-electrodes guide effective treatment

TRUE TIP LOCATION
can help guide you to the ideal treatment location.

Highly Localized Recording at the Center of Ablation

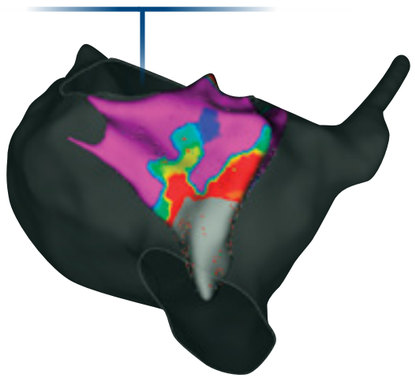
- Mini-electrodes, located at the distal tip, engineered to reduce the gap between mapping and ablation
- Closely positioned mini-electrodes designed to exclude far-field signals



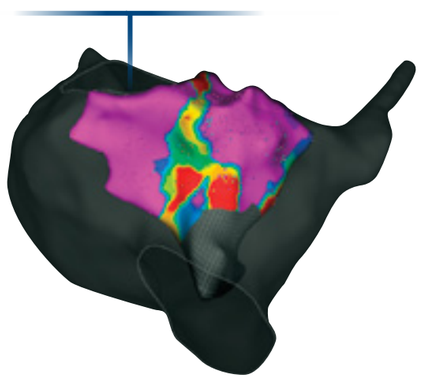
True Tissue Assessment

MiFi technology provided a higher sensitivity and specificity in helping to identify atrial fibrosis and abnormal substrate.

CONVENTIONAL ELECTRODES



MIFI ELECTRODES



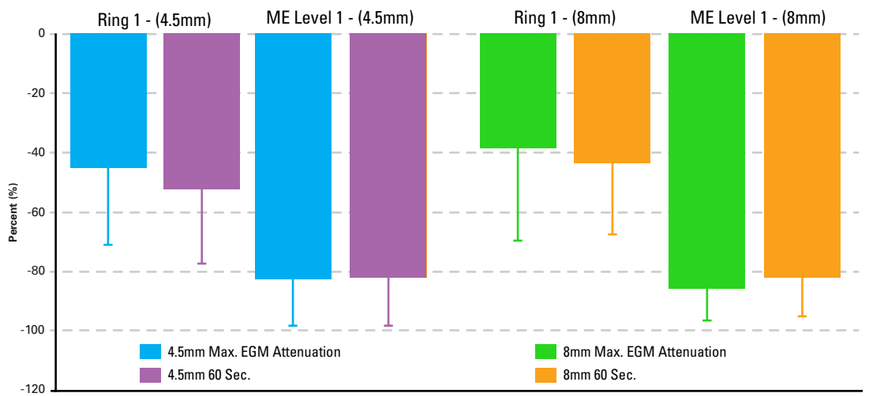
Case images courtesy of Kevin Makati, MD, St. Joseph's Hospital, Tampa, FL.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Advanced Lesion Transmurality Detection

- EGMs with mini-electrodes showed a more substantial reduction in amplitude compared to common bi-poles.[1]
  - Reduction recorded with the mini-electrodes was -82.1% ± 16.2% (4.5mm) and -85.8% ± 10.7% (8mm) (P=NS between catheter but P < 0.001% between ME vs. tip-ring).[2]
- Mini-electrode guided ablation resulted in **91%** transmural lesions for the 4.5mm and **96%** transmural lesions for the 8mm catheter.
- Ablation to maximal EGM attenuation on the mini-electrodes reduced the potential of extracardiac injuries.[2]
- The RF application time to achieve maximal EGM attenuation with the 4.5mm ME OI catheter was 23.4 ± 7.8 seconds and with 8mm 25.9 ± 8.1 seconds (P = NS).

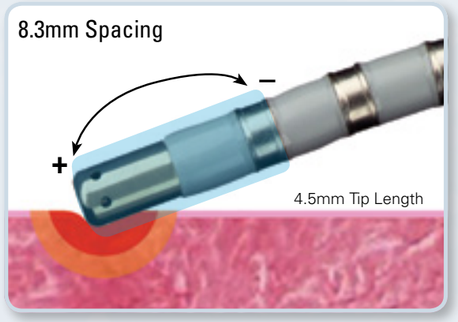
Atrial EGM % Reduction 4.5mm OI vs. 8mm; Maximal EGM Attenuation vs. 60 sec.



Study RF Generator Settings: 4.5mm - 30W, 35 degrees, 15mL/min. 8mm - 65W, 65 degrees, temp mode

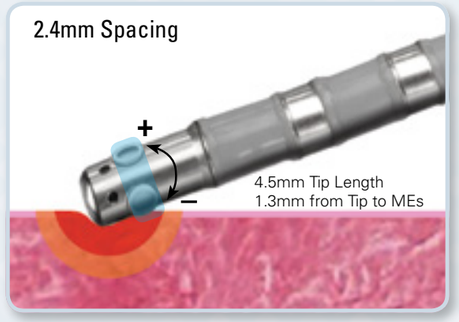
True Tip Location

Can help guide you to the ideal treatment location.



Conventional Bi-Poles (CBPs)

- Capture larger far-field signals
- Provide an antenna length that extends beyond site of ablation
- Cannot pace and ablate simultaneously



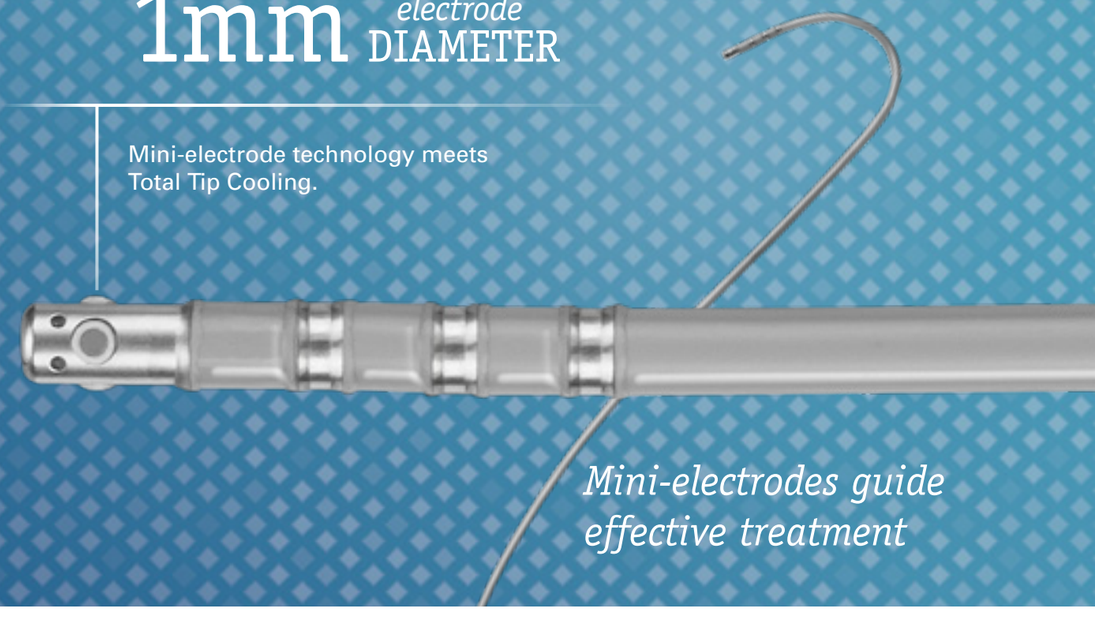
Mini-Electrodes (MEs)

- Provide more accurate recording of focal area[3]
- Allow recording at the precise site of ablation
- Enable pace capabilities during ablation

INTELLATIP MIFI™ OI
ABLATION CATHETER

1mm *electrode* DIAMETER

Mini-electrode technology meets
Total Tip Cooling.

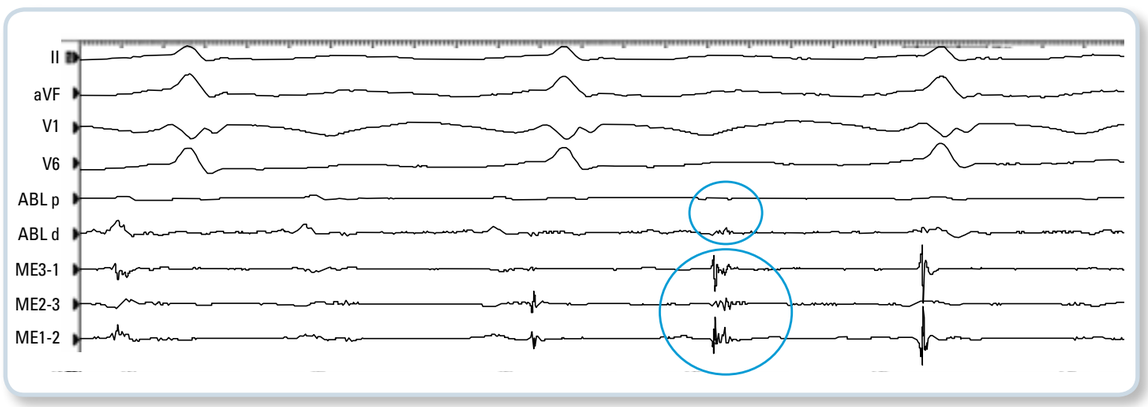


Mini-electrodes guide effective treatment

True Tissue Assessment

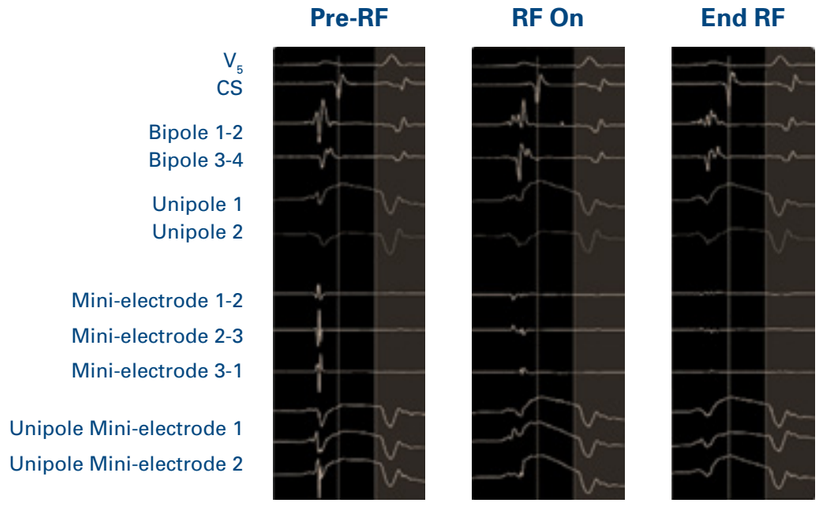
Gap Identification

- Mini-electrode signal fidelity provided enhanced gap detection over conventional bi-poles[4]



True Ablation Feedback

INTELLATIP MIFI technology demonstrates a significant amplitude reduction and signal clarity during ablation as compared to bi-polar electrograms.



Case images courtesy of W. Jackman, MD, University of Oklahoma Health Sciences Center.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

INTELLATIP MIFI™ XP Temperature Ablation Catheter

Ordering Information

Electrode Configuration: Quadripolar Electrode Spacing: 2.5mm

Model Number	Shaft Size	Tip Size	Curve Style	Cable Model Number
M004 PM4500 0	7F	8F/8mm	Standard	M004 620 0
M004 PM4500K2 0	7F	8F/8mm	Large	M004 620 0
M004 PM4790 0	7F	8F/10mm	Standard	M004 620 0
M004 PM4790K2 0	7F	8F/10mm	Large	M004 620 0

INTELLATIP MIFI XP Catheter is indicated for use with an 8.5F sheath
All INTELLATIP MIFI XP Catheters are 110cm in length
All INTELLATIP MIFI XP Catheters require the use of 2 Valleylab® Ground Pads (Model M004 354 1)

Cables and Accessories

Model Number	Description
M004 620 0	INTELLATIP MIFI XP Ablation Catheter Cable (10 ft)
M004 1212 0	INTELLATIP MIFI Filter Module (reference cable included)
M004 3636 0	Reference Cable from Filter Module to Pod (32 in)
M004 653S 0	Cable from Filter Module or Pod to Recorder (2 required)

INTELLATIP MIFI™ OPEN-IRRIGATED Ablation Catheter

Ordering Information

Electrode Configuration: Quadripolar Electrode Spacing: 2.5mm

Model Number	Shaft Size	Tip Size	Curve Style	Cable Model Number
M004 PM9620 0	7.5F	7F/4.5mm	Standard	M004 627 0
M004 PM9620K2 0	7.5F	7F/4.5mm	Large	M004 627 0
M004 PM9620N4 0	7.5F	7F/4.5mm	Asymmetric	M004 627 0

INTELLATIP MIFI OI Catheter is indicated for use with an 8F sheath
All INTELLATIP MIFI OI Catheters are 110cm in length
All INTELLATIP MIFI OI Catheters require the use of 1 Valleylab® Ground Pad (Model M004 354 1)

Cables and Accessories

Model Number	Description
M004 627 0	INTELLATIP MIFI OI Ablation Catheter Cable (10 ft)
M004 1212 0	INTELLATIP MIFI Filter Module (reference cable included)
M004 3636 0	Reference Cable from Filter Module to Pod (32 in)
M004 653S 0	Cable from Filter Module or Pod to Recorder (2 required)
M004 117 0	METRIQ™ Irrigation Tubing Set

Bidirectional Curve Options

Standard Radius Curve

Large Radius Curve (K2)

Asymmetric 4 Curve (N4)

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

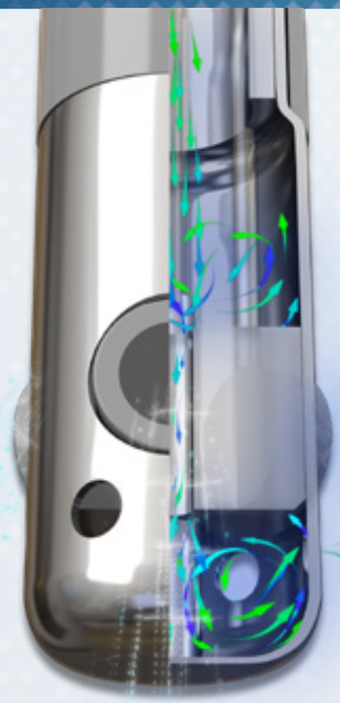
INTELLATIP MIFI™ OI TECHNOLOGY

only from Boston Scientific

Unparalleled Clarity. Cool Performance.

MiFi Mini-Electrode Technology

- Provide more accurate recording of a focal area[1]
- Allow recording at the precise site of ablation
- Enable pacing capabilities during ablation



Total Tip Cooling

- Dual internal chamber cooling
- Proximal directed exit flow cools the entire tip electrode externally
- Designed to reduce potential of char, coagulum and thrombus