INTELLATIP
MiFi™ XP
Unparalleled Clarity
The IntellaTip MiFi™ XP, with MicroFidelity (MiFi) sensor technology, introduces a new generation of high-resolution ablation catheters. IntellaTip MiFi technology, only from Boston Scientific, is engineered to deliver highly localized electrical information of unparalleled clarity to allow you to see the critical information you need, in real-time.

True Tip Location. True Tissue Assessment. True Ablation Feedback.

3 Sophisticated Mini-Electrodes

- Enable localized recording of a small area
- Deliver signals with unparalleled clarity
- Allow multiple channels for highly localized EGMs
True Tip Location

Unique design of the IntellaTip MiFi™ XP catheter allows for precise identification of the catheter tip 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

Accurate EGM Localization

- EGMs with mini-electrodes provide accurate information of tip location
- Mini-electrode electrograms clearly demonstrate when the tip enters the right atrium

1. Data on File. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
True Tissue Assessment

Highly localized signal, from the mini-electrodes, allows for distinction between viable and non-viable tissue types with more accuracy.

**Tissue Substrate Identification**

- IntellaTip MiFi™ XP technology provides higher specificity and sensitivity in predicting atrial fibrosis and identifying abnormal substrate ²

**Gap Identification**

- In an atrial flutter clinical trial, EGMs from the mini-electrodes provided information to help identify conduction gaps in the line of block that were not visible using conventional recording ³

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² Chen S., et al. (May, 2012). A Novel Map and Ablate Technology to Identify Arrhythmogenic Atrial Substrate. Poster session presented at Heart Rhythm Society, Boston, MA. (Right atrial canine model utilizing EnSite NavX™, n=9). Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

³ Sanders P. Royal Adelaide Hospital, Australia. Data on File. (MiFi CTI clinical trial, n=10). Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
True Ablation Feedback

The IntellaTip MiFi™ catheter technology provides more effective ablation EGM information and lesion maturation feedback in thin tissue.

Lesion Maturation Feedback

- EGM amplitude reduction, post ablation, was greater when measured with mini-electrodes compared to conventional 8 mm tip.
- EGM amplitude reduction on the mini-electrodes, post ablation, was correlated to transmurality.

<table>
<thead>
<tr>
<th>Electrodes</th>
<th>Amplitude in mV</th>
<th>% values indicate % reduction in maximum EGM amplitude between pre and post ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conv. Bipole Pair</td>
<td>27.3%</td>
<td>27.3%</td>
</tr>
<tr>
<td>ME Pair (Max Amp Reduction)</td>
<td>77.3%</td>
<td>77.3%</td>
</tr>
<tr>
<td>ME Pair (Int. Amp Reduction)</td>
<td>69.4%</td>
<td>69.4%</td>
</tr>
<tr>
<td>ME Pair (Low Amp Reduction)</td>
<td>63.0%</td>
<td>63.0%</td>
</tr>
</tbody>
</table>

Redefining Ablation Technology

At Boston Scientific, we are committed to delivering innovative technologies designed to help increase first procedure success rates.

The IntellaTip MiFi XP catheter marks the first time that a single catheter has been able to present a true, multi-dimensional picture of exactly what is happening at and around the tip of the ablation catheter. This is just another step forward in our journey toward redefining ablation technology.

To learn more about Boston Scientific’s breakthrough ablation technologies visit [http://www.bostonscientific.com/redefining-ep](http://www.bostonscientific.com/redefining-ep).

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**IntellaTip MiFi XP Temperature Ablation Catheter**

**Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events**

**INDICATIONS FOR USE** The Boston Scientific Corporation (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 anticoagulation 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 tissue. Care must be taken to ensure that any equipment 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. Rotating 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 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 misapplications. Regularly inspect and test re-usable cables and accessories. **POTENTIAL 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, arrhythmia, arterial or pulmonary embolism, 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, hemorhox, 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.

**CAUTION** Federal Law (USA) restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

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**Cables and Accessories**

<table>
<thead>
<tr>
<th>Model No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 1212 0</td>
<td>Filter Module (reference cable included)</td>
</tr>
<tr>
<td>M004 3636 0</td>
<td>Reference Cable from Filter Module to Pod (32 in)</td>
</tr>
<tr>
<td>M004 620 0</td>
<td>Cable from Catheter to Pod and to Filter Module (10 ft)</td>
</tr>
<tr>
<td>M004 653S 0</td>
<td>Cable from Filter Module or Pod to Recorder (2 required)</td>
</tr>
</tbody>
</table>

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**IntellaTip MiFi XP Temperature Ablation Catheter Information**

- **Electrode Configuration: Quadrupolar**
- **Electrode Spacing: 2.5 mm**
- **Indicated for use with an 8.5F sheath**

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**Bidirectional Curve Options**

- **Standard Radius Curve**
- **Large Radius Curve (K2)**
- **Asymmetrical-4 Curve (N4)**