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IntellaTip MiFi™ XP
Temperature Ablation Catheter

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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.

DEVICE DESCRIPTION
The IntellaTip MiFi XP Temperature Ablation Catheter (henceforth, referred to as the IntellaTip MiFi XP Catheter) is a quadripolar ring electrode cardiac ablation catheter, which includes three diagnostic mini electrodes embedded in the tip electrode that are designed to provide additional localized electrogram information. It is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities. The IntellaTip MiFi XP Catheter is available with an 8F (2.67 mm) diameter tip and 2 electrode tip lengths, 8 mm and 10 mm (Figure 1 illustrates the IntellaTip MiFi XP Catheter).

The IntellaTip MiFi XP Catheter is capable of accessing high power (up to 100 watts/2 amperes) using a Maestro Radiofrequency (RF) Cardiac Ablation Controller, (henceforth, referred to as the Controller).

The IntellaTip MiFi XP Catheter connects to the Controller via a Maestro Pod (henceforth, referred to as the Pod). The Pod allows additional connections to standard hospital Electrophysiology (EP) recorders / monitors. The IntellaTip MiFi XP Catheter also connects to the IntellaTip MiFi Filter Module (henceforth, referred to as the Filter Module). The Filter Module provides electrical filtering specifically for the mini electrodes.

Note: The IntellaTip MiFi XP Catheter has not been qualified for use with the EPT-1000XP™ / EPT-1000P™ Cardiac Ablation Systems.

User Information
The IntellaTip MiFi XP Catheter is to be used by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation and in the specific approach to be used, in a fully-equipped electrophysiology laboratory.

Contents
One (1) Sterile IntellaTip MiFi XP Catheter

INTENDED USE / INDICATIONS FOR USE
The BSC IntellaTip MiFi XP Catheter is indicated for interruption of accessory Atrioventricular (AV) conduction pathways associated with tachycardias, for treatment of AV nodal reentrant tachycardia, for treatment of atrial flutter tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia – typically chronic, drug refractory atrial fibrillation.

CONTRAINDICATIONS
Do not use this device:

- In patients with active systemic infection;
- Via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
- Via the retrograde transaortic approach in patients with aortic valve replacement;
- In patients 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:

- Before using, inspect for physical damage including electrical insulation on the cables and the IntellaTip MiFi XP Catheter shaft. Replace damaged equipment.
- 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 ablation 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.
- There are no patient safety and effectiveness data with this catheter for left-sided atrial flutter and/or pulmonary vein isolation for atrial fibrillation.
- 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.
- Peri-procedural anticoagulation 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.
- During RF ablation, care must be taken not to deliver RF energy on or near the coronary artery even on the right side of the heart, as the resulting myocardial injury can be fatal.
- Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation which may result in embolism.
- It is important to start each RF application at low power and carefully follow the power titration as specified in the instructions for use. Too rapid an increase in power during ablation may lead to arrhythmias, damage to adjacent structures, embolism and/or perforation caused by steam pop.
- Stimulation of cardiac tissues caused by pacing stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may need defibrillation that could also result in skin burns.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation and in the specific approach to be used, in a fully-equipped electrophysiology laboratory.

Note: The IntellaTip MiFi XP Catheter can access high power (100 watts/2 amperes) only when used with the Controller, Pod and accessories. Attempting to use the IntellaTip MiFi XP Catheter with a non-Maestro Controller results in a maximum delivery of 50 watts/1 amperes.

For all ablation catheters, RF power is delivered between the catheter's distal electrode and two commercially available external Dispersive Pads. The use of Dispersive Pads, which meet or exceed IEC 60601-2-2 requirements, is required.

A summary of the technical specifications for the IntellaTip MiFi XP Catheter is provided in Table 1, Technical Specifications.

Table 1. Technical Specifications

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>STERILE</td>
</tr>
<tr>
<td>EO Sterilization</td>
<td>Single Use Only</td>
</tr>
<tr>
<td>Distal Torque Attributes</td>
<td>High torque</td>
</tr>
<tr>
<td>Handle Design</td>
<td>IntellaTip MiFi XP Catheter handle</td>
</tr>
<tr>
<td>IntellaTip MiFi XP Catheter Length</td>
<td>60 cm to 130 cm</td>
</tr>
<tr>
<td>IntellaTip MiFi XP Catheter Shaft Diameter</td>
<td>7F (2.3 mm)</td>
</tr>
<tr>
<td>Distal-Tubing Length</td>
<td>6.6 cm to 15 cm</td>
</tr>
<tr>
<td>Stiffness</td>
<td>Firm</td>
</tr>
<tr>
<td>Tip Electrode without Mini Electrodes</td>
<td>8F (2.67 mm) / 8 mm</td>
</tr>
<tr>
<td>Tip Electrode with Mini Electrodes</td>
<td>Compatible with 8.5F sheath</td>
</tr>
<tr>
<td>Curve Configuration</td>
<td>Standard, K2</td>
</tr>
<tr>
<td>Symmetric</td>
<td>N4</td>
</tr>
<tr>
<td>Asymmetric</td>
<td></td>
</tr>
<tr>
<td>Electrode Spacing</td>
<td></td>
</tr>
<tr>
<td>Tip-to-First-Ring Ring-to-Ring</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>2.5 mm</td>
<td></td>
</tr>
<tr>
<td>Electrode Configuration</td>
<td>Quadrupolar (4 electrodes)</td>
</tr>
<tr>
<td>Mini Electrode Configuration</td>
<td>3 electrodes, radially spaced 120° apart</td>
</tr>
<tr>
<td>Mini Electrode Diameter</td>
<td>1.19 mm</td>
</tr>
<tr>
<td>Ring Electrode Length</td>
<td>1.25 mm</td>
</tr>
<tr>
<td>Electrical Connectors</td>
<td>Quick Connect</td>
</tr>
</tbody>
</table>

Note: thermoquad polarizing sheath.
• Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet IEC 68061-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.

• Maximum IntellaTip MiFi™ Catheter Rated Voltage: 176 Vrms (251 Vpk).

• When using the IntellaTip MiFi XP Catheter, it is required that two Dispersive Pads which meet or exceed the requirements of IEC 60601-2-2 be used as the ablation return electrodes or skin burns may result. Use of only one Dispersive Pad will not allow the operator to fully access the higher power capabilities of the Controller.

• Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as 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. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure.

• Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and prepubescent children.

• Patients undergoing AV nodal modification or ablation of septal accessory pathways are at risk for inadvertent AV block. It is advisable to use lower initial power in such patients and to monitor anterior conduction closely during RF power delivery.

• Pacemakers and implantable cardioverters / 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 O00 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.
  e. Deactivate implanted cardioverters / defibrillators during delivery of RF power.
  f. Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment.

• During a transaortic approach, adequate fluoroscopic visualization is necessary to avoid placement of the ablation catheter within the coronary vasculature. Catheter placement and RF power application within the coronary artery has been associated with myocardial infarction and death.

• Patients undergoing left sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, embolism and/or atrial esophageal fistula.

• 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 vicinity of the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

• Use of catheter or cables with unprotected male pin connectors present a risk. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator.

• Caution should be given to patients undergoing cardiac RF ablation procedures who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation to reduce risk of embolism.

• To avoid patient injury, manipulate the sheath carefully when performing the transseptal puncture especially if the patient has any of the following conditions:
  • Enlarged aortic root
  • Marked right atrial enlargement
  • Small left atrium
  • Marked skeletal deformity or distortion of the thoracic configuration (e.g. scoliosis)

• If using a long sheath, fibrin may accumulate in or on the sheath / catheter assembly during the procedure.

• Aspirate when removing the dilator or catheter.

• Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.

• Do not deliver RF energy at the upper power setting without moving the tip of the catheter to reduce the incidence of perforation and/or tamponade.

• The Boston Scientific IntellaTip MiFi XP Catheters are intended for use with the BSC high power Controllers and accessories only.

• No modification of this equipment is allowed.

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.

• Do not use the IntellaTip MiFi XP Cardiac Ablation System in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of a RF generator and the ablation system may adversely impact the image quality.

• Do not deliver RF energy with the catheter outside the target site. RF generators can deliver significant electrical energy and may cause patient or operator injury.

• 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 rotations (90 degrees). If the desired catheter tip position is not achieved, adjust the catheter’s curve to disengage the tip from the heart wall before resuming rotation of the handle and catheter shaft.

• Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.

• 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 Cardiac Ablation 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.

• 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.

• Adequate filtering must be used to allow continuous monitoring of the surface Electrocardiogram (ECG) during RF power applications.

• 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. Furthermore, the risk / benefit in asymptomatic patients has not been studied.

• The Cardiac Ablation Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and Dispersive Pads, particularly when operating the device.

• During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.

• Placement of the Dispersive Pads on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.

• Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the Dispersive Pads or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.

• Avoid use of electrodes and stimulating devices that could provide paths for high frequency current. Reduce the burn hazard by placing the electrodes as far away as possible from the ablation site and the Dispersive Pads.

• The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the ablation procedures are performed.

• Electromagnetic Interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.

• When crossing the aortic valve with the IntellaTip MiFi XP Catheter, it is recommended that the catheter tip be deflected to resemble a “pigtail” curve to avoid damage to the valve leaflets.

• Regularly inspect and test reusable cables and accessories.

• For optimal use ensure the catheter and cable connections remain dry throughout the procedure.

POTENTIAL 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
• Angina
• Arrhythmias (new or exacerbation of existing arrhythmias)
• Atrioventricular node damage (transient / permanent)
ATMOSPHERIC PRESSURE: 70 kPa to 106 kPa

HANDLING AND STORAGE
Do not use if package is opened or damaged.

INSTRUCTIONS FOR USE

1. Prepare connections from the IntellaTip MiFi XP Catheter to the Filter Module and Pod with the appropriate heart chamber.

2. Install the two Dispersive Pad connectors into the “INDIFFERENT ELECTRODE” ports located on the front panels of the Pod.

3. Connect the Pod to the ISOLATED PATIENT CONECTOR located on the Controller’s front panel using the attached patient cable.

4. Connect the red cable plug into the center port marked “Recording System” on the Filter Module.

5. Connect the yellow cable plug into the port marked “Reference Electrode” on the Filter Module.

6. Connect the 2-prong plug-end of the Reference Cable to the port marked “Reference Electrode” on the Filter Module.

7. Connect the 2-prong socket-end of the Reference Cable to the “INDIFFERENT ELECTRODE” port on the Pod.

MATERIALS REQUIRED
Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. In addition to the IntellaTip MiFi XP Catheter, the following devices and materials will be required:

- IntellaTip MiFi XP to Maestro Cable
- Maestro RF Cardiac Ablation Controller
- Maestro Pod
- IntellaTip MiFi Filter Module
- Filter Module to RF Pod Cable (henceforth, referred to as the Reference Cable)
- Two (2) Pod or Filter Module to Recorder Cable

ACCESSORIES:
- IntellaTip MiFi XP CATHETER INSPECTION, SET UP, AND OPERATION

INSPECTION PRIOR TO USE
Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative. Check the “Use By” date on the device package.

Prior to use of the BSC high power Cardiac Ablation System, the individual components including the IntellaTip MiFi XP Catheter, the Controller, Filter Module, Pod, IntellaTip MiFi™ Reference Cable (henceforth referred to as the Reference Cable), Quick Connect Instrument Cable(s), and Foot Switch should be carefully examined for damage or defects as should all equipment used in the procedure.

Do not use defective equipment.

SETTING UP THE SYSTEM
Refer to the Controller & Accessories Operator’s Manuals for detailed instructions for connecting the system and setting ablation parameters.

ATTACHING THE DISPERSIVE PADS
Read the manufacturer’s manual before installing the Dispersive Pads.

1. Place two Dispersive Pads on the patient on a well-vascularized, convex skin surface that is in close proximity to the skin surface of the back (left upper quadrant of the back is suggested unless the patient’s scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area.

2. Avoid scar tissue, bony prominences, adipose tissue or distal areas from the heart (thigh), or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.

3. Install the two Dispersive Pad connectors into the “INDIFFERENT ELECTRODE” ports located on the front panels of the Pod. See Step 5 below to insert the Reference Cable in between the Dispersive Pad connectors and the Pod.

Figure 2 illustrates the setup for the IntellaTip MiFi XP Catheter, Controller, and compatible cables.

DIRECTIONS FOR USE
Prior to insertion of the IntellaTip MiFi XP Catheter, prepare the entry site according to standard aseptic practices.

Size the 8.5F hemostatic introducer sheath, according to the tip electrode diameter for the cardiac ablation catheter in use.

1. Insert the catheter percutaneously into the appropriate vein by the Seldinger technique using an 8.5F hemostatic introducer and/or a long sheath.

2. Once inside the vessel, the catheter tip can be deflected as necessary to facilitate advancement into the selected heart chamber.

3. Connect the Pod to the ISOLATED PATIENT CONECTOR located on the Controller’s front panel using the attached patient cable. Be sure to carefully follow the instructions in the Controller and Accessories Operator’s Manual prior to making any connections.

4. Prepare connections from the IntellaTip MiFi XP Catheter to the Filter Module and Pod with the IntellaTip MiFi XP Catheter to Maestro Cable following the connection sequence below.

a. Connect the black cable plug into the IntellaTip MiFi XP Catheter.

b. Connect the red cable plug into the center port marked “STD/XP” on the Pod.

c. Connect the yellow cable plug into the port marked “Reference Electrode” on the Filter Module.

Note: If the cable needs to be disconnected for any reason, disconnect the cable from the Pod. Then reconnect the black cable plug into the IntellaTip MiFi XP Catheter followed by connecting the red cable plug into the center port marked “STD/XP” on the Pod.

5. Prepare connections from the Filter Module to the Recording System with the Pod or Filter Module to Recorder Cable.

a. Connect the quick connect cable plug into the port marked “Recording System” on the Filter Module.

b. Connect the red cable plug into the center port marked “STD/XP” on the Pod.

c. Connect the yellow cable plug into the port marked “Catheter Cable” on the Filter Module.

6. Prepare connections from the Pod to the Filter Module.

a. Connect the 2 mm shrouded pins to the “INDIFFERENT ELECTRODE” on the Filter Module.

b. Connect 1 additional Dispersive Pad directly to the remaining port marked “INDIFFERENT ELECTRODE” on the Pod.

Black (K) v5.0
7. Refer to the figures in this manual and that of the Controller, Filter Module, and Cables and verify all cable connections.

8. When the ablation site has been accessed and the tip of the catheter is in contact against the endocardial surface, intracardiac electrogram signals may be obtained. Bipolar electrogram recordings can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes even during RF ablation.

Note: The mini electrodes on the IntellaTip MiFi™ XP Catheter may also be used to provide additional electrogram information.

9. The IntellaTip MiFi Catheter or a multi-polar catheter can be used to assess bidirectional conduction across the isthmus.

10. When the targeted site has been located, the IntellaTip MiFi XP Catheter can be used therapeutically in the “Ready” mode to deliver RF energy. RF power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue.

11. Use lower power first when first delivering RF energy, begin by using a low power setting (i.e., 50 W). If the created lesion is unsuccessful or inadequate, incrementally increase the power output with successive ablation attempts to minimize the potential for thrombus formation and/or inadvertent damage to cardiac tissues.

12. Ensure that the ablation parameters are set as instructed in the appropriate Controller and Accessories Operator’s Manual.

Note: The Controller automatically adjusts power (up to a maximum of 100 watts), within a user-selected upper power limit, to achieve the desired temperature, in the Temperature Control mode.

13. The IntellaTip MiFi XP Catheter tip curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation.

Note: The Maestro Cardiac Ablation Systems are designed so that the temperature set limit cannot exceed 80 ºC in Temperature Control Mode.

14. To begin RF power delivery, press the RF POWER CONTROL Button on the Controller’s front panel once or hold the Foot Switch down. The POWER Display shows the RF power delivered to the IntellaTip MiFi XP Catheter (in watts).

15. During RF delivery, monitor key parameters and adjust therapy delivery accordingly.

16. If any of the following conditions occur during operation, discontinue RF power delivery and perform corrective action as indicated. If a problem is encountered during the procedure, first ensure that all connections are secure and correct, then follow the steps in Table 2.

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible Cause</th>
<th>Corrective Action Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of temperature rise</td>
<td>Inadequate contact between electrode and tissue</td>
<td>1. Discontinue RF delivery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Adjust catheter position to contact and stability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Reinitiate RF delivery</td>
</tr>
<tr>
<td>Low temperature</td>
<td>Electrode not stable on endocardium</td>
<td>1. Discontinue RF delivery</td>
</tr>
<tr>
<td>Fluctuating temperature</td>
<td></td>
<td>2. Adjust catheter position to contact and stability</td>
</tr>
<tr>
<td>Fluctuating power</td>
<td></td>
<td>3. Reinitiate RF delivery</td>
</tr>
<tr>
<td>Sudden drop in temperature</td>
<td>Loss of contact or shift in electrode position</td>
<td>1. Discontinue RF delivery immediately to prevent ablation of non-targeted tissue</td>
</tr>
<tr>
<td>Sudden rise in power</td>
<td></td>
<td>2. Tip position should be assessed using fluoroscopic and electrogram information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Reinitiate RF delivery</td>
</tr>
</tbody>
</table>

CATHETER REMOVAL

1. Prior to removing the catheter, straighten the distal end of the catheter completely.

2. Withdraw the catheter from the vessel.

3. Remove the introducer and/or long introducer sheath and then follow standard practice for management of the insertion site.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.
Figure 1. IntellaTip MiFi™ XP Catheter

Figure 2. System Set up for IntellaTip MiFi XP Catheter, Controller, and Compatible Cables