Boston Scientific

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IntellaTip MiFi™ XP

Temperature Ablation Catheter

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℞ ONLY

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 reuse, 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 Temperature Ablation Catheter).

The IntellaTip MiFi XP Catheter is capable of accessing high power up to (100 Watts/2 Amps) using the BSC Cardiac Ablation Controller, (henceforth, referred to as the Controller).

The IntellaTip MiFi XP Catheter connects to the Controller via the radiofrequency (RF) Cardiac Ablation Pod (henceforth, referred to as the Pod). The Pod allows additional connections to standard hospital electrophysiology 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-1000XPT Cardiac Ablation Systems.

Boston Scientific Corporation (BSC) recommends operating the Controller in Temperature Control mode to access high power (100 Watts/2 Amps).

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

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

Description	Specification
Sterilization EO Sterilization Single Use Only	STERILE
Distal Torque attributes	High Torque
Handle Design	IntellaTip MiFi XP Catheter Handle
IntellaTip MiFi XP Catheter Length	60 cm to 130 cm
IntellaTip MiFi XP Catheter Shaft Diameter	7F (2.3 mm)
Distal-Tubing Length Stiffness	 6.6 cm to 15 cm Firm
Tip Electrode without Mini Electrodes	8F (2.67 mm) / 8 mm 8F (2.67 mm) / 10 mm
Tip Electrode with Mini Electrodes	Compatible with 8.5F Sheath
Curve Configurations Symmetric Asymmetric	 Standard, K2 N4
Electrode Spacing Tip-to-First-Ring Ring-to-Ring	 2.5 mm 2.5 mm
Electrode Configuration	Quadripolar (4 Electrodes)
Mini Electrode Configuration	3 electrodes, radially spaced 120° apart
Mini Electrode Diameter	1.19 mm
Ring Electrode Length	1.25 mm
Electrical Connectors	Quick Connect

INDICATIONS FOR USE

The BSC IntellaTip MiFi™ XP Catheter is indicated for use with the Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The 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 Controller & Accessories Operator's Manuals.

The IntellaTip MiFi XP Catheters are intended for use with the Controller and accessories.

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 pads satisfying the requirements of IEC 60601-1/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.

Placement of the dispersive pads 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 dispersive pads 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

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

CLINICAL STUDIES

Objective

The objective of the study was to evaluate the safety and efficacy of the Blazer® II XP Catheter and EPT-1000XP™ Cardiac Ablation System Controller and Accessories for radiofrequency ablation of sustained or recurrent type I atrial flutter.

Study Design

The study was a prospective, multi-center, single-arm study using objective performance criteria and historical control data from the medical literature. Clinical efficacy and safety assessments were performed at one, three and six months and at one and two years following the index procedure.

Study Endpoints

The primary endpoints for the study were as follows:

- Acute Procedural Success – defined as the demonstration of bi-directional isthmus block with non-inducible type I atrial flutter with only the use of the Blazer II XP Catheter and EPT-1000XP Controller and Accessories as assessed at the end of the ablation procedure.
- Six-Month Success – defined as demonstration of Acute Success and continued absence of targeted type I atrial flutter for the first six months after the index procedure.
- Complication Rate – refers to major complications experienced by patients exposed to the investigational device which occur within seven days post procedure.
- Objective Performance Criteria (OPC):

  Objective performance criteria were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined in Table 2.

Table 2. Objective Performance Criteria for Atrial Flutter Ablation

Endpoint	OPC	
	%	One-Sided 95% Confidence Bound[1]
Acute Success	86%	80%
Major Complications	3%	7%
Six-Month Success	86%	80%

1Exact binomial using a commercially-available software package.

Patient Accountability

The table below documents the accountability of patients throughout the study.

Table 3. Patient Accountability

Description	N
Patients enrolled in the study	250
Patients not ablated	0
Patients ablated with EPT-1000XP Cardiac Ablation System	250
Patients ablated only with EPT-1000XP Cardiac Ablation System	247
Patients ablated with EPT-1000XP Cardiac Ablation System and non-investigational catheter*	5
Patients ablated only with non-investigational catheter	2

*Patients were first ablated with the EPT-1000XP Cardiac Ablation System only. If flutter procedure could not be completed, then physicians used another catheter to complete the procedure. These patients were considered acute failures.

Patient Demographics

The majority of patients in the study are male (83%, N = 205/247). The average age of the male patients is 60.5 ± 11.1 years. There are 42 (17%) females enrolled in the study, with an average age of 63.4 ± 12.4 years.

Results

A. Intraprocedural Data

The table below describes the intraprocedural data:

Table 4. Intraprocedural Data (N = 209*)

Description (N)	Mean ± SD	Range
Total # of RF Applications/procedure (N = 209 procedures)	11.5 ± 10.6	1.0 - 86.0
Total Duration of RF Applications (minutes) (N = 209 procedures)	14.6 ± 12.1	2.0 - 74.9
Duration per delivery (seconds) (N = 2405 RF applications)	75.9 ± 37.4	11.0 - 120.0
Maximum Set Power (Watts) (N = 2405 RF applications)	76.9 ± 17.1	30.0 - 100.0
Average delivered power (Watts) (N = 2405 RF applications)	54.3 ± 20.5	6.4 - 96.7
Maximum Set Temperature (˚Celsius) (N = 2405 RF applications)	64.2 ± 4.8	45.0 - 80.0
Average delivered temperature (˚Celsius) (N = 2405 RF applications)	54.6 ± 6.3	45.0 - 77.9

*Based on RF diskette data received
• RF Application with time set < 6 seconds, temperature set < 6 degrees or duration < 11 seconds are excluded from the analysis
• Maximum power allowed is 100 watts, Maximum temperature allowed is 80 ºC

The index procedure and fluoroscopy times are shown in the table below.

Table 5. Fluoroscopy/Procedure Index Times (N = 234)

Description	Number of Procedures	Mean (± SD) Duration	Range
Total Procedure (hours)	234	2.1 (±1.3)	0.3 - 9.8
Ablation Time (hours)	231	0.7 (±0.7)	0.03 - 4.5
Total Fluoroscopy (minutes)	232	28.5 (±20.2)	2.8 - 129.0
Ablation Only Fluoroscopy (minutes)	222	14.8 (±13.8)	0.6 - 102.0

B. Acute Procedural Success (bi-directional isthmus block)

Acute success evaluation was based on 250 patients treated with the Blazer® II XP Catheter and EPT-1000 XP™ Controller and Accessories. The table below describes the information:

Table 6. Acute Ablation Outcomes (N = 250)

	# Success/ # Patients Ablated	Percentage (one-sided 95% confidence bound[1])
Acute Success	235/250	94% (91.5)

[1]Exact binomial using a commercially-available software package.

C. Freedom From Atrial Flutter Recurrence At Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional isthmus conduction block (BDB) and non-inducibility of atrial flutter (AFL) post ablation was achieved and were considered evaluable or an assessment of long-term (six-month) success. The patients were divided into evaluable at six months and not evaluable at six months. There were also 30 patients of the total 250 patients that had not completed the six-month follow-up.

Reasons that patients were classified "not evaluable":

- Treatment with anti-arrhythmic therapy = 31 patients. This was defined as treatment with Class IA, IC or III at both the one-month and three-month, or at the six-month follow-up. The rationale was that this treatment might suppress the recurrence of atrial flutter and obscure the actual rate of recurrence.
- Implanted defibrillators/pacemakers = 11 patients. The rationale for not evaluating these patients was that the effect of pacing on atrial flutter is unknown and the presence of pacing might make the assessment of atrial flutter difficult.
- Persistent atrial fibrillation = 1 patient. Persistent atrial fibrillation might essentially "overdrive" the atrial flutter. This one patient developed atrial fibrillation shortly after the procedure and remained in that rhythm for the duration of the study.
- Withdrawn consent/lost to follow-up = 6 patients. These patients were determined to be not evaluable if they were lost to the study prior to six-month follow-up.
- Death = 5 patients prior to the six-month follow-up. These patients would have been evaluable if they had a recurrence of atrial flutter and were not on medications that would alter the assessment of that recurrence.

Based on these criteria, information was available on a total of 151 patients. Results are described in the table below.

Table 7. Freedom From Atrial Flutter At 6 Months

Description	N
Patients ablated only with EPT-1000XP Cardiac Ablation System and successful BDB and AFL non-inducibility (Acute Success)	151
Number of patients free from recurrence	145
Number of patients with recurrence of atrial flutter	6

D. Adverse Events and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A major adverse event was defined as any clinical event which occurred within the first week following the use of the investigational device and was life- threatening; or resulted in permanent impairment of a body function or permanent damage to a body structure; necessitated significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or required hospitalization or an extended hospital stay.

Twenty-two (22) major adverse events were reported for twenty (20) patients. These events included lower extremity ischemia, cerebral infarct, thrombus (2 events), fractured femur, cerebral emboli, pulmonary embolism, hematoma, pseudoaneurysm (2 events) and AV fistula. Eight patients died during the study. Of the eight deaths, five occurred during the six-month study follow-up period, and all were related to underlying pre-existing conditions.

Major Adverse Events

Of the 250 patients treated with the Blazer II XP Catheter and EPT-1000XP Controller and accessories, twenty-two (22) major adverse events were reported in twenty (20) patients. The major adverse event rate (number of patients with the major adverse events per the number of patients in the study) was 8% (20/250).

A detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but not relating specifically to the investigational device or ablation procedure. The table below details the major adverse events (AE) information.

Table 8. Major Adverse Events

	Days post ablation	Adverse Event
1	8	Atrial tachycardia
2	1	Pacer implant one day post ablation procedure for junctional rhythm*
3	2	Atrial fib
4	0	Laryngotracheitis due to traumatic intubation
5	0	Left buttock induration, treated with narcotics
6	3	Groin hematoma
7	0 3	Pulmonary embolus* Fractured femur
8	1	Systemic embolus to legs bilaterally, right popliteal and left tibioperoneal
9	1	Pacemaker implantation due to prolonged CSNRT
10	8	DVT
11	1	TIA
12	2	Right groin hematoma
13	1	Transection femoral artery with subsequent AV fistula
14	1	Femoral AV fistula repair
15	2	Pseudoaneurysm/hematoma
16	5 6	Ablation for left atrial tachycardia CVA, multiple cerebellar infarcts
17	1	Atrial Fib
18	4	CVA in patient with pre-existing cerebrovascular disease
19	4	Cholecystitis
20	1	Fever

All the adverse events above can be attributed to the procedure. The adverse events in two patients (*) could possibly be attributed to the use of the device for a rate of 2/250 or 0.8%. Eight (8) patients died during the course of the study. The deaths were non-temporally related to the ablation procedure. Details regarding patient deaths are summarized in Table 9.

Table 9. Deaths

Days post Ablation	Death summary
345	79 year old man with CHF s/p CABG 1994, collapse at home in shower, in asystolic arrest when ambulance on scene, autopsy showed AMI and cardiac hypertrophy.
53	41 year old man with dilated cardiomyopathy, sudden collapse at work 53 days post ablation, in fine VF was cardioverted to junctional rhythm without perfusion, degenerated to asystole, no autopsy performed.
38	71 year old woman with history of total knee replacement developed a pulmonary embolus 10 hours post a successful ablation procedure which was performed without anticoagulation. This large left pulmonary artery embolus was associated with bilateral pleural effusions and a small pericardial effusion. She was treated with heparin and coumadin. She also fell after the ablation procedure, prior to d/c and sustained a periprosthetic left femur fracture, during treatment and recovery she developed MRSA sepsis from a CVP line, and died from complications.
214	73 year old man s/p MI, hypertensive, COPD. Did not have a successful ablation procedure. He had worsening respiratory symptoms 6 months post ablation, and was admitted to a nursing home under hospice care. Death was thought to be due to pre-existing respiratory disease.
59	73 year old woman with hypertension CHF, on CPAP at night had abrupt onset of severe SOB, chest pain and cough 60 days post ablation. Taken to ER where she rapidly deteriorated to cardiopulmonary arrest 3 hours after onset. No clear reason for death documented.
40	52 year old man with history of PVD, CAD MI 1990, end stage cardiomyopathy, cardiogenic shock one month prior to ablation. He underwent a successful right atrial ablation for typical atrial flutter on 6/16/00. He continued to have left atrial tachycardia and underwent a second ablation procedure on 6/21/00 during which he had multiple bilateral infarcts in the posterior cerebellum. His neurological exam improved but he was transferred to hospice care because of ongoing CHF. Cause of death was thought to be due to worsening CHF.
455	74 year old man developed staphylococcal SBE of the mitral valve more than one year post successful ablation procedure.
30	48 year old woman died after a complicated elective gastric bypass surgery procedure.

Statistical Analysis

The table below summarizes the safety and effectiveness of the device when compared to the control group OPC for safety, acute success, and long-term success.

Table 10. Comparison of endpoints between EPT-1000XP™ Cardiac Ablation System Study and OPC

Endpoints	OPC		EPT-1000XP Study	
	%	One-sided 95% confidence Bound[1]	% (N)	One-sided 95% Confidence Bound[1]
Acute Success	86%	80%	94% (235/250)	91.5% (lower bound)
Major Complications	3%	7%	8% (20/250)	10.8% (upper bound)
Six-month Success	86%.	80%	96% (145/151)	93.4% (lower bound)

1Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success (91.5% vs. 80%) and six-month success endpoints (93.4% vs. 80%), the results demonstrate that the EPT-1000XP Cardiac Ablation System met the OPC for acute success and six-month success rates. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

EQUIPMENT 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. Ancillary materials required to perform cardiac ablation are as follows:

- One (1) - 8.5 French (2.83 mm) hemostatic percutaneous Catheter introducer and/or a long introducer sheath to match the 8.5 French (2.83 mm) diameter of the electrode tip with mini electrodes.
- Two (2) - dispersive pads meeting IEC 60601-1/IEC 60601-2-2 requirements for electro-surgical electrodes.

INTELLATIP MIFI™ XP TEMPERATURE ABLATION CATHETER SET UP AND OPERATION INSPECTION PRIOR TO USE

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. Do not use the device if past the "Use By" date.

Prior to use of the BSC 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 Footswitch 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 ablation site (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 receptacles located on the front panels of the Pod. See Step 5 below to insert the Reference Cable in between the dispersive pad connector and the Pod. *Figure 2 illustrates the cable configuration for the Catheter, Controller, Filter Module and Pod.*

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 sheath 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 CONNECTOR 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 model 620 cable following the connection sequence below.
   4a. Connect the black cable plug into the IntellaTip MiFi XP Catheter.
   4b. Connect the red cable plug into the center port marked "STD/XP" on the Pod.
   4c. Connect the yellow cable plug into the port marked "Catheter Cable" on the Filter Module.

   Note: If the 620 cable needs to be disconnected for any reason, disconnect the 620 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 model 653S cable.
   5a. Connect the quick connect cable plug into the port marked "Recording System" on the Filter Module.
   5b. Connect the 2 mm shrouded pins to the Recording System recording block in the appropriate channels.
6. Prepare connections from the Pod to the Filter Module.
   6a. Connect the shrouded **pin**-end (2 mm Shrouded Pin) of Reference Cable to the port marked "Reference Cable" on the Filter Module.
   6b. Connect the 2-prong **plug**-end of the Reference Cable to the dispersive pad port on the Pod.
   6c. Connect the 2-prong **socket**-end of the Reference Cable to the dispersive pad.
   6d. Connect 1 additional dispersive pad directly to the remaining port marked "Indifferent Electrode" on the Pod.
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 XP 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 BSC Cardiac Ablation System is designed so that the temperature set limit cannot exceed 80 °C 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 Footswitch 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 11.

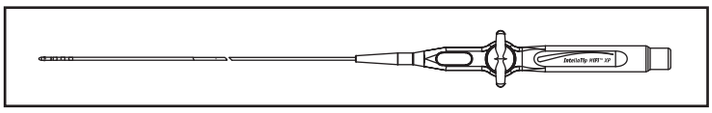

Figure 1. IntellaTip MiFi XP Temperature Ablation Catheter

Table 11. Correcting Abnormal Conditions

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

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**.

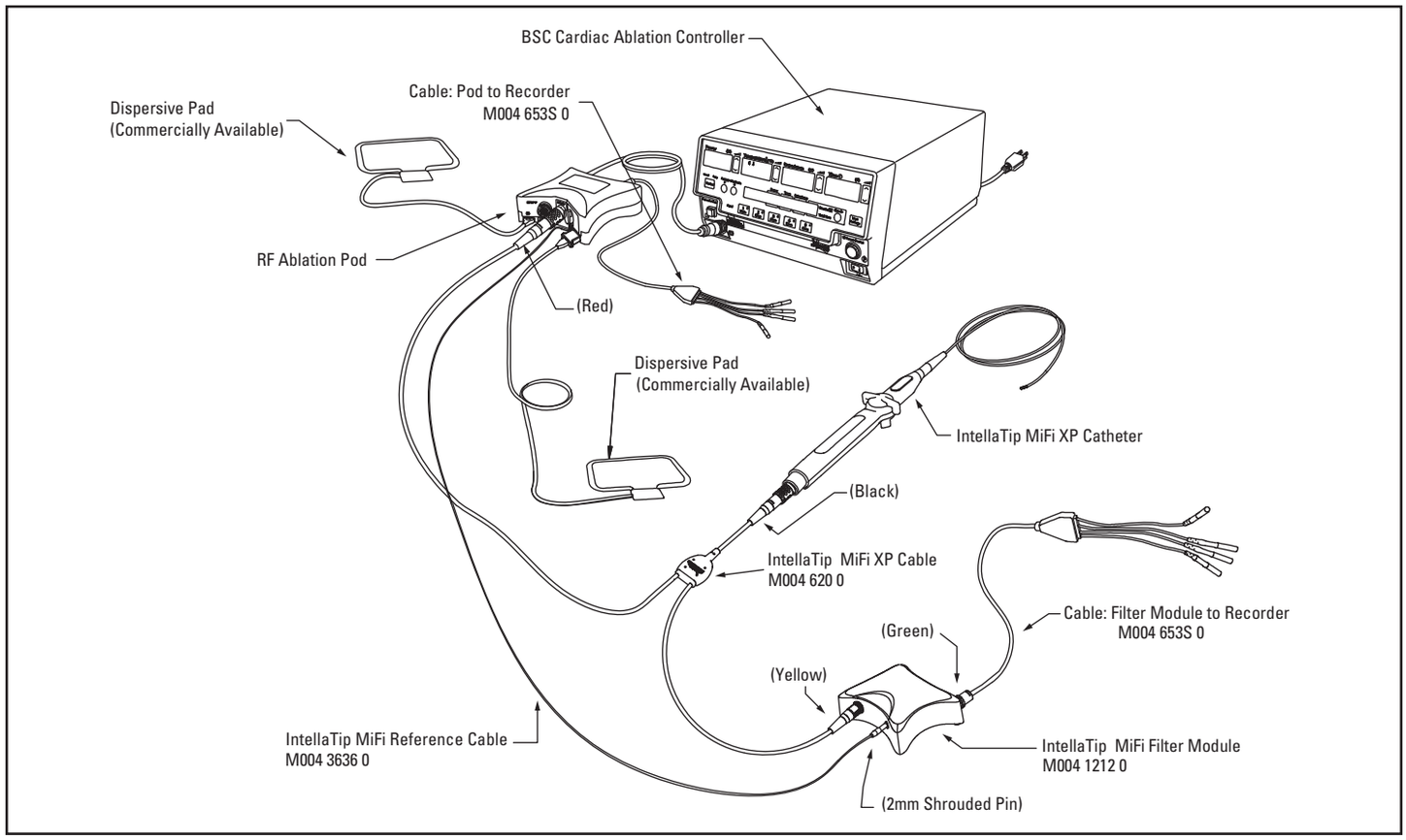

Figure 2. Cable Configuration for IntellaTip MiFi XP Temperature Ablation Catheter with the BSC Cardiac Ablation System

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