



90902676-01

2017-04  
< en >

# IntellaNav™ XP

## Temperature Ablation Catheter

### TABLE OF CONTENTS

**WARNING** ..... 1

**DEVICE DESCRIPTION** ..... 1

    Table 1. Technical Specifications ..... 1

    User Information ..... 2

    Contents ..... 2

**INTENDED USE/INDICATIONS FOR USE** ..... 2

**CONTRAINDICATIONS** ..... 2

**WARNINGS** ..... 2

**PRECAUTIONS** ..... 2

**ADVERSE EVENTS** ..... 2

    Potential Adverse Events ..... 2

**CLINICAL STUDIES** ..... 2

    Objective ..... 2

Study Design ..... 2

Study Endpoints ..... 2

    Table 2. Objective Performance Criteria for Atrial Flutter Ablation ..... 3

Patient Accountability ..... 3

    Table 3. Patient Accountability ..... 3

Patient Demographics ..... 3

Results ..... 3

A. Intraprocedural Data ..... 3

    Table 4. Intraprocedural Data (N = 209\*) ..... 3

    Table 5. Fluoroscopy/Procedure Index Times (N = 234) ..... 3

B. Acute Procedural Success (bi-directional isthmus block) ... 3

    Table 6. Acute Ablation Outcomes (N = 250) ..... 3

C. Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up ..... 3

    Table 7. Freedom from Atrial Flutter at 6 months ..... 3

D. Adverse Events and Deaths ..... 3

Major Adverse Events ..... 3

    Table 8. Major Adverse Events ..... 3

    Table 9. Patient Deaths ..... 4

Statistical Analysis ..... 4

Table 10. Comparison of Endpoints Between EPT-1000XP™ Cardiac Ablation System Study and OPC ..... 4

**HOW SUPPLIED** ..... 4

**ADDITIONAL EQUIPMENT REQUIRED FOR SAFE USE** ..... 4

    Handling and Storage ..... 4

    Operating Environment ..... 4

    Transport Environment ..... 4

    Storage Environment ..... 4

**IntellaNav XP CATHETER SET UP AND OPERATION**

**INSPECTION PRIOR TO USE** ..... 4

**INSPECTION PRIOR TO USE** ..... 4

**SETTING UP THE SYSTEM** ..... 4

    Attaching the Dispersive Pads ..... 4

**DIRECTIONS FOR USE** ..... 4

    Table 11. Correcting Abnormal Conditions ..... 5

**CATHETER REMOVAL** ..... 5

**WARRANTY** ..... 5

    Figure 1. IntellaNav XP Catheter ..... 5

    Figure 2. System Connections ..... 5

### Rx 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 IntellaNav XP Temperature Ablation Catheter (henceforth, referred to as the IntellaNav XP Catheter) is a quadripolar ring electrode cardiac ablation catheter. It is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities.

The electrode segment of the IntellaNav XP Catheter is comprised of a distal tip electrode and three ring electrodes. The IntellaNav XP Catheter delivers RF energy for cardiac ablation through the distal tip electrode which is 8 mm in length and has an 8F (2.67 mm) diameter; the distal tip electrode has an embedded temperature sensor and incorporates a position sensor for magnetic tracking and navigation of the catheter on a Rhythmia Mapping System. The three ring electrodes record Electrogram (EGM) signals for mapping and deliver stimulus for pacing.

The IntellaNav XP Catheter has an electrical connector located in the handle, which allows the catheter to be connected to a Rhythmia Connection Box using the IntellaNav Ablation Catheter Cable. The Rhythmia Connection Box and Rhythmia Mapping System allow the catheter to interface with standard recording equipment and the Maestro 3000™ Cardiac Ablation Controller or the Maestro 4000™ Cardiac Ablation Controller via the Radiofrequency (RF) Ablation Pod.

The IntellaNav XP Catheter is capable of accessing high power (up to 100 Watts) when connected to the Maestro 3000 Cardiac Ablation Controller or the Maestro 4000 Cardiac Ablation Controller via the Radiofrequency (RF) Ablation Pod (henceforth, referred to as the Controller and the Pod). Boston Scientific (BSC) recommends operating the Controller in Temperature Control mode to access high power (100 Watts).

RF power is delivered between the catheter's distal tip electrode and two commercially available external Dispersive Pads. Dispersive Pads (Valleylab™ Model E7506) were tested with the BSC high power Cardiac Ablation System to meet safety requirements per IEC 60601-1/IEC60601-1-2.

The IntellaNav XP Catheter has not been tested for use with the EPT-1000XP™/EPT-1000XPT™ Cardiac Ablation Systems.

A summary of the technical specifications for the IntellaNav 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	Similar to the IntellaTip MiFi™ XP Catheter Handle
IntellaNav XP Catheter Usable Shaft Length	104 cm to 115 cm
IntellaNav XP Catheter Shaft Diameter	7F (2.33 mm)
Distal-Tubing Length Standard and N4 Models K2 Model	8.6 cm 11.1 cm
Distal Tip Electrode Dimensions Diameter x Length	8F (2.67 mm) x 8 mm
Distal Tip Electrode	Compatible with 8F Sheath
Curve Configurations Symmetric Asymmetric	Standard, K2 N4
Electrode Spacing Distal Tip-to-First-Ring Ring-to-Ring	2.5 mm 2.5 mm
Electrode Configuration	Quadripolar (4 Electrodes)
Ring Electrode Length	1.27 mm
Electrical Connectors	Quick Connect

## User Information

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.

## Contents

One (1) sterile IntellaNav™ XP Catheter.

## INTENDED USE/INDICATIONS FOR USE

The Boston Scientific Corporation IntellaNav XP Catheter is indicated for use with the BSC high power Cardiac Ablation Controllers (Maestro 3000™ Controller and Maestro 4000™ Controller) and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The BSC high power Cardiac Ablation Controllers 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, pre-, 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 IntellaNav 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 based on an individual, patient-centered medical assessment of peri-procedural stroke risk.
- Do not pass the IntellaNav 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.

- Do not deliver RF energy when the tip electrode is withdrawn or partially withdrawn into a sheath, to minimize the risk of char or coagulum formation.
- There are no data to support the safety and effectiveness of this device in the pediatric population.
- Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation that may result in embolism.

## PRECAUTIONS

Observe these precautions, before using the device:

- Do not place the distal end of the catheter near magnets. Magnetization of the catheter may result in degradation of magnetic tracking precision. Such degradation may be manifested by an unstable or complete loss of rendering of the position and/or orientation of the catheter by a magnetic tracking system. If this occurs, the catheter should be replaced.
- Do not attempt to operate the Controller before thoroughly reading the appropriate BSC high power Cardiac Ablation Controller & Accessories Operator's Manuals.
- The IntellaNav XP Catheters are intended for use with the BSC Controller and accessories only.
- The IntellaNav 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 signal filtering must be used to allow continuous monitoring of the surface Electrocardiograms (ECGs) during RF power applications.
- When using the IntellaNav XP Catheter, it is required that two Dispersive 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 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.
- Electromagnetic Interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Equipment/accessories carrying a current at 150-300 kHz Alternating Current near the catheter cable may cause direct coupled interference and therefore may disrupt the operation of non-BSC RF Generators. It may be necessary to take mitigation measures, such as re-orienting, relocating, or shielding the interfering equipment/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
- Cerebral vascular accident
- Chest pain/discomfort
- Complete heart block (transient/permanent)
- 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
- Pseudoaneurysm
- Pulmonary edema
- 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™ 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 (OPC) 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 <sup>1</sup>
Acute Success	86%	80%
Major Complications	3%	7%
Six-Month Success	86%	80%

<sup>1</sup>Exact binomial using a commercially-available software package.

**Patient Accountability**

**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 (°C) (N = 2405 RF applications)	64.2 ± 4.8	45.0 - 80.0
Average delivered temperature (°C) (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 °C

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-1000XP Controller and Accessories. The table below describes the information:

**Table 6. Acute Ablation Outcomes (N = 250)**

Description	# Success/# Patients Ablated	Percentage (One-sided 95% Confidence Bound) <sup>1</sup>
Acute Success	235/250	94% (91.5)

<sup>1</sup>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 noninducibility of Atrial Flutter (AFL) post ablation was achieved and were considered evaluable for 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 bioperoaneal
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. Patient 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 <sup>1</sup>	% (N)	One-sided 95% Confidence Bound <sup>1</sup>
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)

<sup>1</sup>Exact 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**

The IntellaNav™ XP Catheter is supplied sterile using an Ethylene Oxide (EO) process.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

**ADDITIONAL EQUIPMENT REQUIRED FOR SAFE USE**

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) IntellaNav Ablation Catheter Cable
- One (1) Rhythmia Connection Box
- One (1) Maestro 3000™ Cardiac Ablation Controller with (RF) Ablation Pod, or One (1) Maestro 4000™ Cardiac Ablation Controller with (RF) Ablation Pod
- One (1) - 8 French (2.67 mm) hemostatic percutaneous catheter introducer or a long introducer sheath.
- Two (2) - Dispersive Pads meeting IEC 60601-1/IEC 60601-1-2 requirements for electro-surgical electrodes.

(Refer to corresponding manufacturer’s user manuals for specific material information)

**Handling and Storage**

**Operating Environment**

Ambient Temperature: Uncontrolled

Relative Humidity: Uncontrolled

Atmospheric Pressure: 70 kPa to 106 kPa

**Transport Environment**

Temperature: -29 °C to 60 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

**Storage Environment**

Ambient Temperature: -29 °C to 60 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

**IntellaNav XP 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 high power Cardiac Ablation System, the individual components including the IntellaNav XP Catheter, the Controller, the Rhythmia Connection Box, Pod, 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 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 Dispersive Pad receptacles located on the front panels of the Pod.

Figure 2 illustrates the cable configuration for the Catheter, Connection Box, Controller, and Pod.

**DIRECTIONS FOR USE**

Prior to insertion of the IntellaNav XP Catheter, prepare the entry site according to standard aseptic practices. Size the 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 8F (2.67 mm) 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 IntellaNav XP Catheter to the Rhythmia Connection Box using the IntellaNav Ablation Catheter Cable. The end of the IntellaNav Ablation Catheter Cable with the red band shall be inserted into the Connection Box. Refer to Figure 2. Ensure that the cable/catheter connection remains dry throughout the procedure. Refer to a Rhythmia Mapping System DFU/IFU and/or Rhythmia Connection Box DFU for catheter connection information via the Connection Box.
4. 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 signals can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes even during RF ablation.
5. The IntellaNav XP Catheter or a multi-polar catheter can be used to assess bidirectional conduction across the isthmus.
6. When the targeted site has been located, the IntellaNav XP Catheter can be used therapeutically in the “Ablate” 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.
7. 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.
8. Ensure that the ablation parameters are set as instructed in the appropriate BSC high power 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.

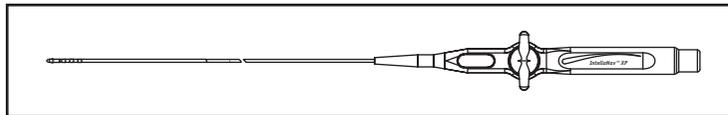
- The IntellaNav™ XP Catheter tip curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation.

**Note:** The BSC high power Cardiac Ablation System is designed so that the temperature set limit cannot exceed 80 °C in Temperature Control Mode, when used with the IntellaNav XP Catheter.

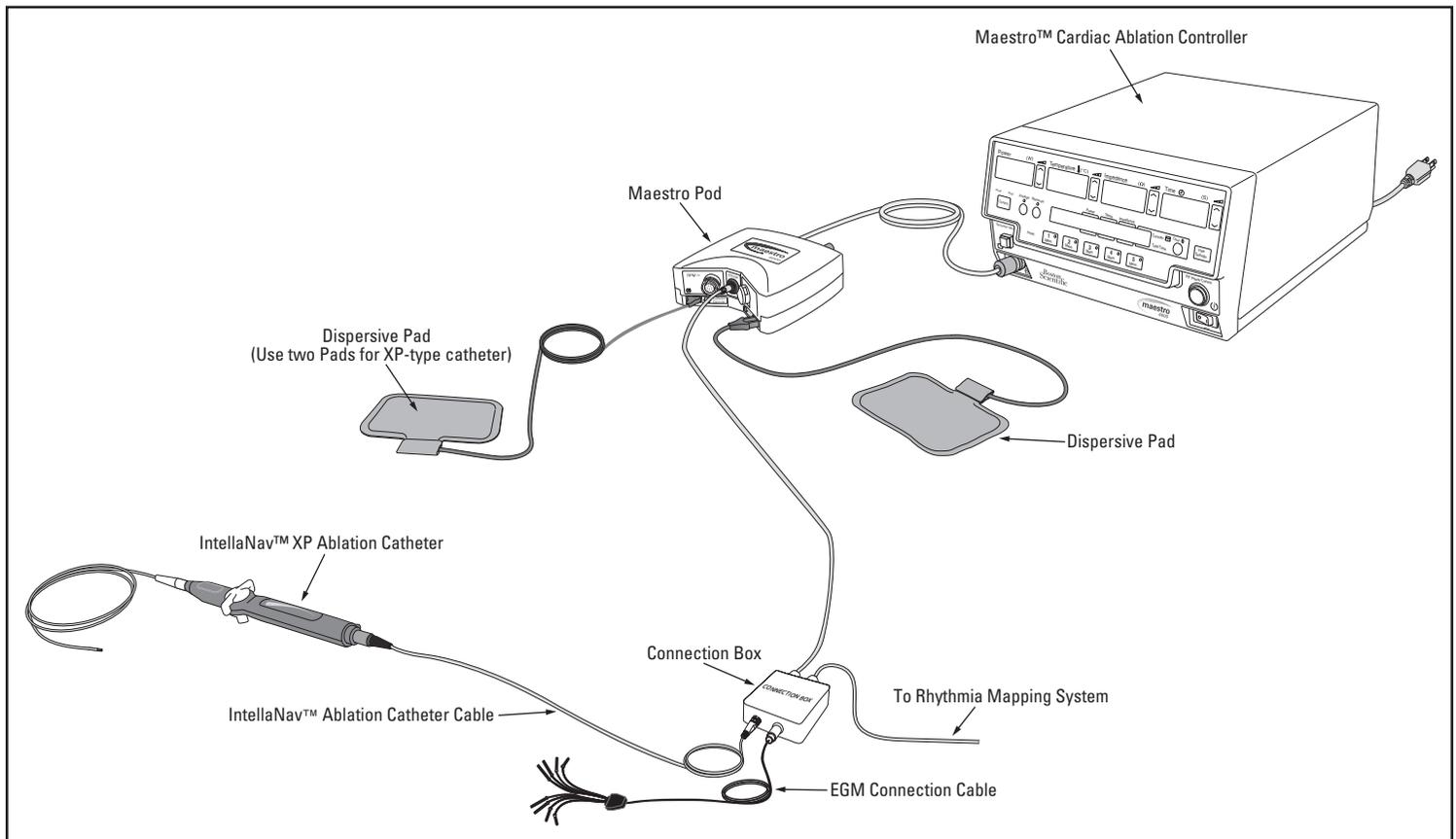
- To begin RF power delivery, press the RF POWER CONTROL Button on the Controller's front panel once or hold the Foot Switch down. The POWER Display shows the RF power delivered to the IntellaNav XP Catheter (in watts).
- During RF delivery, monitor key parameters and adjust therapy delivery accordingly.
- 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, and then follow the steps in Table 11.

**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 improve contact and stability. 3. Reinitiate RF delivery.
<ul style="list-style-type: none"> <li>Low temperature</li> <li>Fluctuating Temperature</li> <li>Fluctuating Power</li> </ul>	Electrode not stable on endocardium	1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Reinitiate RF delivery.
<ul style="list-style-type: none"> <li>Sudden drop in temperature</li> <li>Sudden rise in power</li> </ul>	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.



**Figure 1. IntellaNav XP Catheter**



**Figure 2. System Connections**

### CATHETER REMOVAL

- Prior to removing the catheter, straighten the distal end of the catheter completely.
- Withdraw the catheter from the vessel.
- Remove the introducer 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.**

Valleylab is a trademark of Covidien AG Corporation.

**EC REP** **EU Authorized Representative**

Boston Scientific Limited  
Ballybrit Business Park  
Galway  
IRELAND

**AUS** **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd  
PO Box 332  
BOTANY  
NSW 1455  
Australia  
Free Phone 1800 676 133  
Free Fax 1800 836 666

**ARG** **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link [www.bostonscientific.com/arg](http://www.bostonscientific.com/arg)

 **Legal Manufacturer**

Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752  
USA  
USA Customer Service 888-272-1001

 **Do not use if package is damaged.**

 **Recyclable Package**

© 2017 Boston Scientific Corporation or its affiliates.  
All rights reserved.