Boston Scientific

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Blazer® II
Blazer® II HTD
Temperature Ablation Catheters

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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 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 directions. Failure to do so may result in patient complications.

DEVICE DESCRIPTION

The Boston Scientific Corporation (BSC) Cardiac Ablation System consists of a Cardiac Ablation Controller (henceforth, referred to as the Controller) and a RF Cardiac Ablation Pod (henceforth, referred to as the Pod), which are used in conjunction with a BSC cardiac ablation catheter.

Detailed Instructions for Use of the BSC Cardiac Ablation Systems, are provided in the appropriate Operator's Manual. Information further detailed in this Directions For Use (DFU) specifically addresses the ablation catheters. The ablation catheter is connected to the Controller via the Pod. The Pod provides for additional connection to standard hospital electrophysiology recorders. The catheter-to-Pod connection may be made through the use of the Quick Connect Instrument Cable, which incorporates BSC's proprietary "Quick Connect" connectors, illustrated in Figure 1. The "Quick Connect" configurations allows for rapid connection and disconnection of the catheter. Usable catheter length from distal tip electrode to the catheter handle ranges from 60 to 130 cm. Blazer II Catheter and Blazer II HTD Catheters employ a tip mounted, thermally isolated thermistor for temperature sensing, which enables temperature monitoring at the endocardial surface during ablation. For all ablation catheters, monopolar RF power is delivered between the catheter's distal electrode and a commercially available external dispersive pads. The Blazer II Catheters and Blazer II HTD Catheters have a relatively higher torque attribute available. The handle and steering mechanism for the Blazer II Catheters are represented in Figure 2. Electrode tip configurations, illustrated in Figure 3, are represented by a conventional "straight" tip electrode. Straight tip electrodes are available in sizes ranging from 6F (2.00 mm)/4 mm to 8F (2.67 mm)/5 mm.

The diameter of the catheter shaft ranges from 6F (2.00 mm) to 7F (2.33 mm). Quadripolar catheter configurations are available (three ring electrodes). Ring electrodes are utilized for either electrogram recording and for pacing. The quadripolar design has available ring electrode spacings ranging from 1 mm to 10 mm. The distal tip electrode-to-first ring electrode is a fixed distance of 2.5 mm for all catheter configurations.

Curve options for both catheters include a variety of symmetric and asymmetric ranges of motion. Asymmetric curves, by design, have limited articulation. Distal-end lengths range from the standard length of 6.9 cm to the extended length of 15.5 cm. For Blazer II Catheters, the stiffness characteristic of the distal-end shaft is available as either firm or soft.

INDICATIONS FOR USE

When using the Blazer II Catheter/Blazer II HTD Catheters:
The Boston Scientific Cardiac Ablation System is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia.

CONTRAINDICATIONS

The use of the device is contraindicated in patients with active systemic infection. The transeptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

WARNINGS

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. Careful consideration must therefore be given for the use of the device in pregnant women.

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 Catheter Rated Voltage: 178 Vrms (251 Vpk).

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 cardioverter/defibrillators can be adversely affected by RF signals. It is important to:

a) have temporary external sources of pacing available during ablation,
b) temporarily reprogram the pacing system 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, and
d) perform complete pacing system analysis on all patients after ablation.

Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.

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 the post-ablation period for clinical manifestations of infarction.

The steerable ablation catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

The use of catheters or cables with unprotected male pin connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of component with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.

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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 tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

No modification of this equipment is allowed.

PRECAUTIONS

Before using, inspect for physical damage including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.

The Blazer® II Catheter and the Blazer® II HTD Catheter are 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 1 1/2 full rotations (540°). 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.

Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transeptal 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 sterile packaging and catheter should be inspected prior to use.

It is recommended not to exceed thirty (30) radiofrequency power applications per catheter.

The Boston Scientific Blazer II Temperature Ablation Catheter and Blazer II HTD Catheters are intended for use with the Controller and accessories.

Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the Controller Operator's Manual.

The impedance display of the 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 prebending of the distal curve can damage the steering mechanism and may cause patient injury.

Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation in a fully-equipped electrophysiology laboratory.

Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.

The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.

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.

Read and follow the dispersive pads manufacturer's instructions for use; the use of dispersive pads, which meet or exceed IEC 60601-2-2 requirements, is required.

Placement of the dispersive pad(s) on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.

The Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and dispersive pad(s), particularly when operating the device. 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 pad(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.

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 Controller during the delivery of RF power may adversely affect the performance of other equipment.

Regularly inspect and test re-usable cables and accessories. The instrument cables and adapter cables may be sterilized only up to ten times by ethylene oxide sterilization.

Boston Scientific relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the cardiac ablation procedure.

ADVERSE EVENTS

The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise noted with an asterisk). A total of 57 adverse events were observed in the 513 procedures performed during the clinical study.

- Death
- Cardiac Tamponade, Perforation, Pericardial Effusion
- Cerebral Vascular Accident
- Myocardial Infarction
- Endocarditis
- Pulmonary Edema
- Pulmonary Embolism, Venous Thrombus
- *Puncture Site Hematoma, Ecchymosis (2.1%)
- Aortic Valve Insufficiency/Wall Motion Abnormality
- Arrhythmic
- Permanent Atrioventricular Block
- Ventricular Fibrillation
- *Non-sustained Ventricular Tachycardia (1.6%)
- Conduction System Abnormalities
- *Atrial Fibrillation, Flutter, Tachycardia (2.5%)
- Pacemaker Failure-to-sense
- Phrenic Nerve Damage

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

ELECTROPHYSIOLOGY ENDPOINTS

Target sites are selected based on both the location of the ablation catheters on fluoroscopy and on the characteristics of the intracardiac electrogram recorded from the distal poles of the ablation catheter. The effectiveness of each radiofrequency power application is assessed by recording of the surface ECG, intracardiac signals and by incremental pacing and extrastimulation. These maneuvers provide objective evidence of whether conduction has been blocked in the targeted pathway and whether SVT remains inducible. Specific endpoints for each type of ablation are as follows:

Accessory Pathway

Successful ablation is defined as the complete elimination of conduction over the accessory pathway. This is evident as an abrupt in increase in the AV and V-A interval recorded at the target site. This is accompanied by a change in the retrograde activation sequence. In patients with manifest pre-exitations, successful ablation is associated with disappearance of the delta wave from the surface ECG. Patients with successful AP ablation no longer have inducible SVT mediated by the pathway.

AVNRT

There are two techniques for AV nodal modification in patients with typical AVNRT. Lesions made anteriorly, near the apex of the triangle of Koch, selectively affect fast AV nodal pathway functions. Endpoints for fast pathway ablations include an increase in the AH interval and interval and an increase in the VA block cycle length by at least 50% over baseline.

Lesions made posteriorly, near the ostium of the coronary sinus interfere with slow AV nodal pathway function. Endpoints for slow pathway ablation include the occurrence of junctional ectopy during delivery of RF power as well as changes in AV nodal function. After successful slow pathway ablation, there is often elimination of dual AV nodal physiology. However, in some patients, there is attenuation without complete elimination of slow pathway function. These patients have discontinuous AV nodal function curves and sometimes have single AV nodal entrant echo beats after ablation. An endpoint which is sought in all patients after AV nodal modification is the elimination of inducible, sustained AVNRT.

AV Junction Ablation

The occurrence of persistent complete AV block after RF power applications is the endpoint for AV junctional ablation. Complete AV block is readily diagnosed by observation of the surface ECG and/or intracardiac electrograms.

CLINICAL STUDIES

In clinical studies of the SteeroCath-T™ Temperature Ablation Catheter and SteeroCath-A™ Catheter in over 450 patients, the following ablation procedures were performed:

- Accessory Pathway Ablation. Candidates were patients with Wolff-Parkinson-White (WPW) Syndrome or concealed accessory pathways. Successful ablation of accessory pathways was curative.
- AV Nodal Modification. Candidates were patients with AV nodal reentrant tachycardias (AVNRT). Successful AV nodal modifications obviated the need for a pacemaker and was curative.
- AV Junction Ablation. Candidates were patients with atrial fibrillation or flutter. Successful ablation of the AV junction produced third degree atrioventricular (AV) block and necessitated insertion of a permanent ventricular pacemaker.

A total of 462 patients were enrolled in the study. Six patients were excluded from the analysis of efficacy, either because their arrhythmias could not be induced and they were not treated with the device (4 patients), or they did not meet the study inclusion criteria (2 patients).

An intention-to-treat analysis for evaluating effectiveness was based on the 456 patients who met the inclusion criteria. The outcome of the initial procedure was used in the calculation of success, and the use of non-protocol catheters during that initial procedure constituted a failure. Successful ablations were performed in 207 of 257 (81%) of patients with accessory pathways, 116 of 126 (92%) of patients with AVNRT, and 52 of 56 (93%) of patients with a rapid ventricular response to an atrial arrhythmia, for an overall success rate in patients with a single ablation indication of 85% (375/439). For the remaining 17 patients who had two indications for ablation, complete success was obtained in 9 patients (53%), and partial success, that is defined as one successfully ablated target, was observed in 3 patients (18%).

The outcomes from procedures in all 462 enrolled patients were included in the safety analysis, which included 42 repeat ablations after an initial failure or recurrence, and 9 additional ablation procedures in patients who were later identified as having a second ablation indication. A total of 57 complications were reported during these 513 procedures for a complication rate of 11%. Seventeen of the 57 complications were attributed to the ablation catheter.

Five deaths were reported among the patients during follow-up. Pulmonary embolism secondary to femoral vein thrombosis and endocarditis at the ablation site contributed to deaths that occurred within two months of the ablation procedure, in 2 of the 458 patients (0.44%).

The following were also noted:

- Clinical data indicated an overall recurrence rate of approximately 10% for patients undergoing successful ablation with the BSC Cardiac Ablation System. Most recurrences were noted in AV Modification procedures and recurrences were rarely noted following AV junction ablation.
- No data were collected to support that the thermistor ablation catheter is more safe and effective than the standard ablation catheter. Although a significant reduction in the incidence of impedance rise was observed during the study when the thermistor catheter was used because the operator could decrease power when measured temperature increased, no benefit to the patient was demonstrated.

- Typical anticoagulation protocols during left-sided procedures in the clinical study included:
  1) an initial intravenous heparin injection of 3,000-10,000 units,
  2) maintenance of appropriate heparinization by heparin drip or repeat bolus if necessary; followed by
  3) post procedural administration of one aspirin per day for a period of one to three months unless contraindicated.
- The average fluoroscopy time was 39.9 + 29.9 minutes and ranged from a minimum of 5 minutes to a maximum of 157 minutes.

Table A summarizes power delivery and temperature data from the study for the three different types of ablation procedures performed in the clinical trials.

Table A. Summary of Power Delivery for Accessory Pathway, AV Modification and AV Junctional Ablation Procedures

	Number of RF Applications >10 Seconds		Applied Power (Watts)		Duration (Seconds)	
AV Junction:	Range:	1-14	Range:	14-50	Range:	11-120
Ablation	Median:	3	Median:	31.5	Median:	41.9
Total (N=52)						
AV Modification:	Range:	1-44	Range:	5-50	Range:	11-120
Total (N=115)	Median:	5	Mean:	29.3	Mean:	32.3
Accessory Pathway:	Range:	1-34	Range:	3-50	Range:	11-111
Total (N=207)	Median:	3	Mean:	33.2	Mean:	29.3

Although no specific protocol was designed to evaluate the use of thermometry, there were no differences observed in safety and effectiveness of the device with or without the thermistor. The following observations were noted:

- Insufficient tissue heating was occasionally associated with either a lack of, or non-permanent interruption of conduction at the target site. Conversely, high temperatures increased the likelihood of an impedance rise due to coagulum formation on the electrode tip.
- During successful ablations, temperature rose steadily before leveling off at a constant temperature plateau. Operators tended to reduce RF power levels when the measured temperature showed no sign of leveling off as it approached a desired target temperature level. When RF power was not reduced in the presence of an excessively rapid temperature rise, the temperature would typically exceed the targeted temperature.
- When temperature did not increase upon the delivery of RF power, or when the temperature was rather low and irregular, operators typically suspected the catheter tip-to-endocardium contact was unstable. Similarly, sudden temperature drops observed during ablation were interpreted as indicating loss of tissue contact, or a shifted tip position. When these temperature patterns were observed, ablation was stopped, and the catheter was repositioned to improve tip-tissue stability and ensure the intended site was being accessed. RF power delivery was then resumed after repositioning, to avoid ineffective power delivery and/or ablation of unintended regions.

Clinical Data Reported in the Medical Literature

RF ablation catheters for the treatment of cardiac arrhythmias which incorporate temperature sensing capability (Blazer® II Temperature Ablation Catheter) are a mature technology. The biophysics of RF lesion creation which using conventional RF technology is also well characterized and predictable as reported in the medical literature [13-15].

Safety And Effectiveness

There is extensive medical literature reporting the safe and effective use of conventional RF ablation catheters for treating a variety of arrhythmias in addition to those performed in the clinical trials. Table B shows data pooled from the medical literature (using various catheters) on three arrhythmias to specifically illustrate different ablation techniques. Literature data for these arrhythmias were chosen to demonstrate the safety and effectiveness of using conventional RF catheters to create either focal or linear lesions in any of the four chambers of the heart. Existing data for the treatment of these three arrhythmias are discussed in more detail below.

Table B. Safety and Effectiveness of RF Ablation Using Conventional RF Ablation Catheters

Arrhythmia	N	Acute Success	Chronic Success	Complications	Comments
Atrial Flutter [1,6-8,10,11,16]	1437	72-100%	85-100%	0-6%	Linear lesions across isthmus
Ventricular Tachycardia [10,11,16]	1463	66-85%	86%	2-8%	Right and left ventricles
Atrial Tachycardia [4,16]	494	91%	85%	3%	Right and left atria

Atrial Flutter

Atrial flutter is usually a well defined macro-reentrant circuit with the critical zone defined as the isthmus between the tricuspid valve and the inferior vena cava. Radiofrequency ablation of atrial flutter in this location with the creation of a linear lesion across the tricuspid isthmus has proven to be successful in the majority of patients treated. This technique using RF ablation is becoming a first line therapy for atrial flutter with highly predictable results. In the 1998 North American Society for Pacing and Electrophysiology (NASPE) Prospective Catheter Ablation Registry [16]. 477 patients were treated with RF ablation for atrial flutter. The major complication rate was less than 3% and included bleeding/hematoma (3 patients), cardiac tamponade (1 patient), hemopneumothorax (1 patient), new tricuspid regurgitation (1 patient), hypoxia (1 patient), and hypotension (1 patient).

Ventricular Tachycardia

Patients being treated with RF ablation for ventricular tachycardia (VT) usually have either ischemic VT or "normal heart" VT. Patients with ischemic VT often have multiple co-morbidities and have undergone various other treatment modalities, including multiple antiarrhythmic medications. Radiofrequency ablation of VT requires placement of the catheter in either the right or the left ventricle depending on the underlying substrate. Acute and chronic success rates are variable because patients often have multiple VT morphologies, especially in ischemic heart disease patients where the underlying disease substrate is progressive. Radiofrequency ablation procedures for "normal heart" VT are often curative, whereas procedures for ischemic VT are often palliative (i.e., reduces the number of implantable cardioverter defibrillator discharges for ventricular tachycardia episodes). In the 1998 NASPE Prospective Catheter Ablation Registry [16], 299 patients were treated with RF ablation for VT. The major complication rate was 3.8% and included cardiac tamponade (2 patients), respiratory failure (1 patient), sepsis (1 patient), worsening congestive heart failure (2 patients), and pericarditis (1 patient).

Atrial Tachycardia

A third atrial arrhythmia commonly treated with RF ablation is atrial tachycardia (AT). Radiofrequency ablation of AT usually involves creating a local lesion in either the right or left atrium. Electrophysiologic mechanisms of AT include automaticity, triggered automaticity, and reentry. Success rates vary because of the heterogenicity of this arrhythmia. In the 1998 NASPE Prospective Catheter Ablation Registry[16], there were 216 patients that had atrial tachycardia ablations and the major complication rate was 3%. The reported complications were cardiac tamponade (2 patients), transient AV block (1 patient), aspiration pneumonia (1 patient), and right atrial to aortic fistulae (1 patient).

American College of Cardiology/American Heart Association Guidelines

Under the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Clinical Electrophysiological and Catheter Ablation Procedures [12], RF ablation is given a Class I indication for the treatment of many tachyarrhythmias.

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. Ancillary materials required to perform cardiac ablation:

- 8F (2.67 mm) hemostatic introducer sheath.
- Dispersive Pads meeting standard IEC 60601-1/IEC 60601-2-2 requirements for electrosurgical electrodes, such as the Valley Labs Polyhesive Electrode #E7506.

CATHETER SET-UP AND OPERATION

Inspection Prior to Use

Prior to use of the Boston Scientific Cardiac Ablation System, the individual components including the Controller, steerable ablation catheter, Quick Connect Instrument Cable, Pod and Footswitch should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the steerable ablation catheter.

Setting Up the System

Please refer to the Operator's Manual for the Controller. The Operator's Manual describes the steps to follow to connect the system, set ablation parameters, and deliver radiofrequency power.

Carefully read all instructions prior to use. Failure to do so may result in complications.

Attaching the Dispersive Pads

1. Remove the dispersive pad from the packaging and peel off the backing to expose the conductive gel surface. Check to be sure the pad is moist and sticky to the touch before placing it on the patient. A dry electrode will have limited grounding capability.
2. Place the dispersive pad on a well-vascularized convex skin surface which is in close proximity to the ablation site. Do not place this electrode on the thigh, since this location is associated with higher impedance (see "Precautions"). Avoid scar tissue, body rominence, adipose tissue, and areas where fluid may pool. Shave, clean, and dry the application site as needed.
3. Check to be sure that excellent contact has been achieved over the entire area of the dispersive pad. Burns can result when RF power is delivered to a dispersive pad with poor contact. Plug the dispersive pad connector into the two-prong socket marked "INDIFFERENT ELECTRODE" on the front panel of the Pod. Make sure that the dispersive pad connector is firmly pressed into the socket.

DIRECTIONS FOR USE

The steerable ablation catheter is usually inserted into a vein or artery and is then positioned into the appropriate chamber of the heart under fluoroscopic guidance. A transeptal approach may be used (see "Contraindications" and "Warnings"). Precise placement of the catheter prior to ablation is accompanied by endocardial mapping using the tip and/or ring electrodes. Once appropriate positioning has been achieved, radiofrequency power is delivered via the Controller resulting in the ablation of the targeted cardiac tissue. Prior to insertion of the steerable ablation catheter, prepare the entry site according to standard aseptic technique practices.

1. Insert the catheter percutaneously into the appropriate artery or vein by the Seldinger technique using an 8F (2.67 mm) hemostatic introducer sheath.
2. Once inside the vessel, the catheter tip can be deflected as necessary to facilitate advancement into the selected heart chamber. The degree of tip deflection is controlled by the Steering Lever on the catheter handle. If the Steering Lever is pushed forward from its neutral position, the tip will curve proportionately up to a maximum of 270 degrees in one direction depending upon the curve option selected. Pulling the Steering Lever back will cause the tip to deflect in the opposite direction. To prevent overstressing the tip, the Steering Lever movement is limited by the handle design.
3. When crossing the aortic valve with the ablation catheter, it is recommended that the catheter tip be deflected to resemble a "pigtail" curve to avoid damage to the valve leaflets.
4. The catheter curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation. The adjustable Tension Control Lever may be tightened to retain the tip in the desired curvature or to increase steering resistance. Catheters are shipped with the Tension Control Lever in the "(-)" position, which is the minimum tension adjustment. In this position, the catheter steers freely and will not hold a preset curve. Rotating the Tension Control Wheel clockwise increases tension. In the "(+)" position, maximum tension is achieved. The catheter should not be steered in the maximum "(+)" position.
5. Connect the Pod to the Controller "Isolated Patient Connection" located on the front panel using the attached patient cable. Be sure to carefully follow the instructions in the Operator's Manual to connect the Pod.
6. Connect the steerable ablation catheter to the Pod with the appropriate Quick Connect cable (See Figure 1 for cable numbers).
7. Once 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. Unipolar electrograms can be obtained between the distal tip electrode and any commercially available low impedance ECG electrode. Bipolar electrogram recordings can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes.
8. Once the arrhythmogenic site has been located, the same catheter can be used therapeutically in the "Ablate" mode to deliver discrete bursts of radiofrequency power. Radiofrequency power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue. To deliver radiofrequency power from the Controller to the catheter, follow the instructions in the Controller Operator's Manual.
9. If the physician knows that the tip is in a confined space or in a region of unusually low flow such as under a valve leaflet, a lower initial power set point (10-20 watts) should be used. Otherwise, start the ablation at an intermediate RF power level of 20-25 watts, which will facilitate subsequent upward or downward adjustments.

CATHETER REMOVAL

1. Prior to removing the catheter, ensure that the distal end of the catheter is straightened completely.
2. Withdraw the catheter from the vessel.
3. Remove the introducer sheath, then follow standard practice for management of the insertion site.

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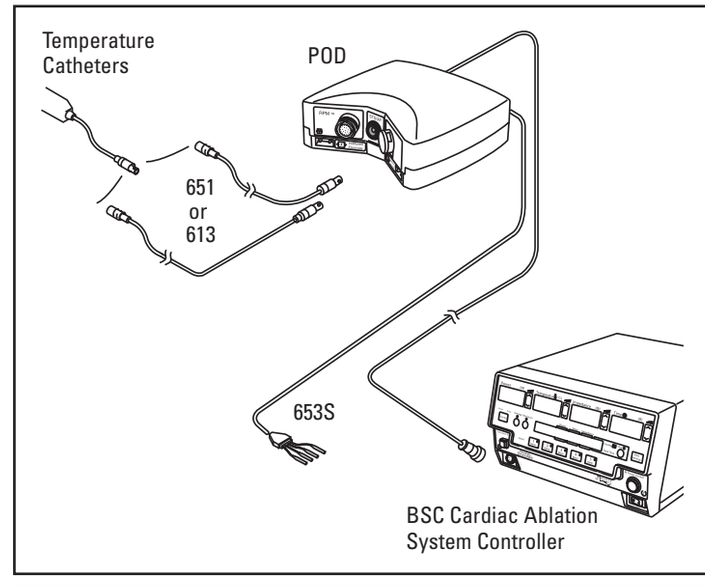
WARRANTY

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**.



Model 613 10 Ft (3.0 m) or **Model 651** 3 Ft (0.9 m)	**Model 653S** 3 Ft (0.9 m)
Thermistor Catheter Cable Quick Connect/9-Pole	Recording System-APM Adapter Cable

Figure 1. Cable Configuration for Pod

Temperature Catheters

-Blazer II® Catheter

-Blazer II® HTD Catheter

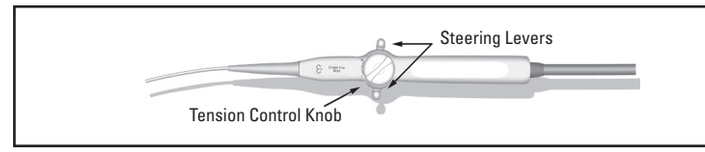


Figure 2. Temperature Ablation Catheter

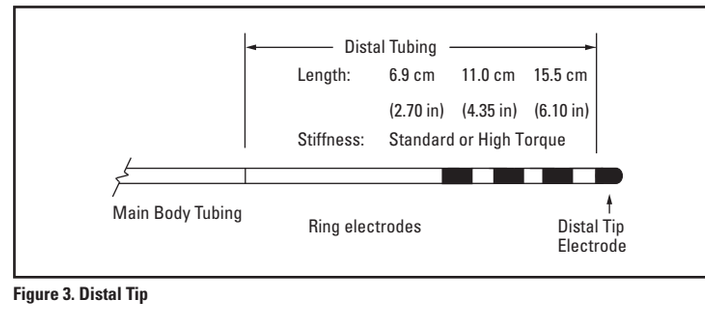


Figure 3. Distal Tip

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Recyclable Package

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