Blazer Prime® XP
Temperature Ablation Catheter

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Table 1. Technical Specifications

Description .......................... Specification

Sterilization ......................... STERILE

Distal Torque attributes ............ High Torque

Handle ................................. Blazer III® Catheter

Catheter Length ..................... 60 cm to 130 cm

Catheter Shaft Diameter ............ 7F (2.3 mm)

Distal-Tubing Length ............... 6.6 cm to 15 cm

Firm

Electrode Tip ......................... 8F (2.67 mm)/8 mm

Conduct Tip ......................... 8F (2.67 mm)/10 mm

8F (2.67 mm)/10 mm

Curvature Configurations ......... Quardrupolar (4 Electrodes)

Symmetric Asymmetric............. Standard, K2

N4

Electrode Spacing ................. 2.5 mm

Tip-to-First-Ring .................... 2.5 mm

Ring-to-Ring ........................ 2.5 mm

Electrode Configuration .......... Quadrupolar (4 Electrodes)

Electrode Ring Length ............. 1.25 mm

Electrical Connectors ............... Quick Connect

INDICATIONS FOR USE

The Boston Scientific Corporation Blazer Prime 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 myoma;

• via the retrograde approach in patients with atrial valve replacement.

WARNINGS

Before operating the device, read these warnings carefully:

Per-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.

For all ablation catheters, radiofrequency (RF) power is delivered through the distal electrode and 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 Blazer Prime XP Catheters is provided in Table 1, Technical Specifications.
d. Perform complete pacing system analysis on all patients after ablation.

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

Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.

Maximum Catheter Rated Voltage: 175 Vrms (251 Vpk).

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.

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 thrombi in the left atrial appendage.

Do not pass the 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 unfavorable insufficiency and/or premature failure of the prosthetic valve.

No modification of this equipment is allowed.

PRECAUTIONS

Observe these precautions, before using the device:

Do not attempt to operate the Controller before thoroughly reading the appropriate Controller & Accessories Operator’s Manual.

The Blazer Prime® XP Catheters are intended for use with the Controller and accessories.

The Blazer Prime XP Temperature Ablation Catheter is highly torqueable. 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 to disengage the catheter tip from the heart wall before resuming rotation of the handle and catheter shaft.

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

When using Blazer Prime XP Catheters, it is required that two dispersive pads be applied to the patient’s body. Avoid using dispersive pads close to cardiac pacemaker leads.

Avoid using dispersive pads close to cardiac pacemaker leads.

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
- arthrodynia
- 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
- diffusion (pericardial/pleural)
- hematoma/bruising
- hemoptysis
- hemorrhage
- hemorrhax
- 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)
- venous 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 as assessed at the end of the ablation procedure.

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 postprocedure.

- 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

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>OPC</th>
<th>One-Sided 95% Confidence Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Success</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Major Complications</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Six-Month Success</td>
<td>80%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Exact binomial using a commercially available software package.

Patient Accountability

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

Table 3. Patient Accountability

<table>
<thead>
<tr>
<th>Description</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients enrolled in the study</td>
<td>250</td>
</tr>
<tr>
<td>Patients not ablated</td>
<td>0</td>
</tr>
<tr>
<td>Patients ablated with EPT-1000XP Cardiac Ablation System</td>
<td>250</td>
</tr>
<tr>
<td>Patients ablated only with EPT-1000XP Cardiac Ablation System</td>
<td>247</td>
</tr>
<tr>
<td>Patients ablated with EPT-1000XP Cardiac Ablation System and non-investigational catheter*</td>
<td>5</td>
</tr>
<tr>
<td>Patients ablated only with non-investigational catheter</td>
<td>2</td>
</tr>
</tbody>
</table>

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

*Based on 2405 RF applications totals only.

- RF Application with time set < 1 second, temperature set < 0 degrees or duration < 11 seconds are excluded from the analysis.
- Maximum power allowed is 120 watts. Maximum temperature allowed is 90°C.

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of Procedures</th>
<th>Mean ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Procedure (hours)</td>
<td>234</td>
<td>2.1 (±1.3)</td>
<td>0.3 - 9.8</td>
</tr>
<tr>
<td>Ablation Time (hours)</td>
<td>231</td>
<td>0.7 (±0.7)</td>
<td>0.03 - 4.5</td>
</tr>
<tr>
<td>Total Fluoroscopy (minutes)</td>
<td>222</td>
<td>28.5 (±20.2)</td>
<td>2.8 - 129.0</td>
</tr>
<tr>
<td>Ablation Only Fluoroscopy (minutes)</td>
<td>222</td>
<td>14.8 (±13.8)</td>
<td>0.6 - 102.0</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Description</th>
<th># Success/# Patients Ablated</th>
<th>Percentage (one-sided 95% confidence bound)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Success</td>
<td>235/250</td>
<td>94% (91.5)</td>
</tr>
</tbody>
</table>

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 (AF) post ablation was achieved and were considered evaluable for an assessment of long-term 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 antiarrhythmic 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>
<thead>
<tr>
<th>Description</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients ablated only with EPT-1000XP Cardiac Ablation System and successful BDB and AF non-inducibility (Acute Success)</td>
<td>151</td>
</tr>
<tr>
<td>Number of patients free from recurrence</td>
<td>145</td>
</tr>
<tr>
<td>Number of patients with recurrence of atrial flutter</td>
<td>6</td>
</tr>
</tbody>
</table>

D. Adverse Events and Deaths

An adverse event was defined 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, hematomas, 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>
<thead>
<tr>
<th>Days post ablation</th>
<th>Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Atrial tachycardia</td>
</tr>
<tr>
<td>2</td>
<td>Pacer implant one day post ablation procedure for junctional rhythm*</td>
</tr>
<tr>
<td>3</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>4</td>
<td>Laryngotracheitis due to traumatic intubation</td>
</tr>
<tr>
<td>5</td>
<td>Left buttock induration, treated with narcotics</td>
</tr>
<tr>
<td>6</td>
<td>Gastrointestinal perforation</td>
</tr>
<tr>
<td>7</td>
<td>Pulmonary embolus*</td>
</tr>
<tr>
<td>8</td>
<td>Systemic embolus to legs bilaterally, right popliteal and left iliofemoral</td>
</tr>
<tr>
<td>9</td>
<td>Pacemaker implantation due to prolonged CSNRT</td>
</tr>
<tr>
<td>10</td>
<td>DVT</td>
</tr>
<tr>
<td>11</td>
<td>TIA</td>
</tr>
<tr>
<td>12</td>
<td>Right groin hematoma</td>
</tr>
<tr>
<td>13</td>
<td>Transsection femoral artery with subsequent AV fistula</td>
</tr>
<tr>
<td>14</td>
<td>Femoral AV fistula repair</td>
</tr>
<tr>
<td>15</td>
<td>Pseudoaneurysm/hematoma</td>
</tr>
<tr>
<td>16</td>
<td>Ablation for left atrial tachycardia</td>
</tr>
<tr>
<td>17</td>
<td>CVA, multiple cerebellar infarcts</td>
</tr>
<tr>
<td>18</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>19</td>
<td>CVA in patient with pre-existing cerebrovascular disease</td>
</tr>
<tr>
<td>20</td>
<td>Fever</td>
</tr>
</tbody>
</table>

*Exact binomial using a commercially-available software package.

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.
**Death summary**

**EPT-1000XP Study**

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 diet 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 6/18/00. 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.

---

**Ancillary materials required to perform cardiac ablation are as follows:**

- A fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.
- Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with the following equipment:
  - Without power limit, to achieve the desired temperature, in the ablation parameters. 
  - To ensure 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.

**EQUIPMENT REQUIRED**

- Do not use if labeling is incomplete or illegible.
- Do not use if package is opened or damaged.
- Do not use if the catheter is in contact with 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 during RF ablation.
- The Blazer Prime XP Catheter or a multi-polar catheter can be used to assess bidirectional conduction across the isthmus.
- Ensure that the ablation parameters are set as instructed in the appropriate Controller and Accessories Operator's Manual prior to making any connections.

**DIRECTIONS FOR USE**

Prior to insertion of the Blazer Prime XP Catheter, prepare the entry site according to standard aseptic practices.

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 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. Connect the catheter to the model 613 or 651 instrument cable and plug the cable into the Pod.
5. When the ablation site has been accessed and the tip of the catheter is in contact with the endocardial surface, intracardiac electrogram signals may be obtained.
6. The Blazer Prime XP Catheter or a multi-polar catheter can be used to assess bidirectional conduction across the isthmus.
7. When the targeted site has been located, the same 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.
8. 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.
9. 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.

---

**Table 9. Patient Deaths**

<table>
<thead>
<tr>
<th>Days post Ablation</th>
<th>Death summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>345</td>
<td>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.</td>
</tr>
<tr>
<td>53</td>
<td>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.</td>
</tr>
<tr>
<td>38</td>
<td>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 diet and sustained a periprosthetic left femur fracture, during treatment and recovery she developed MRSA sepsis from a CVP line, and died from complications.</td>
</tr>
<tr>
<td>214</td>
<td>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.</td>
</tr>
<tr>
<td>59</td>
<td>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.</td>
</tr>
<tr>
<td>40</td>
<td>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 6/18/00. 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.</td>
</tr>
<tr>
<td>455</td>
<td>74 year old man developed staphylococcal SBE of the mitral valve more than one year post successful ablation procedure.</td>
</tr>
<tr>
<td>30</td>
<td>48 year old woman died after a complicated elective gastric bypass surgery procedure.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>OPC</th>
<th>EPT-1000XP Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>One-sided 95% confidence Bound1</td>
<td>% (N)</td>
</tr>
<tr>
<td>Acute Success</td>
<td>86%</td>
<td>80%</td>
</tr>
<tr>
<td>Major Complications</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Six-month Success</td>
<td>86%</td>
<td>80%</td>
</tr>
</tbody>
</table>

1. Use lower power first when first delivering RF energy.
2. Connect the catheter to the model 613 or 651 instrument cable and plug the cable into the Pod.
3. When the ablation site has been accessed and the tip of the catheter is in contact with 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 during RF ablation.
4. The Blazer Prime XP Catheter or a multi-polar catheter can be used to assess bidirectional conduction across the isthmus.
5. When the targeted site has been located, the same 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.
6. 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.
7. 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.
10. The 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.

11. 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 catheter (in watts).

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

13. 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.

### Table 11. Correcting Abnormal Conditions

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible Cause</th>
<th>Corrective Action Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of temperature rise</td>
<td>Inadequate contact between electrode and tissue</td>
<td>1. Discontinue RF delivery 2. Adjust Catheter position to contact and stability 3. Reinitiate RF delivery</td>
</tr>
<tr>
<td>Low temperature</td>
<td>Electrode not stable on endocardium</td>
<td>1. Discontinue RF delivery 2. Adjust Catheter position to contact and stability 3. Reinitiate RF delivery</td>
</tr>
<tr>
<td>Sudden drop in temperature Sudden rise in power</td>
<td>Loss of contact or shift in electrode position</td>
<td>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</td>
</tr>
</tbody>
</table>

### CATHETER REMOVAL

1. Prior to removing the catheter, straighten the distal end of the catheter completely.
2. Withdraw the catheter from the vessel.
3. Remove the introducer and/or long introducer sheath and then follow standard practice for management of the insertion site.

### WARRANTY

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