Blazer® Open Irrigated Ablation Catheter

TABLE OF CONTENTS

WARNING .................................................................................................................. 1
DEVICE DESCRIPTION.................................................................................................. 1
INTENDED USE / INDICATIONS FOR USE............................................................. 2
CONTRAINDICATIONS............................................................................................... 2
PRECAUTIONS......................................................................................................... 2
POTENTIAL ADVERSE EVENTS ............................................................................. 3

CLINICAL STUDIES................................................................................................. 3
Objective .................................................................................................................... 3
Study Design ............................................................................................................ 3
Study Endpoints ...................................................................................................... 3
Patient Accountability .............................................................................................. 3
Table 1: Subject Disposition and Accountability for Endpoint Analysis .......... 4
Table 2: Randomized Subjects Withdrawal Summary .......................................... 4
Study Population Demographics and Baseline Parameters ................................ 4
Table 3: Baseline Characteristics (Randomized Cohort N=230) ......................... 4

RESULTS.................................................................................................................. 5
Procedural Data ........................................................................................................ 5
Ablation Parameters ................................................................................................. 5
Table 4: Ablation Parameters* ................................................................................ 5
Fluids Received During the Procedure .................................................................... 5
Table 5: Fluid and Flow Rates Recorded During the Ablation Procedure ........... 5
Primary Safety Endpoint ......................................................................................... 5
Table 6: Primary Safety Endpoint Results (Randomized Treatment Subjects N=220) 5
Table 7: Primary Safety Endpoint Events by Group (Randomized Treatment Subjects N=220) 5
Primary Effectiveness Endpoint: Acute Success .................................................. 6
Table 8: Primary Effectiveness Endpoint Results: Acute Success (Randomized Treatment Subjects N=220) 6
Secondary Effectiveness-Chronic Success ............................................................... 6

STUDY CONCLUSION............................................................................................ 6
HOW SUPPLIED.................................................................................................... 6

MATERIALS REQUIRED....................................................................................... 6
Accessories.............................................................................................................. 7
Optional Equipment for the Maestro 4000® Controller / MetriQ™ Pump System 7
Handling and Storage ............................................................................................ 7
Operating Environment ......................................................................................... 7
Transport Environment .......................................................................................... 7
Storage Environment ............................................................................................. 7

SETUP AND OPERATIONAL INSTRUCTIONS....................................................... 7
End of Procedure .................................................................................................... 7
Troubleshooting ..................................................................................................... 7

WARRANTY............................................................................................................ 7

Figure 2. System Set Up for Blazer®-Open Irrigated Ablation Catheter with Maestro 4000 Controller and 100 W Pod, MetriQ™ Pump and Irrigation Tubing Set, and compatible cables

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 re-use, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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 diseases(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 ancillary device instructions prior to use including the Maestro 4000 Controller Operator’s Manual, MetriQ™ Pump Operator’s Manual, and MetriQ Irrigation Tubing Set directions for use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

DEVICE DESCRIPTION

The Blazer Open-Irrigated Ablation Catheter (herein referred to as the Blazer OI Catheter) is a 7.5F (2.5 mm) quadrupolar open-irrigated ablation catheter designed to deliver radiofrequency (RF) energy to the 4 mm catheter tip electrode for cardiac ablation.

The Blazer OI Catheter is to be used with the Boston Scientific Corporation (BSC) Open-Irrigated System, which consists of: Maestro 4000 Controller, Maestro 4000 100 W Pod (limited to 50 W for the Blazer OI Catheter), MetriQ Pump, MetriQ Irrigation Tubing Set and BSC MD04910 Cable.

The Blazer OI Catheter incorporates an open-irrigated cooling mechanism through a tip that is partitioned into two chambers. The proximal chamber circulates normal saline (0.9 %) within the tip to cool the proximal electrode and mitigate overheating while the distal chamber allows the fluid to flow through six irrigation holes into the patient’s vasculature, thereby cooling the tip/tissue interface. A luer connection at the proximal end of the handle connects the catheter to the MetriQ Irrigation Tubing Set, allowing the MetriQ Pump to generate the flow of saline to the catheter.

The electrode segment is comprised of a tip electrode and three ring electrodes. The tip electrode has an embedded temperature sensor and delivers RF energy for cardiac ablation. The ring electrodes record Electrogram (EGM) signals for mapping and deliver stimuli for pacing. The Blazer OI Catheter interfaces with standard recording equipment. The handle includes the electrical connector for the cable connection to the Maestro 4000 Pod and one luer fitting used to connect the catheter to the MetriQ Irrigation Tubing Set.

The Blazer OI Catheter offers a choice of three curve configurations: standard, large, and asymmetric. All curves come in a 115cm shaft length. Additionally, there is a 175cm length available in the large curve configuration.

The Blazer OI Catheter is shown in Figure 1. A system connectivity diagram (Figure 2) shows how the catheter connects to the Maestro 4000 Cardiac Ablation System.
User Information

The Blazer ® OI Catheter is a component of the Open-Irrigated System and is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance in its preparation and load the Maestro ® Irrigation Tubing Set, operating the Maestro ® Pump and Maestro 4000 ® Controller may only be provided by trained electrophysiology laboratory staff.

Contents

• One (1) Sterile Blazer Open-Irrigated Ablation Catheter

INTENDED USE / INDICATIONS FOR USE

The Blazer ® Open-Irrigated Ablation Catheter, when used with a Maestro 3000 ® Radiofrequency (RF) Controller and Maestro Irrigation Pump, is indicated for:

• cardiac electrophysiological mapping
• delivering diagnostic pacing stimuli
• RF ablation of sustained or recurrent type I atrial flutter in patients aged 18 years or older

CONTRAINDICATIONS

The Blazer Open-Irrigated Ablation Catheter is contraindicated for use in:

• with active systemic infection;
• with a mechanical prosthetic heart valve through which the catheter must pass;
• unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
• where you have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral access;
• who are hemodynamically unstable;
• who have myxoma or an intracardiac thrombus;
• who have had a ventriculotomy or atriotomy within the preceding eight weeks.

WARNINGS

• Cardiac mapping and ablation procedures should be performed only by physicians who have been trained in cardiac catheterization and in the techniques of open-irrigated RF powered catheter mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab.
• Carefully read all ancillary device instructions prior to use, including the Maestro 4000 ® Controller Operator’s Manual, the Maestro Pump Operator’s Manual and the Maestro Irrigation Tubing Set directions for use. Observe all contraindications, warnings, and precautions noted in these directions. Failure to do so may result in patient complications.

Note: The Blazer OI Catheter is not designed to be compatible with the Maestro 3000 ® Cardiac Ablation System.

Before using, inspect the Blazer OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device (s) if necessary.

NOTE: The Maestro 4000 ® Controller is a Class I, Type A, General Purpose Medical Equipment. Do not use in isolation.

Contents are supplied STEERED using an EN process and should be used by the “Use By” date on the device package. Do not use this product if the printed expiration date has passed.

In the event of Maestro 4000 Controller cut-off (impedance or temperature), the Blazer OI Catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.

The ICD could be damaged by the ablation procedure. Interrogate the ICD prior to the procedure to confirm absence of mural thrombus and/or embolism. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.

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

Significant radiation exposure can result in acute radiation injury as well as dose-related morbidity and mortality. Take all appropriate measures to minimize radiation exposure to both patients and clinical staff.

In the event of a suspected failure of the integrity of fluid flow through the Blazer OI Catheter or there is a rapid temperature rise of greater than 15 degrees C noted on the Maestro 4000 Controller, the procedure should be ceased and the Blazer OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the Blazer OI Catheter and the Maestro Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of embolization.

Prior to the procedure, always identify the patient’s risk of volume overload. Monitor the patient’s fluid balance throughout the procedure and adjust as necessary. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Excessive curves or kinking of the Blazer OI Catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.

Manuel bending or twisting of the distal curve can damage the steering mechanism and increase patient and/or catheter damage. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Before using, inspect the Blazer OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device (s) if necessary.

NOTE: The Maestro 4000 ® Controller is a Class I, Type A, General Purpose Medical Equipment. Do not use in isolation.

Contents are supplied STEERED using an EN process and should be used by the “Use By” date on the device package. Do not use this product if the printed expiration date has passed.

In the event of Maestro 4000 Controller cut-off (impedance or temperature), the Blazer OI Catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.

The ICD could be damaged by the ablation procedure. Interrogate the ICD prior to the procedure to confirm absence of mural thrombus and/or embolism. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.

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

Significant radiation exposure can result in acute radiation injury as well as dose-related morbidity and mortality. Take all appropriate measures to minimize radiation exposure to both patients and clinical staff.

In the event of a suspected failure of the integrity of fluid flow through the Blazer OI Catheter or there is a rapid temperature rise of greater than 15 degrees C noted on the Maestro 4000 Controller, the procedure should be ceased and the Blazer OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the Blazer OI Catheter and the Maestro Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of embolization.

Prior to the procedure, always identify the patient’s risk of volume overload. Monitor the patient’s fluid balance throughout the procedure and adjust as necessary. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Excessive curves or kinking of the Blazer OI Catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.

Manuel bending or twisting of the distal curve can damage the steering mechanism and increase patient and/or catheter damage. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Before using, inspect the Blazer OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device (s) if necessary.

NOTE: The Maestro 4000 ® Controller is a Class I, Type A, General Purpose Medical Equipment. Do not use in isolation.

Contents are supplied STEERED using an EN process and should be used by the “Use By” date on the device package. Do not use this product if the printed expiration date has passed.

In the event of Maestro 4000 Controller cut-off (impedance or temperature), the Blazer OI Catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.

The ICD could be damaged by the ablation procedure. Interrogate the ICD prior to the procedure to confirm absence of mural thrombus and/or embolism. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.

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

Significant radiation exposure can result in acute radiation injury as well as dose-related morbidity and mortality. Take all appropriate measures to minimize radiation exposure to both patients and clinical staff.

In the event of a suspected failure of the integrity of fluid flow through the Blazer OI Catheter or there is a rapid temperature rise of greater than 15 degrees C noted on the Maestro 4000 Controller, the procedure should be ceased and the Blazer OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the Blazer OI Catheter and the Maestro Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of embolization.

Prior to the procedure, always identify the patient’s risk of volume overload. Monitor the patient’s fluid balance throughout the procedure and adjust as necessary. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Excessive curves or kinking of the Blazer OI Catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.

Manuel bending or twisting of the distal curve can damage the steering mechanism and increase patient and/or catheter damage. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

Before using, inspect the Blazer OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device (s) if necessary.

NOTE: The Maestro 4000 ® Controller is a Class I, Type A, General Purpose Medical Equipment. Do not use in isolation.

Contents are supplied STEERED using an EN process and should be used by the “Use By” date on the device package. Do not use this product if the printed expiration date has passed.

In the event of Maestro 4000 Controller cut-off (impedance or temperature), the Blazer OI Catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.
POTENTIAL ADVERSE EVENTS

- fluid volume overload
- hematoma
- hemorhage
- hypotension
- infection
- lead dislodgement
- myocardial infarction
- nerve injury (phrenic/vagus)
- pericarditis
- pleuritis
- pneumothorax
- pseudoaneurysm
- pulmonary/pleural edema
- radiation exposure
- renal insufficiency/Failure
- skin burn (radiation/debribrator/cardioverter)
- tamponade
- transient ischemic attack (TIA)
- thrombosis
- valvular regurgitation
- vasoospasm
- vaso/vagal reactions
- vessel trauma (perforation/dissection/rupture)

CLINICAL STUDIES

Boston Scientific conducted a clinical study (BLOC-CTI) to establish a reasonable assurance of safety and effectiveness of rigid, non-irrigated cardiac ablation using the Blazer OI Catheter in the treatment of type I Atrial Flutter (AFL). The clinical study was conducted using a surrogate system consisting of the Stockert 790 Radiofrequency Generator and the CoolFlow® Irrigation Pump and Tubing Set. However, on the basis of the engineering testing and animal studies, the results of the BLOC-CTI study may be extrapolated to the use of Blazer OI Catheter with the Maestro 4000 Generator and Maestro Pump. These data from the clinical study are summarized below.

Objective

A multi-center clinical study was conducted using the Blazer OI Catheter. The purpose of the clinical study was to demonstrate that the Blazer Open-Irri gated Investigational Catheter is non-inferior to that of the Control Catheters when used to ablate the cavo-tricuspid isthmus for the treatment of sustained or recurrent type I atrial flutter.

Study Design

BLOC-CTI [Blazer Open-Irrigated Radiofrequency Catheter for the Treatment of Type I Atrial Flutter (AFL)] was a prospective, randomized, controlled, single-blinded, multi-center U.S. investigation. A roll-in cohort was introduced into the study for investigators to use the Blazer OI Catheter and a Control Catheter but those subjects were not part of the endpoint analyses. In this study, the Control devices were open-irrigated radiofrequency (RF) ablation catheters that received FDA market-approval for the treatment of type I atrial flutter and the Investigational device was the Blazer OI Catheter.

Patients were treated between January 17, 2011 and January 15, 2014. The database for this Premarket Approval (PMA) reflected data collected through January 15, 2014 and included 302 patients. There were 24 investigational sites.

All adverse events and deaths reported in this study were reviewed and adjudicated by a Clinical Events Committee (CCE). The CCE was comprised of independent physicians, and its decisions were based upon independent physician review of data.

Study Endpoints

Primary Safety Endpoint

The Primary Safety Endpoint was the procedure-related complication-free rate at 7 days post-procedure. Procedure-related complications were defined as adverse events that are related to the ablation procedure or catheter and result in death, life threatening complication, or a persistent or significant disability/incapacity or required intervention to prevent impairment of a body function or damage to a body structure. The difference in procedure-related complication free rates between the randomized groups was calculated and compared against a 10% non-inferiority margin.

Primary Effectiveness Endpoint

The Primary Effectiveness Endpoint was Acute Success. Acute Success was defined as demonstration of bi-directional cavo-tricuspid isthmus (CTI) block 30 minutes following the last RF application in the CTI with the sole use of the randomized Investigational or selected Control Catheter only. Acute Success was evaluated for each randomized group and the difference between the two groups was compared against a 10% non-inferiority margin.
Study Population Demographics and Baseline Parameters

The average age of the subjects was 66.4 years for the Control Group and 66.6 years for the Investigational Group. For both treatment groups, the majority of subjects were male. The Control Group enrolled 96 male subjects (76.8%) and the Investigational Group enrolled 102 male subjects (81.6%). There were 29 females enrolled in the Control Group (23.2%) and 23 female subjects enrolled in the Investigational Group (18.4%). The demographics of the study population are typical for an atrial flutter ablation study performed in the US.

Table 1: Subject Disposition and Accountability for Endpoint Analysis

<table>
<thead>
<tr>
<th>Reason</th>
<th>Control</th>
<th>Investigational</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject refused testing/follow-up</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Subject “lost to follow-up”</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 2: Baseline Characteristics (Randomized Cohort N=250)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Measurement or Category</th>
<th>Control (N=125)</th>
<th>Investigational (N=125)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>N</td>
<td>125</td>
<td>125</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>69 ± 10</td>
<td>65 ± 11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>35 - 85</td>
<td>25 - 91</td>
<td></td>
</tr>
<tr>
<td>Gender [N (%)]</td>
<td>Female</td>
<td>29 (23.2)</td>
<td>23 (18.4)</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>96 (76.8)</td>
<td>102 (81.6)</td>
<td></td>
</tr>
</tbody>
</table>

Cardiac and cardiovascular disease history

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Measurement or Category</th>
<th>Control (N=125)</th>
<th>Investigational (N=125)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angio/angioplasty [N (%)]</td>
<td>13 (10.4)</td>
<td>12 (9.6)</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>CABG [N (%)]</td>
<td>25 (20.0)</td>
<td>24 (19.2)</td>
<td>0.87</td>
<td></td>
</tr>
<tr>
<td>Device-Implant (CRT) [N (%)]</td>
<td>1 (0.8)</td>
<td>0 (0)</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>Device-Implant (ICD) [N (%)]</td>
<td>8 (6.4)</td>
<td>5 (4.0)</td>
<td>0.39</td>
<td></td>
</tr>
<tr>
<td>Pacemaker-Implant [N (%)]</td>
<td>3 (2.4)</td>
<td>10 (8.0)</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Heart valve repair/ replacement [N (%)]</td>
<td>5 (4.0)</td>
<td>12 (9.6)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Type II Diabetes [N (%)]</td>
<td>35 (28.0)</td>
<td>30 (24.0)</td>
<td>0.70</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia [N (%)]</td>
<td>75 (60.0)</td>
<td>77 (61.6)</td>
<td>0.80</td>
<td></td>
</tr>
<tr>
<td>1st Degree AV Block [N (%)]</td>
<td>12 (9.6)</td>
<td>17 (13.6)</td>
<td>0.44</td>
<td></td>
</tr>
<tr>
<td>2nd Degree AV Block (Mobitz I) [N (%)]</td>
<td>2 (1.6)</td>
<td>9 (7.2)</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>2nd Degree AV Block (Mobitz II) [N (%)]</td>
<td>2 (1.6)</td>
<td>9 (7.2)</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation [N (%)]</td>
<td>67 (53.6)</td>
<td>72 (57.6)</td>
<td>0.37</td>
<td></td>
</tr>
<tr>
<td>Atrial flutter [N (%)]</td>
<td>2 (1.6)</td>
<td>2 (1.6)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Sickle cell syndrome [N (%)]</td>
<td>9 (7.2)</td>
<td>7 (5.6)</td>
<td>0.61</td>
<td></td>
</tr>
</tbody>
</table>

RESULTS

Procedural Data

The goal of the ablation procedure was to produce bi-directional conduction block between the tricuspid annulus and inferior vena cava at the CFA. Subjects with type I atrial flutter were randomized to be treated with either the Investigational device or the Control device in the ablation procedure.

Three subjects were ablated for a concomitant arrhythmia, two subjects for atrial tachycardia and one subject for atrial fibrillation and atrial flutter, during the index procedure for type I atrial flutter.

Control Catheters Used

Investigators used a total of 112 Control Catheters as the initial catheter in the ablation procedure for 111 Randomized Control subjects and one (1) randomized to the Investigation group. The ThermoCool Open-Irigated catheter (Biosense Webster) was the most frequently used catheter in the Control group (96/112), followed by the Thermocool 0.014 Nav catheters (32/112) and the St Jude Medical Cool Path, Therapy Cool Path, and Safire BLU Duo Ablation catheters (14/112).
### Table 4: Ablation Parameters*

<table>
<thead>
<tr>
<th>Ablation Parameters</th>
<th>Measurement</th>
<th>Control N=111</th>
<th>Investigational N=109</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Applications with randomized catheter</td>
<td>N</td>
<td>1260</td>
<td>1313</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>14 ± 12</td>
<td>15 ± 10</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>1 - 71</td>
<td>1 - 47</td>
</tr>
<tr>
<td>Ablation Duration (seconds)</td>
<td>N</td>
<td>1260</td>
<td>1313</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>96 ± 91</td>
<td>91 ± 78</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 999</td>
<td>0 - 742</td>
</tr>
<tr>
<td>Starting Power</td>
<td>N</td>
<td>1260</td>
<td>1306</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>20 ± 2</td>
<td>19 ± 2</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 35</td>
<td>0 - 30</td>
</tr>
<tr>
<td>Max Power (W)</td>
<td>N</td>
<td>1255</td>
<td>1298</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>36 ± 7</td>
<td>37 ± 9</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 90</td>
<td>0 - 50</td>
</tr>
<tr>
<td>Average Power (W)</td>
<td>N</td>
<td>1255</td>
<td>1301</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>21 ± 7</td>
<td>32 ± 8</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 48</td>
<td>0 - 49</td>
</tr>
<tr>
<td>Max Temperature (°C)</td>
<td>N</td>
<td>1250</td>
<td>1300</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>38 ± 5</td>
<td>33 ± 3</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>23 - 63</td>
<td>0 - 72</td>
</tr>
<tr>
<td>Average Temperature (°C)</td>
<td>N</td>
<td>1255</td>
<td>1301</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>24 ± 4</td>
<td>28 ± 2</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>23 - 51</td>
<td>21 - 46</td>
</tr>
<tr>
<td>Max Impedance (Ω)</td>
<td>N</td>
<td>1254</td>
<td>1299</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>141 ± 51</td>
<td>155 ± 46</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>62 - 999</td>
<td>0 - 160</td>
</tr>
<tr>
<td>Average Impedance (Ω)</td>
<td>N</td>
<td>1255</td>
<td>1300</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>119 ± 30</td>
<td>132 ± 34</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>35 - 380</td>
<td>33 - 230</td>
</tr>
</tbody>
</table>

*Only includes data from randomized catheters.

### Table 5: Fluid and Flow Rates Recorded During the Ablation Procedure

- **Procedural fluids** administered via the Open-irrigated catheters and non-catheter sources were recorded as shown in Table 5. The Investigational Catheter used more fluid than the Control Catheter. Patients randomized to the Control Group received an ablation using any open irrigated RF ablation catheter with FDA-mark approval for the treatment of type I AFL, when used in conjunction with the catheter’s corresponding market-approved generator and pump. Fluid infusion rates for the Control Catheter pump(s) were programmed per the manufacturer’s instructions for use of type I AFL, when used in conjunction with the catheter’s corresponding market-approved generator and pump.

<table>
<thead>
<tr>
<th>Procedure Parameter</th>
<th>Measurement</th>
<th>Control</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid infusion rate for RF applications ~30 W</td>
<td>N</td>
<td>110</td>
<td>109</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>14 ± 7</td>
<td>20 ± 6</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 30</td>
<td>15 - 30</td>
</tr>
<tr>
<td>Fluid infusion rate for RF applications &gt;30 W</td>
<td>N</td>
<td>110</td>
<td>107</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>25 ± 7</td>
<td>30 ± 1</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>13 - 30</td>
<td>15 - 30</td>
</tr>
<tr>
<td>Total fluid infused through ablation catheter (mL)</td>
<td>N</td>
<td>108</td>
<td>106</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>611 ± 433</td>
<td>689 ± 386</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>20 - 2346</td>
<td>50 - 1681</td>
</tr>
<tr>
<td>Total fluid infused through non-catheter sources (mL)</td>
<td>N</td>
<td>109</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>446 ± 337</td>
<td>544 ± 416</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 1900</td>
<td>0 - 2000</td>
</tr>
<tr>
<td>Total fluid output from the patient (mL)</td>
<td>N</td>
<td>110</td>
<td>109</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>113 ± 304</td>
<td>133 ± 393</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 1305</td>
<td>0 - 2200</td>
</tr>
</tbody>
</table>

### Table 6: Primary Safety Endpoint Results (Randomized Treatment Subjects N=220)

**Primary Safety Events**

<table>
<thead>
<tr>
<th>Event</th>
<th>Investigational Group N = 109</th>
<th>Control Group N = 111</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Accident (CVA) Resulting in Death</td>
<td>0</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Jugular Venous Reactions</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Complication-Related Procedure</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>4.6% (9.78%) Pass</td>
<td>4.6% (9.78%) Pass</td>
</tr>
</tbody>
</table>

*Only includes data from randomized catheters.

### Table 7: Primary Safety Endpoint Events by Group (Randomized Treatment Subjects N=220)

<table>
<thead>
<tr>
<th>Event</th>
<th>Investigational Group N = 109</th>
<th>Control Group N = 111</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Accident (CVA) Resulting in Death</td>
<td>0</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Jugular Venous Reactions</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Complication-Related Procedure</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>4.6% (9.78%) Pass</td>
<td>4.6% (9.78%) Pass</td>
</tr>
</tbody>
</table>

*Only includes data from randomized catheters.

### Primary Safety Endpoint

The objective of the Primary Safety Endpoint was to demonstrate that the proportion of subjects free from procedure-related complications in the Investigational group is non-inferior to that in the Control group. The safety of the Blazer® OI Catheter was evaluated by the Procedure-related Complication-Free Rate at 7 days Post-procedure. The Primary Safety Endpoint was determined after all adverse events that occurred within seven (7) days of the procedure were adjudicated by an independent Clinical Events Committee.

The Primary Safety Endpoint analysis includes all Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis (mITT), the 7 day Procedure-related Complication-Free rate was 98.2 % in the Control group and 93.6 % in the Investigational group. The difference in the 7 day Procedure-related Complication-free rate between the Control and the Investigational groups was 4.8 %. The upper 95% confidence bound of 9.78 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups. The results of the Primary Safety Endpoint are shown in Table 6. The Primary Safety Endpoint results were consistent across three analysis cohorts (i.e. mITT, PP and AT) and supported the safety of the Blazer® OI Catheter for the treatment of type I atrial flutter.
Primary Effectiveness Endpoint: Acute Success

The objective of the Primary Effectiveness Endpoint was to demonstrate that the proportion of subjects with Chronic Success in the Investigational group was non-inferior to that in the Control group. Acute Success was defined as demonstration of bi-directional CTV block 30 minutes following the last RF application in the CTV, with the sole use of the randomized Investigational or selected Control Catheter.

The Primary Effectiveness Endpoint analysis includes all 220 Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis, the Acute Success rate was 88.3 % in the Control group and 87.2 % in the Investigational group, respectively, as shown in Table 8. The difference in the Acute Success rates between the Control and the Investigational groups was 2.0 %. The upper 95 % confidence bound of 8.4 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups.

The results of the Per-Protocol and As Treated analyses were consistent with the mITT analysis and supported the effectiveness of the Blazer® Open-Irrigated Ablation Catheter for the treatment of type I atrial flutter.

Table 8: Primary Effectiveness Endpoint Results: Acute Success (Randomized Treatment Subjects N=220)

<table>
<thead>
<tr>
<th>Analysis Cohort</th>
<th>Study Group</th>
<th>Successful Procedures</th>
<th>Total Procedures</th>
<th>% Success</th>
<th>Difference (One-Sided Upper 95% Bound)</th>
<th>Endpoint Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Intention- to-Treat</td>
<td>Control</td>
<td>99</td>
<td>111</td>
<td>89.2 %</td>
<td>2.20% (5.37 %)</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>Investigational</td>
<td>95</td>
<td>109</td>
<td>87.2 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per-Protocol</td>
<td>Control</td>
<td>99</td>
<td>111</td>
<td>86.2 %</td>
<td>2.15% (9.52 %)</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>Investigational</td>
<td>94</td>
<td>108</td>
<td>87.0 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>As Treated</td>
<td>Control</td>
<td>100</td>
<td>112</td>
<td>88.3 %</td>
<td>2.35% (9.61 %)</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>Investigational</td>
<td>94</td>
<td>108</td>
<td>87.0 %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Secondary Effectiveness-Chronic Success

The objective of each of the Secondary Effectiveness Endpoints was to demonstrate that the proportion of subjects with Chronic Success in the Investigational group was non-inferior to that in the Control group. Chronic Success was evaluated for All Treated subjects and randomized subjects who had Acute Success separately.

Subjects that were followed through 3 months or had an ECG documented recurrence of type I atrial flutter with less than 5 months of follow-up were considered to have complete data. Subjects that withdrew prior to 3 months or had no arrhythmia recurrence or did not follow the protocol regarding follow-up requirements were considered to have incomplete data.

Subjects with incomplete data were reviewed to determine if there was sufficient data to determine Chronic Success. Subjects with insufficient data to determine Chronic Success were included in the analysis, but could not be considered as Chronic Successes, and therefore counted against the endpoint.

Among the 220 Randomized Treatment subjects, 19 bon control and nine investigational had incomplete data due to death in 1, one investigational, request to be withdrawn in 1 (4, one control and three investigational), or missing follow-up ECG visit in 1 (4, nine control and nine investigational).

Six subjects in the Investigational group (five acute successes and one acute failure) had ECG documented type I AFl recurrence. For three subjects, the AFl recurrence was due to EF, and the fifth subject had an AFl recurrence due to ECG documented type I AFl reoccurrence or on AADs for type I AFl during follow-up.

Chronic Success in Acute Successes

The analysis of this secondary endpoint was performed in the Modified Intention-to-Treat cohort and included only Randomized Treatment subjects who had Acute Success (99 Control and 95 Investigational). The Chronic Success rate was 88.3 % in the Control group and 87.2 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 1.0 %. The upper 95 % confidence bound of 4.0 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups.

Chronic Success in All Treated Subjects

The analysis of this secondary endpoint was performed in the Modified Intention-to-Treat cohort and included all 220 Randomized Treatment subjects (111 Control and 109 Investigational). In this analysis, all acute failures were classified as chronic failures.

The Chronic Success rate was 80.2 % in the Control Group and 74.3 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 5.9 %. The upper 95 % confidence bound of 15.0 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups.

How Supplied

The Blazer® Open-Irrigated Ablation Catheter is supplied sterile using an ethylene oxide (EO) process. Peel-off labels for device and accessories are used for device traceability. In addition to the Blazer® Catheter, please refer to Materials and Equipment Required section below for a detailed list of other materials typically required in an Electrophysiology (EP) procedure.

STUDY CONCLUSION

The clinical study met its predefined success criteria by meeting both primary safety and effectiveness endpoints. The study showed a clinically meaningful reduction in arrhythmia-related symptoms following type I atrial flutter catheter ablation.

The clinical study demonstrated non-inferiority of the Blazer® Catheter to the catheters used in acute success (defined as the achievement of bivalvular central-tricuspid isthmus block), an accepted surrogate effectiveness endpoint for type I atrial flutter ablation (AFl). The clinical study failed to statistically demonstrate non-inferiority in chronic success, which was a secondary effectiveness endpoint of the study. However, it should be noted that the study was not powered to test the non-inferiority hypothesis for chronic success. Consistent with the results of other AFl ablation studies for similar technologies, approximately 85 % of the subjects in the investigational group had acute success and complete follow-up data were free of type I AFl recurrence during 3 months follow-up, the study’s definition of chronic success. Moreover, the observed difference in chronic success between the two study groups (about 5 %) is not considered clinically meaningful.

Taken together, the study results support a reasonable assurance of safety and effectiveness of the Blazer® Catheter when used in accordance with the Indications for Use.

Materials Required

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

- **Maestro® 4000® Controller** (M04940000)
- **Maestro® 4000 Pod 100 Watt** (M04940100)
- **Moritz™ Pump** (M04940100)
- **Blazer® 000 to Maestro® 4000 Pod Cable** (M0494100)
- **Moritz™ Irrigation Tubing Set** (M0494170)
- **Cable, Generator to Pump or Remote (20, 50 and 75 ft. length)** (M0494610)
Accessories:
- Commercially available disposable disposable pads that meet or exceed IEC 60601-1/IEC 60601-2-2 requirements (M004540).
- Sterile, normal saline (1 u heparin/ml) saline (commercially available).
- Blazer OI Catheter (M004420X) / Maestro 4000 Pod (M004218500).

Optional Equipment for the Maestro 4000® Controller / MetriQ™ Pump System
- Maestro 4000 Remote (M004420X).
- Maestro Footswitch (M004218500).
- MetriQ Pump Footswitch (M004415F0).

Storage and Handling

Operating Environment to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

Note: This should be done prior to introducing any intracardiac catheters.

3. Open the Blazer OI Catheter and Cable packages and the MetriQ Irrigation Tubing Set package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.

4. Obtain vascular access via a vein (e.g., a femoral vein) by placing an 8F (2.8 mm) venous introducer sheath using a standard percutaneous technique under aseptic conditions.

5. Connect the Maestro 4000 Controller to the MetriQ Pump using the appropriate interface cable (M004461). Note: The serial terminal that connects to the MetriQ Pump is labeled. Power on the MetriQ Pump but leave the Maestro 4000 Controller turned OFF.

6. Connect the Maestro 4000 Controller to a recording system with the appropriate interface cables according to the operator's manuals.

Note: Make sure that the MetriQ Pump is in Automatic mode (displayed on the screen) and that the following flows are set on the pump: 2 ml/min (Standby), 17 ml/min (Low Ablation Flow - 30 W or less), 30 ml/min (High Ablation Flow - Above 30 W). Refer to the MetriQ Pump Operator's Manual for instructions on how to adjust the pump settings if required.

7. Connect the Blazer OI Catheter to the Maestro 4000 Controller via the Maestro 4000 Pod using the appropriate interface cables (M004610). The end of the cable with the red band should be inserted into the Maestro 4000 Pod while the end with all gray coloring inserts into the Blazer OI Catheter. Refer to Figure 2. Ensure that the cable / catheter connection remains dry throughout the procedure.

Note: If a three-dimensional (3-D) catheter navigation and mapping system is going to be used, please follow the standard operating procedure of the electrophysiology lab or the directions for use contained in the manufacturer's operator's manual.

8. Ensure Power Control mode is enabled on the Maestro 4000 Controller.

9. The Controller's default temperature limit is 50°C, but can be set lower at physician discretion.

10. Refer to either the MetriQ Tubing Set or Maestro® Pump DUF for instructions to connect the MetriQ Irrigation Tubing Set to irrigation fluid and install into the MetriQ Pump.

11. Connect the Blazer OI Catheter to the MetriQ Irrigation Tubing Set via the luer fitting at the proximal end of the catheter handle. Care must be taken to ensure all luer fittings are secure to prevent leaking.

12. Purge the Blazer OI Catheter and MetriQ Irrigation Tubing Set using the triple arrow purge button on the MetriQ Pump. Fluid should exit all six (6) irrigation ports during the flushing process. Assumes that no arms remains within the MetriQ Irrigation Tubing Set or lumen and all irrigation ports are patent.

13. Check the catheter steering by articulating the steering knob prior to inserting the catheter in the sheath.

14. Before placing the Blazer OI Catheter in the sheath, begin continuous irrigation at a flow rate of 3.0 ml/min, i.e., stand-by flow. Check for any leaks at the tip of the Blazer OI Catheter (other than normal saline flowing out of the distal port), at the Blazer OI Catheter handle, and at the luer connections and tubing joints.

15. Under fluoroscopic guidance, insert the Blazer OI Catheter into the sheath and advance through the vasculature into the heart.

16. The degree of tip deflection of the catheter is controlled by the Steering Knob on the Blazer OI Catheter handle (See Figure 1). If the Steering Knob is turned in a clockwise direction 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. Turning the Steering Knob in the counter-clockwise direction will cause the tip to deflect in the opposite direction. To prevent oversteering the tip, the Steering Knob movement is limited by the handle design. The tension adjust knob may be when used when the desired catheter placement is achieved.

17. Determine the area of interest for ablation.

18. Set the initial power level to 15 W - 20 W.

19. Increase the irrigation flow rate to 17 ml/min up to 5 seconds before the onset of RF energy delivery and maintain this higher flow rate until 5 seconds after termination of the energy application. Then return the flow rate to 2 ml/min.

Note: Confirm the increased irrigation flow rate prior to onset of RF energy by observation of a decrease in tip electrode temperature at least of a 2°C. If it is necessary to ablate with power levels of 31 W - 59 W, irrigation flow rates should be increased to 30 ml/min starting 5 seconds before onset and ending 5 seconds after RF energy delivery. Then, return the flow rate to 2 ml/min.

20. Start the procedure at 15 W - 20 W. Power may be increased by 5 W - 10 W increments as needed to create a transmural lesion. A greater than 80 % reduction in unipolar electrogram amplitude or emergence of double potentials of equal and low amplitude may be indicators of a transmural lesion.

21. Do not ablate for greater than 60 seconds in duration without moving the tip of the Blazer OI Catheter.

22. RF current may be reapplied to the same or alternate sites using the same catheter.

End of Procedure
1. Prior to removing the Blazer OI Catheter, straighten the distal end of the Blazer OI Catheter completely.
2. Withdraw the Blazer OI Catheter when the procedure is finished.
3. Turn-off Maestro 4000 Controller and MetriQ Pump.
4. Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

Troubleshooting

Problems | Possible Cause | Corrective Action Procedure
--- | --- | ---
Temperature not displayed | Poor catheter/cable connections | 1. Verify that the M004610 Cable is plugged into both the Maestro 4000 Pod and Blazer OI Catheter.
2. Replace cable and/or catheter.
3. If the Maestro 4000 still does not display temperature, there may be a malfunction in the temperature sensing system.
4. Consult the user manual and correct this malfunction prior to reapplying RF energy.

- Impedance cutoff
- Temperature cutoff | Char/coagulum on tip-electrode | 1. Discontinue RF delivery.
2. Straighten the distal end and withdraw Blazer OI Catheter.
3. Inspect tip electrode for any char/coagulum.
4. If present, gently wipe the tip section with a sterile gauze dampened with sterile saline (do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode).
5. Prior to reinstrumentation, ensure the irrigations ports are patent. If irrigation port occlusion occurs:
   a. Ensure Blazer OI Catheter is removed from the patient.
   b. Fill 1 ml or 2 ml syringe with sterile saline and attach to the stop-cock screw of the Blazer OI Catheter.
   c. Carefully inject the saline from the syringe into the Blazer OI Catheter fluid port without air or bubbles.
   d. Reinsert the distal end of the Blazer OI Catheter without irrigation ports during the flushing process.
   e. Repeat steps 1 and 2, if necessary.
   f. If the irrigation ports are cleared, the Blazer OI Catheter can be reintroduced into the patient. WARNING: Do not continue to use the Blazer OI Catheter if still occluded.

Suspected failure of fluid flow integrity | Leak in catheter and/or irrigation tubing set | 1. Discontinue RF delivery.
2. Straightening the distal end and withdraw catheter.
3. Replace Blazer OI Catheter and irrigation tubing set, prime outside of the patient.
4. Replace Blazer OI Catheter and/or irrigation tubing set if parameters do not appear normal or if there is an abnormality of the integrity of fluid flow.
5. Refer to the Blazer Irrigation Pump user manual to verify fluid flow is accurate.
6. Contact BSC representative to replace irrigation pump.

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 all 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 expenses directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for BSC, 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.

ThermaCool and CoolFast are trademarks of Boston Scientific Corporation.
CooLPath and Safe are trademarks of St. Jude Medical.
TheraCath is a trademark of Irvine Biomedical, Inc.
Steckler is a trademark of Sirona Group Deutschland GmbH.
Figure 2. System Set Up for Blazer® Open-Irrigated Ablation Catheter with Maestro 4000® Controller and 100 W Pod, MetriQ™ Pump and Irrigation Tubing Set, and compatible cables.