Empower Irrigated Ablation Procedures
Cool.

Total Tip Cooling™ Design

Internal Cooling:
Dual chambers cool the entire tip

Greater Cooling Capacity:
Consistently cooler throughout RF delivery¹

External Washing:
Optimized flow pattern actively washes tip

Conventional Open-Irrigated Tip

BLAZER™ Open-Irrigated Tip

- Greater Cooling Capacity²
- Active Tip Washing

Infrared thermal images are from bench testing performed by Boston Scientific. N=1. Data on file.


Product illustrations of catheter construction designed by Boston Scientific, not actual photos.
Confident.

**Tip/Tissue Interface Comparison:** BLAZER OI and ThermoCool SF at 30 seconds

**BLAZER OI:**
Effective power delivery with steady tissue temperature rise

**Control.**

The BLAZER platform performs as an extension of your hand, eliciting control through benefits such as:

- Bi-Directional Steering
- Tip Stability
- Lateral Contact
- Torqueability
- Trackability
- Fine Micro-Movements

1 M+
BLAZER™
Catheters
used clinically worldwide since launch
Empower Efficiency

Simple connectivity and intelligent user interface enables quick setup and efficient operation.

Intelligent User Interface

- Comprehensive, real-time diagnostic information on one screen
- Large, easy-to-read display can be viewed from a distance
- Quick, intuitive menu navigation

IntellaSight Infusion Monitoring

- Provides real-time feedback on five different saline assessments
  - Volume Remaining
  - Volume Infused
  - Volume Dispensed
  - Low Fluid Warning
  - New Saline Bag
Empower Performance

Automatic communication between system components activates enhanced features to deliver safe, reliable performance throughout the procedure.

Bubble and Occlusion Detection

- Reliable sensor technology designed to prevent air infusion and occlusion
- Simple placement process to ensure accurate tubing alignment
- Smaller tubing designed to effectively clear bubbles and increase flow

Automatic Titration

- Intelligent, automatic titration for optimal power-to-fluid control
- Instant, clear display of titration status

Example Scenario: METRIQ™ Pump automatically delivers saline at hi-flow (30 mL/min) when the MAESTRO 4000™ Controller power level is set to 30 Watts.
Empower Integration

The MAESTRO 4000™ RF Generator fully integrates with today’s most advanced products to diagnose and treat cardiac arrhythmias.

Compatible with Our Full Portfolio of Cutting-edge Catheters

BLAZER™ OPEN-IRRIGATED with Total Tip Cooling™
INTELLATIP MIFI™ Multi-Dimensional Ablation Technology
BLAZER™ Ablation Technology

Boston Scientific EP Lab

iLAB™ Ultrasound Imaging System
METRIQ™ Irrigation Pump
MAESTRO 4000™ Cardiac Ablation System
RHYTHMIA Signal Station

Comprehensive Portfolio of Diagnostic and Therapeutic Catheters

MicroPace Cardiac Stimulator
LABSYSTEM™ PRO Windows 7 EP Recording System
RHYTHMIA™ Mapping System
Product Ordering Information

**BLAZER™ OPEN-IRRIGATED Ablation Catheter**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Shaft Size</th>
<th>Tip Size</th>
<th>Curve Style</th>
<th>Shaft Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 9620 0</td>
<td>7.5F</td>
<td>7F/4mm</td>
<td>Standard</td>
<td>110cm</td>
</tr>
<tr>
<td>M004 9620K2 0</td>
<td>7.5F</td>
<td>7F/4mm</td>
<td>Large</td>
<td>110cm</td>
</tr>
<tr>
<td>M004 9620K2E0</td>
<td>7.5F</td>
<td>7F/4mm</td>
<td>Large/Extra Long</td>
<td>115cm</td>
</tr>
<tr>
<td>M004 9620N4 0</td>
<td>7.5F</td>
<td>7F/4mm</td>
<td>Asymmetric</td>
<td>110cm</td>
</tr>
</tbody>
</table>

**METRIQ™ Irrigation Pump**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 4100 0</td>
<td>METRIQ™ Pump</td>
</tr>
<tr>
<td>M004 661 0</td>
<td>Cable, Generator to Pump or Remote (20ft)</td>
</tr>
<tr>
<td>M004 663 0</td>
<td>Cable, Generator to Pump or Remote (50ft)</td>
</tr>
<tr>
<td>M004 664 0</td>
<td>Cable, Generator to Pump or Remote (75ft)</td>
</tr>
</tbody>
</table>

**MAESTRO 4000™ Cardiac Ablation System**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 4000 0</td>
<td>MAESTRO 4000 Controller</td>
</tr>
<tr>
<td>M004 4020 0</td>
<td>MAESTRO 4000 Remote</td>
</tr>
<tr>
<td>M004 21850 0</td>
<td>MAESTRO Foot Switch</td>
</tr>
<tr>
<td>M004 4010 0</td>
<td>MAESTRO 4000 Pod, 100W (US)</td>
</tr>
</tbody>
</table>

**BLAZER™ OPEN-IRRIGATED Accessories**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 671 0</td>
<td>Cable, BLAZER OPEN-IRRIGATED Catheter to MAESTRO 4000™ Generator</td>
</tr>
<tr>
<td>M004 117 0</td>
<td>METRIQ Irrigation Tubing Set</td>
</tr>
</tbody>
</table>

**Bidirectional Curve Options**

- Standard Radius Curve
- Large Radius Curve (K2, K2E)
- Asymmetric 4 Curve (N4)

Catheter configurations are illustrative representations only and may not reflect actual performance.
INDICATIONS FOR USE
The Blazer® Open-Irrigated Ablation Catheter, when used with a compatible Radiofrequency (RF) Controller and Irrigation Pump, is intended for use in cardiac electrophysiology procedures, including catheter ablation of atrial flutter in patients age 18 years or older. The pump should not be used in conjunction with the Blazer® Open-Irrigated Catheter. Note: The Blazer® Catheter is not designed to be used with the Maestro 3000® RF Cardiac Ablation System. Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk to somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopy imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in pregnant children. Patients undergoing an atrial flutter ablation are at risk for complete atrioventricular block which may require temporary or permanent pacing. Therefore, always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. Stimulation of cardiac tissues caused by pacing stimuli and RF energy may lead to ventricular fibrillation. These rhythms may require defibrillation that could also result in skin burns. Prior to the procedure, always identify the patient’s risk of volume overload. Monitor the patient’s fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. 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. In the event of RF Controller cut-off (impedance or temperature), the Blazer® Catheter must be withdrawn and the tip electrode cleared of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent and free from debris. Irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism. Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution. This Blazer® Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmia, embolism, thrombus and/or patient death. 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. If there is uncertainty regarding the patient’s conduction 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 mural thrombus and/or thrombus in the left atrial appendage.

PRECAUTIONS
The Blazer® Open-Irrigated Ablation Catheter is not intended to be used with a RF generator output setting exceeding 50W or 212 Volts peak. The Blazer® Open-Irrigated Ablation Catheter contains Bis (2-ethylhexyl) phthalate (DEHP). BS has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BS has not assessed the residual patient risk associated with phthalates which may be contained in non-BSA specialty devices required for use in conjunction with the Blazer® Open-Irrigated Catheter.

ADVERSE EVENTS
Potential adverse events which may be associated with catheterization include: Allergic reaction (including anaphylaxis), Angina, Arrhythmias (new or exacerbation of existing arrhythmias), Cardiac perforation, Cardiac respiratory arrest, Catheter embolism, Cerebrovascular accident (CVA), Chest discomfort, Conduction pathway injury, Complete heart block (transient/permanent), Complications of sedative agents/anesthetics, Congestive heart failure, Death, Edema, Effusion (pericardial/pulmonary), Embolism (venous/arterial) (e.g., air embolism, cerebrovascular accident, Myocardial Infarction (MI), pulmonary embolism), Esophageal injury, Excavation of existing conditions, Fistula (arterial/venous/atrio-esophageal), Fluid volume overload, Gastroesophageal/Gastrointestinal (GI) (e.g., Hematemesis, Hemorrhage, Hemoptysis, Hypertension, Hypotension, Inadvertent injury to adjacent structures, Infection; Lead dislodgement, Myocardial infarction; Nerve injury (phrenic/vagus), Paresthesias, Pleurothorax, Pneumoneumothorax, Pulmonary/pleural edema, Pulmonary venous stenosis, Radiation exposure, Renal insufficiency/failure, Perforation, Residual Atrial Septal Defects (ASD); Skin burn (radiofrequency/cardiocutaneous), Tamponade, Transient ischemic attack (TIA); Thrombosis; Vascular damage; Vasospasm; Vasovagal reactions, Vessel trauma (perforation/disruption/rupture). 91137219 (Rev A)

MAESTRO 4000™ Cardiac Ablation System Indications for Use, Contraindications, Warnings, Potential Adverse Events

INTENDED USE/INDICATIONS FOR USE
The Maestro 4000 Cardiac Ablation System is intended for use with BSC cardiac ablation catheters in cardiac ablation procedures. Note: Refer to the individual catheter Directions for Use for catheter comparability to the Maestro 4000 Cardiac Ablation System. It is also important to carefully review the specific indications, contraindications, warnings, precautions and adverse events included with each catheter prior to use of the catheter with the Maestro 4000 Cardiac Ablation System.

CONTRAINDICATIONS
There are no specific contraindications for the use of the Maestro 4000 Cardiac Ablation System itself. However, users should read and understand the specific indications, contraindications, warnings, and precautions included with any cardiac ablation catheter used in conjunction with the System. The contraindications listed in the catheter Directions for Use also apply to the use of the Maestro 4000 Cardiac Ablation System. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each catheter prior to use of the Maestro 4000 Cardiac Ablation System.

ADVERSE EVENTS
Users should also read and understand the specific indications, contraindications, warnings, and precautions included with any catheter used in conjunction with the System. Potential adverse events associated with the use of the Maestro 4000 Cardiac Ablation System are, but not limited to, the following: Additional intervention required; Arrhythmia; Burns; Cardiac Arrest; Cardiac Tamponade; Cardiac Ventricular Arrhythmia (CVA); Complete Heart Block; Conduction Pathway Injury; Congestive Heart Failure; Death; Discomfort; Edema; Electrical Shock; Embolism; Esophageal Exposure to Biohazardous Material; Fistula; Hematoma; Infection; Injury (Not Otherwise Specified); Laceration; Myocardial Infarction; Myocardial Trauma; Necrosis; Nerve Injury; Perforation; Percutaneous Fistula; Perforation, Cardiac Effusion; Perforation, Pericardial Effusion; Prolonged Procedure, Renal damage/failure, Swallowing Disorders, Tissue Damage, Transient Ischemic Attack (TIA); Thrombosis; Vascular damage; Vasospasm; Vasovagal reactions, Vessel trauma (perforation/disruption/rupture). 91137219 (Rev A)

METRIO™ Pump Indications for Use, Contraindications, Warnings, Potential Adverse Events

INTENDED USE/INDICATIONS FOR USE
The MetriQ Pump is intended for use in conjunction with a BSC open-irrigated cardiac ablation catheter, MetriQ Irrigation Tubing Set, and Maestro 4000 Cardiac Ablation System to deliver irrigation solution into a patient during cardiac ablation procedures.

CONTRAINDICATIONS
There are no specific contraindications for use of the MetriQ Pump itself. However, users should read and understand specific indications, contraindications, warnings and precautions included with any open-irrigated cardiac ablation catheter used in conjunction with the pump.

WARNINGS
To avoid no-drug use, do not use the pump in the presence of flammable anesthetics or in an oxygen rich environment. The MetriQ Pump needs special precautions regarding EVC and needs to be installed and put into service according to the Electromatic Compatibility Information section of this manual. The pump should not be used adjacent to, or stacked with, other equipment that is sensitive to moisture. Moving parts such as the door, pole clamp and rotating pump head, while designed for safe operation, should be operated with care to prevent injury to the operator. Intentional misuse of the pump may cause serious injuries to operator and/or patient. The flow of irrigation fluid will stop when the alarm is activated due to bubble detection, occlusion detection, wrong pump motor speed, the user attempts to open the door during flow, or a System Fault is detected. To continue irrigation, all alarms must be attended immediately or insufficient irrigation may result. Loss of communication with the Maestro 4000 Controller will result in the MetriQ Pump to stop flow. The MetriQ Pump will flow irrigation fluid but will automatically switch from a HIGH ABLATION FLOW or LOW ABLATION FLOW rate to STANDBY FLOW. If the pump was STOPPED there will be no change. If the pump was in STANDBY flow it will not change the flow rate. The flow of irrigation fluid rate may delay the procedure or require additional intervention. Hospital personnel are responsible for periodically verifying and monitoring the flow rate delivered to prevent improper irrigation of fluid. Flow should be verified visually by noting the chip rate in the drip chamber. During use, monitor tubing set for visible bubbles and stop the pump if all bubbles are observed to prevent possible occurrence of embolism. Do not press the pump button while catheter is in the patient or embolism may occur. The bubble detector is necessarily disabled during purging. In the event of a power loss, the catheter must be withdrawn and all procedural steps must be restarted to reduce the risk of embolism. The MetriQ Pump is designed for use with the MetriQ Irrigation Tubing Set, the Maestro 4000 Controller and the BSC Open-Irrigated Catheters. Use of other types of RF controllers, tubing and catheters may impair proper operation of the pump and can result in improper irrigation resulting in serious consequences to the patient. The pump, catheter and tubing set are designed for use with standard irrigation solutions such as normal saline (0.9% NaCl solution) only. RF ablation system MAY NOT BE maintained when used with incompatible fluids or delivery devices. Hospital personnel are responsible for verifying the use of proper irrigation fluid and ensuring the tubing is sufficiently primed to prevent possible occurrence of embolism.

ADVERSE EVENTS
Users should also read and understand the specific indications, contraindications, warnings, and precautions included with any catheter used in conjunction with the MetriQ Pump and any other cardiac ablation catheter used in conjunction with the pump. All tradenames are the properties of their respective owners.