Boston Scientific
Advancing science for life™

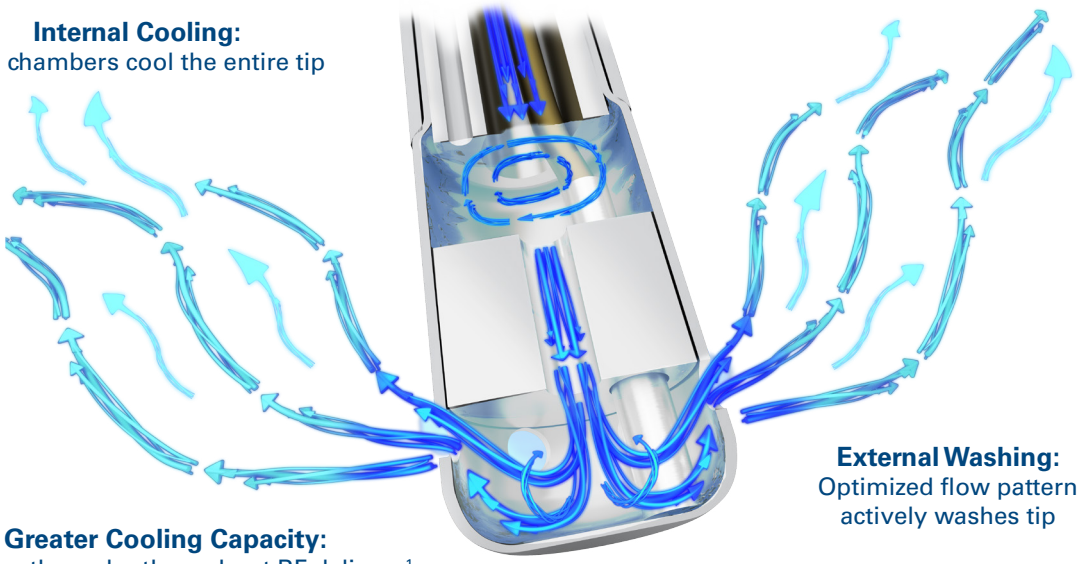
BLAZER™ OPEN-IRRIGATED ABLATION CATHETER, MAESTRO 4000™ CARDIAC ABLATION SYSTEM and METRIQ™ PUMP

Empower Irrigated Ablation Procedures

Cool.

Total Tip Cooling™ Design

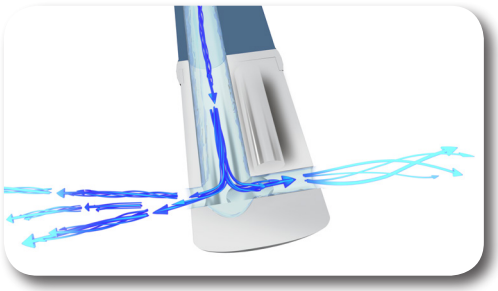
Internal Cooling:
Dual chambers cool the entire tip



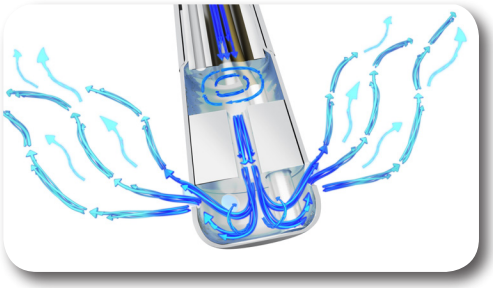
External Washing:
Optimized flow pattern actively washes tip

Greater Cooling Capacity:
Consistently cooler throughout RF delivery[1]

Conventional Open-Irrigated Tip

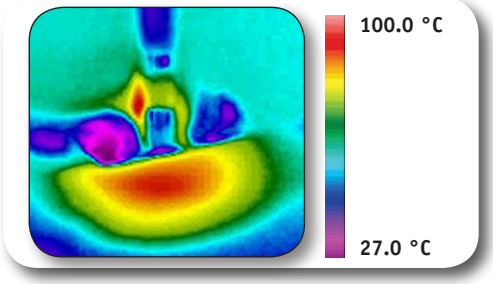


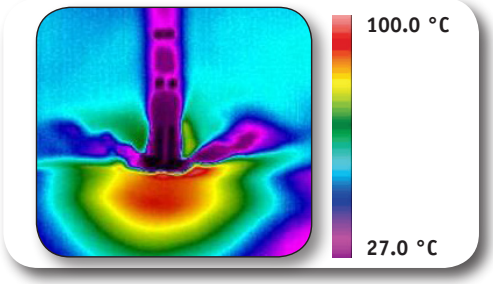
BLAZER™ Open-Irrigated Tip



- Greater Cooling Capacity[2]
- Active Tip Washing

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





- Reduced Proximal Heating[2]
- Uniform Cooling of Tip

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

[1] Testing completed by Boston Scientific. n = 1. Data on File. Bench test results are not necessarily predictive of clinical performance.

[2] Oley LA, Koblish J, Mirigian M, Tee SH, Harvey G, Subramaniam R. Boston Scientific, San Jose, CA. Use of high-resolution infrared thermography to analyze thermal profiles of a novel cooled RF ablation catheter. Heart Rhythm, 2009; 6 (Suppl 1): p. S217) (PDM: 90526597)

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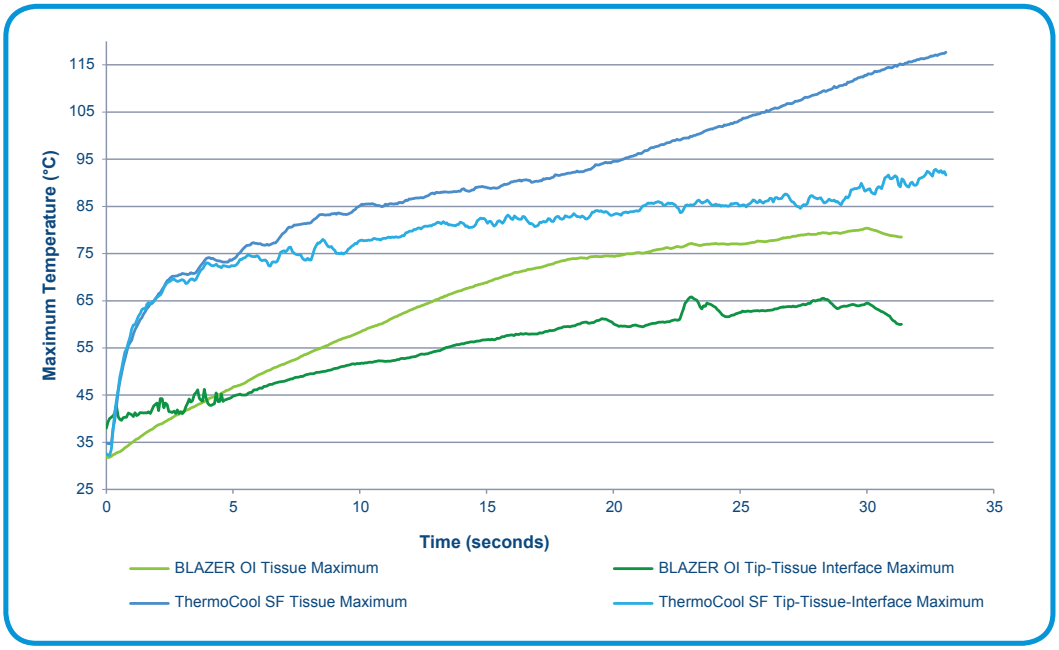
Confident.

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

BLAZER OI:
Effective power delivery with steady tissue temperature rise



Oley LA, Koblish J, Mirigian M, Tee SH, Harvey G, Subramaniam R. Boston Scientific, San Jose, CA. Use of high-resolution infrared thermography to analyze thermal profiles of a novel cooled RF ablation catheter. Heart Rhythm, 2009; 6(Suppl 1): p. S217) (PDM: 90526597)

1M+ BLAZER™ Catheters used clinically world wide since launch

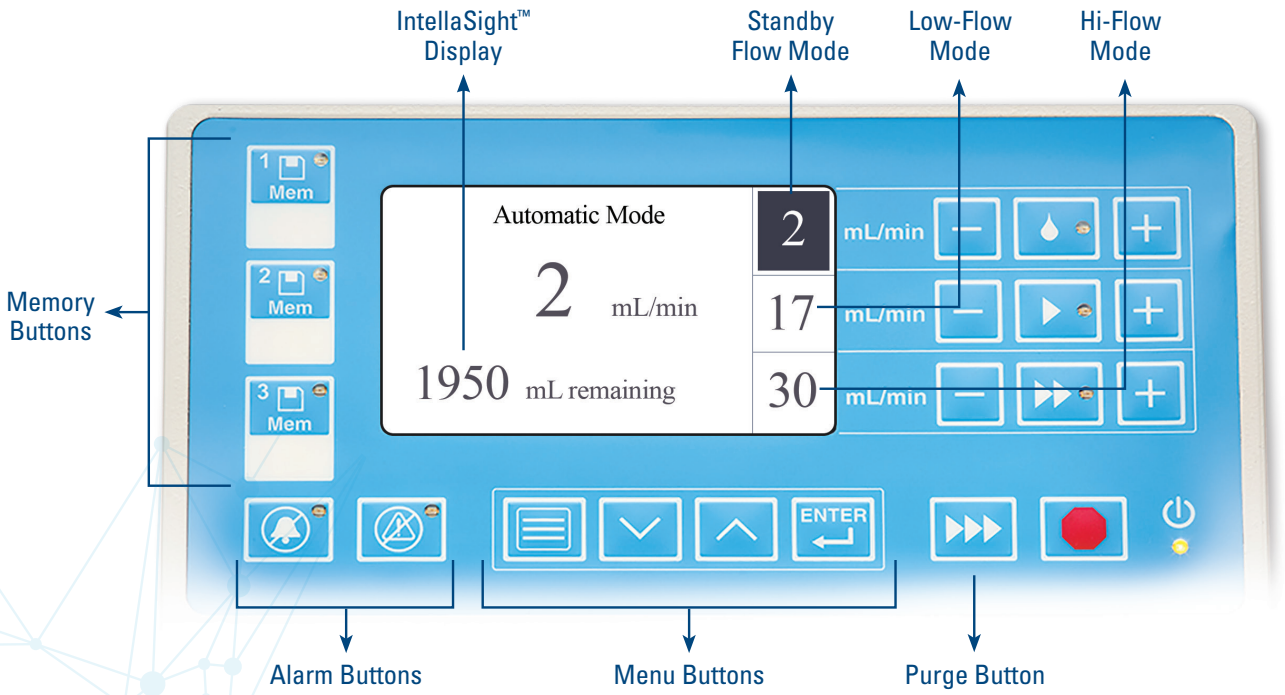
Control.

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

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

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

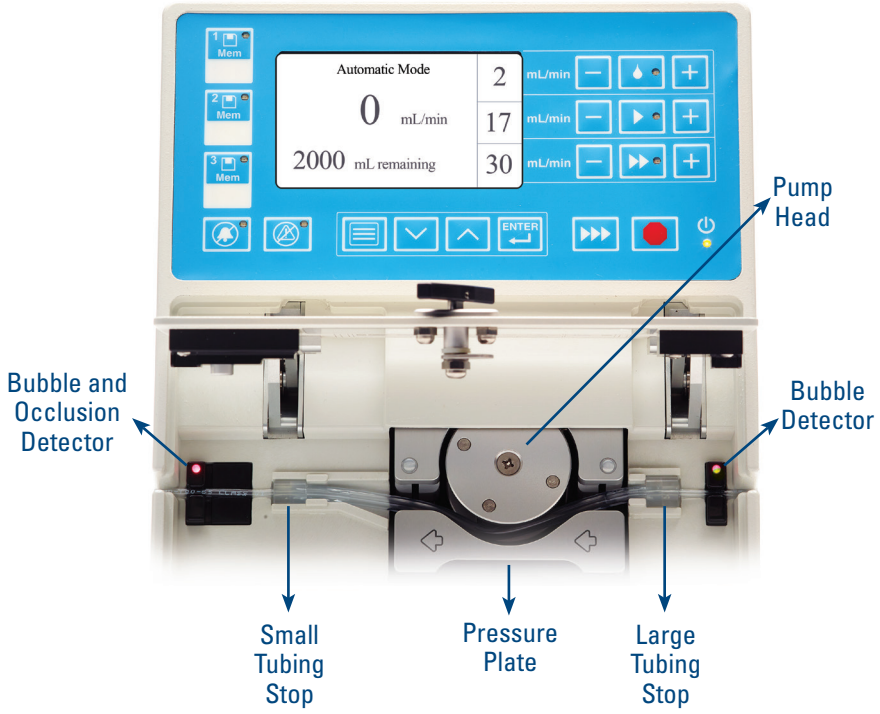
- Provides real-time feedback on five different saline assessments
  - Volume Remaining
  - Volume Infused
  - Volume Dispensed
  - Low Fluid Warning
  - New Saline Bag

Empower **Performance**

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

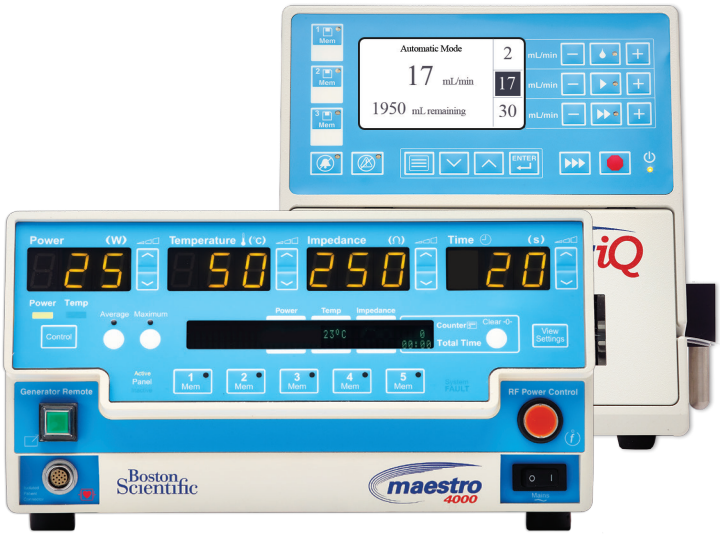
Bubble and Occlusion Detection

- 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

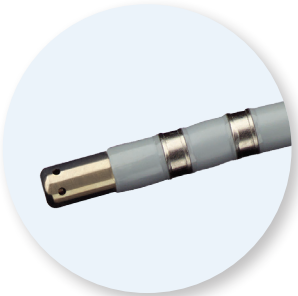


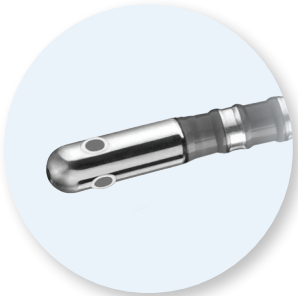
Example Scenario: METRIQ™ Pump automatically delivers saline at hi-flow (30 mL/min) when the MAESTRO 4000™ Controller power level is set to 30 Watts.

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



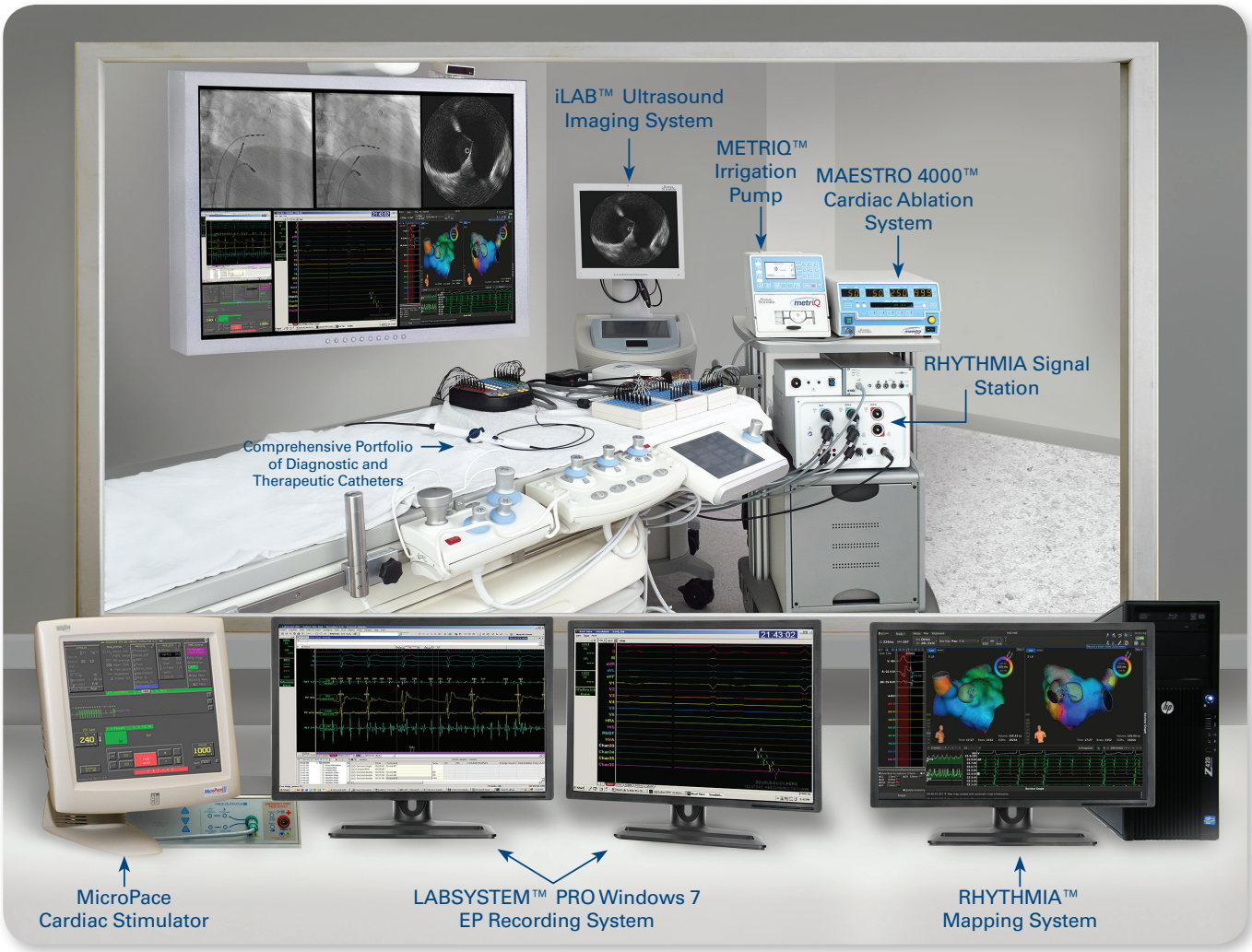


BLAZER™ OPEN-IRRIGATED with Total Tip Cooling™

INTELLATIP MIFI™ Multi-Dimensional Ablation Technology

BLAZER™ Ablation Technology

Boston Scientific EP Lab



Product Ordering Information

BLAZER™ OPEN-IRRIGATED Ablation Catheter

Electrode Configuration: Quadripolar Electrode Spacing: 2.5mm

Model Number	Shaft Size	Tip Size	Curve Style	Shaft Length
M004 9620 0	7.5F	7F/4mm	Standard	110cm
M004 9620K2 0	7.5F	7F/4mm	Large	110cm
M004 9620K2E 0	7.5F	7F/4mm	Large/Extra Long	115cm
M004 9620N4 0	7.5F	7F/4mm	Asymmetric	110cm

METRIQ™ Irrigation Pump

Model Number	Description
M004 4100 0	METRIQ™ Pump
M004 661 0	Cable, Generator to Pump or Remote (20ft)
M004 663 0	Cable, Generator to Pump or Remote (50ft)
M004 664 0	Cable, Generator to Pump or Remote (75ft)

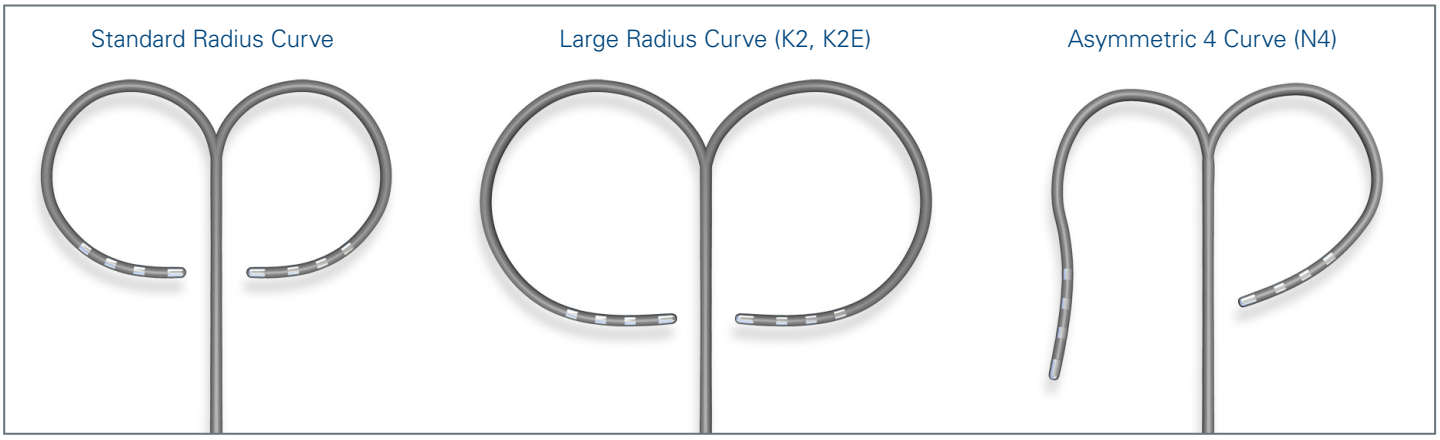
MAESTRO 4000™ Cardiac Ablation System

Model Number	Description
M004 4000 0	MAESTRO 4000 Controller
M004 4020 0	MAESTRO 4000 Remote
M004 21850 0	MAESTRO Foot Switch
M004 4010 0	MAESTRO 4000 Pod, 100W (US)

BLAZER™ OPEN-IRRIGATED Accessories

Model Number	Description
M004 671 0	Cable, BLAZER OPEN-IRRIGATED Catheter to MAESTRO 4000™ Generator
M004 117 0	METRIQ Irrigation Tubing Set

Bidirectional Curve Options



Catheter configurations are illustrative representations only and may not reflect actual performance.

BLAZER® OPEN-IRRIGATED Catheter

Indications for Use, Contraindications, Warnings, Potential Adverse Events

Blazer® Open-Irrigted Ablation Catheter INDICATIONS FOR USE The Blazer Open-Irrigated Ablation Catheter, when used with a Maestro 4000™ Radiofrequency (RF) Controller and MetriQ™ Irrigation Pump, is indicated for: cardiac electrophysiological mapping; delivering diagnostic pacing stimuli; RF ablation of sustained or recurrent type 1 Atrial Flutter in patients age 18 years or older. **CONTRAINDICATIONS** The Blazer® Open-Irrigated Ablation Catheter is contraindicated for use in patients: 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; who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach; 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 thoroughly trained in invasive cardiology 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. Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps 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 prepubescent children. Patients undergoing an atrial flutter ablation are at risk for complete AV block which requires the implantation of a temporary and or permanent pacemaker. 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 stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias 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 Maestro 4000™ Controller cut-off (impedance or temperature), the Blazer® Open-Irrigated Ablation 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. Inspect 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® Open-Irrigated Ablation Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, 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 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 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 200 Volts peak. The Blazer® Open-Irrigated Ablation Catheter contains Bis (2-ethyhexyl) phthalate (DEHP). BSC has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BSC has not assessed the residual patient risk associated with phthalates which may be contained in non-BSC ancillary devices required for use in conjunction with the Blazer Open-Irrigated Ablation Catheter. **POTENTIAL ADVERSE EVENTS** Potential adverse events which may be associated with catheterization and ablation include: allergic reaction (including anaphylaxis), angina, arrhythmias (new or exacerbation of existing arrhythmias), arterial-venous fistula, cardiac perforation, cardiac/respiratory arrest, catheter entrapment, cerebrovascular accident (CVA), chest discomfort, conduction pathway injury, complete heart block (transient/permanent), complications of sedative agents/anesthesia, congestive heart failure, death, effusion (pericardial/pleural), embolism (venous/arterial) (i.e., cerebrovascular accident, myocardial infarction, pulmonary embolism), fluid volume overload, hematoma, hemorrhage, hypertension, hypotension, infection, lead dislodgement, myocardial infarction, nerve injury (phrenic/vagus), pericarditis, pleuritis, pneumothorax, pseudoaneurysm, pulmonary/pedal edema, radiation exposure, renal insufficiency/failure, skin burns (radiation/defibrillator/cardiovertor), tamponade, transient ischemic attack (TIA), thrombosis, valvular damage, vasospasm, vasovagal reactions, vessel trauma (perforation/dissection/rupture).

MAESTRO 4000™ Cardiac Ablation System

Indications for Use, Contraindications, Warnings, Potential Adverse Events

Maestro 4000™ Cardiac Ablation System 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 compatibility to the Maestro 4000 Cardiac Ablation System. **CONTRAINDICATIONS** There are no specific contraindications for use of the MetriQ Pump 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. Note: The contraindications listed in the catheter Directions For Use also apply to the use of the Maestro 4000 Cardiac Ablation System. **WARNINGS** Do not attempt to operate the Maestro 4000 Cardiac Ablation System prior to reading the entire Operator's Manual. All instructions should be read, understood, and followed carefully. **POTENTIAL ADVERSE EVENTS** Users should 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 Maestro 4000 Cardiac Ablation System are, but not limited to, the following: additional intervention required, arrhythmia, burns, cardiac arrest, cardiac tamponade, cerebral vascular accident (CVA), complete heart block, conduction pathway injury, congestive heart failure, death, discomfort, edema, electrical shock, embolism, esophagitis, exposure to biohazardous material, fistula, hematoma, infection, injury (not otherwise specified), laceration, myocardial infarction, myocardial trauma, necrosis, nerve injury, perforation, pericardial effusion, pericarditis, pleural effusion, prolonged procedure, renal damage/failure, respiratory distress/insufficiency, swallowing disorders, tissue damage, transient ischemic attach (TIA), vasospasm, vessel occlusion, vessel trauma.

METRIQ™ Pump

Indications for Use, Contraindications, Warnings, Potential Adverse Events

MetriQ™ Pump 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 the specific indications, contraindications, warnings, and precautions included with any open-irrigated cardiac ablation catheter used in conjunction with the pump. **WARNINGS** To avoid the risk of explosion, do not use the pump in the presence of flammable anesthetics or in an oxygen rich environment. The MetriQ™ Pump needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic 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 NOT stop the flow of 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 loss of irrigation flow 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 infusion of irrigation fluid. Flow should be verified visually by noting the drip rate in the drip chamber. During use, monitor tubing set for visible bubbles and stop the pump if air bubbles are observed to prevent possible occurrence of embolism. Do not press the purge 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 cause improper 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%). Specified flow rate accuracy 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. **POTENTIAL ADVERSE EVENTS** Users should also read and understand the specific indications, contraindications, warnings and precautions included with any catheter used in conjunction with the Maestro 4000 Cardiac Ablation System. Potential adverse events associated with the MetriQ Pump when used with the Maestro 4000 Cardiac Ablation System are, but not limited to, the following: Additional intervention required, Arrhythmia, Burns, Cardiac Arrest, Cardiac Tamponade, Cerebral Vascular Accident (CVA), Complete Heart Block, Conduction Pathway Injury, Congestive Heart Failure, Death, Discomfort, Edema, Embolism, Esophagitis, Fistula, Infection, Injury (Not Otherwise Specified), Myocardial Infarction, Myocardial Trauma, Necrosis, Nerve Injury, Perforation, Pericardial Effusion, Pericarditis, Pleural Effusion, Prolonged Procedure, Renal damage/failure, Swallowing Disorders, Tissue Damage, Transient Ischemic Attack (TIA),Vasospasm, Vessel Occlusion, Vessel Trauma.

Boston Scientific

Advancing science for life™

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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