

Blazer™

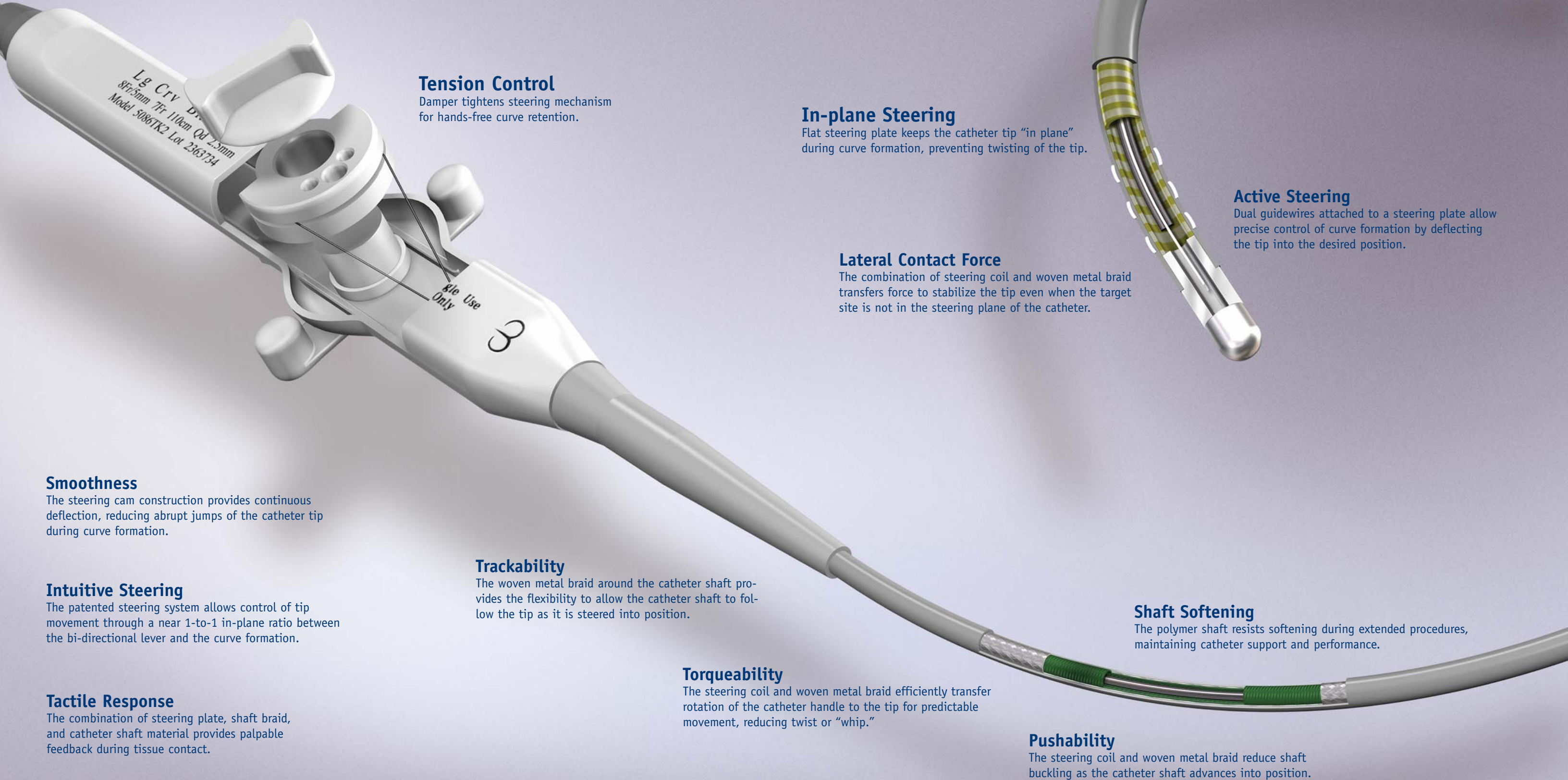
Temperature Ablation Catheter



**The most important connection
between your hands and their hearts**

Familiar. Accurate. Predictable.

Anatomy of a Blazer™ Catheter



Tension Control

Damper tightens steering mechanism for hands-free curve retention.

In-plane Steering

Flat steering plate keeps the catheter tip "in plane" during curve formation, preventing twisting of the tip.

Active Steering

Dual guidewires attached to a steering plate allow precise control of curve formation by deflecting the tip into the desired position.

Lateral Contact Force

The combination of steering coil and woven metal braid transfers force to stabilize the tip even when the target site is not in the steering plane of the catheter.

Smoothness

The steering cam construction provides continuous deflection, reducing abrupt jumps of the catheter tip during curve formation.

Intuitive Steering

The patented steering system allows control of tip movement through a near 1-to-1 in-plane ratio between the bi-directional lever and the curve formation.

Tactile Response

The combination of steering plate, shaft braid, and catheter shaft material provides palpable feedback during tissue contact.

Trackability

The woven metal braid around the catheter shaft provides the flexibility to allow the catheter shaft to follow the tip as it is steered into position.

Torqueability

The steering coil and woven metal braid efficiently transfer rotation of the catheter handle to the tip for predictable movement, reducing twist or "whip."

Shaft Softening

The polymer shaft resists softening during extended procedures, maintaining catheter support and performance.

Pushability

The steering coil and woven metal braid reduce shaft buckling as the catheter shaft advances into position.

INDICATIONS:

When using the SteeroCath-T, and Blazer II Ablation Catheters: The Boston Scientific Cardiac Ablation System is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia. When using the SteeroCath-A Ablation Catheter: The Boston Scientific Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia - typically chronic, drug refractory atrial fibrillation.

CONTRAINDICATIONS:

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

WARNINGS:

- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- Patients undergoing AV nodal modification or ablation of septal accessory pathways are at risk for inadvertent AV block. It is advisable to use lower initial power in such patients and to monitor anterior conduction closely during RF power delivery.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a) have temporary external sources of pacing available during ablation, b) temporarily reprogram the pacing system to minimum output or 000 mode to minimize risk of inappropriate pacing, c) exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and d) perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
- During a transaortic approach, adequate fluoroscopic visualization is necessary to avoid placement of the ablation catheter within the coronary vasculature. Catheter placement and RF power application within the coronary artery have been associated with myocardial infarction and death.
- Patients undergoing left-sided ablation procedures should be closely monitored during the postablation period for clinical manifestations of infarction.
- The steerable ablation catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of component with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the vicinity of the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

PRECAUTIONS:

- Contents supplied STERILE using an (ethylene oxide (EO)/Radiation) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Before using, inspect for physical damage including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.
- The Blazer II™ catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than 1 1/2 full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall, before resuming rotation of the handle and catheter shaft.
- Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing rightsided procedures.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- The sterile packaging and catheter should be inspected prior to use.
- It is recommended not to exceed thirty (30) radiofrequency power applications per catheter.
- The Boston Scientific steerable ablation catheter is intended for use with the EPT-1000 Cardiac Ablation Controller and accessories only.
- Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the EPT-1000 Cardiac Ablation Controller Operator's Manual.
- The catheter impedance LED display of the Cardiac Ablation Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation in a fully-equipped electrophysiology laboratory.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.
- The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- Read and follow the dispersive indifferent patch (DIP) electrode manufacturer's instructions for use; the use of DIP electrodes which meet or exceed ANSI/AAMI HF-18 requirements is recommended.
- Placement of the DIP electrode on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
- The Cardiac Ablation Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the ablation procedures are performed.
- Electromagnetic interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Regularly inspect and test reusable cables and accessories. The instrument cables and adapter cables only may be sterilized up to ten times by ethylene oxide sterilization.
- Boston Scientific relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the cardiac ablation procedure.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. See the appropriate technical manuals for detailed information regarding instructions for use, indications, contraindications, warnings and precautions, and potential adverse events.

**Boston
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