

BLAZER PRIME™ HTD TEMPERATURE ABLATION CATHETER INDICATIONS FOR USE When using the Blazer Prime HTD Catheter: The Boston Scientific Cardiac Ablation System is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia. **CONTRAINDICATIONS** The use of the device is contraindicated in patients with active systemic infection. The transeptal 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. Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use. 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 has been associated with myocardial infarction and death. Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation 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 present 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** Before using, inspect for physical damage including electrical insulation on the cables and the catheter shaft. Replace damaged equipment. The Blazer Prime HTD Temperature Ablation 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 transeptal cardiac procedures and should be considered for selected patients undergoing right-sided 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 Blazer Prime HTD Catheter is intended for use with the EPT-1000™ Controller and accessories or the Maestro 3000™ Controller and accessories only. Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the 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 IEC 60601-1/IEC 60601-1- 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 re-usable cables and accessories. The instrument cables and adapter cables may be sterilized only 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. **ADVERSE EVENTS** The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise noted with an asterisk). A total of 57 adverse events were observed in the 513 procedures performed during the clinical study. Cardiac/Vascular, Death, Cardiac Tamponade, Perforation, Pericardial Effusion, Cerebral Vascular Accident, Myocardial Infarction, Endocarditis, Pulmonary Edema, Pulmonary Embolism, Venous Thrombus, *Puncture Site Hematoma, Echymosis (2.1%), Aortic Valve Insufficiency/Wall Motion Abnormality, Arrhythmic, Permanent Atrioventricular Block, Ventricular Fibrillation, *Non-sustained Ventricular Tachycardia (1.6%), Conduction System Abnormalities, *Atrial Fibrillation, Flutter, Tachycardia (2.5%), Pacemaker Failure-to-sense.

BLAZER PRIME™ XP TEMPERATURE ABLATION CATHETER INDICATIONS FOR USE The Boston Scientific Corporation Blazer Prime XP Catheter is indicated for use with the BSC high power Cardiac Ablation Controllers (the Maestro 3000™ Controller, the EPT- 1000XP™ Controller, and the EPT-1000XPT™ Controller) and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The BSC high power Cardiac Ablation Controllers and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures. **CONTRAINDICATIONS** Do not use this device: in patients with active systemic infection; via the transeptal approach in patients with left atrial thrombus or myxoma; via the retrograde approach in patients with aortic valve replacement. **WARNINGS** Before operating the device, read these warnings carefully: Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anti-coagulation therapy, during and post-ablation to reduce the incidence of major complications. Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children. Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a. Retain temporary external sources of pacing available during ablation. b. Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing. c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads. d. Perform complete pacing system analysis on all patients after ablation. Implanted cardioverter/defibrillators should be deactivated during delivery of RF power. Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue. Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use. In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage. Do not pass the catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve. **PRECAUTIONS** Observe these precautions, before using the device: Do not attempt to operate the Controller before thoroughly reading the appropriate BSC High power Cardiac Ablation Controller & Accessories Operator's Manual. The Blazer Prime XP Catheters are intended for use with the BSC high power Controllers and accessories only. The Blazer Prime XP Temperature Ablation Catheter is highly torqueable. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than one and one-half times the full rotation (540 degrees). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall before resuming rotation of the handle and catheter shaft. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Excessive bending or kinking of the catheter shaft may damage internal wires. Manual pre-bending of the distal curve 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 RF Powered Catheter Ablation in a fully-equipped electrophysiology laboratory. Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block. Adequate filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECG) during radiofrequency power applications. When using Blazer Prime XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller. Placement of the DIP electrodes on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off. 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 electrodes or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Regularly inspect and test re-usable cables and accessories. Potential Adverse Events Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to: allergic reaction (including anaphylaxis), angina, arrhythmias, arterial or pulmonary embolism, arterial-venous fistula, atrioventricular node damage (transient/permanent), back pain and/or groin pain, cardiac perforation, cardiac respiratory arrest, catheter entrapment, complete heart block (transient/permanent), cerebral vascular accident, chest pain/discomfort, complications of sedative agents (e.g. aspiration pneumonia), death, effusion (pericardial/pleural), hematoma/bruising, hemoptysis, hemorrhage, hemothorax, hypotension, infection, myocardial infarction, nerve palsy or weakness, pericarditis, phrenic nerve damage/diaphragmatic paralysis, pleurisy, pneumothorax, pulmonary edema, pseudoaneurysm, radiation exposure, sinoatrial node damage, skin burn (defibrillator/cardioverter/radiation), tamponade, transient ischemic attack (TIA), valvular damage, vasovagal reactions, visual blurring.

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CAUTION Federal Law (USA) restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

Blazer Prime™

Temperature Ablation Catheter

Raising the bar on performance.

Feel the difference.



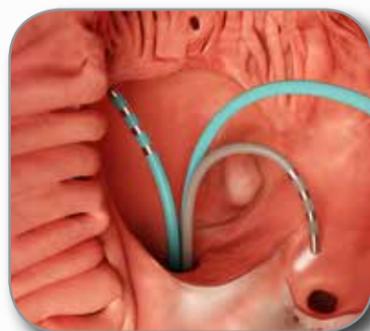
Blazer Prime™ Temperature Ablation Catheter – *Intuitively engineered for exceptional performance.*

**Performance
always matters.**

The Blazer Prime Catheter raises the bar on ablation catheter performance. Intuitively engineered construction combined with our trusted Blazer Catheter platform provide an ablation catheter designed to function as a physical extension of your hand. Manipulation of the handle translates predictably into movement of the catheter tip. Control and durability provide procedural confidence.



Left Side Accessory Pathway



AVNRT



Atrial Flutter

Better Torqueability¹

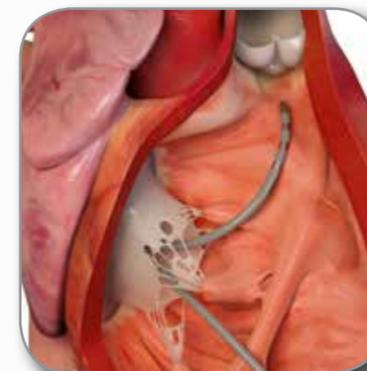
Extra support in proximal shaft is designed to:

- improves the “push” response from catheter handle to tip
- contribute to better overall torque of the catheter

Better Tip Stability & Durability³

Fiber-reinforced distal section and more rugged center support provide flexible strength to optimize tip control and durability:

- improves lateral contact strength
- increases back steering strength
- enhances distal torque

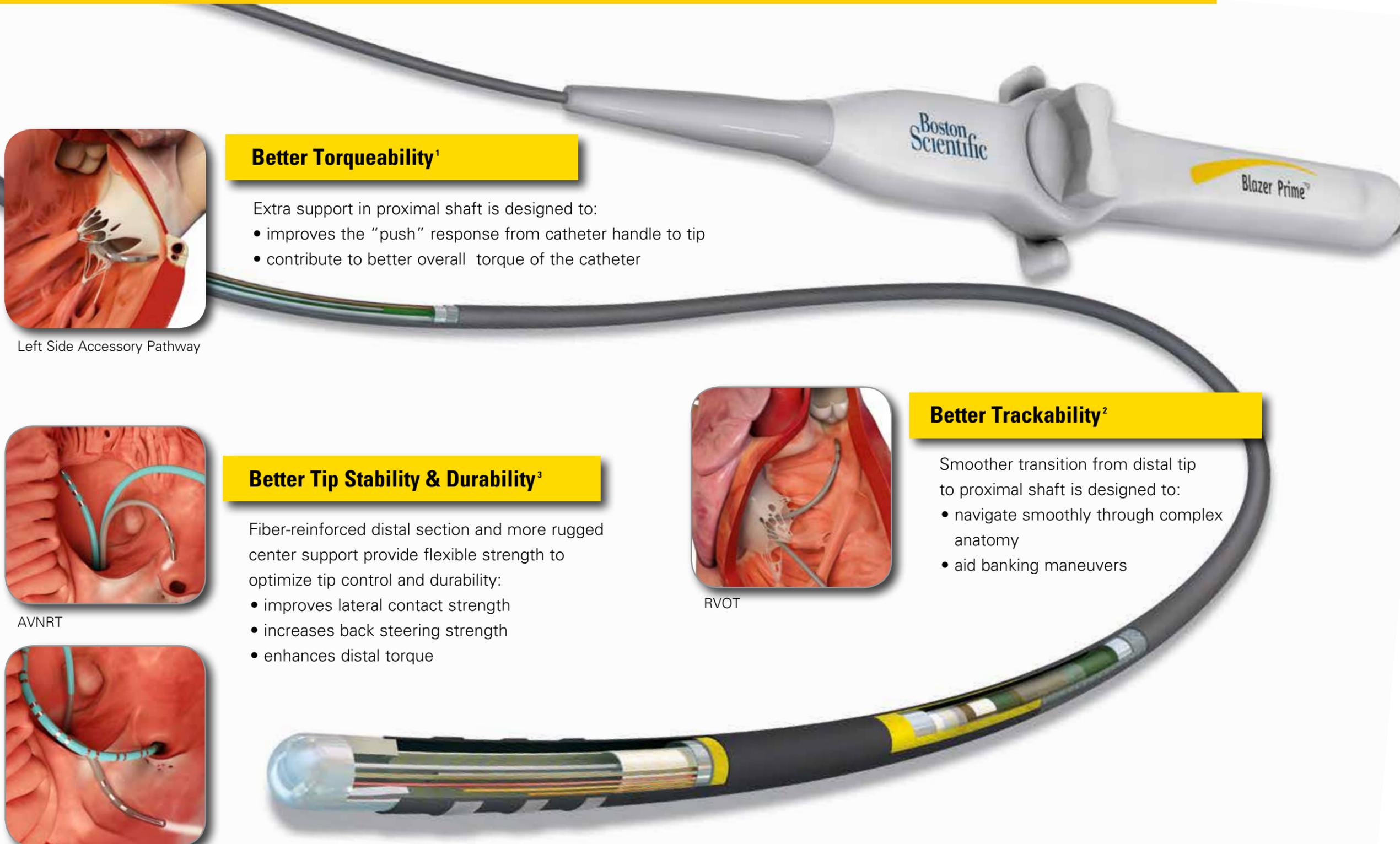


RVOT

Better Trackability²

Smoother transition from distal tip to proximal shaft is designed to:

- navigate smoothly through complex anatomy
- aid banking maneuvers



¹ Distal torque bench testing compared Blazer Prime and Blazer™ II HTD temperature ablation catheters. Bench testing performed by Boston Scientific. N=5. Data on file. Bench testing not necessarily predictive of clinical outcomes.

² Catheter stiffness profile/3-point bend bench testing compared Blazer Prime and Blazer II HTD temperature ablation catheters. Bench testing performed by Boston Scientific. N=5. Data on file. Bench testing not necessarily predictive of clinical outcomes.

³ Curve retention/curve angle degradation bench testing compared Blazer Prime and Blazer II HTD temperature ablation catheters. Bench testing performed by Boston Scientific. N=5. Data on file. Bench testing not necessarily predictive of clinical outcomes.

Feel the difference.