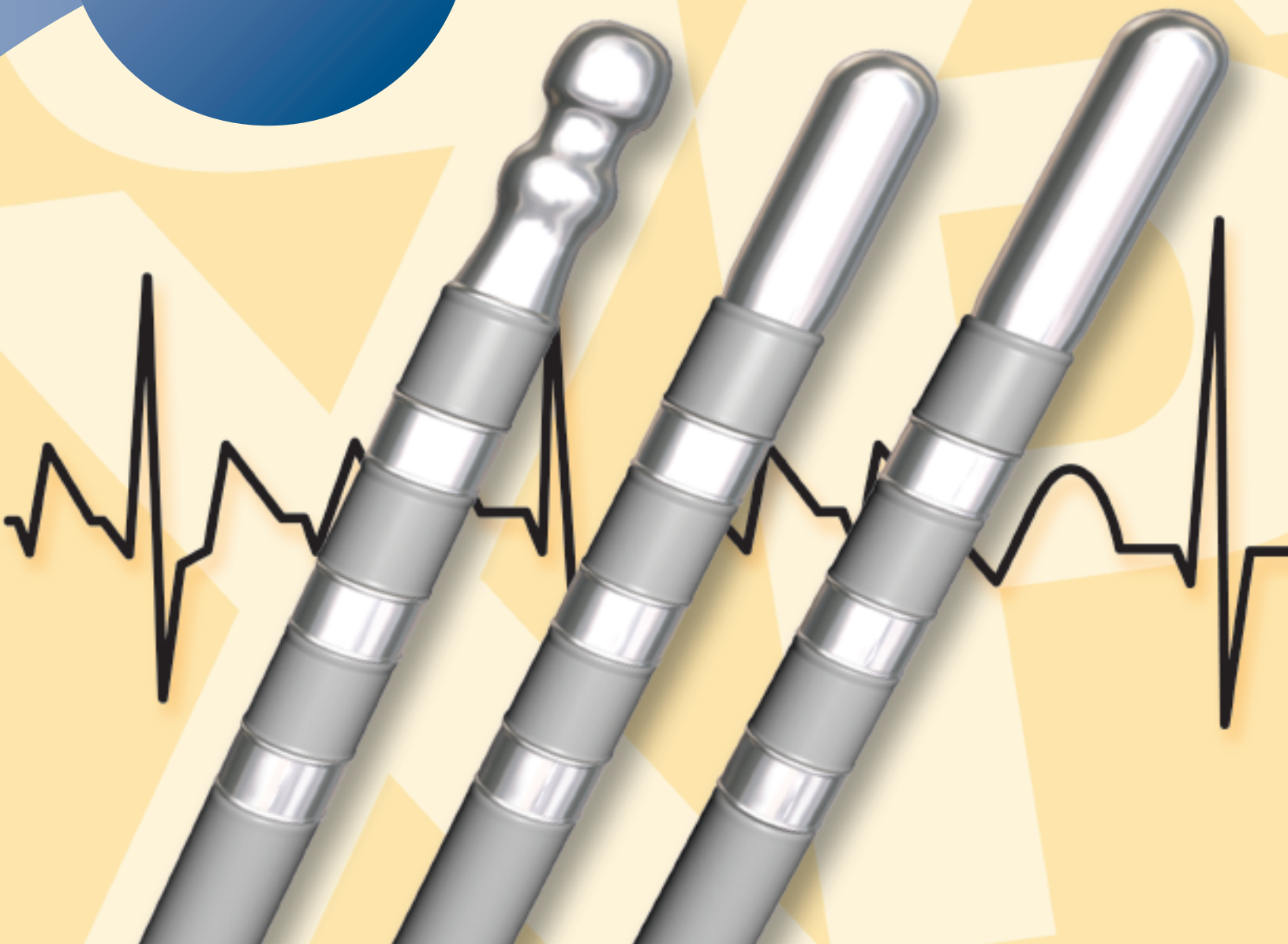


# Blazer II XP™

Cardiac Ablation Catheter

Boston  
Scientific

**XP**ect  
**X**tra **P**ower  
**X**celerated **P**erformance  
**X**ce**P**tional outcomes



# EPT-1000XP™ Cardiac Ablation System

Taking performance to a higher power in the treatment of **atrial flutter**  
**Featuring the Blazer II XP™ Temperature Ablation Catheter**

## Xtra Performance

All the advantages of a familiar and predictable platform

Blazer® catheter technology

- bidirectional steering
- smooth tip deflection
- tip isolated temperature sensor

EPT-1000® RF Controller technology

- proprietary temperature measuring algorithm
- intuitive user interface
- proven, robust, reliable



*8 FR/8mm contour tip*



*8 FR/8mm tip*



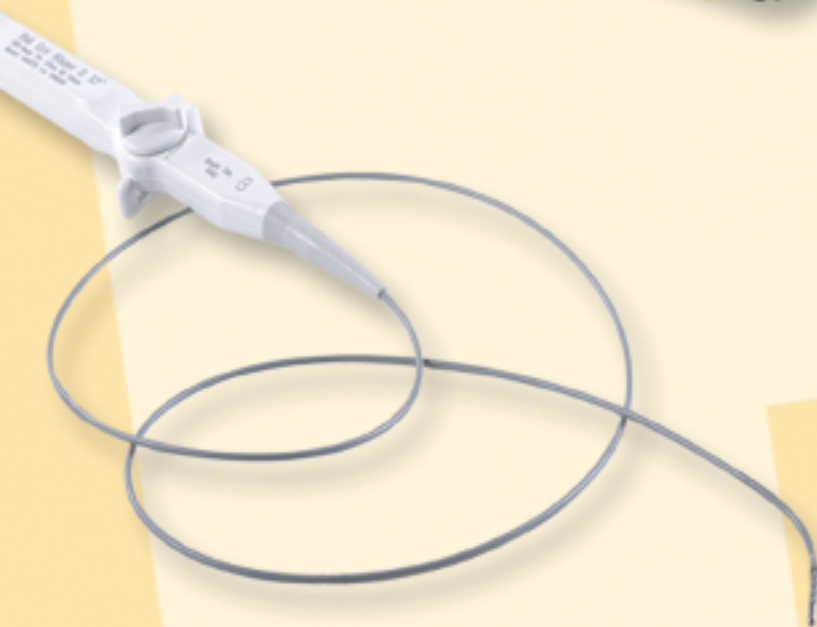
*10 FR/10mm tip*



## Xtra Power

- Up to 100 watts RF power for thick isthmus regions
- 8mm and 10mm tip electrode catheters for larger volume lesions
- 8mm contour tip electrode designed to enhance tissue contact stability

stem



## XcePtional outcomes\*

Chronic results demonstrate **96%** effective for the long term treatment of type 1 atrial flutter

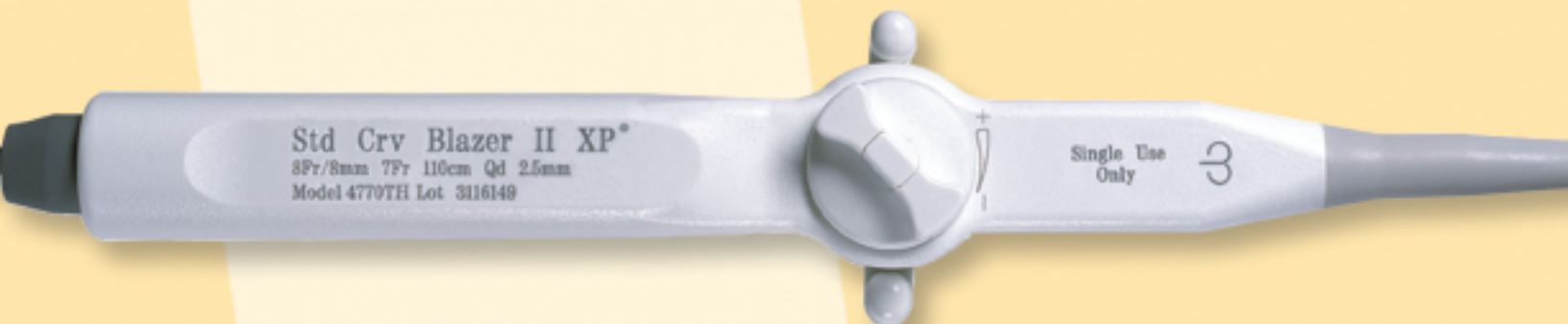
10mm tips have been shown to:

- require fewer RF applications to achieve bidirectional block
- reduce ablation time
- shorten procedure time

Multicenter clinical trial quality of life data shows

- marked improvement in daily activity
- severity and frequency of symptoms decreased by an average of **75%**
- reduced need for medication

\*based on clinical trial results to date.



**Indication for Use:** The Boston Scientific Corporation Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The EPT-1000 XP™ Cardiac Ablation Controller 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 transseptal approach in patients with left atrial thrombus or myxoma; and via the retrograde approach in patients with aortic valve replacement. **Warnings:** Before operating the device, read these warnings carefully: Peri-procedural anticoagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy pre-, during and postablation 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. 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 *EPT-1000 XP Cardiac Ablation Controller & Accessories Operator's Manual*. The Blazer II XP™ Cardiac Ablation Catheters are intended for use with the Controller and accessories only. Contents supplied **STERILE** using an ethylene oxide 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 diseases(s) from one patient to another. Contamination of the device may lead to injury, illness or death to the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. The Blazer II XP™ 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 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 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 electrocardiogram (ECG) during radiofrequency power applications. When using XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of ANSI/AAMI Standard HF-18 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, cerebral vascular accident, 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

**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, contradictions, warnings and precautions, and potential adverse events.

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*Delivering what's next.™*

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