Blazer™ Family of Ablation Catheters

Predictable Handling
Designed for consistent handling – whether mapping or delivering therapy.
- Precise micro-movements
- Torqueability
- In-plane steering
- Tip stability

Dependable Performance
Catheter can be relied upon to perform consistently throughout long cases.
- Curve retention

Proven Results
One of the top selling therapeutic catheters.
- Over 1 million catheters sold*
What makes a Blazer™ a BLAZER?

**Introduction**

**Handle**
- Tension control knob
- Bi-wing steering knob
- Tactile curve reference on handle

**Distal Tip**
- Patented steering design
  - Only catheter with steering wires attached to steering plate
  - Unique Kevlar™ wrap secures steering wires around metal steering plate

**Catheter Body**
- Woven metal braid
- Steering coil

**Steering Plate**
- (metal)

**Kevlar™ Wrap**

**Distal Tip Detail**
What makes a Blazer™ a BLAZER?

Introduction

Handle
- Tension control knob
- Bi-wing steering knob
- Flats on handle

Distal Tip
- Design allows for precise micro-movements

Patented Steering Design
- Only catheter with steering wires attached to steering plate
- Unique Kevlar wrap secures steering wires around metal steering plate

Catheter Body
- Woven metal braid
- Steering coil

Robust catheter body transmits torque delivering excellent tip stability

Patented steering design provides in-plane steering and curve retention throughout long cases
Blazer™ II and Blazer™ II HTD
Temperature Ablation Catheter

Predictable Handling
Over 25 models designed to maneuver and maintain contact in various anatomies.

Dependable Performance
Durable construction provides curve retention throughout long cases.

Proven Results
Over 1 million catheters sold*

* From 1999 through 2014
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The Blazer™ II Platform
AVNRT & Accessory Pathway Toolsets

The Blazer™ II Platform
AVNRT & Accessory Pathway Toolsets

Blazer™ II
(7F/4mm, 8F/5mm)

Blazer™ II HTD
(7F/4mm, 8F/5mm)

Blazer™ II Prime
(7F/4mm, 8F/5mm)

---

Catheter Curve References

Small (TK1)  Standard (T)  Large (TK2)  Asymmetric 4 (TN4)

Note: Blazer Prime Catheters and Chilli II Catheters only in Standard, Large and Asymmetric

Blazer® Temperature Ablation Catheter Distal Segments

<table>
<thead>
<tr>
<th>Model Suffix</th>
<th>Distal Length</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T</td>
<td>Standard</td>
<td>Electrode Spacing: 2.5mm</td>
</tr>
<tr>
<td>TM</td>
<td>Medium</td>
<td>Curve dimensions are the same as standard distal</td>
</tr>
<tr>
<td>L</td>
<td>Large</td>
<td>Electrode Spacing: 2.6mm</td>
</tr>
<tr>
<td>TL</td>
<td>Extended</td>
<td>Curve dimensions are the same as standard distal</td>
</tr>
</tbody>
</table>

Blazer Prime® Temperature Ablation Catheter Distal Segments

| Distal Length | Electrode Spacing: 2.6mm |

^ Dimensions are for reference only.

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Blazer™ II XP
Temperature Ablation Catheter

Predictable Handling
• Assists in reaching the Isthmus and maintaining contact
• Allows for backsteering approach

Proven Clinical Results
• The market leading large tip catheter in the US for treating Type 1 Atrial Flutter.
• Lower recurrence rates
• More efficient procedures with 10mm tip
• 100 W available with the Maestro 3000™ Cardiac Ablation System
• Greater than 70W required in 85% of procedures

Dependable Performance
• Excellent curve retention to reach and maintain contact with Isthmus.
The Blazer™ II XP Platform
Type 1 Atrial Flutter Toolsets

Blazer™ II XP
(8F/8mm, 8F/10mm)

Blazer™ Prime XP
(8F/8mm, 8F/10mm)

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

^ Dimensions are for reference only.
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The Blazer™ II XP is Efficient

Fewer RF applications, less ablation time

A typical Isthmus is approximately 3cm long\(^1\)

Benefits of a 10mm vs. 8mm:
- 29% fewer RF applications\(^2\)
- 38% less ablation time\(^2\)

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Blazer™ II XP Temperature Ablation Catheter
Blazer XP Clinical Information

Market leading ablation catheter for right sided procedures. The Data Speaks for Itself…

FDA SUBMISSION DATA FOR TYPE 1 ATRIAL FLUTTER

BOSTON SCIENTIFIC: FDA Submission Data for Blazer II XP¹

<table>
<thead>
<tr>
<th>FDA Approval</th>
<th>PMA #</th>
<th># of Patients</th>
<th>Acute Success</th>
<th>Chronic Success</th>
<th>Overall Success</th>
<th>Total Procedure Time*</th>
<th>Total Fluoroscopy Time*</th>
<th>Total RF Applications</th>
<th>Saline Infused</th>
<th>Major Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/25/2003</td>
<td>P020025</td>
<td>250</td>
<td>94%</td>
<td>96%</td>
<td>90%</td>
<td>126 min</td>
<td>28.5 min</td>
<td>11.5</td>
<td>0 L</td>
<td>8%</td>
</tr>
</tbody>
</table>

Design:
Prospective, non-randomized, multi-center study to determine the safety and efficacy of ablatiing type 1 isthmus dependent atrial flutter (AFL) with Blazer II XP.

*Note: These times pertain to cases where only flutter was ablated (no other arrhythmias).

### BOSTON SCIENTIFIC: Blazer II XP Large-Tip (8 & 10mm) Clinical Trial

<table>
<thead>
<tr>
<th>Year Published</th>
<th>Authors</th>
<th>Publication</th>
<th>Total # of Patients</th>
<th>Catheter Used</th>
<th>Acute Success</th>
<th>Atrial Flutter Recurrence</th>
<th>Mean Follow-up</th>
<th>Mean Procedure Time</th>
<th>Mean Fluoro Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>Feld, G. et al</td>
<td>Journal of The American College of Cardiology</td>
<td>169</td>
<td>Blazer II XP 10mm</td>
<td>93%</td>
<td>3%</td>
<td>6 Months</td>
<td>122 min</td>
<td>28.4 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Blazer II XP 8mm (Straight)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Blazer II XP 8mm (Contoured)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Design: Prospective, non-randomized, multi-center study (subset of patients from PMA Study) to determine the safety and efficacy of ablating type-1 isthmus dependent AFL with Blazer II XP.

*Feld et al: “A maximum power over 70W was required in 85% of patients”. (p. 1472)*
Blazer Prime™
Bidirectional Temperature Ablation Catheter

Predictable Handling
Through enhanced control
• 70% greater pushability\(^1\)
  reducing the need for a long sheath
• 17% greater torqueability
• 59% greater lateral contact\(^3\)
• Improved trackability\(^2\)

Dependable Performance
• 200% improvement in curve retention\(^3\)

Blazer Prime for:
- Flutter
- AVNRT
- Accessory Pathways
- RVOT


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Blazer Prime™
Bidirectional Temperature Ablation Catheter

Enhanced Torqueability
(Mandrel)

Proximal Section
(70cm)

Transition Zone
(5cm)

Distal Section
(11cm)

Enhanced Trackability
(Polyimide Tubing)

Enhanced Curve Retention
(Stronger Steering Plate)

Enhanced Tip Stability
(Fiber Weave)

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Blazer Prime™ HTD/XP vs. Blazer™ II HTD/XP Catheter

Catheter Construction

Proximal Section

Blazer™ II HTD, Blazer™ II XP Catheter

Support Mandrel

Transition Zone

Blazer Prime™ HTD, Blazer Prime™ XP Catheter

Proximal-to-Distal Transition Zone

Distal Segment

Steering Plate

Material Change to Steering Plate – Higher Yield Stainless Steel

Fiber Weave

Polyimide Tubing – Improved transition

Kevlar Wrap

Ordering Information

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Blazer™ II vs. Blazer™ II XP

Current Density
A larger tip catheter requires higher power to reach current densities (and therefore resistive heating intensities) necessary for creating effective lesions.

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Electrode Surface Area</th>
<th>Impedance (Ω)</th>
<th>Current Density (amps/in²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7F/4mm</td>
<td>0.050</td>
<td>100</td>
<td>8.9</td>
</tr>
<tr>
<td><strong>8F/8mm</strong></td>
<td><strong>0.098</strong></td>
<td><strong>60</strong></td>
<td><strong>5.9</strong></td>
</tr>
<tr>
<td>8F/10mm</td>
<td>0.123</td>
<td>50</td>
<td>5.1</td>
</tr>
</tbody>
</table>

>70W were required in 85% of the procedures during the atrial flutter clinical trial*

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A larger tip catheter requires higher power to reach current densities (and therefore resistive heating intensities) necessary for creating effective lesions.

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Electrode Surface Area</th>
<th>Impedance (Ω)</th>
<th>Current Density (amps/in²)</th>
<th>Power (W)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7F/4mm</td>
<td>0.050</td>
<td>100</td>
<td>8.9</td>
<td>10.9</td>
</tr>
<tr>
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<td>0.098</td>
<td>60</td>
<td>5.9</td>
<td>7.2</td>
</tr>
<tr>
<td><strong>8F/10mm</strong></td>
<td><strong>0.123</strong></td>
<td><strong>50</strong></td>
<td><strong>5.1</strong></td>
<td><strong>6.3</strong></td>
</tr>
</tbody>
</table>

>70W were required in 85% of the procedures during the atrial flutter clinical trial*

Blazer™ II XP Temperature Ablation Catheter

Competitive Information
### HEAD-TO-HEAD STUDY: Blazer II XP vs NaviStar ThermoCool™

<table>
<thead>
<tr>
<th>Year Published</th>
<th>Authors</th>
<th>Total # of Patients</th>
<th>Catheter Used</th>
<th># of Patients</th>
<th>Max Generator Settings</th>
<th>Acute Success</th>
<th>Atrial Flutter Recurrence</th>
<th>Mean Follow-up</th>
<th>Mean Procedure Time</th>
<th>Mean Fluoro Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Leria, T. et al&lt;sup&gt;2&lt;/sup&gt;</td>
<td>198</td>
<td>Blazer 10mm (BSC)</td>
<td>143</td>
<td>100W, 60-65°C</td>
<td>1.2% / yr</td>
<td>19 Months</td>
<td>70 min</td>
<td>24 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NaviStar DS 8mm (J&amp;J)</td>
<td>55</td>
<td>60W, 60-65°C</td>
<td>10.1% / yr</td>
<td></td>
<td>105 min</td>
<td>37 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NaviStar ThermoCool (J&amp;J)</td>
<td>14</td>
<td>50W</td>
<td>6.9% / yr</td>
<td></td>
<td>180 min</td>
<td>110 min</td>
<td></td>
</tr>
</tbody>
</table>

Design: Single-center registry comparing ablation of isthmus dependent AFL with 10mm tip catheter set to 100W, 8 mm tip set to 60W, irrigated tip catheter set to max of 50W.

*Leiria et al: “Procedure time & fluoroscopic time were shorter with the 10mm catheter vs. 8mm and open-irrigated”. (p.501)*

Study not sponsored by Boston Scientific. *Study did not break out Acute Success rate for each catheter.

Study not sponsored by Boston Scientific.

*Acute success includes cross-over to the other catheter after 30 minutes of RFA.
### HEAD-TO-HEAD STUDY: Blazer II XP vs NaviStar ThermoCool™

<table>
<thead>
<tr>
<th>Year Published</th>
<th>Authors</th>
<th>Total # of Patients</th>
<th>Catheter Used</th>
<th># of Patients</th>
<th>Max Generator Settings</th>
<th>Acute Success</th>
<th>Atrial Flutter Recurrence</th>
<th>Mean Follow-up</th>
<th>Mean Procedure Time</th>
<th>Mean Fluoro Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Ilg, K. et al⁷</td>
<td>60</td>
<td>Blazer 10mm (BSC)</td>
<td>30</td>
<td>100W, 60°C</td>
<td>0%</td>
<td></td>
<td>6 Months</td>
<td>95 min</td>
<td>23.5 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NaviStar ThermoCool (J&amp;J)</td>
<td></td>
<td>40W, 48°C</td>
<td>98%*</td>
<td>10%</td>
<td></td>
<td>114 min</td>
<td>23.9 min</td>
</tr>
</tbody>
</table>

Design: Prospective, randomized, single-center study to compare the efficiency of CTI ablation to eliminate AFL using a large tip catheter (10 mm) and open irrigated tip catheter.

Ilg et al: “Complete conduction block across the CTI is achieved more quickly with a LTC (Large Tip Catheter) than an OITC (Open Irrigated Tip Catheter).” (p.1007)

Study not sponsored by Boston Scientific.

*Acute success includes cross-over to the other catheter after 30 minutes of RFA.

---


Blazer™ II XP Temperature Ablation Catheter

The gold standard of ablation catheters for Atrial Flutter.
The Data Speaks for Itself…
Proven Clinical Results

<table>
<thead>
<tr>
<th>PMA Data¹</th>
<th>Blazer II XP 8mm, 10mm</th>
<th>Recurrence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Success Rate</td>
<td>94%</td>
<td>4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Competitive Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blazer II XP 8mm, 10mm</td>
</tr>
<tr>
<td>Ilg et al.²</td>
</tr>
<tr>
<td>Leiria et al.⁴</td>
</tr>
</tbody>
</table>

Blazer II XP has a high Acute Success Rate.¹
Blazer II XP has a much lower Recurrence Rate in these two studies.

* Recurrence rate with mean follow-up at 6 months.
** Recurrence rate per year with mean follow-up at 19 months.

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¹ SSE Clinical Data on file Boston Scientific Corporation.
³ List prices of catheters.
Blazer™ II XP Temperature Ablation Catheter

Competitive Information

**Market leading ablation catheter for right sided procedures. The Data Speaks for Itself…**

FmA SUBMISSION DATA FOR TYPE 1 ATRIAL FLUTTER

<table>
<thead>
<tr>
<th>BIOSENSE WEBSTER: FDA Submission Data for Navistar ThermoCool™²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA Approval</strong></td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>11/05/2004</td>
</tr>
</tbody>
</table>

Design:
Prospective, non-randomized, multi-center study to determine if the Navistar ThermoCool catheter when used in conjunction with the Carto EP/XP Navigation system is safe and effective at the treatment of type 1 atrial flutter.

*Note: These times pertain to cases where only flutter was ablated (no other arrhythmias).
## Blazer™ II Temperature Ablation Catheter

### Ordering Information

**Tip:** 7F/4mm

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5031T 0</td>
<td>7F</td>
<td>Standard</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TK1 0</td>
<td>7F</td>
<td>Small</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TM 0</td>
<td>7F</td>
<td>Standard</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TMK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031TL 0</td>
<td>7F</td>
<td>Standard</td>
<td>Extended</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

**Made to Order Items (minimum order 25 units; see Ordering Information section for details)**

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5031TMN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

**Tip:** 8F/5mm

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5086T 0</td>
<td>7F</td>
<td>Standard</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086TK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086TN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086TMK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086TL 0</td>
<td>7F</td>
<td>Standard</td>
<td>Extended</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

**Made to Order Items (minimum order 25 units; see Ordering Information section for details)**

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
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<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5086TK1 0</td>
<td>7F</td>
<td>Small</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086TM 0</td>
<td>7F</td>
<td>Standard</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>
## Tip: 7F/4mm

**Electrode Configuration:** Quadripolar  
**Electrode Spacing:** 2.5mm

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5031TH 0</td>
<td>7F</td>
<td>Standard</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031THK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031THN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031THM 0</td>
<td>7F</td>
<td>Standard</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5031THMK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>M004 5031TMN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

## Tip: 8F/5mm

**Electrode Configuration:** Quadripolar  
**Electrode Spacing:** 2.5mm

<table>
<thead>
<tr>
<th>Catheter Model No.</th>
<th>Shaft Size</th>
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<th>Distal Shaft Length</th>
<th>Cable Model No.*</th>
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<tbody>
<tr>
<td>M004 5086TH 0</td>
<td>7F</td>
<td>Standard</td>
<td>Standard</td>
<td>M004 651 0</td>
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<tr>
<td>M004 5086THK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Standard</td>
<td>M004 651 0</td>
</tr>
<tr>
<td>M004 5086THN4 0</td>
<td>7F</td>
<td>Asymmetric 4</td>
<td>Standard</td>
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<tr>
<td>M004 5086THMK2 0</td>
<td>7F</td>
<td>Large</td>
<td>Medium</td>
<td>M004 651 0</td>
</tr>
</tbody>
</table>

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<th>Catheter Model No.</th>
<th>Shaft Size</th>
<th>Curve Style</th>
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### Blazer™ II XP Temperature Ablation Catheter

#### Ordering Information

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**Made to Order Items (minimum order 25 units; see Ordering Information section for details)**

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## Blazer Prime™ HTD Temperature Ablation Catheter

### Ordering Information

#### Blazer II HTD
- **Tip**: 7F/4mm Straight
- **Electrode Configuration**: Quadripolar
- **Electrode Spacing**: 2.5mm

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#### Blazer II XP
- **Tip**: 8F/5mm Straight
- **Electrode Configuration**: Quadripolar
- **Electrode Spacing**: 2.5mm

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## Blazer Prime™ XP Temperature Ablation Catheter

### Ordering Information

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**Tip:** 8F/8mm Straight  
**Electrode Configuration:** Quadripolar  
**Electrode Spacing:** 2.5mm

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<tr>
<th>Catheter Model No.</th>
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**Tip:** 8F/10mm Straight  
**Electrode Configuration:** Quadripolar  
**Electrode Spacing:** 2.5mm

**Made to Order Items (minimum order 25 units; see Ordering Information section for details)**

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<th>Catheter Model No.</th>
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**Tip:** 8F/8mm Contour (VM)  
**Electrode Configuration:** Quadripolar  
**Electrode Spacing:** 2.5mm

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<th>Catheter Model No.</th>
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Blazer™ Family

Abbreviated DFUs
**Indication for Use**
When using the Blazer II Catheter/Blazer II HTD Catheters: 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 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 tendineae. 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 II Catheter and the Blazer II HTD Catheter are 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.
Precautions (cont’d)

• The Boston Scientific Blazer II Temperature Ablation Catheter and Blazer II HTD Catheters are intended for use with the EPT-1000™ Cardiac Ablation System 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 60601-1-2 requirements is recommended.
• Placement of the DIP electrode on the thigh could be associated with the 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, Ecchymosis (2.1%)
• Aortic Valve Insufficiency/Wall Motion Abnormality
• Arrhythmic
• Permanently Atrioventricular Block
• Ventricular Fibrillation
• *Non-sustained Ventricular Tachycardia (1.6%)
• Conduction System Abnormalities
• *Atrial Fibrillation, Flutter, Tachycardia (2.5%)
• Pacemaker Failure-to-sense
• Phrenic Nerve Damage
Indication for Use*
The Boston Scientific Corporation Blazer II 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 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 anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic, anti-coagulation therapy, pre-, 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 II XP Catheters are intended for use with the BSC high power Controllers and accessories only.
- 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 technique 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 II 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 the 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.
Adverse Events

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
Indication 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 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.
- 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.
- Implantable 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 transseptal 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.
Precautions (cont'd)

- 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 (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 electrodes on the thigh could be associated with the 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.
- 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 electrodes 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, Ecchymosis (2.1%)
  - Aortic Valve Insufficiency/Valve Motion Abnormality
  - Arrhythmia
  - Permanent Atrioventricular Block
  - Ventricular Fibrillation
  - *Non-sustained Ventricular Tachycardia (1.6%)
  - Conduction System Abnormalities
  - *Atrial Fibrillation, Flutter, Tachycardia (2.5%)
  - Pacemaker Failure-to-sense

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Indication for Use*
The Boston Scientific Corporation Blazer Primer 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; and
• 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, pre-, 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 tendineae. 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 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 technique 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 contacts. 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 the 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.

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Adverse Events

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