Blazer™ Family of Ablation Catheters

Predictable. Dependable. Proven.

Boston Scientific

Navigation Tips

Blazer™

Predictable. Dependable. Proven.

Predictable Handling

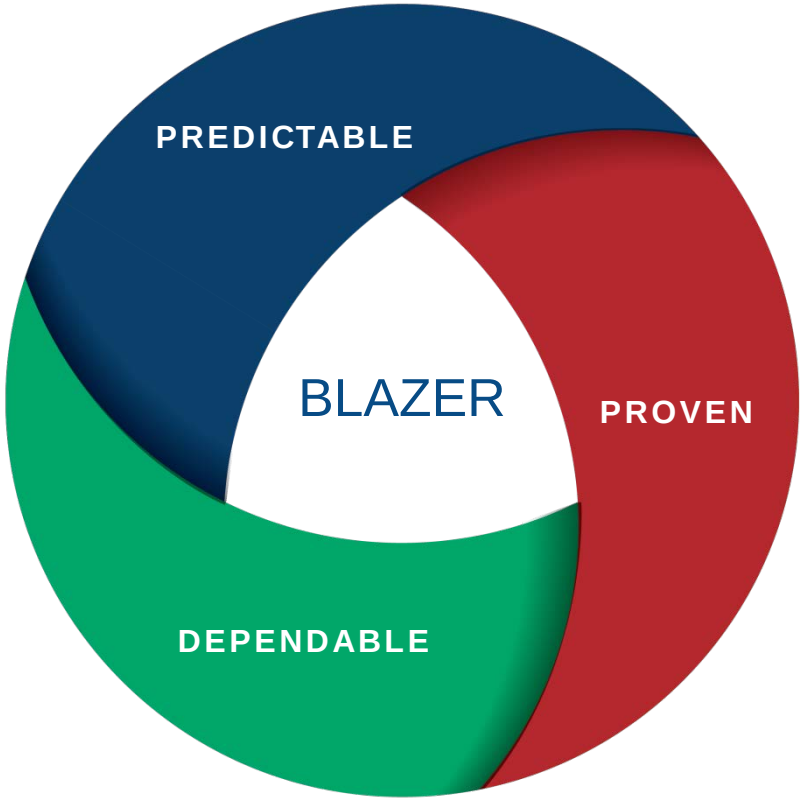
Designed for consistent handling – whether mapping or delivering therapy.

- 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.

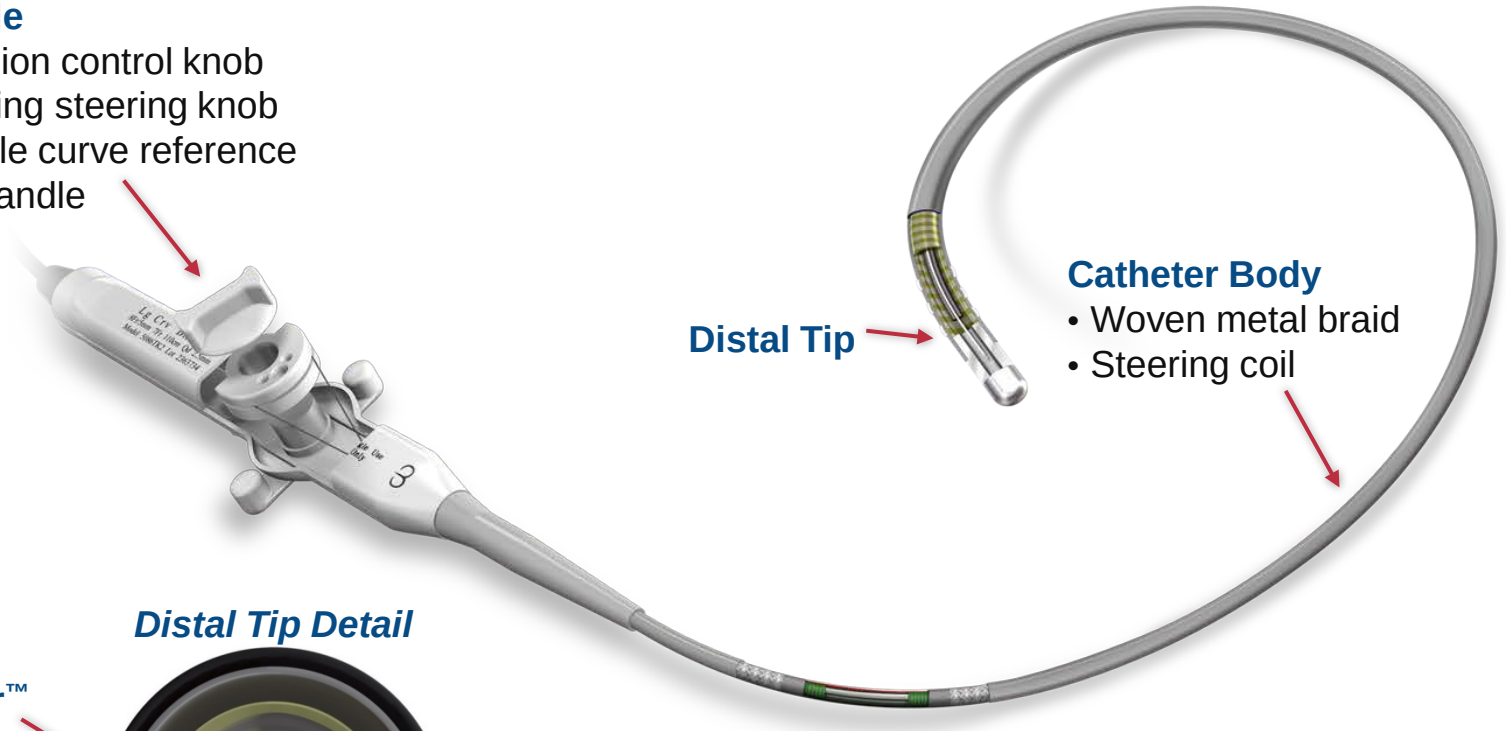
- Over 1 million catheters sold*

*From 1999 through 2014

What makes a Blazer™ a BLAZER?

Introduction

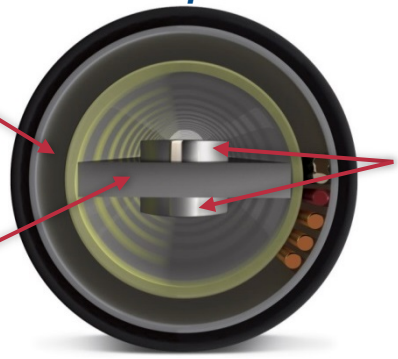
Handle
- Tension control knob
- Bi-wing steering knob
- Tactile curve reference on handle



Distal Tip

Catheter Body
- Woven metal braid
- Steering coil

Distal Tip Detail



Kevlar™ Wrap

Steering Plate (metal)

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

What makes a Blazer™ a BLAZER?

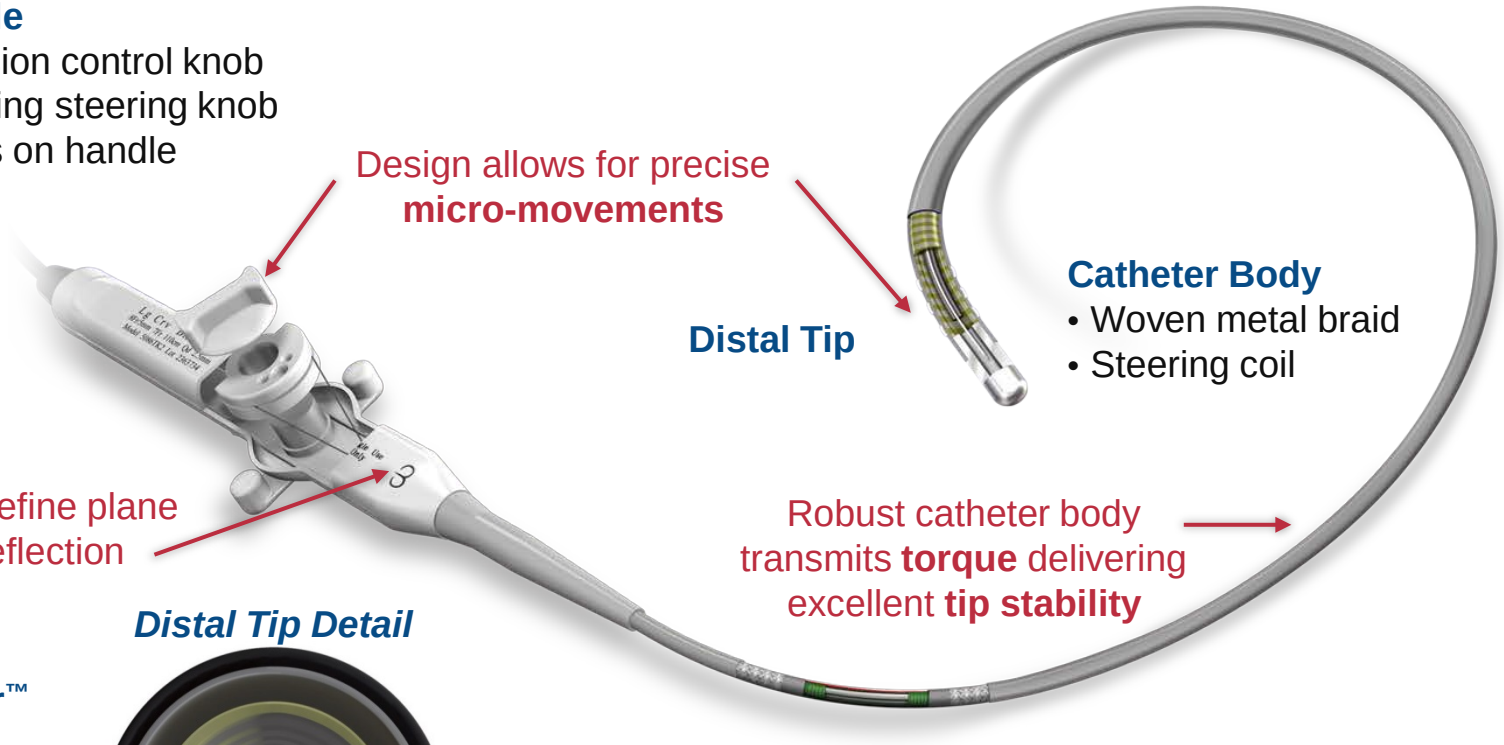
Introduction

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

Design allows for precise **micro-movements**

Distal Tip

Catheter Body
- Woven metal braid
- Steering coil



'Flats' define plane of deflection

Robust catheter body transmits **torque** delivering excellent **tip stability**

Distal Tip Detail

Kevlar™ Wrap

Steering Plate (metal)

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

Patented steering design provides **in-plane steering** and **curve retention** throughout long cases

Blazer™ II and Blazer™ II HTD

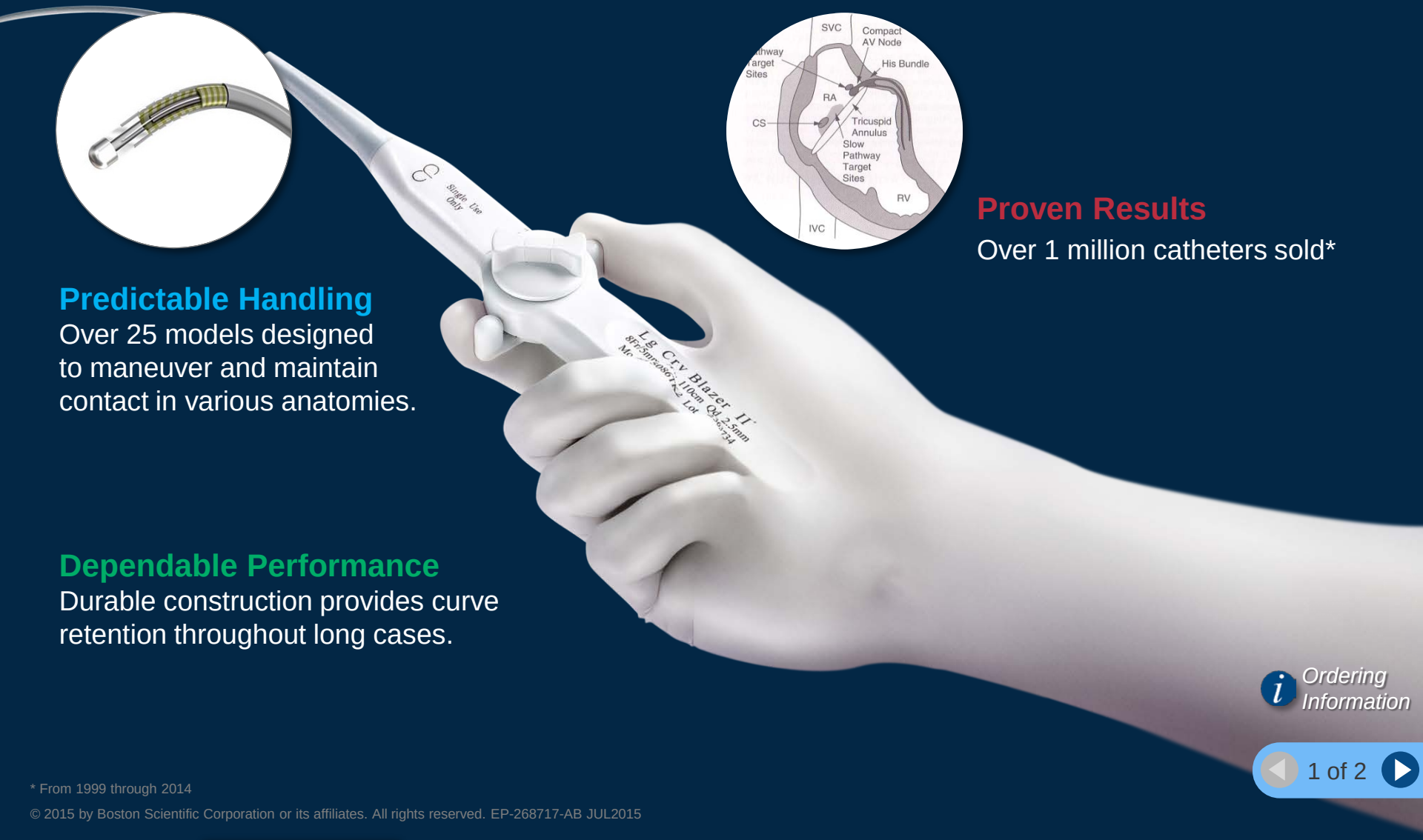
Temperature Ablation Catheter

Boston Scientific

Blazer™ II and Blazer™ II HTD

Temperature Ablation Catheter

Boston Scientific



Predictable Handling

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

Proven Results

Over 1 million catheters sold*

Dependable Performance

Durable construction provides curve retention throughout long cases.

i Ordering Information

1 of 2

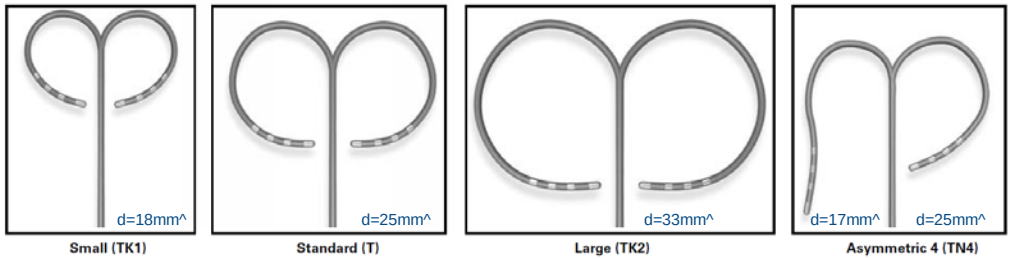
* From 1999 through 2014

The Blazer™ II Platform

AVNRT & Accessory Pathway Toolsets

Boston Scientific

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

	Model Suffix	
6.9 cm*	= T	**Standard Distal Length** • Electrode Spacing: 2.5mm
11 cm*	= TM	**Medium Distal Length** • Curve dimensions are the same as standard distal • Electrode Spacing: 2.5mm
13.5 cm*	= L	**Large Distal Length** • Electrode Spacing: 2.5mm
15.5 cm*	= TL	**Extended Distal Length** • Curve dimensions are the same as standard distal • Electrode Spacing: 2.5mm

Blazer Prime® Temperature Ablation Catheter Distal Segments

11 cm*	= T	**Distal Length** • Electrode Spacing: 2.5mm

* Std/N4 curve distal lengths shown; K2 curve distal length slightly longer.

Blazer™ II
(7F/4mm, 8F/5mm)

Blazer™ II HTD
(7F/4mm, 8F/5mm)

Blazer™ II Prime
(7F/4mm, 8F/5mm)

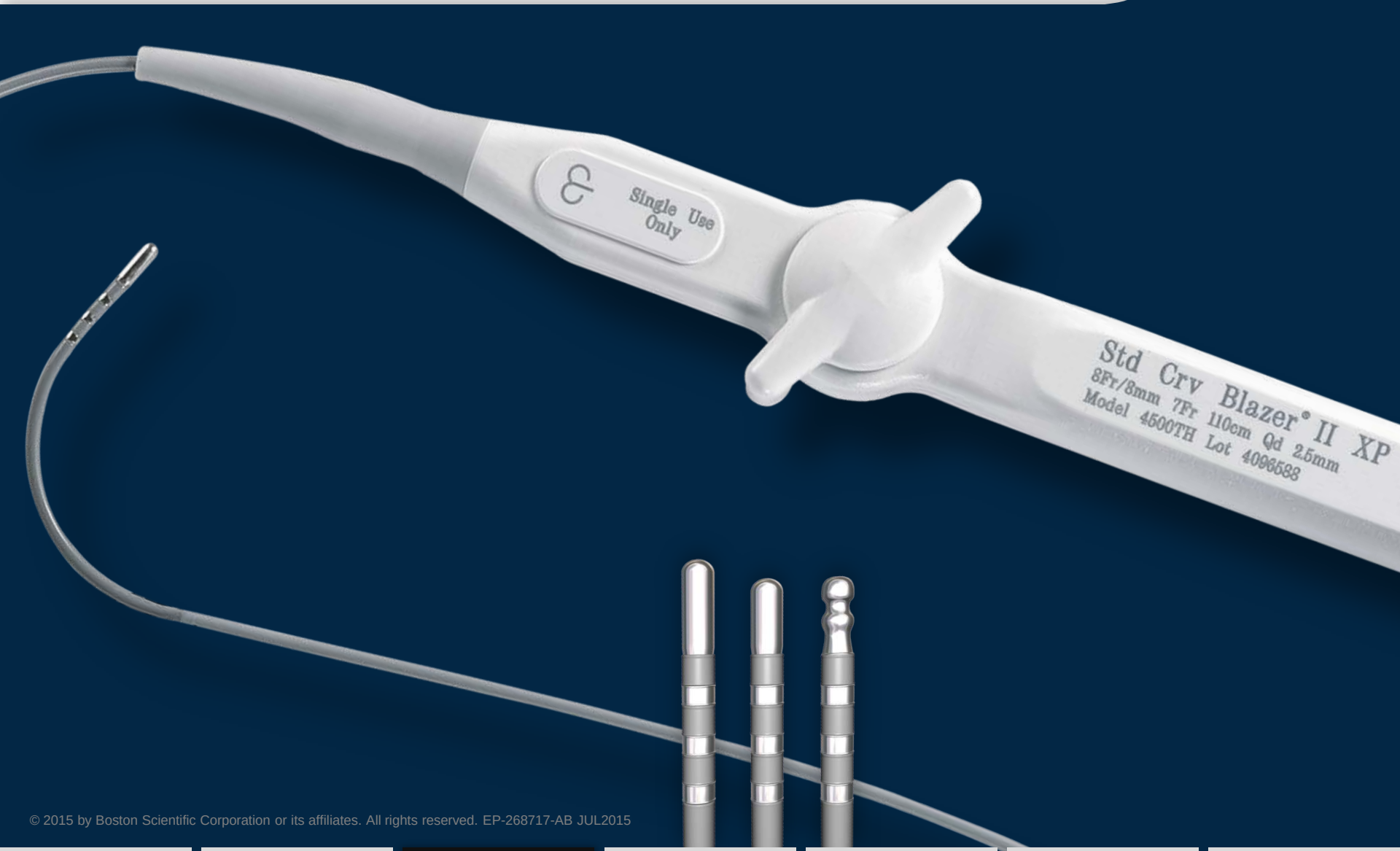
Ordering Information

^ Dimensions are for reference only.

Blazer™ II XP

Temperature Ablation Catheter

Boston Scientific



Blazer™ II XP

Temperature Ablation Catheter

Boston Scientific

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 information*
- More efficient procedures with 10mm tip *More information*
- 100 W available with the Maestro 3000™ Cardiac Ablation System
- Greater than 70W required in 85% of procedures *More information*

Dependable Performance

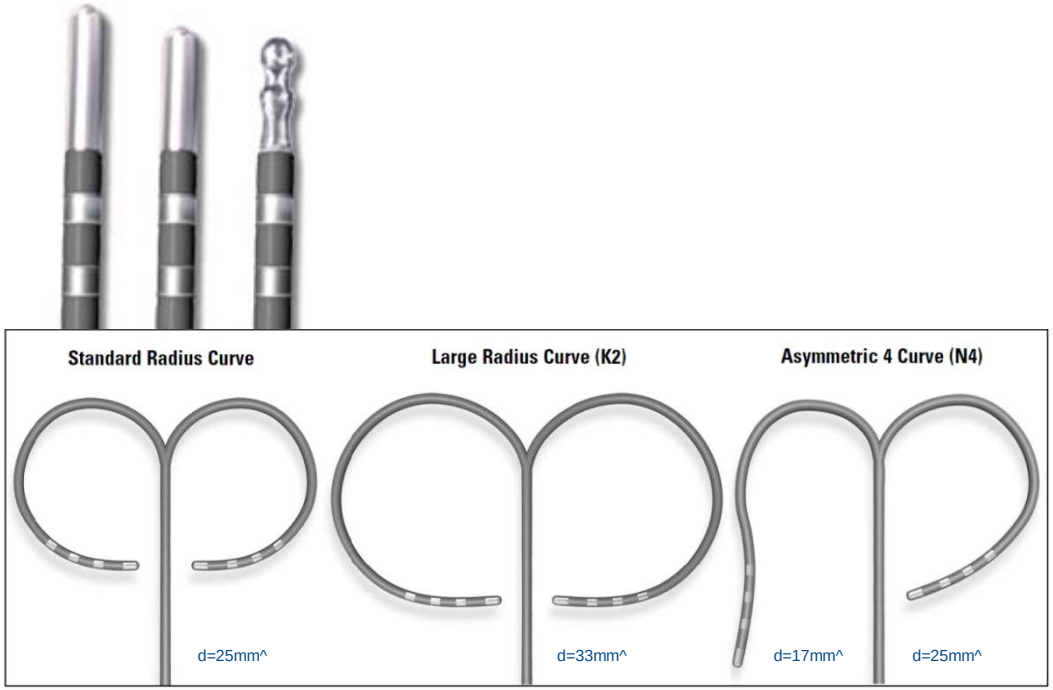
- Excellent curve retention to reach and maintain contact with Isthmus.

Ordering Information

1 of 5

The Blazer™ II XP Platform

Type 1 Atrial Flutter Toolsets



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

Blazer II™ XP
(8F/8mm, 8F/10mm)

Blazer™ Prime XP
(8F/8mm, 8F/10mm)

Ordering Information

2 of 5

^ Dimensions are for reference only.

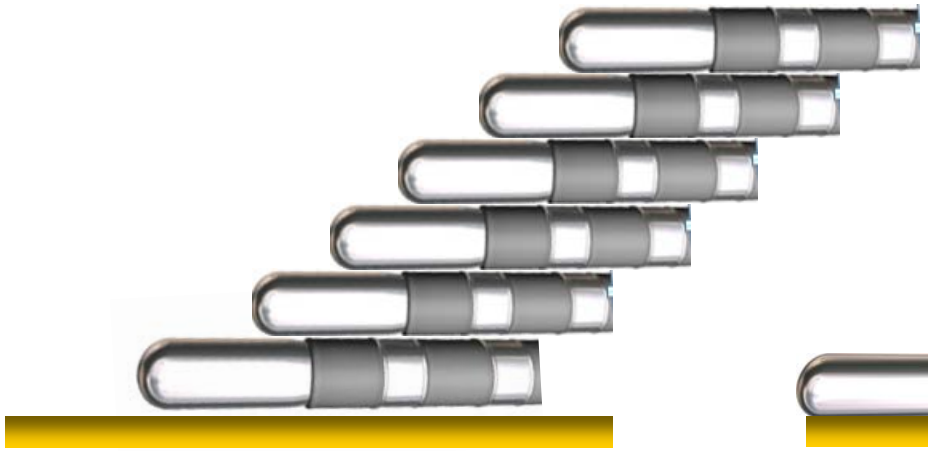
The Blazer™ II XP is Efficient

Fewer RF applications, less ablation time

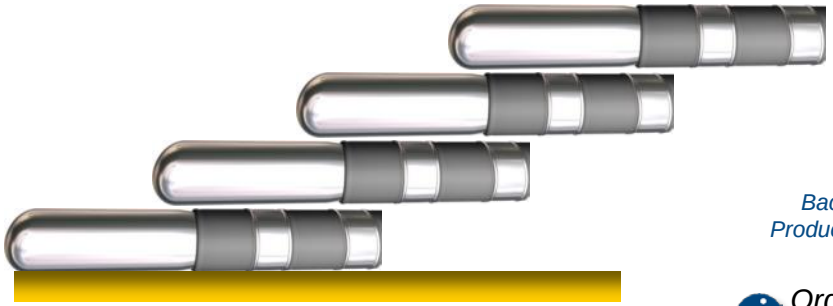
A typical Isthmus is approximately 3cm long[1]

Benefits of a 10mm vs. 8mm:

- 29% fewer RF applications[2]
- 38% less ablation time[2]



8mm Tip



10mm Tip

Back to Product Page

Ordering Information

1. Da Costa A, Faure E, Thevenin J, Messier M, Bernard S, Abdel K, et al. Effect of isthmus anatomy and ablation catheter on radiofrequency catheter ablation for the cavotricuspid isthmus. Circulation 2004; 110:1030-1035. (2) Petersen HH, Chen X, Pietersen A, Svendsen JH, Hauns o S. Lesion dimensions during temperature-controlled radiofrequency catheter ablation of left ventricular porcine myocardium: Impact of ablation site, electrode size, and convective cooling. Circulation 1999; 99:319-325. Boston Scientific Image Library. 2. Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

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 XP[1]

			SUCCESS DATA			PROCEDURE DATA				COMPLICATION DATA
FDA Approval	PMA #	# of Patients	Acute Success	Chronic Success	Overall Success	Total Procedure Time*	Total Fluoroscopy Time*	Total RF Appllications	Saline Infused	Major Complications
8/25/2003	P020025	250	94%	96%	90%	126 min	28.5 min	11.5	0 L	8%

Design:

Prospective, non-randomized, multi-center study to determine the safety and efficacy of ablating 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).

Ordering Information

http://www.fda.gov

[1] SSE Clinical Data on file. Boston Scientific Corporation.
[2] Biosense Webster. P0030031 Summary of Safety and Effectiveness Data version 5.1

Blazer™ II XP *Temperature Ablation Catheter*

Blazer XP Clinical Information

Boston Scientific

BOSTON SCIENTIFIC: Blazer II XP Large-Tip (8 & 10mm) Clinical Trial									
Year Published	Authors	Publication	Total # of Patients	Catheter Used	Acute Success	Atrial Flutter Recurrence	Mean Follow-up	Mean Procedure Time	Mean Fluoro Time
2004	Feld, G. et al[3]	Journal of The American College of Cardiology	169	Blazer II XP 10mm Blazer II XP 8mm (Straight) Blazer II XP 8mm (Contoured)	93%	3%	6 Months	122 min	28.4 min

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.

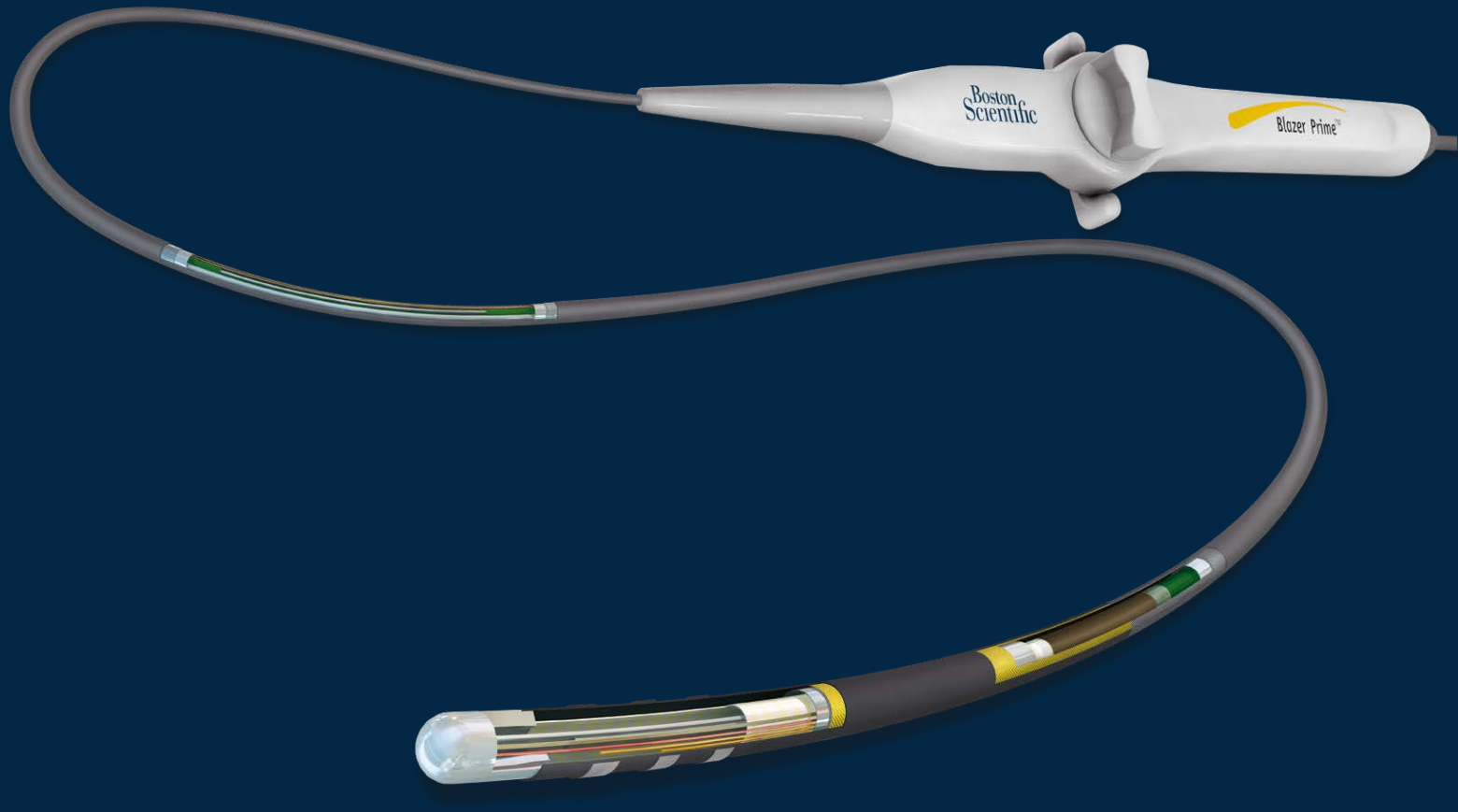
Feld et al: "A maximum power over 70W was required in 85% of patients". (p.1472)

Ordering Information

[1] Ilg, K. J., et al. Randomized Comparison of CTI Ablation for Atrial Flutter Using an OI-Tip versus a Large-Tip RF Ablation Catheter. Journal of Cardiovascular Electrophysiology. 2011. vol 22. 1007-1012
[2] Leiria et al. Improved Flutter Ablation Outcomes Using a 10mm-tip Ablation Catheter. Indian Pacing & Electrophysiology Journal. 2010. vol 10. Num 11. 496-502
[3] Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

Blazer Prime™

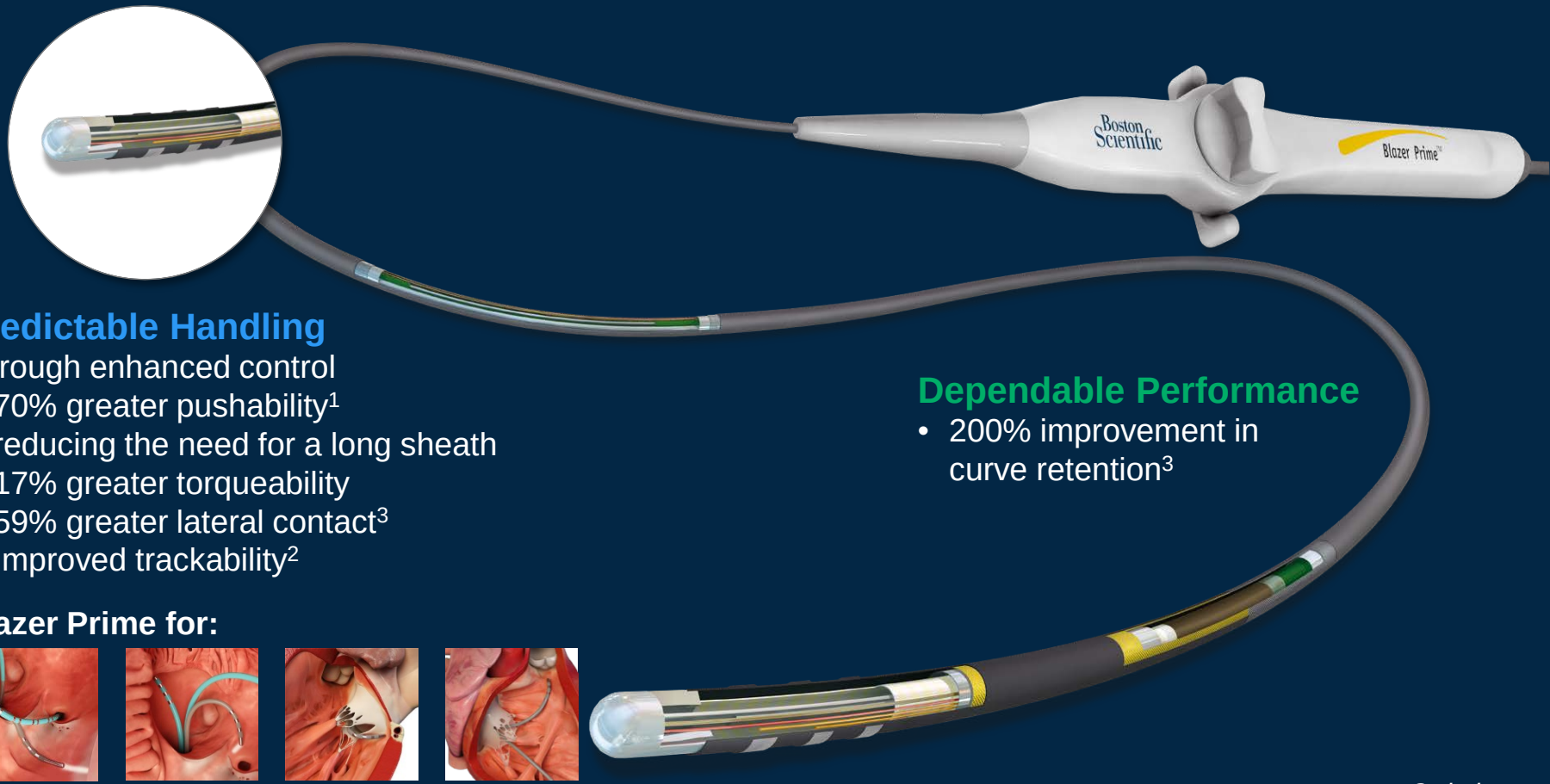
Bidirectional Temperature Ablation Catheter



Blazer Prime™

Bidirectional Temperature Ablation Catheter

Boston Scientific



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

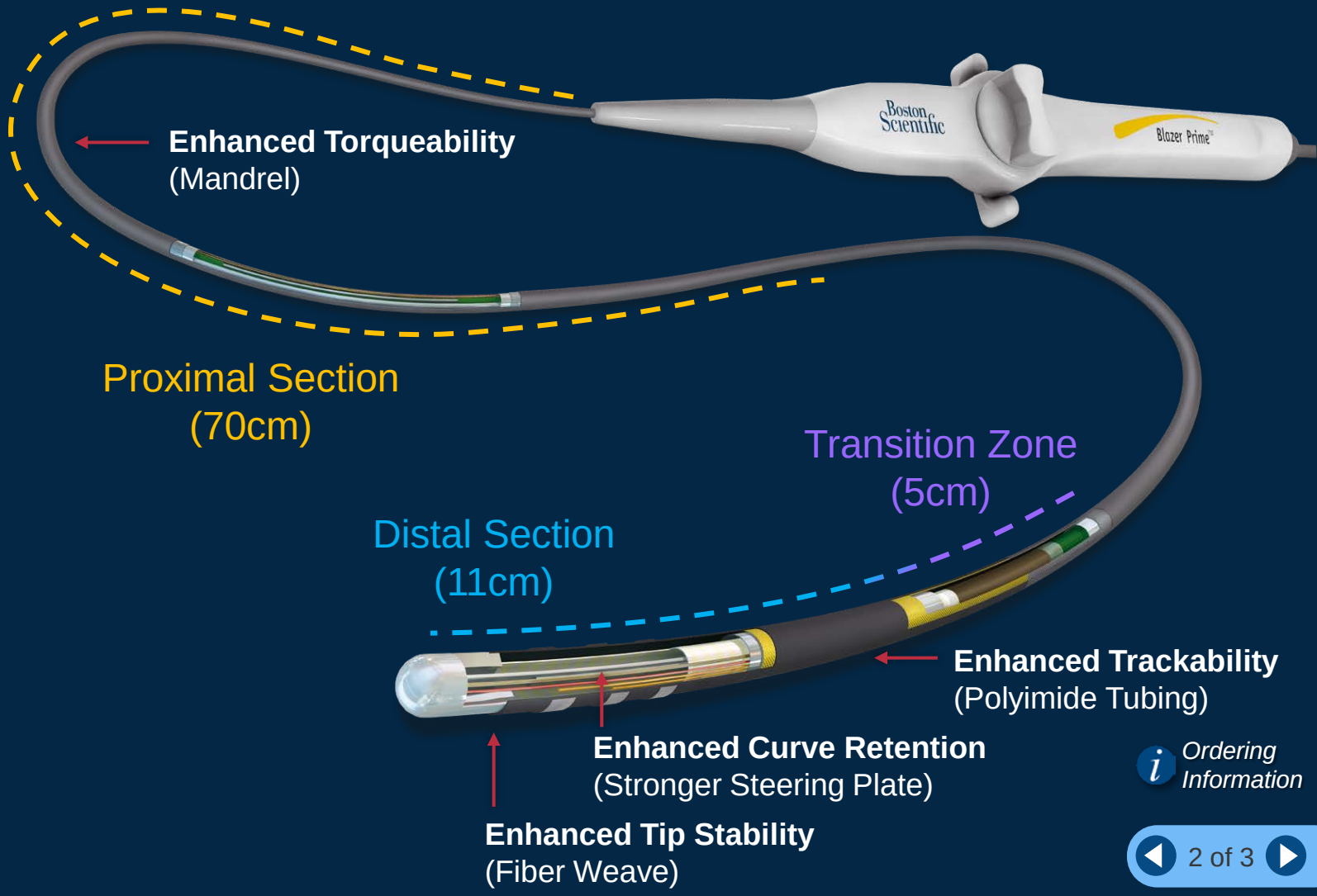
Ordering Information

(1) 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 performances. (2) 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 performance. (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 test not necessarily predictive of clinical performance.

Blazer Prime™

Bidirectional Temperature Ablation Catheter

Boston Scientific



Ordering Information

2 of 3

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

Catheter Construction

Boston Scientific

Proximal Section

Transition Zone

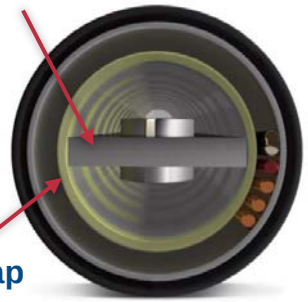
Distal Segment

Blazer™ II HTD, Blazer™ II XP Catheter

Proximal-to-Distal Transition Zone

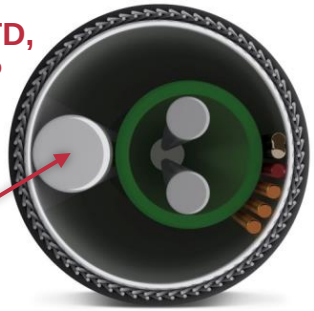
Steering Plate

Kevlar Wrap



Blazer Prime™ HTD, Blazer Prime™ XP Catheter

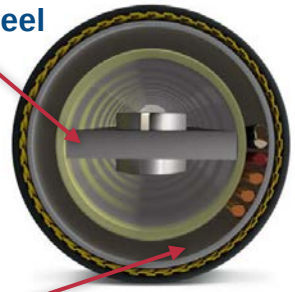
Support Mandrel



Polyimide Tubing – Improved transition

Material Change to Steering Plate – Higher Yield Stainless Steel

Fiber Weave



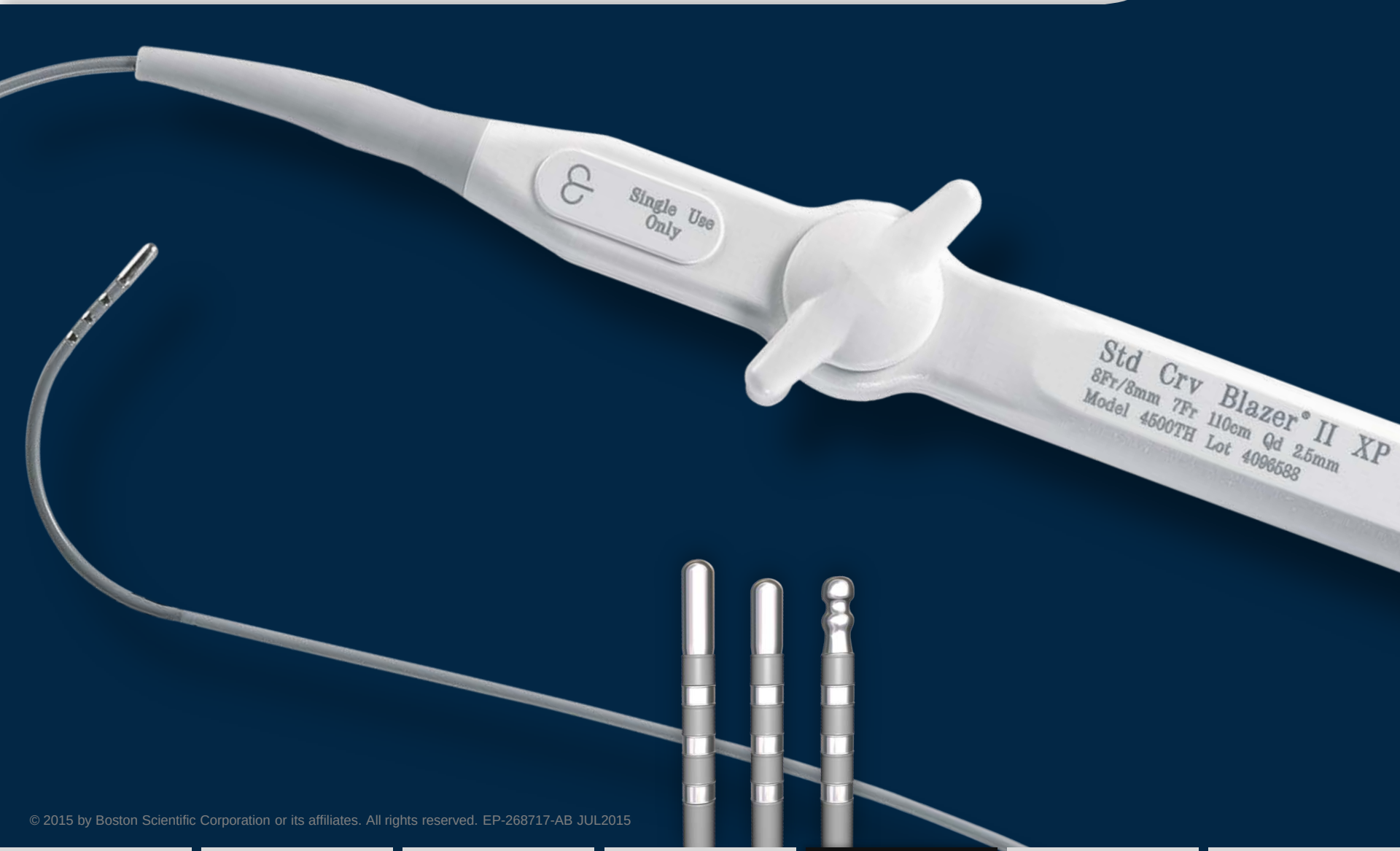
Ordering Information

3 of 3

Blazer™ II vs. Blazer™ II XP

Current Density

Boston Scientific



Blazer™ II vs. Blazer™ II XP

Current Density

Boston Scientific

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

Catheter Size	Electrode Surface Area	Impedance (Ω)	Current Density (amps/in^2)	Power (W)								
				20	**30**	40	50	60	**70**	80	**90**	**100**
7F/4mm	0.050	100		8.9	10.9	12.6	14.1					
8F/8mm	0.098	60		5.9	7.2	8.3	9.3	10.2	**11.0**	11.7	12.5	13.1
8F/10mm	0.123	50		5.1	6.3	7.3	8.1	8.9	9.6	10.3	10.9	11.5

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

Back to Product Page

^Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

Blazer™ II vs. Blazer™ II XP

Current Density

Boston Scientific

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

Catheter Size	Electrode Surface Area	Impedance (Ω)	Current Density (amps/in^2)	Power (W)								
				20	**30**	40	50	60	**70**	80	**90**	**100**
7F/4mm	0.050	100		8.9	10.9	12.6	14.1					
8F/8mm	0.098	60		5.9	7.2	8.3	9.3	10.2	11.0	11.7	12.5	13.1
8F/10mm	0.123	50		5.1	6.3	7.3	8.1	8.9	9.6	10.3	**10.9**	11.5

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

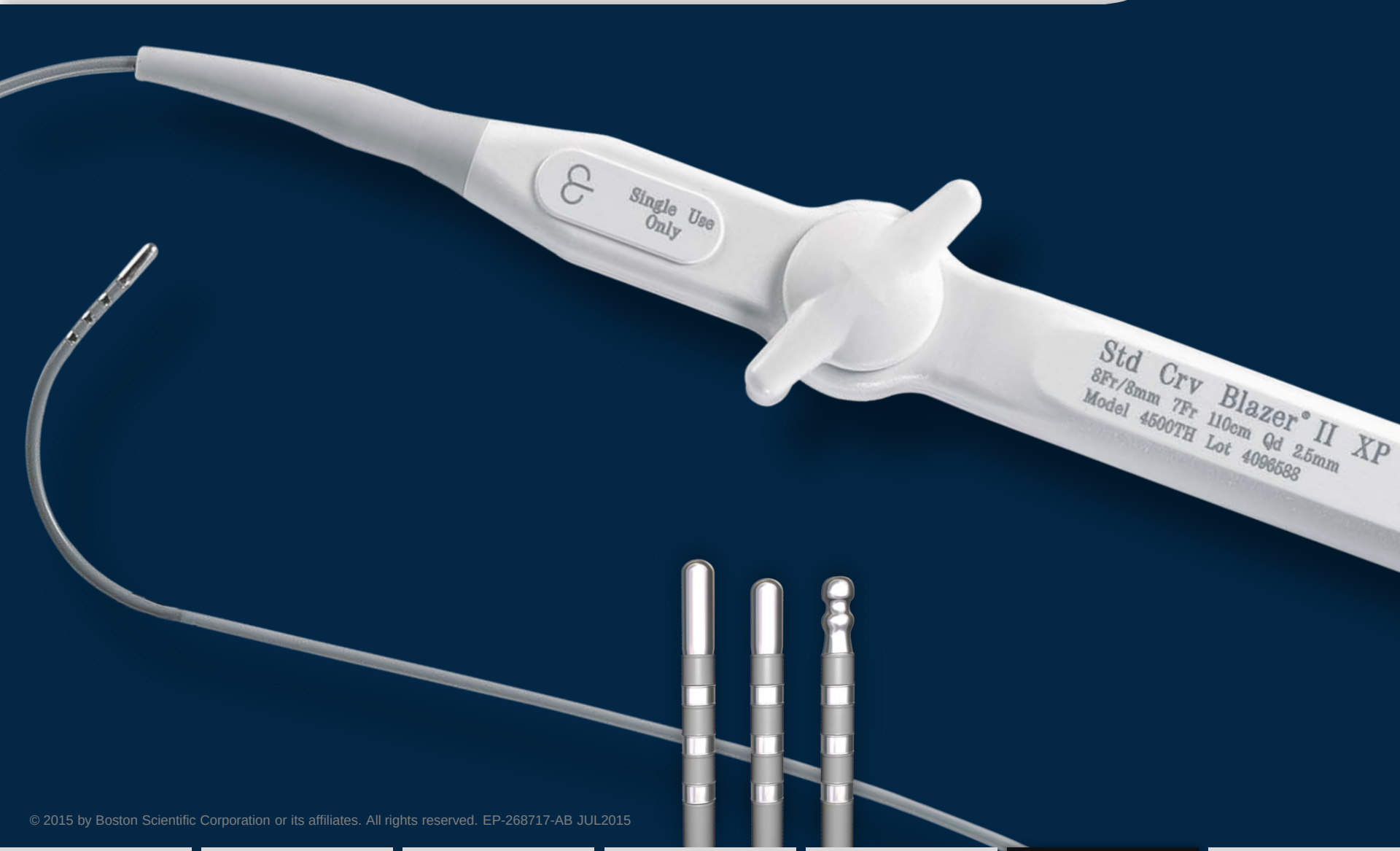
Back to Product Page

^Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

Blazer™ II XP Temperature Ablation Catheter

Competitive Information

Boston Scientific



Blazer™ II XP *Temperature Ablation Catheter*

Competitive Information

Boston Scientific

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

Year Published	Authors	Total # of Patients	Catheter Used	# of Patients	Max Generator Settings	Acute Success	Atrial Flutter Recurrence	Mean Follow-up	Mean Procedure Time	Mean Fluoro Time
2010	Leria, T. et al[2]	198	Blazer 10mm (BSC)	143	100W, 60-65°C	97.6%*	1.2% / yr	19 Months	70 min	24 min
			NaviStar DS 8mm (J&J)	55	60W, 60-65°C		10.1% / yr		105 min	37 min
			NaviStar ThermoCool (J&J)	14	50W		6.9% / yr		180 min	110 min

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.

[1] Ilg, K. J., et al. Randomized Comparison of CTI Ablation for Atrial Flutter Using an OI-Tip versus a Large-Tip RF Ablation Catheter. Journal of Cardiovascular Electrophysiology. 2011. vol 22. 1007-1012
[2] Leiria et al. Improved Flutter Ablation Outcomes Using a 10mm-tip Ablation Catheter. Indian Pacing & Electrophysiology Journal. 2010. vol 10. Num 11. 496-502
[3] Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

Blazer™ II XP *Temperature Ablation Catheter*

Competitive Information

Boston Scientific

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

Year Published	Authors	Total # of Patients	Catheter Used	# of Patients	Max Generator Settings	Acute Success	Atrial Flutter Recurrence	Mean Follow-up	Mean Procedure Time	Mean Fluoro Time
2011	Ilg, K. et al[1]	60	Blazer 10mm (BSC)	30	100W, 60°C	98%*	0%	6 Months	95 min	23.5 min
			NaviStar ThermoCool (J&J)		40W, 48°C		10%		114 min	23.9 min

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.

[1] Ilg, K. J., et al. Randomized Comparison of CTI Ablation for Atrial Flutter Using an OI-Tip versus a Large-Tip RF Ablation Catheter. Journal of Cardiovascular Electrophysiology. 2011. vol 22. 1007-1012
[2] Leiria et al. Improved Flutter Ablation Outcomes Using a 10mm-tip Ablation Catheter. Indian Pacing & Electrophysiology Journal. 2010. vol 10. Num 11. 496-502
[3] Feld G, Wharton M, Plumb V, et al. Radiofrequency catheter ablation of type 1 atrial flutter using large tip 8- or 10-mm electrode catheters and a high-output radiofrequency energy generator. J Am Coll Cardiol. 2004;43:1466-72.

Blazer™ II XP *Temperature Ablation Catheter*

Competitive Information

Boston Scientific

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

		Blazer II XP 8mm, 10mm
PMA Data[1]	Acute Success Rate	94%
	Recurrence Rate	4%

Blazer II XP has a high Acute Success Rate.[1]

		Blazer II XP 8mm, 10mm	ThermoCool™ 3.5mm
Ilg et al.[2]	Recurrence Rate	0%*	10%*
Leiria et al.[4]	Recurrence Rate	1.2%**	6.9%**

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.

[1] SSE Clinical Data on file. Boston Scientific Corporation.
[2] Ilg, K. J., et al. Randomized Comparison of CTI Ablation for Atrial Flutter Using an OI-Tip versus a Large-Tip RF Ablation Catheter. Journal of Cardiovascular Electrophysiology. 2011. vol 22. 1007-1012
[3] List prices of catheters.
[4] Leiria et al. Improved Flutter Ablation Outcomes Using a 10mm-tip Ablation Catheter. Indian Pacing & Electrophysiology Journal. 2010 vol 10. Num 11. 496-502

Back to Product Page

3 of 4

INTRODUCTION | BLAZER II BLAZER II HTD | BLAZER II XP | BLAZER PRIME | CURRENT DENSITY | COMPETITIVE INFO | ORDERING INFORMATION

Blazer™ II XP *Temperature Ablation Catheter*

Competitive Information

Boston Scientific

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

FDA SUBMISSION DATA FOR TYPE 1 ATRIAL FLUTTER

BIOSENSE WEBSTER: FDA Submission Data for Navistar ThermoCool™[2]

			SUCCESS DATA			PROCEDURE DATA				COMPLICATION DATA
FDA Approval	PMA #	# of Patients	Acute Success	Chronic Success	Overall Success	Total Procedure Time*	Total Fluoroscopy Time*	Total RF Appllications	Saline Infused	Major Complications
11/05/2004	P030031	186	85%	93%	79%	314 min	48.7 min	19.0	1 L	15.8%

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).

http://www.fda.gov

[1] SSE Clinical Data on file. Boston Scientific Corporation.
[2] Biosense Webster. P0030031 Summary of Safety and Effectiveness Data version 5.1

Blazer™ Family
Ordering Information

Boston Scientific

Blazer™ II *Temperature Ablation Catheter*

Ordering Information

Tip: 7F/4mm ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **5031T** 0	7F	Standard	Standard	M004 **651** 0
M004 **5031TK1** 0	7F	Small	Standard	M004 **651** 0
M004 **5031TK2** 0	7F	Large	Standard	M004 **651** 0
M004 **5031TN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0
M004 **5031TM** 0	7F	Standard	Medium	M004 **651** 0
M004 **5031TMK2** 0	7F	Large	Medium	M004 **651** 0
M004 **5031TL** 0	7F	Standard	Extended	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)				
M004 **5031TMN4** 0	7F	Asymmetric 4	Medium	M004 **651** 0

Tip: 8F/5mm ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **5086T** 0	7F	Standard	Standard	M004 **651** 0
M004 **5086TK2** 0	7F	Large	Standard	M004 **651** 0
M004 **5086TN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0
M004 **5086TMK2** 0	7F	Large	Medium	M004 **651** 0
M004 **5086TL** 0	7F	Standard	Extended	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)				
M004 **5086TK1** 0	7F	Small	Standard	M004 **651** 0
M004 **5086TM** 0	7F	Standard	Medium	M004 **651** 0

Back to Product Page

1 of 5

Blazer™ II HTD *Temperature Ablation Catheter*

Ordering Information

Boston Scientific

Tip: 7F/4mm ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **5031TH** 0	7F	Standard	Standard	M004 **651** 0
M004 **5031THK2** 0	7F	Large	Standard	M004 **651** 0
M004 **5031THN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0
M004 **5031THM** 0	7F	Standard	Medium	M004 **651** 0
M004 **5031THMK2** 0	7F	Large	Medium	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)				
M004 **5031TMN4** 0	7F	Asymmetric 4	Medium	M004 **651** 0

Tip: 8F/5mm ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **5086TH** 0	7F	Standard	Standard	M004 **651** 0
M004 **5086THK2** 0	7F	Large	Standard	M004 **651** 0
M004 **5086THN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0
M004 **5086THMK2** 0	7F	Large	Medium	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)				
M004 **5086THM** 0	7F	Standard	Medium	M004 **651** 0
M004 **5086THMN4** 0	7F	Asymmetric 4	Medium	M004 **651** 0

Back to Product Page

2 of 5

Blazer™ II XP *Temperature Ablation Catheter*

Ordering Information

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

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **4500TH** 0	7F	Standard	Standard	M004 **651** 0
M004 **4500THM** 0	7F	Standard	Medium	M004 **651** 0
M004 **4500THK2** 0	7F	Large	Standard	M004 **651** 0
M004 **4500THMK2** 0	7F	Large	Medium	M004 **651** 0
M004 **4500THN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0

Tip: 8F/10mm Straight ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **4790TH** 0	7F	Standard	Standard	M004 **651** 0
M004 **4790THM** 0	7F	Standard	Medium	M004 **651** 0
M004 **4790THK2** 0	7F	Large	Standard	M004 **651** 0
M004 **4790THMK2** 0	7F	Large	Medium	M004 **651** 0
M004 **4790THN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0

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

Catheter Model No.	Shaft Size	Curve Style	Distal Shaft Length	Cable Model No.*
M004 **4770TH** 0	7F	Standard	Standard	M004 **651** 0
M004 **4770THK2** 0	7F	Large	Standard	M004 **651** 0
M004 **4770THMK2** 0	7F	Large	Medium	M004 **651** 0
M004 **4770THN4** 0	7F	Asymmetric 4	Standard	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)				
M004 **4770THN4** 0	7F	Standard	Medium	M004 **651** 0

Back to Product Page

3 of 5

Blazer Prime™ HTD *Temperature Ablation Catheter*

Ordering Information

Tip: 7F/4mm Straight ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Cable Model No.*
M004 **P5031TH** 0	7F	Standard	M004 **651** 0
M004 **P5031THK2** 0	7F	Large	M004 **651** 0
M004 **P5031THN4** 0	7F	Asymmetric 4	M004 **651** 0

Tip: 8F/5mm Straight ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Cable Model No.*
M004 **P5086TH** 0	7F	Standard	M004 **651** 0
M004 **P5086THK2** 0	7F	Large	M004 **651** 0
M004 **P5086THN4** 0	7F	Asymmetric 4	M004 **651** 0

Back to Product Page

4 of 5

Blazer Prime™ XP *Temperature Ablation Catheter*

Ordering Information

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

Catheter Model No.	Shaft Size	Curve Style	Cable Model No.*
M004 **P4500TH** 0	7F	Standard	M004 **651** 0
M004 **P4500THK2** 0	7F	Large	M004 **651** 0
M004 **P4500THN4** 0	7F	Asymmetric 4	M004 **651** 0

Tip: 8F/10mm Straight ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Cable Model No.*
M004 **P4790TH** 0	7F	Standard	M004 **651** 0
M004 **P4790THK2** 0	7F	Large	M004 **651** 0
Made to Order Items (minimum order 25 units; see Ordering Information section for details)			
M004 **P4790THN4** 0	7F	Asymmetric 4	M004 **651** 0

Tip: 8F/8mm Contour (VM) ***Electrode Configuration:*** Quadripolar ***Electrode Spacing:*** 2.5mm

Catheter Model No.	Shaft Size	Curve Style	Cable Model No.*
M004 **P4770THK2** 0	7F	Large	M004 **651** 0

Back to Product Page

5 of 5

Blazer™ Family

Abbreviated DFUs

Blazer™ II and Blazer™ II HTD Temperature Ablation Catheters (US DFU)

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 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 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 tamonade. 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.

Blazer™ II and Blazer™ II HTD Temperature Ablation Catheters (US DFU)

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
- Permanent 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

Blazer™ II XP Temperature Ablation Catheter (US DFU)

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.

Blazer™ II XP Temperature Ablation Catheter (US DFU)

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.

Blazer™ II XP Temperature Ablation Catheter (US DFU)

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

Blazer Prime™ HTD Temperature Ablation Catheters (US DFU)

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.
- 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 transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- Careful catheter manipulatioin must be performed in order to avoid cardiac damage, perforation, or tamonade. 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.

Blazer Prime™ HTD Temperature Ablation Catheters (US DFU)

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/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 (US DFU)

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 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 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 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.

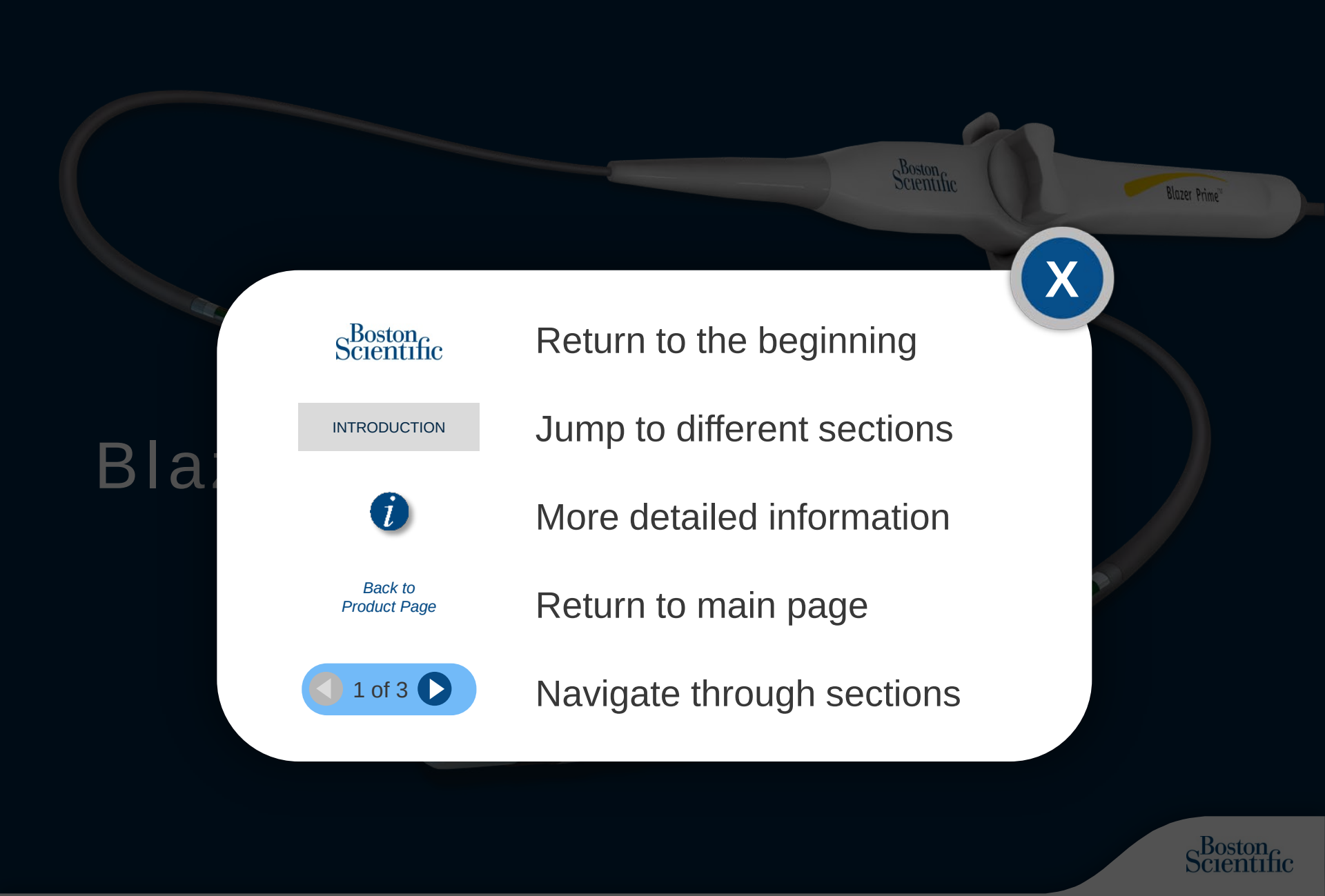
Blazer Prime™ XP Temperature Ablation Catheter (US DFU)

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



Bla

X

Boston Scientific

INTRODUCTION

Back to Product Page

1 of 3

Return to the beginning

Jump to different sections

More detailed information

Return to main page

Navigate through sections

Boston Scientific

Navigation Tips