BLAZE Clinical Registry Summary

Objective
To evaluate the safety and performance of the Boston Scientific FilterWire EZ™ Embolic Protection System during angioplasty/stenting of saphenous vein grafts (SVGs).

Design
Prospective, multi-center registries using the FilterWire EZ Embolic Protection System. The vessel size range in the BLAZE Registry was 3.5mm to 5.5mm and the vessel size range in the BLAZE II Registry was 2.25mm to 3.5mm.

End Point
The primary safety end point of both studies was the cumulative incidence of major adverse cardiac events (MACE), defined as death, Q-wave or non-Q-wave myocardial infarction (MI), emergent coronary artery bypass surgery (CABG), or target vessel revascularization (TVR), at 30-days post-procedure.

Investigative Sites
Ninety (90) patients were enrolled at sixteen (16) U.S. and six (6) European clinical sites in the BLAZE Registry. One hundred thirty one (131) patients were enrolled at nineteen (19) U.S. clinical sites in the BLAZE II Registry.

Conclusions
- In the SAFER Trial, which studied PCI of SVGs with versus without embolic protection, the GuardWire Plus® System reduced MACE by 42%.[1]
- The FIRE Trial determined that the 30-day MACE rates for the FilterWire EX Embolic Protection System (9.9%) were not statistically different than the PercuSurge GuardWire Plus System (11.6%) when tested to a trial delta of 5.5% (p=0.0016).[2]
- The BLAZE Registries using the FilterWire EZ System show comparable results to the FIRE randomized trial, confirming the safety and performance of the FilterWire® Embolic Protection System.

		BLAZE Registry (n=90)	**BLAZE II Registry* (n=131)**	**Combined BLAZE Registry (n=221)**
Age (years)		70.3	68.1	**69.0**
Male Gender		82.2%	71.1%	**79.2%**
Baseline Thrombosis Level:	0/1	36.0%	81.1%	**63.3%**
	2	34.9%	11.4%	**20.6%**
	3	25.6%	6.1%	**13.8%**
	4	3.5%	0.0%	**1.4%**
RVD (mm)**		3.38	2.83	**3.04**
MLD (mm)**		1.12	0.80	**0.92**
Diameter Stenosis**		66.6%	71.9%	**69.8%**
Lesion Length (mm)**		12.79	12.10	**12.37**
Baseline TIMI:	0/1	1.1%	1.5%	**1.4%**
	2	14.9%	3.8%	**8.2%**
	3	83.9%	94.7%	**90.4%**
30-day MACE (Death, MI, Emergent CABG, TVR)		**6.7%**	**3.8%**	**5.0%**
Death		0%	0%	**0%**
MI-Q-wave		0%	0.8%	**0.5%**
MI-Non-Q-wave		6.7%	3.1%	**4.5%**
Emergent CABG		0%	0%	**0%**
TLR		0%	0%	**0%**
TVR (not involving target lesion)		0%	0%	**0%**

*FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System pending 510(k); not available for sale in the United States.
** Baseline lesion characteristics

[1]Baim DS, *et al*. Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts. *Circulation*. 2002; 105; 1285-1290.
[2] Stone G.W., *et al*. Randomized Comparison of Distal Protection With a Filter-Based Catheter and a Balloon Occlusion and Aspiration System During Percutaneous Intervention of Diseased Saphenous Vein Aorto-Coronary Bypass Grafts. *Circulation*. 2003; 108; 548-553.

	BLAZE Registry (3.5mm-5.5mm)		**BLAZE II Registry** (2.25mm-3.5mm)		**Combined BLAZE Registry** (2.25mm-5.5mm)	
Baseline Demographics						
N	90 pts		131 pts		221 pts	
Age (years)	70.3		68.1		69.0	
Male Gender	82.2%		71.1%		79.2%	
Diabetes	43.3%		44.3%		43.3%	
Hx MI	67.0%		54.2%		59.3%	
HTN	76.4%		88.5%		83.6%	
Ejection Fraction	50.6%		52.8%		51.9%	
Baseline Thrombus Level						
0-1 (minimal)	36.0%		81.1%		63.3%	
2	34.9%		11.4%		20.6%	
3	25.6%		6.1%		13.8%	
4	3.5%		0.0%		1.4%	
Baseline Angiographic Features						
SVG to:						
LAD	22.2%		25.6%		24.2%	
CX	46.7%		36.8%		40.8%	
RCA	31.1%		37.6%		34.9%	
Lesion Location:						
Ostial/Proximal	57.5%		49.2%		52.5%	
Mid	36.8%		38.6%		37.9%	
Distal	5.7%		11.4%		9.1%	
Lesion Length, mean (mm)	12.79		12.10		12.37	
Ulcerated Lesion (%)	21.8%		10.6%		15.1%	
Eccentric Lesion (%)	72.1%		39.7%		52.5%	
	Baseline	**Final**	**Baseline**	**Final**	**Baseline**	**Final**
RVD (mm)	3.38	3.44	2.83	2.82	3.04	3.06
MLD (mm)	1.12	3.21*	0.80	2.59*	0.92	2.83*
% Diameter Stenosis	66.6	5.8*	71.93	7.42*	69.8	6.8*
%TIMI:						
0/1	1.1%	0.0%	1.5%	0.0%	1.4%	0.0%
2	14.9%	0.0%	3.8%	0.0%	8.2%	0.0%
3	83.9%	100.0%	94.7%	100.0%	90.4%	100.0%
Efficacy/Safety Measures						
Overall 30-day MACE (Death, MI, Emergent CABG or TVR)	**6.7%**		**3.8%**		**5.0%**	
Death	0%		0%		0%	
MI-Q-wave	0%		0.8%		0.5%	
MI-Non-Q-wave	6.7%		3.1%		4.5%	
Emergent CABG	0%		0%		0%	
TLR	0%		0%		0%	
TVR (not involving target lesion)	0%		0%		0%	
Device Success**	97.8%		98.5%		98.1%	
Clinical Success***	92.2%		94.7%		93.7%	
Sub-acute Thrombosis (30-days)	0%		0%		0%	
Perforation	0%		0%		0%	

* In-stent
** Device Success = successful placement and removal of the FilterWire System
*** Clinical Success = device success without procedural complication