FilterWire EZ™
Embolic Protection System

Predictable Protection Made Easy*

The FilterWire EZ™ Embolic Protection System is meant to provide ease of use to make this system ideal for carotid artery stenting. With clinically proven safety and efficacy, the FilterWire EZ™ System is engineered to provide predictable outcomes.

Predictable Protection*

Clinically Proven

• 30-day BEACH[1] and CABERNET[2] trial results demonstrate safety and efficacy.

Captures Debris Effectively*

• 110 µm pore filter design permits continuous blood flow while maintaining embolic capture efficiency.
• Suspended nitinol filter loop provides 360° apposition in straight or tortuous anatomy.*

Ease of Use

Promotes Procedural Efficiency

• Peel-away delivery sheath with pre-loaded protection wire designed to simplify device preparation while providing rapid exchange convenience.
• Radiopaque loop designed for full deployment verification with one angiographic view.

Eases Crossing and Retrieval

• 3.2F (1.1mm) delivery sheath crossing profile and silicone-coated tip designed to facilitate crossing of lesions.
• Retrieval sheath designed for maximum filter coverage while withdrawing through deployed stent.
• Nitinol filter loop closes for effective particle retention during retrieval.

Simplifies Filter Sizing

• One size provides protection in vessels with 3.5mm to 5.5mm diameter landing zone.

BEACH 30-Day Major Adverse Event Rates[1]

Composite 30-Day	5.6%
• Death	1.5%
• Stroke	4.2%
- Minor Ipsilateral	1.9%
- Major Ipsilateral	1.0%
• MI Rate	0.8%
Technical Success	97.1%

N=480

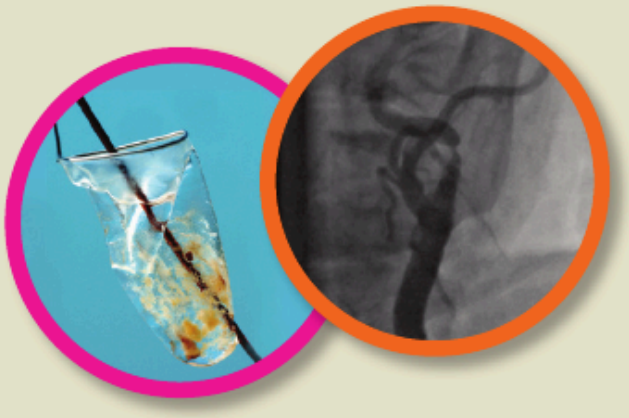
CABERNET 30-Day Major Adverse Event Rates[2]

Composite 30-Day	3.9%
• Death	0.5%
• Stroke	3.4%
- Minor Ipsilateral	2.1%
- Major Ipsilateral	1.3%
• MI Rate	0.2%
Technical Success	99.1%

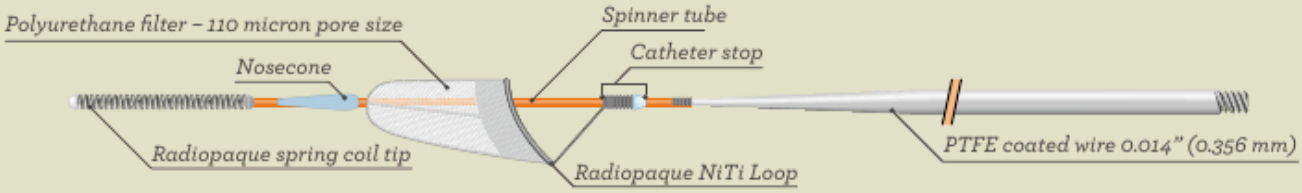
N=443

*Data on file, Boston Scientific Corporation.

CRV
Cardiology, Rhythm and Vascular



FilterWire EZ™ Embolic Protection System



Product Information

6F (2 mm) Guide Catheter or Sheath-Compatible (minimum ID 0.066" / 1.68 mm)

Order Number	Description	Crossing Profile	Vessel Diameter Coverage
H749 20105-190 0	FilterWire EZ System, 190cm*	3.2F (1.1mm, 0.042")	3.5mm-5.5mm
H749 20105-300 0	FilterWire EZ System, 300cm	3.2F (1.1mm, 0.042")	3.5mm-5.5mm
H749 50100-150 0	EZ Bent Tip Retrieval Sheath	4.0F (1.3mm, 0.052")	N/A

*Compatible with AddWire™ Extension Wire order code H749 22150-010.

Carotid Solutions from Boston Scientific

Boston Scientific offers great depth of technology specifically designed to address challenges of carotid artery disease. From surgical to endovascular options, Boston Scientific delivers tools physicians need to provide the right treatment to patients.

[1]**BEACH Trial Design:** Multi-center, prospective, single-arm study. N=747, Roll-In Group N=189, Bilateral Group N=78, Pivotal Group N=480 (symptomatic ≥50% stenosis N=112; asymptomatic ≥80% stenosis N=368.) 47 U.S. clinical sites participated in the study.
BEACH Trial Objective: To evaluate the outcomes of patients with carotid artery stenosis at high risk for carotid endarterectomy (CEA) using the Carotid WALLSTENT™ Monorail™ Endoprosthesis and the FilterWire EX™ and FilterWire EZ™ Distal Protection Systems.

Primary Endpoints: A 1-year composite endpoint of cumulative morbidity and mortality that included:
- ≤24 hours: all non-Q-wave Myocardial Infarction (MI)
- ≤30 days: all Q-wave MI, all Death, all Stroke
- >30 days, ≤1 year: Ipsilateral Stroke and Neurological Death

BEACH 30-Day Major Adverse Event Rates:
Pivotal Group: 5.6%†
- Death: 1.5%
- Stroke: 4.2%
- MI: 0.8%

BEACH 1-Year Major Adverse Event Rates:
Pivotal Group: 9.1%†
- Death: 3.2%
- Stroke: 7.0%
- MI: 1.1%

†Patients may have had more than one event.
System Technical Success includes FilterWire EZ™ System Technical Success combined with Carotid WALLSTENT™ Monorail™ Endoprosthesis Technical Success and is calculated on the number of system placement attempts.

CABERNET: **C**arotid **A**rtery Revascularization using the **B**oston Scientific **E**PI FilterWire EZ and the **E**ndo**T**ex NexStent.

[2]**CABERNET Trial Design:** A prospective, non-randomized, multi-center registry. N=488. (Pivotal Group N=454.) (Symptomatic 50% stenosis by Doppler ultrasound and angiogram; asymptomatic 80% stenosis by Doppler ultrasound or 60% stenosis as determined by angiogram without any neurological symptoms.) 21 sites participated in the registry. At 2 sites the registry was transitioned to other institutions. Of the remaining 21 sites, there were 15 U.S. sites and 4 O.U.S. sites.
CABERNET Trial Objective: To evaluate the safety and efficacy of the NexStent™ Monorail™ Carotid Stent and Delivery System and the Boston Scientific FilterWire EX™ and FilterWire EZ™ Embolic Protection Systems by assessing the outcomes of patients with carotid artery stenosis in the ICA, CCA or ICA/CCA bifurcation who are at high risk for carotid endarterectomy (CEA).

Primary Endpoint #1
A composite major adverse event rate including:
0-30 days: all Death, Stroke and MI (Q and non-Q-wave), plus Ipsilateral Stroke, including any death related to ipsilateral stroke, from 31-365 days (1 year).
CABERNET 1-Year Major Adverse Event Rates:
Pivotal Group: 4.5%†
- Death: 0.5%
- Stroke: 4.0%
- MI: 0.3%

†Patients may have had more than one event.

Primary Endpoint #2
0-365 days (1 year): all Death, all Stroke, all MI (Q and non-Q-wave).
Note: All D/S/MI means any death, stroke or MI that is related or NOT related to the target treated lesion/vessel. For example, if a patient died of cancer, their death was included in the final calculation.
1-Year Major Adverse Event Rates:
Pivotal Group: 11.5%*
- Death: 4.5%**
- Stroke: 5.0%
- MI: 4.0%

*11 patients experienced multiple events.
**No neurological deaths.

BEACH is a study sponsored by Boston Scientific Corporation.
CABERNET is a registry sponsored by Boston Scientific Corporation.

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