Predictable protection made easy

With its advanced technology designed for simplicity and effectiveness, the FilterWire EZ Embolic Protection System is designed to deliver efficient, predictable protection.

Ease of Use

Captures Debris Efficiently

- Uniform 110-micron-pore filter is designed to permit continuous blood flow while maintaining embolic capture efficiency
- Suspended nitinol filter loop is intended to provide 360° apposition in straight or tortuous anatomy
- Radiopaque loop allows full deployment verification with one angiographic view

Easy to Deliver and Retrieve

- Pre-loaded rapid-exchange protection wire with peel-away delivery sheath is intended to simplify device preparation
- Highly flexible system is designed to provide excellent tracking through tortuous anatomy
- 3.2F crossing profile, tapered nosecone and silicone-coated tip are designed to facilitate lesion crossing
- Retrieval sheath is designed to maximize filter coverage while withdrawing through a deployed stent

Simplifies Filter Sizing

- One size is intended to provide protection in vessels with 3.5mm to 5.5mm diameter landing zone

Clinical Efficacy

Clinically Proven Technology

- The BEACH Trial results demonstrate safety and efficacy of the FilterWire EZ System with the Carotid WALLSTENT® Monorail® Endoprosthesis
- Death, stroke and MI rate at 30 days was 5.6% (27/478) **

BEACH Trial†
Ipsilateral Stroke Rate at 30 Days (N=478)

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<tr>
<th>Pivotal Group</th>
<th>Ipsilateral Stroke</th>
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†See BEACH Trial Design and Primary Endpoint data on reverse side.

*Angiographic image provided courtesy of Jim Stewart, MD. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

**Peri-procedural Morbidity and Mortality: Non-Q-wave MI through 24 hours post-procedure and death, stroke and Q-wave MI through 30 days post-procedure.
FilterWire EZ™ Embolic Protection System

**Indications**

Primary Endpoint: 1-year morbidity and mortality defined as the cumulative incidence of the following:
- Non-Q-wave MI: 0.2%
- Late Neurological Death: 1.6%
- Stroke: 4.5%
- Late Stroke/Stroke: 2.5%

**Adverse Events**

- **Thromboembolic Events**
  - Embolic occlusion or embolization
  - Peri-procedural death

- **Infectious Events**
  - Infection

- **Hypotension**
  - Hypotension

- **Life-Threatening Reactions**
  - Life-threatening reaction

- **Deaths**
  - Death

**Contraindications**

- **Allergy to Heparin**
- **Patients with severe allergy to heparin**

**Warnings**

- **Filter wire entanglement or damage**
- **Filter migration**
- **Filter embolization**
- **Distal wire erosion**
- **Undetected embolization**
- **Macroembolization**

**Precautions**

- **MRI**
  - Non-clinical testing has not been performed to rule out the possibility of filter movement or migration.

**Instructions for Use**

- **FilterWire EZ™ Embolic Protection System**
- **FilterWire EZ™ Embolic Protection System (FilterWire EZ™ Embolic Protection System)**

**References**

- **AddWire™ Extension Wire**
  - Five-pack order code H74 92215 0-012
  - C-code used for this product is C1884

**Clinical Studies**

- **Cerebrovascular**
  - N=189, Bilateral Group N=78, Pivotal Group N=480 (symptomatic ≥50% stenosis N=112; asymptomatic ≥80% stenosis N=385; 47 U.S. clinicalsites)

**Contact Information**

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**To order product or for more information, contact customer service at 1.888.272.1001.**

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