Pipeline™ Embolization Device

The power to redefine aneurysm treatment.
The Pipeline™ device redefines treatment for large or giant wide-necked aneurysms by reconstructing the parent artery and restoring its natural course.

The power to redefine aneurysm treatment.

Images courtesy of Henry Woo, MD
As the first approved flow diverter in the US market, the Pipeline device provides the power to achieve unparalleled long-term clinical success in the treatment of large or giant wide-necked aneurysms.

**Redefine: Aneurysm Treatment & Outcomes**

Reconstruct the parent artery and avoid intrasaccular manipulation

- Optimized radial force and flexibility
  - 48-strand braided mesh design for flexible conformability
  - 75% cobalt chromium/25% platinum tungsten for radial force and uniform radiopacity
- Braided mesh design creates scaffolding for endothelial repavement
- Ability to telescope multiple devices for variable degrees of surface coverage or to create longer constructs

Remodel the vessel while keeping perforators open

- Optimized flow diversion
  - 30-35% surface coverage at nominal diameter
- Perforators stay open

Image from preclinical study. Scanning electron microscopy (SEM) of rabbit vertebral artery shows that the aneurysmal neck was completely occluded with neointima. The lumbar arteries, vertebral artery, and other branches were all patent.
Clinical Results

The Pipeline™ device is the most effective long-term solution for treatment of large or giant wide-necked aneurysms.

Complete and Durable Occlusion
Large ophthalmic aneurysm treated with the Pipeline device.

Long-Term Follow-Up
Large ophthalmic aneurysm treated with the Pipeline device.

Images courtesy of Henry Woo, MD
Images courtesy of Tibor Becske, MD and Peter Kim Nelson, MD
Images courtesy of Henry Woo, MD
The PUFs trial proved the safety and efficacy of the Pipeline™ device for treatment of large or giant wide-necked aneurysms.²

**ANEURYSM CHARACTERISTICS**
The study was comprised of challenging aneurysms that are difficult to treat successfully with traditional treatments.³,⁴

- Large or giant wide-necked aneurysms
- Saccular or fusiform
- Petrous to superior hypophyseal ICA

0% rate of recurrence for completely occluded aneurysms during trial.²

<table>
<thead>
<tr>
<th>PRIMARY EFFICACY ENDPOINT²</th>
<th>SECONDARY EFFICACY ENDPOINT²</th>
<th>PRIMARY SAFETY ENDPOINT²</th>
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<tbody>
<tr>
<td>180 days</td>
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<tr>
<td>73.6% = 78/106⁶</td>
<td>81.8% = 81/99⁹</td>
<td>5.6% = 6/107⁸</td>
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<tr>
<td>% of Aneurysms with Complete Occlusion without &gt;50% Stenosis or Alternative Treatment</td>
<td>% of Aneurysms with Complete Occlusion</td>
<td>% of Patients with Major Stroke or Neurologic Death at 180 Days</td>
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³ The study enrolled 110 aneurysms. Four were excluded because of wrong location/size or access not obtained. 106 aneurysms were included in the primary efficacy endpoint analysis. ⁴ Seven patients without 6-month angiographic follow-up were excluded from this analysis. ⁵ Eight additional patients without 1-year angiographic follow-up were excluded from this analysis. ⁶ Includes all patients with attempted treatment. 108 patients were enrolled. One patient was excluded from analysis because of an access failure. 107 patients were included in the primary safety endpoint analysis.
The Pipeline™ embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The Pipeline™ embolization device should be used by physicians who have received appropriate training for this device.

### CONTRAINDICATIONS:

The Pipeline™ embolization device is contraindicated for patients with any of the following conditions: 1) Patients with an active bacterial infection; 2) Patients in whom dual antiplatelet therapy (aspirin and clopidogrel) is contraindicated; 3) Patients who have not received dual antiplatelet agents prior to the procedure; or 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location. **WARNINGS:** 1) While advancing the Pipeline™ embolization device inside the microcatheter, do not pull back or torque the wire. This may make device release more difficult or impossible; 2) Do not rotate the delivery wire for more than 10 full turns. Over-rotation may cause delivery wire breakage. If the Pipeline™ embolization device inside the microcatheter, do not pull back or torque the wire. This may make device release more difficult or impossible; 2) Do not rotate the delivery wire for more than 10 full turns. Over-rotation may cause delivery wire breakage. If the Pipeline™ embolization device is not open after 10 turns, remove the entire system (microcatheter and Pipeline™ embolization device delivery system) simultaneously; 3) If the capture coil tip of the delivery system becomes stuck in the mesh of a delivered Pipeline™ embolization device, rotate the wire clockwise while advancing the wire to try to release it, then slowly pull back on the delivery wire; 4) Persons with known allergy to platinum or cobalt/chromium alloy (including the major elements Platinum, Cobalt, Chromium, Nickel or Molybdenum) may suffer an allergic reaction to the Pipeline™ embolization device. Images of devices are for illustrative purposes only and may vary from finalized sterile product.

### Indications for Use:

The Pipeline™ embolization device is indicated for the endovascular treatment of adults (22 years of age and older) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments. **CAUTION:** Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. **CONTRAINDICATIONS:** The use of the Pipeline™ embolization device is contraindicated for patients with any of the following conditions: 1) Patients with an active bacterial infection; 2) Patients in whom dual antiplatelet therapy (aspirin and clopidogrel) is contraindicated; 3) Patients who have not received dual antiplatelet agents prior to the procedure; or 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location.

**REFERENCES:**


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Results may vary. Not all patients receive the same results.

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