5 YEAR RESULTS

DESIGN
Multi-center, prospective, interventional, single-arm trial

OBJECTIVE
To evaluate the safety and effectiveness of the Pipeline™ implant in the treatment of complex intracranial aneurysms.

PRIMARY ENDPOINT
Efficacy: Index treatment success, defined as complete occlusion of target intracranial aneurysm at 180-day angiography in the absence of major stenosis.
PRE-SET TARGET RATE: >50%

Safety: Occurrence of ipsilateral major stroke or neurologic death by 180 days.
PRE-SET TARGET RATE: <20%

POPULATION & SAMPLE SIZE
108 patients with a wide-necked, large, or giant intracranial aneurysm in the petrous, cavernous, or paraophthalmic regions of the internal carotid artery.

SITES
10 centers worldwide

OCCLUSION AT 5 YEARS FOLLOW-UP

95% NEUROLOGIC COMPLICATIONS RESULTING IN PERMANENT MORBIDITY OR MORTALITY FROM 6 MONTHS TO 5 YEARS

0% RECURRENCE OF ANEURYSMS AFTER COMPLETE OCCLUSION

PUFS TRIAL FOLLOW-UP

(Pipeline™ Embolization Device for Uncoilable or Failed Aneurysms)

Medtronic
### THE PIPELINE™ EMBOLIZATION DEVICE IS SAFE AND HIGHLY EFFECTIVE

**Angiographic Complete Occlusion Rates**

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<thead>
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<th>180 days</th>
<th>1 year</th>
<th>3 years</th>
<th>5 Years</th>
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<tr>
<td>73.6%</td>
<td>86.8%</td>
<td>93.4%</td>
<td>95.2%</td>
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**Major Ipsilateral Stroke or Neurological Death**

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<tr>
<th></th>
<th>180 days</th>
<th>1 year</th>
<th>3 years</th>
<th>5 Years</th>
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</thead>
<tbody>
<tr>
<td>5.6%</td>
<td>0.0%</td>
<td>0.0%</td>
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**Essential Prescribing Information (EPI) Statement:**

The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. **Indications for Use:** The Pipeline™ Flex embolization device is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) 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. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. **Warnings:** 1) Resheathing of the Pipeline™ Flex embolization device more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 2) Persons with known allergy to platinum or cobalt/chromium alloy (including the major elements platinum, cobalt, chromium, nickel, molybdenum or tungsten) may suffer an allergic reaction to the Pipeline™ Flex embolization device implant. 3) Person with known allergy to tin, silver, stainless steel or nickel/cobalt alloy may suffer an allergic reaction to the Pipeline™ Flex embolization device delivery system. 4) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance. 5) Delayed rupture may occur with large and giant aneurysms. 6) Placement of multiple Pipeline™ Flex embolization devices may increase the risk of ischemic complications. Precautions: 1) Do not use if the sterile package is damaged. 2) Do not use the Pipeline™ Flex embolization device in patients in whom angiography demonstrates inappropriate anatomy, such as severe pre or post-aneurysmal narrowing. 3) The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. 4) Physicians should undergo appropriate training prior to using the Pipeline™ Flex embolization device in patients. 5) The Pipeline™ Flex embolization device is provided sterile for single use only. Store in a cool, dry place. 6) Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. Do not use kinked or damaged components. 7) Use the Pipeline™ Flex embolization device implant prior to the “Use By” date printed on the package. 8) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. A thrombosing aneurysm may aggravate pre-existing, or cause new symptoms of mass effect and may require medical therapy. 9) Do not attempt to reposition after deployment. 10) Do not use in patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as severe intracranial vessel tortuosity or stenosis. 11) Do not use in patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as severe intracranial vessel tortuosity or stenosis. 12) Use of implants with labeled diameter larger than the parent vessel diameter may result in decreased effectiveness and additional safety risk due to incomplete foreshortening resulting in an implant longer than anticipated. Potential Complications: Potential complications, some of which could be fatal, include, but are not limited to the following: Adverse reaction to anti-platelet/anticoagulation agents or contrast media, Blindness, Coma, Device fracture, Device migration or misplacement, Dissection of the parent artery, Embolism, Graft failure, Headache, Hemorrhage, Hydrocephalus, Infection, Intracerebral bleeding, Ischemia, Mass effect, Neurological deficits, Parent Artery Stenosis, Perforation, Perforator occlusion, Postprocedure bleeding, Ruptured or perforated aneurysm, Seizure, Stroke, Thromboembolism, Transient Ischemic Attack (TIA), Vasospasm, Vessel occlusion, Vessel perforation, Vision impairment. Contraindications: The use of the Pipeline™ Flex embolization device is contraindicated for patients with any of the following conditions: 1) Patients with 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. 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location.