Introducing a New Treatment Method for Brain Aneurysms

Pipeline® Embolization Device

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

This 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 the appropriate training for this device.

**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. **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 does 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.

Plavix is a trademark of Sanofi.
What is a brain aneurysm?

- An aneurysm is an outpouching in an artery caused by weakness in the vessel wall.
- As the aneurysm grows, it may cause neurologic symptoms such as headaches, vision loss, etc.
- Untreated cerebral aneurysms may rupture, resulting in hemorrhagic stroke.
- Hemorrhagic stroke has potentially devastating consequences including:
  - Severe functional disability
  - Cognitive loss
  - Death

What are the different types of aneurysms?

- Aneurysms can be classified by size:
  - Small aneurysms are less than 10 mm in diameter
  - Large aneurysms are 10-25 mm in diameter
  - Giant aneurysms are greater than 25 mm in diameter

- Aneurysms can also be classified by shape:
  - Saccular
  - Wide-Necked
  - Fusiform
What are traditional treatment methods for aneurysms?

**TRADITIONAL TREATMENT METHODS INCLUDE:**

— **Parent Artery Deconstruction:**
  - Permanently removing or destroying the artery from which the aneurysm originates.

— **Surgical Clipping:**
  - Surgical procedure requiring an opening of the skull.
  - Placement of a clip on the neck of the aneurysm to prevent blood flow into aneurysm.

— **Endovascular Embolization:**
  - Minimally invasive approach through a small incision in the leg.
  - Placement of embolic coils or liquids into aneurysm to prevent blood flow into aneurysm.

**The Pipeline® Embolization Device is a new treatment option for large or giant aneurysms with wide necks.**

— Pipeline® Embolization Device is the first and only flow diversion device approved by the FDA

— The Pipeline Device received FDA approval in April of 2011 after completing a clinical trial called PUFs (Pipeline for Uncollable or Failed Aneurysms)

— The Pipeline Device has been used to treat patients in Europe since 2009

— During the procedure, the Pipeline Device (a braided cylindrical mesh device) is implanted across the aneurysm neck and allows for healing of the diseased vessel

— The Pipeline Device can be used by itself to treat aneurysms

**benefits**

- The Pipeline Device has been shown to be effective at treating large, giant and wide-necked aneurysms in the internal carotid artery.

- The Pipeline Device is a relatively new technology compared to traditional treatment methods.

**risks**

- Medications like aspirin and Plavix™ are required before and after treatment as instructed by your doctor.

- 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.

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*L as outlined in PUFs trial results.

**Discuss all risks with your doctor.**

— Large, giant and wide-necked aneurysms can be challenging to treat with traditional methods

  - Long-term care of these aneurysms can be difficult.
What can I expect before, during and after my procedure?

**PRE-PROCEDURE EXAMS:**

- You will undergo a series of exams and diagnostic procedures to fully assess the size, shape and location of your aneurysm. Exams and procedures generally include the following:

  - Medical history review
  - Physical examination
  - Blood tests
  - Neurological examination
  - Imaging (CT, MRI)
  - Angiography

**PRE-PROCEDURE MEDICATIONS:**

- Your doctor may require you to prepare for the procedure for a few days in advance.

  - Preparation may include taking aspirin and other medications several days before the procedure. Additional medications may be prescribed by your doctor depending on your general health and other medications you are taking.

**DURING THE PROCEDURE:**

- The procedure may be done under local or general anesthesia. Because patients must remain still for long periods of time, general anesthesia is usually preferred. Your doctor will determine the best and safest method for treating your aneurysm.

- The Pipeline procedure time includes accessing the aneurysm location and placing the Pipeline Device in the vessel. The entire procedure may only take an hour, but 2-3 hours is not uncommon.

**AFTER THE PROCEDURE:**

- After the procedure is complete, you will be moved to a recovery room.

- You will likely experience some pain and tenderness in the groin area where the micro catheter was inserted into your blood vessel.

- You will be required to take medications (such as aspirin and Plavix™) after the procedure. Your doctor will provide you with specific instructions.

  - It is very important for your safety to carefully follow the directions and medications prescribed by your doctor.

- You will be provided with an MRI card that explains how the Pipeline Device will behave under different medical scans.

  - Please keep this card with you at all times.

- Please contact your doctor for more information.