

PIPELINE™ FLEX EMBOLIZATION DEVICE

| Diameter (mm) | Length (mm) | Reference Number | Diameter (mm) | Length (mm) | Reference Number | Diameter (mm) | Length (mm) | Reference Number |
|---------------|-------------|------------------|---------------|-------------|------------------|---------------|-------------|------------------|
| 2.5           | 10          | PED-250-10       | 3.5           | 10          | PED-350-10       | 4.5           | 10          | PED-450-10       |
| 2.5           | 12          | PED-250-12       | 3.5           | 12          | PED-350-12       | 4.5           | 12          | PED-450-12       |
| 2.5           | 14          | PED-250-14       | 3.5           | 14          | PED-350-14       | 4.5           | 14          | PED-450-14       |
| 2.5           | 16          | PED-250-16       | 3.5           | 16          | PED-350-16       | 4.5           | 16          | PED-450-16       |
| 2.5           | 18          | PED-250-18       | 3.5           | 18          | PED-350-18       | 4.5           | 18          | PED-450-18       |
| 2.5           | 20          | PED-250-20       | 3.5           | 20          | PED-350-20       | 4.5           | 18          | PED-450-18       |
|               |             |                  | 3.5           | 25          | PED-350-25       | 4.5           | 20          | PED-450-20       |
|               |             |                  | 3.5           | 30          | PED-350-30       | 4.5           | 25          | PED-450-25       |
|               |             |                  | 3.5           | 35          | PED-350-35       | 4.5           | 25          | PED-450-25       |
| 2.75          | 10          | PED-275-10       |               |             |                  | 4.5           | 30          | PED-450-30       |
| 2.75          | 12          | PED-275-12       | 3.75          | 10          | PED-375-10       | 4.5           | 35          | PED-450-35       |
| 2.75          | 14          | PED-275-14       | 3.75          | 12          | PED-375-12       |               |             |                  |
| 2.75          | 16          | PED-275-16       | 3.75          | 14          | PED-375-14       | 4.75          | 10          | PED-475-10       |
| 2.75          | 18          | PED-275-18       | 3.75          | 16          | PED-375-16       | 4.75          | 12          | PED-475-12       |
| 2.75          | 20          | PED-275-20       | 3.75          | 18          | PED-375-18       | 4.75          | 14          | PED-475-14       |
|               |             |                  | 3.75          | 20          | PED-375-20       | 4.75          | 16          | PED-475-16       |
| 3.0           | 10          | PED-300-10       | 3.75          | 25          | PED-375-25       | 4.75          | 18          | PED-475-18       |
| 3.0           | 12          | PED-300-12       | 3.75          | 30          | PED-375-30       | 4.75          | 20          | PED-475-20       |
| 3.0           | 14          | PED-300-14       | 3.75          | 35          | PED-375-35       | 4.75          | 25          | PED-475-25       |
| 3.0           | 16          | PED-300-16       |               |             |                  | 4.75          | 30          | PED-475-30       |
| 3.0           | 18          | PED-300-18       | 4.0           | 10          | PED-400-10       | 4.75          | 35          | PED-475-35       |
| 3.0           | 20          | PED-300-20       | 4.0           | 12          | PED-400-12       |               |             |                  |
| 3.0           | 25          | PED-300-25       | 4.0           | 14          | PED-400-14       | 5.0           | 10          | PED-500-10       |
| 3.0           | 30          | PED-300-30       | 4.0           | 16          | PED-400-16       | 5.0           | 12          | PED-500-12       |
| 3.0           | 35          | PED-300-35       | 4.0           | 18          | PED-400-18       | 5.0           | 14          | PED-500-14       |
|               |             |                  | 4.0           | 20          | PED-400-20       | 5.0           | 16          | PED-500-16       |
|               |             |                  | 4.0           | 25          | PED-400-25       | 5.0           | 18          | PED-500-18       |
|               |             |                  | 4.0           | 30          | PED-400-30       | 5.0           | 20          | PED-500-20       |
|               |             |                  | 4.0           | 35          | PED-400-35       | 5.0           | 25          | PED-500-25       |
| 3.25          | 10          | PED-325-10       |               |             |                  | 5.0           | 30          | PED-500-30       |
| 3.25          | 12          | PED-325-12       | 4.25          | 10          | PED-425-10       | 5.0           | 35          | PED-500-35       |
| 3.25          | 14          | PED-325-14       | 4.25          | 12          | PED-425-12       |               |             |                  |
| 3.25          | 16          | PED-325-16       | 4.25          | 14          | PED-425-14       |               |             |                  |
| 3.25          | 18          | PED-325-18       | 4.25          | 16          | PED-425-16       |               |             |                  |
| 3.25          | 20          | PED-325-20       | 4.25          | 18          | PED-425-18       |               |             |                  |
| 3.25          | 25          | PED-325-25       | 4.25          | 20          | PED-425-20       |               |             |                  |
| 3.25          | 30          | PED-325-30       | 4.25          | 25          | PED-425-25       |               |             |                  |
| 3.25          | 35          | PED-325-35       | 4.25          | 30          | PED-425-30       |               |             |                  |
|               |             |                  | 4.25          | 35          | PED-425-35       |               |             |                  |

**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 silicone elastomer 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 product 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 system 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. 9) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 10) Do not attempt to reposition after deployment. 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, Groin injury, Headache, Hemorrhage, Hydrocephalus, Infection, Intracerebral bleeding, Ischemia, Mass effect, Neurological deficits, Parent Artery Stenosis, Perforation, Perforator occlusion, Post-procedure 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 anti-platelet 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.

† The PUFs study only included the Pipeline™ Embolization Device. The Pipeline™ Flex Embolization Device contains the same implant as the Pipeline™ Embolization Device.

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17. SA-00008-XX
18. Scientific Communication Document search (2018) showing clinical summaries. No other studies meet these criteria.



Pipeline™ Flex<sup>†</sup>  
Embolization Device

LEADING. LASTING.  
ALWAYS ADVANCING.

Medtronic





# LEADING.

## OUR COMMITMENT:

**As the leader in Flow Diversion** we are consistently committed to offering not only innovative technology, but also comprehensive support.

**With over 350 years of combined experience<sup>14</sup> supporting US flow diversion procedures** on our sales team, targeted physician education programs, and a dedicated Pipeline Specialist team we are your partners in treating patients with even the most challenging aneurysms.

**ALONG WITH YOU, MEDTRONIC IS READY TO LEAD THE FUTURE OF FLOW DIVERSION.**





# LASTING.

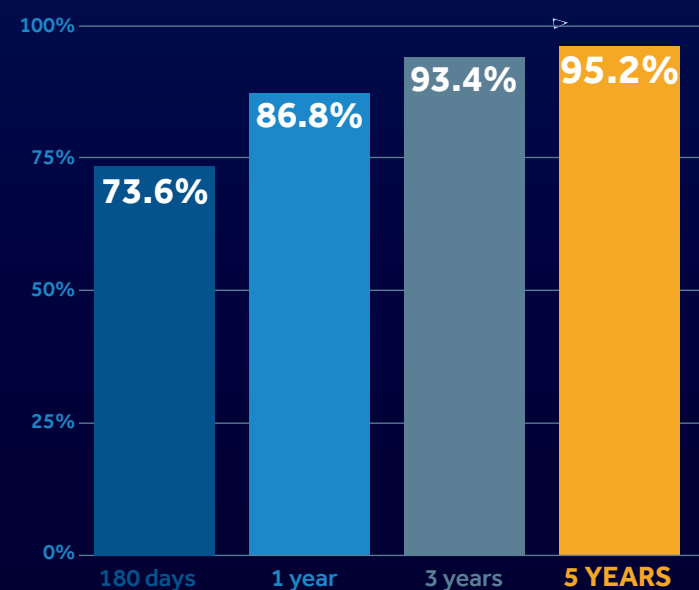
A LEGACY  
OF SUCCESS.  
A HISTORY  
OF PROOF.

**CLINICALLY PROVEN:**  
PUFs TRIAL 5 YEAR RESULTS

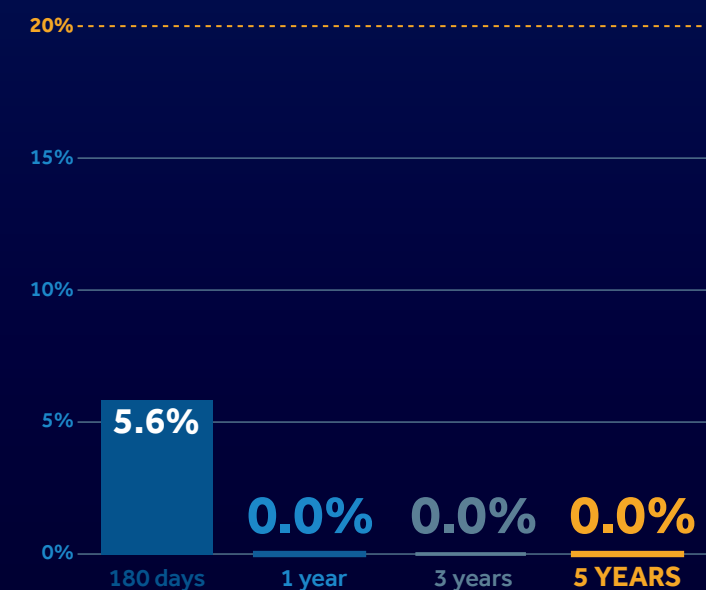
**0%**  
RECURRENCE

**95%**  
COMPLETE  
OCCLUSION

## PROGRESSIVE COMPLETE OCCLUSION<sup>6</sup>



## NO NEW MAJOR IPSILATERAL STROKE OR NEUROLOGICAL DEATH AFTER 6 MONTHS<sup>6</sup>



Pipeline™ is the most studied flow diverter worldwide with a proven safety and efficacy profile.<sup>16,18</sup>

**PUFs**<sup>1,6</sup>  
n=106

**ASPIRe**<sup>12</sup>  
n=191

**Buenos Aires Experience**<sup>7</sup>  
n=53

**PITA**<sup>8</sup>  
n=31

**Ankara Experience**<sup>9</sup>  
n=251

**Hong Kong Experience**<sup>10</sup>  
n=178

**Australian Registry**<sup>11</sup>  
n=57

\* These studies were conducted OUS and may not comply with the U.S. indication for use. See IFU for U.S. indication.

\*\* Studies listed may only include the Pipeline™ embolization device. The Pipeline™ Flex embolization device contains the same implant as the Pipeline™ embolization device.

Results may vary; all patients do not achieve the same outcomes.



# ALWAYS ADVANCING.

## INNOVATION: A FOCUS ON FLOW DIVERSION.

We are driven to continually advance the horizons of aneurysm treatment. Partner with us as we take flow diversion Further, Together.

### DELIVERY REDEFINED:

Our Pipeline™ Flex embolization device – with its **innovative delivery system** – exemplifies the meaningful innovations we pursue as we transform aneurysm care.

- **Fully resheathable**, allowing you to reposition and redeploy up to two times.<sup>4</sup>
- Redesigned distal tip – **30% softer** and 55° angle for better vessel deflection.<sup>5</sup>
- **PTFE Sleeves for instant braid release** and controlled distal landing zone.

### PROVEN BRAID DESIGN:

The **high-density, single-layer scaffold** offered by the Pipeline™ Flex embolization device **provides flow diversion from the neck and re-endothelialization** leading to 95% complete occlusion and 0% recurrence after complete occlusion at 5 years.<sup>1</sup>

- 48-strand braided mesh designed for flexible conformability.
- 75% cobalt chromium and 25% platinum tungsten for radial force and uniform radiopacity.<sup>17</sup>
- 30-35% surface coverage at nominal diameter.<sup>3</sup>

### ADVANCING ACCESS:

With an inner lumen **engineered to prevent ovalization** and deliver devices with **minimal friction**, Phenom™ catheter family offers an **.027 microcatheter** and the Phenom™ Plus **.045 support catheter** for Pipeline™ Flex procedures.<sup>13,15</sup>