ACCEPT NO SUBSTITUTE.

Pipeline™ Flex† Embolization Device
DEVELOPING THE THERAPY

Since 2011, we’ve been the leader in Flow Diversion – disrupting aneurysm treatment, advancing the practice, and raising the standard of care. Medtronic is consistently committed to innovative technology and comprehensive, collaborative support.

Our experienced, consultative field team is at the ready with support for your US flow diversion procedures and targeted physician education programs. With our time-tested technology and uncompromising service, we are your partner for treating your aneurysm patients.
SAFETY IN NUMBERS

The Pipeline™ Flex embolization device has a low wall profile that is consistent by design.21

Pipeline™ Flex provides reliable safety across multiple aneurysm types.1,6,20

TIME-TESTED EFFICACY

Pipeline™ Flex provides uniform cell coverage that is consistent by design.22

Pipeline™ Flex achieves reliable efficacy across multiple aneurysm types at 1 year20 and out to 5 years.1,6

PRIMARY SAFETY ENDPOINT results at 1 year

PREMIER20 2.1%

PUFs1,6 5.6%

PREMIER: The primary safety endpoint was incidence of major stroke (ischemic or hemorrhagic) in the territory supplied by the treated artery, defined as an increase in NIHSS score by 4 points or neurologic death within 1 year after treatment.

PUFs: The primary safety endpoint of the PUFs study was the incidence of major ipsilateral stroke (defined as an increase of 2-4 points on the National Institute of Health Stroke Scale and present after 7 days) as adjudicated by the Clinical Events Committee or neurological death within 180 days of PED placement.

TRUSTED POSITIONING

The design and material properties of the Pipeline™ Flex lead to uniform wall apposition.23

When delivered through the Phenom™ 27 catheter, specifically designed for flow diversion,24,25 system stability is optimized.24

PRIMARY EFFECTIVENESS ENDPOINT results at 1 year

PREMIER 76.8%

Long Term Complete Occlusion Rates

PUFs 95% at 5 yrs

0% Recurrence

PUFs: The primary effectiveness endpoint of the study was complete occlusion of the aneurysm without major (>50%) stenosis of the parent artery or adjunctive use of complimentary embolic agent as seen on 180-d angiography and judged by the independent CRL.

PREMIER: The primary effectiveness endpoint of the study was complete aneurysm occlusion of the target aneurysm without major stenosis (<50%) of the parent artery or retreatment of the target aneurysm at one-year post-procedure, as adjudicated by an independent Core Laboratory (Core Lab 1) or retreatment of the target IA one-year post-procedure.
Medtronic has joined forces with Sim&Cure to bring you a unique, preoperative planning software platform, enabling you to simulate and plan your Pipeline™ Flex procedures with a patient-specific surgical strategy.

With Sim&Size you can select the optimal size of device to fit each patient’s anatomy, improving device size selection, implant placement, proximal landing zone accuracy – and more – for a safe, efficient, more cost-effective treatment.

**SIZING:**
Automatic measurement according to each patient’s vessel characteristics.

**SIMULATION:**
3D patient specific simulations based on the angiographic medical images.

**DOCTORS:**
Assist doctors in choosing the appropriate patient specific sizing for optimal flow diversion.

**A POWERFUL PARTNERSHIP FOR PRECISION PLANNING**
INVESTING IN EVIDENCE-BASED MEDICINE

The Pipeline™ embolization device is the most studied flow diverter worldwide with a proven safety and efficacy profile. 16,18

PREMIER 20
n=141

IntrePED 26
n=793

ASPIRe 12
n=191

PUFs 1,6
n=107

Ankara Experience 9
n=191

PITA 8
n=31

Hong Kong Experience 10
n=143

Australian Registry 11
n=54

Buenos Aires Experience 7
n=53

OVER 1700 PATIENTS clinically evaluated with the Pipeline™ embolization device.

* 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.
## PIPELINE™ FLEX EMBOLIZATION DEVICE

### ESSENTIAL PRESCRIBING INFORMATION (EPI) STATEMENT: 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 intracranial aneurysms. It is intended to be used in conjunction with the Pipeline™ Embolization Device to occlude intracranial aneurysms and to treat patients with unruptured or ruptured intracranial aneurysms. The Pipeline™ Embolization Device is contraindicated for use in patients with known allergy to platinum or cobalt/chromium alloy. The Pipeline™ Embolization Device (MEDT-300) is intended for microcatheter use with the Pipeline™ Flex Embolization Device. 

### Warnings:

1. Redshirting 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 major alloying elements: cobalt, chromium, molybdenum or tungsten) may suffer an allergic reaction to the Pipeline™ Flex Embolization device.
3. Persons with known allergy to tin, silver, stainless steel or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex Embolization device.
4. Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of adverse events and/or death. Factors which may contribute to post procedural device movement include (but are not limited to) the following: Failure to adequately size the implant (i.e., under sizing), failure to obtain adequate wall apposition during the implant deployment, implant withdrawal, Severe vessel tapering. Tortuous anatomy. Delayed deployment may occur with large and giant aneurysms. Placement of multiple Pipeline™ Flex embolization devices may occlude treatment targets.
5. Use in microcatheters with a diameter of 3.75 mm or less increases the risk of intraarterial embolization and microcatheter damage. See the Pipeline™ Flex Embolization Device User Manual for complete indications for use.
6. The Pipeline™ Flex Embolization Device and microcatheter refer to page 4 in the instructions for use for additional information.
7. It is not appropriate to reposition the device after full deployment. The benefits of use may not outweigh the risks associated with the use of the Pipeline Embolization Device in patients.
8. The Pipeline™ Flex Embolization device is provided sterile for single use only. Store in a cool, dry place. Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. Do not use if the device is damaged or expired.
9. Use the Pipeline™ Flex Embolization Device under the direct supervision of a licensed physician. Only by physicians trained in endovascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment.
10. Physicians should undergo appropriate training prior to using the Pipeline™ Flex embolization device in patients.

### Potential Complications:

- **Interpersonal Conflict:** Potential complications of the device and/or endovascular procedure include, but are not limited to the following:
  - Adverse reactions to anti-platelet/anticoagulation agents, anesthesia, reactions due to radiation exposure (such as alopecia, burns ranging in severity from skin irritation to severe burns).
  - Disrupting anaphylaxis in patients with a known allergy to iodinated contrast media.
  - Thromboembolic complications including ischemic stroke (unintended territory).
  - Device complications like fracture, breakage, placement, migration or delayed reformation to or reaction to device materials.
  - Systemic Complications like infection, <br>Fig. 4: A single case report of an arteriovenous malformation resection associated with an embolization accident.  
  - Contraindications include, but are not limited to, allergic reaction to any components of the embolization device.
  - Complication associated with various medical conditions such as tumors, inflammation, tissue necrosis, and death.
  - Aspirin use can increase the risk of serious complications, such as stroke and death.

### Table: Pipeline™ Flex Embolization Device Specifications

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