Medtronic
Neurovascular

Brain aneurysm treatment with flow diversion

FLOW DIVERSION

A minimally invasive treatment option for certain brain aneurysms using the Pipeline™ Embolization Device Family.

Please talk to your doctor about your treatment options.

About the condition

Types of brain aneurysms

The types of brain aneurysms can be classified by both size and shape.[3]

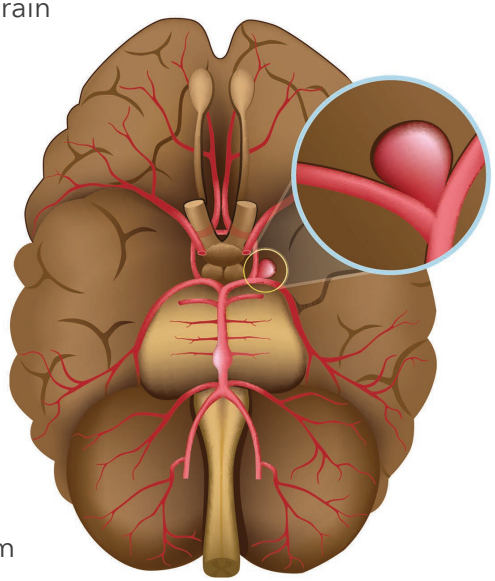
Aneurysm size classifications:			
Small	<7 mm in diameter	Large	13-25 mm in diameter
Medium	7-12 mm in diameter	Giant	>25 mm in diameter

What is a brain aneurysm?

A cerebral or brain aneurysm is a bulge or ballooning in an artery in the brain caused by weakness in the blood vessel wall.[1]

Untreated brain aneurysms may have risk of rupture, resulting in what's called hemorrhagic or cerebral stroke. The annual rate of rupture is approximately 8-10 per 100,000 people, or about 30,000 people in the United States.[2]

It is slightly more common in women than men, especially those who are in their late 40s to mid-50s. However, an aneurysm may occur at any age.[2]

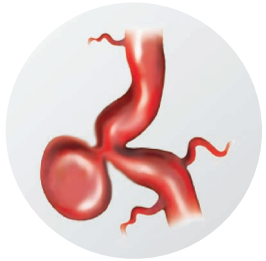


Brain aneurysms are more common than you may think. **An estimated 1 in 50 people has a brain aneurysm.**[2]

Shape classifications:

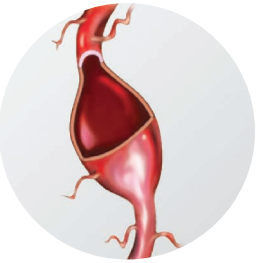
Saccular Aneurysm

Also known as "berry" aneurysms due to their round, sac-like shape, saccular aneurysms are the most common type, accounting for 80-90% of cases.[1]



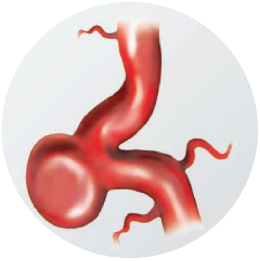
Fusiform Aneurysm

This aneurysm resembles an engorged blood vessel and can extend several centimeters in length.[1]



Wide-Necked Aneurysm

A saccular aneurysm with a neck 4 millimeters wide, or twice as wide as the aneurysm is tall, is known as a wide-necked aneurysm.[4]



Most common signs and symptoms of ruptured aneurysms[5]

Sensitivity to light

Stiff neck

The worst headache of your life

Pain behind one eye

Dizziness, blurry vision

In cases of small and unchanging brain aneurysms, there can be no symptoms. However, as an aneurysm grows larger, it can put pressure on surrounding tissues and nerves, causing neurologic symptoms sometimes called mass effect.[5]

Symptoms of unruptured aneurysm include, but not limited to[5]:

- Blurred or double vision
- A dilated pupil
- Pain above and behind one eye
- Weakness/numbness on one side of the face
- Change in headache pattern

If not treated, a brain aneurysm can continue to expand and eventually rupture.

Be sure to talk to your doctor about your symptoms and to learn more about aneurysms.

Are you at risk?

A brain aneurysm can result from a congenital defect, some inherited diseases, or other degenerative conditions, such as hypertension (high blood pressure) or athero-sclerosis (fat build-up inside the arteries, often leading to heart attack or stroke). Other risk factors include cigarette smoking, cocaine use, blood vessel wall infection, and head trauma.[6]

Brain aneurysm treatment options

Endovascular flow diversion:

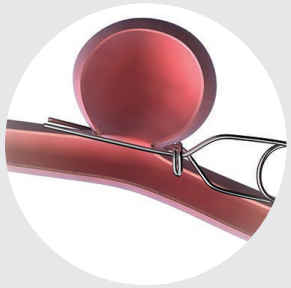
Endovascular flow diversion is a minimally invasive treatment in which a device known as a neurovascular stent is placed in the parent blood vessel of a brain aneurysm to divert blood flow away from the aneurysm. Over time, blood flow into the aneurysm may slow down, eventually ceasing to enter the aneurysm altogether. As the body's natural healing process works with the flow diversion stent, the blood vessel may heal, and the aneurysm may shrink or even disappear over time.[7]

Flow diversion with the Pipeline™ Embolization Device Family:

The Pipeline™ Embolization Device Family is designed to divert blood flow away from brain aneurysms in certain segments of the internal carotid artery (ICA). The device features a braided cylindrical mesh tube that is implanted across the base or neck of the aneurysm. The device decreases blood flow to the aneurysm, reconstructing the diseased section of the parent vessel. This may result in the aneurysm shrinking in size or resolving over time. Pipeline™ was the first flow diversion device approved by the FDA in 2011.[8,9]

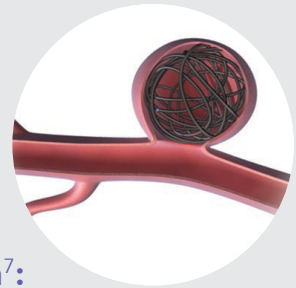
Traditional treatment options:

Other treatment methods for brain aneurysms include: observation, surgical clipping, and endovascular coiling.[7]



Invasive surgical clipping[7]:

- Surgical procedure requiring an opening of the skull or a craniotomy.
- Placement of a clip on the neck of the aneurysm to prevent blood flow into the aneurysm.



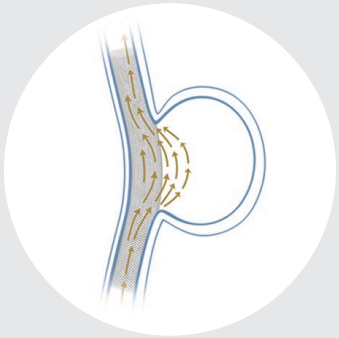
Endovascular coil embolization[7]:

- Minimally invasive approach through a small incision in the leg.
- Placement of embolic coils into aneurysm to prevent blood flow into aneurysm.

Flow diversion process[10]

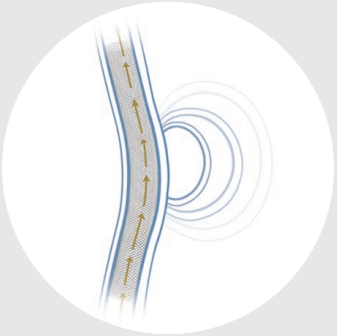
Before flow diversion

Blood flows freely into the aneurysm.



Flow diversion technique

After treatment with the Pipeline™ device, blood flow into the aneurysm slows. Over time, blood may no longer flow into the aneurysm.



After flow diversion

As the body's natural healing process works with the Pipeline™ stent implant, the aneurysm may shrink.

Benefits and risks

The Pipeline™ Embolization Device Family has been shown to be **effective at treating small, medium, large or giant wide-necked intracranial aneurysms**, located in specific segments of the internal carotid artery (ICA).† [4, 11]

Potential complications include but are not limited to:[8]

- Death
- Transient and permanent neurological deficits including stroke and transient ischemic attack (TIA), intra- and extra-cranial bleeding
- Vascular injuries including vasospasms and perforation
- Device deformation, fracture, and migration
- Complications of using contrast media and anticoagulant, antiplatelet medications
- Infections

Talk to your doctor about the potential risks and benefits of various treatment options. Refer to the Instructions for Use for complete potential complications.

Scan the QR codes to access the Instructions for Use (IFU):

Pipeline™ Shield Embolization Device with Shield Technology™ IFU

Pipeline™ Vantage Embolization Device with Shield Technology™ IFU

† As outlined in PUFs and PREMIER trial results.

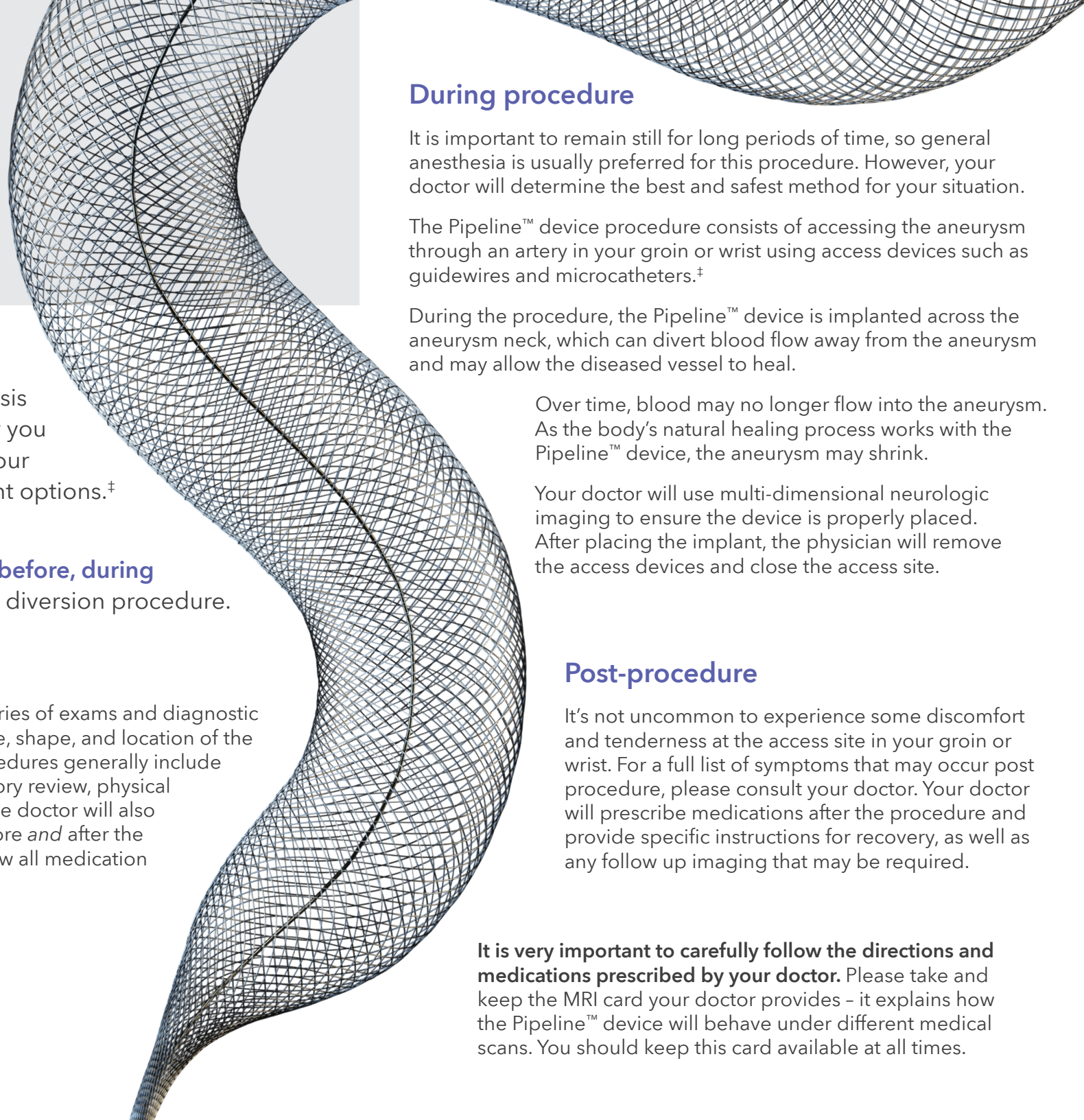
Complete occlusion for small + medium aneurysms, **over 81.9% of patients treated with a Pipeline™ device experienced complete aneurysm occlusion** with no recurrence by one-year follow-up.[11]

95% occlusion for large + giant aneurysms and **0% recurrence** of aneurysms after complete occlusion by 5-year follow-up, for subjects with available imaging.[4]

What is the Pipeline™ flow diversion procedure like?[1,2]

While your doctor is your primary resource for diagnosis and care, this page will offer you a better understanding of your condition and your treatment options.‡

Here's what you can expect **before, during and after** the aneurysm flow diversion procedure.



Pre-procedure

First, the doctor will perform a series of exams and diagnostic procedures to fully assess the size, shape, and location of the brain aneurysm. Exams and procedures generally include diagnostic imaging, medical history review, physical examination, and blood tests‡. The doctor will also prescribe some medications before *and* after the procedure. It is important to follow all medication instructions given by the doctor.

During procedure

It is important to remain still for long periods of time, so general anesthesia is usually preferred for this procedure. However, your doctor will determine the best and safest method for your situation.

The Pipeline™ device procedure consists of accessing the aneurysm through an artery in your groin or wrist using access devices such as guidewires and microcatheters.‡

During the procedure, the Pipeline™ device is implanted across the aneurysm neck, which can divert blood flow away from the aneurysm and may allow the diseased vessel to heal.

Over time, blood may no longer flow into the aneurysm. As the body's natural healing process works with the Pipeline™ device, the aneurysm may shrink.

Your doctor will use multi-dimensional neurologic imaging to ensure the device is properly placed. After placing the implant, the physician will remove the access devices and close the access site.

Post-procedure

It's not uncommon to experience some discomfort and tenderness at the access site in your groin or wrist. For a full list of symptoms that may occur post procedure, please consult your doctor. Your doctor will prescribe medications after the procedure and provide specific instructions for recovery, as well as any follow up imaging that may be required.

It is very important to carefully follow the directions and medications prescribed by your doctor. Please take and keep the MRI card your doctor provides – it explains how the Pipeline™ device will behave under different medical scans. You should keep this card available at all times.

‡ Please discuss all risks and warnings with your doctor.

Pipeline™ Vantage Embolization Device with Shield Technology™ essential prescribing information (EPI) statement

CAUTION: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.This device should be used only by physicians with a thorough understanding of angiography and/or percutaneous neurointerventional procedures. **Indications for Use:** The Pipeline™ Vantage Embolization Device with Shield Technology™ 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. The Pipeline™ Vantage Embolization Device with Shield Technology™ is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm. **Contraindications:** 1) Patients with active bacterial infection. 2) Patients in whom dual antiplatelet and/or anticoagulation therapy (aspirin and clopidogrel) is contraindicated. 3) Patients who have not received 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. 5) Patients in whom the parent vessel size does not fall within the indicated range. **Warnings:** 1) Pre-deploying the distal end of the device prior to introduction into the micro catheter may cause damage to the distal end of the braid. 2) Pushing delivery wire without retracting the micro catheter at the same time will cause the open-end of the braid to move distally in the vessel. This may cause damage to the braid or vessel. 3) Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Vantage device and can lead to damage to the Pipeline™ Vantage device and micro catheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by: • Unloading the micro catheter to the inner curves of vessel by pulling back on the system (i.e., the micro catheter and delivery wire together). • Continue unloading the system until advancement of the device (inside of micro catheter) is observed, while minimizing the distal tip movement to prevent loss of position. • Begin to re-advance the delivery wire while maintaining reduced load in the micro catheter. This process should be repeated until the device passes through tortuous area and the delivery force is decreased. 4) Following distal deployment and device anchoring: • Avoid stretching and/or creating tension in the implant before unsheathing the proximal end. • Avoid deploying the implant if kinking or twisting is observed. Fully deploying the device under the conditions above may lead to poor wall apposition, unanticipated device foreshortening, device migration, thromboembolic risk, and impaired aneurysm occlusion. Device kinking, twisting, or stretching may be resolved with appropriate positioning of the micro catheter or by resheathing the entire implant and repeating distal deployment, adjusting the technique combination of unsheathing the implant and pushing the delivery wire. If it cannot be resolved, consider replacing the device. 5) Avoid deploying the implant if kinking or twisting is observed. 6) Avoid deploying the implant if kinking or twisting is observed. 7) Incomplete wall apposition can result in unanticipated device foreshortening, device migration, and/ or device deformation which can lead to thromboembolic risks, elevated neointimal hyperplasia formation and/or reduced intracranial aneurysm occlusion. 8) Resheathing the Pipeline™ Vantage device more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 9) Resheathing the Pipeline™ Vantage device past the distal marker of the delivery system may cause damage to the distal end of the braid. 10) Malapposition to the vessel wall at the proximal end of the implant may lead to stenosis, stroke or death. 11) 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™ Vantage Embolization Device with Shield Technology™ implant. 12) Person with known allergy to platinum alloy (including major elements platinum, tungsten, iridium), tin, silver, stainless steel or silicone elastomer may suffer an allergic reaction to the Pipeline™ Vantage Embolization Device with Shield Technology™ delivery system. 13) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance 14) Post-procedural movement (migration and/or foreshortening) of the Pipeline™ Vantage Embolization Device with Shield Technology™ implant may occur following implantation and can result in serious adverse events and/or death. 15) 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 stretching • Vasospasm • Severe vessel tapering • Tortuous anatomy 16) Delayed rupture may occur with large and giant aneurysms. 17) Placement of multiple Pipeline™ Vantage Embolization Device with Shield Technology™ may increase the risk of ischemic complications 18) Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Vantage Embolization Device with Shield Technology™ and can lead to damage to the Pipeline™ Vantage Embolization Device with Shield Technology™ and micro catheter. Advancement or retraction of the Pipeline™ Vantage Embolization Device with Shield Technology™ against resistance may result in damage, including unintended device or component separation, fracture, or breakage of the delivery system due to inherent flexibility limits of device design. Device damage may result in patient injury or death. Refer to page 4 in the Instructions for Use for additional information. 19) Do not attempt to reposition the device after full deployment. 20) The benefits may not outweigh the risks of treatment of small and medium asymptomatic extradural intracranial aneurysms, including those located in the cavernous internal carotid artery. The risk of rupture for small and medium asymptomatic extradural intracranial aneurysms is very low if not negligible. 21) A decrease in the proportion of patients who achieve complete aneurysm occlusion without significant parent artery stenosis has been observed with the use of the device in the communicating segment (C7) of the internal carotid artery (47.4% (9/19 subjects in the PREMIER study at 1 year)), including those IAs fed by the posterior circulation or have retrograde filling. Ensure appropriate patient selection and weigh the benefits and risks of alternative treatments prior to use of this device for the treatment of intracranial aneurysms located in this region of the ICA. The following anatomical characteristics, associated with retrograde filling, should be carefully considered during procedural planning of C7 intracranial aneurysms: 1. PComm of fetal origin (A PCA of fetal origin is defined as a small, hypoplastic, or absent P1 segment of the PCA with the PComm artery supplying a majority of blood flow to the ICA); 2. PComm overlapping with the aneurysm neck; and/or 3. PComm branch arising from the dome of the aneurysm. 22) Pipeline™ Vantage Embolization Device with Shield Technology™ has not been tested for radial artery access. Radial artery access should only be used when femoral artery access is not feasible. 23) For additional Materials of Concerns information such as CA Prop 65 or other product stewardship programs, go to www.medtronic.com/productstewardship.**Precautions:** 1) The Pipeline™ Vantage Embolization Device with Shield Technology™ should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. 2) Physicians should undergo appropriate training prior to using the Pipeline™ Vantage Embolization Device with Shield Technology™ in patients. 3) The Pipeline™ Vantage Embolization Device with Shield Technology™ is intended for single use only. Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. 4) Do not use kinked or damaged components. 5) Do not use product if the sterile package is damaged. 6) Use the Pipeline™ Vantage Embolization Device with Shield Technology™ system prior to the "Use-by date" printed on the package. 7) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 8) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 9) 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. 10)The Pipeline™ Vantage Embolization Device with Shield Technology™ may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment. 11) Take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible. 12) Carefully weigh the benefits of treatment vs. the risks associated with treatment using the device for each individual patient based on their medical health status and risks factors for intracranial aneurysm rupture during their expected life time such as age, medical comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits of device use may not outweigh the risks associated with the device in certain patients; therefore, judicious patient selection is recommended. • In the INSPIRE-A registry, there was an observation of increased braid deformity in female patients, especially in female patients less than 45 years of age 13) The safety and effectiveness of the device has not been established for treatment of fusiform IAs. 14)There may be a decrease in effectiveness and increase in safety events when the device is used in patients ≥ 60 years old. 15) The safety and effectiveness of the device has not been evaluated or demonstrated for ruptured aneurysms. **Potential Complications:** Potential complications of the device and the endovascular procedure include or are synonymous with, but may not be limited to the following: Access site complications such as hematoma, pain, retroperitoneal hemorrhage, skin discoloration, nerve damage, abscess, edema; Adverse reactions to antiplatelet/anticoagulation agents, contrast media, or anesthesia such as pain, hemorrhage, organ failure, aspiration, nausea; Cardiac complications such as arrhythmia, myocardial infarction; Compartmental complications such as brain edema, intracranial hypertension, mass effect, hydrocephalus; Complications of radiation exposure such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia; Device complications such as kink, stretching, device fracture, device migration, device misplacement, friction, foreign body in patient, premature deployment, inadequate deployment, premature detachment, non-detachment, braid deformation; Hematologic complications such as coagulopathy, thrombosis, hemolysis, intracranial hemorrhage; Neurological deficits or dysfunctions such as headache, seizures, coma, emotional changes, paresis, transient ischemic attack, stroke; Systemic complications such as fever, infection, inflammation, edema, shock, toxicity, hypersensitivity, allergic reaction, organ failure, hypotension, hypertension, pain; Decreased therapeutic response including need for target aneurysm treatment; Vascular complications such as dissection, perforation, rupture, ischemia, vasospasm, hyperplasia, stenosis, necrosis, granuloma, fistula, pseudoaneurysm, occlusion, thromboembolism, embolism including to unintended territory; Visual complications such as transient blindness, blindness, diplopia, reduced visual acuity/field, retinal artery occlusion, retinal ischemia, retinal infarction, scintillations, blurred vision, eye floaters; Death. *Consult instructions for use for other therapy devices and medications for additional potential complication information. If a serious incident related to the device occurs, contact your Medtronic representative and the competent authority in your respective country/region.

Pipeline™ Flex Embolization Device with Shield Technology™ essential prescribing information (EPI) statement

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The following anatomical characteristics, associated with retrograde filling, should be carefully considered during procedural planning of C7 intracranial aneurysms: PComm of fetal origin (A PCA of fetal origin is defined as a small, hypoplastic, or absent P1 segment of the PCA with the PComm artery supplying a majority of blood flow to the ICA); PComm overlapping with the aneurysm neck; and/or PComm branch arising from the dome of the aneurysm. 15) The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient. **Precautions:** 1) The Pipeline™ Flex Embolization Device with Shield Technology™ should be used only by physicians trained in percutaneous, intravascular techniques, and procedures at medical facilities with the appropriate fluoroscopy equipment. 2) Physicians should undergo appropriate training prior to using the Pipeline™ Flex Embolization Device with Shield Technology™ in patients. 3) The Pipeline™ Flex Embolization Device with Shield Technology™ is intended 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 kinked or damaged components. Do not use product if the sterile package is damaged. 4) Use the Pipeline™ Flex Embolization Device with Shield Technology™ system prior to the "Use By" date printed on the package. 5) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 6) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 7) 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. 8) The Pipeline™ Flex Embolization Device with Shield Technology™ may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment. 9) Take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible. 10) Carefully weigh the benefits of treatment vs. the risks associated with treatment using the device for each individual patient based on their medical health status and risks factors for intracranial aneurysm rupture during their expected life time such as age, medical comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits of device use may not outweigh the risks associated with the device in certain patients; therefore, judicious patient selection is recommended. 11) The safety and effectiveness of the device has not been established for treatment of fusiform IAs. 12) There may be a decrease in effectiveness and increase in safety events when the device is used in patients ≥ 60 years old. 13) The safety and effective-ness of the device has not been evaluated or demonstrated for ruptured aneurysms. 14) If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient. **Potential Complications:** Potential complications of the device and the endovascular procedure include, but are not limited to, the following: Access site complications like hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; Adverse reaction to anti-platelet/anticoagulation agents,anesthesia, reactions due to radiation exposure (such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts and delayed neoplasia) or contrast media, including organ failure; Vascular Complications like vasospasm, stenosis, dissection, perforation, rupture, fistula formation, pseudo aneurysm, occlusion, thromboembolic complications including ischemia (to unintended territory); Device complications like fracture, breakage (including unintended device or component separation), misplacement, migration/delayed foreshortening or reaction to device materials may occur; Systemic Complications like: Infection, Pain, fever, allergic reactions, organ failure, nerve damage; Bleeding/hemorrhagic complication including retroperitoneal hemorrhage; Neurological Deficits or dysfunctions including Stroke, Infarction, Loss of vision, Seizures, TIA, Headache, Cranial Nerve Palsies, Confusion, Coma, Hand Dysfunction; Decreased therapeutic response including need for target aneurysm retreatment; Risks associated with visual symptoms include Amaurosis Fugax/transient blindness, Blindness, Diplopia, Reduced visual acuity/field, Retinal artery occlusion, Retinal ischemia, Retinal infarction, Vision impairment including scintillations, blurred vision, eye floaters; Intracranial Hemorrhage (including from Aneurysm Rupture) Brain Edema, Hydrocephalus, Mass Effect; Death. **Complete indications, Contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.**

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