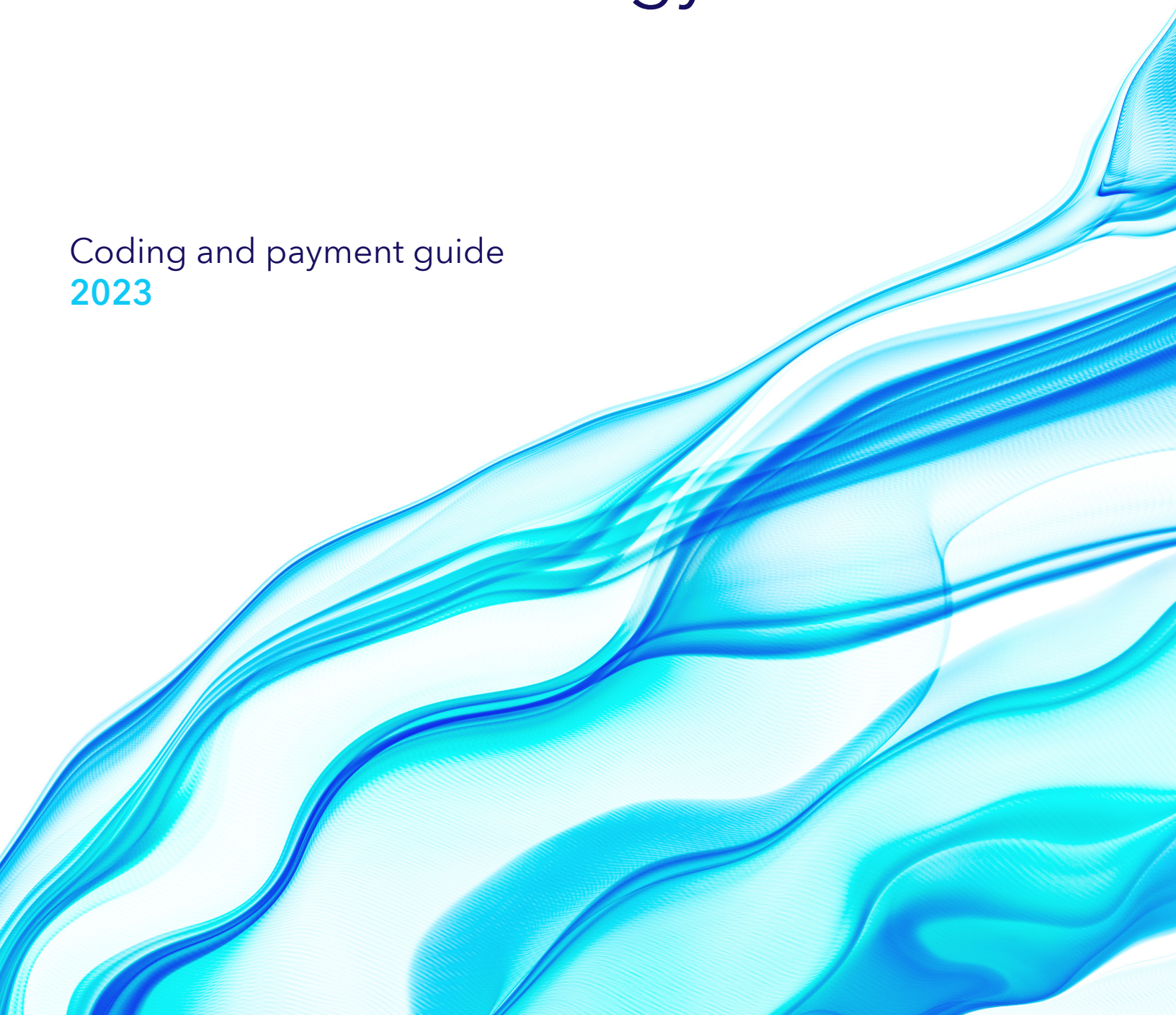
Medtronic

Pipeline™ flex embolization device with Shield Technology™

Coding and payment guide
2023



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For questions please contact medtronic at neuro.us.reimbursement@medtronic.com

ICD-10 codes

ICD-10-PCS procedure codes[1]

ICD-10-PCS procedure codes are used by hospitals to report surgeries and procedures performed in the inpatient setting.

ICD-10-PCS code	Code description
Pipeline™ flex embolization device procedure[2,3]	
03VG3HZ	Restriction of intracranial artery with intraluminal device, flow diverter, percutaneous approach
Cerebral Arteriograhpy	
B31R1ZZ	Fluoroscopy of intracranial arteries using low osmolar contrast
B31RYZZ	Fluoroscopy of intracranial arteries using other contrast[4]

Physician coding and payment

Effective January 1, 2023 - December 31, 2023

CPT® procedure codes[10]

Physicians use CPT codes for all services. Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the relative value unit (RVU), which is then converted to a flat payment amount.

CPT code	Code description	Multiple procedure discounting[9]	Medicare RVUs (facility setting)[10,11]	Medicare national average (facility setting)[13,12]
Pipeline™ flex embolization procedure[16,17]				
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, central nervous system (intracranial, spinal cord)	Yes	34.55	$1,171
75894-26	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	No	2.10	$71
Cerebral angriography[18,19]				
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch when performed	Yes	10.83	$367
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch when performed	Yes	10.76	$364
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery)	No	7.26	$246
Catherization[20]				
36216	Selective catheter placement, arterial system, initial second order thoracic or brachiocephalic branch, within a vascular family	Yes	7.90	$268
36217	Selective catheter placement, arterial system, initial third order or more selective thoracic or brachiocephalic branch, within a vascular family	Yes	9.66	$327
Complete angiography[21]				
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization, or infusion other than for thrombolysis	No	2.67	$90

Hospital inpatient coding and payment

Effective October 1, 2022 - September 30, 2023

MS-DRG assignments

Under Medicare's MS-DRG methodology for hospital inpatient payment, each inpatient stay is assigned to one of about 765 diagnosis-related groups, based on the ICD-10-CM codes assigned to the diagnoses and ICD-10-PCS codes assigned to the procedures. Each MS-DRG has a relative weight that is then converted to a flat payment amount. Implanted devices are typically included in the flat payment and are not paid separately. Only one MS-DRG is assigned for each inpatient stay, regardless of the number of procedures performed. MS-DRGs shown are those typically assigned to the following scenarios.

MS-DRG[5]	MS-DRG title[5,6]	Relative weight[5]	Geometric mean length of stay[5]	Subject to PACT [5,7]	Medicare national average[8]
Non-ruptured intracranial aneurysm					
025	Craniotomy and endovascular intracranial procedures W MCC	4.5405	6.6	Yes	$31,146
026	Craniotomy and endovascular intracranial procedures W CC	3.0235	3.6	Yes	$20,740
027	Craniotomy and endovascular intracranial procedures WO CC/MCC	2.4954	1.8	Yes	$17,117

HCPCS device codes[9]

HCPCS device codes are assigned by the entity that purchased and supplied the device to the patient. In the case of Pipeline™ Flex, that is the hospital. However, hospitals assign HCPCS device codes only when the device is provided in the hospital outpatient setting. HCPCS device codes cannot be assigned or billed for procedures performed in the inpatient setting. If a hospital wishes to assign a HCPCS device code for an inpatient case for internal purposes only, such as for tracking, please refer to the Addendum: HCPCS Device Codes at https://www.medtronic.com/us-en/healthcare-professionals/reimbursement/neurovascular.html .

References and notes

1. Centers for Medicare & Medicaid Services. International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS). https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs. Updated October 1, 2022.
2. In code 03VG3HZ, the fourth character represents the body part. G-Intracranial Artery includes the basilar artery, intracranial portion of the internal carotid artery (petrous to the superior hypophyseal segment), intracranial portion of the vertebral artery, and middle cerebral artery, as well as the anterior cerebral artery and posterior cerebral artery, per the ICD-10-PCS Body Part Key. See also Coding Clinic, 1st Q 2016, p.19.
3. Root operation V-Restriction is used because the objective of placing a device into the lumen of the artery is to allow blood to flow through the rest of the artery while excluding the aneurysmal portion. Coding Clinic, 1st Q 2014, p.9. Coding Clinic, 4th Q 2019, p.27 for H-Flow Diverter.
4. Fifth character Y-Other Contrast can be used for iso-osmolar contrast, eg, Visipaque, per Coding Clinic 3rd Q 2016, p.36.
5. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Policy Changes and FY2023 Rates Final Rule 87 Fed. Reg. 48780-49499. https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf Published August 10, 2022. Correction Notice 87 Fed. Reg. 66558-66575. https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-24077.pdf Published November 4, 2022.
6. W MCC in MS-DRG titles refers to secondary diagnosis codes that are designated as major complications or comorbidities. MS-DRGs W MCC have at least one major secondary complication or comorbidity. Similarly, W CC in MS-DRG titles refers to secondary diagnosis codes designated as other (non-major) complications or comorbidities, and MS-DRGs W CC have at least one other (non-major) secondary complication or comorbidity. MS-DRGs WO CC/MCCs have no secondary diagnoses that are designated as complications or comorbidities, major or otherwise. Note that some secondary diagnoses are only designated as CCs or MCCs when the conditions were present on admission, and do not count as CCs or MCCs when the conditions are acquired in the hospital during the stay.
7. Post-Acute Care Transfer (PACT) status refers to selected DRGs in which payment to the hospital may be reduced when the patient is discharged by being transferred out. The DRGs impacted are those marked "Yes" and the patient must be transferred out before the geometric mean length of stay to certain post-acute care providers, including rehabilitation hospitals, long term made as double the per diem rate for the first day plus the per diem rate for each remaining day up to the full DRG payment. care hospitals, skilled nursing facilities, hospice, or to home under the care of a home health agency. When these conditions are met, the DRG payment is converted to a per diem and payment is made at double the per diem rate for the first day plus the per diem rate for each remaining day up to the full DRG payment.
8. Payment is based on the average standardized operating amount ($6,375.74) plus the capital standard amount ($483.79). Centers for Medicare & Medicaid Services. Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Policy Changes and FY2023 Rates. Final Rule 87 Fed Reg 49429-49430 https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf . Published August 10, 2022. Correction Notice 87 Fed. Reg. 66564 https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-24077.pdf . Published November 4, 2022. Tables 1A-1D. The payment rate shown is the standardized amount for facilities with a wage index greater than one. The average standard amounts shown also assume facilities receive the full quality update. The payment will also be adjusted by the Wage Index for specific geographic locality. Therefore, payment for a specific hospital will vary from the stated Medicare national average payment levels shown. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.
9. Healthcare Common Procedure Coding System (HCPCS) Level II codes C-codes are maintained by the Centers for Medicare & Medicaid Services. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed January 16, 2023.
10. CPT copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to government use. Fee schedules, relative value, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.
11. Modifier -26 is appended to certain imaging codes to show that the physician is reporting only the professional interpretation, because the hospital is providing the imaging equipment and technicians.
12. For codes marked "Yes", multiple procedure discounting indicates that when a procedure code is reported on the same day as another higher-weighted procedure code, the highest-weighted code is paid at 100% of the fee schedule amount and additional codes are paid at 50% of the fee schedule amount. Procedure codes marked "No" are always paid at 100% of the fee schedule amount regardless of whether they are submitted with other procedure codes. See also the current 2023 release of the PFS Relative Value File at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files .
13. Centers for Medicare & Medicaid Services. Medicare Program; CY2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies Final Rule; 87 Fed. Reg. 69404-70699. https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf . Published November 18, 2022. The total RVU as shown here is the sum of three components: physician work RVU, practice expense RVU, and malpractice RVU.
14. RVUs and the Medicare National Average are shown for the facility setting only because the Pipeline Flex embolization procedure is always performed in the hospital, rather than the non-facility (physician office) setting.
15. Medicare national average payment is determined by multiplying the sum of the three RVUs by the conversion factor. The conversion factor for CY 2023 is $33.8872 per 87 Fed. Reg. 70177. https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf . Published November 18, 2022. See also the current 2023 release of the PFS Relative Value File at http:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files . Final payment to the physician is adjusted by the Geographic Practice Cost Indices (GPCI). Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the payment amount shown.
16. Some payers recognize code 61635 for placement of embolization devices that have stent-like features. However, code 61635 is not displayed because it is assigned for placement of a dilation stent to open vessel stenosis. This is the opposite effect of the Pipeline™ Flex device, which excludes the aneurysm by partially closing a vessel.
17. Component coding conventions apply to code 61624, so radiological supervision and interpretation is coded separately. Code 75894 represents the radiologic service linked to code 61624.
18. Codes 61624 and 75894 for the Pipeline™ Flex embolization procedure include intraprocedural road-mapping and fluoroscopic guidance necessary to perform the intervention. However, cerebral angiography may be coded separately with 61624 when it is truly diagnostic. According to CPT manual instructions (Radiology section, Vascular Procedures heading), a truly diagnostic study means that no prior angiography is available and the decision to intervene is based on the current angiography or, if angiography was previously performed, the patient's condition has changed since the prior angiography, there is inadequate visualization of the anatomy or pathology on prior angiography, or there is a clinical change during the procedure requiring new evaluation. See also CPT manual instructions (Surgery section, Cardiovascular System chapter, Diagnostic Studies of Cervicocerebral Arteries heading) and National Correct Coding Initiative (NCCI) Policy Manual, 01/01/2023, Chapter V, D13.
19. A 4-view cervical and cerebral angiography, from catheter placement in the internal carotid arteries and vertebral arteries bilaterally, is typically coded 36224-50 and 36226-50. Add-on code +36228 would also be assigned if additional angiography was performed from catheter placement in, for example, the superior hypophyseal artery.
20. Catheter placement may be coded separately with 61624. Code 36216 would typically represent catheterization of the left internal carotid artery. Code 36217 would typically represent catheterization of the right internal carotid artery or higher level, eg, the superior hypophyseal artery on either side. However, if diagnostic angiography codes 36224-36226 are also assigned, catheterization may not be coded separately because it is included in these procedure codes.
21. The CMS Medically Unlikely Edit (MUE) for code 75898 is 2 units, although denials for units in excess of the MUE value may be appealed.

Brief statement (EPI) for Pipeline Flex with shield

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 for the Pipeline™ Flex Embolization Device with Shield Technology™ can be viewed at https://www.medtronic.com/manuals.
Indications for Use: The Pipeline™ Flex 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™ Flex 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 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. 5) Patients in whom the parent vessel size does not fall within the indicated range.

Warnings: 1) Pushing delivery wire without retracting the micro catheter at the same time will cause the open end braid to move distally in the vessel. This may cause damage to the braid or vessel. 2) Use in tortuous anatomy may result in difficulty or inability to deploy the Pipeline™ Flex Embolization Device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by: Unloading the microcatheter to the inner curves of vessel by pulling back on the system (i.e., the microcatheter and delivery wire together). Continue unloading the system until advancement of the device (inside the microcatheter) 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 microcatheter. This process should be repeated until the device passes through tortuous area and the delivery force is decreased. 3) Resheathing of the Pipeline™ Flex Embolization Device with Shield Technology™ more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 4) 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 with Shield Technology™ implant. 5) Person with known allergy to tin, silver, stainless steel, or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex Embolization Device with Shield Technology™ delivery system. 6) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance. 7) Post-procedural movement (migration and/or foreshortening) of the Pipeline™ Flex Embolization Device with Shield Technology™ implant may occur following implantation and can result in serious adverse events and/or death. 8) 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 9) Delayed rupture may occur with large and giant aneurysms. 10) Placement of multiple Pipeline™ Flex Embolization Device with Shield Technology™ may increase the risk of ischemic complications. 11) Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Flex Embolization Device with Shield Technology™ and can lead to damage to the Pipeline™ Flex Embolization Device with Shield Technology™ and microcatheter. Advancement or retraction of the Pipeline™ Flex 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. 12) Do not attempt to reposition the device after full deployment. 13) 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. 14) 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: 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 effectiveness 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; Intra-Cranial 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.

Medtronic

Medtronic Inc.
9775 Toledo Way
Irvine, CA 92618
USA
Tel. 1-763-505-5000
medtronic.com