Medtronic

Axium™ detachable coil family

Coding and payment guide
2023

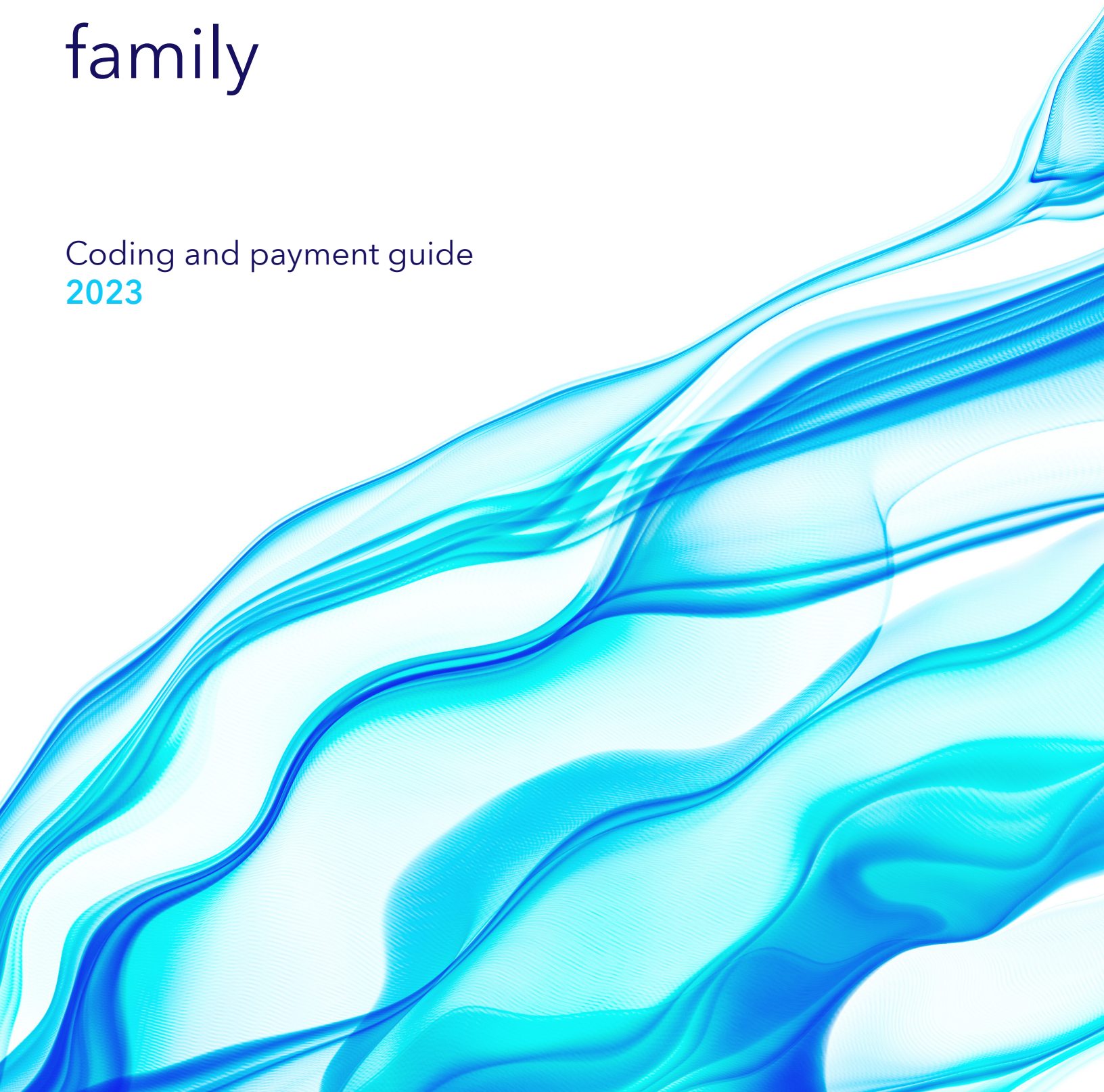


Table of contents

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage and payment policies. This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (eg, instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

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
Placement of Axium detachable embolization coils[2,3,4]	
For aneurysm	
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach
For arteriovenous fistula and arteiovenous malformation	
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach
Cerebral arteriography	
B31R1ZZ	Fluoroscopy of intracranial arteries using low osmolar contrast
B31RYZZ	Fluoroscopy of intracranial arteries using other contrast[5]

Physician coding and payment

Effective January 1, 2023 - December 31, 2023

CPT® procedure codes[11]

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[16]	Medicare RVUs (facility setting)[17,18]	Medicare national average (facility setting)[18,19]
Placement of Axium detachable embolization coils[17,18]				
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
Pre-procedural balloon occlusion test[19]				
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/ intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	Yes	17.16	$582
Cerebral angriography[20,21]				
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

Physician coding and payment - CPT® procedure codes[11] (continued)

CPT code	Code description	Multiple procedure discounting[16]	Medicare RVUs (facility setting)[17,18]	Medicare national average (facility setting)[18,19]
Catherization[22]				
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
Completion angiography[23]				
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[6]	MS-DRG title[6,7]	Relative weight[6]	Geometric mean length of stay[6]	Subject to PACT [6,8]	Medicare national average[11]
Ruptured cerebral aneurysm, arteriovenous fistula, arteriovenous malformation with hemmorrhage					
020	Intracranial vascular procedures W principal diagnosis of hemorrhage W MCC	9.3033	10.7	No	$63,816
021	Intracranial vascular procedures W principal diagnosis of hemorrhage W CC	6.7892	8.1	No	$46,571
022	Intracranial vascular procedures W principal diagnosis of hemorrhage WO CC/MCC	4.3585	3.2	No	$29,897
Non-ruptured cerebral aneurysm,arteriovenous fistula, arteriovenous malformation					
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[10]

HCPCS device codes are assigned by the entity that purchased and supplied the device to the patient. In the case of Axium detachable embolization coils, 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 the coiling procedure codes, 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. The difference between the two sets of codes for placement of Axium embolization coils is the third character for the root operation, which is assigned according to the objective of the procedure. Although the same devices may be used, the objective is different depending on the diagnosis. For coils placed for aneurysm, the root operation is V-Restriction because the objective is to partially close the lumen of the artery, allowing blood to flow through the rest of the artery while excluding the aneurysmal portion (Coding Clinic, 1st Q 2014, p.9). In contrast, for coils placed for arteriovenous fistula or arteriovenous malformation, the root operation is L-Occlusion because the objective is to prevent blood flow between vein and artery by completely closing the unnatural connection, ie, sacrificing the vessel (Coding Clinic, 4th Q 2014, p.37).
4. The use of balloon-assisted coiling and stent-assisted coiling techniques does not alter the ICD-10-PCS codes assigned. Ballooning is considered an integral step in coil placement and is not coded separately. In stent-assisted coiling, both the implanted stent and the coils are being used at the same site for the same objective, and a single code suffices (Coding Clinic, 1st Q 2016, p.19).
5. Fifth character Y-Other Contrast can be used for iso-osmolar contrast, eg, Visipaque per Coding Clinic 3rd Q 2016, p.36.
6. 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.
7. W MCC in MS-DRG titles refers to secondary diagnosis codes that are designated as major com-plications 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.
8. 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 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.
9. 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.
10. 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.
11. 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 units, 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.
12. 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.
13. 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 http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files
14. 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.
15. RVUs and the Medicare National Average are shown for the facility setting only because the coil embolization procedure is always performed in the hospital, rather than the non-facility (physician office) setting.
16. 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.
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. The use of balloon-assisted coiling (balloon remodeling) and stent-assisted coiling techniques does not alter the CPT codes assigned. Ballooning is considered an integral step in coil placement and is not coded separately. In stent-assisted coiling, when the stent and the coils are placed during the same operative encounter, code 61624 encompasses both and the stent is not coded separately ACR Bulletin, March 2007, p.3; CPT Assistant, November 2006, p.8 and July 2016, p.6.
19. A balloon occlusion test may be performed immediately prior to coil embolization, particularly with arteriovenous fistula, for a separate and prolonged assessment of the neurological risks of permanently occluding the vessel. When performed, this may be coded and reported separately. Do not assign 61623 for temporary balloon occlusion that is an inherent component of 61624. National Correct Coding Initiative (NCCI) Policy Manual, 01/01/2023, Chapter VIII, C-29.
20. Codes 61624 and 75894 for Axium detachable coil embolization 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 NCCI Policy Manual, 01/01/2023. Chapter V, D13.
21. 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.

22. 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 middle cerebral artery on either side. However, if codes 61623 or 36224-36226 are also assigned, catheterization may not be coded separately because it is included in these procedure codes.
23. 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 for Axium™ and Axium™ prime detachable coils

Iindications: Axium™ and Axium™ Prime detachable coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ and Axium™ Prime detachable coils are also intended for the embolization of other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Axium™ Prime (Frame) detachable coils are also indicated for arterial and venous embolizations in the peripheral vasculature.

Potential complications include, but are not limited to:

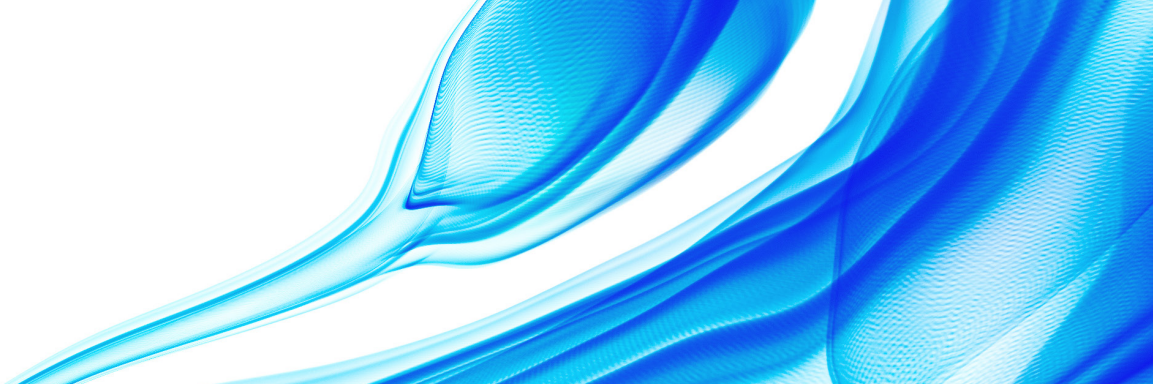
- Puncture site hematoma
- Vessel perforation
- Vasospasm
- Hemorrhage
- Thromboembolic episodes
- Neurological deficits including stroke and death
- Vascular thrombosis
- Ischemia

Warnings:

- The Axium™ or Axium™ Prime Detachable Coil, the dispenser track, and the introducer sheath are supplied in a sterile and nonpyrogenic, unopened and undamaged package. The package should be checked for potential damage. Damaged Axium™ and Axium™ Prime Detachable Coils must not be used, as they may result in patient injury.
- The AXIUM™ PRIME Detachable Coil, the dispenser track, and the introducer sheath are supplied in a sterile and non-pyrogenic, unopened and undamaged package. The package should be checked for potential damage. Damaged AXIUM™ PRIME Detachable Coils must not be used, as they may result in patient injury.
- The Axium™ and Axium™ Prime Detachable Coils are intended for one use only. The Axium™ I.D. (Instant Detacher) is supplied sterile and intended for single patient use. After use do not resterilize and/or reuse. Reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn, may result in patient injury, illness or death.
- Do not use if sterile packaging has been compromised or damaged.
- Damaged implant delivery pusher and/or coils may affect coil delivery to, and stability inside, the vessel or aneurysm, possibly resulting in coil migration or stretching.
- Do not rotate the implant delivery pusher during or after delivery of the coil into the aneurysm. Rotating the delivery pusher during or after coil delivery into the aneurysm may result in a stretched coil or premature detachment of the coil from the implant delivery pusher, which could result in coil migration.
- Do not use hemostats in an attempt to advance delivery pusher. This may result in a kinked pusher which may lead to premature detachment.
- Verify that the distal shaft of the microcatheter is not under stress before the Axium™ or Axium™ Prime Detachable Coil detachment. Axial compression or tensile forces could be stored in the microcatheter causing the tip to move during the Axium™ or Axium™ Prime Detachable Coil delivery. Microcatheter tip movement could cause the aneurysm or vessel to rupture.
- Advancing the delivery pusher beyond the microcatheter tip once the coil has been deployed and detached involves risk of aneurysm or vessel perforation.
- If undesirable movement of the Axium™ or Axium™ Detachable Coil can be seen under fluoroscopy following coil placement and prior to detachment, remove the coil and replace with another more appropriately sized Axium™ or Axium™ Prime Detachable Coil. Movement of the coil may indicate the coil could migrate once it is detached. Angiographic controls should also be performed prior to detachment to ensure that the coil mass is not protruding into the parent vessel.
- High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve safe catheterization of the aneurysm or vessel and correct placement of the first coil. With smaller aneurysms this is a particularly important step.
- If Axium™ or Axium™ Prime Detachable Coil repositioning is necessary, take special care to retract coil under fluoroscopy in a one-to-one motion with the implant pusher. If the coil does not move with a one-to-one motion, or repositioning is difficult, the coil has been stretched and could possibly break. Gently remove and discard both the catheter and coil.
- Due to the delicate nature of the Axium™ and Axium™ Prime Detachable Coil, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial aneurysms, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential malfunctions such as coil breakage and migration.
- If resistance is encountered while withdrawing an Axium™ or Axium™ Prime Detachable Coil, which is at an acute angle relative to the catheter tip, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the catheter at the ostium of the aneurysm, or just slightly inside the parent artery.
- Take care not to puncture gloves or sterile drape while handling implant delivery pusher.
- Multiple placements of Axium™ or Axium™ Prime Detachable Coils may be required to achieve the desired occlusion of some aneurysms or vessels.
- The long term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilization increase

the risks of patient infection and compromised device performance.

- Do not use hemostats in an attempt to advance delivery pusher. This may result in a kinked pusher which may lead to premature detachment.
    a. If attempt to detach fails, remove coil from treatment area and microcatheter and replace with a new AXIUM™ PRIME Detachable Coil.
    b. If coil becomes prematurely detached, remove implant pusher and:
        i. Advance next coil to push remaining tail of prematurely detached coil into treatment area
        ii. Remove prematurely
- Do not resterilize the AXIUM™ I.D. (Instant Detacher). For Single Patient use only.
- The AXIUM™ I.D. (Instant Detacher) is intended for a maximum of 25 cycles.
- The Axium™ or Axium™ Prime Detachable Coil, the dispenser track, and the introducer sheath are supplied in a sterile and nonpyrogenic, unopened and undamaged package. The package should be checked for potential damage. Damaged Axium™ and Axium™ Prime Detachable Coils must not be used, as they may result in patient injury.
- The AXIUM™ PRIME Detachable Coil, the dispenser track, and the introducer sheath are supplied in a sterile and non-pyrogenic, unopened and undamaged package. The package should be checked for potential damage. Damaged AXIUM™ PRIME Detachable Coils must not be used, as they may result in patient injury.
- The Axium™ and Axium™ Prime Detachable Coils are intended for one use only. The Axium™ I.D. (Instant Detacher) is supplied sterile and intended for single patient use. After use do not resterilize and/or reuse. Reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn, may result in patient injury, illness or death.
- Do not use if sterile packaging has been compromised or damaged.
- Damaged implant delivery pusher and/or coils may affect coil delivery to, and stability inside, the vessel or aneurysm, possibly resulting in coil migration or stretching.
- Do not rotate the implant delivery pusher during or after delivery of the coil into the aneurysm. Rotating the delivery pusher during or after coil delivery into the aneurysm may result in a stretched coil or premature detachment of the coil from the implant delivery pusher, which could result in coil migration.
- Do not use hemostats in an attempt to advance delivery pusher. This may result in a kinked pusher which may lead to premature detachment.
- Verify that the distal shaft of the microcatheter is not under stress before the Axium™ or Axium™ Prime Detachable Coil detachment. Axial compression or tensile forces could be stored in the microcatheter causing the tip to move during the Axium™ or Axium™ Prime Detachable Coil delivery. Microcatheter tip movement could cause the aneurysm or vessel to rupture.
- Advancing the delivery pusher beyond the microcatheter tip once the coil has been deployed and detached involves risk of aneurysm or vessel perforation.
- If undesirable movement of the Axium™ or Axium™ Detachable Coil can be seen under fluoroscopy following coil placement and prior to detachment, remove the coil and replace with another more appropriately sized Axium™ or Axium™ Prime Detachable Coil. Movement of the coil may indicate the coil could migrate once it is detached. Angiographic controls should also be performed prior to detachment to ensure that the coil mass is not protruding into the parent vessel.
- High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve safe catheterization of the aneurysm or vessel and correct placement of the first coil. With smaller aneurysms this is a particularly important step.
- If Axium™ or Axium™ Prime Detachable Coil repositioning is necessary, take special care to retract coil under fluoroscopy in a one-to-one motion with the implant pusher. If the coil does not move with a one-to-one motion, or repositioning is difficult, the coil has been stretched and could possibly break. Gently remove and discard both the catheter and coil.
- Due to the delicate nature of the Axium™ and Axium™ Prime Detachable Coil, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial aneurysms, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential malfunctions such as coil breakage and migration.
- If resistance is encountered while withdrawing an Axium™ or Axium™ Prime Detachable Coil, which is at an acute angle relative to the catheter tip, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the catheter at the ostium of the aneurysm, or just slightly inside the parent artery.
- Take care not to puncture gloves or sterile drape while handling implant delivery pusher.
- Multiple placements of Axium™ or Axium™ Prime Detachable Coils may be required to achieve the desired occlusion of some aneurysms or vessels.
- The long term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilization increase the risks of patient infection and compromised device performance.
- Do not use hemostats in an attempt to advance delivery pusher. This may result in a kinked pusher which may lead to premature detachment.
    a. If attempt to detach fails, remove coil from treatment area and microcatheter and replace with a new AXIUM™ PRIME Detachable Coil.
    b. If coil becomes prematurely detached, remove implant pusher and:
        i. Advance next coil to push remaining tail of prematurely detached coil into treatment area
        ii. Remove prematurely
- Do not resterilize the AXIUM™ I.D. (Instant Detacher). For Single Patient use only.
- The AXIUM™ I.D. (Instant Detacher) is intended for a maximum of 25 cycles.



Medtronic

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