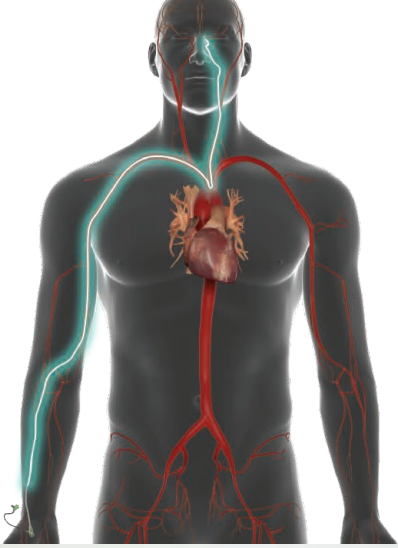
Medtronic

Rist™ Radial Access System

Confidence at hand.

The complete radial solution. Hands down.

The Rist™ Radial Access System features the first guide catheter designed for the unique demands of accessing the neurovasculature through the radial pathway.[1,3,10,11,18]



Rist™ 071
Guide Catheter

Low profile offering

Radial Ready

Radial focused training and support structured specifically for neuro-interventionalists.

FDA cleared for radial access[12]

Axium™ Detachable Coil Family

&

Rist™ 079
Guide Catheter

FDA approved for radial access[13]

Pipeline™ Flex Embolization Device with Shield Technology™

&

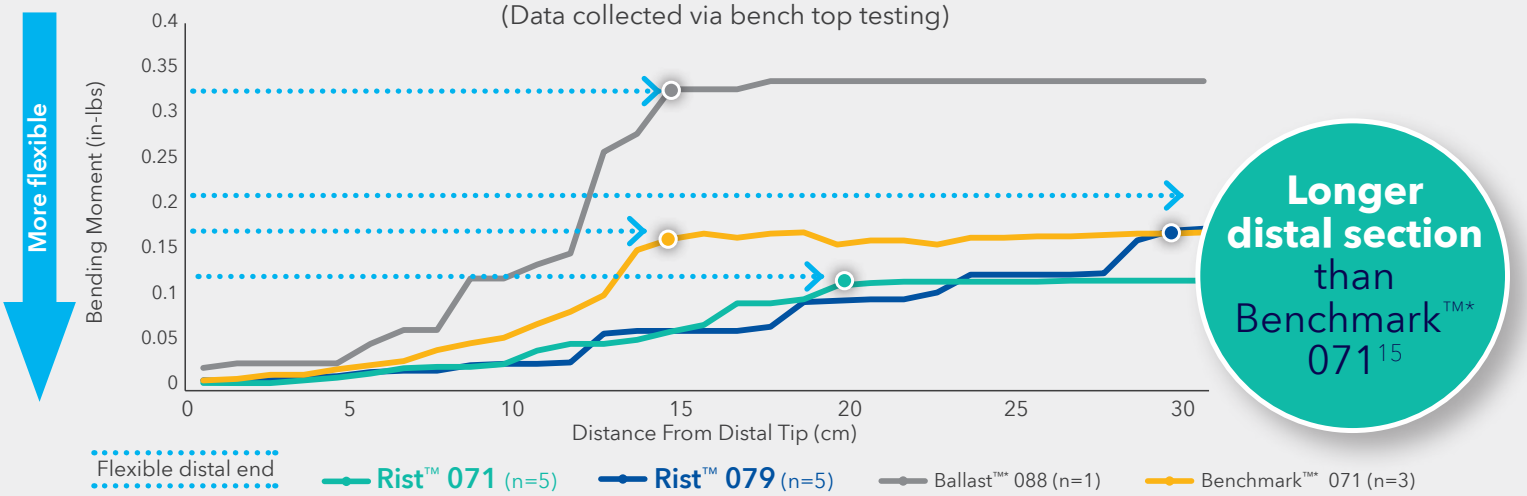
Rist™ 079
Guide Catheter

Transition zones where you need them.

The Rist™ Guide Catheter provides both distal navigability and proximal stability matched to the radial trajectory.[2,3,15]

Stiffness Profile Designed For Radial[2,15]

(Data collected via bench top testing)



Rist™ 071 has **43% longer distal flexible section** versus Benchmark™* 071.[15]

Rist™ 079 has **2x longer distal flexible section** versus Benchmark™* 071.[2]

Bench testing may not be representative of actual clinical performance.

Atraumatic Tip

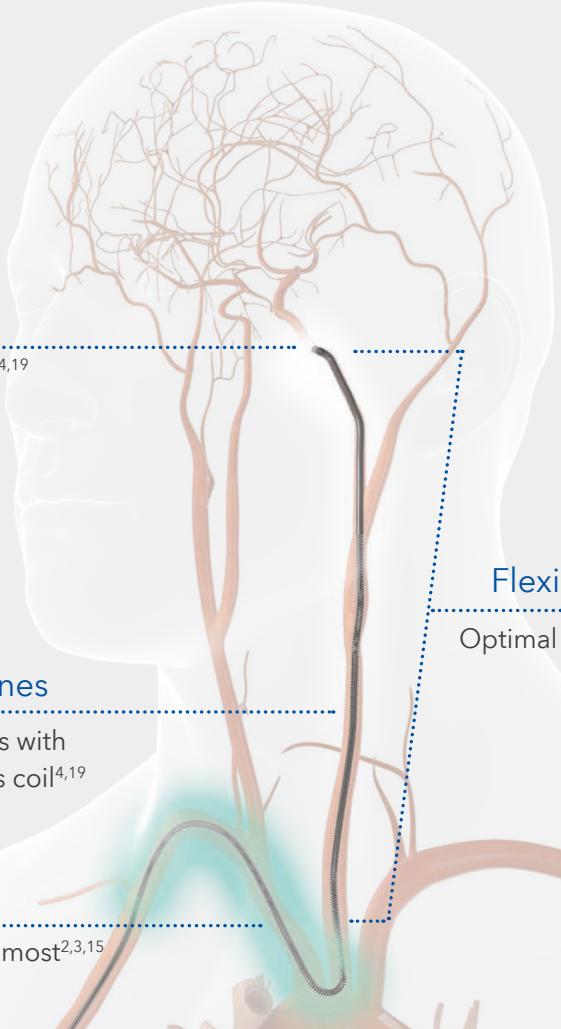
6cm nitinol round wire coil[4,19]

Gradual Transition Zones

Gradual material transitions with stainless steel flatwire cross coil[4,19]

Stiffer Support Zone

Stability where it's needed most[2,3,15]



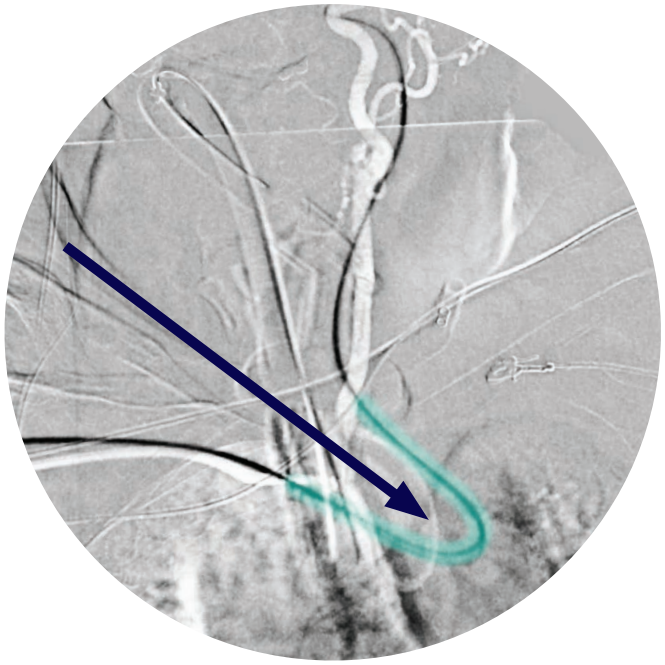
Navigate with confidence.

Flexible Distal Zone

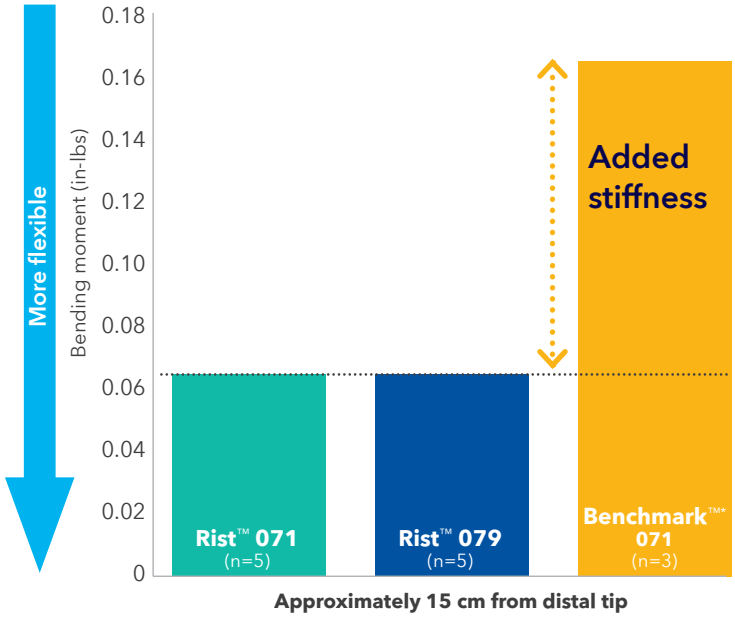
Optimal distal trackability[2,3,15]

Make the turn.

The Rist™ Guide Catheter is engineered to effortlessly navigate through tough acute bends in the radial pathway.[3]



Easier Navigability with Rist™ [2,15]
(Data collected via bench top testing)

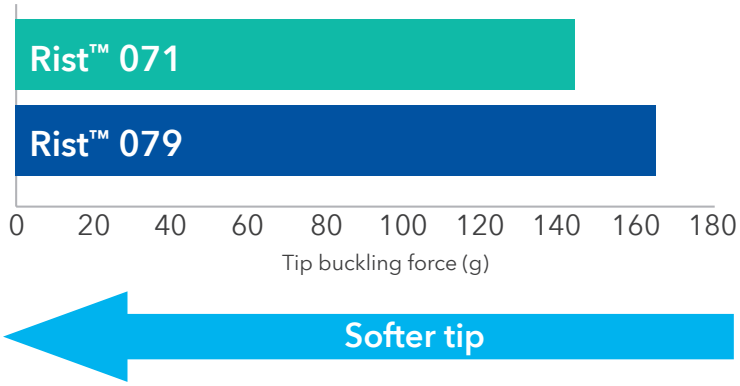


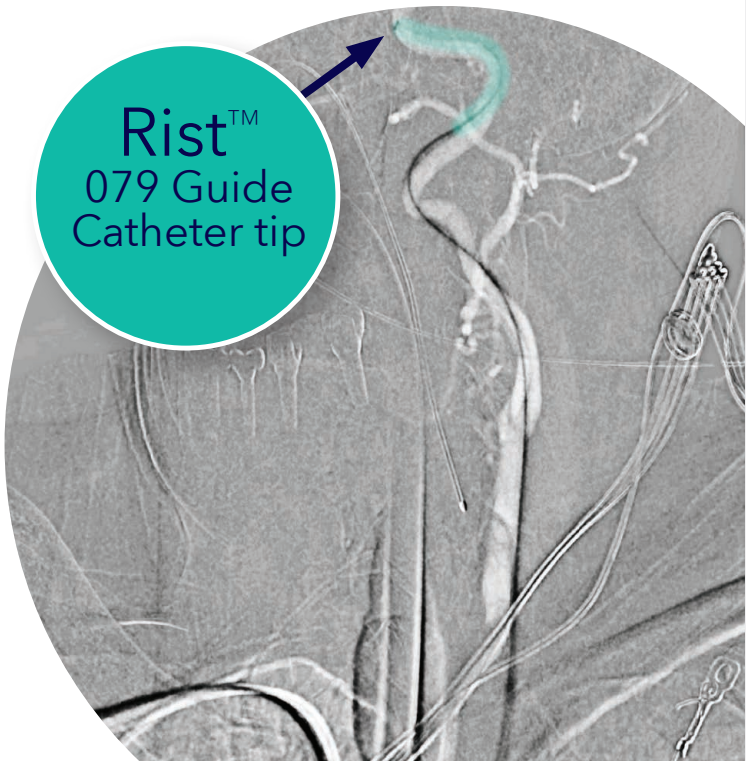
Bench testing may not be representative of actual clinical performance.

Reach for the top.

The Rist™ Guide Catheter is uniquely designed to go higher in the ICA, providing a stable platform where it is needed most.[3]

Rist™ 071 offers added tip softness[15]
(Data collected via bench top testing)

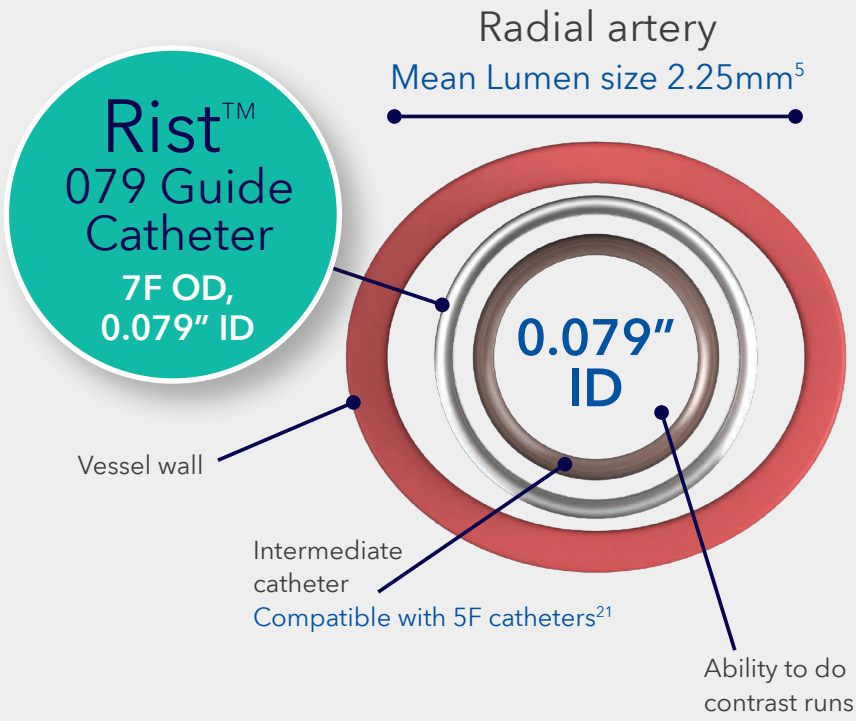




Don’t sacrifice support.

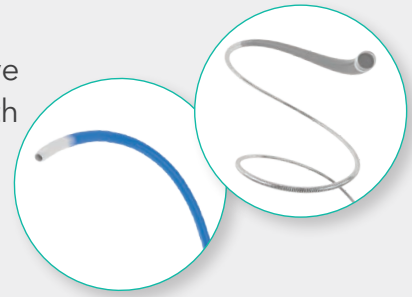
The Rist™ Guide Catheter has different lumen size options, providing the flexibility to choose the optimal size based on procedural needs.[8,20]

Specs	Compatibility
Rist™ 071 Guide Catheter	
6F OD	Compatible with 6F introducer sheaths[16]
0.071″ ID	Compatible with 5.5F (0.070″ OD) or smaller catheters[16]
Rist™ 079 Guide Catheter	
7F OD	Compatible with 7F introducer sheaths[21]
0.079″ ID	Compatible with 6F (0.078" OD) or smaller catheters[21]



Available in 6F and 7F.

The **Rist**™ Radial Access Selective Catheter is designed for use with the **Rist**™ 071 and 079 Guide Catheter and optimized for vessel selection.[3]



The **Rist**™ Radial Access Guide Catheter is the first to provide radial-specific transition zones, different lumen size options, and a range of lengths you need for optimal performance.[3]

Reference Number	Working Length (cm)	OD (in / F)	ID (in)	Tip Shapes
105F-BER-120	120	0.070 / 5.5F	0.040	Berenstein
105F-BER-130	130	0.070 / 5.5F	0.040	Berenstein
105F-SIM-120	120	0.070 / 5.5F	0.040	Sim2
105F-SIM-130	130	0.070 / 5.5F	0.040	Sim2

Reference Number	Working Length (cm)	OD (in / F)	ID (in)	Hydrophilic Coating Length (cm)
106F-071-95	95	0.087 / 6F	0.071	25
106F-071-100	100	0.087 / 6F	0.071	25
106F-071-105	105	0.087 / 6F	0.071	25
107F-079-95	95	0.093 / 7F	0.079	25
107F-079-100	100	0.093 / 7F	0.079	25
107F-079-105	105	0.093 / 7F	0.079	25

WARNING: The safety and effectiveness of this device for radial neurovasculature access indirect comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a trans- femoral approach should be carefully weighed and considered for each patient.

PRECAUTION: 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 include but not limited to: Neurological deficits including hand dysfunction, stroke, and death.

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found on the product labeling supplied with each device. Indications, contraindications, warnings and instructions for use for the Rist™ 071 and 079 Radial Access Guide Catheter, Rist™ Radial Access Selective Catheter, and Pipeline™ Flex Embolization Device with Shield™ Technology can be found at ***www.medtronic.com/manuals***.

Indications for Use:
The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices intothe peripheral, coronary, and neuro vasculature.

The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.

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 fistulaes.

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

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 widenecked 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 readvance 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 schemia, Retinal infarction, Vision impairment including scintillations, blurred vision, eye floaters; Intra-Cranial Hemorrhage (including from Aneurysm Rupture) Brain Edema, Hydrocephalus, Mass Effect; Death.

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1.INC TR-12549 **2**.D00375759 **3**.INC TR-12736; TR-14609 **4**.INC-11815 **5**.Costa, Fransesco et al. Radial Artery Ultrasound within Catherization. Circ Cardiovasc Interv.2016; 9:e003129 doi:10.1161/CIRCINTERVENTIONS.115.003129 **6**.INC-11816 **7**.INC-11694 **8**.D00314259 **9**.D00312142 **10**.INC TR-13494 **11**.INC TR-13523 **12**.K203432 **13**.P100018/S026 **14**.K191551 **15**.D00615119 **16**.M020093CDOC2 **17**.K211990 **18**.INC TR-14569 **19**. INC-13676 **20**.D0050158 **21**.M009679CDOC2