Rist™ Radial Access System

Confidence at hand.
Radial Ready

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. The Rist™ Radial Access System is FDA cleared for radial access.

Axium™ Detachable Coil Family

&

Rist™ 079 Guide Catheter

FDA approved for radial access

Pipeline™ Flex Embolization Device with Shield Technology™

&

Rist™ 079 Guide Catheter

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

Atraumatic Tip

Gradual Transition Zones
Gradual material transitions with stainless steel flatwire cross coil⁴,¹⁹

Stiffer Support Zone
Stability where it’s needed most²,³,¹⁵

Stiffness Profile Designed For Radial²,¹⁵
(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.

Navigate with confidence.
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

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.

Rist™ 071 offers added tip softness¹⁵
(Data collected via bench top testing)

Rist™ 071
(n=5)

Rist™ 079
(n=5)

Benchmark™ 071
(n=5)

Approximately 15 cm from distal tip

Softer tip

Rist™ 079 Guide Catheter tip

Tip buckling force (g)

0 20 40 60 80 100 120 140 160 180

Rist™ 071

Rist™ 079

More flexible

Bending moment (in-lbs)

0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0

Softer tip

Rist™ 079 Guide Catheter tip

Bench testing may not be representative of actual clinical performance.
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

<table>
<thead>
<tr>
<th>Specs</th>
<th>Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rist™ 071 Guide Catheter</td>
<td>6F OD Compatible with 6F introducer sheaths16</td>
</tr>
<tr>
<td></td>
<td>0.071” ID Compatible with 5.5F (0.070” OD) or smaller catheters16</td>
</tr>
<tr>
<td>Rist™ 079 Guide Catheter</td>
<td>7F OD Compatible with 7F introducer sheaths21</td>
</tr>
<tr>
<td></td>
<td>0.079” ID Compatible with 6F or smaller catheters21</td>
</tr>
</tbody>
</table>

Radial artery
Mean Lumen size 2.25mm

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

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Working Length (cm)</th>
<th>OD (in / F)</th>
<th>ID (in)</th>
<th>Tip Shapes</th>
</tr>
</thead>
<tbody>
<tr>
<td>105F-BER-120</td>
<td>120</td>
<td>0.070 / 5.5F</td>
<td>0.040</td>
<td>Berenstein</td>
</tr>
<tr>
<td>105F-BER-130</td>
<td>130</td>
<td>0.070 / 5.5F</td>
<td>0.040</td>
<td>Berenstein</td>
</tr>
<tr>
<td>105F-SIM-120</td>
<td>120</td>
<td>0.070 / 5.5F</td>
<td>0.040</td>
<td>Sim2</td>
</tr>
<tr>
<td>105F-SIM-130</td>
<td>130</td>
<td>0.070 / 5.5F</td>
<td>0.040</td>
<td>Sim2</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Working Length (cm)</th>
<th>OD (in / F)</th>
<th>ID (in)</th>
<th>Hydrophilic Coating Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>106F-071-95</td>
<td>95</td>
<td>0.087 / 6F</td>
<td>0.071</td>
<td>25</td>
</tr>
<tr>
<td>106F-071-100</td>
<td>100</td>
<td>0.087 / 6F</td>
<td>0.071</td>
<td>25</td>
</tr>
<tr>
<td>106F-071-105</td>
<td>105</td>
<td>0.087 / 6F</td>
<td>0.071</td>
<td>25</td>
</tr>
<tr>
<td>107F-079-95</td>
<td>95</td>
<td>0.093 / 7F</td>
<td>0.079</td>
<td>25</td>
</tr>
<tr>
<td>107F-079-100</td>
<td>100</td>
<td>0.093 / 7F</td>
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<td>0.079</td>
<td>25</td>
</tr>
</tbody>
</table>
WARNING: The safety and effectiveness of this device for radial neurovascular access indirect 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.

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 into the peripheral, coronary and neuro vasculature.

The Rist® Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronarv and neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronarv 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 fistulas.

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 aneurysms (22 years of age or older) with large or giant, wide-necked intracranial aneurysms (IA’s) 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 midsegment for the treatment of asymptomatic unruptured aneurysms (22 years of age or older) with large and medium wide-necked (neck width > 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms (IA’s) 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 antplatelet and/or anticoagulation therapy (aspirin and clopidogrel) is contraindicated. 3) Patients who have not received dual antplatelet 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 minimize 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 manipulation and tip deflection. Be careful to avoid torqueing of the microcatheter. This process should be repeated until the device passes through the tortuous area and the delivery force is decreased. 3) Redisheathing 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™. 5) Patient 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™ system prior to the “Use By” date printed on the package. 6) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.

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. 7) Use the Pipeline™ Flex Embolization Device with Shield Technology™ system prior to the “Use By” date printed on the package. 8) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 9) A thrombosing aneurysm may aggravate pre-existing disease, 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 fluid 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 dose 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 (SAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefis 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 IA’s. 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 this device has not been established for treatment of ruptured aneurysms. 14) Using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for each patient.

Potential Complications: Potential complications of the device and the endovascular procedure include, but are not limited to, the following: Access site complications like hemotoma, infection, infection, necrosis, pain and granuloma; Adverse reaction to anti-platelet/anticoagulation agents, anasthesia, reactions due to radiation exposure (such as alopecia, burns ranging in severity from skin redness to skin carbonization and delayed necrosis) 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, Other. 2) Decreased therapeutic response to medical therapies; Risk associated with intra-aneurysmal Blinding, 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.