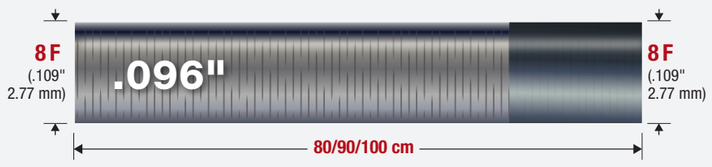
Penumbra Neurovascular Catheters

Select Device Based on Vessel Size

	3MAX®	4MAX	RED®43	RED 62	RED 68	RED 72
Distal OD	1.27 mm	1.42 mm	1.52 mm	1.93 mm	2.13 mm	2.16 mm
Distal ID	.035"	.041"	.043"	.062"	.068"	.072"
Length	160 cm	139 cm	160 cm	138 cm	132 cm	132 cm

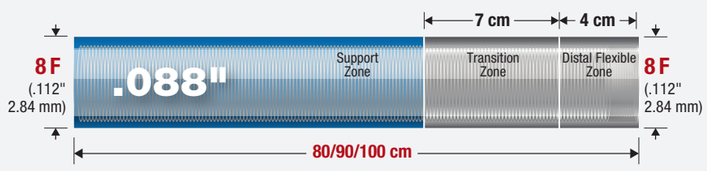
Guide Sheaths

BENCHMARK™ BMX96™



- Constructed using advanced laser-cut stainless steel hypotube technology designed to provide support and flexibility
- Largest ID 8 F access catheter enabling greater intraprocedural visualization and a wider range of delivered therapies[a]

Neuron MAX® 088



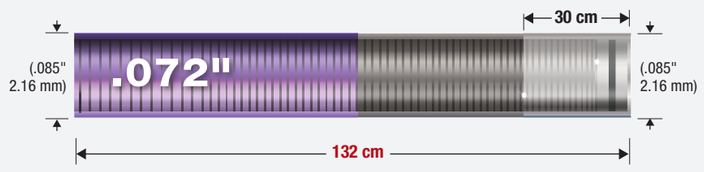
- 6 F long sheath designed to provide robust proximal support and distal trackability for complex neurovascular interventions
- .088" lumen enables delivery of a wide variety of therapies

BENCHMARK BMX®81

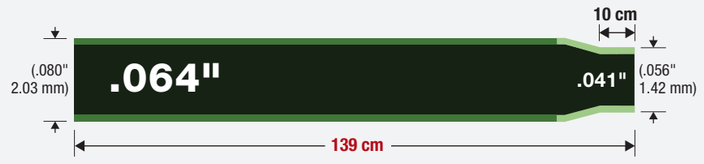
- Advanced Stainless Steel Hypotube Design with Titrated Transitions (T^2) Technology: Engineered to provide support and flexibility for femoral and radial access
- Compatibility-driven design with .081" lumen enabling delivery of multiple therapies

Reperfusion Catheters

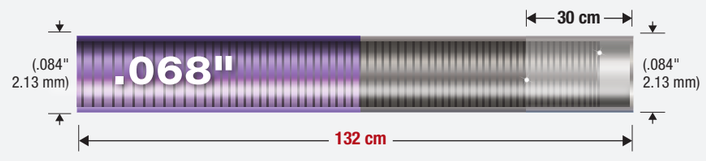
RED 72



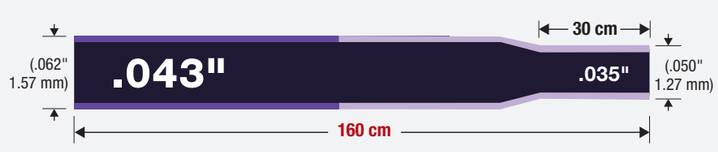
4MAX



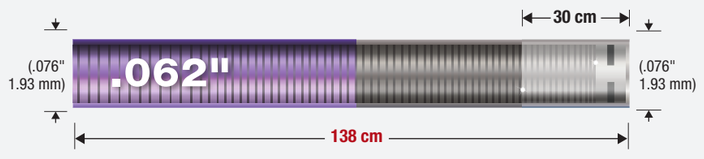
RED 68



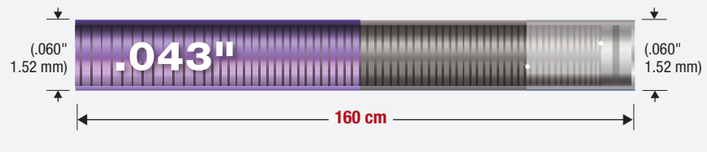
3MAX



RED 62



RED 43



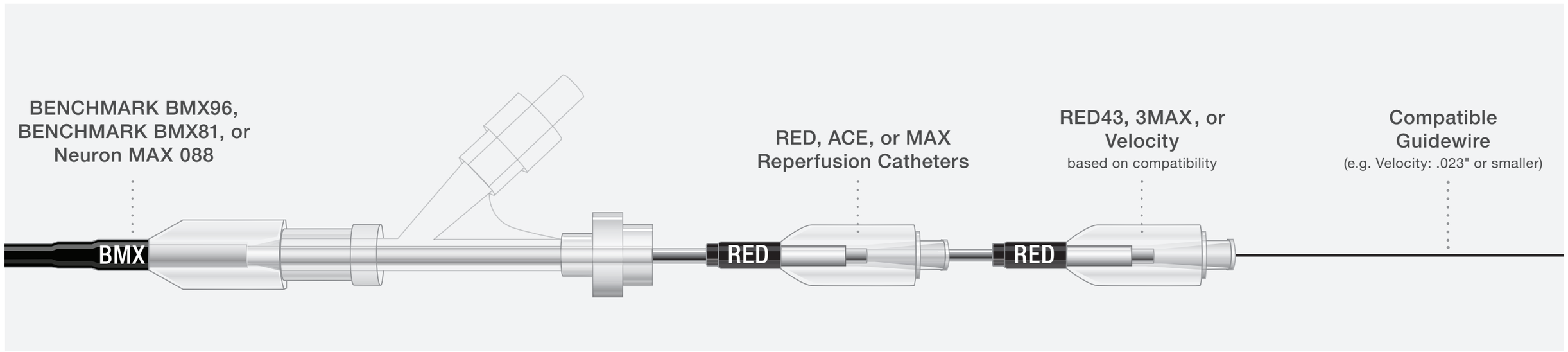
- Delivery and aspiration in the most challenging anatomy
- Minimizes the ledge by occupying more of the reperfusion catheter lumen

Delivery Catheter

Velocity® Delivery Microcatheter

- Designed to facilitate the coaxial delivery of Penumbra reperfusion catheters and revascularization devices

Penumbra System® Setup



a. Data on file at Penumbra, Inc.

Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment. Individual results may vary depending on patient-specific attributes and other factors.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. **A summary of this information is included on the back of this poster**. Please contact your local Penumbra representative for more information.

17788, Rev. D 01/23 USA

www.penumbrainc.com

Penumbra

PENUMBRA SYSTEM® RED™ – Indication for Use
Penumbra Reperfusion Catheters and Separators As part of the PENUMBRA SYSTEM, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. **Penumbra Aspiration Tubing** As part of the PENUMBRA SYSTEM, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no known contraindications. **Warnings** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device. • Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information. • Do not advance, retract or use any component of the PENUMBRA SYSTEM against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR™ against resistance may result in damage to the device or vessel. • Do not use the PENUMBRA SYSTEM with a pump other than the Penumbra Aspiration Pump. • Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events. **Precautions** • The PENUMBRA SYSTEM should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke. • Use prior to the "Use By" date. • Use the PENUMBRA SYSTEM in conjunction with fluoroscopic visualization. • As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended. • The Penumbra SEPARATOR is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such reposition should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques. • Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice. • As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted. • Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure. 1. Adams, et al., Guidelines for the Early Management of Adults with Ischemic Stroke: A Guideline from the AHA/ASA Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists, Stroke May 2007; 38:1655-1711.

PENUMBRA SYSTEM – Indication for Use
Penumbra Reperfusion Catheters and Separators As part of the PENUMBRA SYSTEM, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. **Penumbra 3D™ REVASCULARIZATION DEVICE™** As part of the PENUMBRA SYSTEM, the Penumbra 3D REVASCULARIZATION DEVICE is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. **Penumbra Aspiration Tubing** As part of the PENUMBRA SYSTEM, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no known contraindications. **Warnings** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device. • Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information. • Do not advance, retract or use any component of the PENUMBRA SYSTEM against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter, revascularization device, or SEPARATOR against resistance may result in damage to the device or vessel. • Do not use the PENUMBRA SYSTEM with a pump other than the Penumbra Aspiration Pump. • The Penumbra 3D REVASCULARIZATION DEVICE has not been evaluated in patients with angiographic evidence of pre-existing arterial injury. **Precautions** • The PENUMBRA SYSTEM should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke. • Use prior to the "Use By" date. • Use the PENUMBRA SYSTEM in conjunction with fluoroscopic visualization. • As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended. • The Penumbra SEPARATOR is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques. • Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice. • As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure. 1. Adams, et al., Guidelines for the Early Management of Adults with Ischemic Stroke: A Guideline from the AHA/ASA Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists, Stroke May 2007; 38:1655-1711.

Penumbra Delivery Microcatheters – Indication for Use The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral and neuro vasculature. **Contraindications** There are no known contraindications. **Warnings** The Penumbra Delivery Microcatheters should only be used by physicians who have received appropriate training in interventional techniques. **Precautions** • The devices are intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the Penumbra Delivery Microcatheters in conjunction with fluoroscopic visualization. • Do not advance or withdraw the Penumbra Delivery Microcatheters against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Moving or torquing the device against resistance may result in damage to the vessel or device. • Maintain a constant infusion of an appropriate flush solution. • If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device. **Potential Adverse Events** Possible complications include, but are not limited to, the following: acute occlusion; hematoma or hemorrhage at access site; death; intracranial hemorrhage; hemorrhage; infection (at access site); distal embolization; ischemia (cardiac and/or cerebral); embolus (air, foreign body, thrombus, plaque); aneurysm perforation; false aneurysm formation; neurological deficits including stroke; vessel spasm, thrombosis, dissection, perforation or rupture; air embolism; emboli.

BENCHMARK™ BMX96™ System – Indication For Use The BENCHMARK BMX96 System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. **Contraindications** There are no known contraindications. **Warnings** The BENCHMARK BMX96 System should only be used by physicians who have received appropriate training in interventional techniques. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location; and/or may compromise the structural integrity of the device. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the BENCHMARK BMX96 System in conjunction with fluoroscopic visualization. • Do not advance or withdraw the BENCHMARK BMX96 System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device. • Maintain a constant infusion of an appropriate flush solution. • If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device. **Potential Adverse Events** Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

NEURON MAX® System – Indication for Use The NEURON MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. **Contraindications** There are no known contraindications. **Warnings** The NEURON MAX System should only be used by physicians who have received appropriate training in interventional techniques. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location; and/or may compromise the structural integrity of the device. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the NEURON MAX System in conjunction with fluoroscopic visualization. • Do not advance or withdraw the NEURON MAX System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device. • Maintain a constant infusion of an appropriate flush solution. • If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device. **Potential Adverse Events** Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

BENCHMARK BMX81 Access System – Indication For Use The BENCHMARK BMX81 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. **Contraindications** There are no known contraindications. **Warnings** • The BENCHMARK BMX81 Access System should only be used by physicians who have received appropriate training in interventional techniques. • 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. • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location; and/or may compromise the structural integrity of the device. • Do not use automated high-pressure contrast injection equipment with the BENCHMARK BMX81 Access System because it may damage the device. • Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events. **Precautions** • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer / distributor. • Use prior to the "Use By" date. • Use the BENCHMARK BMX81 Access System in conjunction with fluoroscopic visualization. • Do not advance or withdraw the BENCHMARK BMX81 Access System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device. • Maintain a constant infusion of an appropriate flush solution. • If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device. • Prior to beginning radial artery access, conduct screening, such as an Allen test, to ensure that radial access is appropriate for the patient. • As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible. • Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance. **Potential Adverse Events** Possible complications include, but are not limited to, the following: access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hand dysfunction; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; pathological hand cold intolerance; radial artery spasm, radial artery occlusion and compartment syndrome; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; vessel spasm, thrombosis, dissection, or perforation.