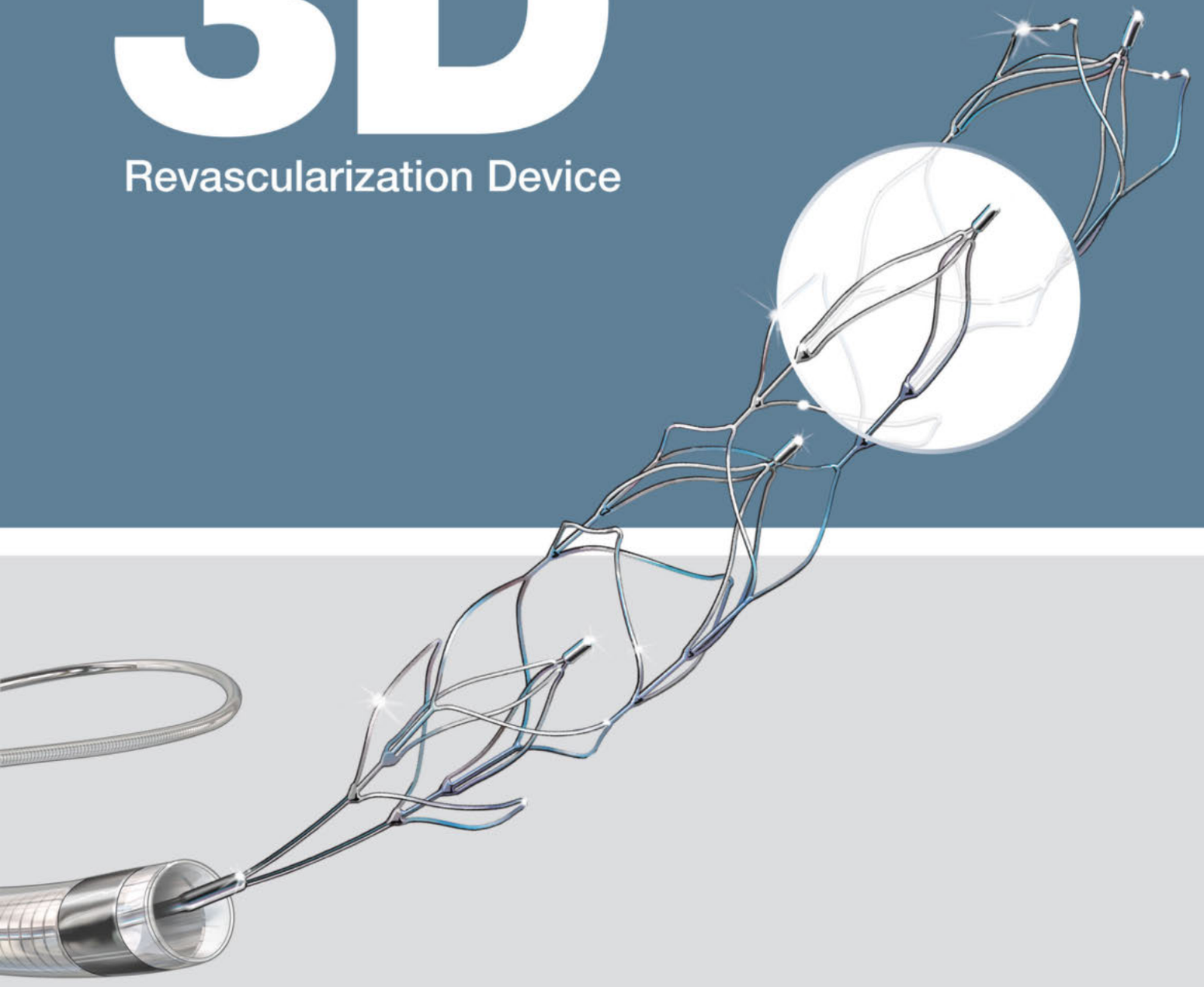
Penumbra System

3D

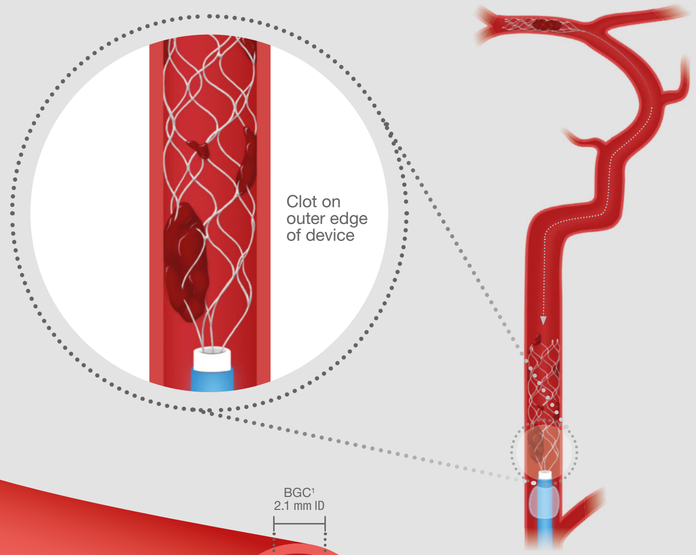
Revascularization Device

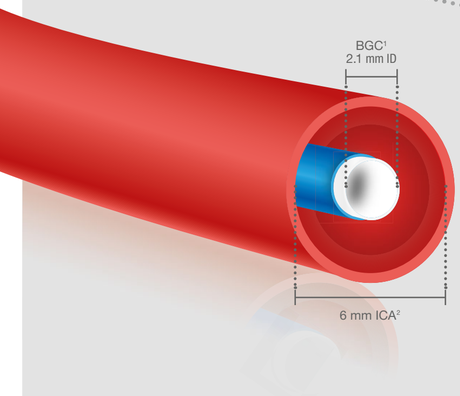


Penumbra

Hollow Tube Design Lacks Intraluminal Clot Capture

Hollow tube design
pushes clot to edge of device,
increasing potential to shear clot





8 F Balloon Guide Catheter[1]
mismatched for hollow tube retrieval
in proximal ICA

Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes.

1. 8 F Balloon Guide Catheter (BGC) measurement based on 8 F Stryker® FlowGate2®
2. Vessel diameters used are common clinical measurements.

Next Generation Technology Engineered to Retrieve Clot

Intraluminal chambers
lock clot centrally within device
for withdrawal into ACE Reperfusion Catheter

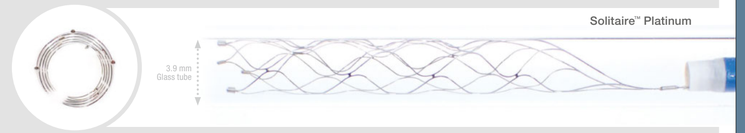
3D Revascularization Device

Lateral view[a] Down the barrel view[b]

First Generation Hollow Tube Design

Hollow tube design
expands and pushes clot against vessel wall,
increasing potential for downstream emboli

Solitaire™ Platinum



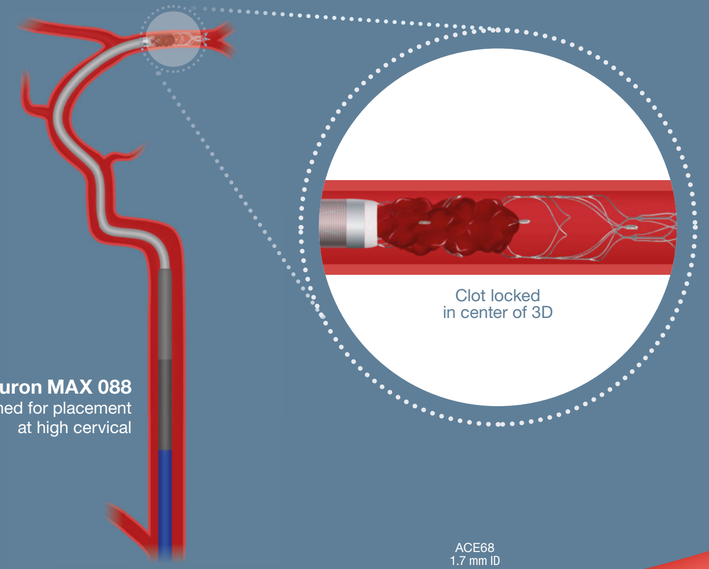
Down the barrel view[b] Lateral view[a]

Trevo® XP ProVue

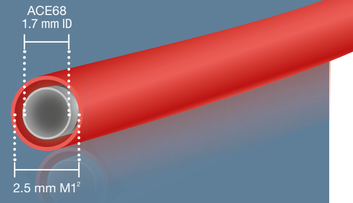
a. Photograph taken at same magnification with devices in 3.9 mm glass tube.
b. Photograph taken at same magnification with devices unconstrained in open air.
Photographs taken by and on file at Penumbra, Inc.

ACE68 + 3D System Optimised to Reduce Clot Shearing

Intraluminal chambers
designed to lock clot within center of device,
potentially reducing risk of clot shearing



Neuron MAX 088
designed for placement
at high cervical



ACE68 Reperfusion Catheter
optimally sized to provide **2.8× more clot capture** in the M1 than 8 F BGC[1] in the ICA[3]

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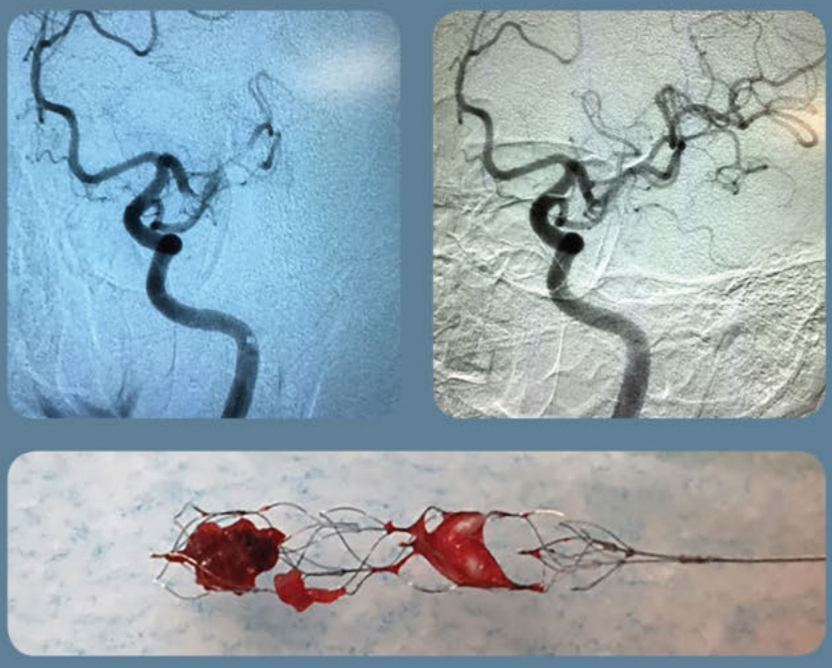
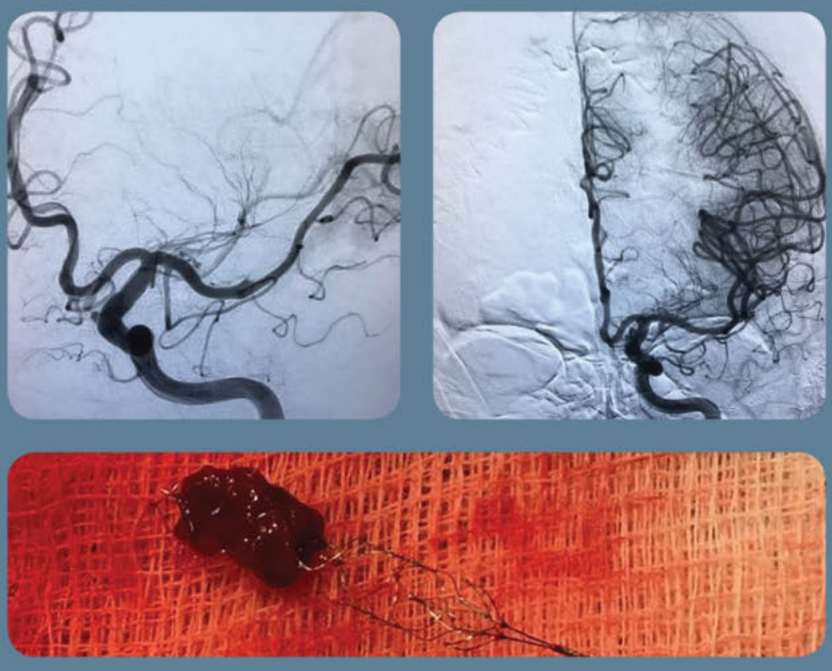
1. 8 F Balloon Guide Catheter (BGC) measurement based on 8 F Stryker® FlowGate2®
2. Vessel diameters used are common clinical measurements.
3. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

3D Revascularization Device Case Examples



Images courtesy of Dr. Zeguang Ren
Tampa General Hospital, FL, USA



Images courtesy of Dr. Raj Agrawal
Desert Radiology, Las Vegas, NV, USA

Images used with permission. Consents on file at Penumbra, Inc.

Ordering Information

Penumbra System

Catalog Number	Description	Proximal OD	Distal OD	Proximal ID	Distal ID	Working Length
Aspiration Kits						
5MAXACE068KIT	ACE68 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	6.0 F	.068"	.068"	132 cm
5MAXACE064KIT	ACE64 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.75 F	.068"	.064"	132 cm
5MAXACE132KIT	ACE60 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.4 F	.068"	.060"	132 cm
PSC054KIT	5MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.0 F	.064"	.054"	132 cm
4MAXCKIT	4MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	4.3 F	.064"	.041"	139 cm
3MAXCKIT	3MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	4.7 F (.062")	3.8 F	.043"	.035"	153 cm
Revascularisation Device		Diameter	Device Length	Working Length		
PSR3D	3D Revascularization Device	4.5 mm	26 mm	20 mm		
Delivery Microcatheter						
VEL160STR	Velocity Microcatheter					

Penumbra System with 3D Revascularization Device – Indication For Use
Penumbra System 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 Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- 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 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.
- Use prior to the "Use By" date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- 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.
- Limit the usage of Reperfusion Catheters to arteries larger than the catheter's outer diameter.

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.

Penumbra System – Indication For Use
Penumbra System Reperfusion Catheters and Separators – Indication For Use
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.
Penumbra Aspiration Tubing – Indication For Use
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.
Contraindications
There are no known contraindications.
Warnings
- 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.
- 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.

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 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.
- Use prior to the "Use By" date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- 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.
- The total time allowed to achieve patient revascularization is 120 minutes of using the Penumbra System.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- Limit the usage of Reperfusion Catheters in arteries larger than the catheter's outer diameter.

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

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 Pump MAX – Indication For Use
The Penumbra Pump MAX is indicated as a vacuum source for the Penumbra Aspiration Systems.
Contraindications
There are no contraindications.
Warnings/Precautions
- The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate.
- Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the pump so that it is difficult to operate the power cord disconnection device.
- Remove and service the pump if liquids or solids have been drawn into the vacuum pump.
- Do not use in the presence of flammable anaesthetic mixture with air or nitrous oxide.
- Do not use in oxygen rich environment.
- To prevent fire or shock hazard, use replacement fuses of equal size and rating.
- To prevent fire or shock hazard, use a replacement power cord of equal rating.
- Do not re-infuse blood or fluid from the canister back into patient.
- Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce service life of the pump. Use only water-base solvents for cleaning.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.

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 compromise the structural integrity of the device.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all defective 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 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

Product availability varies by country. Prior to use, please refer to the Instructions for Use for Penumbra System with 3D Revascularization Device, Penumbra System, Penumbra Pump MAX, Neuron MAX System, Penumbra Delivery Microcatheters for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

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