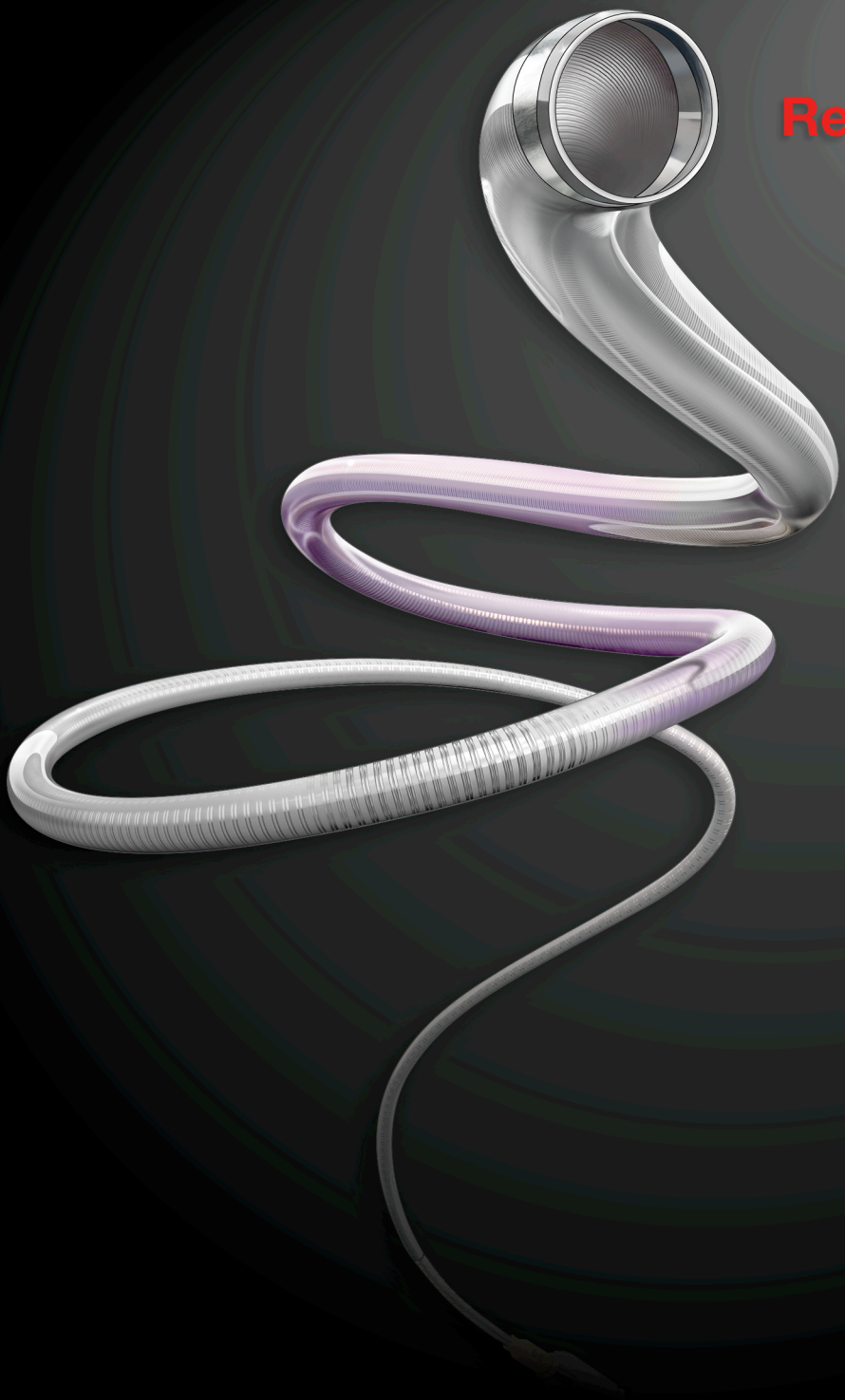
Science of Aspiration
The Penumbra System® Approach

Penumbra

ACE™68 Reperfusion Catheter

ENGINEERED FOR ULTIMATE TRACKING



Revolutionary Design from Hub to Tip

Unique Coil Winding Geometry
Creates optimal tracking profile

Extended flexible distal shaft
Enhances tracking through tortuosity

16 Transitions
Enables 1:1 force transmission

Atraumatic Tip
Improves navigation

New Proximal Polymer Segment
Maximizes pushability

ASPIRATION

POWERED FROM PUMP TO CATHETER TIP

Penumbra System®

EVOLUTION

2008

026 Reperfusion Catheter
032 Reperfusion Catheter
041 Reperfusion Catheter
Penumbra Aspiration Tubing

054 Reperfusion Catheter

2012

3MAX™ Reperfusion Catheter
4MAX™ Reperfusion Catheter
5MAX™ Reperfusion Catheter
MAX™ Aspiration Tubing

ACE™**60** Reperfusion Catheter
ACE64 Reperfusion Catheter

2016

ACE68 Reperfusion Catheter
Hi-Flow Aspiration Tubing

Pump MAX™

Generates full automated vacuum to ingest clot

The Penumbra Pump MAX™ is indicated as a vacuum source for Penumbra Aspiration Systems.

Reperfusion Catheter

Delivers Pump MAX™ aspiration to occlusion

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.

Hi-Flow Aspiration Tubing

Enables maximum aspiration

As part of the Penumbra System,® the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.™

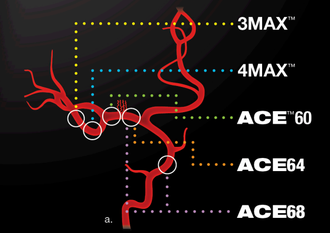
Hi-Flow Aspiration Tubing
Provides large proximal taper and increases flow rate by 25%*

Penumbra System®

ONE POWERFUL ASPIRATION SYSTEM

- Full Vacuum™
- Large trackable catheter designed for aspiration
- Hi-Flow Aspiration Tubing maximizes flow

SIZED FOR THE VESSEL



a. Recommended catheter sizing based on average vessel sizes. Physician should exercise discretion in selecting the reperfusion catheter that will safely fit in the vessel. The outer diameter of the reperfusion catheter should be smaller than the vessel.

Ordering Information

Penumbra System®

Catalog Number	Description	Proximal OD	Distal OD	Proximal ID	Distal ID	Working Length
Aspiration Kits						
5MAXACE068KIT – *New!*	ACE™68 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0F (.080")	6.0F	.068"	.068"	132 cm
5MAXACE064KIT	ACE64 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0F (.080")	5.75F	.068"	.064"	132 cm
5MAXACE132KIT	ACE60 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0F (.080")	5.4F	.068"	.060"	132 cm
PSC054KIT	5MAX™ Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0F (.080")	5.0F	.064"	.054"	132 cm
4MAXCKIT	4MAX™ Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0F (.080")	4.3F	.064"	.041"	139 cm
3MAXCKIT	3MAX™ Reperfusion Catheter+Penumbra Hi-Flow Tubing	4.7F (.062")	3.8F	.043"	.035"	153 cm
Reperfusion Catheters						
5MAXACE068 – *New!*	ACE68 Reperfusion Catheter					
5MAXACE064	ACE64 Reperfusion Catheter					
5MAXACE132	ACE60 Reperfusion Catheter					
PSC054	5MAX Reperfusion Catheter					
4MAXC	4MAX Reperfusion Catheter					
3MAXC	3MAX Reperfusion Catheter					
Separator™ Devices						
PSF054	5MAX Separator					
PSF041	4MAX Separator					
3MAXS	3MAX Separator					
Delivery Microcatheter						
VEL160STR	Velocity® Microcatheter					
Aspiration Accessories						
PMX110	Pump MAX™					
PAPS2	MAX Canister					

Neuron™ MAX 6F 088 Lumen Long Sheath

Catalog Number	Description	Tip Shape	Working Length
(Crosscut Valve, RHV, and Dilator Included)			
PNML6F088804	6F 088 Neuron™ MAX Long Sheath, 80/4 Straight		80 cm
PNML6F088804M	6F 088 Neuron MAX Long Sheath, 80/4 MP		80 cm
PNML6F088904	6F 088 Neuron MAX Long Sheath, 90/4 Straight		90 cm
PNML6F088904M	6F 088 Neuron MAX Long Sheath, 90/4 MP		90 cm

6F Select™ Catheters

Catalog Number	Description	Tip Shape	Working Length
PNS6F105H1	6F Select™ Catheter, H1		105 cm
PNS6F105BER	6F Select Catheter, BER		105 cm
PNS6F125H1	6F Select Catheter, H1		125 cm
PNS6F125SIM – *New!*	6F Select Catheter, SIM		125 cm
PNS6F125SIMV	6F Select Catheter, SIMV		125 cm
PNS6F125BER	6F Select Catheter, BER		125 cm

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.
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 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 Artherosclerotic 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.
Pump MAX™
The Penumbra Pump MAX is indicated as a vacuum source for 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 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 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 the 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 law (USA) restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.

Caution: Federal (USA) law restricts this device 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.
Product availability varies by country. Please contact your local Penumbra representative for more information.

*ACE68 flow increase using Hi-Flow Aspiration Tubing vs. MAX Aspiration Tubing. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

Penumbra

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