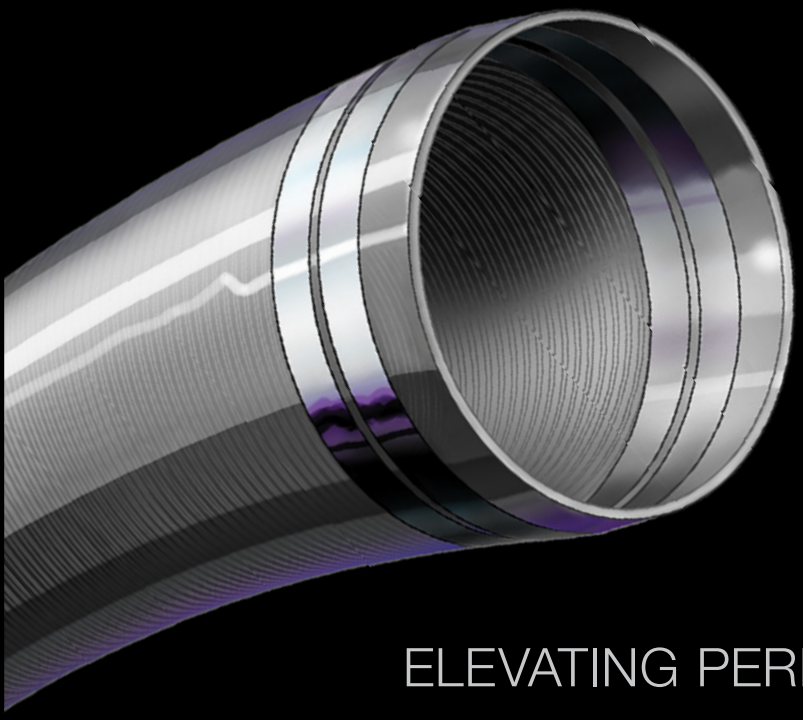
Penumbra System®



ELEVATING PERFORMANCE WITH

Penumbra

JET 7™

Penumbra

+ ENGINE™

Penumbra

Penumbra
JET 7

.072" LUMEN

20 TRANSITIONS
for trackability and navigation

ARTICULATING MARKER BAND
designed to improve tip softness

SUPERIOR FLEXIBILITY
enabled by progressive distal coil wind

ENHANCED PUSHABILITY
featuring Quad-Wire technology

FULL LENGTH PTFE LINER
designed for durability with adjunctive devices

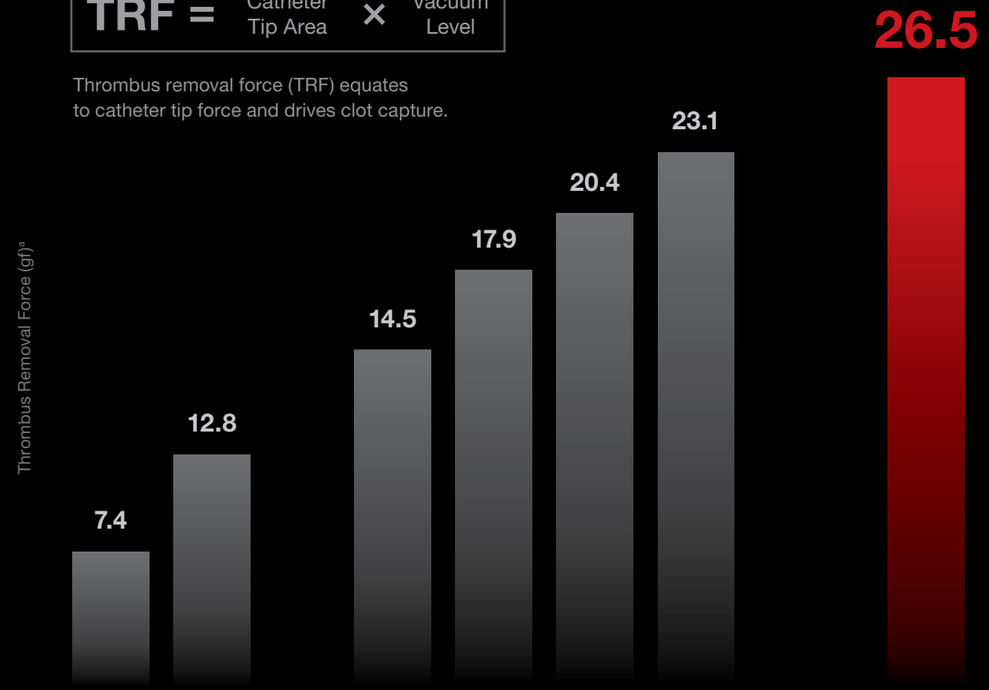
132 cm length

HIGHEST TRF

WITH PENUMBRA JET 7
POWERED BY PENUMBRA ENGINE

TRF = Catheter Tip Area × Vacuum Level

Thrombus removal force (TRF) equates to catheter tip force and drives clot capture.



Original Red Pump
-25 inHg[a]

2008

Pump MAX™
-28.5 inHg[a]

2013

Penumbra ENGINE™
-29.2 inHg[a]

Now!

a. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

ORDERING INFORMATION

Penumbra System®

Catalog Number	Description	Proximal OD (F) (in.)	Distal OD (mm)	Proximal ID (in.)	Distal ID (in.)	Working Length (cm)
Aspiration Kits						
5MAXJET7KIT	Penumbra JET™ 7 Reperfusion Catheter + Penumbra Hi-Flow Tubing	6.0 (.085)	2.16	.072	.072	132
5MAXJETDKIT	Penumbra JET D Reperfusion Catheter + Penumbra Hi-Flow Tubing	6.0 (.080)	1.65	.064	.054	138
5MAXACE068KIT	ACE™68 Reperfusion Catheter + Penumbra Hi-Flow Tubing	6.0 (.080)	2.03	.068	.068	132
5MAXACE132KIT	ACE60 Reperfusion Catheter + Penumbra Hi-Flow Tubing	6.0 (.080)	1.80	.068	.060	132
3MAXCKIT	3MAX™ Reperfusion Catheter + Penumbra Hi-Flow Tubing	4.7 (.062)	1.27	.043	.035	160
Reperfusion Catheters						
5MAXJETD	Penumbra JET D Reperfusion Catheter					
5MAXACE068	ACE68 Reperfusion Catheter					
5MAXACE132	ACE60 Reperfusion Catheter					
3MAXC	3MAX Reperfusion Catheter					
Revascularization Device						
PSR3D	3D Revascularization Device™					
Delivery Microcatheter						
VEL160STR	Velocity® Microcatheter					
Separator™ Devices						
PSF054	5MAX Separator					
3MAXS	3MAX Separator					
Aspiration Accessories						
PMXENGN	Penumbra ENGINE™					
PAPS3	Penumbra ENGINE Canister					

Neuron™ MAX 6 F 088 Lumen Long Sheath

Catalog Number	Description	Tip Shape	Working Length (cm)
(Crosscut Valve, RHV, and Dilator Included)			
PNML6F088904	6 F 088 Neuron MAX Long Sheath, Straight		90

6 F Select™ Catheters

Catalog Number	Description	Tip Shape	Working Length (cm)
PNS6F105BER	6 F Select Catheter, BER		105
PNS6F125SIM	6 F Select Catheter, SIM		125
PNS6F125SIMV	6 F Select Catheter, SIMV		125
PNS6F125BER	6 F Select Catheter, BER		125

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 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 ENGINE – Indication For Use

The PENUMBRA ENGINE is indicated as a vacuum source for Penumbra Aspiration Systems.

Contraindications

There are no contraindications.

Warnings/Precautions

- The canister is intended for single use only. Do not reuse. Reuse may result in canister cracking or vacuum filter blockages, which may result in the inability to aspirate.
- Do not block bottom air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the PENUMBRA ENGINE so that it is difficult to remove the power cord. The means of mains disconnect is to remove the power cord.
- Only use replacement fuse with correct rating (see Table 1 for fuse rating).
- Remove and service the PENUMBRA ENGINE if liquids or solids have been drawn into the PENUMBRA ENGINE.
- Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- Do not use in an oxygen rich environment.
- 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 based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the PENUMBRA ENGINE. Use only water-based solvents for cleaning.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PENUMBRA ENGINE. Otherwise, this could result in degradation of the performance of this equipment.
- Common emitters (such as RFID emitters, security systems, diathermy equipment, and portable transmitters) should not be used in close proximity to the PENUMBRA ENGINE as they can interfere with and result in degradation of the performance of the equipment.
- Equipment is not safe for MR use.
- No modification of this equipment is allowed.

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.

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.

Penumbra

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