Penumbra

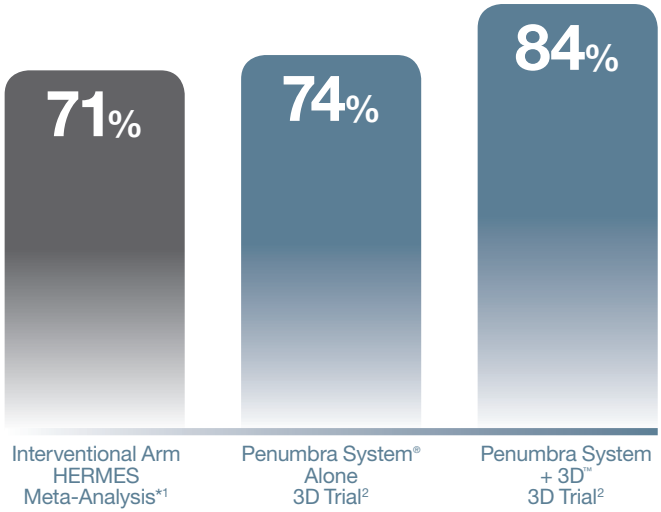
REVASCULARIZATION DEVICE™

Penumbra System®

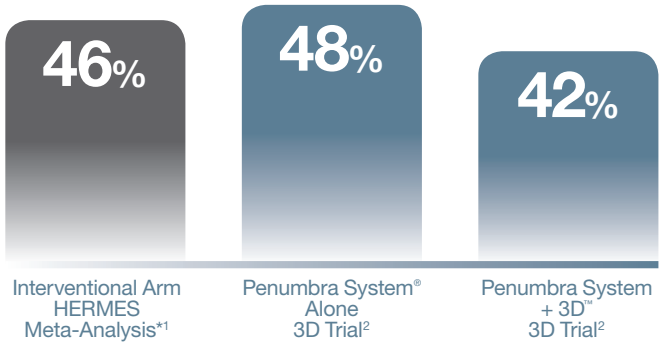
Excellent Revascularization and Good Clinical Outcomes

Analysis of Penumbra System® and 3D™

TICI 2b/3 (core lab adjudicated)



mRS ≤ 2 at 90 days



*RCTs included: MR CLEAN, ESCAPE, REVASCAT, SWIFT PRIME, EXTEND-IA

3D Trial Results[2]

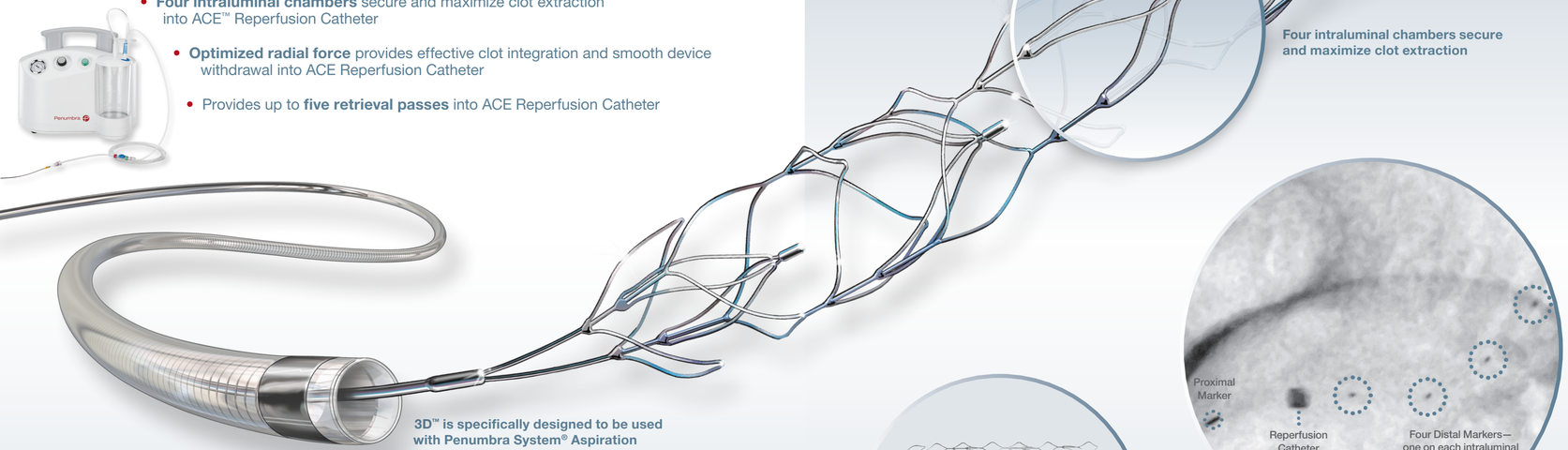
	Penumbra System	Penumbra System® + 3D™	P-Value
n	86	87	
TICI 2b/3	74%	84%	0.14
mRS ≤ 2 at 90 days	48%	42%	0.4295
SICH	3.5%	3.4%	1.0

1. Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet. 2016;387 (10029):1723-1731.
2. Nogueira RG, on behalf of the Penumbra 3D Investigators. The 3D Trial: A randomized study comparing the Penumbra Stent Retriever with aspiration vs. aspiration alone in acute ischemic stroke. Paper presented at: 9th Annual Meeting of the Society of Vascular and Interventional Neurology, November 16-19, 2016, Brooklyn, NY, USA.

3D REVASCULARIZATION DEVICE™

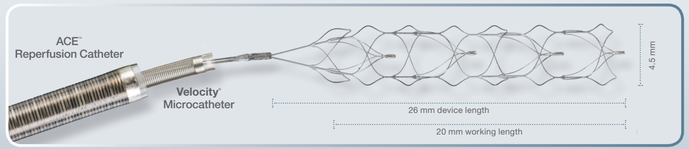
Designed for Use with Aspiration

- **Unique architecture** minimizes vessel wall contact[1] to facilitate atraumatic procedure
- **Four intraluminal chambers** secure and maximize clot extraction into ACE™ Reperfusion Catheter
- **Optimized radial force** provides effective clot integration and smooth device withdrawal into ACE Reperfusion Catheter
- Provides up to **five retrieval passes** into ACE Reperfusion Catheter

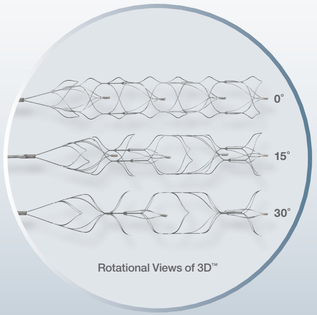


3D™ is specifically designed to be used with Penumbra System® Aspiration

Four intraluminal chambers secure and maximize clot extraction



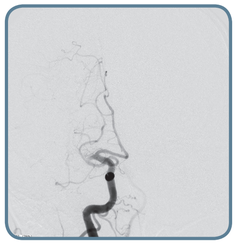
Deliver with Velocity® Microcatheter or 3MAX™ Reperfusion Catheter
Aspirate with ACE™60, ACE64, or ACE68

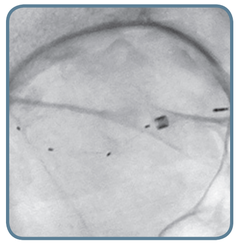


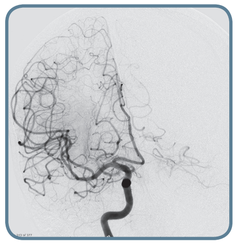
Unique architecture minimizes vessel wall contact[1]

Four distal markers along length of 3D™ provide accurate device placement

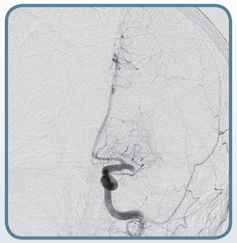
Penumbra System® and 3D™ Cases

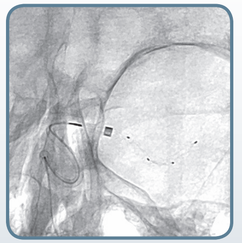


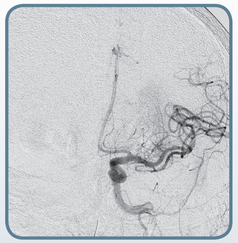




Images courtesy of Dr. Don Frei
Swedish Medical Center, CO, USA







Images courtesy of Dr. Don Heck
Forsyth Medical Center, NC, USA

1. GLP Animal Study. Data 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	ACE™68 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

Revascularization Device		Diameter	Device Length	Working Length
PSR3D – *New!*	3D Revascularization Device	4.5 mm	26 mm	20 mm

Reperfusion Catheters	
5MAXACE068	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 6 F 088 Lumen Long Sheath

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

6 F Select™ Catheters

Popular configuration

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

[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.

Product availability varies by country. 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. Images used with permission. Consents on file at Penumbra, Inc. Please contact your local Penumbra representative for more information.

Penumbra

www.penumbrainc.com

Penumbra, Inc. USA
One Penumbra Place
Alameda, CA 94502
USA
1.888.272.4606
T 1.510.748.3200
F 1.510.748.3232
order@penumbrainc.com
info@penumbrainc.com

Penumbra Europe GmbH
Am Borsigturm 44
13507 Berlin
Germany
T +49 30 2005 676-0
F +49 30 2005 676-10
order@penumbrainc.de
info@penumbrainc.de

Penumbra Neuro Australia Pty Ltd
Suite 3, Level 5, 1 Oxford Street
Darlinghurst NSW 2010
Australia
T +61-1300 817 025
F +61-1300 817 026
order.anz@penumbrainc.com