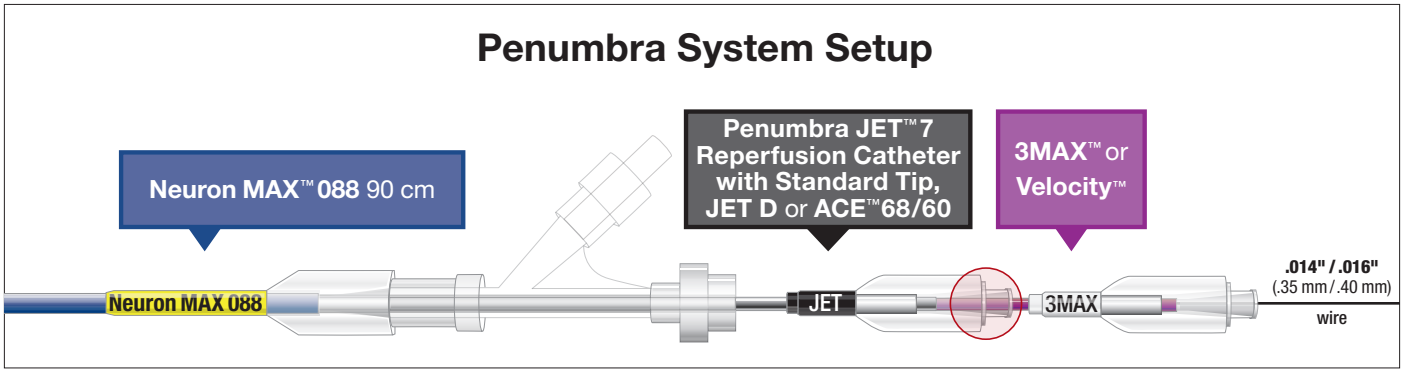
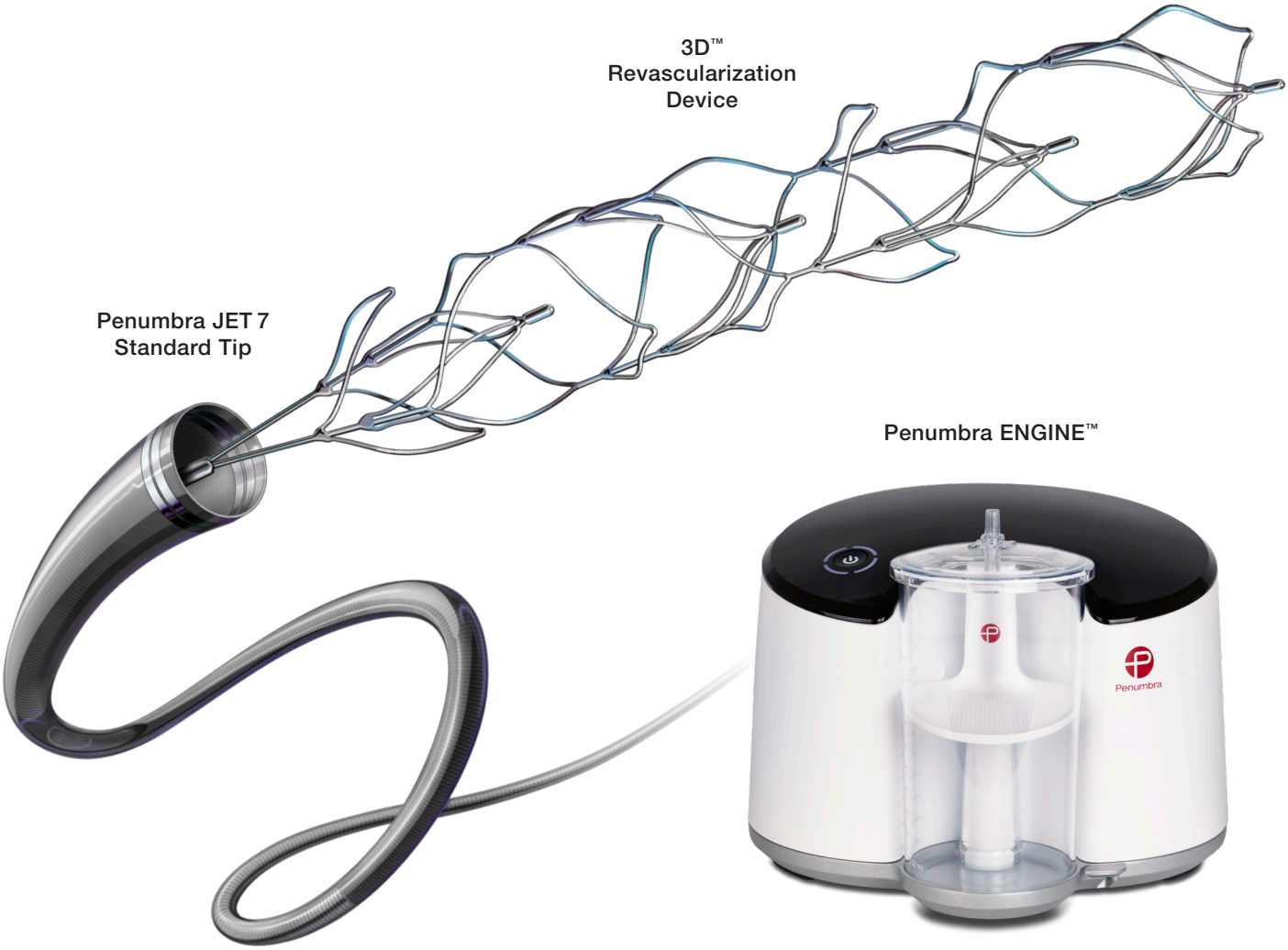
Penumbra System™ Stroke Procedure Devices

Penumbra System Setup





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Date: 2024.04.03 17:01:30 EEST
Reason: MoldSign Signature
Location: Moldova

See back page for more information.

Penumbra

Ordering Information

Penumbra System™

Catalog Number	Description	Proximal OD (F) (in.) (mm)	Distal OD (F) (in.) (mm)	Proximal ID (in.) (mm)	Distal ID (in.) (mm)	Working Length (cm)
Reperfusion Catheters						
5MAXJET7	Penumbra JET™ 7 Reperfusion Catheter with Standard Tip	6 (.085) (2.16)	6 (.085) (2.16)	.072 (1.83)	.072 (1.83)	132
5MAXJETD	Penumbra JET D Reperfusion Catheter	6 (.080) (2.03)	5 (.065) (1.65)	.064 (1.63)	.054 (1.37)	138
5MAXACE068	ACE™68 Reperfusion Catheter	6 (.080) (2.03)	6 (.080) (2.03)	.068 (1.73)	.068 (1.73)	132
5MAXACE132	ACE60 Reperfusion Catheter	6 (.080) (2.03)	5.4 (.071) (1.80)	.068 (1.73)	.060 (1.52)	132
PSC054	5MAX™ Reperfusion Catheter	6 (.080) (2.03)	5 (.065) (1.65)	.064 (1.63)	.054 (1.37)	132
4MAXC	4MAX Reperfusion Catheter	6 (.080) (2.03)	4.3 (.056) (1.42)	.064 (1.63)	.041 (1.04)	139
3MAXC	3MAX Reperfusion Catheter	4.7 (.062) (1.57)	3.8 (.050) (1.27)	.043 (1.09)	.035 (.89)	160
Revascularisation Device			Diameter (mm)	Device Length (mm)		(mm)
PSR3D	3D Revascularization Device™	n/a	4.5	26	n/a	20
Delivery Microcatheter						
VEL160STR	Velocity™ Microcatheter	2.95 (.0387) (.983)	2.6 (.034) (.867)	.025 (.635)	.025 (.635)	160
Aspiration Accessories						
PMXENGN	Penumbra ENGINE™					
PAPS3	Penumbra ENGINE Canister					
PST2	MAX Aspiration Tubing					

Neuron MAX™ 088 6 F Long Sheath

Catalog Number	Description	Tip Shape	Working Length (cm)	Distal Flexible Zone (cm)	Inner Diameter (in.) (mm)
(Crosscut Valve, RHV, and Dilator Included)					
PNML6F088804	Neuron MAX 088 6 F Long Sheath, 80/4 Straight		80	4	.088 (2.24)
PNML6F088804M	Neuron MAX 088 6 F Long Sheath, 80/4 MP		80	4	.088 (2.24)
PNML6F088904	Neuron MAX 088 6 F Long Sheath, 90/4 Straight		90	4	.088 (2.24)
PNML6F088904M	Neuron MAX 088 6 F Long Sheath, 90/4 MP		90	4	.088 (2.24)
PNML6F0881004	Neuron MAX 088 6 F Long Sheath, 100/4 Straight		100	4	.088 (2.24)
PNML6F0881004M	Neuron MAX 088 6 F Long Sheath, 100/4 MP		100	4	.088 (2.24)

6 F Select™ Catheters

Catalog Number	Description	Tip Shape	Working Length (cm)	Distal Flexible Zone (cm)	Inner Diameter (in.) (mm)
PNS6F105H1	6 F Select Catheter, 105 H1		105	9	.040 (1.02)
PNS6F105BER	6 F Select Catheter, 105 BER		105	9	.040 (1.02)
PNS6F125H1	6 F Select Catheter, 125 H1		125	9	.040 (1.02)
PNS6F125SIM	6 F Select Catheter, 125 SIM		125	9	.040 (1.02)
PNS6F125SIMV	6 F Select Catheter, 125 SIM-V		125	9	.040 (1.02)
PNS6F125BER	6 F Select Catheter, 125 BER		125	9	.040 (1.02)

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.

PENUMBRA SYSTEM – Intended Use
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

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 or burns from x-ray exposure.

PENUMBRA SYSTEM – Intended Use
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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.

PENUMBRA ENGINE – Intended Use
The PENUMBRA ENGINE is intended as a vacuum source for Penumbra Aspiration Systems.

NEURON MAX System – Intended Use
The NEURON MAX System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

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 Delivery Microcatheters – Intended 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.

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.

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Product availability varies by country. Please contact your local Penumbra representative for more information.

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