

# Penumbra Coil 400<sup>™</sup>

# **Big Coils**

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## Large Middle Cerebral Artery Aneurysm

Dr. Nelson Lobelo Hospital Infantil San José, Bogotá, Colombia

## **Indirect Cavernous Carotid Fistula**



Dr. Donald Frei Swedish Medical Center, CO

## **Reliable, Instant Detachment**



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- Alexander M, Chowdhary A, Baxter B, et al. Initial U.S. multi-center experience with Penumbra Coil 400<sup>TM</sup>: A series of 30 cases. Intervent Neuroradiol. 2011;17(suppl 1):141–146.

Milburn J, Pansara AL, Vidal G, et al. Initial experience using the Penumbra Coil 400: Comparison of aneurysm packing, cost effectiveness, and coil efficiency [Published online: 15 March, 2013]. J NeuroIntervent Surg. doi:10.1136/neurintsurg-2012-010587. 8

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Berge J, Gariel F, Marnal G, Dousset V. PC400 volumetric coils minimize radiation, reduce procedure time and optimize packing density during endovascular treatment in medium sized cerebral aneurysms. J Neuroradiol. 2016 Feb;43(1):37-42. doi:10.1016/jneurad.2015.10.002.

# **Big Advantages**



## **Vein of Galen**



Dr. Adnan Siddiqui University at Buffalo, NY

## **Transverse Sinus Embolization**



Dr. Philippe Gailloud Johns Hopkins University Medical Center, MD

## Stable, Multi-layer Metal Structure



Photograph taken by and on file at Penumbra, Inc. Rendering for illustrative purposes only.

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Frame			Fill			Fill/Finish					
COMPLEX STANDARD		COMPLEX SOFT		COMPLEX EXTRA SOFT			CURVE EXTRA SOFT				
							all				
Catalog Number	Secondary Diameter (mm)	Length (cm)									
4002C0408 4002C0506	4 5	8 6	4004C0306 4004C0310	3 3	6 10	4006C0202 4006C0203	2 2	2 3	4006U0201 4006U0202	2 2	1 2
4002C0510		10	4004C0406	4	6	4006C0204	2	4	4006U0203	2	3

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4006C0410

4002C1020	10	20
4002C1030	10	30
4002C1040	10	40
4002C1135	11	35
4002C1145	11	45
4002C1235	12	35
4002C1245	12	45
4002C1348	13	48
4002C1450	14	50
4002C1557	15	57
4002C1660	16	60
4002C1857	18	57
4002C2060	20	60
4002C2260	22	60
4002C2457	24	57
4002C2860	28	60
4002C3260	32	60

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### Indication For Use

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4002C0935

- The Penumbra Coil System is indicated for the endovascular embolization of: Intracranial aneurysms Other neurovascular abnormalities such as arteriovenous
- malformations and arteriovenous fistulae Arterial and venous embolizations in the peripheral vasculature

## Contraindications

### e no known contraindications.

Warnings The Penumbra Coil System should only be used by physicians who have received appropriate training in neuro-interventional techniques.

### Precautions

The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may

### 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 accident and pervice menutative 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.

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Potential Adverse Events

without careful assessment of the cause using Moving or torquing the device against resistance may result in damage to the vessel or device.
Maintain a constant infusion of an appropriate flush

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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

Potential Adverse Events Potential complications include, but are not limited to: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture/access site/site of entry; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; thromboembolic episodes; neurological deficits including stroke and possibly death; vascular thrombosis; post-embolization syndrome; revascularization; recanalization; inadequate occlusion; aneurysm rupture; parent artery occlusion; incomplete aneurysm filling.

- 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

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compromise the structural integrity of the device or	
device failure and/or cross-infection and potential patient injury, illness, or death.	Catalog Number
Do not use kinked or damaged devices. Do not use	4004J7
opened or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.	4004J10
Use prior to the "Use By" date.	4004J15
Use device in conjunction with fluoroscopic guidance.	4004,125





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Penumbra Coil

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# **Delivery Microcatheter**

Catalog Number	Tip Shape	ID (in.)	Distal and Proximal OD	Guidewire Compatibility (in.)	Tip Markers	Length (cm)			
PXSLIMSTR	Straight	.025	2.6/2.95 F	.020	2	150			
PXSLIM045	45°	.025	2.6/2.95 F	.020	2	150			
PXSLIM090	90°	.025	2.6/2.95 F	.020	2	150			
PXSLIM130	130°	.025	2.6/2.95 F	.020	2	150			

# 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

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.

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F 1.510.748.3232 order@penumbrainc.com info@penumbrainc.com

Product availability varies by country. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use for Penumbra Coil System and 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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