

POD[®] System



Penumbra 

www.penumbrainc.com

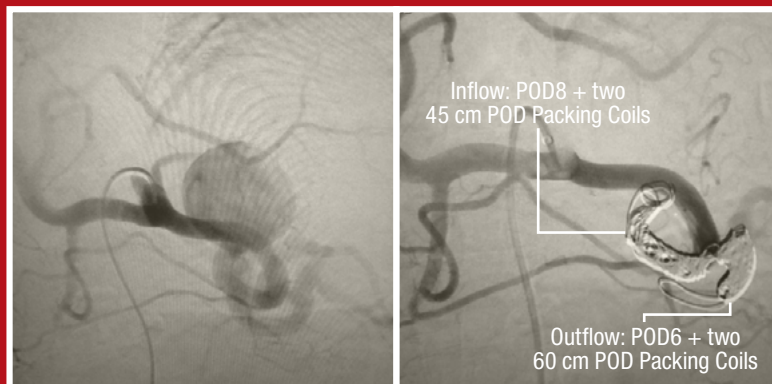
POD® System Case Examples



45 cm of POD Packing Coil in 1.5 to 3 mm diameter dilating vessel

Bronchial Artery Embolization

Dr. Amit Kakkar and Dr. Aksim Rivera, Bronx, NY



POD and POD Packing Coils occluding both inflow and outflow of splenic artery aneurysm

Splenic Artery Sacrifice

Dr. Derek Middleider, Portland, ME



POD4 and 45 cm POD Packing Coil

GDA Sacrifice

Dr. Trushar Patel, Newport Beach, CA



POD Packing Coils fall into collateral side branches in dilating vessel

Pre Fontan Embolization

Dr. Saar Danon, St. Louis, MO

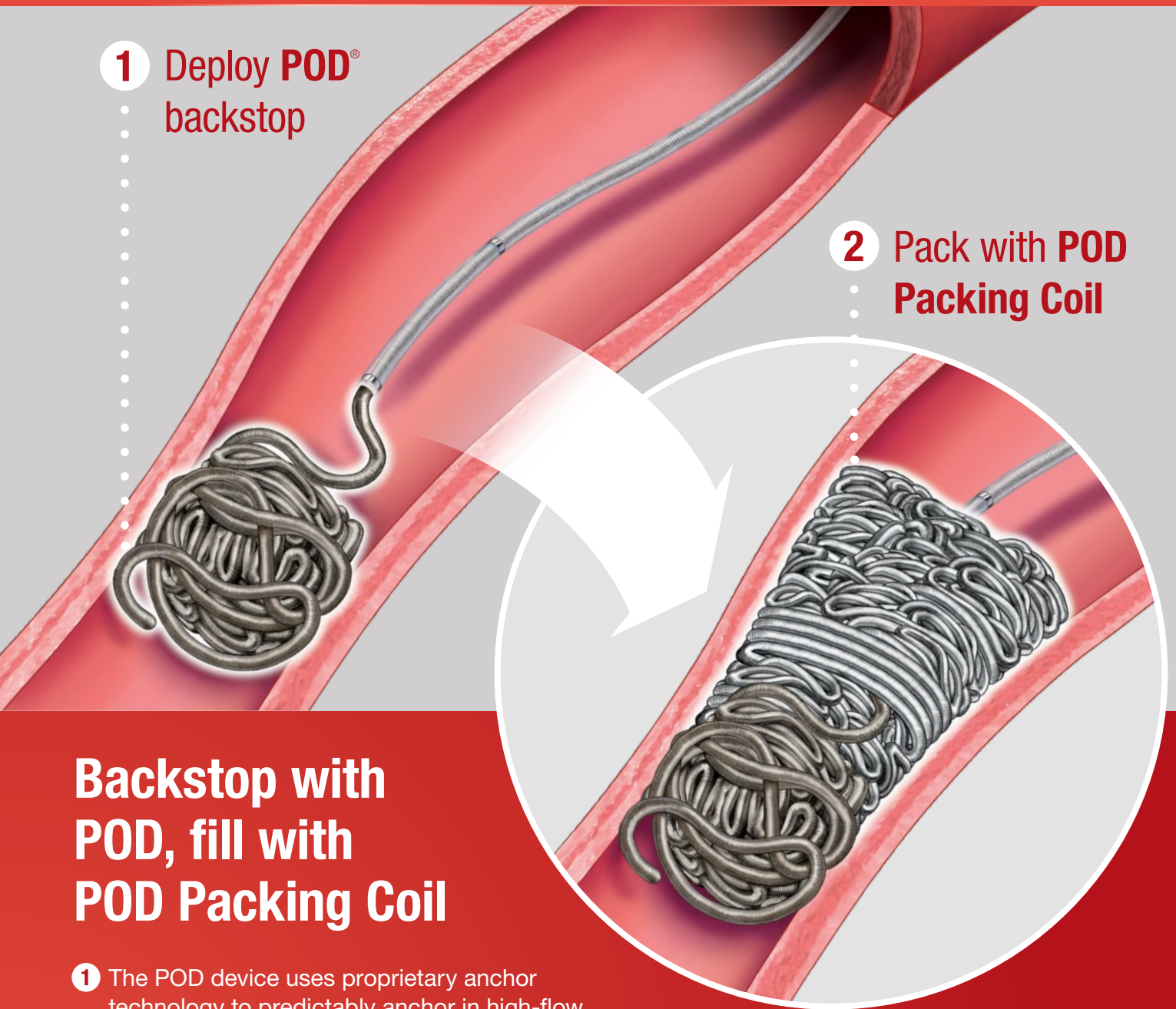
The POD[®] System

1 Deploy POD[®]
backstop

2 Pack with POD
Packing Coil

Backstop with POD, fill with POD Packing Coil

- 1** The POD device uses proprietary anchor technology to predictably anchor in high-flow vessels, then transitions to a soft packing segment for dense, focal packing.
- 2** Select a 15 cm, 30 cm, 45 cm or 60 cm POD Packing Coil to pack densely behind the POD device backstop.



delivers confident vessel sacrifice...

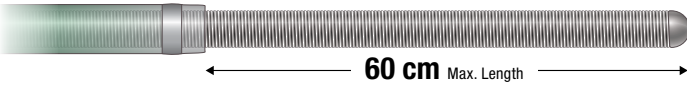

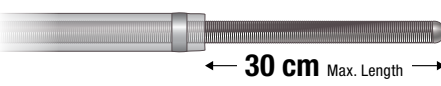
Dense Packing

Soft, shapeless design allows tight packing in any vessel size



Photographs taken by and on file at Penumbra, Inc.

Volume Advantage

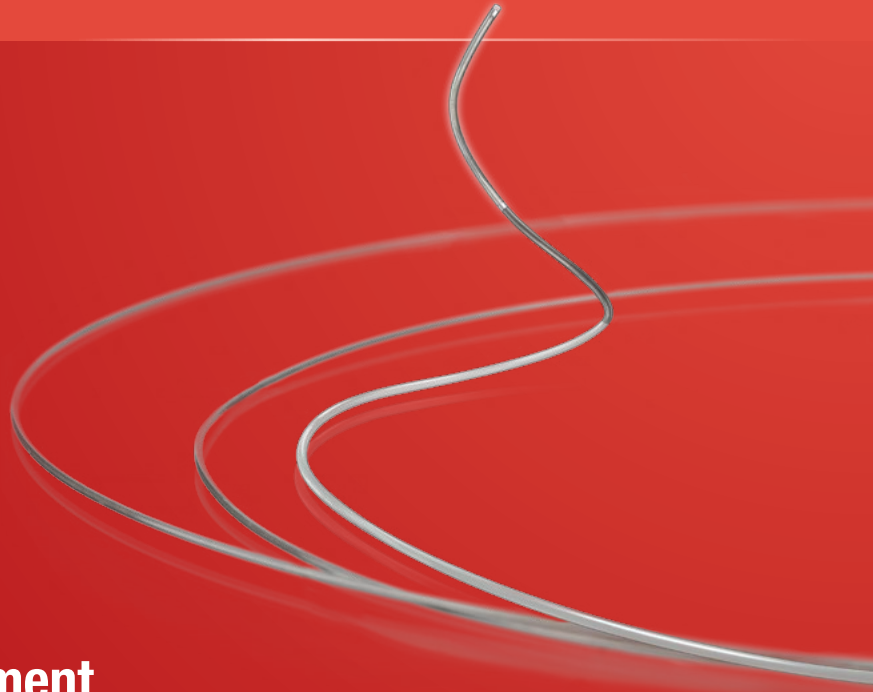
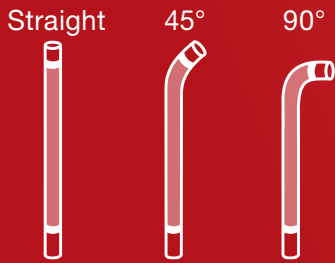
Diameter (in)	Delivery	Maximum Length	Coils Required for Equivalent Volume ^a
POD® System			
.020	LANTERN® microcatheter	 60 cm Max. Length	1
Conventional 35 Coil			
.021	035 diagnostic catheter	 40 cm Max. Length	2
Conventional 18 Coil			
.012	18 microcatheter	 30 cm Max. Length	6

a. Data on file at Penumbra, Inc.

through your high-flow microcatheter

LANTERN[®] Microcatheter

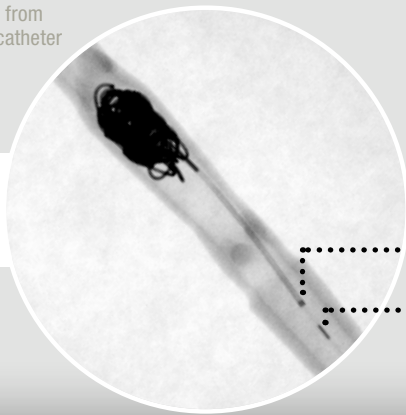
The POD[®] System is designed to be delivered through a high-flow microcatheter, proving the ability to mechanically occlude even extremely distal vessels.



Precision Mechanical Detachment

POD Packing Coil deployed from LANTERN high-flow microcatheter

Coil still within tip of catheter

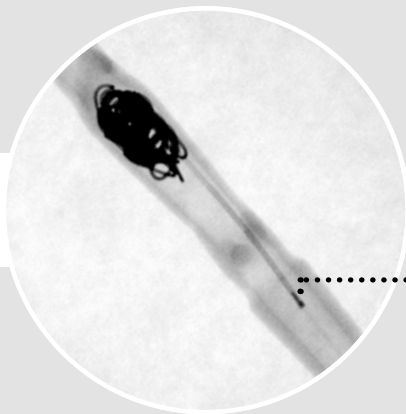


POD[®] Packing Coil is fully retractable and resheathable, allowing user to achieve ideal placement in the target vessel.

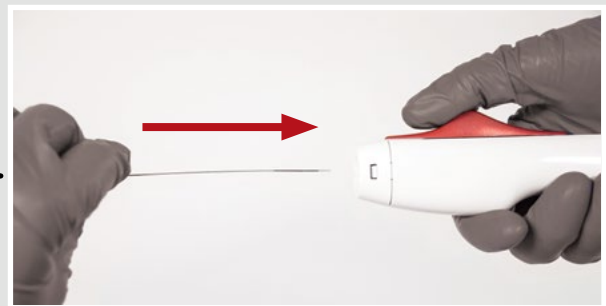
..... Proximal catheter marker

..... Coil alignment marker

Coil in detachment position



Coil alignment marker passes proximal catheter marker to form "T," indicating that POD Packing Coil can now be detached.

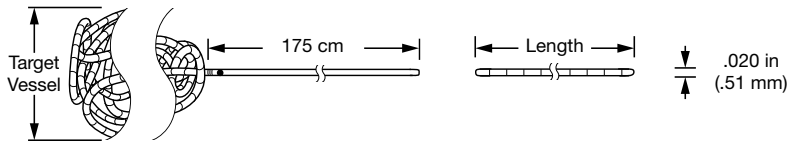


POD[®] System

- Deploy POD device backstop
- Choose desired length of POD Packing Coil

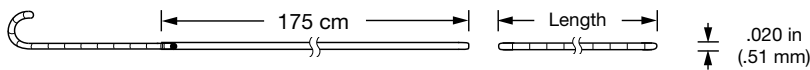
POD[®] System Ordering Information

POD[®] Occlusion Device



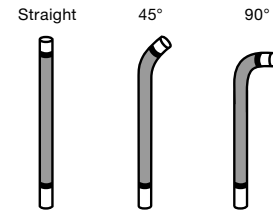
Catalog Number	Product	Target Vessel (mm)	Length (cm)
RBYP0D4	POD4	3.25–4	30
RBYP0D5	POD5	4–5	30
RBYP0D6	POD6	5–6	50
RBYP0D8	POD8	6–8	60

POD[®] Packing Coil



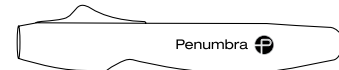
Catalog Number	Product	Length (cm)
RBYP0DJ15	POD [®] Packing Coil J-Soft 15 cm	15
RBYP0DJ30	POD Packing Coil J-Soft 30 cm	30
RBYP0DJ45	POD Packing Coil J-Soft 45 cm	45
RBYP0DJ60	POD Packing Coil J-Soft 60 cm	60

LANTERN[®] Delivery Microcatheter



Catalog Number	Tip Shape	Length (cm)	ID (in)
PXSLIMLAN115STR	Straight		
PXSLIMLAN115T45	45°	115	.025
PXSLIMLAN115T90	90°		
PXSLIMLAN135STR	Straight		
PXSLIMLAN135T45	45°	135	.025
PXSLIMLAN135T90	90°		
PXSLIMLAN150STR	Straight		
PXSLIMLAN150T45	45°	150	.025
PXSLIMLAN150T90	90°		

POD[®] Detachment Handle



Catalog Number	Product
PODH1	Detachment Handle

Product availability varies by country.

Please contact your local Penumbra representative for more information.

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

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 the Penumbra Delivery Microcatheters and POD System for complete product indications, contraindications, warnings, precautions, potential adverse events and detailed instructions for use.

Indication For Use
POD[®] 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
There are no known contraindications.

Warnings
The Penumbra POD 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 compromise

the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness or death.

- Do not use kinked or damaged devices. Do not use opened or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use device in conjunction with fluoroscopic guidance.
- Do not advance or retract the device against resistance without careful assessment of the cause using fluoroscopy. If POD cannot be advanced or retracted, withdraw the device as a unit with the microcatheter.
- 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.

Potential Adverse Events

Potential complications include but are not limited to: Acute occlusion, air embolism, allergic reaction and anaphylaxis from contrast media, aneurysm rupture, arteriovenous fistula, coagulopathy, coil herniation into parent vessel, death, device malfunction, distal embolization, emboli, embolic stroke and other cerebral ischemic events, false aneurysm formation, hematoma or hemorrhage at access site of entry, incomplete aneurysm occlusion, infection, intima dissection, intracranial hemorrhage, ischemia, myocardial infarction, neurological deficits including stroke, parent artery occlusion, peripheral thromboembolic events, post-embolization syndrome, premature device detachment, recanalization, renal failure, respiratory failure, revascularization, thromboembolic episodes, vessel spasm, thrombosis, dissection or perforation

Indication For Use

The Penumbra Delivery Microcatheters are indicated to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.

Contraindications
There are no known contraindications.

Warnings

- The Penumbra Delivery Catheters 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 Catheters in conjunction with fluoroscopic visualization.

- Do not advance or withdraw the Penumbra Delivery Catheters 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 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



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