

Peripheral **Embolization System**

Volume Advantage

A Complete Embolization Platform



d. Based on 8 mm coils: Interlock[™]-35 8 mm × 40 cm, Concerto[™] Helical 8 mm × 30 cm, Ruby Soft 8 mm × 60. Renderings for illustrative purposes only.

Softness Advantage

Embolization System Cases

15 cm 18-System **Fibered Coil** in glass model





Embolization with fibered coils: ~69% thrombus¹ 1. n = 6 sheep, 7 day mean follow-up

30 cm Large Volume **Penumbra Coil** in glass model





Engineered to pack densely, reducing reliance on thrombus formation²

Soft coils pack, forming dense metal occlusion

e. Boston Scientific® Interlock[™] 2D Helical Coil 4 mm × 15 cm delivered through Terumo® Progreat® Microcatheter into 4 mm glass tube.

. 30 cm Packing Coil delivered through Penumbra LANTERN® High-Flow Microcatheter into 4 mm glass tube.

Fohlen A., Namur J., Ghegediban H, et al. Peripheral embolization using hydrogelica in the functional observation of the second construction of

Photographs taken by and on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Renderings for illustrative purposes only

LANTERN Microcatheter

Facilitates Precise Coil Detachment



Splenic Artery Embolization





Dr. Thomas Aquisto Evanston Hospital, IL



Pelvic Congestion Syndrome









PRF

Dr. Parag J. Patel Medical College of Wisconsin, WI

Pre Fontan Embolization



Dr. Saar Danon Cardinal Glennon Children's Hospital, MO

Left Subclavian Embolization

Dr. Frank Arko Atrium Health. NC

Bilateral Iliac Embolization



Dr. Herbert Cordero St. Rose Dominican Siena Campus, NV





Dr. Naiem Nassiri Yale University School of Medicine, CT



Dr. Abindra Sigdel University of Louisville Health, KY





Dr. Justin McWilliams UCLA Medical Center, CA



GDA & Gastric Embolization

Dr. Dmitri Samoilov Medical Center Radiologists, VA

Large Volume System

.025" + High-Flow Microcatheter Compatible

		Ruby	°° Coil			
Rub	y Standard	Frame		Ruby So	ft Fill	
Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Second Diameter	ary L (mm)	ength (cm)
RBY2C0305		5	RBY4C0201			1
RBY2C0312	3	12	RBY4C0202	2		2
RBY2C0320		20	RBY4C0204			4
RBY2C0410		10	RBY4C0305	0		5
RBY2C0420	4	20	RBY4C0315	3		15
RBY2C0435		35	RBY4C0406	4		6
RBY2C0512	F	12	RBY4C0415	4		15
RBY2C0530	5	30	RBY4C0620	0		20
RBY2C0620	C	20	RBY4C0630	6		30
RBY2C0630	0	30	RBY4C0835	0		35
RBY2C0725	7	25	RBY4C0860	0		60
RBY2C0825	0	25	RBY4C1650	16		50
RBY2C0840	0	40	RBY4C2060	20		60
RBY2C1035	10	35				
RBY2C1260	12	60		DO	n ®	
RBY2C1460	14	60		PU	U	
RBY2C1660	16	60				
RBY2C1857	18	60	High-Flow Vessel Sacrifice			
RBY2C2060	20	60	0.1.1	1	*	
RBY2C2457	24	60	Catalog	Product	larget Vessel	Length
RBY2C2860	28	60	DRVDOD2	0002	2	20
RBY2C3260	32	60	DEVDOD4	POD4	3 25 4	20
RBY2C3660	36	60	RRVPOD5	P0D5	1-5	30
RBY2C4060	40	60	RRYPOD6	POD6	5-6	50
				1000	0 0	50

RBYPOD8

RRYPOD10

RBYPOD12

RBYPOD14

LANTERN® Microcatheter

night-riow i o			IVELY		
Catalog Number	Tip Shape	Length (cm)	ID (in.)		Packi
PXSLIMLAN115STR	Straight				
PXSLIMLAN115T45	45°	115	.025	Pack Beh	ind Ruby
PXSLIMLAN115T90	90°				
PXSLIMLAN135STR	Straight			Catalog	Pro
PXSLIMLAN135T45	45°	135	.025	Number	
PXSLIMLAN135T90	90°			RBYPODJ5	Packing
PXSLIMLAN150STR	Straight			RBYPODJ15	Packing
PXSLIMLAN150T45	45°	150	.025	RBYPODJ30	Packing
PXSLIMLAN150T90	90°			RBYPODJ45	Packing
PXSLIMLAN160STR	Straight			RBYPODJ60	Packing
PXSI IMI AN160T45	45°	160	025		
PXSLIMLAN160T90	90°	. 50			Valu
				Larde	e volu

	Packing Coil				
Pack Behind Ruby or POD Backstop					
atalog umber	Product	Length (cm)			
BYPODJ5	Packing Coil 5 cm	5			
BYPODJ15	Packing Coil 15 cm	15			
BYPODJ30	Packing Coil 30 cm	30			
BYPODJ45	Packing Coil 45 cm	45			
BYPODJ60	Packing Coil 60 cm	60			

POD8

P0D10

P0D12

P0D14

6-8

8-10

10 - 12

12-14

60

60

60

60

me System Detachment Handle Product

Detachment Handle

LP System

RH1

.0165" – .021" Low Profile Microcatheter Compatible

Ruby Coil LP			Packing Coil LP			
Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Product	Length (cm)	
RBYLP0102	1	2	RBYPCLP03	Packing Coil LP 3 cm	3	
RBYLP0105		5	RBYPCLP06	Packing Coil LP 6 cm	6	
RBYLP0202	2	2	RBYPCLP10	Packing Coil LP 10 cm	10	
RBYLP0204		4	RBYPCLP15	Packing Coil LP 15 cm	15	
RBYLP0210		10	RBYPCLP30	Packing Coil LP 30 cm	30	
RBYLP0304		4	RBYPCLP45	Packing Coil LP 45 cm	45	
RBYLP0310	3	10	RBYPCLP60	Packing Coil LP 60 cm	60	
RBYLP0315		15				
RBYLP0406		6				
RBYLP0415	4	15		LP System		
RBYLP0430		30	Date	achmont Han	allo	
RBYLP0510	5	10	Del		uic	
RBYLP0530		30	Catalog			
RBYLP0610	C	10	Number Product			
RBYLP0630	0	30	BI PH1 I.P. System Detachn		ent Handle	
RBYLP0740	7	40		El Gystem Detaelini	onenandio	
RBYLP0860	8	60				

Ruby Coil System – Indication for Use

The RUBY Coil System is indicated for arterial and venous embolizations in the peripheral vasculature. Contraindications There are no known contraindications

Warnings The RUBY Coil 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.
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.

POD System – Indication for Use

For POD Coils with nominal sizes < 6 mm. The POD System is indicated for the embolization of: • Intracranial aneurysms. • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. • Arterial and venous embolizations in the peripheral vasculature. For POD Coils with nominal sizes > 6 mm The POD System is indicated for arterial and venous embolizations in the peripheral vasculature.

Contraindications There are no known contraindications. Warnings The 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.
On of 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 Possible complications include, but are not limited to, the following: acute occlusion; air embolism;

allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil hernitation 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.

Penumbra LP Coil System - Indication for Use

The Penumbra LP Coil System is indicated for the 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 LP Coil System should only be used by physicians who have received appropriate training in interventional techniques. • Do not use kinked or damaged devices. Do not use opened or damaged packages. Return damaged devices and packaging to the manufacturer/ distributor. Do not advance or withdraw the device against resistance without careful assessment of the cause using fluoroscopy. If resistance is encountered when withdrawing the coil, withdraw the microcatheter until the resistance subsides. Do not rotate the delivery pusher during use. Rotating the delivery pusher may result in premature detachment, which could lead to coil damage, incorrect positioning, or vessel damage. • Verify repeatedly that the microcatheter is not under stress before coil detachment. Stored forces in the microcatheter could cause the tip to move during detachment, which could lead to lesion rupture. • Advancing the delivery pusher beyond the microcatheter tip could lead to lesion rupture. 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. • Use prior to the "Use By" date. • Use device in conjunction with fluoroscopic guidance. • 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. • 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. • The device may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective lesion treatment.

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; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure; recanalization; renal failure; respiratory failure; revacularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.

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 devices, 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.

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Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the detailed instructions for use. Please contact your local Penumbra representative for more information.

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