# Penumbra Peripheral Embolization System

## **Coil Reference Guide**

## **Large Volume System**

.025"+ High-Flow Microcatheter Compatible

Ruby <sup>®</sup> Coil								
Ruby Standard   Frame				Ruby Soft   Fill				
Initial coil in     Size 1:1 with	a large aneurysm or ve	s and vesse	ls	• Fill coil for a • Comprehens	neurysi ive coil	ms and vess	els	
Catalog	Secondary	_ L	ength	Catalog	Se	condary	Le	ngth
Number BBV2C0305	Diameter (mn	1)	(cm)	Number BBV/(C0201	Dian	neter (mm)	(	1
RBY2C0312	3		12	RBY4C0202		2		2
RBY2C0320			20	RBY4C0204				4
RBY2C0410			10	RBY4C0305		3		5
RBY2C0420	4		20	RBY4C0315				15
RBY2C0512			30 12	RBY4C0406		4		0 15
RBY2C0530	5		30	RBY4C0620		0		20
RBY2C0620	6		20	RBY4C0630		6		30
RBY2C0630	0		30	RBY4C0835		8		35
RBY2C0725	7		25	RBY4C0860		0		60
RBY2C0825	8		25	RB1401650		16		50 60
RBY2C1035	10		35	ND1402000		20		50
RBY2C1260	12		60		Doo	kina O	ail	
RBY2C1460	14		60		Pac	King G	UII	
RBY2C1660	16		60	Dook bob	und D	uby or D(		oton
RBY2C1857	18		60	Pack Del	iiiiu K			stop
RBY2C2457	20		60					
RBY2C2860	28		60					
RBY2C3260	32		60			N. 20		
RBY2C3660	36		60					
RBY2C4060	40		60				HIC: NO	
	POD®			<ul> <li>Space filling</li> <li>Designed to</li> </ul>	g "liquio confor	d metal" coi m to vessel	diameter	
High	-Flow Vesse	Sacrific	9	Catalog Number		Product		.ength (cm)
Anchor				RBYPODJ5	Pac	king Coil 5 cr	n	5
Segment	<u> </u>			RBYPODJ15	Pack	king Coil 15 c	m	15
	7 N 2			RBYPODJ30	Pack	king Coil 30 c	m	30
		683		RBYPODJ45	Pack	king Coll 45 C king Coll 60 c	m	40 60
			Packing		1 401	ang con co c		00
<ul> <li>Distal anche</li> <li>Sized 1:1 w</li> </ul>	or segment to mi ith vessel diame	nimize coil ı ter	nigration	LANTE	<b>RN</b> ®	Micro	cathe	ter
Catalog Number	Product Tar	get Vessel	Length	High-Flov	<b>v</b>   Op	timized fo	r Coil De	ivery
RBYPOD3	P0D3	3	20	Catalog		Tip Shape	Length	ID
RBYPOD4	POD4	3.25-4	30	Number	ECTD	Ctroight	(CM)	(IN.)
RBYPOD5	POD5	4-5	30	PXSLIMLAN11 PXSLIMLAN11	5T45	Straight 45°	115	025
RBYPOD6	POD6	5-6	50	PXSLIMLAN11	5T90	90°	110	.020
RRYPOD10	P0D8 P0D10	ช–ช 8–10	60	PXSLIMLAN13	5STR	Straight		
RBYPOD12	P0D12	10-12	60	PXSLIMLAN13	5T45	45°	135	.025
RBYPOD14	POD14	12-14	60	PXSLIMLAN13	5T90	90° Straight		
				PXSLIMLAN15	031K 0T45	45°	150	.025
				PXSLIMLAN15	0T90	90°	100	.020
				PXSLIMLAN16	OSTR	Straight		
				PXSLIMLAN16	0T45	45°	160	.025
				PXSLIMLAN16	OT90	90°		

### **LP System** .0165" - .021" Low Profile Microcatheter Compatible

	Ruby Coil L	.P	Packing Coil LP			
<ul> <li>Initial coil in</li> <li>Available in ::</li> </ul>	small vessels sizes as small as 1 r	mm in diameter	Space filling "liquid metal" coil     Designed to conform to vessel diameter			
Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Product	Length (cm)	
RBYLP0102		2	RBYPCLP03	Packing Coil LP 3 cm	3	
RBYLP0105	BYLP0105	5	RBYPCLP06	Packing Coil LP 6 cm	6	
RBYLP0202		2	RBYPCLP10	Packing Coil LP 10 cm	10	
RBYLP0204	<b>BYLP0204</b> 2 <b>BYLP0210</b>	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				
<b>RBYLP0406</b> <b>RBYLP0415</b> 4		6				
	4	15				
RBYLP0430		30				
RBYLP0510 5	10					
RBYLP0530	RBYLP0530					
RBYLP0610	RBYLP0610 6					
RBYLP0630	-	30				
RBYLP0740	7	40				
RBYLP0860	8	60				

### Large Volume and LP System **Detachment Handle Steps**

**One-Click Instant Detachment** 

Catalog Number RH1 RLPH1	Product Detachment Handle LP System Detachment H	landle
0	The second	Insert proximal end into detachment handle until it hubs out.
2	The company of the co	Pull back trigger of detachment handle until audible click is heard.
3	W STATE	Release trigger and remove handle. Inspect proximal end of pusher to confirm black stripe has completely separated into two sections.

#### **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; 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 Colls 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 Composition the structural integrity of the device of increase the first of commandation of integrity of the device failure and/or cross-infection and potential patient injury, liness, 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 in order against resistance market and 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 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 acurysm occlusion; infection; initima dissection; intracranial hemorrhage; ischemia; mycaralal 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 Coll 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. In interventional recliniques. \* Do not use kinking to the manufacturer/ distributor. • Do not use opened or duringed 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 prenature 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 indirecatheter could cause the tip to move during detachment, which could lead to before methy. • downedies the delivere when he more during the elivere to the during use the delivere the delivere of the elivere to the elivere of the during use in the during use is the elivere of the eliver 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 compromise the additional mention of the device of micease the risk of committee of the risk of committee of the device in conjunction with fluoroscopic guidance. As in all fluoroscopy procedures, consider all necessary procautions 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; revascularization; 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 vesse or device. • Maintain a constant infusion of an appropriate flush solution. • If flow through the device becomes 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; 

Ultimate device selection is at physician discretion. Renderings for illustrative purposes only. Individual results may vary depending on patient-specific attributes and other factors.

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 complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information. Copyright ©2020-2022 Penumbra, Inc. All rights reserved. The Penumbra P logos, Ruby, POD, and LANTERN are registered trademarks or trademarks of Penumbra. Inc. in the USA and other countries. 18216. Rev. C 02/22 USA

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