Ruby[®] Coil and POD[®] System: A Coil Platform for Fast and Easy Embolization

BY PARAG J. PATEL, MD, AND FRANK R. ARKO III, MD

enumbra, Inc. has been successful in bringing a complete embolization system to interventionalists, facilitating durable and efficient embolizations in more lesions. The embolization system is composed of three unique coil technologies: the Ruby® Coil, POD® (Penumbra Occlusion Device), and POD Packing Coil—all of which are large-volume coils that are similar in caliber to a 035 coil and are deliverable through LANTERN®, a high-flow microcatheter (Figure 1).

Coil shape and softness differentiate each technology. Ruby Coil is a versatile coil that features a three-

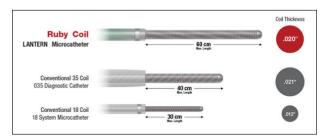


Figure 1. Volume advantage size comparison of the Ruby Coil versus a conventional 35 coil and a conventional 18 coil. Image provided by Penumbra.

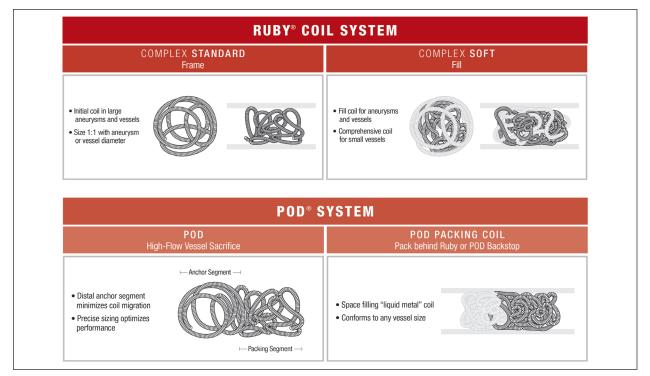
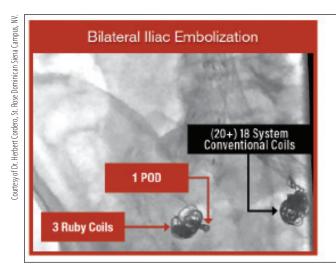


Figure 2. A complete coil embolization platform. Ruby Coil features a three-dimensional shape and is available in standard and soft configurations. Standard coils frame aneurysms or vessels, and soft coils pack densely within or behind a standard coil. POD is a progressively soft coil with a built-in anchor, helping to simplify vessel sacrifice. POD Packing Coil is like liquid metal. The device is designed to pack behind a POD or Ruby backstop. The softness of the coil can conform to any vessel that accommodates your microcatheter. Image provided by Penumbra, Inc.

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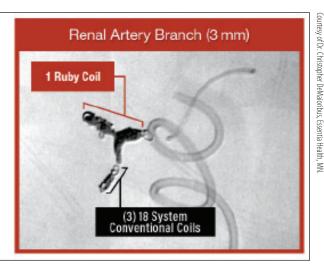


Figure 3. Dense and efficient packing in large lesions and in small vessels.

dimensional shape and is available in standard and soft configurations. Standard coils frame aneurysms or vessels, and soft coils pack densely within or behind a standard coil.

POD is designed to make high-flow vessel sacrifice easier. The distal tip of the device is stiffer, helping the coil to anchor in the vessel. Proximally, the coil becomes softer, allowing the operator to pack densely behind the anchor segment.

POD Packing Coil is like liquid metal. The device is designed to pack behind or within a POD or Ruby backstop. The extreme softness of the coil allows the device to conform to any vessel that accommodates your microcatheter, reducing the necessity to measure and giving operator the ability to deliver coils up to 60 cm in small vessels.

PRODUCT ADVANTAGES

Ruby and POD offer longer lengths, larger volume, and softer coils compared to conventional coil technologies. The volume and softness of these coils offer important advantages over conventional technologies. Not only can embolization be performed with fewer devices per case, but more embolic material can be delivered to a given landing zone. With more embolic material, there is less reliance on the clotting cascade to generate thrombus within the empty spaces between coil loops (Figure 2).

DATA

Ruby, POD, and POD Packing Coil are designed to achieve high packing density. In cerebral aneurysms, packing density is known to be a leading factor in stable embolic occlusions. 1.2 Studies have supported that dense volumetric filing > 24% of the aneurysm volume

promotes occlusion stability in the neurovasculature.^{3,4} In the peripheral vasculature, Yasumoto et al found that in aneurysms with packing density of at least 24%, no compaction or recanalization occurred.⁵

The ACE registry is a single-arm, multicenter registry that is designed to further validate the concept of packing density in peripheral aneurysms and apply the concept of packing density to vessel sacrifice. The initial analysis has shown a decrease in recanalization rates compared to conventional fibered coil technology that has been shown to recanalize in 20.4% of patients undergoing gastroduodenal artery embolization.⁶

In our own practices, we have seen a decrease in recanalization rates and less thrombus breakdown when densely packing with Ruby, POD, or POD Packing Coil.

HOSPITAL SAVINGS

In both small vessels and large lesions, Ruby, POD, and POD Packing Coil can be cost-effective compared to other detachable coils. The larger coil volumes and longer available lengths have helped to dramatically reduce the number of coils per case, limiting case cost and reducing procedure time and radiation exposure (Figure 3).

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 Enriquez J, Javadi S, Murthy R, et al. Gastroduodenal artery recanalization after transcatheter fibered coil embolization for prevention of hepaticoenteric flow: incidence and predisposing technical factors in 142 patients. Acta Radiol. 2013;54:790-794.

CASE REPORTS

SUBCLAVIAN SACRIFICE



Frank R. Arko III, MD

Chief, Vascular and Endovascular Surgery Professor, Cardiovascular Surgery Co-Director, Aortic Institute Sanger Heart and Vascular Institute Carolinas Health Care System Charlotte, North Carolina frank.arko@carolinashealthcare.org Disclosures: Consultant to Penumbra, Inc.

This patient presented with a thoracic aortic aneurysm (Figure 1). Because of the location of the aneurysm, excluding the aneurysm with a thoracic endograft required covering the right subclavian artery with the endograft. To maintain perfusion to the left arm, a carotid subclavian bypass was performed, and the left subclavian artery was embolized to prevent reflux blood flow from causing an endoleak behind the endograft.

From a radial approach, a 4-F diagnostic catheter was introduced through a 4-F sheath and tracked to the subclavian artery (Figure 2). Through the 4-F diag-

WHY I CHOSE RUBY AND POD PACKING COIL

- Large-volume devices delivered through smaller 4-F radial access
- Soft coils densely pack against the endograft, reducing recanalization

nostic catheter, a 115-cm, 45° LANTERN microcatheter was introduced and tracked distally over a 0.018-inch Glidewire® (Terumo Interventional Systems). To embolize the 12-mm origin of the subclavian artery, two 20-mm X 60-cm standard Ruby Coils were first delivered through the LANTERN, stretching longitudinally across the vessel inflow and giving POD Packing Coil a framework to pack within. Five 60-cm POD Packing Coils were then deployed, packing densely within and behind the standard Ruby Coils (Figure 3).

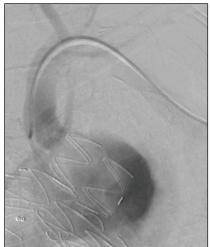


Figure 1. Preprocedure angiogram.



Figure 2. Radial access for subclavian artery embolization.



Figure 3. Postembolization angiogram.

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ILIOLUMBAR TYPE II ENDOLEAK



Manuel R. Perez-Izquierdo, MD, FACS Vascular Institute of Central Florida Orlando, Florida manuel.perez-izquierdo.md@flhosp.org Disclosures: None.

The patient underwent endovascular aortic repair in 2012. At follow-up, a type II endoleak with aneurysm sac growth of 2 cm was revealed. To treat this, access was first achieved via the right common femoral artery, and the ipsilateral hypogastric artery was catheterized with a diagnostic catheter and 035 wire. Various contrast injections showed that an iliac-to-lumbar collateral was supplying the endoleak.

A 135-cm straight LANTERN microcatheter was tracked into the first 2-mm feeding branch over a microwire. Three 2-mm X 4-cm soft Ruby Coils were deployed distally, followed by a 3-mm X 15-cm soft Ruby Coil to completely occlude the smaller feeding collateral (Figure 1).

LANTERN was then tracked into the aneurysm sac, and a subsequent angiographic run was performed showing the irregular shape and presence of mural thrombus (Figure 2). Three 8-mm X 60-cm coils were deployed into the aneurysm sac, efficiently filling the

space (Figure 3). The softness of the coils allowed them to easily conform to the irregular shape.

A fourth 8-mm X 60-cm soft Ruby Coil was then selected. The first 30 cm of this coil was deployed into the aneurysm sac, then LANTERN was tracked proximally into the inflow, and the remaining 30 cm of coil was deployed into the lumbar vessel. Only four additional soft coils were required to densely occlude the entire lumbar collateral. The completion angiogram showed no flow beyond either coil mass (Figure 4).

WHY I CHOSE **RUBY AND LANTERN**

- Ruby: 60-cm soft coils enable fast and easy embolization
- LANTERN: Low-profile, high-flow catheter easily tracks through small iliolumbar collaterals



Figure 1. The smaller feeding collateral was successfully embolized.



Figure 2. High-flow contrast injection through LANTERN visualizing the aneurysm sac and presence of mural thrombus.



Figure 3. Four 60-cm soft coils densely packed the aneurysm sac.



Figure 4. Postprocedure angiogram demonstrating complete occlusion.

PULMONARY AVM



Mahmood Razavi, MD
St. Joseph Hospital
Orange, California
mrazavi@pacbell.net
Disclosures: Consultant to Penumbra, Inc.

To embolize a pulmonary arteriovenous malformation (PAVM), access was first gained in the right common femoral vein. A long sheath was then advanced to the main pulmonary artery. Through the sheath,

WHY I CHOSE POD AND POD PACKING COIL

- POD: Reliable vessel anchoring in high-flow tortuous vessels
- POD Packing Coil: Densely packs without the need to size the vessel diameter
- Confidence in tortuous anatomy: Unlike plugs, coils can occlude both straight and curved vessels

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a diagnostic catheter was delivered to allow selection of the left pulmonary artery. Angiography was performed showing the PAVM in the left lower lobe (Figure 1).

After subselecting the feeding artery with LANTERN, further angiography was performed and revealed a second feeding vessel (Figure 2). The smaller feeding vessel was then embolized using a POD4 and 4-mm X 15-cm soft Ruby Coil behind it. A run was then performed and showed complete occlusion (Figure 3).

The LANTERN microcatheter was then tracked distally into the larger feeding vessel. To embolize the tortuous vessel, POD4 was first deployed. The stiffer distal segment anchored within the outflow venous pedicle despite high flow and tortuosity. The proximal packing segment packed densely behind the distal anchor. After delivering the POD4, POD Packing Coil was selected and densely packed, filling the remaining empty space and conforming to the inconsistent vessel diameter (Figure 4). Angiography was then performed showing that the highflow PAVM was completely occluded (Figure 5).

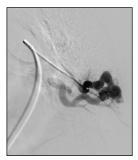


Figure 1. Preprocedure angiogram showing a PAVM in the left lower lobe.

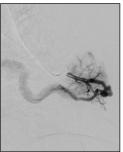
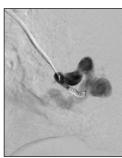


Figure 2. Superselective Figure 3. Complete angiography identifying the smaller feeding vessel.



occlusion after embolization of the smaller feeding vessel with POD. feeding vessel.



Figure 4. POD and POD Packing Coil densely packed within the larger complete embolization

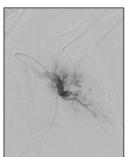


Figure 5. Postprocedure angiogram showing of the high-flow PAVM.

VARICOCELE EMBOLIZATION



Parag J. Patel, MD

Associate Professor of Radiology Division of Vascular & Interventional Radiology

Medical College of Wisconsin Milwaukee, Wisconsin papatel@mcw.edu Disclosures: Consultant to Penumbra, Inc.

Prior to intervention, ultrasound was performed, confirming the existence of a varicocele. Jugular access was achieved, and a 6-F long sheath was delivered into the left gonadal vein. With access to the gonadal vein, a LANTERN microcatheter with a 45° tip and microwire were delivered into the distal segment of the gonadal vein. A contrast injection was performed showing multiple dilated collaterals (Figure 1).

Starting distally, a POD4 was deployed. The anchor segment engaged the vessel wall, and the packing segment packed tightly behind the leading anchor (Figure 2). Behind the POD4, a soft 60-cm POD Packing Coil densely filled within the POD backstop and then

WHY I CHOSE POD PACKING COIL AND LANTERN

- POD Packing Coil: Seeks collateral vessels without catheterization, ensuring durable embolization
- LANTERN: Dual-marker band system enables precise coil deployment

packed proximally. The softness of the POD Packing Coil allowed the coil to fall into the collateral vessels automatically, without catheterizing the vessel (Figure 3). Proximally, a second coil mass was placed. Again, the POD Packing Coil found the collateral vessels and densely packed within the nonuniform vessel (Figure 4).

Precise coil deployment was aided by LANTERN's radiopaque distal 3-cm tip and dual-marker band system. This is an advantage over traditional single-marker band

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Figure 1. A high-flow contrast injection demonstrating multiple dilated collaterals.

Figure 2. Distal coil mass with POD and POD Packing Coil.





Figure 3. POD Packing Coil Figure 4. Dense packing and LANTERN as utilized to seen postprocedurally. fill the collateral vessels.

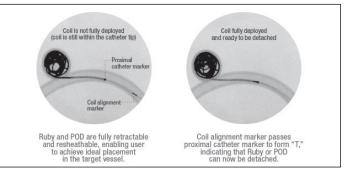


Figure 5. The LANTERN radiopaque distal shaft and proximal marker are easily visualized when the catheter tip is buried within a coil mass. The coil alignment marker enters the visual field and approaches the LANTERN proximal marker as the coil exits the catheter. When the coil alignment marker crosses LANTERN's proximal marker band ("forming a "T"), this confirms that the coil is fully outside the distal tip of the microcatheter and can be detached. Photograph taken by and on file at Penumbra, Inc.

microcatheters, which do not enable positive confirmation that the coil has completely exited the microcatheter when the tip is buried in a dense coil mass.

Ruby, POD, and POD Packing Coil work in conjunction with LANTERN. When the recessed marker on the coil pusher crosses the LANTERN proximal marker, the coil can be confidently detached, even when the tip of the catheter cannot be visualized (Figure 5).

AORTIC DISSECTION



Mazin Foteh, MD Cardiothoracic and Vascular Surgeons Austin, Texas mafoteh@gmail.com Disclosures: Consultant to Penumbra, Inc.



Figure 1. Preprocedure CT showing persistent flow into the false lumen.

The patient had a history of aortic dissection for which a thoracic endograft was placed. He subsequently developed a large 6-cm infrarenal abdominal aortic aneurysm. Additionally, an endograft was placed for this condition. Upon follow-up imag-

WHY I CHOSE RUBY AND POD PACKING COIL

- Ruby Coil: Coil sizes up to 32 mm and 60 cm allow appropriate framing and efficient filling of large spaces
- POD Packing coil: Precisely packs, stopping flow in any vessel that accommodates your microcatheter

ing, continued filling of the false lumen was observed from the celiac trunk and L2 and L3 lumbar vessels with aneurysmal expansion (Figure 1).

To access the false lumen, a transseptal needle was advanced through the true lumen of the aorta from a femoral approach. Access to the false lumen was then achieved by direct puncture above the existing endograft. A contrast injection was performed and confirmed access within the aorta (Figure 2).

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A LANTERN microcatheter was introduced and tracked distally within the false lumen. Long, large-diameter Ruby Coils were deployed, embolizing the large false lumen in a short amount of time. POD Packing Coil was then



Figure 2. Contrast injection visualizing the false lumen of the aortic dissection.



Figure 3. Completion angiogram showing no flow beyond the coil mass.

selected to pack densely, followed by Onyx® liquid embolic system (Medtronic), completely occluding the false lumen proximally. The volume and softness of POD Packing Coil significantly reduced the quantity of Onyx that would

have otherwise been required. Angiography was performed, showing no flow beyond the POD Packing Coil (Figure 3). Follow-up imaging showed complete thrombosis of the false lumen (Figure 4).

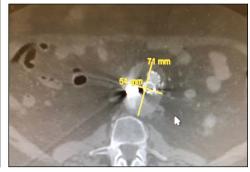


Figure 4. Follow-up CT showing complete false lumen thrombosis.

FUSIFORM SPLENIC ARTERY ANEURYSM



Thomas Aquisto, MD

Chief, Vascular and Interventional Radiology NorthShore University HealthSystem Evanston, Illinois taquisto@northshore.org *Disclosures: None.*

The patient presented with a 2-cm fusiform splenic artery aneurysm. To treat the aneurysm, we elected to

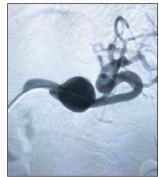


Figure 1. Preprocedure angiogram showing a high-flow tortuous vessel.

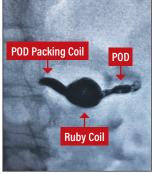


Figure 2. Completion imaging showing dense packing in the vessel outflow, aneurysm sac, and inflow.

WHY I CHOSE RUBY, POD, AND POD PACKING COIL

A complete embolization platform for high-flow anatomy, large aneurysms, and dense vessel packing

embolize both inflow and outflow vessels and the aneurysm sac. Upon accessing the proximal splenic artery, angiography was performed and showed a high-flow tortuous vessel (Figure 1). A LANTERN high-flow microcatheter was introduced and was easily tracked through the tortuosity. Once the outflow vessel was catheterized, a POD4 device was selected to embolize the 4-mm vessel. Using the 45° angle LANTERN, the POD4 easily anchored in the vessel despite the high flow.

With the outflow occluded, LANTERN was then retracted into the aneurysm sac. Four 60-cm Ruby Coils were deployed, filling the aneurysm sac. To complete the embolization, the LANTERN catheter was retracted into the inflow. With the coil mass within the aneurysm sac serving as a backstop, a 60-cm POD Packing Coil was selected. This coil packed densely, completely embolizing the inflow with a single device (Figure 2).

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NEW TECHNOLOGY SHOWCASE: POD PACKING COIL



Vishal Kumar, MD

Assistant Professor of Clinical Radiology Interventional Radiology Department University of California, San Francisco San Francisco General Hospital San Francisco, California vishal.kumar@ucsf.edu Disclosures: None.

Each year, approximately 6 million people in the United States are treated with the oral anticoagulant warfarin or newer oral anticoagulants (NOACs) to prevent blood clot formation. One major side effect of this medical therapy is severe internal bleeding. Some studies have estimated that emergency departments in the United States see approximately 29,000 cases of anticoagulant-associated bleeding annually.

Superselective coil embolization can offer a precise, minimally invasive option in patients with acute major bleeding on NOACs. During embolization, the primary objective is to achieve vessel hemostasis by deploying coils into a blood vessel in order to occlude blood flow. However, many conventional fibered coils rely on the coil fibers to promote in vivo thrombus formation, and patients might require anticoagulant reversal to ensure clotting.

Reversal of anticoagulation may be contraindicated in some cases, such as in patients with newly placed coronary, carotid, or neurologic stents, or in patients with active thromboembolic pathology. Issues related to obtaining type and screen, access to and infusion of blood products, and patients in disseminated intravascular coagulation may limit the efficacy of reversal. Additionally, reversal is not without risk as some patients experience acute transfusion reactions including fever, chills, pruritus, circulatory volume overload, allergic anaphylaxis, or transfusion related acute lung injury.

POD Packing Coil is a unique, nonfibered, bare-metal coil that is not reliant on fiber-assisted thrombus formation. The softer composition of the packing coil forms a denser coil mass, and complete vessel obliteration can be achieved with coil alone. The following case illustrates utilization of a POD

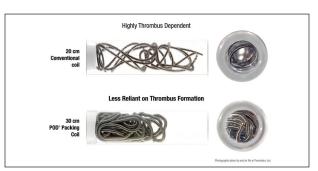


Figure 1. Softness comparison showing the advantage of largevolume, soft, bare platinum coils versus conventional technology. Soft coils pack more densely, creating cross-sectional occlusion. Photograph taken by and on file at Penumbra, Inc.

Packing Coil in the setting of massive gastrointestinal (GI) bleeding in an anticoagulated patient. (Figure 1).

CASE REPORT

The patient presented to the emergency department with a life-threatening anticoagulant-related GI bleed. Despite resuscitative measures and efforts to reverse anticoagulation, the patient remained hemodynamically unstable, necessitating emergent angiography and embolization.

Selective catheterization of the superior mesenteric artery demonstrated active extravasation from a terminal branch arising from the right colic artery (Figure 2). Under fluoroscopic guidance, a single 5-cm POD Packing Coil was deployed through a 2.6-F LANTERN microcatheter. The coil deployed distal to the catheter tip, conforming to the dilating vessel and obliterating flow within the lumen. Due to the small vessel diameter, an initial backstop coil was not necessary for POD Packing Coil to pack behind. Postembolization angiography demonstrated complete occlusion of the target vessel (Figures 3 and 4). The patient did well postprocedure and was able to restart oral anticoagulant therapy as needed.

2. Zareh M, Davis A, Henderson S. Reversal of warfarin-induced hemorrhage in the emergency department. West J Emerg Med. 2011;12:386-392.

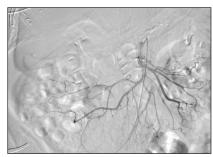


Figure 2. Distal bleed visualized in the right colic artery.

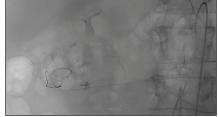


Figure 3. Contrast injection after deployment of 5-cm POD Packing Coil. The dense packing immediately stopped flow within the anticoagulated patient.

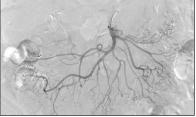


Figure 4. Postprocedure angiogram confirming complete occlusion and cessation of bleeding.

^{1.} Baron TH, Kamath PS, McBane RD. Management of antithrombotic therapy in patients undergoing invasive procedures. N Engl J Med. 2013;368:2113-2124.