Penumbra’s Complete Embolization Platform Now With Low-Profile Compatibility

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With its complete embolization platform, Penumbra has now added low-profile (LP) coil configurations to facilitate durable and efficient embolizations in more lesions. The existing peripheral embolization system is composed of three unique detachable technologies: Ruby® Coil, POD®, and Packing Coil (Penumbra, Inc.), all of which are large-volume coils, similar in caliber to 0.035-inch coils, and deliverable through the company’s high-flow LANTERN® (0.025-inch + inner diameter) microcatheter. LANTERN is designed for complex embolizations with tip shapes available in straight, 45° angle, and 90° angle configurations. In 2020, Penumbra has launched the LP system, consisting of Ruby Coil LP and Packing Coil LP, which are deliverable through low-profile microcatheters (0.0165–0.021 inch) (Figure 1).

Ruby Coils are versatile, three-dimensional (3D) coils designed to frame aneurysms or vessels, with standard and soft configurations. POD is designed for high-flow vessels with a distal anchoring segment and a proximal packing segment. Finally, Packing Coil has no stated diameter and is designed to densely pack in any size vessel. This retractable “liquid metal” technology allows operators to densely pack behind a Ruby or POD backstop with coil lengths up to 60 cm.

LP is the newest addition to the platform and offers the same technology as Penumbra’s large-volume devices but deliverable through low-profile microcatheters (0.0165–0.021 inch). Like the existing large-volume platform, Ruby Coil LP and Packing Coil LP offer longer lengths, larger volume, and softer coils than conventional 18 system coils. Ruby Coil LP is available in sizes as small as 1 mm in diameter, and Packing Coil LP is available in lengths up to 60 cm and can be delivered to any size vessel.

THROMBUS-DEPENDENT OCCLUSION VERSUS MECHANICAL OCCLUSION

Traditionally, fibered and hydrogel-coated coil technologies have been the standard for vessel and aneurysm embolization. These conventional technologies can be composed largely of thrombus to generate an occlusion (69% thrombus, 31% coil), and studies have shown high rates of recanalization (approximately 20%), with significantly higher rates of recanalization when fibered coils are placed further distally versus proximally within the target vessel (Figure 2).

Each of the Penumbra coil technologies is characterized by softness and volume. The enhanced softness of these
PENUMBRA PERIPHERAL EMBOLIZATION PLATFORM
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coils enables a mechanical vessel occlusion without the use of fibers and is therefore less reliant on thrombus formation. With a mechanical vessel occlusion instead of a thrombus-dependent occlusion, studies have shown reduced rates of recanalization (Figure 3). A recent retrospective analysis demonstrated a low rate of recanalization (2.2%) when using soft, large-volume bare platinum Penumbra coils.3

VOLUME AND COST
In both small vessels and large lesions, Penumbra’s large-volume and LP systems can be cost-effective compared with other conventional detachable coils. The large volume and longer lengths may help to reduce the number of coils used per case, which in turn may reduce case cost, procedure time, and radiation exposure (Figure 4).


RENAL ARTERY ANEURYSM

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The patient presented with a renal artery aneurysm (RAA) measuring 20 mm X 18 mm (Figure 1A). This complex aneurysm had two branch vessels emanating off the neck, making treatment challenging without sacrificing any kidney function. To preserve blood flow to the kidney, primary coil embolization of the aneurysm sac was selected as the treatment of choice with 3D-shaped Ruby Coils to frame and densely fill the aneurysm.

Access was achieved via femoral access with a 7-F curved Flexor® Ansel guiding sheath (Cook Medical) at the renal artery origin. The use of a buddy wire (V-18™ ControlWire®, Boston Scientific Corporation) helped provide support and make access for a balloon-assisted technique readily available, if necessary. The buddy wire was positioned in the upper pole segmental renal artery, a dual-marker microcatheter was tracked over a separate wire into the saccular aneurysm. The first 20-mm X 60-cm Ruby Standard initially framed the aneurysm sac (Figure 1B). Following this, a second 18-mm X 60-cm Ruby Standard was delivered to densely pack (Figure 1C). Finally, a 16-mm X 50-cm Ruby Soft was deployed to fully obliterate the aneurysm (Figure 1D). Completion angiography was performed, showing successful occlusion of the aneurysm sac (Figure 1E). With only three coils and without the use of balloon or stent assistance, the RAA was sufficiently excluded and full perfusion to the kidney was maintained.
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Trauma accounts for approximately 150,000 deaths per year in the United States. The spleen is the most commonly injured abdominal organ in trauma patients. Although institutional differences exist, patients with splenic injury and hemodynamic instability are typically managed with splenectomy. For hemodynamically stable patients with splenic injury, recommendations now favor nonoperative management supplemented with image-guided, transcatheter splenic artery embolization (SAE). SAE has a long safety profile in trauma. Furthermore, multiple studies have demonstrated that SAE improves the rate of splenic salvage in trauma patients who are managed nonoperatively.

There are two main techniques for SAE in the trauma setting: proximal SAE and distal SAE. In proximal SAE, the embolic agent is deployed in the mid-splenic artery, after the origin of the dorsal pancreatic artery but before the origin of the pancreaticomagna artery. This decreases the arterial pressure experienced by the injured spleen, allowing it to heal, while still allowing sufficient perfusion via collateral flow. In distal SAE, the catheter is advanced more selectively into the damaged artery or arteries after which they are embolized. Proximal and distal SAE are equally successful for splenic salvage for trauma patients. Yet, proximal SAE is associated with lower rates of minor complications and shorter procedural times. Given this, proximal SAE is our treatment of choice for patients with high-grade splenic injuries, including those with vascular injuries such as hemoperitoneum, pseudoaneurysms, extravasation, or arteriovenous fistulas.

The ability to deliver POD through a microcatheter system has improved our efficiency and confidence in performing proximal SAE for high-grade splenic trauma. The coils are soft enough to navigate through tortuous arteries but, in our experience, still provide excellent stability within this high-flow vessel as a result of the distal anchoring segment. Packing Coils pack tightly behind POD to provide rapid, reliable hemostasis.

**CASE EXAMPLE**

A 33-year-old woman presented to the emergency department after a motor vehicle collision. An initial CT of the abdomen and pelvis with contrast demonstrated a grade IV splenic laceration (Figure 1A) and pelvic fractures (not shown). She was hemodynamically stable and had a Glasgow Coma Scale score of 15. As is standard at our institution, she was referred to interventional radiology for
proximal SAE in the setting of high-grade splenic trauma. The right common femoral artery was accessed under sonographic guidance using a micropuncture kit after which a 6-F vascular sheath was placed over a wire. A 5-F diagnostic catheter (Soft-Vu™ RC 2, AngioDynamics) was used to perform a digital subtraction angiography (DSA) of the celiac artery (Figure 1B). The mid-splenic artery measured 5.7 mm. For stability, the diagnostic catheter was exchanged over a wire for a new 5-F diagnostic catheter (Soft-Vu™ SOS 3). The mid-splenic artery was selected using a microwire (Glidewire®, Terumo Interventional Systems) and a high-flow microcatheter. Once in satisfactory position, proximal SAE was performed using a POD8 followed by a 15-cm Packing Coil (Figure 1C). Hemostasis was obtained in the mid-splenic artery in 14 minutes after coil deployment while collateral flow to the spleen was preserved (Figure 1D). The patient was discharged from the hospital 6 days after the procedure.


Figure 1. A patient with a grade IV splenic laceration. Contrast-enhanced axial CT image demonstrating grade IV splenic laceration (white arrow) with pseudoaneurysm (black arrow) and hemoperitoneum (double white arrows) (A). DSA from the celiac axis demonstrating a patent, tortuous splenic artery (white arrow) with a pseudoaneurysm (black arrow) and early draining veins (double white arrows). The early draining veins are indicative of arteriovenous fistulae in the splenic laceration bed (B). Spot radiograph after successful deployment of a POD8 anchoring coil and a 15-cm Packing Coil (white arrow) (C). DSA demonstrating complete occlusion of the mid splenic artery with preserved collateral flow to the spleen via collateral flow (white arrow) (D).

Benign prostatic hyperplasia (BPH) is an extremely common disease state affecting 50% of men aged > 50 years. With BPH, enlargement of the prostate can result in compression of the urethra and restrict the flow of urine, resulting in lower urinary tract symptoms (LUTS) such as frequency, weak urinary stream, and nocturia. The prostate is a hypervascular organ, receiving blood supply from

Ruby Coil LP and Packing Coil LP: Now Deliverable Through Low-Profile Microcatheters

Prostate Artery Embolization

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the bilateral prostatic arteries. Embolization of these arteries causes partial ischemic necrosis of the prostate, resulting in reduced size of the gland and subsequent relief of the urethral compression and LUTS.

Smaller particulate embolics are the embolization material of choice for prostatic artery embolization (PAE), as they can achieve permanent, dense, distal occlusion of the prostatic blood supply. The prostatic arteries are often small and tortuous, with variable origins, making PAE technically challenging. Furthermore, collateral branches to other organs, such as the bladder, rectum, or penis, may arise from the prostatic circulation; in some cases, these must be occluded (coil protected) to prevent passage of particles into nontarget tissues. The offending collateral branch is often very small and the landing zone is often short, requiring precise placement of a small and soft coil to produce occlusion of the collateral without interrupting flow to the prostate itself.

In the following case, a single 1-mm X 2-cm Ruby Coil LP provided coil protection within a 0.5-mm collateral branch. Dense packing of a soft and small coil in this diminutive vessel helped reduce the risk of nontarget embolization, which allowed me to more completely and confidently embolize the prostate.

**CASE STUDY**

A 79-year-old man presented with BPH, resulting in recurrent bouts of gross hematuria and severe LUTS. Prostate volume was 105 mL. He refused surgical therapy and was referred for PAE to reduce bleeding and improve LUTS. From a transradial approach, a 5-F, 120-cm Berenstein catheter was advanced into the left internal iliac artery, and a 0.021-inch inner-diameter, 150-cm microcatheter was advanced into the prostatic artery. With access into the prostatic artery, contrast was injected (Figure 1). A collateral vessel was identified that passed from the prostatic circulation toward the base of the penis. This required coil protection to avoid nontarget embolization of particles. The microcatheter was passed into the collateral branch, and two 1-mm X 2-cm Ruby Coil LPs were densely packed in the vessel (Figure 2). After coil protection, repeat prostatic artery angiography demonstrated preserved flow into the prostate and no further nontarget supply (Figure 3).

To embolize the prostate itself, 300–500-µm microspheres were injected until complete stasis was achieved. After fully embolizing the prostatic artery, a 1-mm X 5-cm Ruby Coil LP was deployed proximally in the prostatic artery (Figure 4). A dense metal occlusion proximally was utilized to help prevent recanalization of the prostatic artery, which could result in recurrence of hematuria. The right prostatic artery was then embolized using a similar technique.

The procedure was uncomplicated and the patient was discharged home the same day with only minimal postembolization side effects. At 1-month follow-up, the patient reported significant improvement in LUTS and no further episodes of hematuria.

**WHY I CHOSE LP**

- The only commercially available 1-mm peripheral coil
- To selectively occlude and mechanically occlude small vessels
- Compatibility with low-profile microcatheters

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Superselective coil embolization is a new treatment method in acute bleeding procedures to achieve vessel hemostasis. Many conventional fibered coils promote in vivo thrombus formation, which relies on the body’s natural clotting cascade. However, patients may be on oral anticoagulation, warfarin, or other newer oral anticoagulants, which can make the use of thrombus-dependent embolics challenging. Gelfoam® (Pfizer, Inc.) or particles are typical treatment tools to embolize bleeds, but the lack of control they offer may prove challenging. With a complete embolization platform and the only commercially available 1-mm peripheral coil, Penumbra has both large-volume coils and LP coils to selectively and mechanically occlude vessels.

**CASE 1**

The patient presented with two distal bleeds off the upper left hepatic artery (Figure 1A). Access was first gained through the celiac artery with a S-F Kumpe diagnostic catheter through a 5-F sheath. Through a 2.3-F Prowler® Plus microcatheter (Codman Neuro [Johnson & Johnson]), the first proximal bleed was selected and contrast injection demonstrated active extravasation (Figure 1B). A single 3-mm X 10-cm Ruby Coil LP was deployed into the 2.5-mm bleeding vessel (Figure 1C), occluding the branch with a single coil. Following this, a second further distal bleeding vessel was selected, and two 2-mm X 10-cm Ruby Coil LPs were deployed (Figure 1D). The softness of these coils enabled embolization of the side branch that was feeding the bleed without catheterization. With the use of only three coils, both hepatic bleeds were successfully embolized, with no flow observed through the coil masses (Figure 1E).

**CASE 2**

A patient presented with an emergent massive hemorrhoid bleed at midnight requiring a blood transfusion and pressors (Figure 2A). These cases are often challenging due to the complex submillimeter collateral arteries that branch off the internal iliac artery. Upon gaining femoral access ipsilaterally, the distal 1-mm feeding vessel was selected with a 2.3-F Prowler® Plus microcatheter, and a 1-mm X 5-cm Ruby Coil LP was deployed. A 6-cm Packing Coil LP was packed behind the Ruby Coil LP, conforming to the vessel and obliterating flow (Figure 2B).

With only two coils, the bleed was embolized, with a mechanical and durable occlusion. With a 1-mm peripheral coil now available, new applications for coil embolization in sub–1-mm vessels are now possible.
As a vascular surgeon, performance of aortic endografting for abdominal (EVAR), thoracoabdominal (FEVAR), and thoracic (TEVAR) aortic pathologies are an integral part of my practice. An Achilles heel of treating aneurysm and dissection pathologies is the continued perfusion of the aneurysm sac or false lumen, also known as endoleaks. Branch vessel endoleaks in EVAR and FEVAR resolve in a time-dependent fashion, with 30% of patients having one at 1 month and that number decreasing to 10% by 1 year. Yet, about 1% to 2% will be associated with aortic diameter enlargement. Aneurysm sac growth > 5 mm is the recommended threshold for treatment of type II endoleaks, and this is most commonly done with embolization therapies.

TRADITIONAL ENDOLEAK MANAGEMENT

Traditional embolization began shortly after the advent of EVAR with pushable 0.035-inch or 0.018-inch coils. The smaller diameter facilitated delivery through smaller vessels. However, the lack of control with pushable coils led to nontarget embolization (NTE); thus, these devices had to be retrieved or there was a consequence of unintended vessel loss. The growth in the neurovascular space of brain aneurysm treatment led to the development of small-diameter detachable coils, allowing better packing density and control. These devices were not ideally designed for treatment of large vessels and large cavities from endoleaks. Liquid embolics were touted with the ability to fix this issue by using Onyx® (Medtronic) or N-butyl cyanoacrylate (NBCA). The high cost of Onyx and risk of catheter retention and NTE with NBCA have limited the adoption of these technologies by many interventionalists.

In TEVAR, type II endoleaks may occur after carotid subclavian bypass or if the subclavian orifice encompasses the aneurysmal area or if it is involved in dissection. In the past, we have used pushable coils successfully, but have had complications of NTE into the aorta, vertebral artery, or the distal subclavian artery. We have used 0.035-inch detachable coils, which could not be delivered through hydrophilic catheters and could potentially become stuck in 5-F catheters. In search of a better solution, we attempted to use detachable plugs but found several instances of continued vessel patency with flow through the plugs.

EVALUATION AND ADOPTION OF PENUMBRA’S EMBOLIZATION PLATFORM

Penumbra’s embolization platform was evaluated in 2019 by our value analysis committee and was trialed by interventional radiology, interventional neuroradiology, and vascular surgery. During the trial, we found Ruby Coil to be the largest coil available from any manufacturer and deliverable through a high-flow microcatheter. The ability to remove, retrieve, and reposition coils was rated by us as excellent. We have been able to use the Ruby Coil, POD, and Packing Coils to treat endoleaks through transarterial, translumbar, and transcaval routes without difficulty. Ruby Coil’s versatile 3D shape was noted to easily frame large endoleak sacs. Using the Packing Coil, we found an easy ability to densely pack cavities to allow sac occlusion. In the setting of high-flow vessels, we have used POD as our first coil. POD anchors in high-flow vessels, allowing for scaffolding with Ruby Coils and Packing Coils behind it. I have been impressed with the availability of large and long sizes, up to 40 mm X 60 cm, which allows filling of large cavities with fewer coils, leading to potentially lower procedural costs. Penumbra’s embolization platform was approved for the Cleveland Clinic health system after clinician input in 2019 and continues to be helpful in the management of our patients with endoleaks.

SUMMARY

Endoleaks continue to be an inherent challenge to treat through an endovascular approach, and a variety of embolic therapies have been used. Compared with existing conventional coil technology, Penumbra’s large-volume embolization system has simplified our approach to endoleak management and has reduced the overall procedural cost as compared with other detachable coil systems.

This patient presented with an enlarging abdominal aortic aneurysm (AAA) sac after endovascular aneurysm repair (EVAR). The AAA had gradually increased from 5 cm to 5.8 cm and a lumbar type II endoleak was observed on CTA. Conventional angiography was performed, and transarterial embolization was attempted several times but was unsuccessful due to the inability to navigate a microcatheter through the small, tortuous collateral arteries needed to access the AAA sac and endoleak cavity. The CT scan showed favorable anatomy with a good window for posterior access to the endoleak cavity using a direct translumbar AAA sac puncture (Figure 1A).

The patient was placed in the prone position under general anesthesia. An AccuStick™ introducer system (Boston Scientific Corporation) was used to gain translumbar access to the AAA sac. A 21-gauge needle was advanced into the AAA sac under fluoroscopic guidance and blood return was confirmed. A V-18™ ControlWire® guidewire (Boston Scientific Corporation) was inserted, the AccuStick™ introducer sheath was advanced into the AAA sac via Seldinger technique, and a Tuohy Borst adapter was connected. A 2.6-F, 115-cm LANTERN microcatheter was delivered through the introducer sheath into the AAA sac and was used to selectively catheterize the outflow lumbar artery (Figure 1B). A POD4 was initially delivered through the LANTERN microcatheter to anchor within the outflow vessel. Once the POD4 anchored as a backstop, two 60-cm Packing Coils were deployed behind the POD4 to fully occlude the vessel (Figure 1C). Finally, additional 60-cm Packing Coils were placed into the endoleak cavity within the AAA sac to obliterate the endoleak "nidus." Final angiography showed successful treatment of the endoleak with elimination of flow (Figure 1D). Posttreatment duplex ultrasound also confirmed elimination of the endoleak.
The patient presented with a type I b and type II endoleak supplied by the inferior mesenteric artery (IMA) and a lumbar artery after EVAR in 2004, with aneurysm growth of 11 mm over the last year. The concern for this patient was that there could be a variety of sources causing the increase in size of the aneurysm, which was most likely due to a type I b and potentially a type III endoleak. A type II endoleak was also seen as potential for continued growth after repair of the type I b endoleak. The staged repair included first relining each limb and the main body of the graft. After these repairs, we proceeded with treating the type II endoleaks. The first branch filled the lumbar artery off of a lateral circumflex of the left iliofemoral system. A high-flow contrast injection via the LANTERN revealed an iliolumbar vessel feeding the sac (Figure 1). LANTERN was tracked through into the iliolumbar vessel feeding the aneurysm sac. The feeder vessel was embolized initially using a 4-mm X 35-cm Ruby Standard, followed by another 4-mm X 35-cm Ruby Standard packed behind the first coil (Figure 2). Once this vessel was obliterated, we accessed the superior mesenteric artery (SMA) with a 6-F TourGuide™ (Medtronic). Due to the long and tortuous collateral pathway that would require navigation to access the IMA, a long 150-cm LANTERN high-flow microcatheter was selected due to its trackable coil wound design. In addition to the length, the radiopaque distal shaft is particularly helpful in these cases, as it can easily be tracked through the catheter and used to guide the placement of coils within the aneurysm sac.

Figure 1. Preprocedural angiogram performed to confirm access into the aneurysm sac.

Figure 2. A 36-mm X 60-cm Ruby Standard was deployed initially to frame the sac, followed by Packing Coils to fill in the lumbar origins.

Figure 3. Completion angiogram demonstrated no further flow into the aneurysm sac.

**WHY I CHOSE LANTERN**

- Designed as a highly trackable high-flow microcatheter with enhanced visibility due to its 3-cm radiopaque distal shaft.
seen next to or on top of the end endograft. The LANTERN was easily tracked into the main branch of the IMA vessel via the SMA and positioned proximally under visualization due to its 3-cm radiopaque shaft (Figure 3). Three additional Ruby Coils fully occluded the IMA (4-mm X 35-cm Ruby Standard, 4-mm X 35-cm Ruby Standard, 4-mm X 10-cm Ruby Standard). Completion angiography revealed no evidence of persistent endoleak while preserving the side branch of the IMA (Figure 4).

Figure 1. Preprocedural angiogram showing an enlarged type II endoleak (A). Two Ruby Coils deployed into the first iliolumbar vessel feeding the sac (B). The LANTERN high-flow microcatheter positioned at a second collateral vessel off the IMA feeding the sac with its visible 3-cm marker (arrow) (C). Completion angiogram showing mechanical occlusion of the collateral vessel with three Ruby Coils, while preserving the side branch (D).

Disclaimer: The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive of all patients. Individual results may vary depending on a variety of patient-specific attributes. Renderings are for illustrative purposes only.