Supplement to

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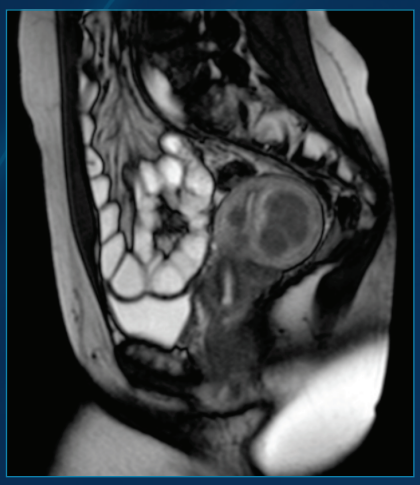
Endovascular TODAY

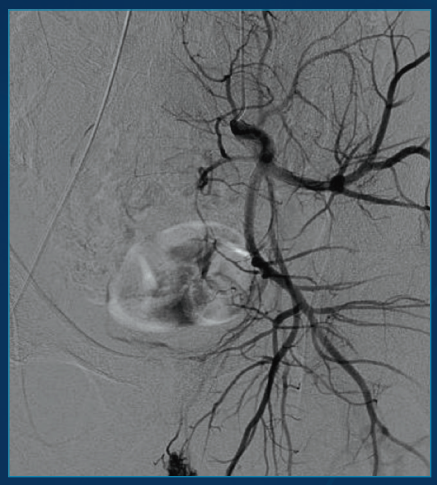
April 2016

THE FIGHT IS ON

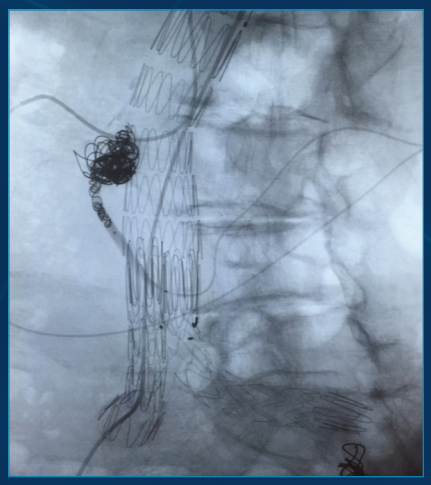
Cases in Advanced Embolization Techniques



CONDITION:
Uterine Fibroids



CONDITION:
Traumatic Priapism



CONDITION:
Type II Endoleak

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Total Fibroid Devascularization With Embozene™ Microspheres

BY LINDALVA BERTELLI FERNANDES, MD

CASE PRESENTATION

A 34-year-old woman presented with pelvic pain, abdominal bloating, and menometrorrhagia (ie, a condition of prolonged bleeding occurring more frequently than normal). She had no prior pregnancy but was seeking treatment from interventional radiology to relieve her symptoms for the possibility of future pregnancy. MRI confirmed the presence of uterine fibroids. Her uterine volume was 134 cm^3 (8.1 X 5.8 X 5.5 cm), and she had three fibroids of significant size. The dominant intramural fibroid was 18.9 cm^3 (4.0 X 3.5 X 2.6 cm) and extended up to the endometrial cavity, located in the uterine posterior wall. The two smaller fibroids were 1.9 cm^3 and 0.9 cm^3; one was intramural and the other was submucosal. The fibroids were enhanced after administration of paramagnetic endovenous contrast (Figure 1).

PROCEDURE DESCRIPTION

Right femoral access was established by placing a 5-F (1.67-mm) introducer sheath, followed by very selective catheterization of the uterine arteries. First, we accessed the uterine arteries with a selective 5-F (1.67-mm) uterine catheter, and then more distal access was obtained with a 2.7-F (0.9-mm) microcatheter. A pre-embolization selective arteriogram showed uterine-to-ovary anastomosis on both sides (Figures 2 and 3). Given this presentation, we chose 900-µm Embozene™ Microspheres for embolization.

We used two vials, each with 2 mL of microspheres, to complete the bilateral embolization. We mixed the microspheres with 7 mL of Ultravist® 300 iodinated contrast (Bayer HealthCare LLC) in a 20-mL syringe, and we injected the microspheres with a 1-mL syringe and three-way stopcock. We performed the embolization by slowly injecting under fluoroscopic guidance.

Bilateral embolization was performed to occlude the ascending branches of the uterine arteries leading to the patient's fibroids. Then, after 5 minutes, we performed another arteriogram with a power injection of 8 mL of contrast (Ultravist 300) at a flow rate of 1.5 mL/sec and a frame of 0.5 seconds. This injection showed patency and preservation of the main uterine arteries and cervical branches.

FOLLOW-UP AND DISCUSSION

Follow-up imaging was performed at 4 and 8 months postembolization. At 4-month follow-up, the patient reported remission of the menometrorrhagia, and her uterine volume had decreased from 134 cm^3 at presentation to 77 cm^3, a reduction of 42%. MRI showed total fibroid devascularization of the dominant intramural

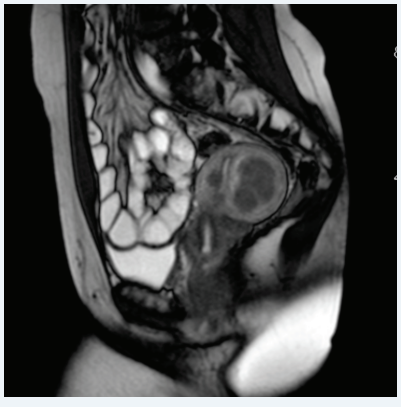

Figure 1. Pre-embolization MRI.

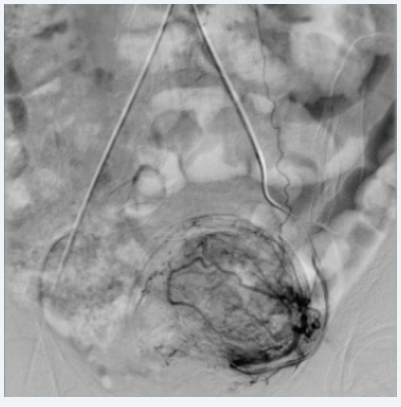

Figure 2. Angiogram of the left uterine artery.

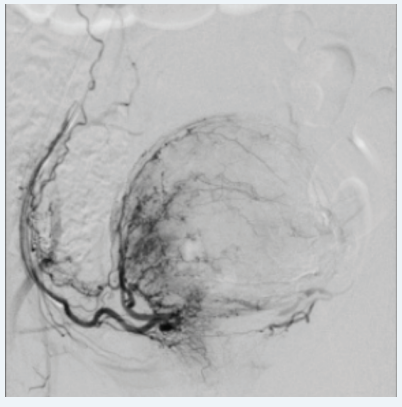

Figure 3. Angiogram of the right uterine artery.

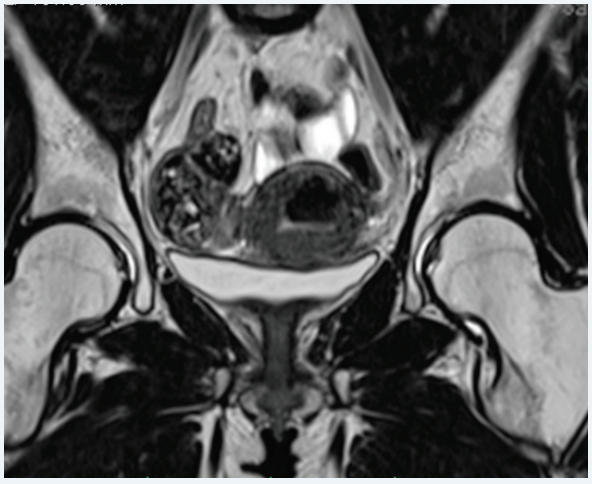

Figure 4. MRI at 4 months postembolization.

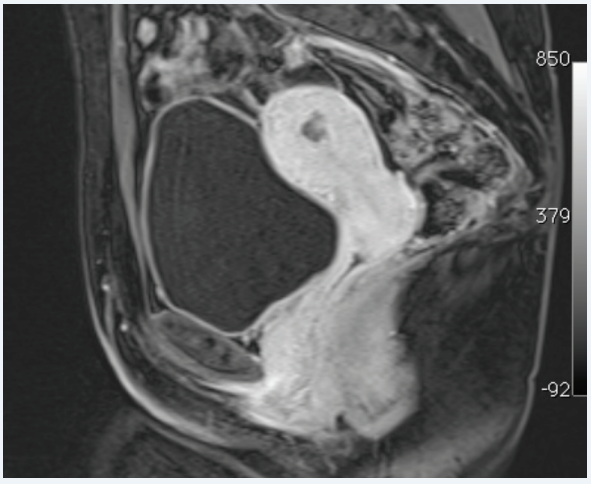

Figure 5. MRI at 8 months postembolization.

> In this case, the efficacy of Embozene™ was demonstrated by the total fibroid devascularization at 4- and 8-month follow-up and by the shrinkage of the dominant fibroid by 96% at 8 months postembolization.

fibroid and a volume reduction of 73%. Further, there was no evidence of the other fibroids (Figure 4).

At 8-month follow-up, the patient reported remission of menometrorrhagia and very good quality of life. Her uterine volume remained unchanged at 77 cm^3, but the fibroid volume further reduced to 0.7 cm^3, a reduction of 96% from the original 18.9 cm^3 (Figure 5).

We conclude that uterine artery embolization by using Embozene™ Microspheres is a safe procedure.

In our experience, we have never had microcatheter obstruction by using Embozene™ Microspheres. In this case, the efficacy of Embozene™ was demonstrated by the total fibroid devascularization at 4- and 8-month follow-up and by the shrinkage of the dominant fibroid by 96% at 8 months postembolization. The relief of fibroid-related clinical symptoms and better quality of life reported by the patient are further important factors of clinical efficacy. ■

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Disclosures: Received no compensation for this article and is not a consultant to Boston Scientific Corporation.

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DIREXION™ Torqueable Microcatheter

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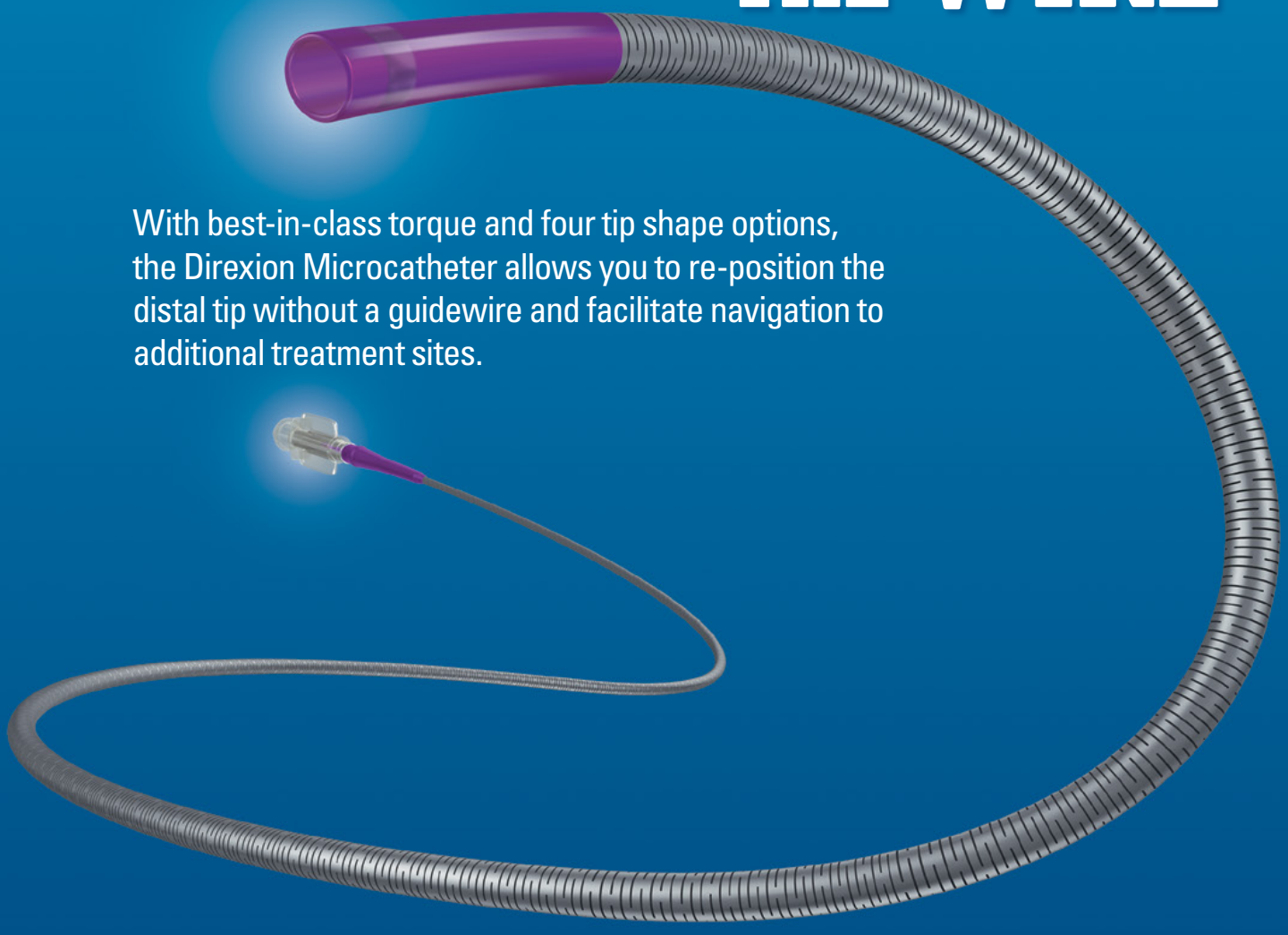

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DIREXION™ DIREXION HI-FLO™

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Repositioning Direxion™ Without a Wire in Two Advanced Embolization Cases

BY R. DANA TOMALTY, MD

CASE 1

Presentation

An 85-year-old woman fell down a few stairs at her home and was brought to the hospital for treatment. She was on warfarin sodium tablets and her prothrombin time was high (PT-INR of 3). She presented with moderate hypotension, alleviated by fluids and blood.

A quick CT showed acute extravasation from her spleen with a large subcapsular bleed (Figure 1). The trauma surgeon asked for a proximal splenic embolization while they prepared the patient for a laparoscopic splenectomy.

Procedure Description

On initial angiography, the origin of the patient's celiac artery was nearly occluded, and it could not be cannulated to access the splenic artery. Instead, we accessed the superior mesenteric artery (SMA) and performed an injection, which demonstrated retrograde filling of the splenic artery through pancreaticoduodenal collateral branches (Figure 2).

With diagnostic access in the SMA, we then placed a preshaped 0.021-inch (0.53-mm) Direxion™ Microcatheter into the vessel and maneuvered predominantly without wire guidance to avoid causing any spasm through the collaterals to the origin of the splenic artery. Due to the impressive flow rates of the 0.021-inch (0.53-mm) Direxion™ Microcatheter, we were able to obtain a good angiogram (Figure 3).

Once we reached our target, we placed several Interlock™-18 Fibered Detachable Coils at the origin of the splenic artery. The stable nature of the Direxion™ Microcatheter allowed us to create a precise, dense pack of coils at our intended location.

The good flow rates of Direxion™ allowed us to then get another good check with a postembolization angiogram (Figure 4). Finally, angiography was completed with a diagnostic catheter injection (Figure 5), which demonstrated complete occlusion of the splenic artery. Upon completion of the embolization procedure, the patient had an uneventful laparoscopic splenectomy.

Discussion

The torque characteristics of the Direxion™ Microcatheter provided by the outer layer of nitinol as well as its soft-shaped tip allowed us to maneuver the catheter predominantly without wire guidance and without causing spasm in this case.

These features are unique to the Direxion™ Microcatheter, and its other features, including excellent flow rates and a stable platform for coiling, helped to make this case possible.

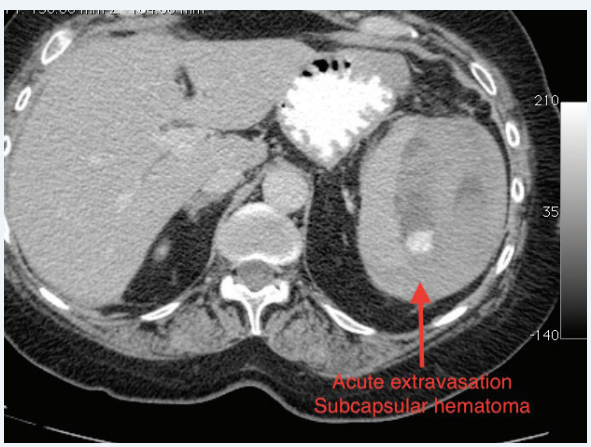

Figure 1. CT showing acute extravasation from the spleen and a large subcapsular bleed.

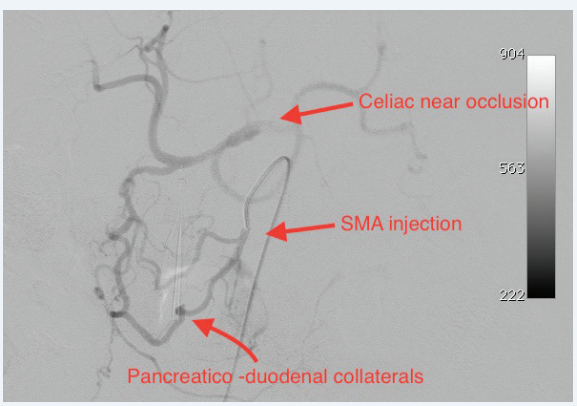

Figure 2. Angiogram showing retrograde filling of the splenic artery through pancreaticoduodenal collateral branches.

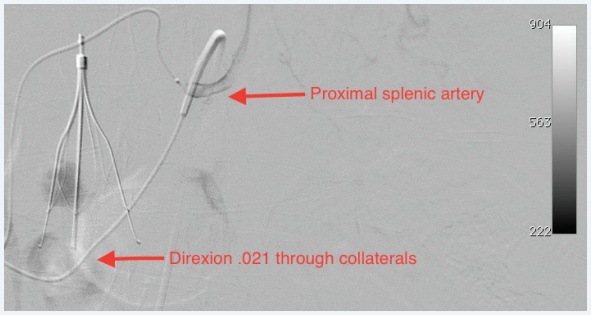

Figure 3. Angiogram showing the Direxion™ Microcatheter moving through the pancreaticoduodenal collateral branches to the proximal splenic artery.

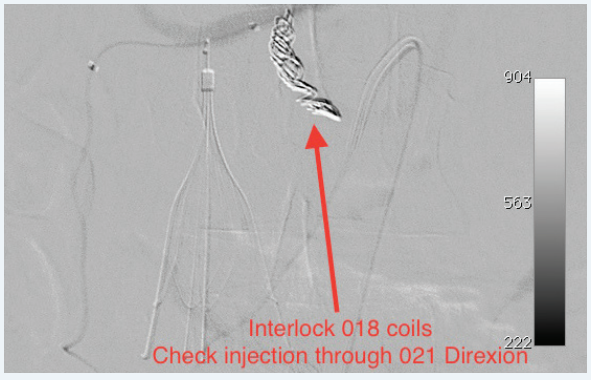

Figure 4. Angiogram showing a nest of Interlock™-18 Fibered Detachable Coils that have occluded the vessel.

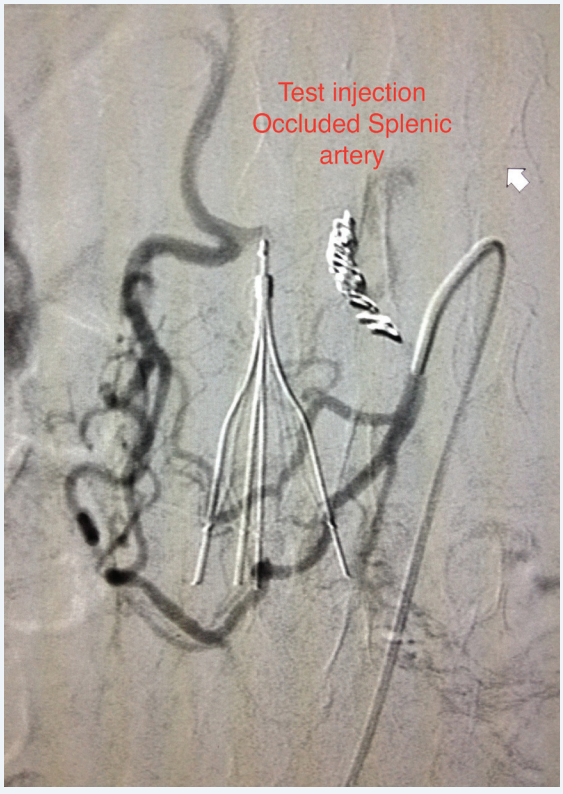

Figure 5. Completion angiogram showing complete occlusion of the splenic artery.

CASE 2

Presentation

A 66-year-old woman presented to the hospital after a motor vehicle accident with active extravasation in her left lateral chest wall, requiring massive transfusions. On CT angiography, she demonstrated active extravasation with a massive hematoma (see Figure 6 on page 8).

Procedure Description

We quickly engaged the intercostal artery with a reverse-curve Mickelson diagnostic catheter and performed an injection (see Figure 7 on page 8), which showed a very small and distal vessel with a sharp takeoff. Intercostal arteries are prone to spasm, but we had to access and embolize the bleed. We placed a 0.021-inch (0.53-mm) Direxion™ Microcatheter through the Mickelson catheter and successfully cannulated the intercostal vessel. The Direxion™ Microcatheter moved easily without a wire, which we elected to do to avoid the risk of wire-induced spasm. We moved very distal with Direxion™ and were still able to perform good injections in the small vessel (see Figure 8 on page 8). Embolization was performed (see Figure 9 on page 8), and the patient stabilized.

Discussion

The Direxion™ Microcatheter has great torqueability and pushability, which allows for distal access in very small vessels without the need for a wire. This technique to reposition the catheter tip without a wire reduces the risk for spasm and possible perforation of the vessel. Once in a distal vessel, the ability to get good injection volumes for excellent angiographic visibility is important, and this can be achieved with Direxion™. Finally, the stability of the Direxion™ Microcatheter is also ideal for coil and other embolizations with little risk of catheter displacement. ■

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Disclosures: Received no compensation for this article and is not a consultant to Boston Scientific Corporation; member of the Boston Scientific Interventional Oncology Advisory Board; consultant for MicroVention.

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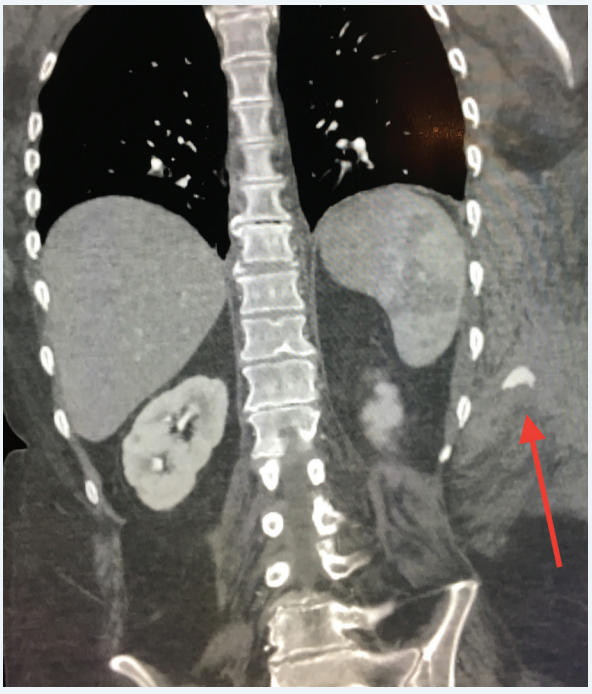

Figure 6. CT angiogram demonstrating active extravasation with a massive hematoma.

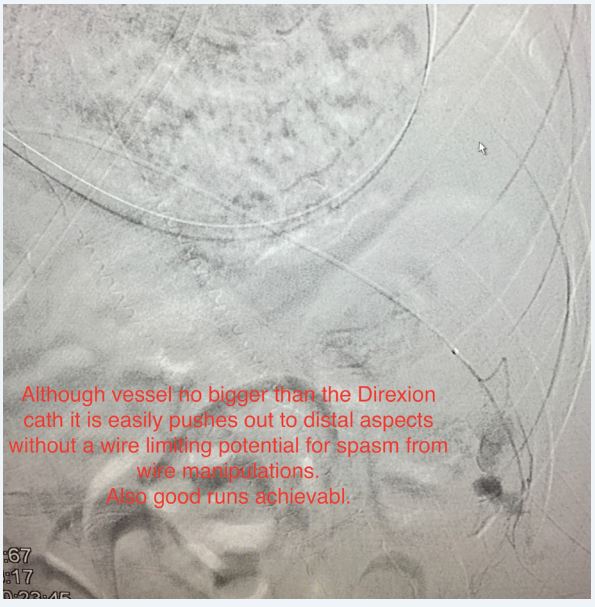

Figure 8. Despite the very small size of the vessel, the Direxion™ Microcatheter moves easily out to the target location without the use of a guidewire.

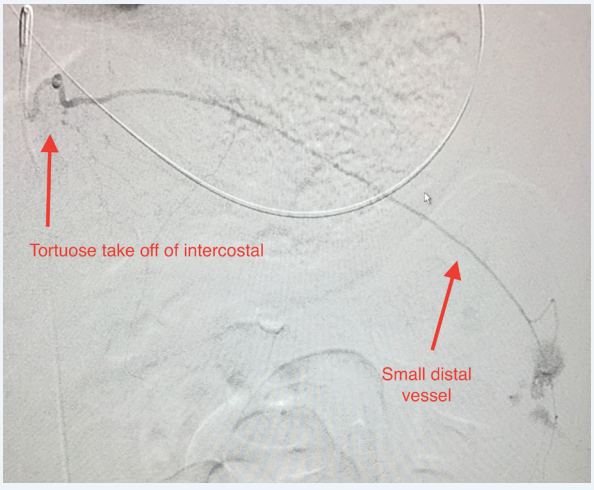

Figure 7. Angiogram of the intercostal artery.

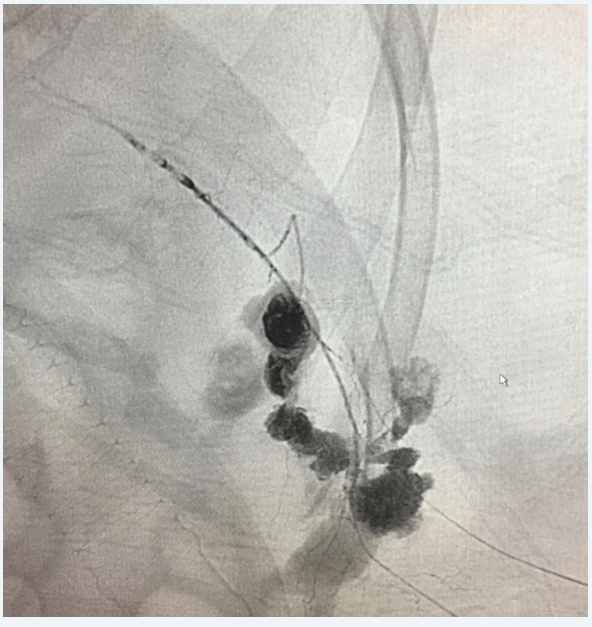

Figure 9. Postembolization angiogram.

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Embolization for High-Flow Priapism

BY MARK HORVATH, DO, AND DANIEL LoCASCIO, MS, MD

CASE PRESENTATION

A 24-year-old man was referred from urology for possible endovascular treatment of high-flow priapism. He originally presented to the urology clinic following symptoms from perineal impalement from a sports-related injury. The patient had complaints of persistent partial erections and an inability to achieve and maintain full erections.

An initial sonogram with Doppler was obtained, which did not demonstrate any abnormality. Dynamic contrast-enhanced MRI revealed an arteriocavernosal fistula involving the left corpora cavernosa (Figure 1).

Potential treatment options for this patient were endovascular embolization and conservative management. According to the American Urologic Association guidelines on the management of high-flow (nonischemic) priapism, up to 62% of cases will resolve spontaneously; however, up to one-third will have an associated complaint of erectile dysfunction.[1] Given the patient's age and desire for a rapid resolution of symptoms, endovascular embolization was chosen.

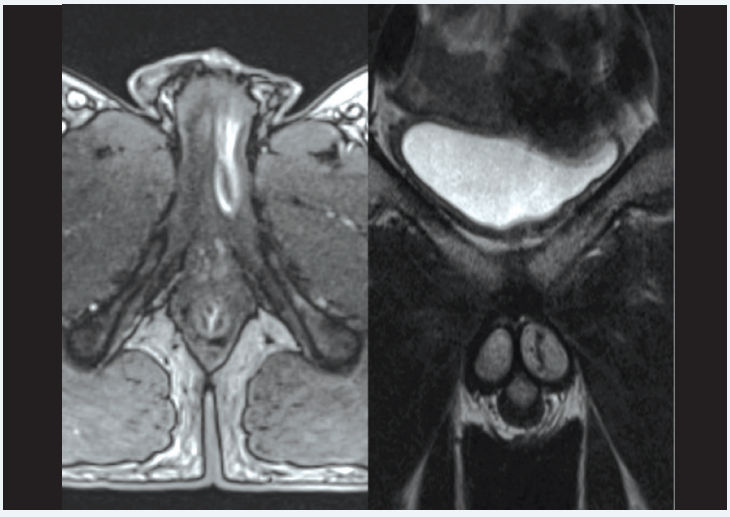

Figure 1. Dynamic contrast-enhanced MRI showing an arteriocavernosal fistula involving the left corpora cavernosa.

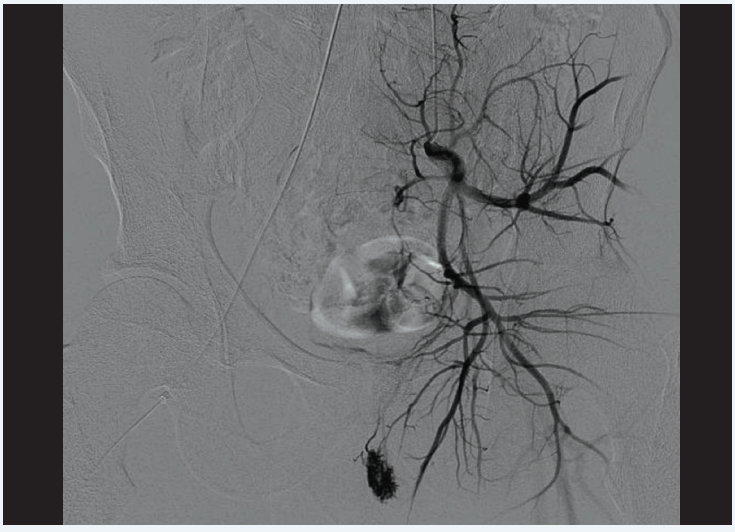

Figure 2. Angiogram demonstrating a large arteriocavernosal fistula with intense arterial blush over the left corpora.

PROCEDURE DESCRIPTION

After using standard techniques to access the right common femoral artery, a 5-F (1.67-mm) sheath was placed, and a 4-F (1.33-mm) hockey stick catheter was used to select the left internal iliac artery. An angiogram demonstrated a large arteriocavernosal fistula with intense arterial blush over the left corpora (Figure 2). Next, a 0.021-inch (0.53-mm) Direxion™ Torqueable Microcatheter and Fathom®-16 Guidewire were used to select the left internal pudendal artery, and a subsequent angiogram revealed similar findings (Figure 3). The microcatheter was then advanced just beyond the site of the arteriocavernosal fistula, and two 2-mm X 4-cm IDC™ Soft Microcoils were deployed.

A repeat angiogram revealed complete resolution of the fistula and preservation of the dorsal penile artery (Figure 4). Of note, the patient's erection was visible on fluoroscopic spot images and immediately detumesced following coil deployment (Figure 5).

The patient had an uneventful overnight hospital stay and was discharged in good condition. The morn-

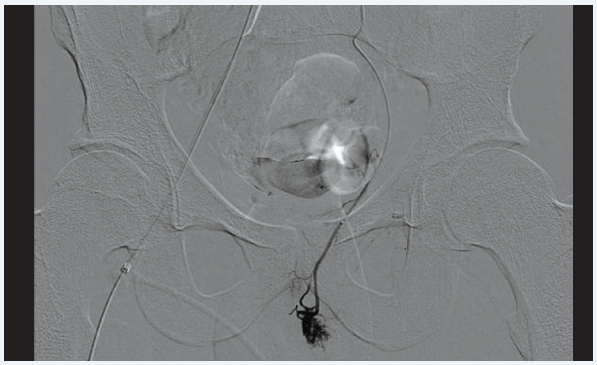

Figure 3. Angiogram obtained after using the Direxion™ Torqueable Microcatheter and Fathom®-16 Guidewire showing similar findings as in Figure 2.

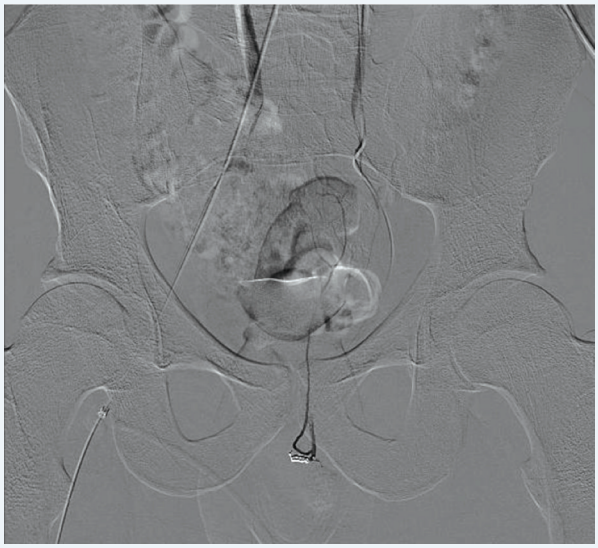

Figure 4. Repeat angiogram showing complete resolution of the fistula and preservation of the dorsal penile artery.

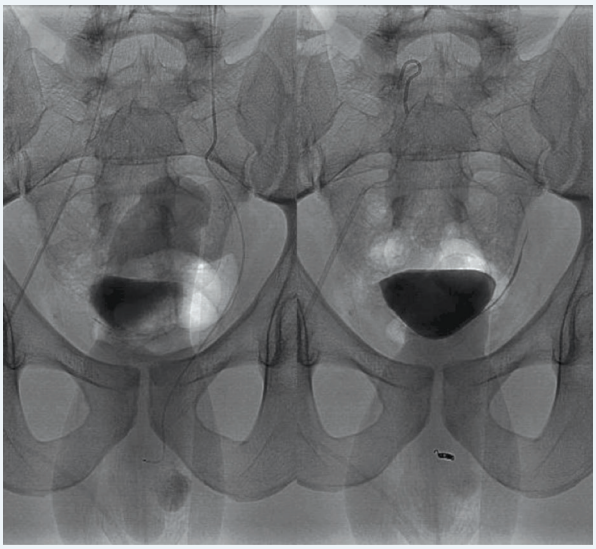

Figure 5. Fluoroscopic image after coil deployment.

ing following the procedure, he endorsed nocturnal penile tumescence, but otherwise the priapism continued to resolve. The patient was seen approximately 7 weeks following embolization and remained very pleased with the result, endorsing full erections and no further priapism.

DISCUSSION

Because of the softness and packing ability of the IDC™ Soft Microcoils, they were an ideal choice for shutting down the fistula while preserving flow to the dorsal penile artery and perforating branches. The postembolization angiogram not only showed preservation of the dorsal penile artery, but also improved flow compared to the pre-embolization angiogram. ■

1. Montague DK, Jarow J, Broderick GA, et al. American Urological Association guideline on the management of priapism. J Urol. 2003;170(4 Pt 1):1319-1324.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE / INDICATIONS FOR USE:** Expel™ MPD™ and MPDL Drainage Catheter and Kit & Expel Large Capacity Drainage Catheter: The drainage catheter is intended to provide percutaneous drainage of abscess fluid collections. Expel Nephrostomy Drainage Catheter and Kit: The drainage catheter is intended to provide external drainage of the urinary tract. **CONTRAINDICATIONS:** The drainage catheter is contraindicated where percutaneous drainage catheterization is unacceptable. For Expel Large Capacity, the drainage catheter is contraindicated where large diameter (≥ 16F) percutaneous drainage catheterization is unacceptable. **WARNINGS:** • Do not use catheter for feeding tube/gastrostomy procedures. Exposure to gastric fluids may damage the catheter. • Not for biliary use. **PRECAUTIONS:** These recommendations are meant to serve only as a basic guide to the use of this catheter. Percutaneous drainage should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure. • Where long-term use is indicated, it is recommended that indwelling time not exceed the following limits, and that the physician evaluate the catheter before this time has elapsed: • 90 days, for Expel MPD and MPDL Draining Catheter and Kit; • 30 days, for Expel Nephrostomy Drainage Catheter and Kit. • Catheters attached to suction should follow normal clinical practices in selecting a static vacuum level. Testing has demonstrated the catheters can withstand a negative pressure of 200 mmHg (26.7 kPa). **ADVERSE EVENTS:** The complications that may result from the use of these devices include, but are not limited to: • Catheter Occlusion and/or Dislodgment • Encrustation • Fistula • Hemorrhage/Hematoma • Infection/Sepsis • Pain • Perforation • Peritonitis • Pneumothorax PI-216201-AE AUG2015

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Needle- and Microcatheter-Guided Coiling of a 6-cm Internal Iliac Artery Aneurysm

BY SAAM TABAR, MD

CASE PRESENTATION

A 63-year-old man presented with a large, 6-cm traumatic aneurysmal arteriovenous fistula of the left internal iliac artery, likely secondary to the bullet in his groin area. The patient had a coiling embolization at an outside hospital prior to this case and had a bullet in his groin area (Figure 1A). We attempted to cannulate the left internal iliac artery from a contralateral approach, but this proved unsuccessful due to the tortuosity of the iliac arteries and pelvic region. Our next step was to access the aneurysmal sac directly, using an 18-gauge needle under CT guidance. CT scans with and without contrast were obtained (Figures 1B and C).

PROCEDURE DESCRIPTION

Direct access was established by placing a 15-cm, 18-gauge needle into the aneurysm sac under CT guidance (Figures 1D and E). We then proceeded to introduce an 0.021-inch (0.53-mm) Renegade® STC Microcatheter with a Fathom® Guidewire through the entry needle, and we began to embolize with fibered Interlock™-18 Detachable Coils. We used the Renegade® STC Microcatheter and Fathom® Guidewire to maneuver around the aneurysm, placing coils around the aneurysmal area in an attempt to fill as much space as possible.

Once the edges of the sac were coiled, we removed the microcatheter and microwire system, upsized to the 0.035-inch (0.89-mm) Interlock™-35 Fibered Detachable Coils, and pushed the coils directly through the needle and into the center of the sac, where they were delivered smoothly.

DISCUSSION

Upon completion of the embolization, we had used 36 Interlock™ Coils, both 0.018- (0.46-) and 0.035-inch (0.89-mm), ranging in size from 10 mm to 22 mm (Figure 1F). Completion angiography showed an interesting nest of collateral vessels feeding into the venous system (Figure 1G).

Upon embolization of the arterial aneurysm, we noted new arteriovenous channels that appeared to supply the outflow directly to the iliac vein and inferior vena cava. Due to the dense network of thrombogenic Dacron® (Invista) fibers on each Interlock™ Coil, we felt confident that this treatment would secure the aneurysmal sac in this large, complex, traumatic arteriovenous fistula. ■

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Disclosures: Received no compensation for this article and is not a consultant to Boston Scientific Corporation.

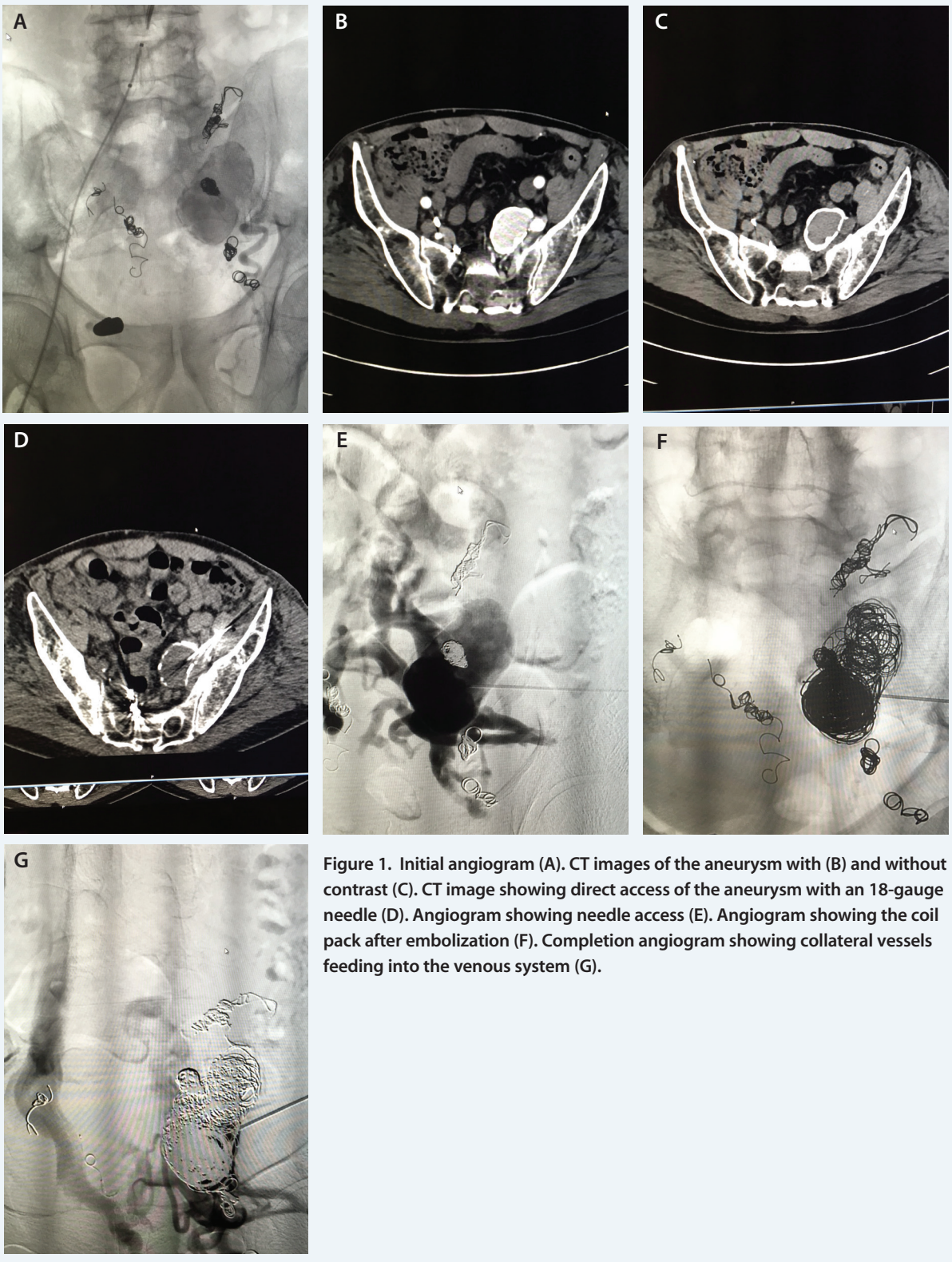

Figure 1. Initial angiogram (A). CT images of the aneurysm with (B) and without contrast (C). CT image showing direct access of the aneurysm with an 18-gauge needle (D). Angiogram showing needle access (E). Angiogram showing the coil pack after embolization (F). Completion angiogram showing collateral vessels feeding into the venous system (G).

Sponsored by Boston Scientific Corporation

Coiling a Type II Endoleak With a 2-RO, 155-cm Direxion™ Microcatheter

BY YING WEI LUM, MD

CASE DESCRIPTION AND DISCUSSION

A patient presented with a type II endoleak with a long and tortuous feeding vessel, which we believed to be the inferior mesenteric artery (Figures 1 and 2). After we initially gained access with a SIM1 diagnostic catheter and advanced more distally with a 0.021-inch (0.53-mm), preshaped, 2-RO-tip Direxion™ Microcatheter, we ran out of length because the 100-cm SIM1 catheter would not allow us to reach the target. We switched out the entire system, using only a 300-cm-long, 0.014-inch (0.36-mm) Fathom® Guidewire. The Fathom®-14 Guidewire provided plenty of support for the exchange, and we did not need to open an additional device such as a long sheath. We advanced a longer, 4-F (1.33-mm) nontapered, angled diagnostic catheter into the inferior mesenteric artery and then reinserted a 155-cm Direxion™ Microcatheter, one of the longest microcatheters on the market. We needed every last centimeter of the 155-cm length, as we used the Direxion™–Fathom® combination to access the target endoleak site and prepare for coil embolization (Figure 3).

We deployed six Interlock™-18 Coils precisely into the aneurysm sac, with help from the two radiopaque markers on the Direxion™ Microcatheter, and left the last coil to trail out into the feeding vessel as an anchor (Figures 4 and 5). To keep cost in mind, we finished the embolization with a few small VortX® Diamond 0.018-inch (0.46-mm) pushable coils to finish packing the coil nest.

The flow to the endoleak site drastically diminished (Figures 6–8), and we feel strongly that the Dacron® (Invista) fibers on the Interlock™-18 Coils will continue to thrombose and create a complete occlusion. ■

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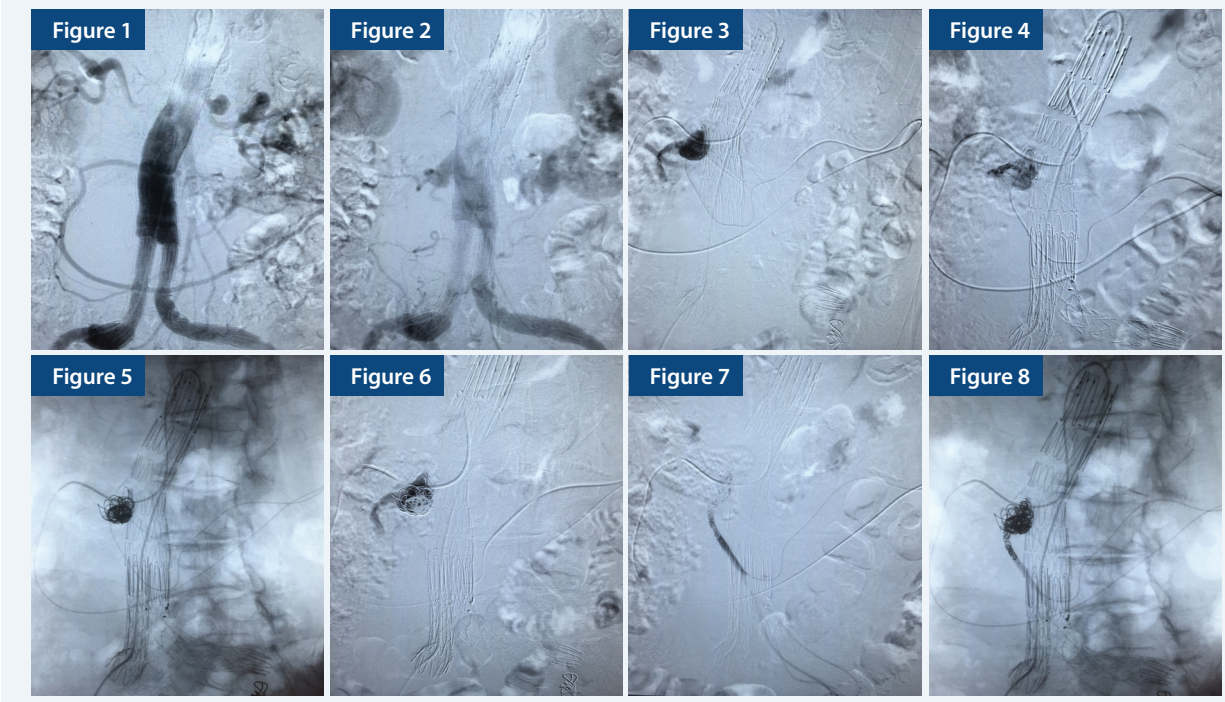
Disclosures: Received no compensation for this article and is not a consultant to Boston Scientific Corporation.



Sponsored by Boston Scientific Corporation

Exceptional Deliverability of the Expel™ Drainage Catheter With Twist-Loc™ Hub

BY R. DANA TOMALTY, MD

CASE DESCRIPTION

A patient presented with a staghorn calculus, a large stone that takes up more than one branch of the collecting system in the renal pelvis (Figure 1). The upper pole calyx was completely filled with stone.

Initial access in the lower pole of the kidney was achieved, but the surgeon wanted upper pole access as well. Using the Seldinger technique, we placed a wire into the upper calyx. The fit of the wire was extraordinarily tight, as the upper calyx was almost entirely filled with stone (Figure 2). Any catheter that we pushed into that zone would meet very high friction and resistance, so we opted for a nephrostomy drainage catheter with robust column strength and buckling resistance.

We chose to use the Expel™ Nephrostomy Drainage Catheter with Twist-Loc™ Hub based on its deliverability profile. The tip taper of the Expel™ Catheter and its metal cannula, which is flexible enough but stable, allowed us to place a nephrostomy tube in the difficult stone-filled area in the renal pelvis (Figure 3). The hydrophilic coating on the distal third of the catheter also helped with insertion and deliverability. Compared with other drainage catheters on the market, the Expel family has consistently performed very well at our institution. ■

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Disclosures: Received no compensation for this article and is not a consultant to Boston Scientific Corporation; member of the Boston Scientific Interventional Oncology Advisory Board; consultant for MicroVention.

Figure 1

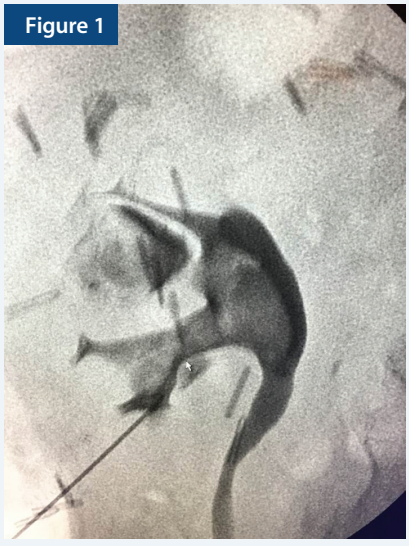


Figure 2

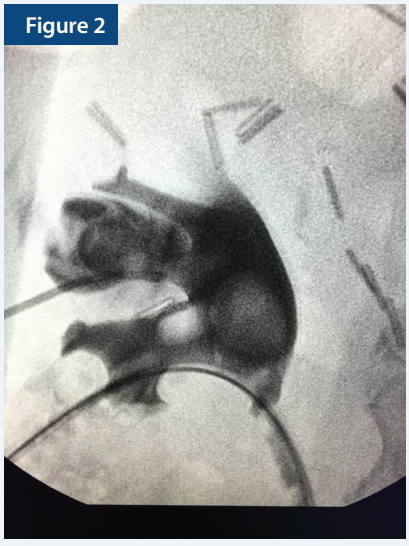
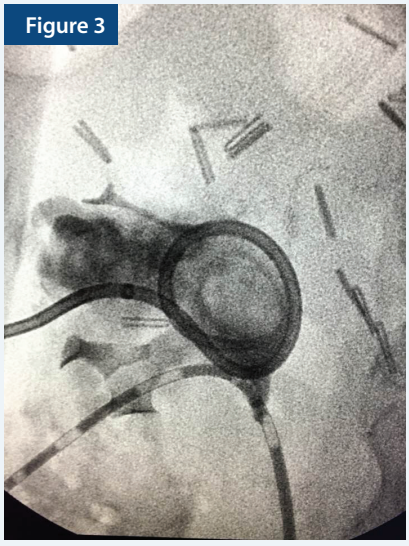


Figure 3



Sponsored by Boston Scientific Corporation

Combined Transfemoral and Transhepatic Embolization of Gastric Varices

BY MONI STEIN, MD, FSIR

Over the last few years, an alternative to the transjugular intrahepatic portosystemic shunt (TIPS) procedure has emerged—balloon-occluded retrograde transvenous obliteration (BRTO) of gastric varices. In this article, a new approach is described, adding the transhepatic access, which allows for blockage of the inflow veins that originate from the portal system, followed by transfemoral BRTO.

CASE PRESENTATION

A 69-year-old woman presented with bleeding large gastric varices related to portal hypertension caused by idiopathic liver cirrhosis. The patient was referred to interventional radiology, as the gastrointestinal endoscopist could not effectively sclerose or band these varices.

A CT scan was performed, which showed a large splenorenal shunt feeding into large gastric varices (Figure 1A). As the shunt was large with voluminous flow, a concern was raised regarding the ability of BRTO alone to safely control and obliterate the varices. An additional step was taken, adding the transhepatic approach with direct access into the portal system and the feeders into the varices. Using the AccuStick™ Introducer System, access was created, and a 6-F (2-mm) vascular sheath was introduced into the splenic vein. Venography demonstrated a large, short gastric vein feeder (Figure 1B), which was cannulated with a 5-F (1.67-mm) cobra tip–shaped catheter and embolized with three 8-mm X 40-cm, two 8-mm X 20-cm, and two 6-mm X 20-cm Interlock™-35 Fibered IDC Occlusion System coils until cessation of flow (Figure 1C). An additional smaller feeder was found, the coronary vein (Figure 1D), which was embolized with two 8-mm X 20-cm and two 6-mm X 20-cm Interlock™-35 coils (Figure 1E).

Subsequently, a transfemoral approach was created, and an 8-F (2.67-mm) vascular sheath was introduced. Using a cobra tip–shaped catheter, the left renal vein was cannulated and the splenorenal shunt was catheterized using a stiff glidewire. A 8.5/11.5-mm, 6-F (2-mm) Berenstein™ occlusion balloon catheter was introduced over an Amplatz wire and was inflated with a 0.55-mL mixture of saline and contrast at 50% strength. Venography was performed, which showed reduced flow through the shunt (Figure 1F). A 10-mL mixture of contrast material, Gelfoam (Pfizer, Inc.), and 1% sodium tetradecyl sulfate was processed as a slurry in a 10-mL syringe and injected through the lumen of the occlusion balloon catheter and was left in place for 15 minutes. Through the inner lumen of the occlusion balloon, two 8-mm X 40-cm and three 8-mm X 20-cm Interlock™-35 Fibered IDC Occlusion System coils were deployed. Repeat venography demonstrated elimination of flow through the shunt (Figure 1G). In order to finalize the procedure, an additional venogram was performed through the transhepatic sheath, which demonstrated no flow into the varices (Figure 1H). Endoscopy after the BRTO procedure demonstrated complete elimination of the gastric varices.

DISCUSSION

The combined transhepatic and transfemoral BRTO approach allows for a safer and more complete bidirectional gastric variceal blockage. Both inflow and outflow veins are obliterated, trapping the varices, which allows for a more efficient and safer application of sclerosing agent. ■

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Disclosures: Received no compensation for this article and is not a consultant for Boston Scientific Corporation.

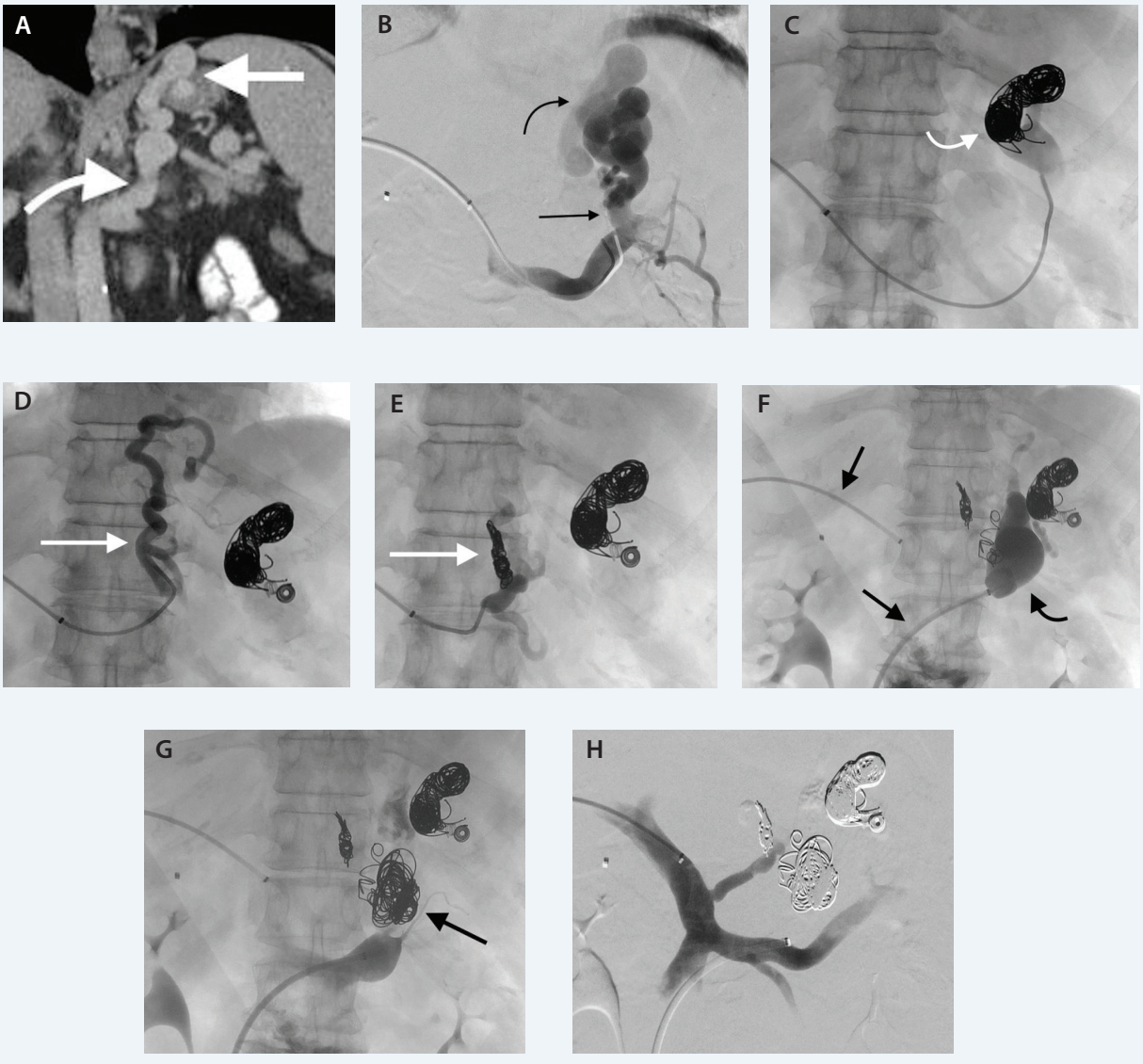

Figure 1. Coronal reconstruction of an abdominal CT scan demonstrating a large feeding coronary vein (curved arrow) into gastric varices (straight arrow) (A). Through a transhepatic approach, splenic venography shows a large, short gastric vein (straight arrow) feeding into gastric varices (curved arrow) (B). Gastric varices embolized with Interlock™-35 coils (curved arrow) until cessation of flow (C). Coronary vein feeder (straight arrow) catheterized with a cobra tip–shaped catheter (D). Coronary vein feeder embolized with Interlock™-35 coils (straight arrow) (E). The splenorenal shunt was cannulated, and venography was done through the occlusion balloon (curved arrow). The transhepatic and transfemoral sheaths are marked with straight arrows (F). Shunt embolized with Interlock™-35 coils (straight arrow) and sclerosing agent until cessation of flow (G). Concluding transhepatic portal venography demonstrates complete obliteration of gastric varices (H).

Expel Drainage Cath w Twist-Loc Hub

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

Catheter and Kit	Intended Use/Indications For Use
Expel™ MPD™ and MPDL Drainage Catheter and Kit	The drainage catheter is intended to provide percutaneous drainage of abscess fluid collections.
Expel Nephrostomy Drainage Catheter and Kit	The drainage catheter is intended to provide external drainage of the urinary tract.

CONTRAINDICATIONS

- The drainage catheter is contraindicated where percutaneous drainage catheterization is unacceptable.

WARNINGS

- Do not use catheter for feeding tube/gastrostomy procedures. Exposure to gastric fluids may damage the catheter.
- Not for bilio-pancreatic use.

PRECAUTIONS

These recommendations are meant to serve only as a basic guide to the use of this catheter. Percutaneous drainage should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure.

- Where long-term use is indicated, it is recommended that indwelling time not exceed the following limits, and that the physician evaluate the catheter before this time has elapsed:
- 90 days, for Expel MPD and MPDL Draining Catheter and Kit;
- 30 days, for Expel Nephrostomy Drainage Catheter and Kit.
- Catheters attached to suction should follow normal clinical practices in selecting a static vacuum level. Testing has demonstrated the catheters can withstand a negative pressure of 200 mmHg (26.7 kPa).

ADVERSE EVENTS

The complications that may result from the use of these devices include, but are not limited to:

- Catheter Occlusion and/or Dislodgment
- Dysuria and Frequency/Urgency
- Encrustation
- Fistula
- Hemorrhage/Hematoma
- Infection/Sepsis
- Pain
- Perforation
- Peritonitis
- Pneumothorax

All Expel™ Drainage Catheter are trademarks of Boston Scientific Corporation or its affiliates.

Interlock & IDC Coils-Combined

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The Interlock IDC Occlusion System is a modified interlocking detachable coil. The Interlock IDC Occlusion Systems are indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. These devices are not intended for neurovascular use.

CONTRAINDICATIONS

None known.

PRECAUTIONS

Do not attempt to use the Interlock - 35 Fibered IDC Occlusion System with a soft-walled delivery catheter.
Do not advance the Interlock IDC Occlusion System if it becomes lodged within the catheter. Determine the cause of the resistance and replace the catheter and coil if necessary.

ADVERSE EVENTS

The complications that may result from a peripheral embolization procedure include, but are not limited to:

- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation, etc.)
- Pain
- Hemorrhage
- Infection necessitating medical intervention
- Foreign body reactions necessitating medical intervention
- Emboli
- Ischemia
- Vasospasm
- Tissue necrosis
- Undesirable clot formation of the vasculature
- Recanalization
- Death
- Temporary neurological deficit

IDC™ Interlocking detachable coil and Interlock™ fibered IDC Occlusion systems are trademarks of Boston Scientific Corporation or its affiliates. All rights reserved.

DIREXION and DIREXION HI-FLO Torqueable Microcatheters

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

CONTRAINDICATIONS

None known.

WARNINGS

- Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation.
- This Direxion Microcatheter family is not intended for use in the coronary vasculature or neurovasculature.
- The Direxion HI-FLO Microcatheter is not designed for the delivery of embolic coils.
- Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction.

PRECAUTIONS

- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter.
- Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

ADVERSE EVENTS

- The Adverse Events include, but are not limited to:
- Allergic reaction
- Death
- Embolism
- Hemorrhage/Hematoma
- Infection
- Pseudoaneurysm
- Stroke
- Vascular thrombosis
- Vessel occlusion
- Vessel spasm
- Vessel trauma (dissection, perforation, rupture)

The Direxion Hi-Flo microcatheter is not designed for the delivery of embolic coils.

Renegade STC 18 Microcatheter, Renegade Fiber Braided Microcatheter and Renegade HI-FLO Microcatheter

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The Renegade STC 18 Microcatheter, Renegade Fiber Braided Microcatheter, and the Renegade HI-FLO Microcatheter are intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Diagnostic, embolic, therapeutic agents to be used in accordance with specifications outlined by the manufacturer.

CONTRAINDICATIONS

None Known.

WARNING

The Renegade STC 18 Microcatheter, Renegade Fiber Braided Microcatheter, and the Renegade HI-FLO Microcatheter are not intended for use in the coronary vasculature or the neurovasculature.

PRECAUTIONS

- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in separation of the microcatheter or guidewire tip, damage to the microcatheter or guidewire tip, or vessel perforation.
- Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

ADVERSE EVENTS

The Adverse Events include, but are not limited to:

- Vessel trauma
- Embolism
- Hemorrhage/Hematoma
- Vasospasm
- Infection
- Air embolism
- Allergic reaction

Fathom Steerable Guidewire

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The FATHOM -16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

CONTRAINDICATIONS

None known.

WARNINGS

The FATHOM Steerable Guidewire is not intended for use in the coronary vasculature or the neuro vasculature.

ADVERSE EVENTS

Complications attributed to endovascular procedures are the following: Vessel trauma, Vessel damage, Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism), Pseudoaneurysm, Seizure/stroke, Vessel dissection, Hematoma at the puncture site, Nerve injury, Infection, Perforation of the vessel, Vessel spasm, Hemorrhage, Vascular thrombosis, Vessel occlusion, Death, Bleeding, Failed treatment, Inability to position guidewire, Damage to the catheter.

Pushable Coils 18-Vortx Dia Strt Fig8 MultiLp CH

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

Boston Scientific's 0.018 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature. The Coil Pusher-16 is intended to be used in conjunction with a microcatheter to deliver and deploy 0.018 pushable occlusion coils.

CONTRAINDICATIONS

None known.

PRECAUTIONS

- The long-term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space.
- Do not advance the coil with force if the coil becomes lodged within the microcatheter. Determine the cause of resistance and replace the microcatheter and the coil when necessary.
- Replace the microcatheter if increased resistance is noted during coil delivery.

ADVERSE EVENTS

The complications that may result from a peripheral embolization procedure include, but are not limited to:

- Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.)
- Death
- Emboli
- Foreign body reactions necessitating medical intervention
- Hemorrhage
- Infection necessitating medical intervention
- Ischemia
- Pain
- Recanalization
- Temporary neurological deficit
- Tissue necrosis
- Undesirable clot formation of the vasculature
- Vasospasm

Berenstein Occlusion Balloon

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE
Boston Scientific Occlusion Balloon Catheters are indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. The Occlusion Balloon Catheter product line consists of two specific designs–Standard and Berenstein Occlusion Balloon Catheters. Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.

CONTRAINDICATIONS
Boston Scientific Occlusion Balloon Catheters are not designed for use in embolectomy procedures. Boston Scientific Occlusion Balloon Catheters are not designed for use as vascular flow-directed catheters (Swan-Ganz type). Any use for procedures other than those indicated in the instructions is not recommended.

PRECAUTIONS
Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

ADVERSE EVENTS
The complications that may result from an occlusion balloon procedure include:

- vessel perforation
- vessel spasm
- hemorrhage
- hematoma
- arrhythmias/bradycardia
- sepsis or infection
- systemic embolization
- short-term hemodynamic deterioration or instability
- death
- vascular thrombosis
- allergic reactions to contrast medium
- pyrogenic reaction
- arteriovenous fistula
- thromboembolic episodes
- vessel dissection
- air embolism

Accustick Introducer

rporation

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE
The AccuStick™ II Introducer System with radiopaque marker facilitates introduction and placement of a guidewire.

CONTRAINDICATIONS
None known.

PRECAUTIONS
None known.

WARNINGS
None known.

ADVERSE EVENTS
Potential risks exist for serious complications to include:

- Perforation of a vessel or viscus
- Laceration of a vessel or viscus
- Bleeding
- Wire or catheter embolism
- Extravasation
- Hematoma
- Hemothorax
- Hydrothorax
- Inflammation, necrosis or scarring
- Risks normally associated with percutaneous interventional procedures
- Pain in region
- Skin infection
- Edema

These and other complications are well documented in medical literature. Use of the AccuStick II Introducer System with radiopaque marker should be reserved by persons knowledgeable of the risks involved and qualified in the procedures.

EMBOZENE™ MICROSPHERES

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

INDICATIONS FOR USE: Embozene™ Microspheres are indicated for embolization of arteriovenous malformations (A.V.M.) and hypervascular tumors (H.V.T.) including uterine fibroids and hepatoma.

CONTRAINDICATIONS: The contraindications of Embozene Microspheres include the presence of vasculature where Embozene™ Microspheres could pass directly into the central nervous system, central circulatory system, internal carotid artery, or other non-target territories. Procedures should not be performed if vascular anatomy precludes correct catheter placement or embolic injection.

WARNINGS AND PRECAUTIONS: Vascular embolization is a high-risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures. Complications can occur at any time during or after the procedure.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

A complete list of indications, contraindications, warnings and precautions are described in Embozene™ Microspheres Instructions for Use. Please consult these before using the product.

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EMBOZENE TANDEM™ AND ONCOZENE™ MICROSPHERES

INDICATIONS FOR USE: EMBOZENE TANDEM™ and ONCOZENE™ Microspheres are indicated for the embolization of arteriovenous malformations and hypervascular tumors including hepatoma.

CONTRAINDICATIONS: The contraindications of EMBOZENE TANDEM™ and ONCOZENE™ Microspheres include the presence of vasculature where EMBOZENE TANDEM™ and ONCOZENE™ Microspheres could pass directly into the central nervous system, central circulatory system, internal carotid artery, or other non-target territories. Procedures should not be performed if vascular anatomy precludes correct catheter placement or embolic injection.

WARNINGS AND PRECAUTIONS: Vascular embolization is a high-risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures. Complications can occur at any time during or after the procedure.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

A complete list of indications, contraindications, warnings and precautions are described in EMBOZENE TANDEM™ and ONCOZENE™ Microspheres Instructions for Use. Please consult these before using the product.

Oncozene is a unregistered or registered trademark of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

SEE OUR FULL AD ON THE BACK COVER.

*Embozene TANDEM is not available for sale in the United States. ONCOZENE is not available for sale outside the United States.

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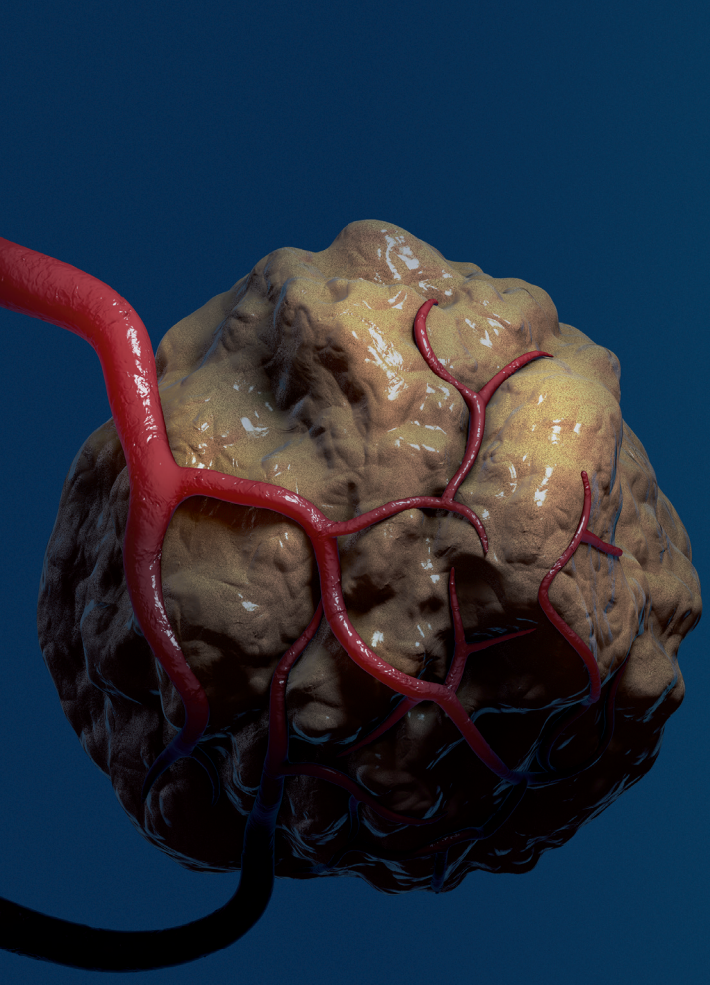
THE FIGHT IS ON



We're in this together. With Boston Scientific's recent addition of ONCOZENE™ and Embozene™ microspheres, we're doubling down our efforts in the fight against tumors – because everyone deserves to win this fight.

Visit www.bostonscientific.com to learn more.