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Endovascular TODAY

April 2017

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Expert Case Experiences

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Treatment of Pedunculated Fibroid With Embozene™

BY MICHAEL SCHMIDLING, MD; RAJESH PATEL, MD; MITCHELL BREZEL, MD; AND NICHOLAS J. PETRUZZI, MD

CASE PRESENTATION

A 52-year-old gravida 0 para 0 woman with a 2-year history of intermittent heavy menstrual bleeding was hospitalized for transfusion due to severe anemia. She also complained of pelvic pain and bulk symptoms including frequent urination. A recent PAP smear and endometrial biopsy both revealed benign cytology. Conservative measures to control bleeding, including hormonal therapy and dilation and curettage had been unsuccessful. The patient wished to pursue uterine artery embolization (UAE).

Previous imaging demonstrated a pedunculated fibroid protruding into the endometrial cavity and lower uterine segment. A fibroid was visible in the upper vaginal vault on speculum exam. Repeat MRI after the consultation showed interval increase in size since 2014. The fibroid measured 4.4 X 2.3 X 2.4 cm. The uterine volume was 137 mL. Thickening of the junctional zone to 25 mm, consistent with adenomyosis, was also noted (Figures 1–3).

PROCEDURE DESCRIPTION

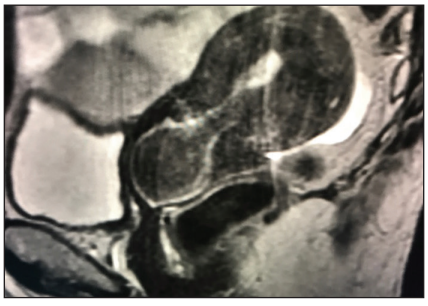
Standard protocol in our center is to perform UAE via radial access after a Barbeau test has confirmed adequacy of ulnar collateral flow to the hand. Ultrasound was used to guide access to the radial artery, and a 4-F hydrophilic-coated radial access sheath was placed. Once access was achieved, the "radial cocktail" containing 3,000 u of heparin, 200 µg of nitroglycerine, and 2.5 mg of verapamil was slowly injected to minimize vasospasm. Subsequently, a 4-F, 120-cm hydrophilic-coated catheter and 2-mm J-tip hydrophilic guidewire were advanced into the distal aorta, followed by catheterization of each internal iliac artery. A Renegade™ Hi-Flo™ Microcatheter was then used to catheterize each uterine artery, and the catheter was parked in the proximal ascending segment (Figures 4–6).

Due to the presence of coexistent adenomyosis, a smaller particle size was chosen, as smaller particle size has shown to be effective in inducing necrosis of adenomyosis.[1] Embolization was then carried out with Embozene™ Microspheres. Each 2-mL vial of 250-µm Embozene™ was mixed with 6 mL of iodixanol 320 contrast and slowly injected. In total, approximately three vials were used.

Patients undergoing UAE at our center are monitored for 3 hours after the procedure, during which hemostasis at the radial access site is achieved with the use of a radial assisted compression device. Postprocedure pain management has been tailored to include the use of a fentanyl patch, nonsteroidal anti-inflammatories with concurrent proton-pump inhibitor, and narcotic pain medications. Over 100 patients have been treated with this protocol with no hospital admissions for pain. In fact, in our experience we have seen improved patient satisfaction since we have moved this procedure to the outpatient setting.

FOLLOW-UP AND DISCUSSION

The patient had an uneventful recovery. At 3 months, repeat MRI showed that the overall volume of the uterus had decreased from 137 mL to 51 mL. The pedunculated fibroid had passed clinically at 3 to 4 weeks without incident. The fibroid was no longer visualized, and there was complete necrosis of adenomyosis with a junctional zone measurement of 4 mm (Figure 7). The patient was asymptomatic and reported light menstrual cycles.



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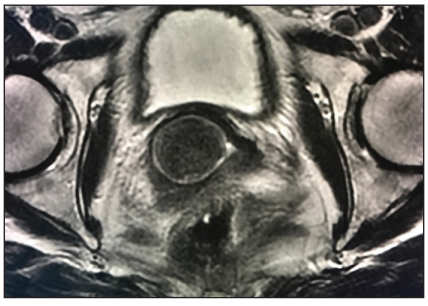

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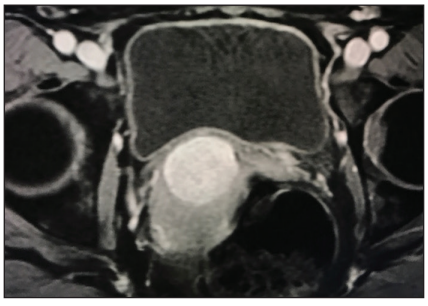

Figure 3.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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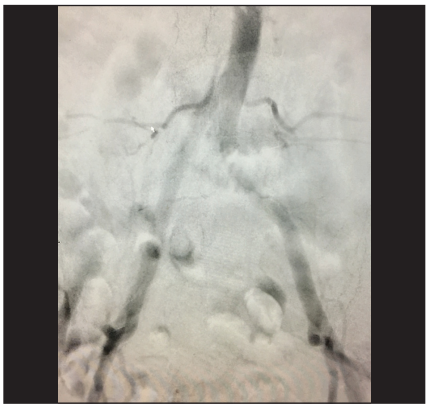

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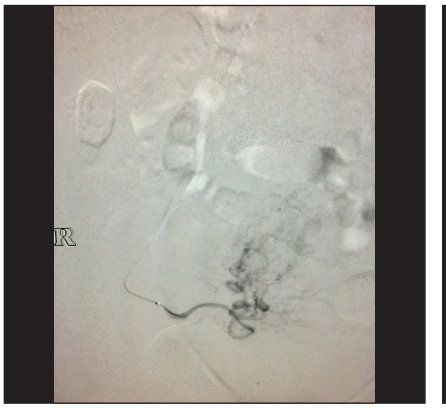

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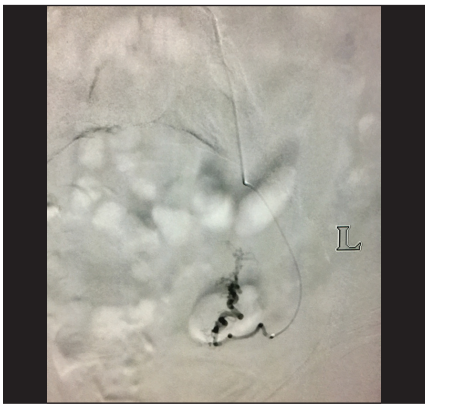

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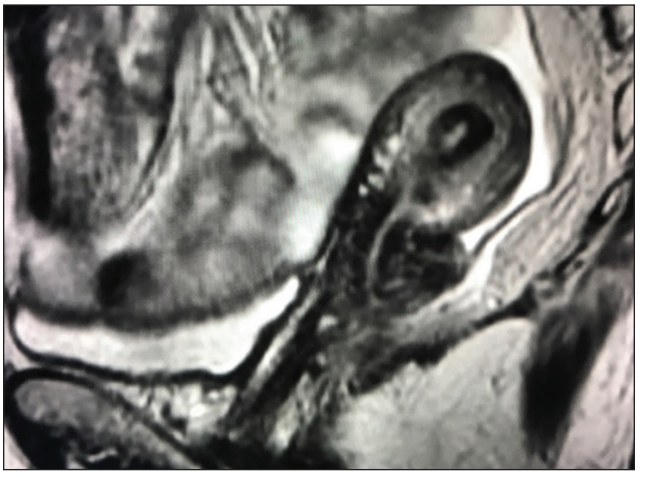

Figure 7.

This case highlights several considerations for UAE. Recommendations for treatment of pedunculated fibroids has been modified over time from more conservative to currently more liberal recommendations. We generally will offer treatment for all pedunculated fibroids after discussions with the patient and referring gynecologist about associated risks of fibroid impaction. This case is particularly interesting noting complete necrosis of the stalk and passage of the entire fibroid. One could postulate this may be related to the smaller particle size used. This case also highlights the safety and efficacy of UAE as an outpatient procedure using radial artery access. ■

1. Kim MD, Kim YM, Kim HC, et al. Uterine artery embolization for symptomatic adenomyosis: a new technical development of the 1-2-3 protocol and predictive factors of MR imaging affecting outcomes. J Vasc Interv Radiol. 2011;22:497–502.

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Embolization of an Aortic Aneurysm Sac and Type II Endoleak

BY PAOLO FACCIOLI, MD, AND SIMONE LIMONTA, MD

CASE PRESENTATION

A 59-year-old woman presented to our institution with a history of fusiform abdominal aortic aneurysm treated with endovascular aneurysm repair and previous coil placement in the false lumen for type II endoleak. CT angiography showed an aneurysm sac enlargement and type IIb endoleak. The angiographic evaluation showed two small branch vessels filling the aneurysm sac (Figure 1).

PROCEDURE DESCRIPTION

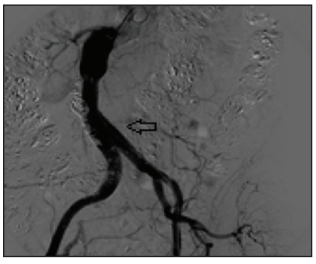
A Bern-shaped Direxion™ 2.4-F Microcatheter and a Fathom™-16 Guidewire were used to distally select and access those tiny branches, and Interlock™-18 Microcoils were deployed.

Angiography of the superior mesenteric artery depicted a long tortuous arc of Riolan and a smooth blush within the aneurysm sac (Figure 2).

The same Direxion™ Microcatheter was used to cannulate the middle colic artery and the arc of Riolan, surpassing several winding loops and a tight turn at the left colic flexure and the left colic artery (Figure 3). The tip of the microcatheter was advanced to the arterial ostium of the inferior mesenteric artery and into the lumen of the sac without rejecting the guiding catheter. Embolization was performed, deploying four Interlock™-18 Microcoils.

FOLLOW-UP

Embolization with the Interlock™-18 Microcoils achieved complete occlusion of the origin of the inferior mesenteric artery, preserving the sigmoid and superior hemorrhoidal arteries (Figure 4). ■



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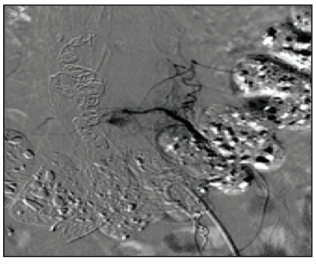

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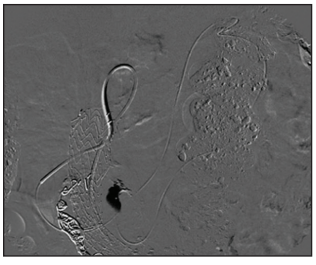

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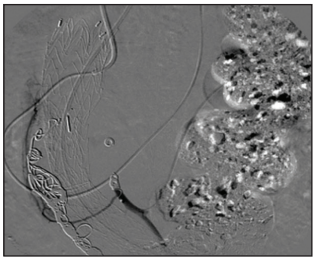

Figure 4.

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Embolization of a Pancreaticoduodenal Pseudoaneurysm Associated With Median Arcuate Ligament Syndrome

BY CIONI ROBERTO, MD; PERRONE ORSOLA, MD; CERVELLI ROSA, MD; AND SCANDIFFIO ROSSELLA, MD

CASE PRESENTATION

A 45-year-old woman with no significant medical history presented to our institution with acute upper abdominal pain. On the initial presentation, her hemoglobin level was 7.5 g/dL.

Contrast-enhanced multidetector CT was performed (Figure 1). In the arterial phase, a 3-mm pseudoaneurysm of the inferior pancreaticoduodenal artery was detected, as well as stenosis at the point where the aorta leads into the celiac artery.

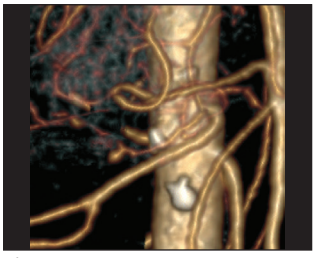
PROCEDURE DESCRIPTION

The patient was transferred to the angiography suite for coil embolization; emergency angiography confirmed the presence of the pseudoaneurysm (Figure 2).

Selective arterial embolization via a femoral approach was performed to treat the vascular lesion. The inferior pancreaticoduodenal artery was embolized with a 2- X 20-mm Interlock™-18 Fibered IDC Occlusion System through the superior mesenteric artery.

Digital subtraction angiography demonstrated incomplete occlusion of the pseudoaneurysm due to a retrograde flow to the celiac axis, by thin and twisting arterial branches (Figure 3). Then, double catheterization of the pseudoaneurysm, from both the cranial access (gastroduodenal artery and superior pancreaticoduodenal artery) and the caudal access (inferior pancreaticoduodenal artery) was performed using a 2.4-F torqueable Bern-shape Direxion™ Microcatheter.

Finally, a coil embolization of all the inflow vessels was achieved using the Interlock™ Fibered IDC Occlusion System.



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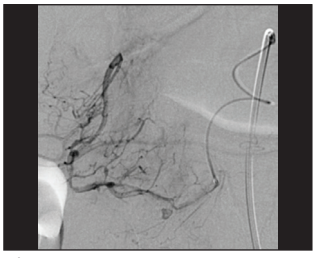

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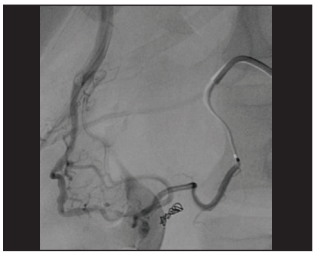

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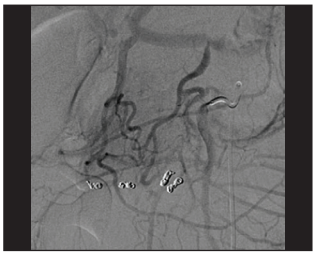

Figure 4.

FOLLOW-UP AND DISCUSSION

Final angiography demonstrated complete devascularization of the pseudoaneurysm (Figure 4). With the agreement of the vascular surgeons it was decided to surgically treat the celiac artery stenosis. The primary objective was to reduce the arterial inflow to the pancreaticoduodenal arch. Thanks to the trackability and flexibility of the torqueable Bern-shape Direxion, we could catheterize these tortuous and small arterial vessels. ■

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Selective Embolization of Traumatic Vascular Kidney Injury

BY ANGELO SPINAZZOLA, MD, AND NICOLA CIONFOLI, MD

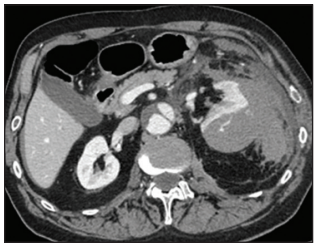
CASE PRESENTATION

A 78-year-old man was admitted to the emergency department and underwent a total body CT scan after a car accident. The scans showed a large subcapsular hematoma with active arterial supply at the middle-lower third level of the left kidney (Figure 1).

PROCEDURE DESCRIPTION

A 2.4-F Direxion™ Torqueable Microcatheter was used to engage the left renal artery and perform a super-selective catheterization of the middle-inferior lobe vessels. The angiogram confirmed active bleeding due to arterial laceration (Figure 2).

The first embolization was performed with 3- X 40-mm Interlock-18™ Detachable Coils. Using the same Direxion™ Microcatheter, with accurate torquablility, we were able to perform distal embolization, preserving renal parenchyma by using a 2- X 40-mm Interlock-18™ Fibered Detachable Coil (Figure 3).



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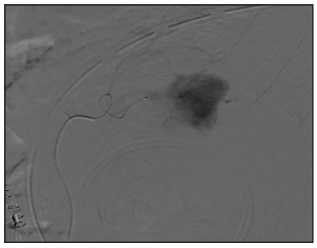

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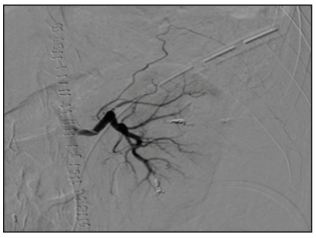

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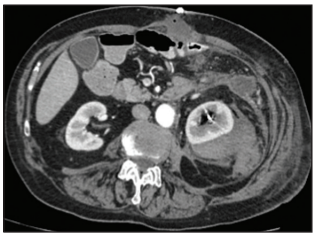

Figure 4.

FOLLOW-UP AND DISCUSSION

Final angiography confirmed a very good and precise embolization. After 5 days, CT scan showed a capsular hematoma reduction and absence of active bleeding (Figure 4). ■

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Disclosures: None.

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Embolization of a Large Hypogastric Ostium Aneurysm With Interlock™-18 Fibered Detachable Coils

BY ALBERTO SIRONI, MD

CASE PRESENTATION

A 77-year-old man presented with a large aneurysm located in the ostium of the hypogastric artery, which was diagnosed during CT control imaging. The angiographic control imaging confirmed a saccular aneurysm that was hemodynamically unstable (Figure 1).

PROCEDURE DESCRIPTION

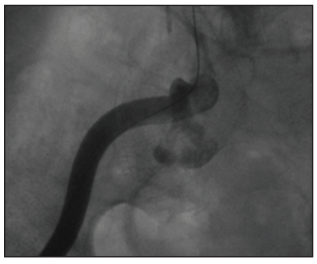
Using a 155-cm Bern-tip Direxion™ Microcatheter preloaded with a Fathom®-16 Guidewire, we were able to engage the hypogastric artery directly from the iliac artery and place the tip inside the aneurysm. The angiographic sac evaluation confirmed the saccular anatomy and showed a large vessel feeding the gluteus (Figure 2).

In order to preserve the hypogastric artery, we chose to embolize with Interlock™-18 Fibered Detachable Coils. The initial framing of the aneurysm was performed using two 22-mm X 60-cm coils. The empty space was packed with two 20-mm X 50-cm coils and three 10-mm X 30-cm coils (Figure 3).

FOLLOW-UP AND DISCUSSION

The last angiographic control showed a complete occlusion of the aneurysm, leaving the gluteus feeding vessel patent (Figure 4).

The Interlock™-18 enabled us to use fewer coils, and the Dacron® fibers allowed us to perform a fast and effective occlusion. ■



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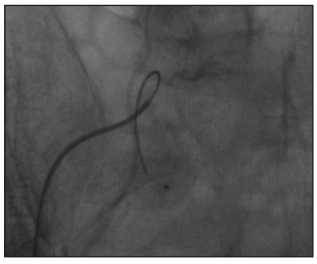

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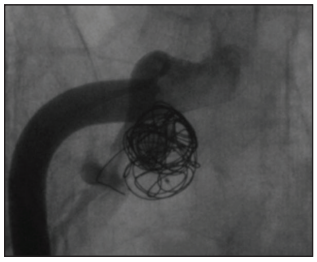

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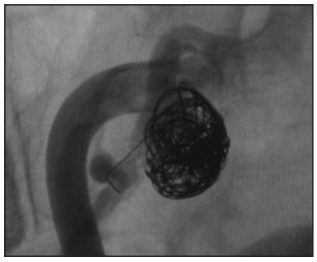

Figure 4.

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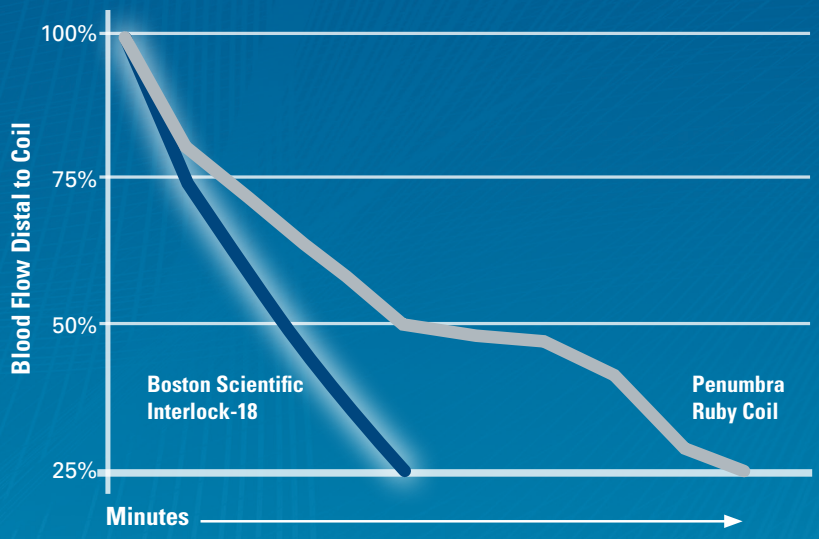
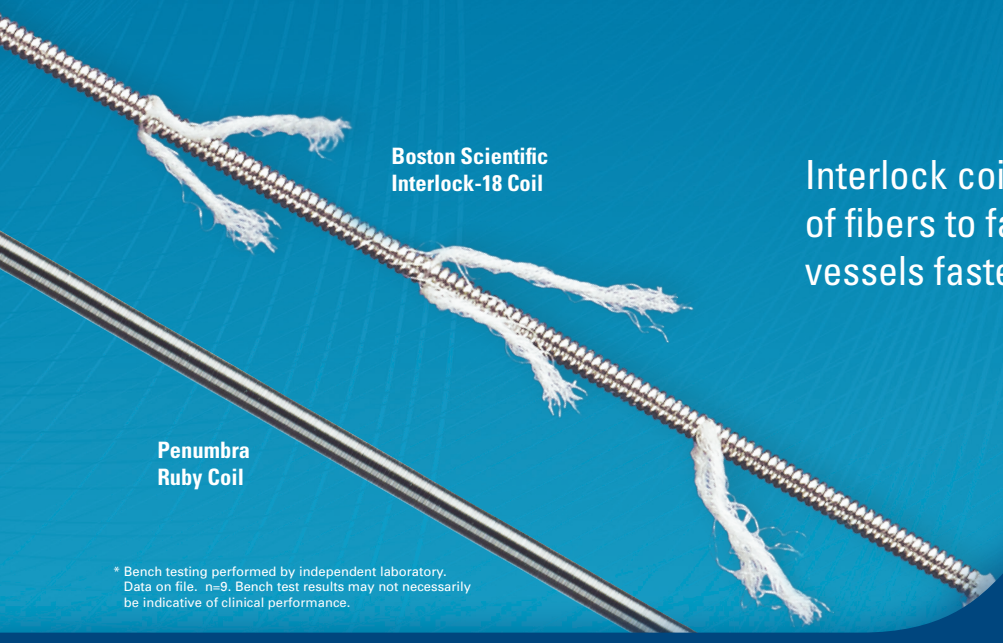
INTERLOCK™ Coils

MORE FIBER. MORE POWER.



Interlock Coils PERFORM FASTER

Penumbra Ruby™ Coils take over 50% longer to reach an occlusion test endpoint.*



Interlock coils feature dense networks of fibers to facilitate shutting down vessels faster, with fewer coils.

* Bench testing performed by independent laboratory. Data on file. n=9. Bench test results may not necessarily be indicative of clinical performance.

INTERLOCK™ FIBERED IDC™ OCCLUSION SYSTEM

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 Fibered IDC Occlusion System is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use. **CONTRAINDICATIONS:** None known. **GENERAL PRECAUTIONS:** Do not advance the Interlock Fibered IDC Occlusion System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter 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, 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 (REV AA)

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Embolization of a Renal Artery Arteriovenous Malformation Using Interlock-18™ Detachable Coils

BY PAOLO FACCIOLI, MD, AND SIMONE LIMONTA, MD

CASE PRESENTATION

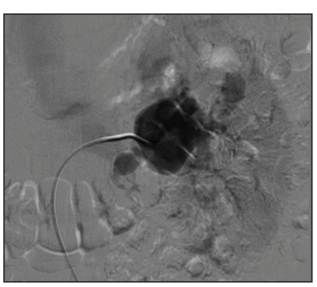
A 46-year-old woman with an arteriovenous malformation of the renal artery of the left kidney underwent angiographic evaluation, which revealed a large anastomosis of the renal artery with the venous system (Figure 1).

PROCEDURE DESCRIPTION

A Bern-shaped Direxion™ Torqueable Microcatheter with a Fathom™-16 Guidewire was used to distally select the feeding vessel. A first Interlock™-18 detachable coil was deployed (Figure 2).

To let the Dacron® fibers work, we waited a few minutes, but the patency persisted.

The same Direxion™ Microcatheter was used to detach a second and third Interlock™-18 coil (Figure 3). The torquability of the microcatheter allowed us to effectively position these coils and preserve the renal function.



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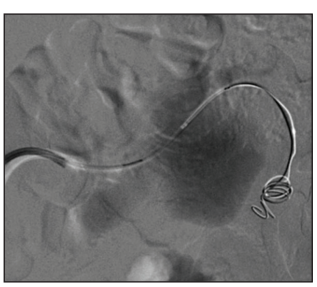

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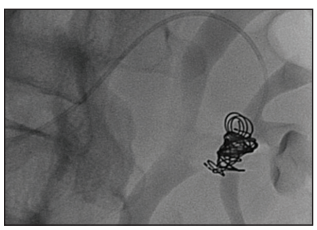

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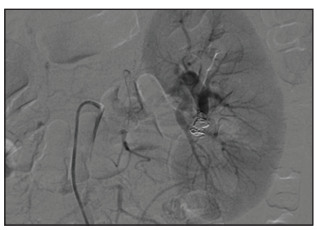

Figure 4.

FOLLOW-UP

The last angiographic control from the diagnostic catheter showed good results (Figure 4).

The anastomosis point was excluded and the renal vascularization was maintained, preserving the renal function. ■

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Disclosures: None.

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Embolization of a Type II Endoleak With Interlock™-18 Coils

BY MAURIZIO CARIATI, MD; PIERLUCA TORCIA, MD; UMBERTO G. ROSSI, MD, EBIR; AND PAOLO RIGAMONTI, MD

CASE PRESENTATION

A 77-year-old man underwent branched endovascular aneurysm repair for an abdominal and left iliac artery aneurysm with a chimney technique to the left renal artery.

At 24 months, a multidetector CT check-up of an inferior mesenteric artery type II endoleak also showed an enlargement of the abdominal aorta sac (Figure 1).

PROCEDURE DESCRIPTION

A 4-F catheter was used to cannulate the middle colic artery. We chose a straight-tip, 0.021-inch, 2.4-F, 155-cm Direxion™ Microcatheter and a Thruway™ Guidewire; however, the Thruway™ Guidewire was too stiff to navigate in this tortuous anatomy. We retracted the guidewire inside the microcatheter and continued without it. Because of the pushability of the Direxion™ Microcatheter, we were able to advance and cannulate the sac (Figure 2). The tip of the microcatheter was placed inside the nidus of the type II endoleak and was confirmed by angiography of the sac.

We used a liquid embolic system to fill the sac and a 3- X 12-cm Interlock™-18 Fibered Detachable Coil to perform embolization of the inferior mesenteric origin (Figure 3).

Despite a small perfusion through the coil, we waited a few minutes to allow the Dacron® fiber network to work because of its thrombogenicity.

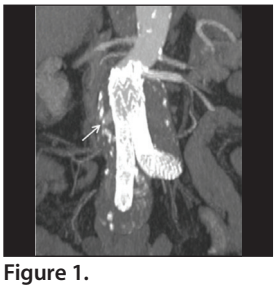
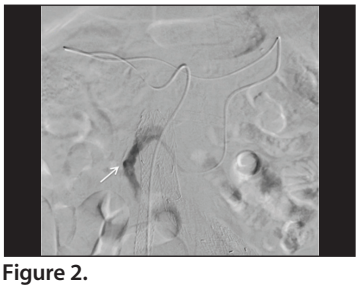


Figure 1.



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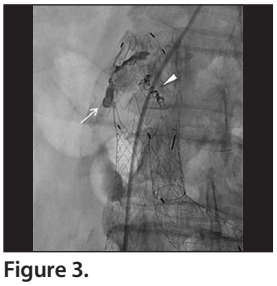

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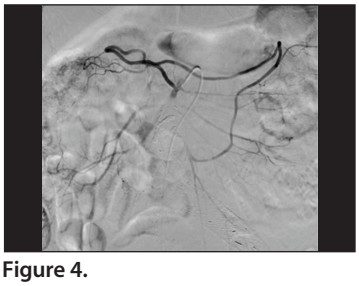

Figure 4.

FOLLOW-UP AND DISCUSSION

Final angiography demonstrated complete exclusion of the type II endoleak, with perfect embolization of the inferior mesenteric artery origin (Figure 4).

The patient was discharged on postoperative day 2 with no complications. Multidetector CT and contrast-enhanced ultrasound follow-up revealed no signs of endoleak with stability of the abdominal aorta sac. ■

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Disclosures: None.

Sponsored by Boston Scientific Corporation

Embolization of a Large Uterine Fibroid

BY ANTONIO RAMPOLDI, MD, AND CARMELO MIGLIORISI, MD

CASE PRESENTATION

A 48-year-old woman presented to our institution with a history of uterine fibroid treated with high-intensity focused ultrasound.

MRI showed three fibroids, including a larger one with intramural measurements of 46 X 50 X 43 mm (Figure 1). Because of some anatomic complications from the last high-intensity focused ultrasound treatment, the patient was a candidate for uterine fibroid embolization.

PROCEDURE DESCRIPTION

From a right femoral approach, we catheterized the left uterine artery. Angiographic evaluation showed no abnormal patterns (Figure 2). Due to a clear vaginal artery, we chose not to intervene.

The right side evaluation, however, showed an abnormal pattern related to the larger fibroid (Figure 3). We chose a 0.021-inch, 2.4-F Direxion™ Torqueable Microcather with the capacity to inject large particles with a good overall flow rate, great control, and navigability. We used one 2-mL syringe of 500-µm Embozene™ Microspheres to embolize any feeding vessel of the fibroid.

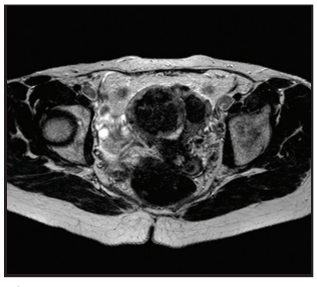
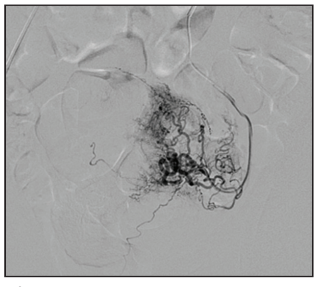


Figure 1.



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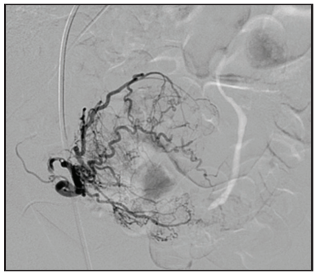

Figure 3.

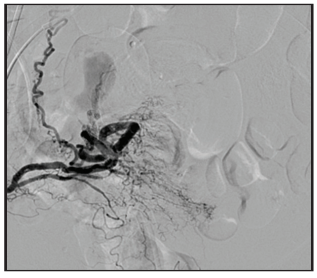

Figure 4.

FOLLOW-UP AND DISCUSSION

The treatment was successfully performed, and the embolization was completed with good fibroid exclusion. Final angiography confirmed exclusion of the fibroid and preservation of tissue vascularization (Figure 4). ■

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Embolization of Inferior Pancreaticoduodenal Artery Aneurysms Using the Direxion™ Torqueable Microcatheter

BY MARCO SANTORO, MD, PHD

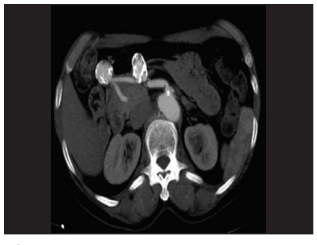
CASE PRESENTATION

A 77-year-old woman was referred for treatment of two aneurysms (24 X 20 mm and 20 X 18 mm) arising from the inferior pancreaticoduodenal artery (Figure 1). The celiac artery showed chronic total occlusion. The case was discussed with the vascular surgery team before deciding to proceed with coil embolization of both aneurysms.

PROCEDURE DESCRIPTION

Femoral access was achieved and preshaped microcatheters were chosen to reach the target lesions. Many unsuccessful attempts were made to cannulate the aneurysms using a preshaped 45° tip microcatheter and a 90° tip microcatheter (Figure 2).

After several failures, a 2.4-F Direxion™ Torqueable Microcatheter with the Transend™-14 System and a preshaped swan neck tip was chosen. The Direxion™ Torqueable Microcatheter was then successfully advanced over a Transend™-14 Guidewire until it reached the two aneurysms (Figure 3). The microcatheter's swan neck–shaped tip was crucial to the success of the procedure because it facilitated access through this challenging anatomy.



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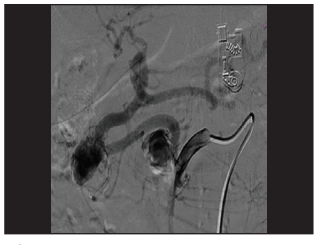

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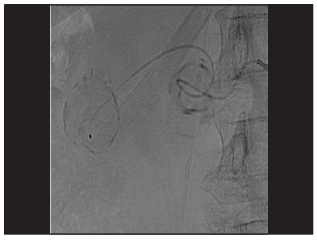

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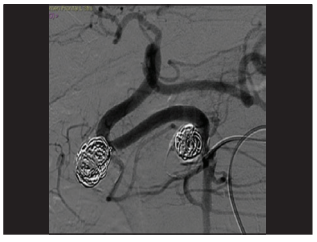

Figure 4.

A coil packing technique was then performed using Interlock™-18 Fibered Detachable Coils to achieve complete embolization of both aneurysms.

FOLLOW-UP AND DISCUSSION

Final angiography (Figure 4) showed that complete embolization of the two aneurysms was successfully achieved, and the native circulation was preserved. ■

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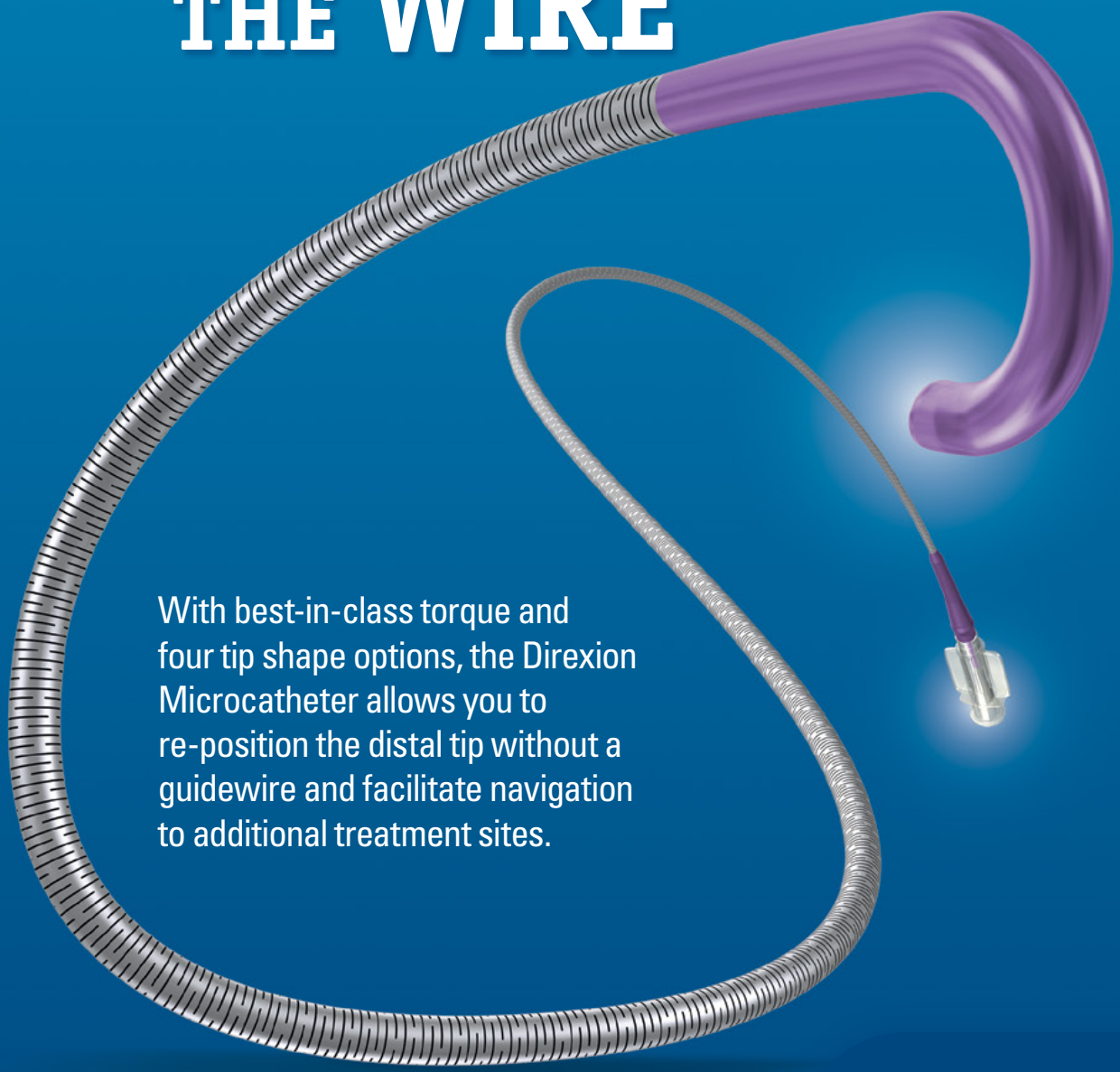
Disclosures: None.

Boston Scientific
Advancing science for life™

DIREXION™ Torqueable Microcatheter

REPOSITION WITHOUT THE WIRE



With best-in-class torque and four tip shape options, the Direxion Microcatheter allows you to re-position the distal tip without a guidewire and facilitate navigation to additional treatment sites.

DIREXION™ DIREXION HI-FLO™

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) **REV AB**

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Partial Splenic Artery Embolization in the Treatment of Hypersplenism

BY RITA GOLFIERI, MD, AND FRANCESCO MODESTINO, MD

CASE PRESENTATION

A 30-year-old woman with a history of hepatitis B virus-related cirrhosis presented to our institution. In 2013, she underwent transarterial chemoembolization for hepatocellular carcinoma, followed by liver transplantation in August 2014.

After surgery, the patient developed portal hypertension and hypersplenism (Figure 1). Partial splenic embolization was proposed.

PROCEDURE DESCRIPTION

From a right femoral access, we catheterized the splenic artery to perform diagnostic angiography using a 5-F sheath and a 4-F cobra catheter (Figure 2). We then decided to go distally to the peripheral intrasplenic branches to perform a more selective embolization.

A torqueable Direxion™ Microcatheter and a Fathom®-16 Guidewire were easily advanced through a tortuous splenic branch to perform superselective catheterization of three vessels supplying the upper middle third of the spleen. Subsequently, we embolized those branches using microcoils (Figure 3). After embolization, the patient developed transient abdominal pain, which remitted with administration of pain relief medication.

FOLLOW-UP AND DISCUSSION

A postembolization CT scan demonstrated a successful embolization with evidence of partial devascularization of the spleen, with minimal perisplenic and perihepatic fluid and the absence of major complications (Figure 4).

The patient showed significant reduction of portal pressure and was discharged a few days later. She was still in good clinical condition at follow-up. ■

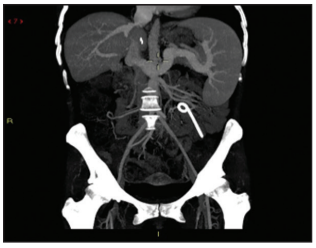
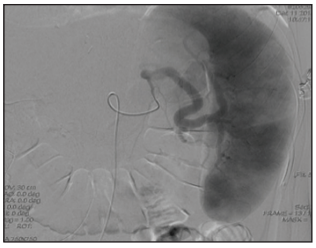


Figure 1.



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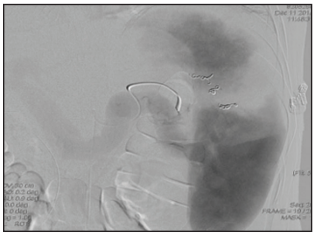

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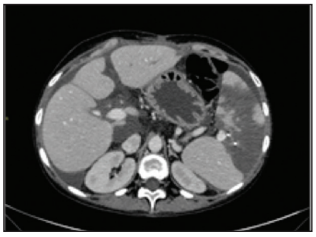

Figure 4.

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Disclosures: None.

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Direxion Direxion HI-Flo

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).

Fathom-16 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.

Oncozene Microspheres

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.*

INDICATIONS

ONCOZENE Microspheres are indicated for the embolization of arteriovenous malformations and hypervascular tumors including hepatoma.

CONTRAINDICATIONS

Embolization procedures shall not be performed if:

- Patient is unable to tolerate vascular occlusion procedures.
- Vascular anatomy precludes correct catheter placement or embolic injection.
- Presence or likely onset of vasospasm.
- Presence of a blood coagulation disorder that would prohibit arterial punctures.
- Presence of severe atheromatous disease that would preclude correct catheter placement.
- Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation.
- Presence of collateral vessel pathways which could potentially endanger non-targeted tissue during an embolization procedure.
- Presence of any vasculature where ONCOZENE Microspheres could pass directly into the central nervous system, central circulatory system, or other non-target territories.
- Patient has high-flow arteriovenous shunt with diameter greater than the selected ONCOZENE Microspheres.
- Patient is pregnant.
- Patient has known allergies to barium sulfate, 3-aminopropyltrialkoxysilane, polyphosphazene or IV radiopaque contrast agent.

WARNINGS

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, and may include, but not be limited to:

- Undesirable reflux or passage of ONCOZENE Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Embolization of the wrong artery or migration of the microspheres to other parts of the body, which may necessitate further treatment.
- Hematoma, or bruising, at the incision site for arterial access.
- Arterial aneurysm at the incision site for arterial access.
- Deep vein thrombosis, or clotting of a deep vein in patient's leg(s).
- Thrombosis of the artery at the incision site for arterial access.
- Pulmonary embolization.
- Ischemia at an undesirable location.
- Capillary bed saturation and tissue damage.

- Ischemic stroke or ischemic infarction.
- Vessel or lesion rupture and hemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Recanalization.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.
- Allergic reaction.
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include a radiation burn and risks to future fertility.
- Death.

Do not use ONCOZENE Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.

Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.

PRECAUTIONS

To maintain safety, the following precautions shall be considered:

- The physician should carefully select the size and quantity of ONCOZENE according to the lesion to be treated based on the physician's education and training and currently available scientific evidence.
- Physicians must decide the most appropriate time to stop the infusion of ONCOZENE Microspheres. Typically, the artery will accept fewer ONCOZENE Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by ONCOZENE Microspheres. Careful fluoroscopic monitoring is required.
- Microparticle embolization must be performed slowly. The injection speed and manner must be controlled Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other nontarget, healthy tissue or organs.
- Safety and effectiveness of ONCOZENE Microspheres in the treatment of uterine fibroids has not been established.
- Safety and effectiveness of ONCOZENE Microspheres for renal embolization uses has not been established.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization are present, it can lead to nontargeted embolization and cause severe complications for the patient.
- Particles smaller than 100 µm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller particles have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure. Possible consequences include, but are not limited to, paralysis, necrosis, swelling, abscess formation and more severe post-embolization syndrome.
- Ischemia of tissue adjacent to the targeted area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as the nervous system.
- Consider upsizing ONCOZENE Microspheres if angiographic appearance of embolization does not quickly appear during injection of the microspheres.
- If there are any symptoms of unwanted embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient vital signs, such as hypoxia or central nervous system changes.

Embozene Microspheres

***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.*

INDICATIONS

Embozene Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

CONTRAINDICATIONS

Embolization procedures shall not be performed if:

• Patient is unable to tolerate vascular occlusion procedures.
• Vascular anatomy precludes correct catheter placement or embolic injection.
• Presence or likely onset of vasospasm.
• Presence of a blood coagulation disorder that would prohibit arterial punctures.
• Presence of severe atheromatous disease that would preclude correct catheter placement.
• Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation.
• Presence of collateral vessel pathways which could potentially endanger non-targeted tissue during an embolization procedure.
• Presence of any vasculature where Embozene Microspheres could pass directly into the central nervous system, central circulatory system or other nontarget territories.
• Patient has high-flow arteriovenous shunt with diameter greater than the selected Embozene Microspheres.
• Patient is pregnant.
• Patient has known allergies to barium sulfate, 3-aminopropyltrialkoxysilane, polyphosphazene or IV radiopaque contrast agent.

WARNINGS

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, and may include, but not limited to:

- Undesirable reflux or passage of Embozene Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Embolization of the wrong artery or migration of the microspheres to other parts of the body, which may necessitate further treatment.
- Hematoma, or bruising, at the incision site for arterial access.
- Arterial aneurysm at the incision site for arterial access.
- Deep vein thrombosis, or clotting of a deep vein in patient's leg(s).
- Thrombosis of the artery at the incision site for arterial access.
- Pulmonary embolization.
- Ischemia at an undesirable location.
- Capillary bed saturation and tissue damage.
- Ischemic stroke or ischemic infarction.
- Vessel or lesion rupture and hemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Recanalization.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.
- Allergic reaction.
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include a radiation burn and risks to future fertility.
- Death.

Do not use Embozene Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.
Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.

PRECAUTIONS
To maintain safety, the following precautions shall be considered:

- Safety and effectiveness of Embozene Microspheres in the treatment of uterine fibroids has not been established
- Safety and effectiveness of Embozene Microspheres for hepatic and renal embolization uses has not been established.
- The physician should carefully select the size and quantity of Embozene Microspheres according to the lesion to be treated based on the physician's education and training and currently available scientific evidence.
- Physicians must decide the most appropriate time to stop the infusion of Embozene Microspheres. Typically the artery will accept fewer Embozene Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by Embozene Microspheres. Careful fluoroscopic monitoring is required.
- Microparticle embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other non-target healthy tissue or organs
- The color of the Embozene Microspheres may be visible through the skin if injected into superficial arteries.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization are present, it can lead to non-targeted embolization and cause severe complications for the patient.
- Microspheres smaller than 100 µm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller microspheres have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure. Possible consequences include, but are not limited to, paralysis, necrosis, swelling, abscess formation and more severe post-embolization syndrome.
- Ischemia of tissue adjacent to the targeted area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as the nervous system.
- Consider upsizing Embozene Microspheres if angiographic appearance of embolization does not quickly appear during injection of the microspheres.
- If there are any symptoms of unwanted embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient vital signs, such as hypoxia or central nervous system changes.

Fibered IDC
Interlock Fibered IDC Occlusion System
IDC Interlocking Detachable Coil

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.

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 re actions necessitating medical intervention, hemorrhage, infection necessitating medical intervention, ischemia, pain, recanalization, temporary neurological deficit, tissue necrosis, undesirable clot formation of the vasculature, vasospasm.

Transend Guidewire with ICE Coating

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 Transend Guidewire is intended for general intravascular use, including the peripheral vasculature. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters.

CONTRAINDICATIONS

This device is not intended for use in coronary arteries.

PRECAUTIONS

This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

ADVERSE EVENTS

Complications attributed to guidewire applications are the following:

- Procedural related complications including but not limited to: vessel trauma, vessel damage, air embolism, thromboembolism, post embolization syndrome (abdominal pain, fever, and nausea/vomiting), hematoma at the puncture site, infection, perforation of the vessel, vessel spasm, hemorrhage, vascular thrombosis, death, bleeding
- Failed treatment
- Inability to position guidewire
- Damage to catheter
- Excessive force against resistance may result in separation of the guidewire tip

Renegade STC 18 Microcatheter
Renegade Fiber Braided Microcatheter
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.

Thruway .014 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 Thruway Guidewire facilitates placement of a catheter during diagnostic or interventional peripheral intravascular procedures including but not limited to renal intervention. The wire can be torqued to facilitate navigation through the vasculature.

CONTRAINDICATIONS

• Not intended for use in coronary arteries.
• Not intended for use in the neurovasculature.

WARNINGS/ADVERSE REACTIONS

The complications that may result from the use of a guidewire in a procedure include:
• Vessel perforation, dissection, trauma or damage
• Embolism
• Hematoma
• Infection
• Vessel spasm
• Hemorrhage
• Renal Failure
• Myocardial Infarction
• Vascular thrombosis
• Stroke
• Death

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