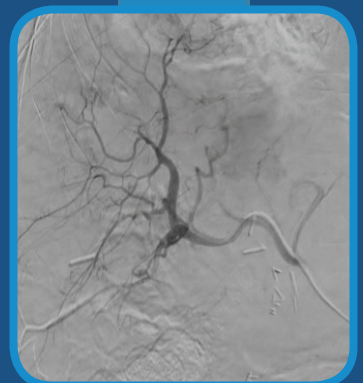
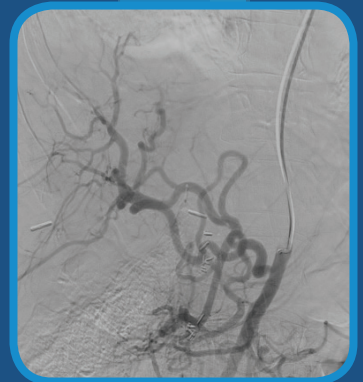
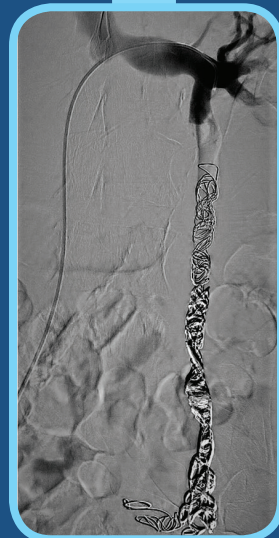
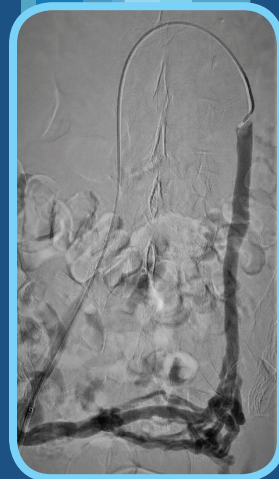


# Endovascular TODAY

April 2019

## OPTIMIZING EMBOLIC THERAPY in Challenging Cases





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# OPTIMIZING EMBOLIC THERAPY in Challenging Cases

## CASE REPORT

# Embolization of Transarterial Type II Endoleak Using Interlock™ Detachable Coils

BY GUSTAVO S. ODERICH, MD; BERNARDO C. MENDES, MD; AND MARIO D'ORIA, MD

An 85-year-old man presented to outpatient consultation with a persistent type II endoleak 4 years after endovascular aneurysm repair for an infrarenal abdominal aortic aneurysm. Previous medical history included coronary artery disease, pulmonary hypertension, and stage 3 chronic kidney disease. CTA revealed a type II endoleak originating from the inferior mesenteric artery (IMA). There was significant enlargement of the aneurysm sac, which measured up to 6.5 cm in the maximal transverse diameter, compared to 6.2 cm and 5.1 cm 1 and 2 years prior to presentation, respectively. The presence of the type II endoleak was confirmed by contrast-enhanced ultrasound (CEUS), which revealed retrograde filling from the IMA (Figure 1).

## PROCEDURE

Under general endotracheal anesthesia, the patient was positioned supine, and right percutaneous femoral access was achieved. The superior mesenteric artery (SMA) was selectively catheterized, and contrast injection revealed flow into the IMA via collaterals, confirming the presence of a large type II endoleak originating from the IMA (Figure 2). Using a Renegade® STC Microcatheter (Boston Scientific Corporation) and a Glidewire® Gold hydrophilic guidewire (Terumo Interventional Systems), the middle colic artery and IMA were selectively catheterized. The microcatheter was then advanced into the aneurysm sac, which was

excluded using numerous Interlock™ -18 Detachable Coils (Boston Scientific Corporation). The proximal IMA was also embolized using Interlock™ -18 Detachable Coils. Completion angiography revealed successful exclusion of the IMA with no evidence of residual endoleak (Figure 3). The postoperative course was uneventful, and the patient was discharged home on postoperative day 1.

## DISCUSSION

Endoleaks are the most common event after endovascular aneurysm repair; lifelong surveillance is recommended because their persistence may lead to aneurysm sac expansion and aortic rupture.<sup>1</sup> Treatment of type II endoleak has been a topic of significant controversy. Support for conservative management derives from the estimated low risk of late rupture secondary to isolated type II endoleak.<sup>2</sup> However, although some authors have argued that prophylactic embolization in selected patients can decrease the risk of persistent type II endoleak and aneurysm sac growth,<sup>3</sup> most would use a strategy of selective secondary intervention in the presence of significant aneurysm sac expansion, which is supported by current guidelines.<sup>4</sup>

Access to the aneurysm sac can be achieved via multiple approaches depending on type II endoleak location and delineation based on preoperative imaging. The transarterial approach usually represents the first-line option.<sup>5</sup> When the IMA is involved, an SMA-to-IMA access (via the arc of Riolo or marginal artery of Drummond) may be chosen. Once stable access is achieved and an introducer sheath can be advanced in the proximal SMA, a floppy system composed of a microcatheter and microwire (similar to the combination utilized in the presented case) is preferred to navigate through the collateral into the IMA and the aortic aneurysm sac. Alternatively, the authors have found the 0.014-inch Fathom™ Steerable Guidewire (Boston Scientific Corporation) to have excellent steerability.

Complete obliteration of the endoleak nidus with elimination of all inflow and outflow vessels is required

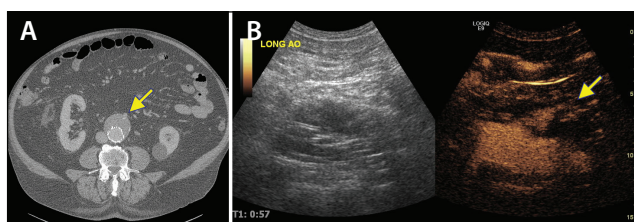
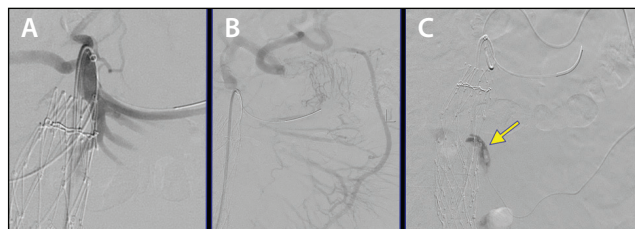


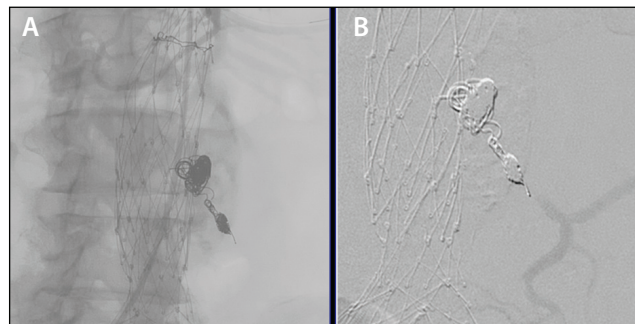
Figure 1. Preoperative CTA (A) and CEUS (B) demonstrated the presence of type II endoleak with retrograde flow from a patent IMA (arrows).



**Figure 2.** Intraoperative angiography showed placement of a coaxial system within the SMA (A) and identified the large SMA-IMA collateral (B). Successful retrograde navigation through the middle colic artery down to the IMA (C) with confirmation of retrograde flow within the aneurysm sac (arrow).

to prevent recurrence and can be achieved with different materials, typically a combination of plugs, coils, and/or Onyx™ liquid embolic (Medtronic). One benefit of Onyx™ is its ability to advance beyond the site of delivery and disperse through the endoleak nidus to fill the ingress and egress vessels. Being radiopaque, it can be closely followed under fluoroscopic guidance, and injection may be stopped if there is inadvertent nontarget delivery. Coils represent a feasible alternative, allowing for easy trackability during the procedure and quick placement within small vessels. In the case described in this article, the choice of coils was based on their accurate deployment and control because of the detachable mechanism and polyethylene terephthalate fibered structure, which is highly thrombogenic and provides a uniquely stable, permanent platform for blood stasis, thrombus organization, and neointima formation. To avoid persistent flow through the coils, care must be taken to ensure they are properly packaged within the endoleak nidus. Finally, plugs can safely and effectively occlude the target vessel right at the ostium, preserving any anastomosis that remains patent.

Although generally safe, secondary interventions for type II endoleak are often unsatisfactory because persistence/recurrence are commonly encountered.<sup>6</sup> Therefore, follow-up imaging is key to evaluate technical and clinical success. Type II endoleak persistence/recurrence may be difficult



**Figure 3.** Completion angiography showed a widely patent SMA (A) and IMA distally to the placed coils with absence of residual sac filling (B).

to identify in the presence of Onyx™ or coils, because both cause significant scatter artifact on CTA. However, sac diameter measurements are usually not inhibited by the artifact and, when combined with duplex ultrasound and/or CEUS, recurrent flow within the sac can still be estimated with reasonable certainty.

## CONCLUSION

Treatment of type II endoleak can be performed safely and effectively utilizing several approaches. When a transarterial route is performed, appropriate utilization of a support system into the SMA or internal iliac artery is recommended, followed by use of a microcatheter and a steerable microwire. Treatment is usually accomplished with a combination of plugs, coils, and/or Onyx™. Continued imaging follow-up after type II endoleak treatment is required to identify persistence/recurrence as well as stabilization or regression of the aneurysm sac. ■

1. Candell L, Tucker LY, Goodney P, et al. Early and delayed rupture after endovascular abdominal aortic aneurysm repair in a 10-year multicenter registry. *J Vasc Surg.* 2014;60:1146-1153.
2. Sidloff DA, Stather PW, Choke E, et al. Type II endoleak after endovascular aneurysm repair. *Br J Surg.* 2013;100:1262-1270.
3. Alerci M, Giamboni A, Wyttenbach R, et al. Endovascular abdominal aneurysm repair and impact of systematic preoperative embolization of collateral arteries: endoleak analysis and long-term follow-up. *J Endovasc Ther.* 2013;20:663-671.
4. Wanhainen A, Verzini F, Van Herzele I, et al. Editor's choice — European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg.* 2019;57:8-93.
5. Gallagher KA, Ravin RA, Meltzer AJ, et al. Midterm outcomes after treatment of type II endoleaks associated with aneurysm sac expansion. *J Endovasc Ther.* 2012;19:182-192.
6. Ultee KHJ, Buttner S, Huurman R, et al. Editor's choice — systematic review and meta-analysis of the outcome of treatment for type II endoleak following endovascular aneurysm repair. *Eur J Vasc Endovasc Surg.* 2018;56:794-807.

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## CASE REPORT

# Embozene™ Microspheres for Uterine AVM Embolization

BY JUAN FRANCISCO MORALES-LEON, MD; ROBERT J. RAYMOND, MD;  
MARY BROOKES EZELL, MD; BRUCE BORDLEE, MD; AND JAMES CARIDI, MD, FSIR

A 27-year-old woman who was gravida 3 para 2 presented to an obstetrics and gynecology clinic with complaints of persistent pelvic pain and vaginal bleeding following medical termination of pregnancy with methotrexate (without dilation and curettage [D&C]) about 4 weeks earlier. Physical exam at that time was notable for a 12-week-sized markedly tender uterus. Pelvic ultrasound revealed a large, hypervascular uterus with a large uterine arteriovenous malformation (AVM) measuring at least 3.5 cm X 1 cm in the sagittal plane (Figure 1).

The patient had a past medical history significant for systemic lupus erythematosus, arthritis, genital herpes, and cervicitis. Her most recent prior pelvic ultrasound was unremarkable (about 2 months prior to presentation). The AVM malformation was confirmed with a pelvic CTA, which also demonstrated dilated vessels within the endometrium, raising the concern of retained products of conception (Figure 2). Because the patient desired future fertility, she was referred to the interventional radiology department for a possible uterine AVM embolization.

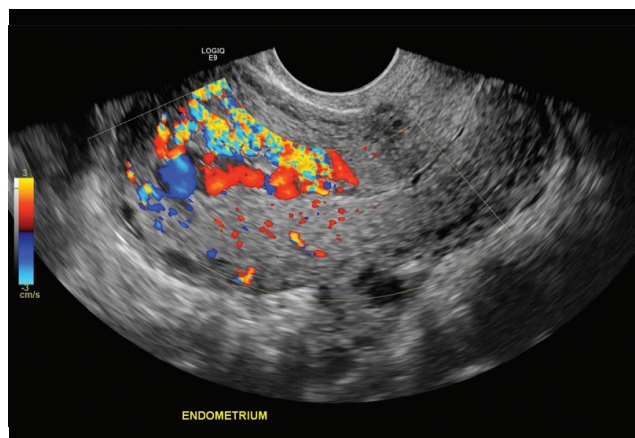


Figure 1. Sagittal ultrasound of the uterus showed a 3.5-cm X 1-cm uterine AVM at the time of initial presentation.

## PROCEDURE

The embolization was performed as an outpatient procedure, utilizing a right groin access that was achieved under direct ultrasound guidance. A 4-F Omni™ Flush catheter (AngioDynamics) was advanced through a 5-F Pinnacle® introducer sheath (Terumo Interventional Systems) into the distal abdominal aorta, with subsequent aortoiliac angiography demonstrating patent vessels with filling of a large uterine AVM, predominantly supplied by

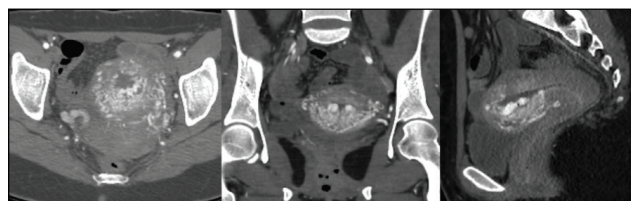


Figure 2. Pelvic CTA showing axial, coronal, and sagittal views of approximately 5-cm X 5-cm X 1.5-cm dilated disorganized vascular structures encompassing the anterior and lateral uterine walls and fundus.

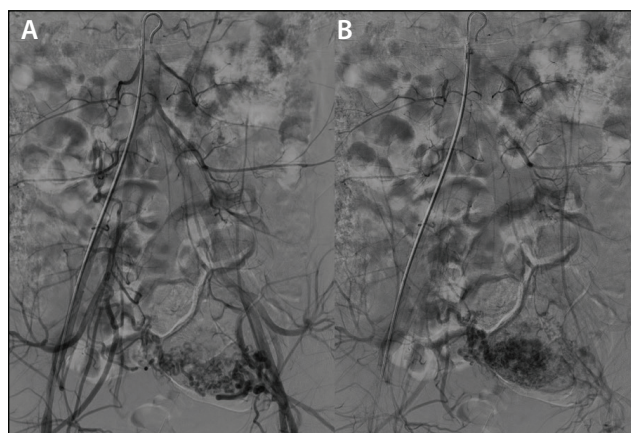
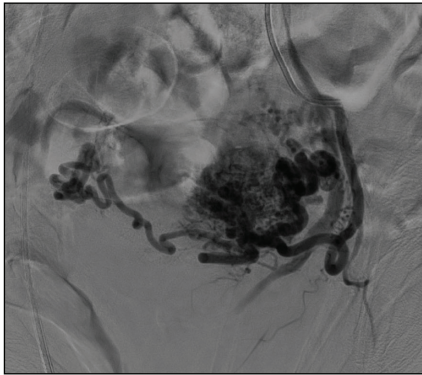
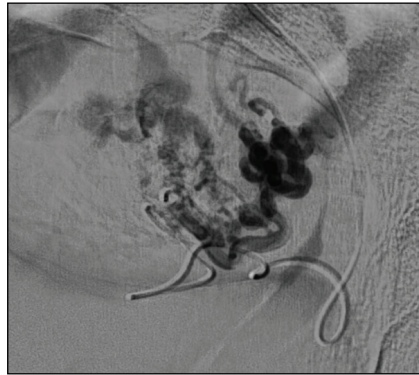


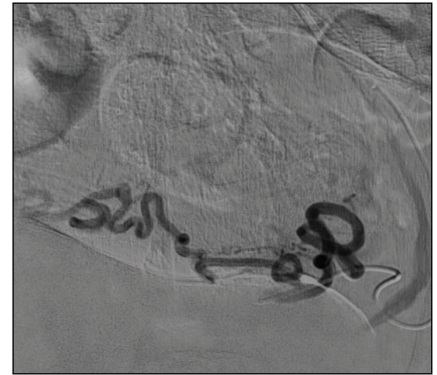
Figure 3. Arterial (A) and venous (B) phase frontal aortoiliac angiogram demonstrated filling of a large uterine AVM, supplied by the left uterine artery without evidence of feeders from the right uterine artery (B).



**Figure 4.** Frontal angiography of a selective left hypogastric catheterization showed AVM filling.



**Figure 5.** Superselective angiogram of the distal left uterine artery with a straight Renegade® STC-18 Microcatheter exhibited filling of the AVM.



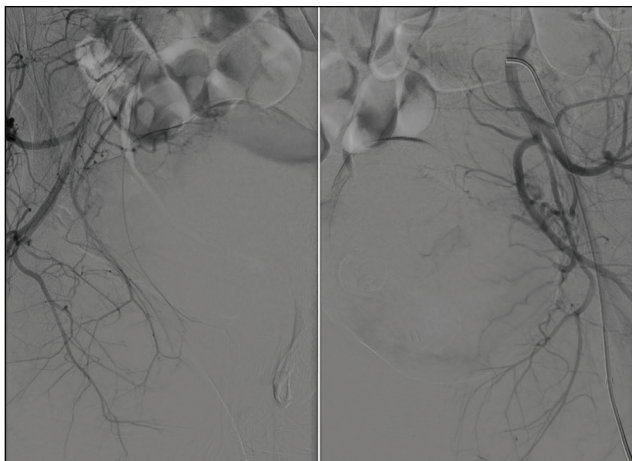
**Figure 6.** Frontal angiographic image after the use of gelfoam for further embolization; no residual filling of the AVM was visible.

the left uterine artery (Figure 3). The catheter was then manipulated into the left hypogastric artery (Figure 4). Subsequently, a straight 0.021-inch 130-cm Renegade® STC-18 Microcatheter (Boston Scientific Corporation) was then advanced into the distal left uterine artery over a Fathom®-16 Guidewire (Boston Scientific Corporation). Additional images were obtained (Figure 5) before delivering four vials of 700- $\mu$ m Embosphere™ Microspheres (Boston Scientific Corporation). Due to a small amount of residual flow to the AVM, a gelfoam slurry was then used for further embolization, after which, near stasis was achieved with no filling of the AVM (Figure 6).

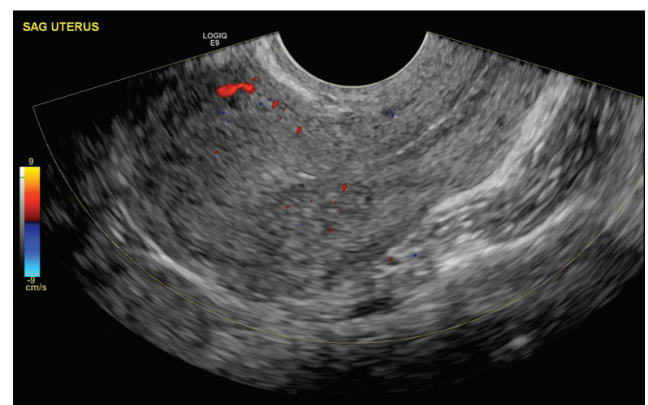
Interrogation of the right internal iliac artery was also performed and demonstrated no feeding vessels to the AVM. Because the patient desired future fertility and no flow to the malformation was identified, the decision was made to stop the procedure at this point.

## RESULTS

Approximately 3 hours after the procedure, the patient began experiencing profuse vaginal bleeding followed by tachycardia and hypotension. The patient was sent for emergent repeat angiography (Figure 7). Because the right side was not embolized, the repeat bleeding was thought to come from that source, but was negative. Left uterine artery evaluation also revealed no radiographic evidence of bleeding. Ovarian artery interrogation was also negative. Products of conception were of primary concern after reviewing the imaging. An emergent D&C was then performed, revealing remaining products of conception as the source. Bleeding ceased following the procedure. The patient stabilized and the rest of her hospital course was unremarkable aside from mild pelvic pain. A 3-month follow-up pelvic ultrasound revealed complete resolution of the uterine AVM with a normal-appearing uterus and endometrium (Figure 8).



**Figure 7.** Repeated frontal angiogram demonstrated no filling of the uterine AVM.



**Figure 8.** Pelvic ultrasound at 3-month follow-up showed complete resolution of the uterine AVM.

## DISCUSSION

Uterine AVMs are almost always acquired and rarely congenital. They are typically seen in premenopausal women, and risk factors include multiple gestations, D&C, intrauterine devices, cesarean section, and infection. Uterine AVMs result from failed development of a primitive capillary plexus resulting in multiple intra- and extrauterine feeding arteries and large draining veins with an intervening vascular nidus. Acquired uterine AVMs result from abnormal communications between the intramural arterial branches and the myometrial venous plexus without an intervening vascular nidus. Acquired uterine AVMs are typically easier to treat with transarterial embolization due to a lack of extrauterine arterial supply with only one or both uterine arteries supplying one or two feeding vessels.

Uterine AVMs have the potential for life-threatening vaginal bleeding, mandating early diagnosis and treatment. It is important to note that treatment for uterine bleeding with D&C is contraindicated in the setting of a uterine AVM, as it can paradoxically worsen the bleeding. Depending on the severity of symptoms, uterine AVM treatment options range from watchful waiting and medical management to endovascular or surgical intervention. If asymptomatic, monitoring is preferred; spontaneous resolution is common. If symptoms are minimal, medical treatment with oral contraceptives or danazol is a potential option, with the reasoning that decreased blood flow to the uterus may permit the AVM to thrombose. For stable to unstable patients with acute to subacute bleeding, the patient's desire for future fertility must be considered when determining surgical versus endovascular intervention. During instances of acute massive bleeding that require emergent intervention or if future fertility is no longer desired, hysterectomy should be considered as a definitive option. Catheter-directed uterine artery embolization is preferred when future fertility is desired.

When performing uterine AVM embolization, angiography of bilateral uterine arteries must be performed to evaluate for cross filling of feeder vessels. Furthermore, cross filling may not be apparent on initial angiography. Embolization can be performed with gelfoam, polyvinyl alcohol particles, microspheres,

or glue. Complications of uterine artery embolization include pelvic pain, perianal skin sloughing, uterovaginal or rectovaginal fistulas, and lower extremity neurologic deficits. Retained products of conception can potentially result in profuse postprocedural bleeding under the guise of a failed intervention. Following a negative repeat angiogram, retained products of conception should be reconsidered as the source, especially in the setting of recent pregnancy. ■

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## CASE REPORT

# Metastatic Neuroendocrine Tumor Using Direxion™ Microcatheter and Embozene™ Microspheres

BY EDWARD KIM, MD

A 72-year-old man had a metastatic neuroendocrine tumor of the liver that had undergone radioembolization 2 years prior; he presented with an enlarging 4-cm solitary lesion in Couinaud segment 5 visible on recent 3-month follow-up surveillance MRI. Of note, the patient had a prior history of surgery with ligation of the common hepatic artery origin. A history and physical examination was performed without evidence of encephalopathy or abdominal ascites. The patient's performance status assessment indicated an ECOG (Eastern Cooperative Oncology Group) score of 0. Laboratory studies revealed unremarkable liver function tests, total bilirubin level of 0.6 mg/dL, and albumin level of 4.2 g/dL. The coagulation profile and platelet levels were unremarkable. MRI demonstrated multiple lesions throughout the noncirrhotic liver with an enlarging solitary lesion in segment 5 (Figure 1). The patient was reviewed in a multidisciplinary neuroendocrine conference, and it

was decided to proceed with embolization using 40- $\mu$ m Embozene™ Microspheres (Boston Scientific Corporation) for palliative treatment of oligometastatic disease.

## PROCEDURE

Angiography was performed to identify the tumor vascular supply and determine the optimal route for delivery of embolic materials. Through radial access, initial superior mesenteric angiography was performed, which identified a reconstitution of the right hepatic artery (RHA) arising through the pancreaticoduodenal arcade (Figure 2). Catheterization of the celiac artery was performed and reconstitution of the RHA arising from the right gastric artery was demonstrated (Figure 3). The RHA and segmental branch artery were selectively catheterized with a 2.4-F Direxion™ Microcatheter (Boston Scientific Corporation) over a Fathom®-16 Guidewire (Boston Scientific Corporation) (Figure 4). Embolization was performed with 40- $\mu$ m Embozene™ Microspheres

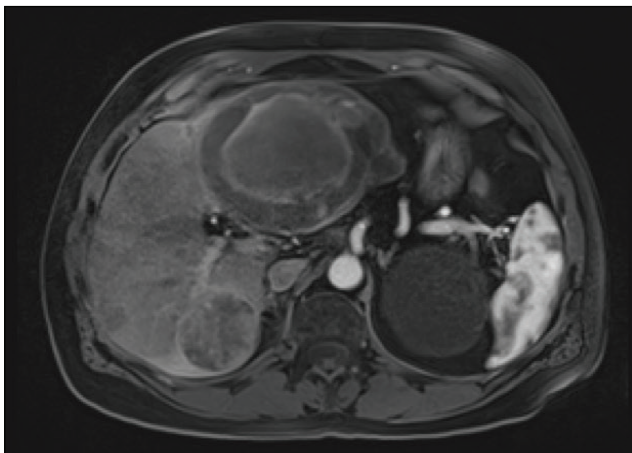
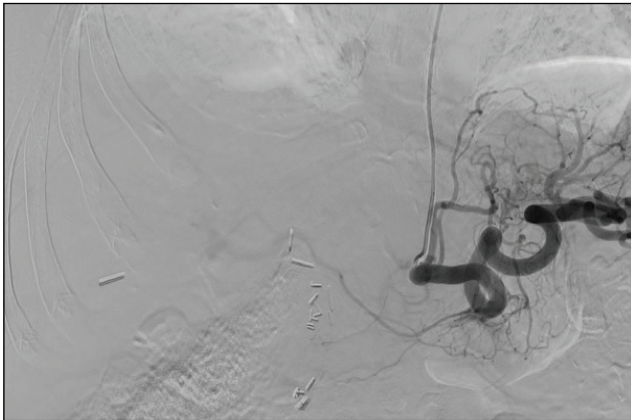


Figure 1. MRI demonstrated multiple lesions throughout the noncirrhotic liver with an enlarging solitary lesion in segment 5.

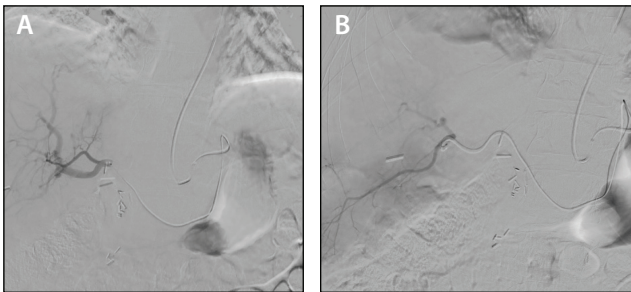


Figure 2. Initial superior mesenteric angiography was performed from radial access and identified a reconstitution of the RHA arising through the pancreaticoduodenal arcade.





**Figure 3.** Catheterization of the celiac artery was performed, and reconstitution of the RHA arising from the right gastric artery was demonstrated.



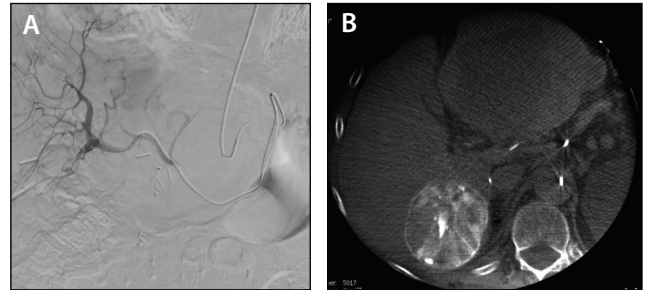
**Figure 4.** The RHA (A) and segmental branch artery (B) were selectively catheterized with a 2.4-F Direxion™ Microcatheter over a Fathom®-16 Guidewire.

until stasis was achieved. Confirmation postembolization angiography as well as cone-beam CT were performed (Figure 5).

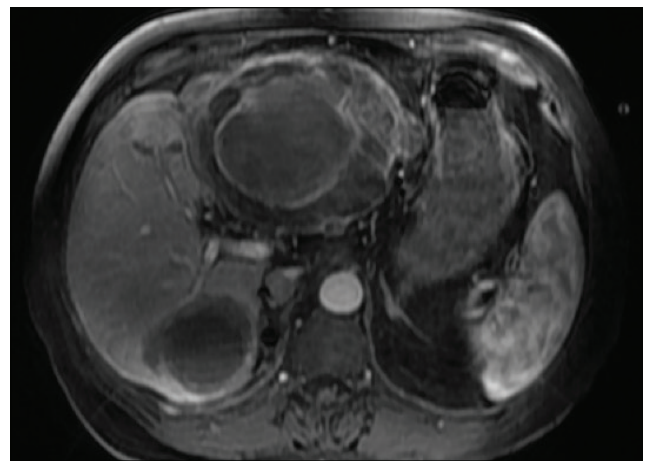
A 4-week postprocedure liver MRI demonstrated 100% complete response (Figure 6). Follow-up laboratory studies were unremarkable and without treatment toxicity.

## DISCUSSION

Catheterization and navigation through collateral vessels with microcatheter and wire manipulation may be challenging due to difficulty in selection and tracking of the microcatheter. As demonstrated in this case, the shapeable tip of the Fathom®-16 Guidewire and stable support in combination with the trackability of the Direxion™ Microcatheter allowed ease of catheterization



**Figure 5.** Embolization was performed with 40-μm Embosphere™ Microspheres until stasis. Confirmation postembolization angiography (A) and cone-beam CT were performed (B).



**Figure 6.** A 4-week postprocedure liver MRI demonstrated 100% complete response.

of the RHA through the left and right gastric arteries despite surgical ligation of the common hepatic artery. Further subselection of segment 5 of the RHA was possible from radial access without an issue with length despite multiple turns. Tightly calibrated 40-μm Embosphere™ Microspheres allowed distal embolization of the target tumor vessels with complete response on follow-up MRI. ■

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*Disclosures: None.*

## CASE REPORT

# Transarterial Embolization and Thermal Ablation for Hepatocellular Carcinoma

BY CHUKWUSOMNAZU E. NWANZE, MD; MICHAEL A. BEVILACQUA, MD;  
AND ERIC K. HOFFER, MD

A 61-year-old man with an otherwise unremarkable medical history presented to orthopedic surgery for chronic left shoulder pain, sequelae of a remote left shoulder trauma from a fall. He was planned for left shoulder arthroplasty. Routine preoperative clearance workup revealed incidental thrombocytopenia (platelet count was 47,000/ $\mu$ L). Due to this finding, the planned left shoulder surgery was deferred pending a comprehensive workup for the etiology of the isolated thrombocytopenia.

Further workup revealed an aspartate aminotransferase level of 53 U/L (normal range, 0–39 U/L), a normal alanine aminotransferase of 40 U/L, alkaline phosphatase level of 90 U/L, total bilirubin level of 1.3 mg/dL, negative hepatitis serology, normal renal function, alpha-fetoprotein level of 8.9  $\mu$ g/L, carcinoembryonic antigen of 7.4  $\mu$ g/L, and a mildly elevated iron panel. CT imaging of the abdomen demonstrated splenomegaly with perisplenic and gastroesophageal varices. Multiple liver lesions were also found on CT.

A follow-up MRI of the abdomen confirmed a 4.9-cm segment 6 mass classified as LR-M, a 2.3-cm segment 6 LI-RADS 5 lesion, and a 2-cm segment 8 LI-RADS 3 lesion. The MRI also confirmed the previous CT findings of splenomegaly with perisplenic and gastroesophageal varices. The patient had no family history of liver disease. Social history was significant for alcohol use.

Due to the LR-M classification of the dominant segment 6 mass, he underwent a percutaneous CT-guided liver

biopsy that histologically confirmed a well-differentiated hepatocellular carcinoma (HCC) (Figure 1).

The patient's working diagnosis was multifocal HCC in the setting of Child-Pugh class A cirrhosis with a MELD score of 9. Preliminary assessment was intermediate ([BCLC] Barcelona Clinic Liver Cancer stage B) HCC. He was active, working, and fully functional ([ECOG] Eastern Cooperative Oncology Group 0).

The multidisciplinary liver tumor board consensus was a recommendation for locoregional therapy, with the goal of tumor destruction to prevent disease progression with the potential for downstaging and consideration of liver transplant in the future. The options of bland embolization, chemoembolization, and radioembolization combined with thermal ablation were discussed with the patient, and he agreed with the recommendation for transarterial bland embolization (TAE) followed by microwave ablation of the segment 6 and segment 8 lesions.

## PROCEDURE

The patient's procedure was essentially uncomplicated with standard left radial access technique after a Barbeau test per protocol. A 5-F, 125-cm radial artery catheter was used to select the celiac trunk (Figure 2). After the celiac axis was selected, a 3-F Renegade® HI-FLO™ Microcatheter (Boston Scientific Corporation) was advanced into the right hepatic artery and on to the target lesions in segment 6 (Figure 3). The arteries were embolized to occlusion with a mix of ethiodol (to facilitate ablation targeting) and 100- $\mu$ m Embosphere™ Microspheres (Boston Scientific Corporation) (Figure 4).

The patient returned 1 month later for the planned thermal ablation of the aforementioned tumors. This procedure was performed under general anesthesia using CT fluoroscopy and 3D-reconstructed images for an oblique approach for the LeVein CoAccess™ Electrode System (Boston Scientific Corporation) (Figure 5).

Follow-up MRI 6 months after ablation categorized the treated lesions as LR-TR nonviable

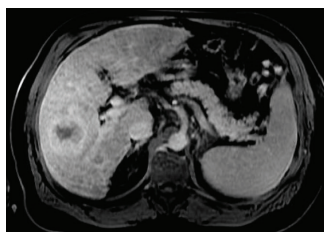


Figure 1. CT-guided liver biopsy confirmed the diagnosis of HCC.



Figure 2. A 5-F, 125-cm radial artery catheter was used to select the celiac trunk.

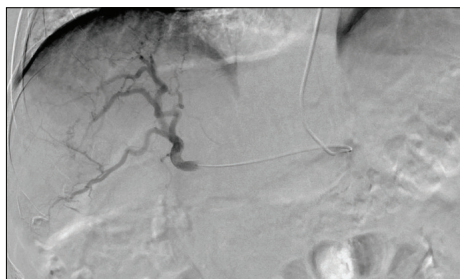


Figure 3. Right hepatic arteriogram through a 3-F Renegade® HI-FLO™ Microcatheter placed coaxially.

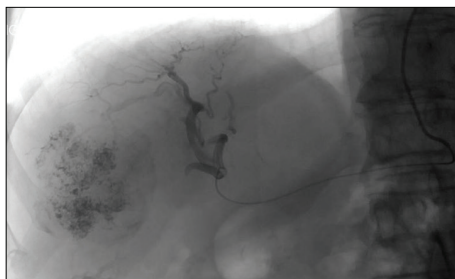


Figure 4. Right hepatic arteriogram performed after selective catheterization and embolization of the lower right lobe segmental arteries.

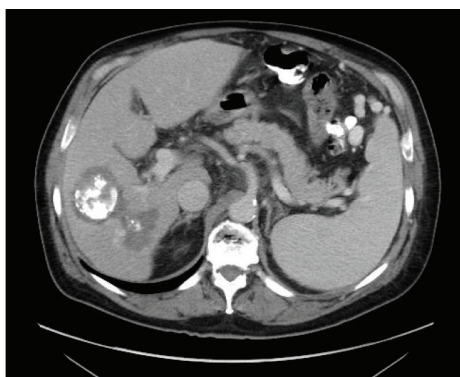


Figure 5. Contrast-enhanced CT after ablation of the right lobe lesions with the LeVeen CoAccess™ Electrode System. Residual ethiodol remained in the tumors.

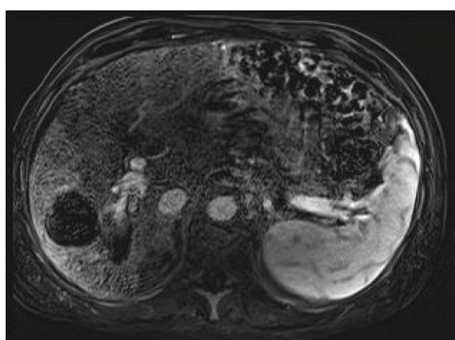


Figure 6. Follow-up MRI at 6 months showed no enhancement of the treated lesions.

(treated, probably or definitely not viable), consistent with successful treatment of multifocal HCC by combination of bland TAE and thermal ablation (Figure 6). At 1-year follow-up, with no new findings, the patient was considered downstaged and is currently listed for transplant.

## DISCUSSION

The indications for TAE in this presented patient's case were unresectable HCC outside the Milan criteria for liver transplant with intermediate BCLC stage B disease and the possibility of downstaging to resection or transplant criteria. With a fully functional performance status and no evidence of hematologic dysfunction, encephalopathy, or other clinical findings suggesting poorly compensated advanced liver dysfunction, the patient was an excellent candidate for TAE.

HCC is a significant cause of morbidity and mortality in patients with liver cirrhosis. Transarterial chemoembolization (TACE) is currently recommended as the standard of care in patients with unresectable HCC by the National Comprehensive Cancer Network and the American Association for the Study of Liver Diseases.<sup>1</sup> Both TACE and bland TAE without the delivery of chemotherapeutic

agents are based on hepatic physiology and anatomy. Although the hepatic parenchyma receives most of its blood supply from the portal vein, neoplastic hepatocytes receive their blood supply principally from the hepatic artery due to tumor-associated angiogenesis and neovascularity. Therefore, the embolization of the hepatic artery branches preferentially impacts tumor cells over normal hepatocytes. Randomized controlled trials have demonstrated the superiority of TACE over best supportive care and the equivalence of bland embolization with TACE.<sup>2,3</sup> The combination of ablation with embolization appears to extend the efficacy of ablation for larger (> 3 cm) tumors.<sup>4</sup> ■

1. Bruix J, Sherman M; American Association for the Study of Liver Diseases. Management of hepatocellular carcinoma: an update. *Hepatology*. 2011;53:1020-1022.

2. Facciorusso A, Bellanti F, Villani R, et al. Transarterial chemoembolization vs bland embolization in hepatocellular carcinoma: a meta-analysis of randomized trials. *United European Gastroenterol J*. 2017;5:511-518.

3. Kluger MD, Halazun KJ, Barroso RT, et al. Bland embolization versus chemoembolization of hepatocellular carcinoma before transplantation. *Liver Transpl*. 2014;20:536-543.

4. Lee HJ, Kim JW, Hur YH, et al. Conventional chemoembolization plus radiofrequency ablation versus surgical resection for single, medium-sized hepatocellular carcinoma: propensity-score matching analysis. *J Vasc Interv Radiol*. 2019;30:284-292.e1

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*Disclosures: None.*



## CASE REPORT

# Gonadal Vein Embolization for Pelvic Congestion Syndrome

BY DAVID FELDSTEIN, MD

A 68-year-old woman presented with persistent pelvic pain and pressure predominantly on the left side that she had experienced for several years. The symptoms were exacerbated upon prolonged standing, and would improve after lying down and in the morning hours. There was no reported postmenopausal bleeding. Her symptoms were consistent with pelvic congestion syndrome. Treatment options included conservative hormonal therapy (eg, medroxyprogesterone), hysterectomy with oophorectomy, and gonadal vein embolization. After discussing the efficacy of the provided treatment options, the patient decided to proceed with gonadal vein embolization.

## PROCEDURE

Embolization was performed via a right transfemoral vein approach. The left renal vein was selected utilizing a 5-F cobra catheter. Digital subtraction venography demonstrated significant reflux throughout a dilated left gonadal vein (Figure 1). Multiple distended collaterals were visualized draining across midline into the right hemipelvis. Delayed imaging also revealed collateral drainage into the left internal iliac vein. A Renegade® STC-18 Microcatheter (Boston Scientific Corporation) with a Fathom™-16 Steerable Guidewire (Boston Scientific Corporation) were advanced through the 5-F base catheter into the distal gonadal vein. Embolization of the left gonadal vein and associated tributaries was then performed using multiple Interlock™-18 Fibered IDC Coils (Boston Scientific Corporation) ranging in diameters of 10 to 12 mm. Coils were placed within 3 to 5 cm of the left gonadal/renal vein confluence. Postembolization venography demonstrated successful occlusion of the left gonadal vein and its tributaries/collaterals (Figure 2).

## RESULTS

At 2-week follow-up, the patient demonstrated significant improvement in pelvic pain/pressure. There were no reported access site complications. If symptoms recur, the likelihood of right gonadal vein embolization was discussed. Right gonadal vein embolization was not performed at the

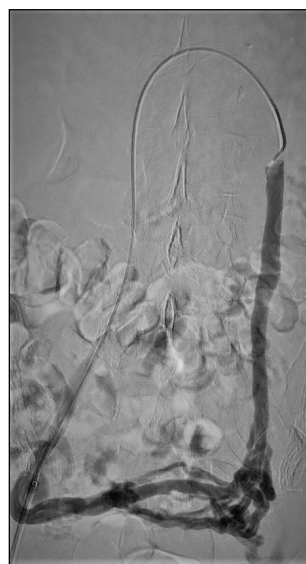


Figure 1. Initial digital subtraction venography.

time of initial therapeutic intervention, due to predominantly left-sided symptoms.



Figure 2. Postembolization venography showed successful occlusion of the left gonadal vein and its tributaries and collateral vessels.

## DISCUSSION

The 0.018-inch coil delivery system is preferred for this procedure, as it allows for preferential selection of the distal gonadal vein branches, as well as the smaller tributaries/collaterals. Literature suggests that lack of embolization of these tributaries/collaterals can lead to clinical failure and/or recurrence. ■

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*Disclosures: None.*

## Direxion and 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       | • Infection           | • Vessel spasm        |
| • Death                   | • Pseudoaneurysm      | • Vessel trauma       |
| • Embolism                | • Stroke              | (dissection,          |
| • Hemorrhage/<br>Hematoma | • Vascular thrombosis | perforation, rupture) |
|                           | • Vessel occlusion    |                       |

90960724 Rev/Ver. AB

## 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.

### INTENDED USE/INDICATIONS FOR USE

Embozene Microspheres are intended for the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids (UFE) and hepatoma, and for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH). The device is not intended for neurovascular use.

### MAGNETIC RESONANCE IMAGING

Embozene Microspheres are MR safe.

### 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 non-target 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-aminopropyltriethoxysilane, polyphosphazene or IV radiopaque contrast agent.

### CONTRAINDICATIONS SPECIFIC TO UFE

In addition to the general embolization contraindications, uterine fibroid embolization procedures shall not be performed if:

- Presence of suspected or active pelvic inflammatory disease.
- Presence of malignancy of the pelvic region.
- Presence of endometrial neoplasia or hyperplasia.
- Presence of submucosal fibroids with more than 50% growth into the uterine cavity.
- Presence of pedunculated serosal fibroid as the dominant fibroid(s).
- Presence of fibroids with significant collateral feeding by vessels other than the uterine arteries.

### CONTRAINDICATIONS SPECIFIC TO PAE

In addition to the general embolization contraindications, Prostatic Artery Embolization (PAE) procedures for benign prostatic hyperplasia shall not be performed if:

- |   |  |  |
|---|--|--|
| • Evidence of prostatic cancer or bladder cancer. | • Interest in the preservation of fertility. | • Peak urinary flow rate (greater than) 12 ml/sec. |
| • Urethral stricture.                             | • Patients with renal impairment.            | • Large bladder diverticulas or stones.            |
| • Prostate size (less than) 40 grams.             |  | • Neurogenic bladder.                              |
| • Active prostatitis.                             |  | • Detrusor failure.                                |

### WARNINGS

- Vascular embolization is a high risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures.
- Care must be taken to choose larger sized Embozene Microspheres when embolizing arteriovenous malformations with large shunts to avoid passage of the microspheres into the venous and subsequently to the pulmonary circulation.
- Extreme caution should be used for any procedures above the neck, and risk benefit assessment should be performed to avoid non-target embolization complications.
- 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.
- 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.
- Do not use heparinized saline as this could lead to microsphere agglomeration. Agglomeration may impede microsphere delivery through the catheter or result in non-target embolization.
- Should catheter obstruction occur, remove the catheter from the patient. Do not use forceful injection, guidewires or other instruments to dislodge the blockage.

### WARNINGS SPECIFIC TO UFE

- Do not use microspheres smaller than 500  $\mu$ m.
- The diagnosis of uterine sarcoma could be delayed by taking a nonsurgical approach (such as UFE) to treating fibroids. It is important to pay close attention to warning signs for sarcoma (e.g., rapid tumor growth, postmenopausal with new uterine enlargement, MRI findings) and to conduct a more thorough work-up of such patients prior to recommending UFE. Recurrent or continued tumor growth following UFE should be considered a potential warning sign for sarcoma and surgery should be considered.

### WARNINGS SPECIFIC TO UFE AND PREGNANCY

There is no long-term data on the effects of UFE on the ability to become pregnant and carry a fetus to term, and on the development of the fetus. This procedure should only be performed on women who do not intend future pregnancy. Women who become pregnant following UFE may be at increased risk for the following:

- |                         |                                    |                                      |
|-------------------------|------------------------------------|--------------------------------------|
| • Postpartum hemorrhage | • Abnormal placentation            | UFE may increase the risk of uterine |
| • Preterm delivery      | • Devascularization of the uterine | rupture of women                     |
| • Caesarean delivery    | myometrium                         | who subsequently                     |
| • Malpresentation       | resulting from                     | become pregnant                      |
|                         |                                    | following UFE.                       |

### WARNINGS SPECIFIC TO PAE

- An appropriate urological work-up should be performed on all patients (e.g., urological history and appropriate testing, such as Prostate-Specific Antigen test and, when appropriate, biopsy to rule out carcinoma).
- The effect of prostatic embolization on male fertility has not been determined. Therefore, this procedure should only be performed on men who are willing to accept the risk of future infertility.
- Three-dimensional planning imaging (e.g., magnetic resonance angiography [MRA], computed tomographic angiography [CTA]) should be performed prior to embolization on patients who have had any previous invasive treatment to the prostate (e.g., surgery, ablation, etc.) or pelvic irradiation.

## PRECAUTIONS

To maintain safety, the following precautions shall be considered:

- Safety and effectiveness of Embosphere Microspheres in the treatment of uterine fibroids has not been established
- Safety and effectiveness of Embosphere Microspheres for hepatic and renal embolization uses has not been established.
- The physician should carefully select the size and quantity of Embosphere 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 Embosphere Microspheres. Typically the artery will accept fewer Embosphere Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by Embosphere 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 Embosphere 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.
- 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 Embosphere 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.

## INTERACTION WITH PHARMACEUTICALS

There are no known chemical interactions between Embosphere Microspheres and pharmaceuticals.

## ADVERSE EVENTS

Potential adverse events associated with the use of Embosphere Microspheres include, but may not be limited to:

- Allergic reaction
- Capillary bed saturation and tissue damage
- Cerebrovascular accident (CVA)
- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the microcatheter and subsequent dislodgement, vasospasm, nerve injury, vessel trauma [e.g., dissection, perforation, rupture])
- Death
- Foreign body reactions (e.g., pain, rash, fever, inflammation)
- Hemorrhage
- Incomplete occlusion of vascular beds or territories may give rise to the possibility of post-procedural hemorrhage, development of alternative vascular pathways, recanalization, or recurrence of symptoms
- Infection
- Ischemia at an undesirable location
- Ischemic infarction
- Neurological deficits including cranial nerve palsies
- Post-embolization syndrome
- Pulmonary embolization
- Thrombosis
- Undesirable reflux, passage/migration or placement of Embosphere™ Microspheres, resulting in non-target embolization
- Vessel or lesion rupture

## POTENTIAL ADVERSE EVENTS SPECIFIC TO UFE:

- Hysterectomy
- Infection of the pelvic region
- Premature ovarian failure (i.e., menopause)
- Temporary or permanent stopping of menstrual bleeding
- Tissue passage, fibroid sloughing, or fibroid expulsion post-UFE
- Uterine rupture
- Uterine/Ovarian necrosis
- Vaginal discharge
- Worsening of fibroid-related symptoms or the onset of new symptoms
- Potential adverse events specific to PAE:
- Acute urinary retention
- Bladder ischemia or necrosis requiring surgical intervention
- Diarrhea
- Hematuria/Hematospermia
- Rectal Bleeding
- Rectal or lower colonic strictures
- Sexual dysfunction or impaired fertility
- Urethral or anal burning sensation
- Urethral stricture
- Urinary incontinence
- Urinary symptoms (e.g. dysuria, urgency, frequency)

## 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

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## 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

90960711 Rev/Ver. AB

## LeVein Needle Electrode Family

**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 LeVein Needle Electrode Family is intended to be used in conjunction with the RF 3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions. These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved.

## PRECAUTION

Before using, inspect the package for any breach to the sterile barrier and inspect product for any damage. If package is broken or product is damaged DO NOT USE. Immediately return package and product to Boston Scientific.



## WARNINGS

- The colored insulated cannula must be used at all times when accessing tissue. Use of the electrode without the colored insulated cannula may result in serious burns to the patient and/or user.
- Damage to the insulation of the introducer may result in serious burns to the patient and/or user.
- Precaution: The LeVein Needle Electrode Family must be used in conjunction with the Boston Scientific RF 3000™ Generator.
- For patients with permanent pacemakers and Implantable Cardiac Defibrillators (ICD) additional precautions should be taken.

## ADVERSE EVENTS

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

- |  |                                      |                            |
|--|--------------------------------------|----------------------------|
| • Abscess                                    | • Diarrhea                           | • Persistent Fever > 39° C |
| • ARDS (Acute Respiratory Distress Syndrome) | • Electric Shock                     | • Pleural Effusion         |
| • Arrhythmia                                 | • Fistula, including biliary fistula | • Renal Failure            |
| • Ascites                                    | • Hematoma                           | • Tumor Recurrence         |
| • Biloma                                     | • Hemorrhage                         | • Tumor Seeding            |
| • Burn                                       | • Infection                          |                            |
| • Death                                      | • Liver Failure                      |                            |
| • Delayed hemorrhage into ablated tissue     | • Liver Insufficiency                |                            |
|  | • Pain                               |                            |
|  | • Perforation                        |                            |
|  | • Peritonitis                        |                            |

90960743 Rev/Ver. AB

## 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 HI-FLO Microcatheter is 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, or therapeutic agents to be used in accordance with specifications outlined by the manufacturer.

## CONTRAINDICATIONS

None Known.

## WARNINGS

The Renegade Microcatheter and Microcatheter Kit 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 | • Hemorrhage/ | • Infection         |
| • Embolism      | Hematoma      | • Air embolism      |
|                 | • Vasospasm   | • Allergic reaction |

90960755 Rev/Ver. AB

## Renegade STC 18 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 is 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 is 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 | • Hemorrhage/ | • Infection         |
| • Embolism      | Hematoma      | • Air embolism      |
|                 | • Vasospasm   | • Allergic reaction |

90960758 Rev/Ver. AB

# EVERY FIBER MAKES A DIFFERENCE

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