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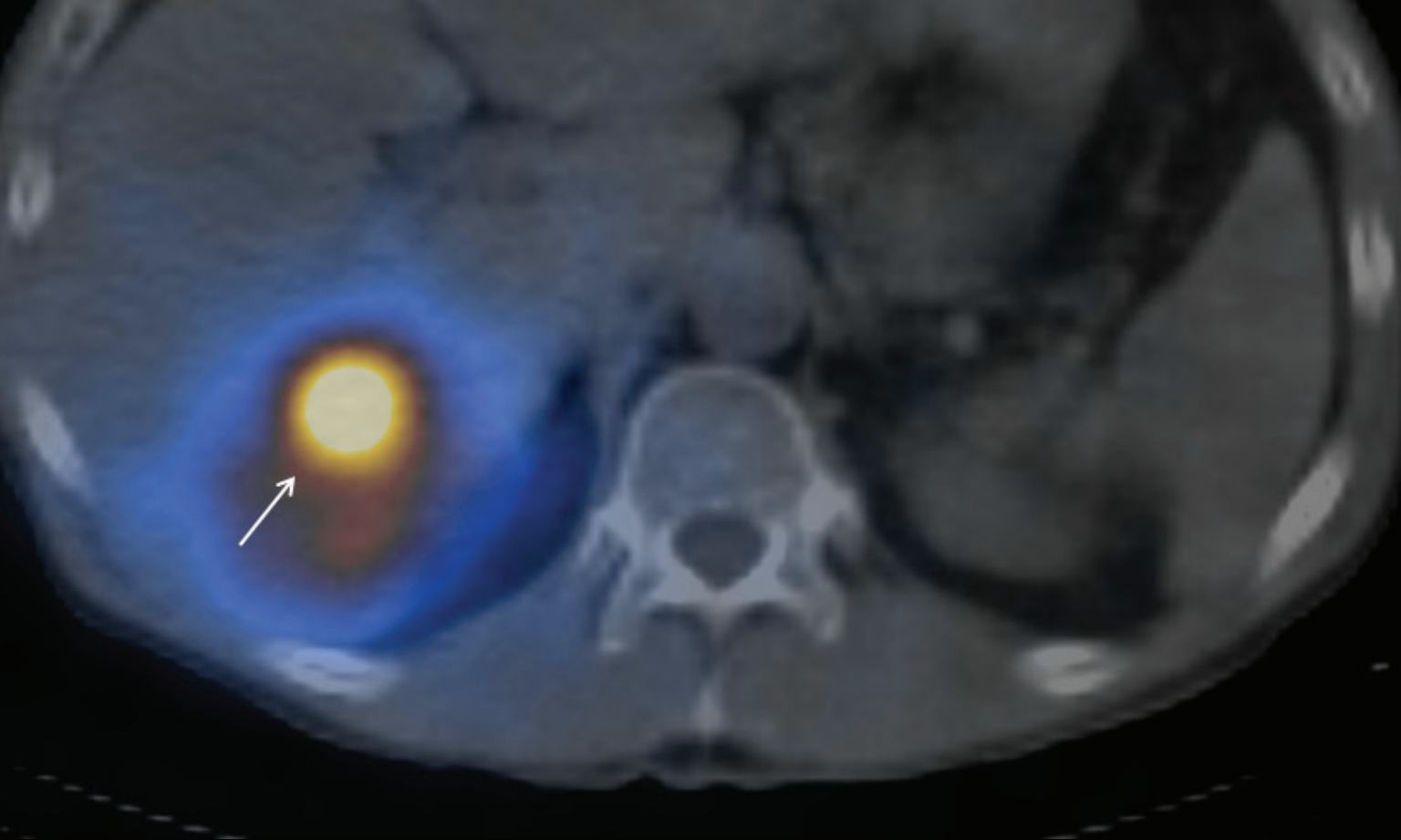
# Endovascular TODAY

October 2017



SETTING  
STANDARDS.  
**EXCEEDING  
EXPECTATIONS.**

Interventional  
Oncology Tools  
& Techniques



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## CASE REPORT

# Embozene™ Microspheres for Treatment of Neuroendocrine Tumors

BY HENRY J. KREBS, MD, CANCER TREATMENT CENTERS OF AMERICA

A 63-year-old man had a medical history significant for aortic valve replacement, chronic anticoagulation, and osteoarthritis. He was in his usual state of health until he was diagnosed with a neuroendocrine tumor of the small bowel after an emergent small bowel obstruction in 2013. He began care in August 2014, when staging workup confirmed multifocal liver metastasis, low-grade carcinoid syndrome, and nodal disease in his abdomen. Treatment with lanreotide was administered from 2014 until September 2016 with slowly progressive disease. Treatment was discontinued in September 2016 due to acute and recurrent pancreatitis requiring hospitalization. A suspicious mass in the area of the pancreas was

identified at that time, and further workup indicated it was not another malignancy but rather nodal metastatic disease from his neuroendocrine tumor. The cause of pancreatitis was thought to be from gallstones, so cholecystectomy was performed laparoscopically in February 2017. He had not been on treatment since September 2016. On imaging, his disease was slowly progressive, with further increase in bilobar disease on MRI in June 2017.

Since November 2016, the patient became increasingly symptomatic with carcinoid syndrome manifested primarily by worsening diarrhea. The interventional radiology department was consulted for liver-directed therapy.

Preoperative MRI (Figures 1A and 1B) confirmed numerous bilobar metastases up to 6 cm in diameter, which had progressed by RECIST (Response Evaluation Criteria in Solid Tumors) criteria since a previous scan in November 2016.

Because the patient was being considered as a candidate for possible peptide receptor radionuclide therapy with lutetium 177 dotatate, it was elected to proceed with bland embolization rather than yttrium-90 radioembolization to control radiation exposure to the healthy liver.

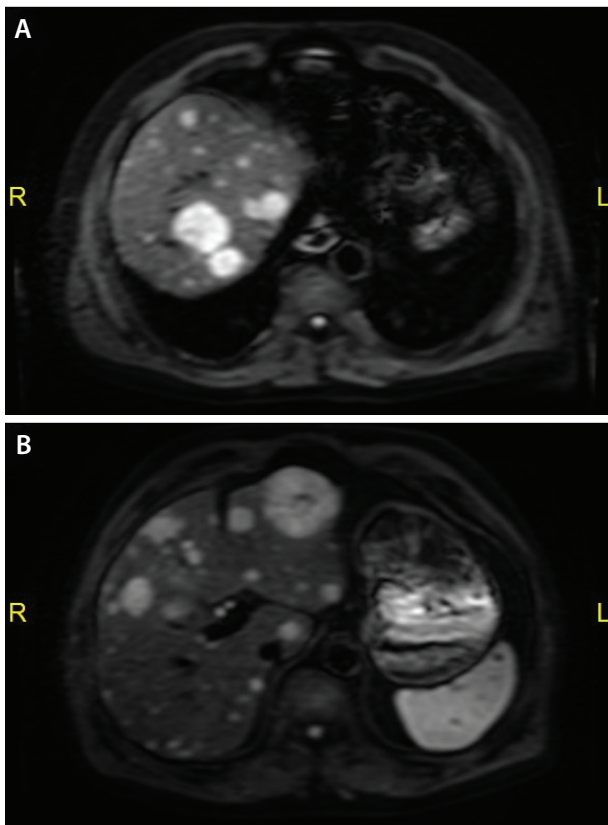


Figure 1. Preoperative MRI.



Figure 2. Angiogram of the celiac artery.





Figure 3. Angiogram of the left hepatic artery.

### PROCEDURE DESCRIPTION

The treatment was performed as an outpatient procedure utilizing a left radial access approach to minimize the anticoagulant interruption. Left radial access was achieved with ultrasound guidance, and selective superior mesenteric and celiac artery arteriography was performed using a 5-F base catheter. The celiac study (Figure 2) confirmed extensive bilobar disease with standard hepatic vascular anatomy and a widely patent portal vein. Selective microcatheter angiography of the left and right hepatic vessels (Figure 3) was performed with a 0.027-inch Renegade® HI-FLO Microcatheter (Boston Scientific Corporation) over a Fathom®-16 Guidewire (Boston Scientific Corporation).

Superselective catheterization of the dominant feeding vessels to the largest tumors in each lobe was achieved, and embolization was performed to stasis using 100- $\mu$ m Embosphere™ Microspheres (Boston Scientific Corporation). One syringe total was used to accomplish the bilobar embolization.

### FOLLOW-UP

Follow-up CT scans (Figures 4A and 4B) were obtained and confirmed excellent localization and penetration

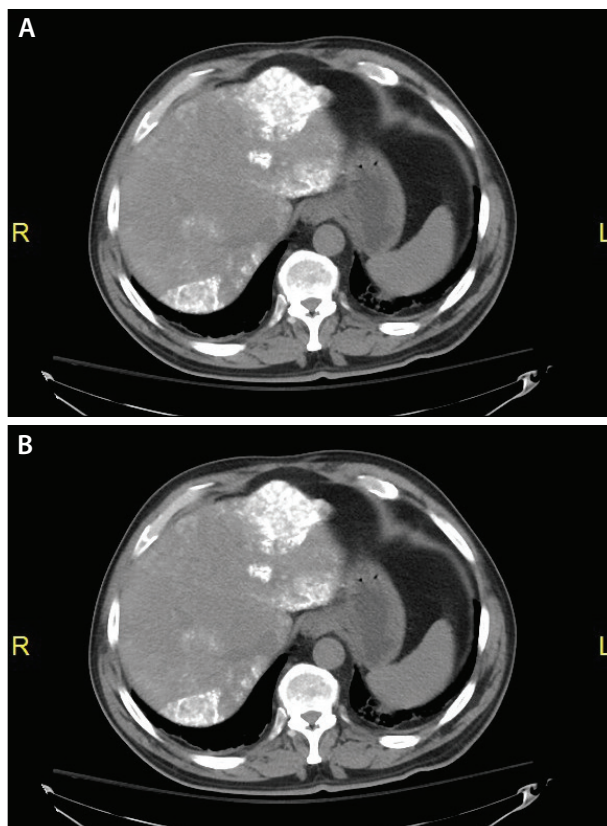


Figure 4. Postembolization CT scans.

of the tumors in each lobe. The patient was monitored overnight with minimal postembolization pain and was discharged the next day. The patient's diarrhea was significantly improved by 1 week postprocedure, and he was scheduled for follow-up imaging including Ga 68 Netspot imaging (Advanced Accelerator Applications USA, Inc.) at 3-month follow-up. ■

### Henry J. Krebs, MD

Interventional Radiologist  
Cancer Treatment Centers of America  
Newnan, Georgia  
*Disclosures: None.*



## CASE REPORT

# Yttrium-90 Segmentectomy Flow Diversion Using Embozene™ Microspheres

BY PAUL O'CONNOR, MD; AARON M. FISCHMAN, MD; AND EDWARD KIM, MD;  
MOUNT SINAI HEALTH SYSTEM

A 62-year-old man with cirrhosis and active HIV and hepatitis C virus was found to have a 3.2-cm hepatocellular carcinoma (HCC) within Couinaud segment 6 on surveillance liver protocol MRI. The patient was referred for transplantation. A history and physical examination were 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 mildly elevated transaminases, total bilirubin of 1 mg/dL, and an albumin level of 4.2 g/dL. Coagulation profile and platelet levels were unremarkable. Alpha fetoprotein level was 19 ng/mL. MRI demonstrated cirrhosis with evidence of portal hypertension and a segment 6 HCC without vascular invasion (Figure 1). The patient is Child-Pugh class A and BCLC (Barcelona Clinic Liver Class) stage A. The case was reviewed in multidisciplinary liver conference and the decision was made to proceed with yttrium-90 (Y-90) radioembolization with glass microspheres (TheraSphere, BTG International) as a bridge to liver transplantation.

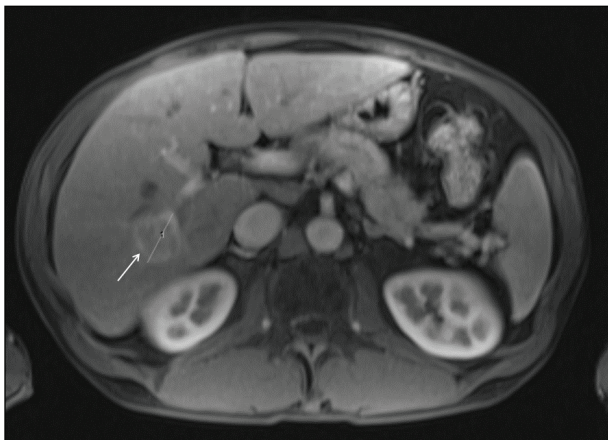


Figure 1. Postcontrast MRI performed during portal venous phase demonstrates a central segment 6 HCC.

## PROCEDURE DESCRIPTION

Prior to Y-90 therapy, planning angiography was performed to identify tumor vascular supply and determine the lung shunt fraction by administration of technetium-99m macroaggregated albumin in the proposed vessel of Y-90 treatment delivery. Initial angiography was performed with a 5-F CONTRA 2 Catheter (Boston Scientific Corporation), identifying a replaced right hepatic artery (RHA) arising from the superior mesenteric artery. Tumor blush was present within segment 6. The right hepatic artery and segmental branch arteries were selectively catheterized with a Direxion HI-FLO™ Microcatheter (Boston Scientific Corporation) over a Fathom®-16 Guidewire (Boston Scientific Corporation). Cone-beam CT (CBCT) was performed during segmental contrast injection to confirm tumor supply. CBCT performed during superselective contrast injection of the sixth segmental artery demonstrated tumor blush and extensive normal parenchymal enhancement (Figure 2). Two small ves-

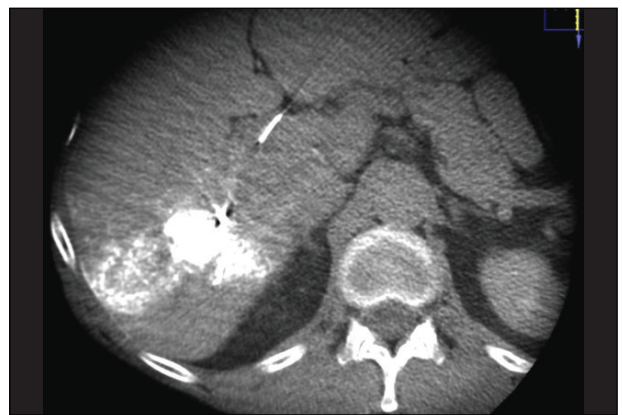
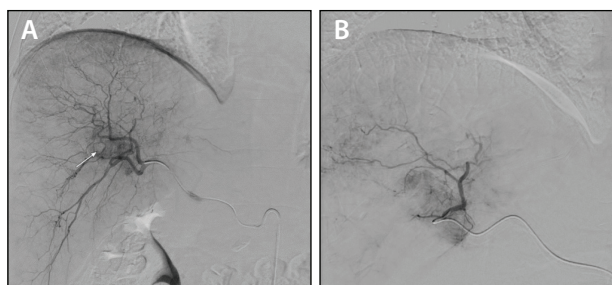
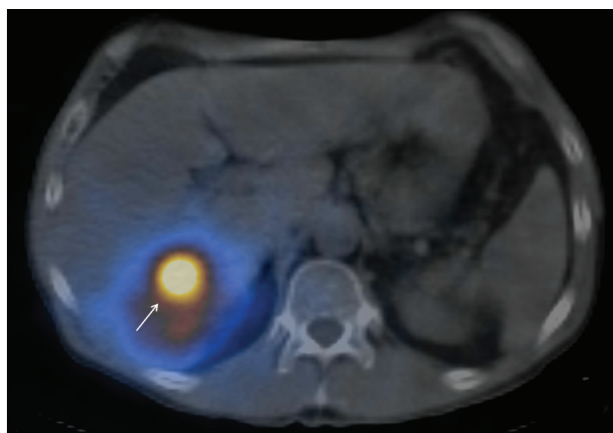


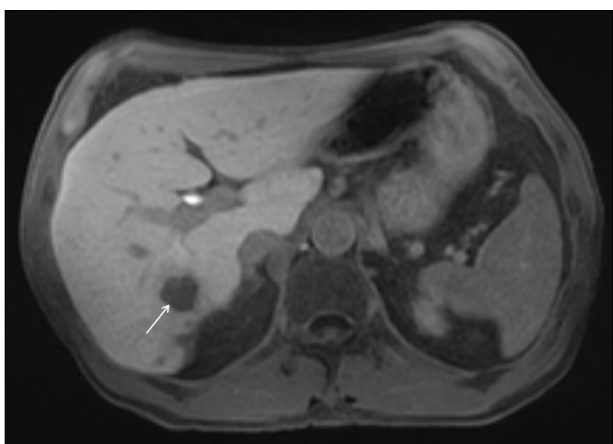
Figure 2. CBCT performed during superselective injection within the segment 6 artery demonstrated tumor enhancement as well as significant liver parenchymal enhancement. Arterial injection was performed at a rate of 0.5 mL/sec to mimic flow conditions during Y-90 therapy injection.



**Figure 3.** Selective angiography performed from the RHA demonstrating tumor blush corresponding to the segment 6 HCC found to be supplied from two small vessels arising from the proximal sixth segmental branch not accessible with a microcatheter (A). RHA after injection of 250-µm Embosphere particles within segment 6 branch just distal to the origin of the tumor-supplying vessels, resulting in significant vessel pruning (B).



**Figure 4.** SPECT/CT performed after Y-90 delivery demonstrating radioactive material primarily within the central aspect of segment 6 containing the HCC.



**Figure 5.** Contrast-enhanced MRI performed during hepatobiliary phase demonstrating complete necrosis of the segment 6 HCC without significant radiation changes to the surrounding liver parenchyma.

sels supplying the tumor originated from the proximal aspect of the sixth segmental branch. The microcatheter system was then placed just beyond the vessels supplying the tumor to perform bland embolization for the purposes of flow diversion prior to Y-90 therapy. Bland embolization was performed utilizing a quarter of a vial of 250-µm Embosphere™ Microspheres (Boston Scientific Corporation) suspended in 6 mL of iopamidol-300 contrast until stasis was achieved. Follow-up angiography demonstrated satisfactory pruning of the treated segmental vessel (Figures 3A and 3B).

Single-photon emission CT (SPECT)/CT performed during Y-90 therapy administration demonstrated radiation deposition primarily with the segment 6 HCC (Figure 4). A 6-week postprocedure liver MRI demonstrated 100% HCC necrosis with minimal radiation changes to the surrounding liver parenchyma (Figure 5). Follow-up laboratory studies were unremarkable and without treatment toxicity.

## DISCUSSION

Centrally located tumors or those supplied by small vessels may be problematic for catheter-directed therapy due to unfavorable flow dynamics, leading to suboptimal therapy delivery to the tumor and deposition within the functioning hepatic parenchyma and resulting in incomplete tumor response and liver toxicity. As demonstrated in this case, bland embolization of the hepatic artery distal to the tumor supplying vessels using properly sized particles can reduce competitive blood flow and is generally well tolerated. Microsphere embolization for blood flow diversion can improve Y-90 deposition within the tumor while minimizing adjacent parenchyma damage. ■

### Paul O'Connor, MD

Division of Interventional Radiology  
Mount Sinai Health System  
New York, New York

*Disclosures: None.*

### Aaron M. Fischman, MD

Division of Interventional Radiology  
Mount Sinai Health System  
New York, New York

*Disclosures: None.*

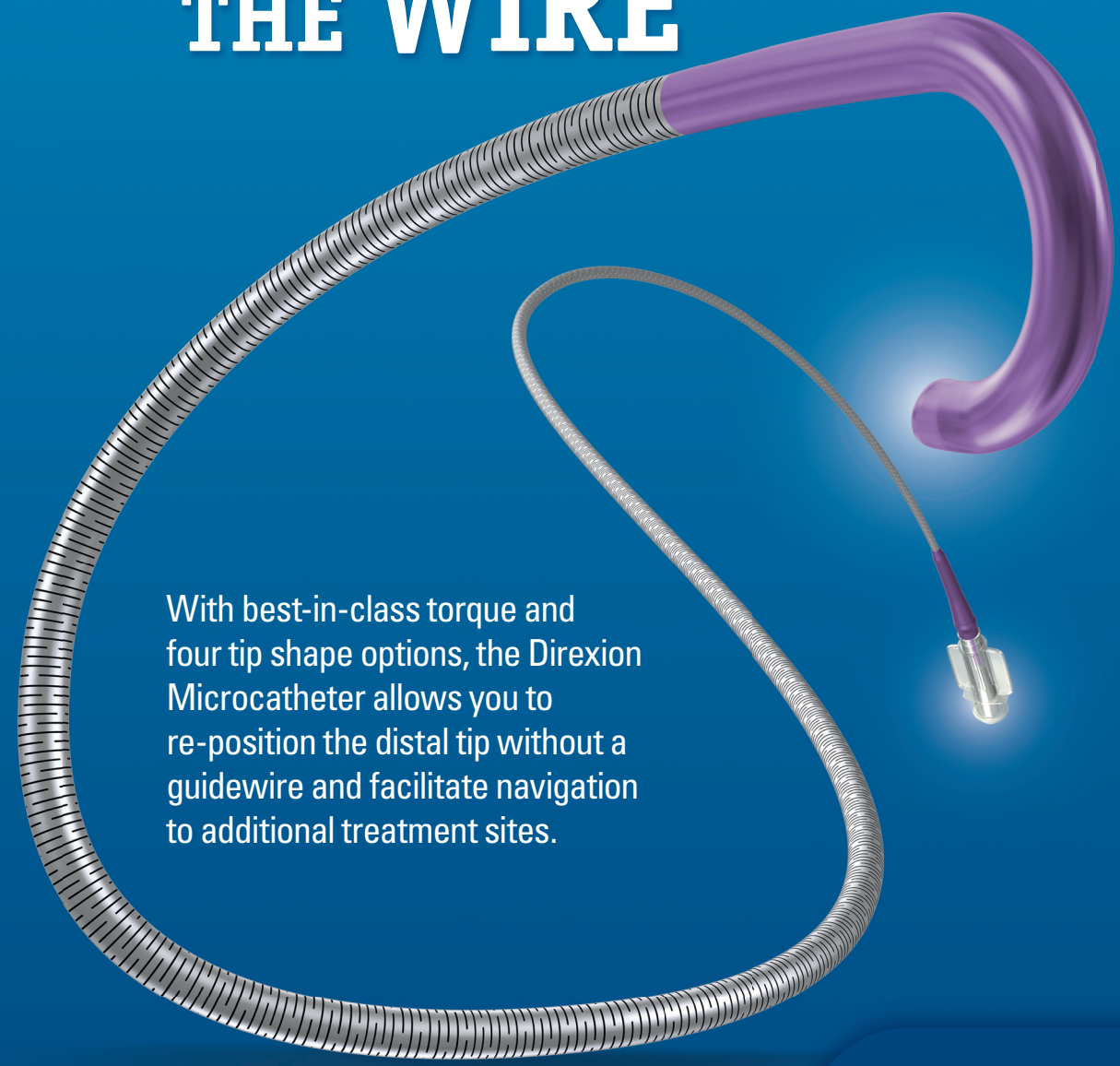
### Edward Kim, MD

Division of Interventional Radiology  
Mount Sinai Health System  
New York, New York

*Disclosures: None.*

**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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## CASE REPORT

# Coiling a Hepatic Bleed With Direxion™ Microcatheters and IDC™ Soft Microcoils

BY MOHAMMAD A. ALI, MD, UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

A 34-year-old man presented to the emergency department after a motorized scooter accident. CT scan demonstrated grade 4 liver laceration with areas of active extravasation (Figure 1), grade 5 right renal injury, and right adrenal hemorrhage. The patient was initially in a stable clinical condition but was taken to the operating room after decompensating. The interventional radiology department was urgently consulted during surgery, as the trauma team could not adequately control the hepatic bleeding. The patient presented with dropping systolic pressures despite transfusions.

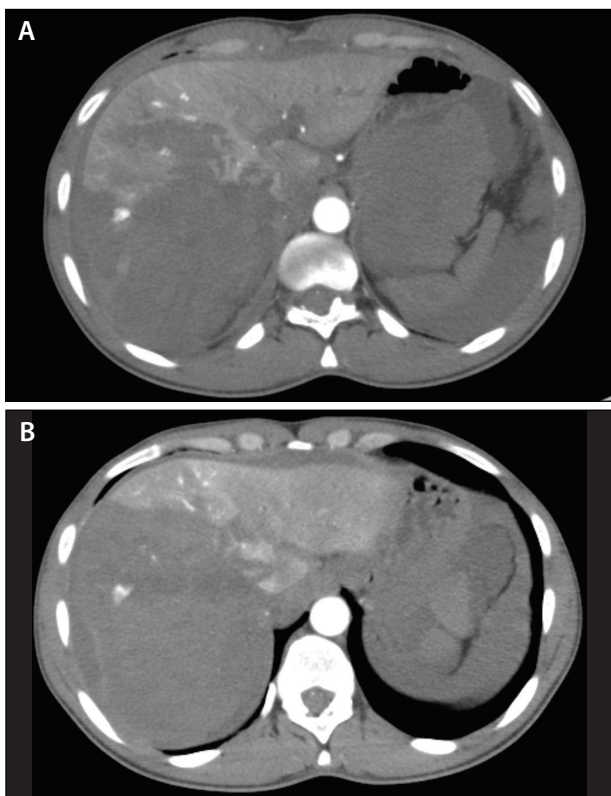


Figure 1. Two slices of the initial CT scan before the intervention demonstrating a liver laceration.

## PROCEDURE DESCRIPTION

Once the patient was transferred to interventional radiology, a diagnostic catheter was placed into the aorta and selected out of the celiac artery. Multiple angiograms were obtained without visualizing the bleed. Celiac runs initially only showed a replaced left hepatic artery. The proper hepatic artery had a surgical tie (Pringle maneuver) around it, preventing visualization of the right hepatic vasculature (Figure 2). Attempts were made to cross the proper hepatic artery with numerous microwires, but these attempts were unsuccessful. The microwire in use was exchanged for a 180-cm Straight Fathom®-16 Guidewire (Boston Scientific Corporation) to cross the Pringle and advance the 130-cm Straight Direxion HI-FLO™ Microcatheter (Boston Scientific Corporation) into the right hepatic artery.

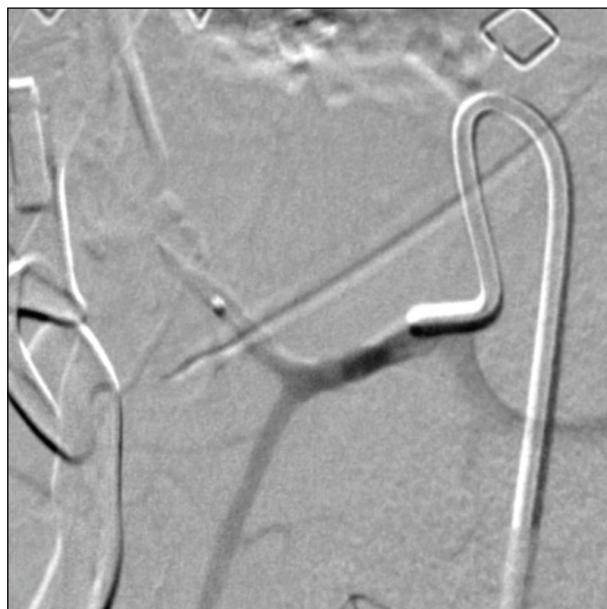
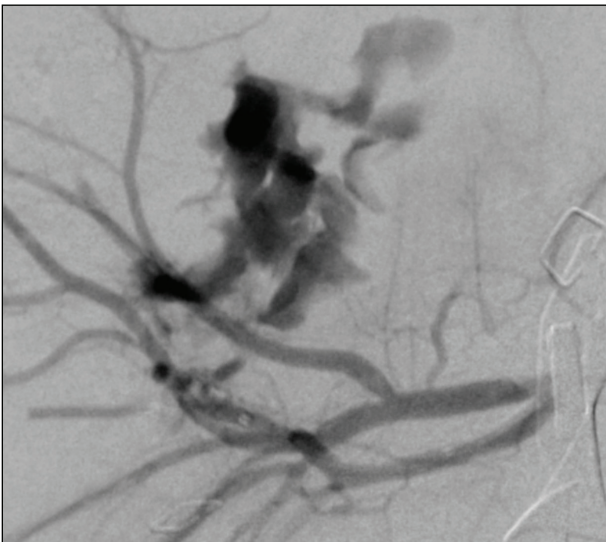


Figure 2. Angiogram showing the Pringle at the level of the proper hepatic artery, which prevented visualization of the right hepatic artery.



**Figure 3.** Angiogram of the right hepatic artery demonstrating active extravasation.



**Figure 4.** Angiogram of the selective inferior branch showing profuse extravasation.

A right hepatic angiogram demonstrated active extravasation. The microcatheter and wire were advanced into one of the right segmental branches and a repeat angiogram was obtained. The bleed was not seen off of that particular vessel but seemed to be coming from another inferior branch that had a more proximal takeoff from the right hepatic artery (Figure 3). The catheter and wire were pulled back, but despite multiple attempts, access of the inferior branch was unsuccessful.



**Figure 5.** Angiogram of the right hepatic artery demonstrating hemostasis of both proximal and distal bleeding after embolization.

It was then decided to use the 0.021-inch, 155-cm Angled Direxion™ Microcatheter in order to access the inferior branch. We did not want to lose purchase after having difficulty crossing the Pringle, so a 300-cm Transcend™-18 Microwire (Boston Scientific Corporation) was inserted, and we exchanged the straight catheter for the 0.021-inch Angled Tip 130-cm Direxion™ Microcatheter. Immediately after inserting the Direxion™ Catheter, we were able to access the inferior branch. Angiograms of this vessel actually demonstrated two areas of extravasation (one peripheral and one more central) (Figure 4).

The catheter was parked at the distal end of the vessel (past the first bleed, but proximal to the second bleed). We deployed three 2- X 4-mm and three 3- X 6-mm IDC™ Soft Microcoils (Boston Scientific Corporation) embolizing the distal bleed and coiling across the more proximal central bleed. Postembolization angiograms were obtained and hemostasis of both bleeds was achieved (Figure 5).

## DISCUSSION

The patient recovered well and did not show any evidence of additional bleeding while in the hospital. He was extubated and transferred from the surgical intensive care unit to a regular hospital room. One week after the embolization procedure, the trauma team was preparing for the patient's discharge. ■

### Mohammad A. Ali, MD

University of Mississippi Medical Center  
Jackson, Mississippi

*Disclosures: None.*



CASE REPORT

# Coiling a Type II Endoleak

BY DAVID ALLISON, MD, PEACHTREE VASCULAR SPECIALISTS

**A** 76-year-old woman with a history of endovascular aortic aneurysm repair was monitored for an enlarging aneurysm sac and a type II endoleak.

Because of the location of the previously placed stent graft and the endoleak (Figure 1), an endovascular approach via the left internal iliac artery was selected. Using a 5-F, 0.038-inch inner diameter selective diagnos-

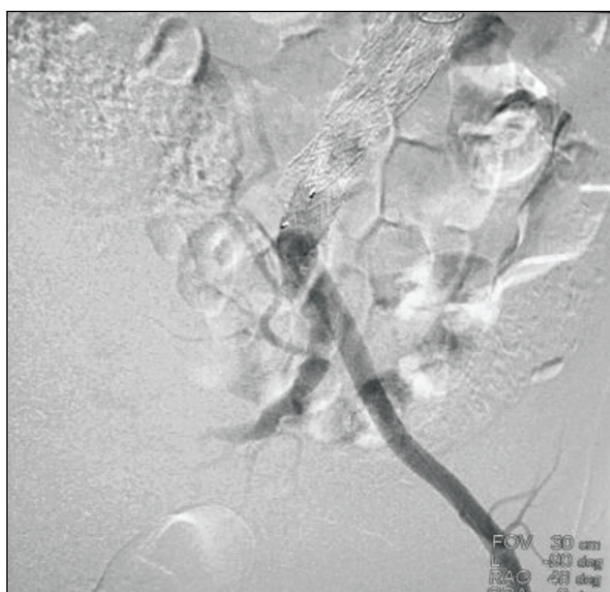


Figure 1. The previously placed stent graft and endoleak.



Figure 2. The origin of the left ilio-lumbar artery.

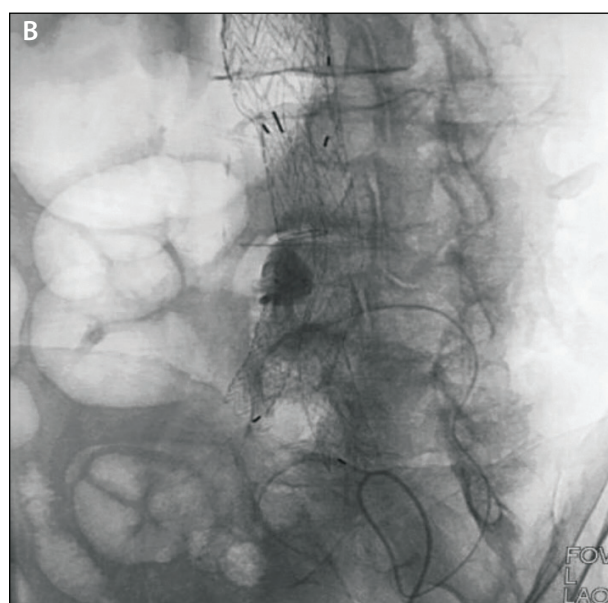
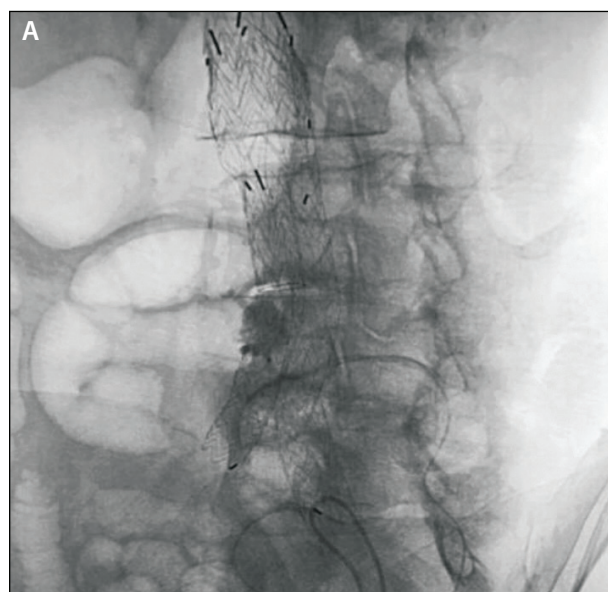


Figure 3. A large aneurysmal void was identified as the cause of the endoleak.

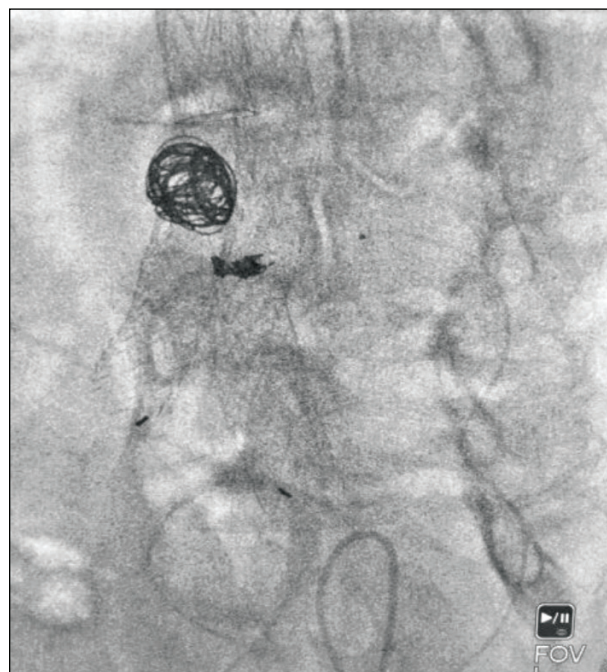




**Figure 4.** The sac and the feeding vasculature were embolized.

tic catheter, the origin of the left iliolumbar artery was identified with a contrast injection (Figure 2). Because of the small diameter and the significant tortuosity of the origin of the iliolumbar artery, the 5-F catheter was advanced only slightly beyond the origin of the vessel.

An 0.021-inch inner lumen diameter Direxion™ J-shaped Microcatheter (Boston Scientific Corporation) and a torqueable 0.016-inch Angled Fathom®-16 Steerable Guidewire (Boston Scientific Corporation) were passed through the diagnostic catheter into the iliolumbar artery. After significant catheter and wire manipulation through the anastomosis with the left lumbar artery, access to the sac was achieved, and a contrast injection revealed a large aneurysmal void that was causing the endoleak (Figures 3A and 3B). After positioning the microcatheter within the aneurysm and



**Figure 5.** Using six coils, occlusion of the type II endoleak was achieved.

removing the guidewire, the process of embolizing both the sac and the feeding vasculature began (Figure 4).

The embolization procedure was completed using a number of Interlock™-18 Fibered Platinum Coils (Boston Scientific Corporation), each with a wide diameter and a long length to ensure adequate wall apposition. Using a total of six coils, 210 cm of coil were rapidly deployed in both the endoleak channel and feeding vessel, and occlusion of the type II endoleak was achieved (Figure 5). ■

#### **David Allison, MD**

Interventional Radiologist  
Peachtree Vascular Specialists  
Stockbridge, Georgia  
*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).

## 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.

### WARNINGS

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 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: vessel trauma, embolism, hemorrhage/hematoma, vasospasm, infection, air embolism, allergic reaction.

## 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.

## 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

## 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.

## 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 IDC Coil 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 IDC Interlocking Detachable Coil 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.

## 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 poten-



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tially endanger non-targeted tissue during an embolization procedure.

- Presence of any vasculature where Embosphere 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 Embosphere Microspheres.
- Patient is pregnant.
- Patient has known allergies to barium sulfate, 3-aminopropyltriethoxysilane, 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 Embosphere 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 Embosphere 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.

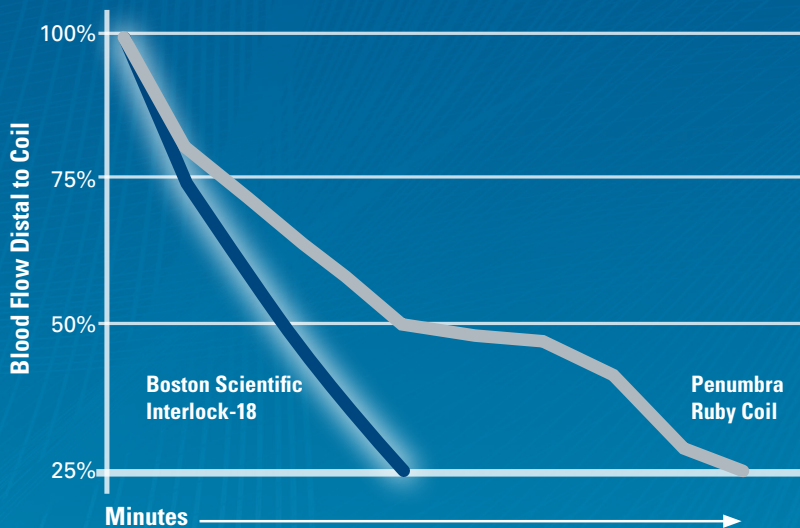
#### PRECAUTIONS

To maintain safety, the following precautions shall be considered:

- Safety and effectiveness of 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  $\mu\text{m}$  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 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.

INTERLOCK™ Coils

# MORE FIBER. MORE POWER.



## Interlock Coils PERFORM FASTER

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

Boston Scientific  
Interlock-18 Coil

Penumbra  
Ruby Coil

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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