

CASE STUDY

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

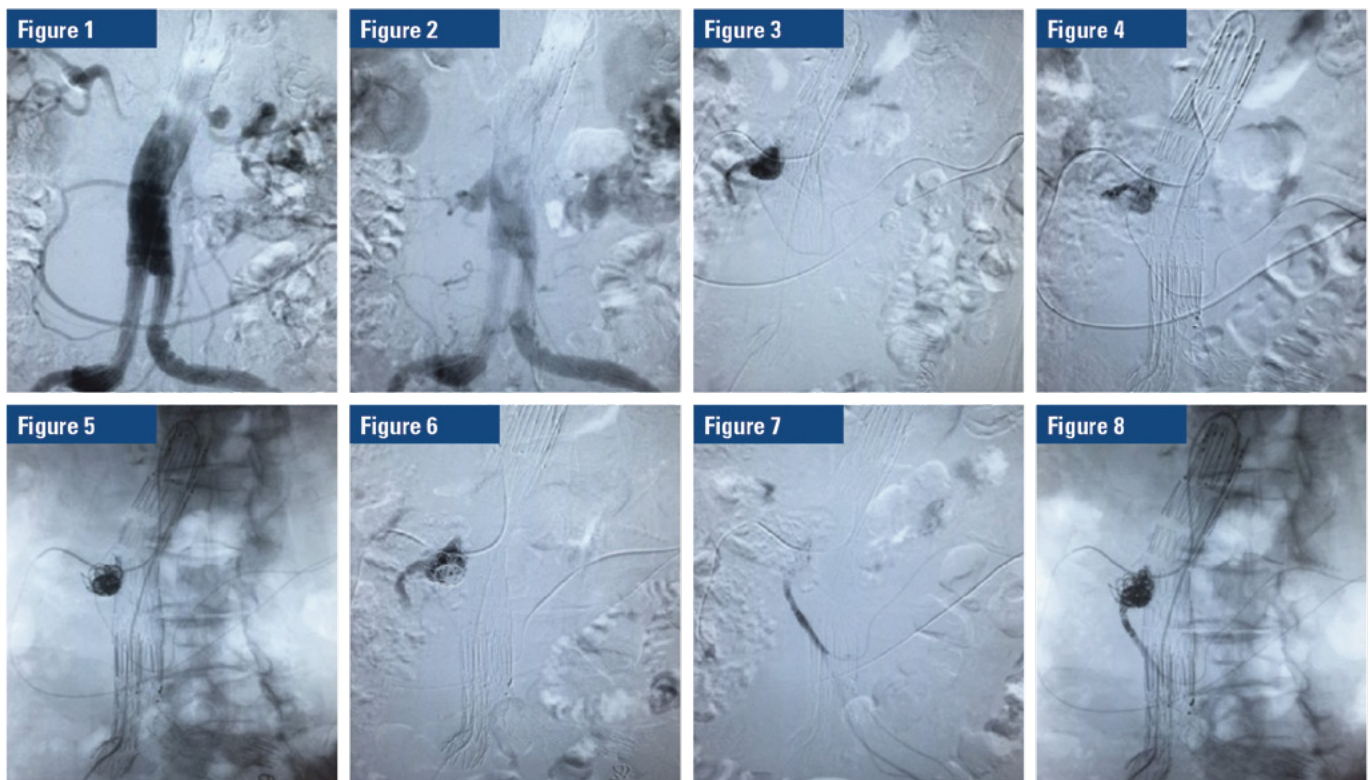
BY YING WEI LUM, MD

CASE DESCRIPTION AND DISCUSSION

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

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

The flow to the endoleak site drastically diminished (**Figures 6–8**), and we feel strongly that the Dacron fibers



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

FATHOM-14 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 -14 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 **92289647 A.1**

FIBERED IDC, INTERLOCK FIBERED IDC OCCLUSION SYSTEM, IDC INTERLOCKING DETACHABLE COIL

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

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

CONTRAINDICATIONS: None known. **PRECAUTIONS:** Do not attempt to use the Interlock - 35 Fibered IDC Occlusion System with a soft-walled delivery catheter. Do not advance the Interlock IDC Occlusion System if it becomes lodged within the catheter. Determine the cause of the resistance and replace the catheter and coil if necessary. **ADVERSE EVENTS:** The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation, etc.) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Emboli • Ischemia • Vasospasm • Tissue necrosis • Undesirable clot formation of the vasculature • Recanalization • Death • Temporary neurological deficit **91056109 Rev/Ver. AA**

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 • Death • Embolism • Hemorrhage/Hematoma • Infection • Pseudoaneurysm • Stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel trauma (dissection, perforation, rupture) **90960724 AB.6**

RENEGADE™ HI-FLO MICROCATETER

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. **WARNING:** 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 • Embolism • Hemorrhage/Hematoma • Vasospasm • Infection • Air embolism • Allergic reaction **90960724 AB.6**

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