

## CASE STUDY

### Share Your Direxion™ Story

### Preablative Embolization for Solitary HCC

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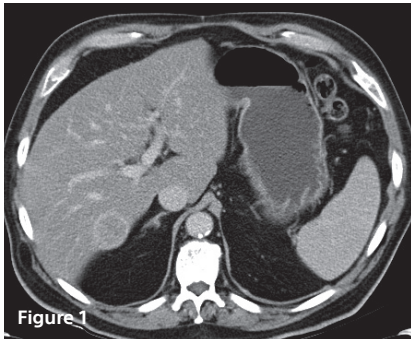


Figure 1

A 79-year-old man with a history of a solitary hepatocellular carcinoma (HCC) in segment 6 presented to the interventional radiology department for hepatic angiography and preablative embolization (Figure 1).



Figure 2

After using standard techniques to access the right common femoral artery, a 5 F sheath was placed. Subsequently, a selective 4 F reverse-curve catheter and a hydrophilic guidewire were used to cannulate the celiac artery. There was difficulty advancing the 4 F catheter over the wire and into the common hepatic artery, so it was decided to park the selective catheter at the celiac artery origin and use a microcatheter from there. A 0.027" Renegade™ HI-FLO™ Microcatheter and a Fathom™ 16 Steerable Guidewire were used to cannulate the right hepatic artery (Figure 2).

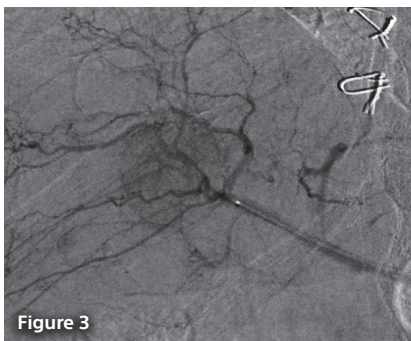


Figure 3

The angiogram (contrast injector set for flow rate of 4 mL/s for total volume of 8 mL at pressure of 800 psi) showed the tumor, but there were other areas in question. **The microcatheter was exchanged for a 0.027" Direxion HI FLO™ Torqueable Microcatheter, and a repeat angiogram showed innumerable smaller tumors as well.** (Figure 3).

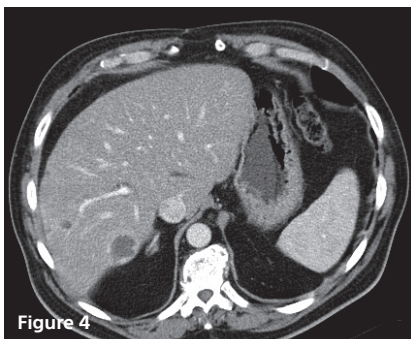


Figure 4

An intra-procedural decision was made to forego embolization and administer macroaggregated albumin to prepare for yttrium 90 treatment. **The higher flow rates and pounds per square inch that the Direxion Microcatheter provides completely changed this patient's management.** Had he gone on to ablation, only one of his tumors would have been addressed. By changing his treatment to yttrium 90, all of his tumors were treated, and most had a near-complete treatment response (Figure 4).

“ **The higher flow rates that Direxion provides completely changed this patient's management.** ”

**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 Rev/Ver. AB.6**

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