

Deployment of the:

Interlock™-35 Coil

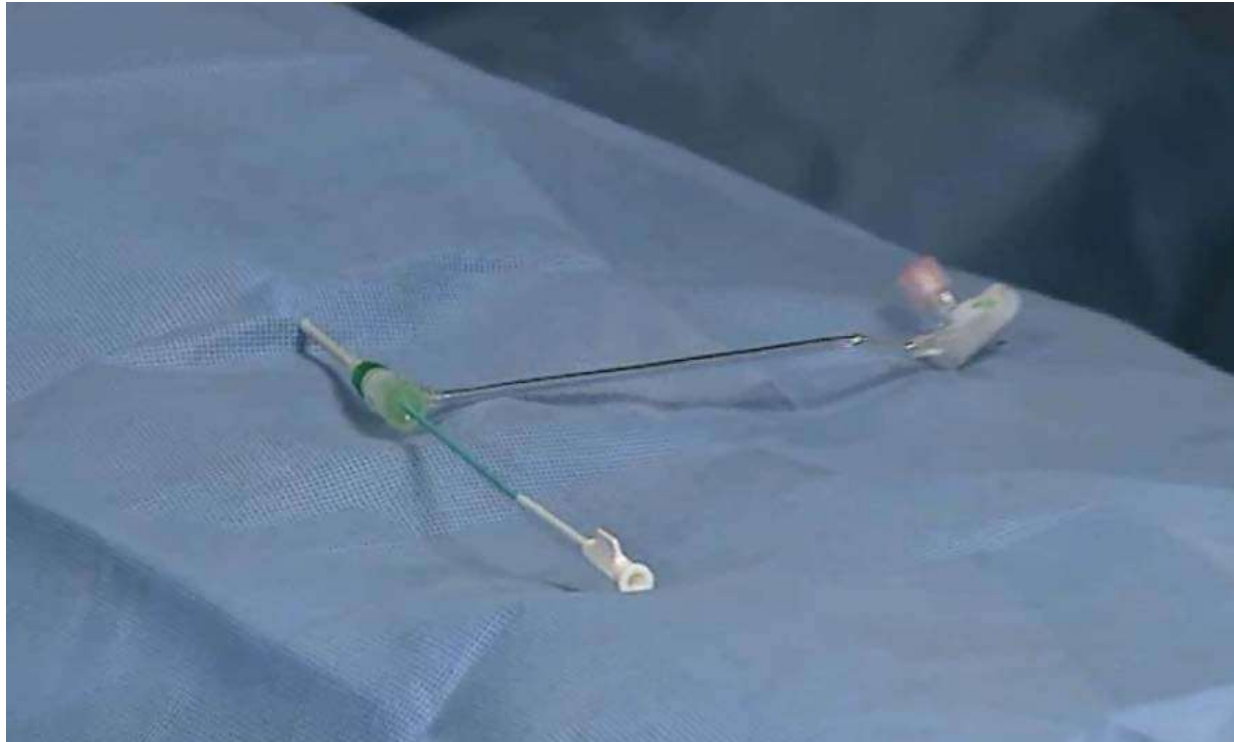
Hand Flush Technique

**Prior to Use, Please Review
the Interlock™-35 Coil
Directions for Use (DFU)**



- **Per the DFU, the Interlock™ - 35 Fibered IDC™ Occlusion System is designed to be delivered under fluoroscopy through a 5F (1.70 mm) OD [0.89 mm] or 0.038 in [0.97 mm] inner lumen Imager™ II Selective Diagnostic Catheter without side flushing holes.**
- **Do not attempt to use the Interlock™ - 35 Fibered IDC™ Occlusion System with a soft-walled delivery catheter, such as the Terumo Glidecath™ Catheter or AngioDynamics Soft-Vu® Catheter. The Interlock™ - 35 Fibered IDC™ Occlusion System will encounter significant resistance if advancement through a soft-walled delivery catheter is attempted.**

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Place the catheter in the area to be embolized per standard technique. Take care to position the catheter tip parallel with, not perpendicular to, the vessel wall to facilitate deployment of the coil.

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Fill a 10cc syringe with an appropriate solution. Attach the filled 10cc syringe to the flush port on the dispenser hoop. Flush the dispenser hoop vigorously, bathing the coil within.

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Slowly withdraw the Interlock™ - 35 Fibered IDC™ Occlusion System from its dispenser coil and inspect assembly. Discard if there is any evidence of damage.

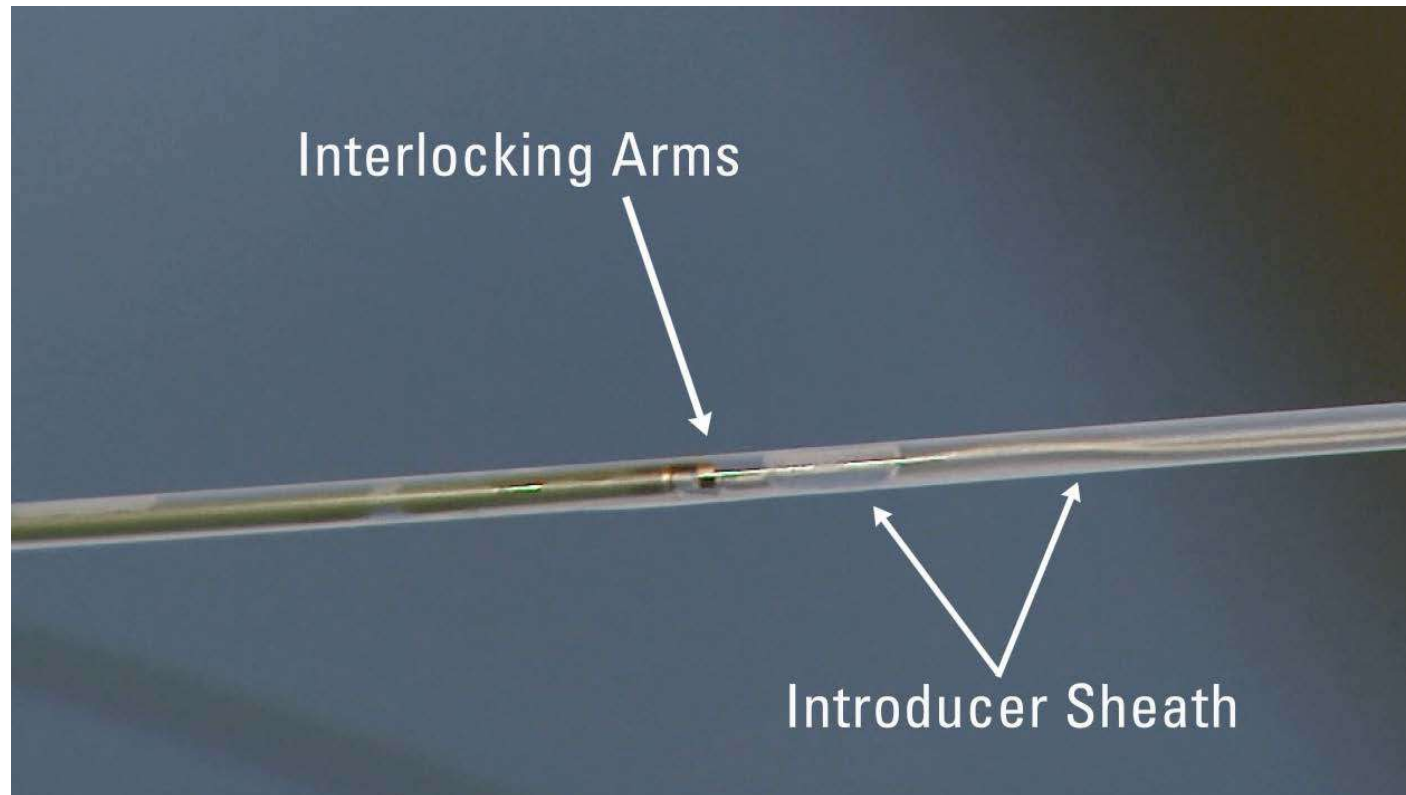
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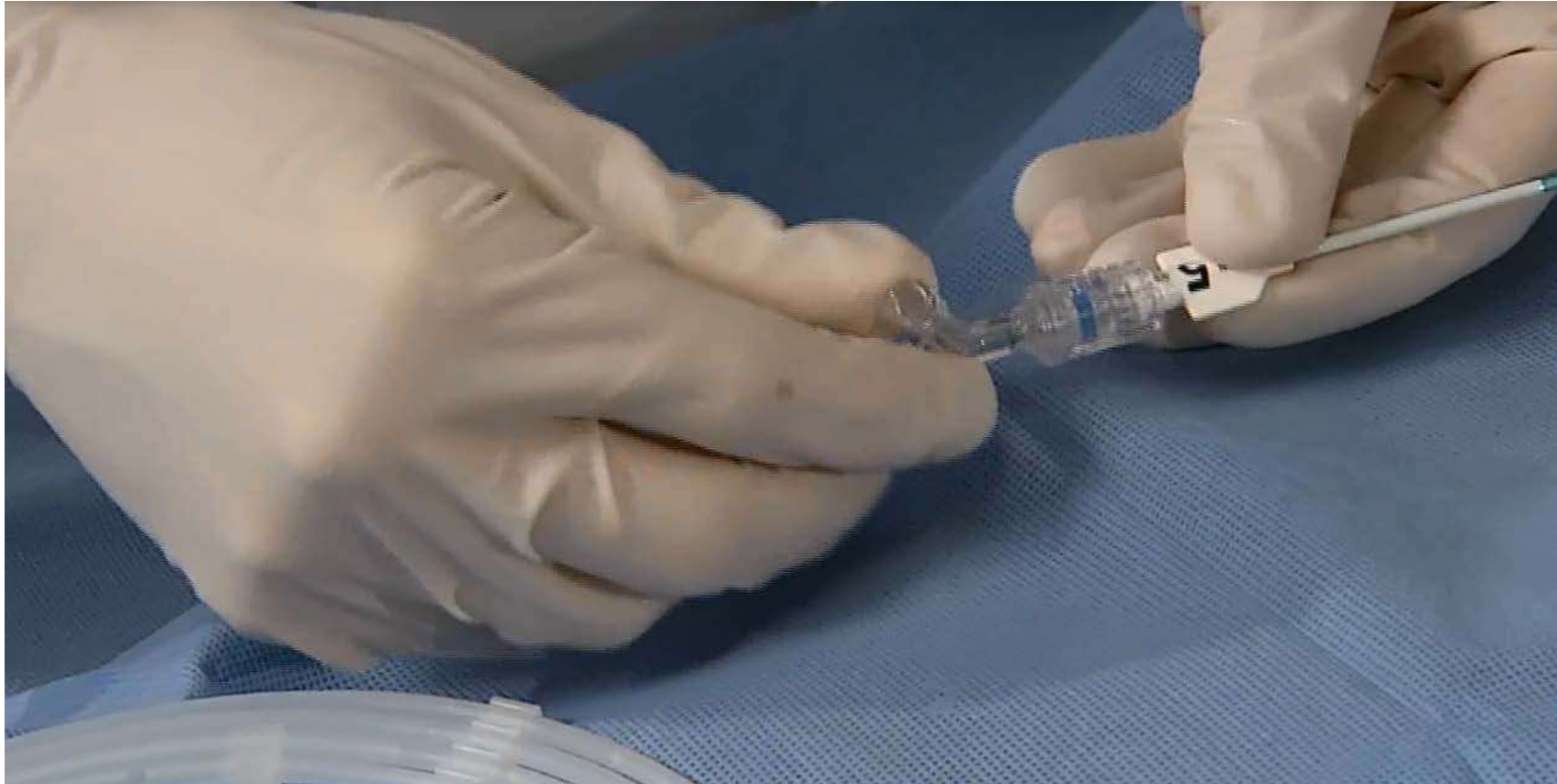


Ensure that the Interlock™ - 35 Fibered IDC™ Occlusion System arms are interlocked inside the introducer sheath. Do not remove the Interlock Fibered IDC Occlusion System assembly from the introducer sheath.

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Attach the included RHV to the proximal luer adapter on the hub of the catheter.

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Connect a 20cc syringe filled with heparinized saline to the side arm of the RHV.

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Open the thumbscrew of the RHV and carefully insert the Interlock™ - 35 Fibered IDC™ Occlusion System until the distal tip of the introducer sheath is firmly seated in the catheter hub.

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Tighten the RHV thumbscrew to prevent retrograde flow, but not so tight as to pinch the introducer sheath and inhibit forward movement of the delivery wire.

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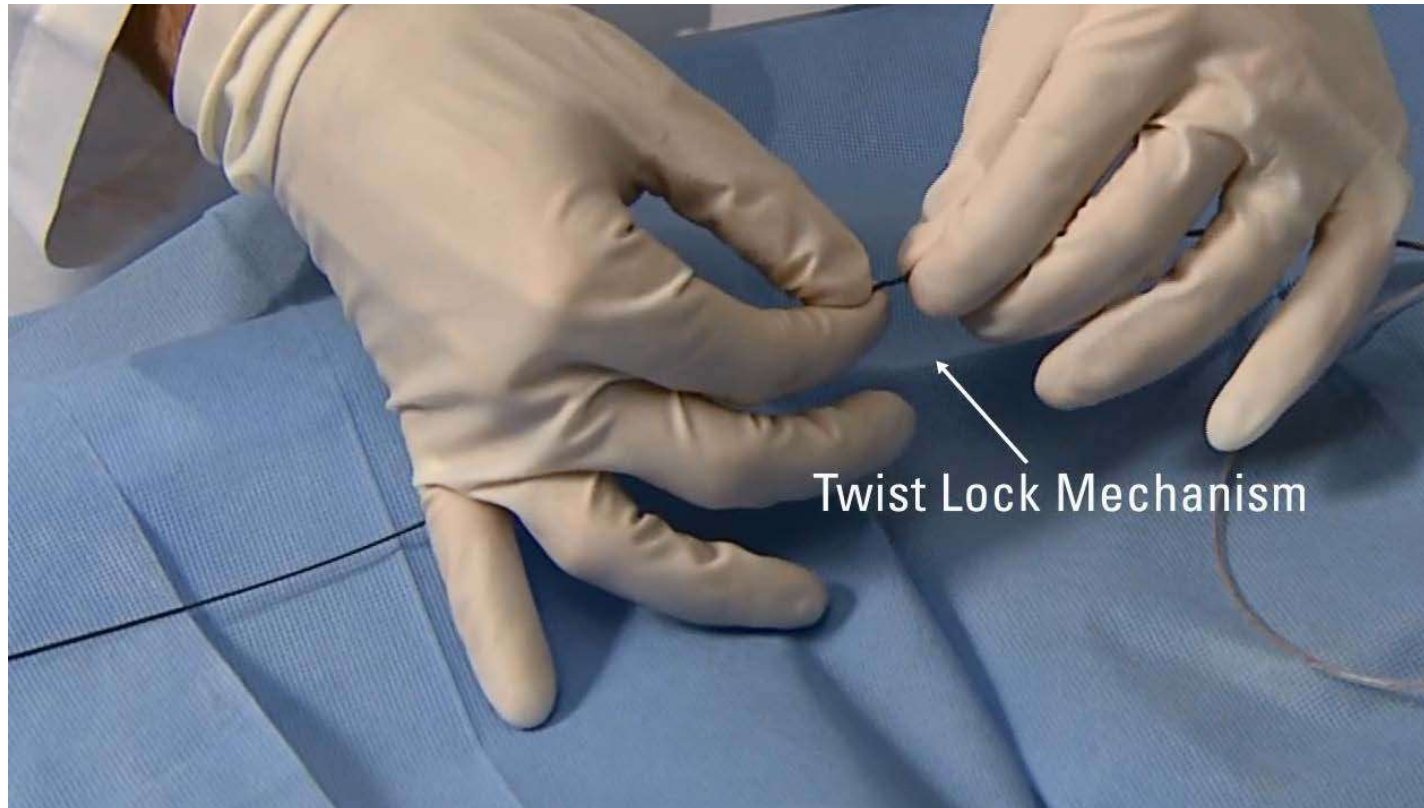


Prior to advancing the Interlock™ - 35 Fibered IDC™ Occlusion System from its introducer sheath into the catheter, ensure that blood is minimized within the RHV or on the fibers of the coil which are visible within the coil introducer. If blood is present, inject flush solution into RHV using the 20cc syringe connected to RHV sideport. Continue flushing until blood is minimized on coil or within RHV.

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Release the Interlock™ - 35 Fibered IDC™ Occlusion System inside its introducer sheath by gently pinching the sheath on both sides of the twist-lock mechanism and rotating proximal side counter-clockwise.

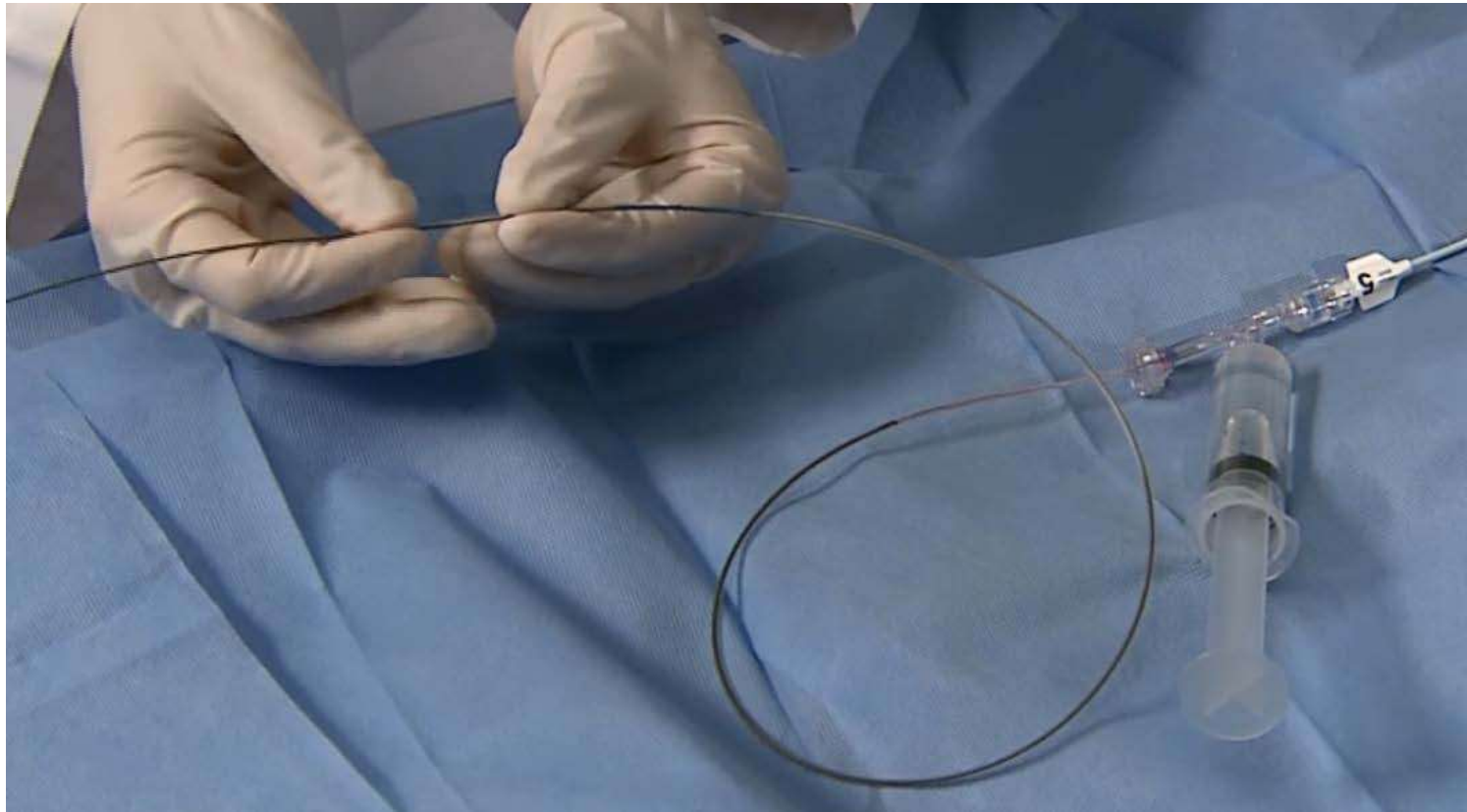
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Transfer the Interlock™ - 35 Fibered IDC™ Occlusion System and delivery wire from the introducer sheath into the catheter by advancing the delivery wire in a smooth, continuous manner.

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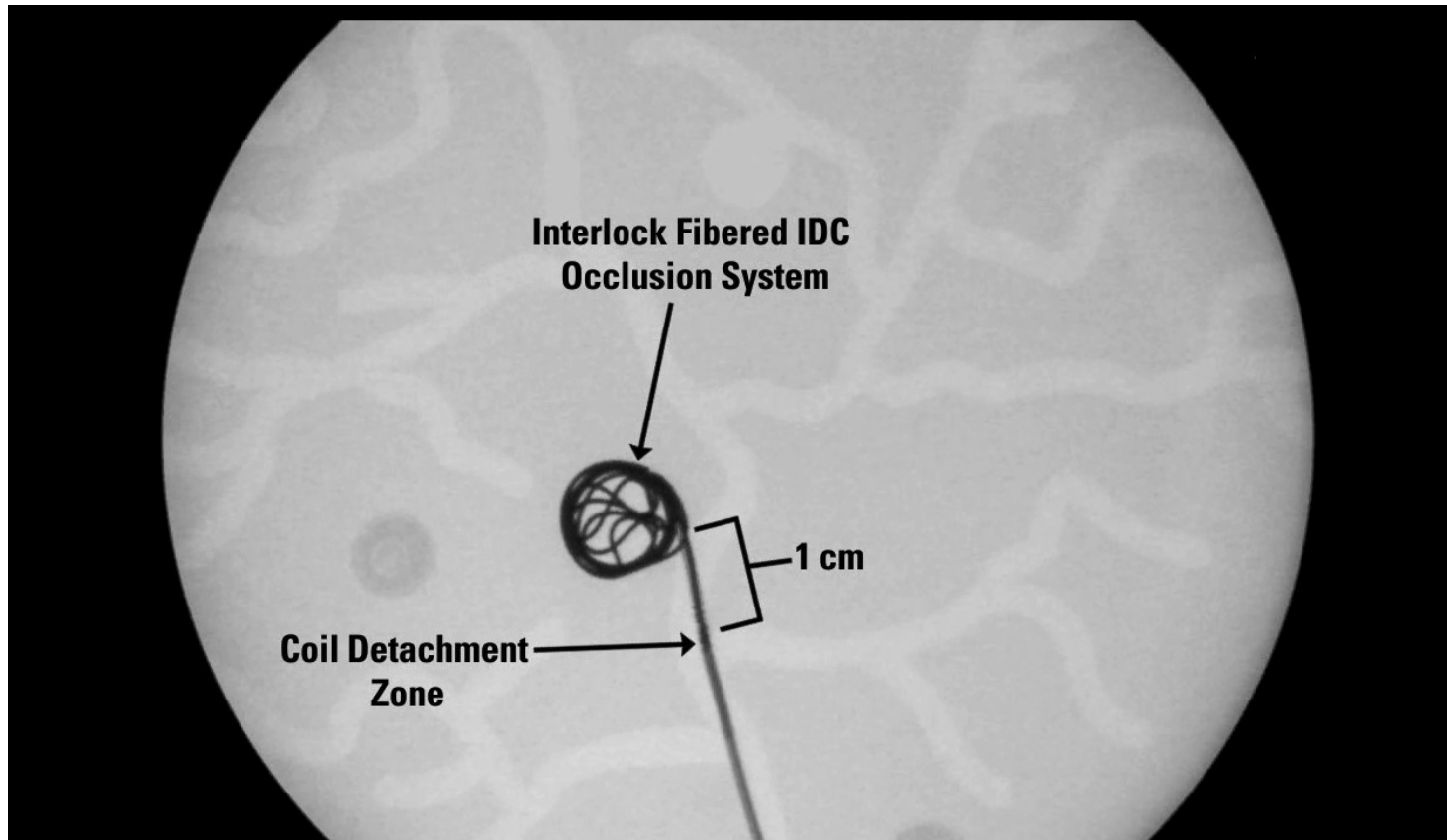
Gently withdraw and remove the introducer sheath once the coil is visibly transferred completely into the delivery catheter. The Interlock™ - 35 coil and interlocking arms should not be visible. Do not discard the sheath in case it is necessary to remove the Interlock™ - 35 Fibered IDC™ Occlusion System prior to deployment.

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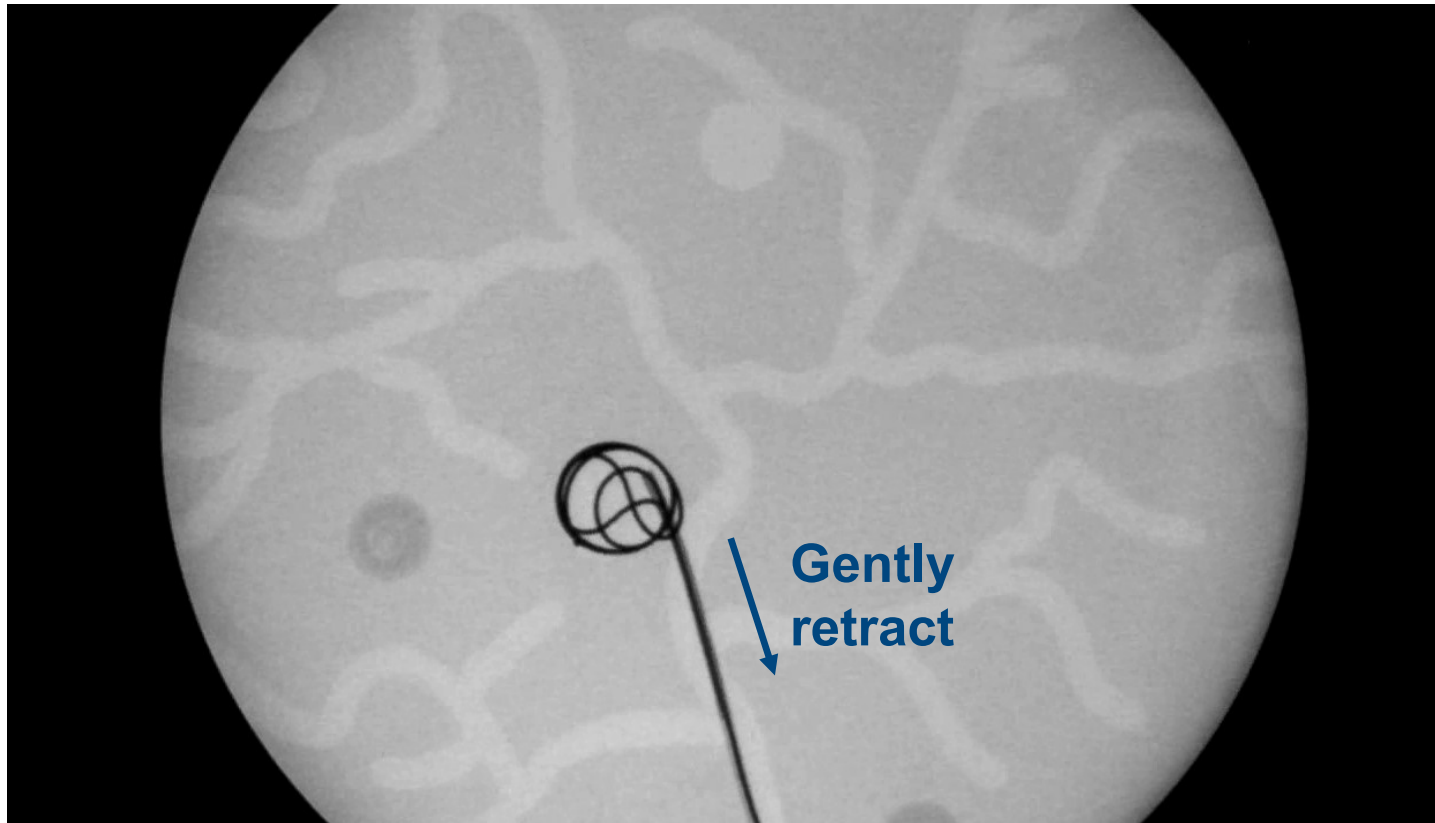


Maneuver the Interlock™ - 35 Fibered IDC™ Occlusion System under fluoroscopy until the coil detachment zone is approximately 1 cm proximal to the catheter tip.

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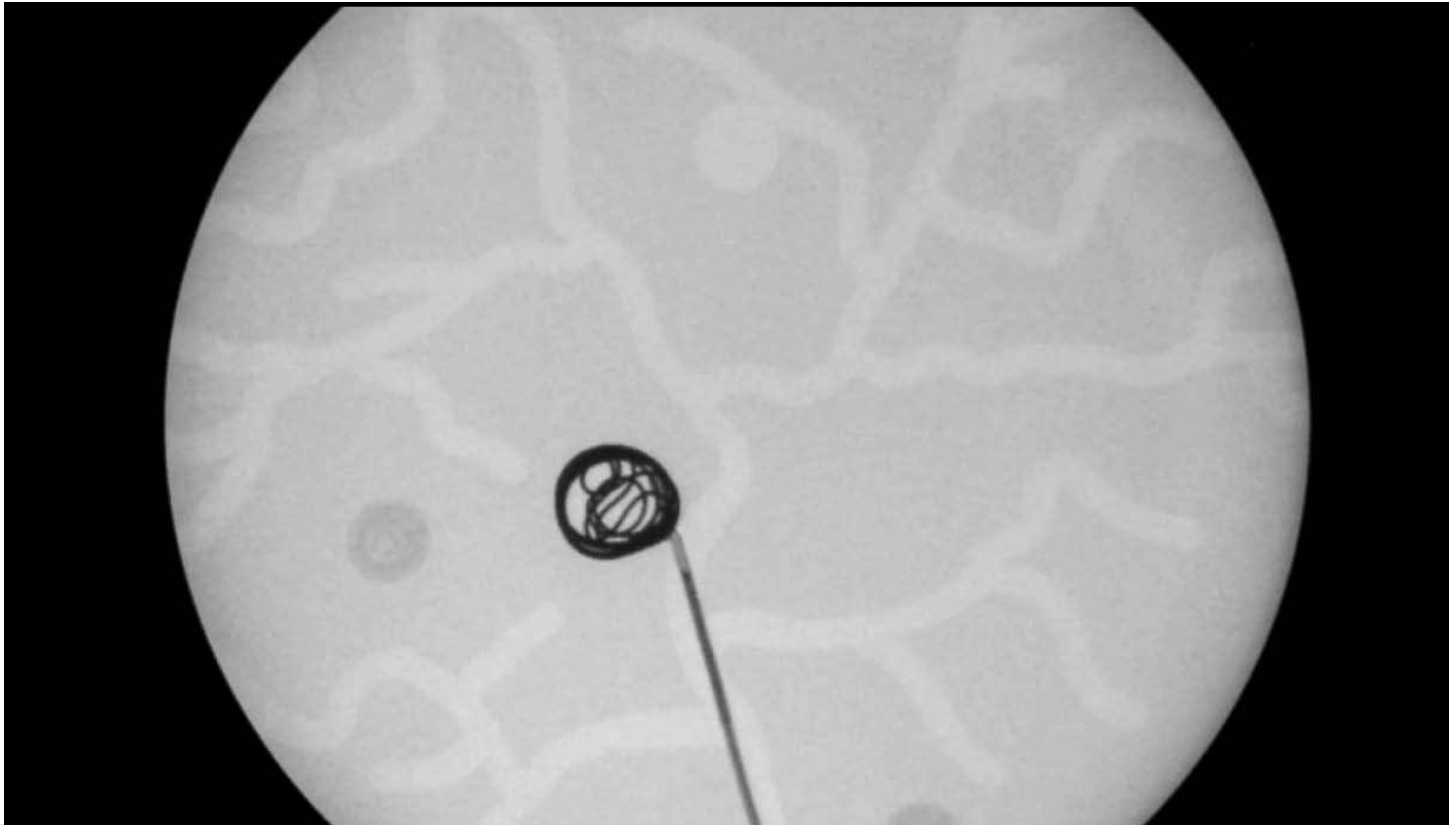


If Interlock™ - 35 Fibered IDC™ Occlusion System repositioning is necessary, gently retract it under fluoroscopy. If repositioning is difficult or impossible, remove and discard the Interlock™ - 35 Fibered IDC™ Occlusion System .

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To deploy the coil, slowly advance the delivery wire under fluoroscopy until interlocking arms pass catheter's tip. If deployment resistance is encountered, slowly rotate delivery wire until coil deploys.

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Upon conclusion of coil deployment, carefully remove the delivery wire from the catheter so that the delivery arm does not catch on the valve in the RHV Thumbscrew. If multiple embolization devices are required to achieve desired occlusion, please repeat the steps outlined previously or refer to the steps outlined in the Interlock™ - 35 Fibered IDC™ Occlusion System Directions for Use.

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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 - 35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.

PRECAUTIONS: Do not attempt to use the Interlock - 35 Fibered IDC Occlusion System with a soft-walled delivery catheter. Do not advance the Interlock - 35 Fibered 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

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