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Interlock^{**}-18 Coil A little smaller and A lot Bigger

> Product Deployment Slide Deck

Prior to Use, Please review the Interlock 18 Coil Directions For Use

0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44 46

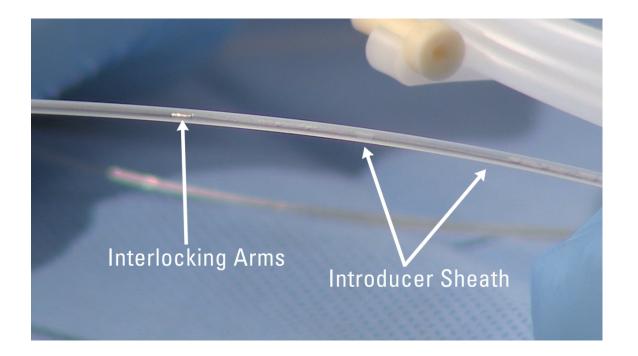




Slowly withdraw the Interlock Fibered IDC Occlusion System from its dispenser coil and inspect assembly. Discard if there is any evidence of damage.

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Ensure that the Interlock 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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Release the Interlock 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 counterclockwise 2-3 rotations.

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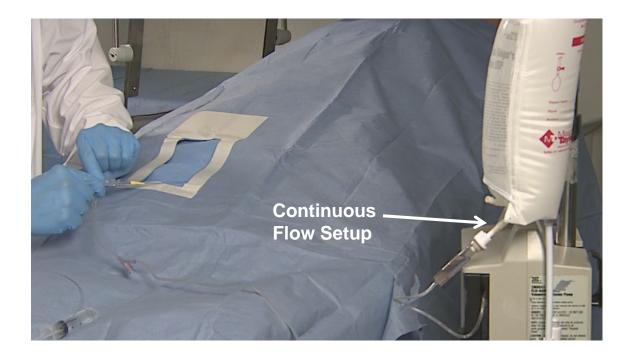
Attach the included RHV to the proximal luer adapter on the hub of the microcatheter.

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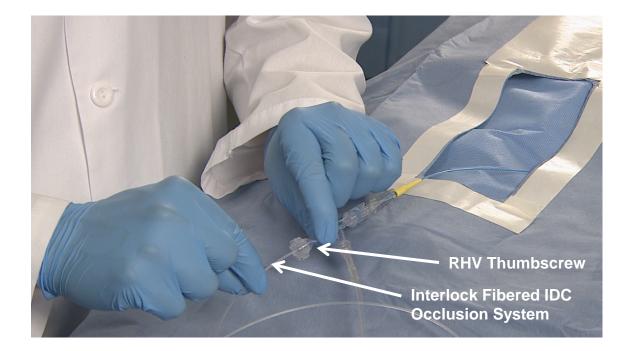




Begin continuous flow of an appropriate flush solution. In general, one drop of flush solution every 1-3 seconds from a pressure bag containing the flush solution is recommended.

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Open the thumbscrew of the RHV and carefully insert the Interlock Fibered IDC Occlusion System.

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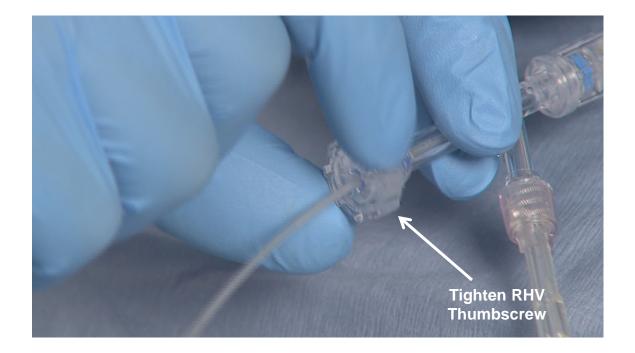




Insert the Interlock Fibered IDC Occlusion System until the distal tip of the introducer sheath is firmly seated in the microcatheter hub.

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Tighten the RHV thumbscrew just enough 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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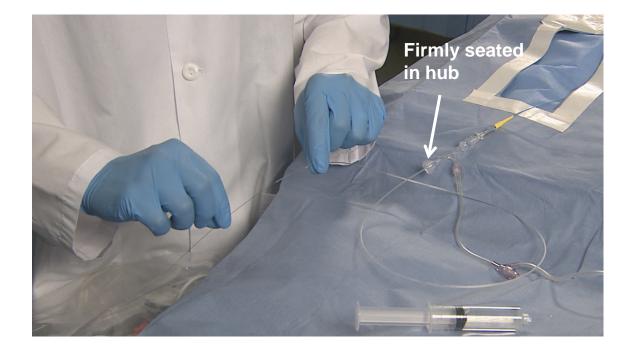




Transfer the Interlock[™] Fibered IDC[™] Occlusion Coil and delivery wire from the introducer sheath into the microcatheter by advancing the delivery wire in a smooth, continuous manner.

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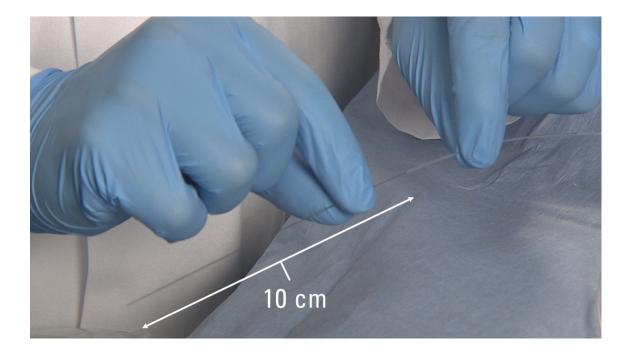




Ensure that the introducer sheath remains firmly seated in the microcatheter hub to prevent premature deployment.

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Gently withdraw and remove the introducer sheath from the microcatheter once the proximal end of the delivery wire is within 10 cm of the proximal end of the sheath.

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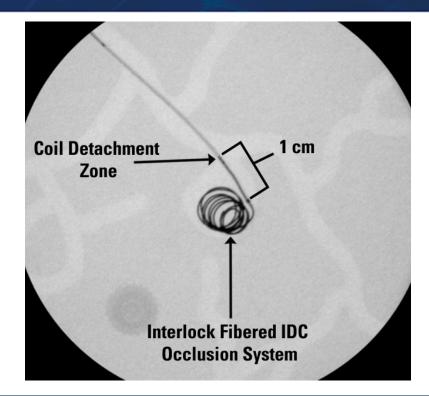




Do not discard the sheath in case it is necessary to remove the Interlock Fibered IDC Occlusion System prior to deployment.

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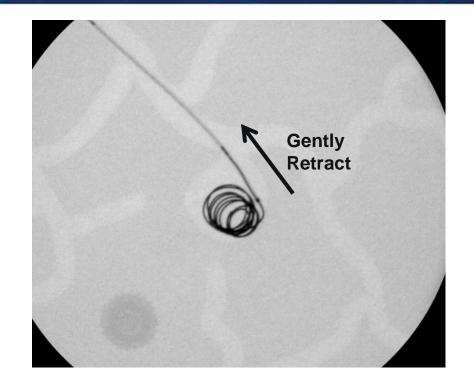




Maneuver the Interlock Fibered IDC Occlusion System under fluoroscopy until the coil detachment zone is approximately 1 cm proximal to the microcatheter radiopaque tip marker.

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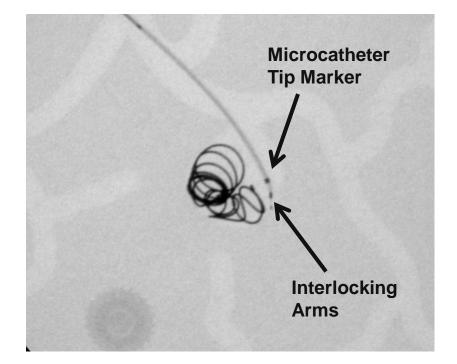




If Interlock Fibered IDC Occlusion System repositioning is necessary, gently retract the Interlock Coil under fluoroscopy. If repositioning is difficult or impossible, remove and discard the Interlock Fibered IDC Occlusion System.

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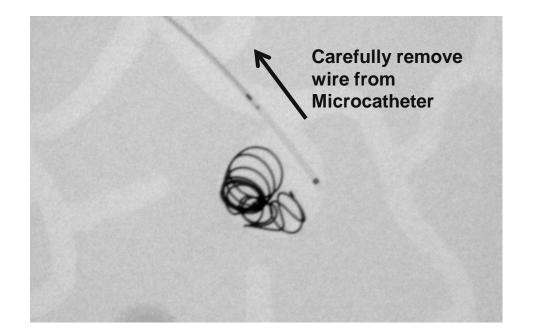




To deploy the coil, slowly advance the delivery wire under fluoroscopy until the interlocking arms pass microcatheter's tip marker.

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Upon conclusion of coil deployment, carefully remove the delivery wire from the microcatheter. If multiple embolization devices are required to achieve desired occlusion, please repeat the steps outlined previously or refer to Steps 1-9 in the Interlock 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 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

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