

AZUR[®]

Peripheral HydroCoil Embolization System

PUSHABLE IN-SERVICE GUIDE

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DIRECTIONS FOR USE

Please refer to the IFU for a complete statement of the indications, contraindications, warnings, and instructions for use supplied with each device. Always follow the IFU.

Step 1

Before opening the packaging, confirm correct coil size. Also check the coil expiration date. Remove both AZUR[®] Peripheral Hydrocoil Embolization System introducer sheath and its stylet from the protective pouch.



Confirm correct coil size



Check coil expiration date



Open package

Steps 2-4

Step 2:

Verify that both ends of the AZUR® Peripheral Hydrocoil Embolization System are visible through the introducer sheath.



Step 3:

Remove the proximal cap from the introducer sheath.



Step 4:

Fill a 1 cc syringe with saline and connect it into the introducer hub. Slowly inject saline until a steady stream escapes from the distal cap vent.



Allow 3 minutes to hydrate and soften the coil, which will enable it to take its shape upon delivery. The introducer sheath must be held level during injection.

Note: The Hydrogel will not begin to expand until the coil is exposed to blood.

Steps 5-7

Step 5:

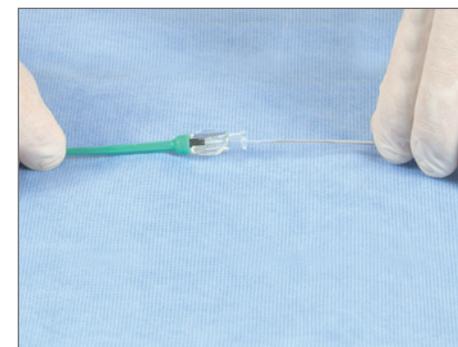
Verify that both ends of the AZUR® Peripheral Hydrocoil Embolization System are visible through the introducer sheath. Remove the distal cap.

Note: The syringe must remain attached until stylet insertion.



Step 6:

Insert the tapered introducer tip into the catheter hub until it is fully seated. Note: The introducer sheath will not go into the catheter. If using a rotating hemostatic Y valve (RHV), do not over tighten the RHV around the introducer. Excessive tightening could damage the coil.



Step 7:

With the introducer sheath held in place, insert the stylet into the hub. Push all the way through the introducer sheath until the shaped proximal end seats on the introducer hub.



Steps 8-10

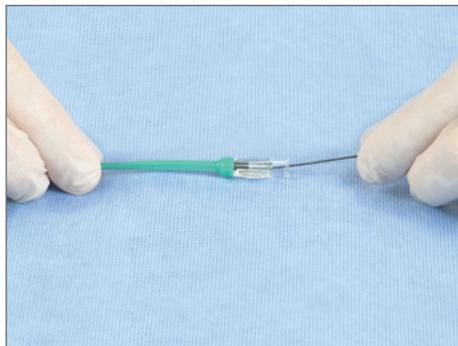
Step 8:

Remove the introducer and stylet.



Step 9:

Insert a pushing guidewire into the delivery catheter. Push until the AZUR® coil has fully exited the end of the catheter.



Step 10:

Remove the guidewire. Repeat steps 1-10 to deliver multiple AZUR® pushable coils.



Note: Once the coil has been deployed, and prior to removing the delivery catheter, advance the guidewire through the catheter tip to verify that no part of the coil remains within the catheter lumen.

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RX ONLY. Caution: Federal law restricts this device to sale by or on the order of a physician. The advertisement is directed to physicians only, and not to consumers. Refer to product labels and packaging insert for complete warnings, precautions, potential complications, and instructions for use. Products may not have regulatory approval in all countries. Please contact your local sales representative if you have questions about the availability of products in your area.

References:

Refer to AZUR Hydrocoil Detachable IFU PD110088 Rev B Revised 2012-11

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