

AZUR[®]

Peripheral HydroCoil Embolization System

DETACHABLE 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. Open package and remove hoop.



Confirm correct coil size



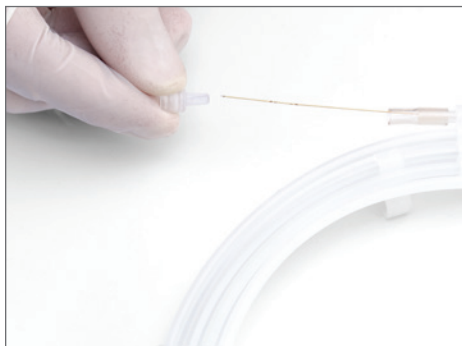
Check coil expiration date



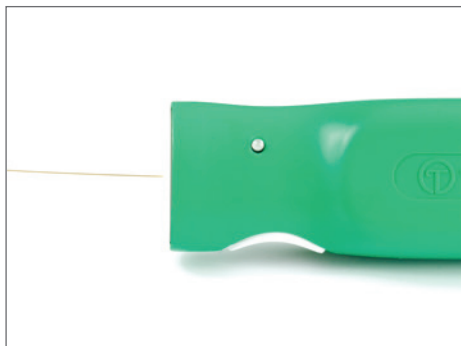
Open package and remove hoop

Step 2

Gently remove clear cap from the delivery system. Prior to using the device, insert the proximal end of the delivery pusher into the funnel section of the AZUR® Detachment Controller; **DO NOT PRESS BUTTON.**



Remove clear cap from the delivery system



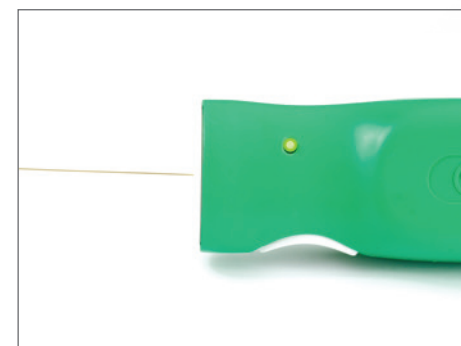
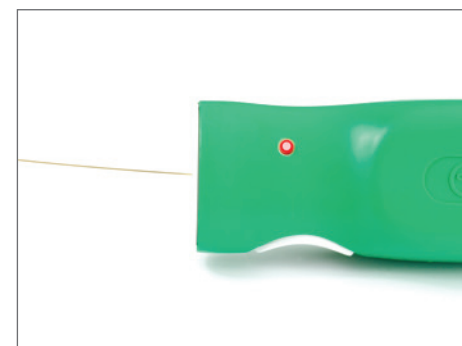
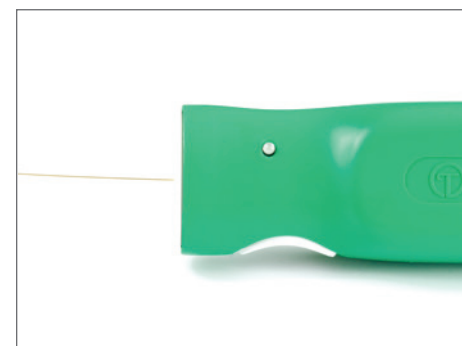
Insert the proximal end of the delivery pusher into the controller.

Step 3

If light does not light, replace the AZUR® Detachment Controller.

If a **red light** appears, replace the AZUR® Detachment Controller.

If the indicator light remains **solid green**, continue using the AZUR® Detachment Controller. ***Do not press button.***

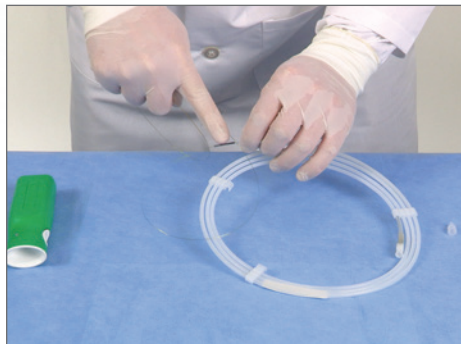


IMPORTANT: Do not press button at any time during Step 3.

Steps 4-6

Step 4:

Pull the AZUR® Peripheral Hydrocoil Embolization System out of the housing hoop, until you see the black shrink lock.



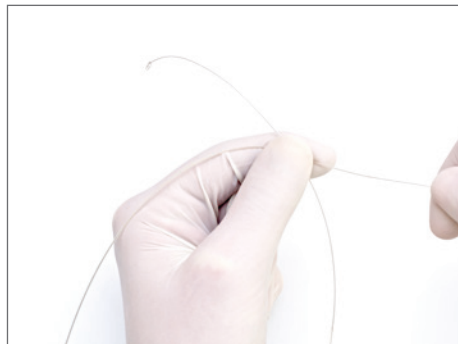
Step 5:

Slide the black shrink lock proximally to expose the tab on the introducer sheath. Note: Shrink lock does not peel away.



Step 6:

Continue to pull the AZUR® Peripheral Hydrocoil Embolization System out of the housing hoop.



Slowly advance coil out of the introducer sheath and inspect distal tip of coil for any irregularities or damages.

Step 7

The following pre-softening procedure is optional. The AZUR® Peripheral Hydrocoil Embolization System may also be used without pre-softening.

Step 7 (optional):

Prepping techniques include using warm sterile saline solution or steam until coil takes shape; about 5–10 seconds.



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

Steps 8-9

Step 8:

With the distal end of the introducer sheath pointed downward, gently retract the coil completely into the introducer sheath about 1-2 cm.



Step 9:

Insert the distal tip of the coil introducer sheath into the microcatheter/guidecatheter hub.

Note: The coil introducer sheath will not go into the microcatheter/guidecatheter. If using rotating hemostatic Y valve (RHV), do not over-tighten the RHV around the introducer. Excessive tightening could damage the coil.

Push the coil into the lumen of the microcatheter/guidecatheter. Use caution to avoid catching the coil on the junction between the introducer sheath and the hub of the microcatheter/guidecatheter.

Push the AZUR® Peripheral Hydrocoil Embolization System through the microcatheter/guidecatheter until the proximal end of the delivery pusher meets the proximal end of the introducer sheath.



Step 10-11

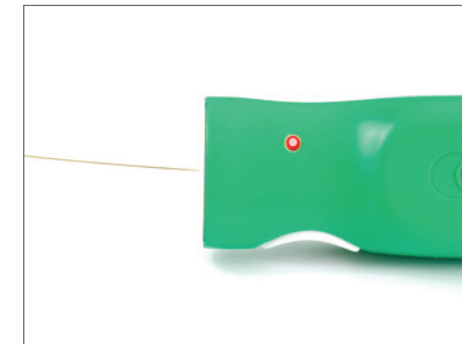
Step 10:

Deliver the coil to the appropriate location. Verify the coil position and connect the proximal end of the delivery pusher to the AZUR® Detachment Controller.

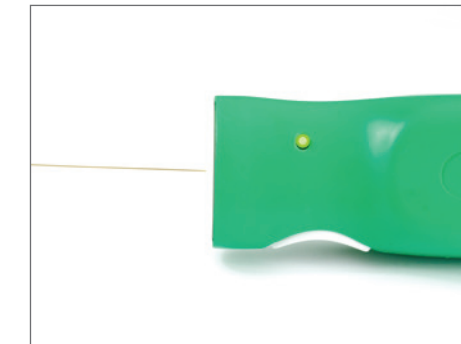


Step 11:

If a **red light** appears, wipe the end of the coil with a saline soaked 4 x 4 gauze to wipe away contrast or blood.



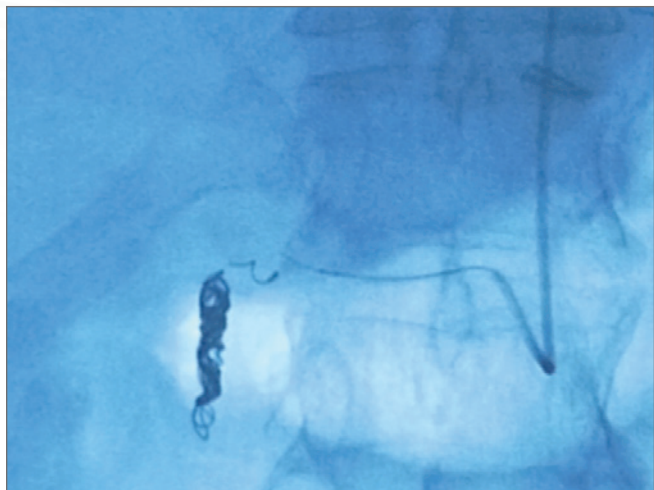
If the indicator light remains **solid green**, continue using the AZUR® Detachment Controller.



Press the button and wait for the detachment cycle, which consists of three audible tones accompanied by three amber lights.

Step 12

Verify the detachment of the coil under fluoroscopy by pulling back slowly on the delivery pusher and confirming there is no coil movement. Remove the delivery pusher.



Repeat steps 1-12 to deliver multiple AZUR® detachable coils.

Note: Please refer to the full Instructions for Use for complete instructions on how to use this medical device. The information presented here is intended only as a summary of key operational instructions and important considerations related to the system.

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References:

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

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