

Expanding TERUMO Territory.™

AZUR™

Peripheral HydroCoil®
Embolization System

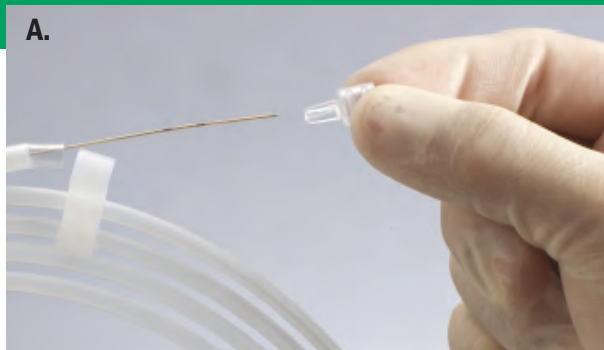
**Detachable Coil
Setup Guide**



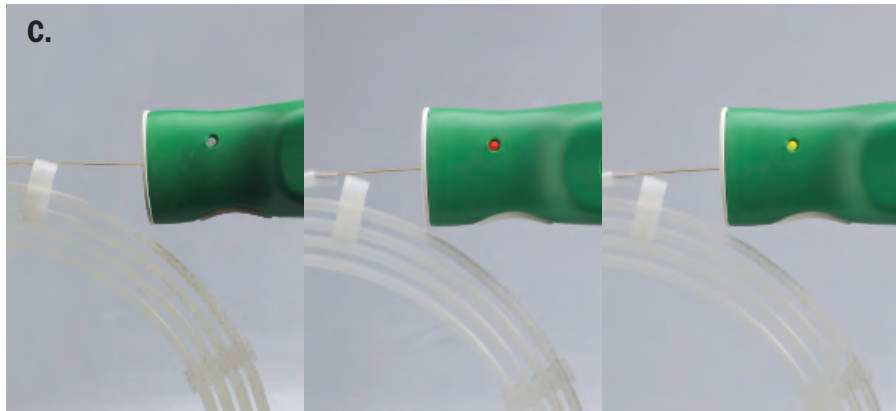
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TERUMO INTERVENTIONAL SYSTEMS

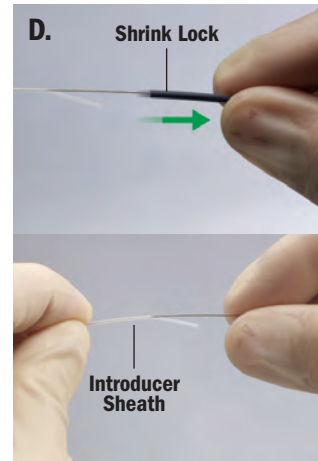
Detachable Coil Setup Guide



1. Gently remove clear cap from the delivery system (Figure A). **Avoid contaminating this end of the delivery pusher with foreign substances such as blood or contrast.** Prior to using the device, insert the proximal end of the delivery pusher into the funnel section of the AZUR Detachment Controller (Figure B).

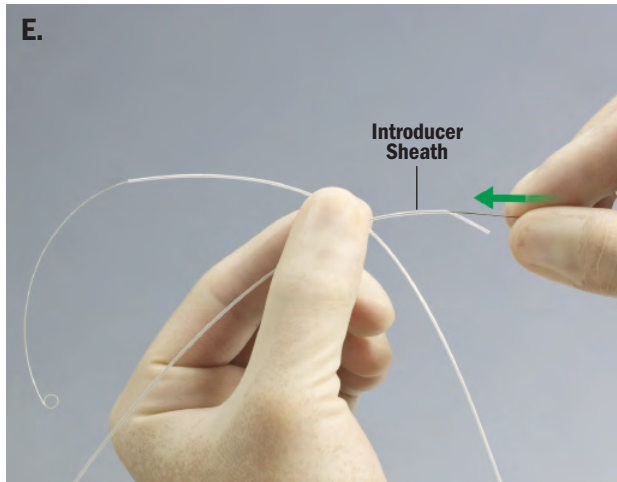


2. Wait 3 seconds and observe the indicator light on the AZUR Detachment Controller (Figure C). **Note: Do not press the button.**
- i) If the indicator light does not light, replace the AZUR Detachment Controller.
 - ii) If a **red** light appears, replace the AZUR Detachment Controller.
 - iii) If the light turns **green** and then turns off at any time during the 3-second observation, replace the AZUR Detachment Controller.
 - iv) If the indicator light remains solid **green** for the entire 3-second observation, continue using the AZUR Detachment Controller.
- Remove the AZUR Detachment Controller. Pull the AZUR out of the loop.

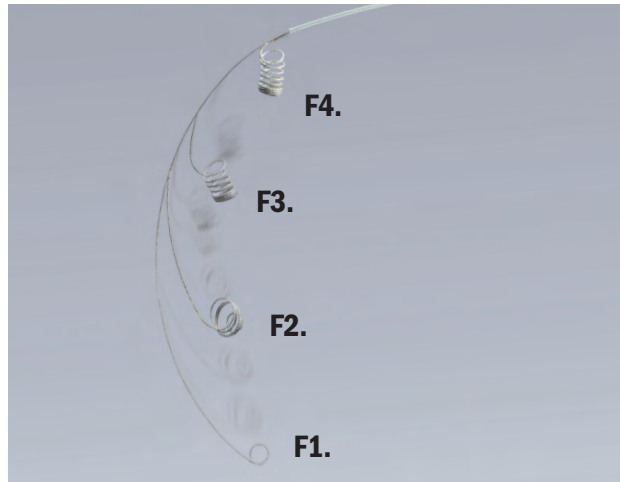


3. Slide the black shrink lock proximally, to expose the tab on the introducer sheath (Figure D).

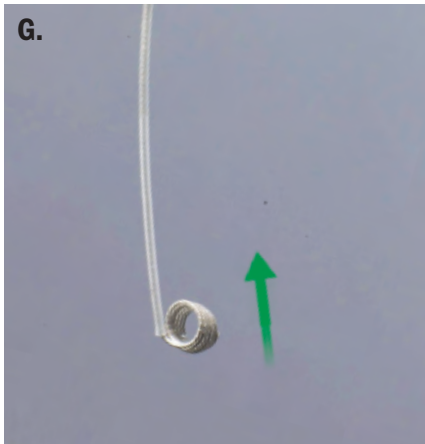
Note: Shrink lock does not peel away.



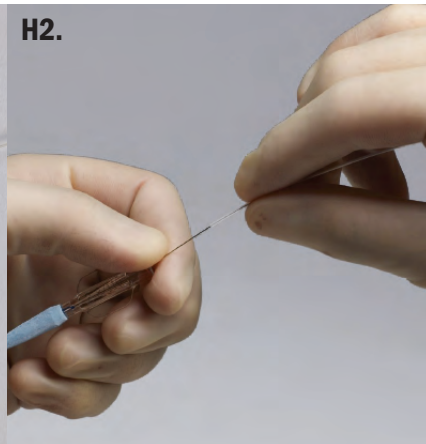
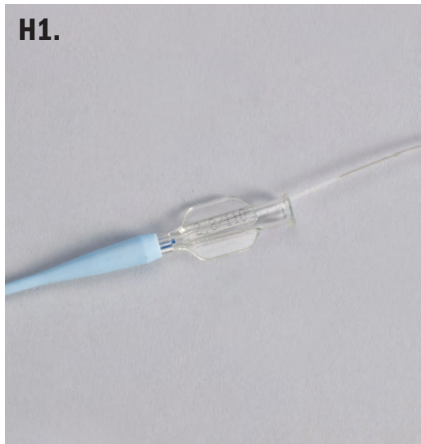
4. Slowly advance the AZUR Peripheral HydroCoil Embolization System (AZUR) coil out of the introducer sheath and inspect the coil for any irregularities or damages (Figure E).



5. **The following presoftening procedure is optional.** Using a sterile technique, advance the AZUR out of the distal end of the introducer sheath (Figure F1) and immerse it in a warm sterile saline solution or warm lactated Ringer's solution. Alternatively, hold it in a flow of steam until it curls; about 5–10 seconds (Figures F2–F4). AZUR may also be used without presoftening.

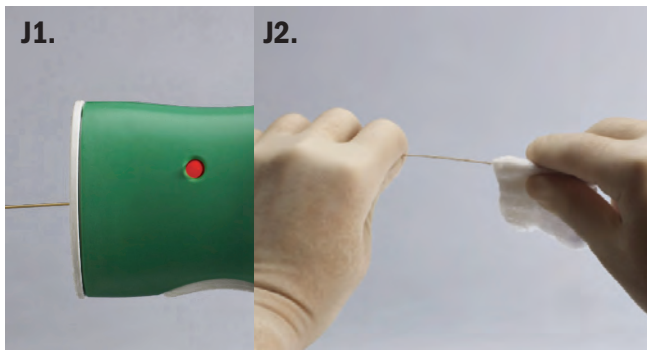
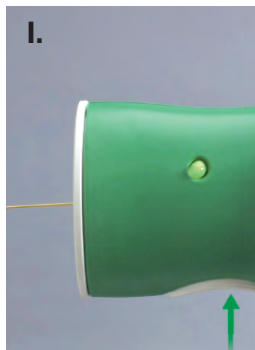


6. With the distal end of the introducer sheath **pointed downward** and the coil still in the warm saline/lactated Ringer's (or in the flow of a steam source), gently retract the coil completely into the introducer sheath; about 1–2 cm (Figure G).



7. Insert the distal tip of the introducer sheath into the microcatheter hub (Figures H1–H2).

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



8. 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 (an audible tone will sound and the light will flash green) (Figure I). Press the button and wait for the detachment cycle, which consists of three audible tones accompanied by three amber lights. 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.

Note: If a red light appears (Figure J1), wipe the end of the coil with a saline soaked 4 x 4 gauze to wipe away contrast or blood (Figure J2), then reinsert the delivery pusher into the funnel. Replace the detachment controller after 30 detachments.

9. Repeat steps 1–8 to deliver multiple AZUR coils.

Note: If necessary, verify the position of the coil angiographically through the catheter. Prior to removing the microcatheter from the treatment site, place an appropriately sized guidewire completely through the microcatheter lumen to ensure that no part of the coil remains within the microcatheter.

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.

Glidewire[®] GT

Hydrophilic Coated Guidewires

ProgreatTM

Hydrophilic Coated Microcatheters

AZUR™

Peripheral HydroCoil®
Embolization System



Progreat™

Glidewire® GT

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Pinnacle® R/O II Radiopaque Marker Introducer Sheaths
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