

Deployment Sequence

Zenith AlphaTM
THORACIC ENDOVASCULAR GRAFT

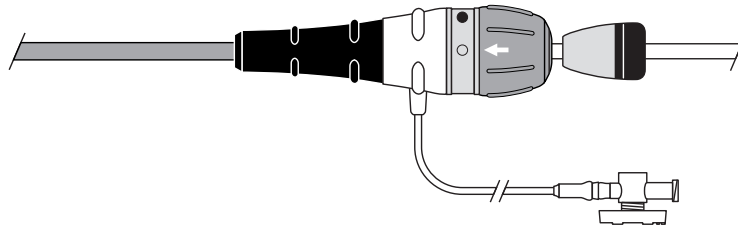


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Preparation and flush

Proximal and distal components

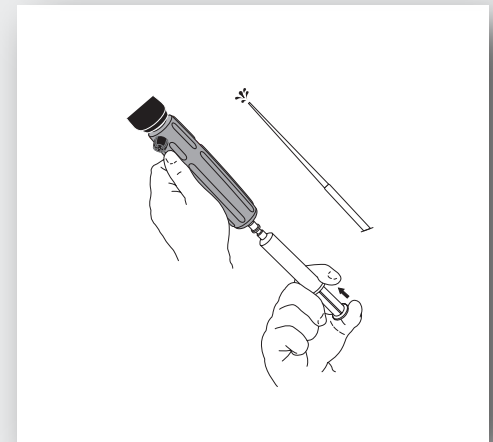
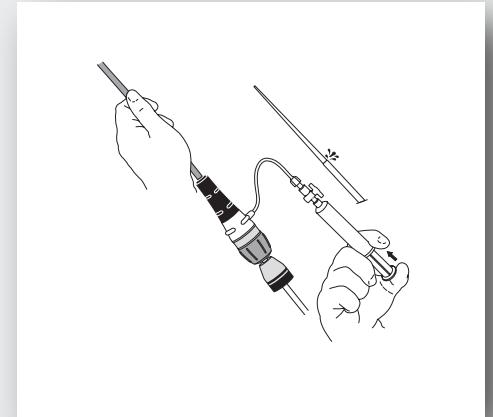
- Remove the yellow hubbed inner stylet from the dilator tip.
- Verify that the Captor Sleeve is within the Captor® Hemostatic Valve.



Preparation and flush

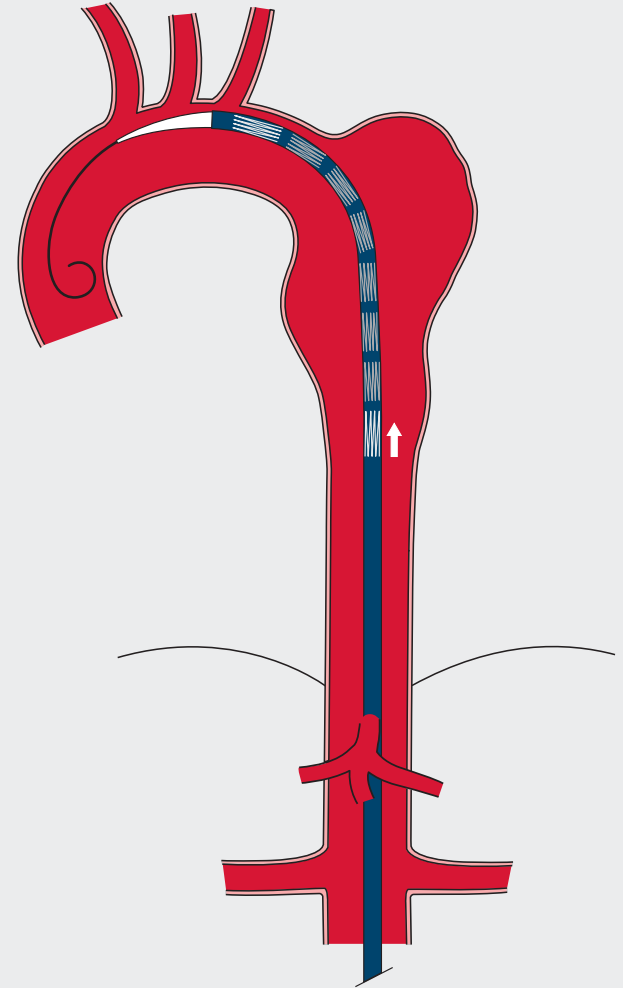
Proximal and distal components

- Elevate the distal tip of the system
- Flush the hemostatic valve with heparinized saline until fluid emerges from the tip of the introducer sheath.
Note: use 60 mL total of heparinized saline
- Attach the syringe with heparinized saline to the hub on the rotation handle and flush the hub until fluid exits the dilator tip.
- Soak sterile gauze pads in saline solution and use them to wipe the Flexor introducer sheath to activate the hydrophilic coating. Hydrate both sheath and dilator tip liberally.



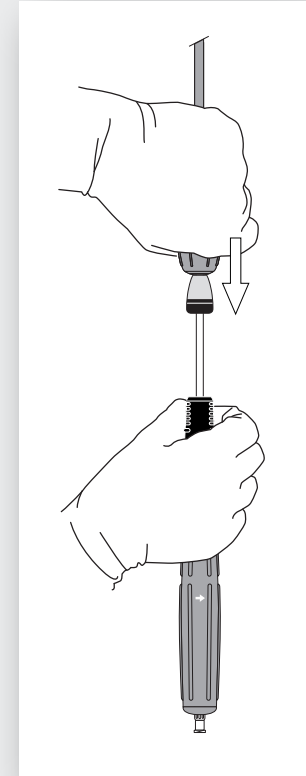
Placement of the proximal component

- Introduce the system over the Lunderquist® Extra-Stiff Double Curved Wire Guide and advance the system until the desired graft position is reached.
- Ensure that the Captor® Hemostatic Valve on the Flexor® Introducer Sheath is turned to the open position.



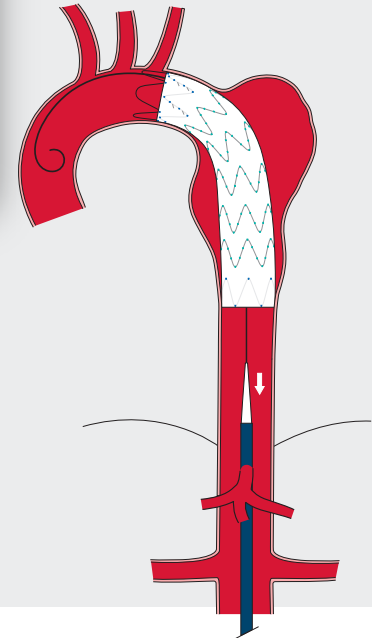
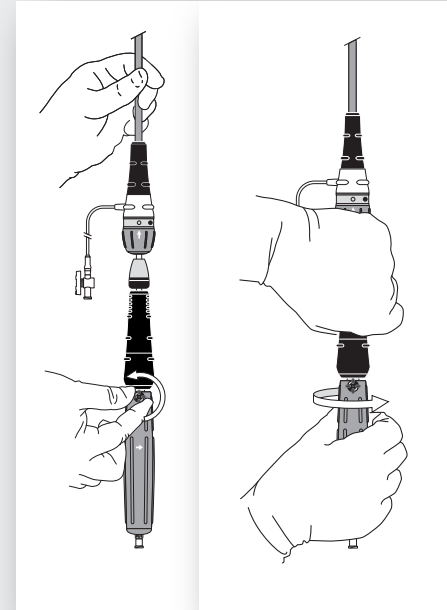
Placement of the proximal component

- Stabilize the gray positioner and withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor sleeve docks with the black gripper.



Placement of the proximal component

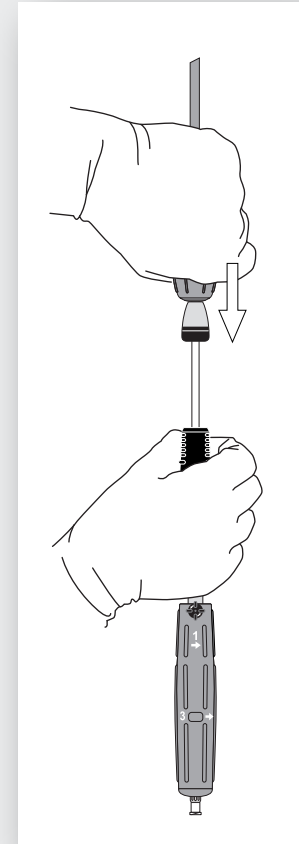
- Turn the black safety-lock knob in the direction of the arrows to engage the blue rotation handle.
- To release the proximal attachment, turn the blue rotation handle in the direction of the arrows until the handle stops. The uncovered stent and the proximal end of the graft open and release the distal attachment of the introducer.
- Remove the introduction system. Leave the wire guide in the graft.



Placement of the distal component

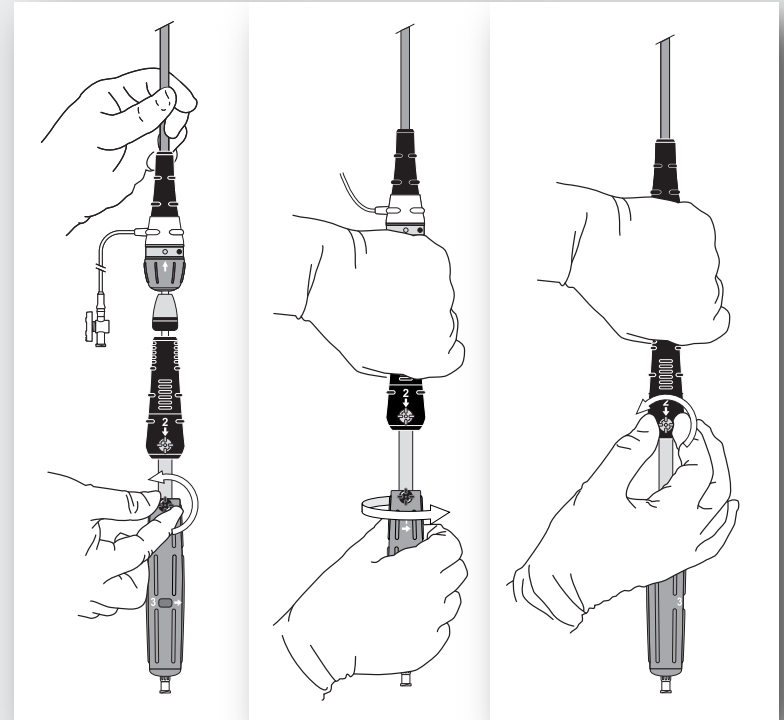
- Introduce the introduction system over the Lunderquist Extra-Stiff Double Curved Wire Guide until the desired graft position is reached. Maintain at least a 3 stent overlap (75 mm) with the proximal component.
- Withdraw the sheath until the graft is fully expanded. Continue to withdraw the sheath until the valve assembly with the Captor[®] sleeve docks with the telescoping black gripper.

Note: Care should be taken to avoid landing the bare stent in regions of localized angulation greater than 45 degrees. If the bare stent is landed in localized angulations greater than 45 degrees, it may be difficult to release the bottom cap, as observed in the clinical study.



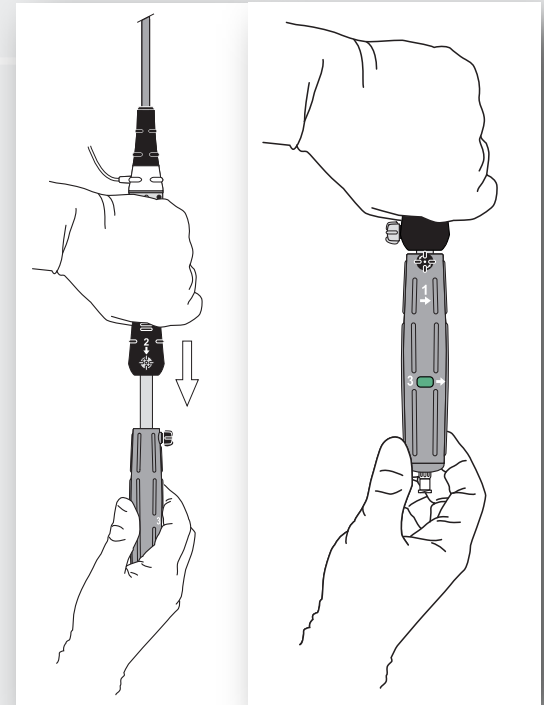
Placement of the distal component

- Release the distal attachment by first loosening the black safety lock knob on the blue rotation handle, then turn the handle clockwise following the directional arrow until a stop is felt (label 1).
- Turn the gray safety lock knob on the black gripper in the direction of the arrow (label 2).



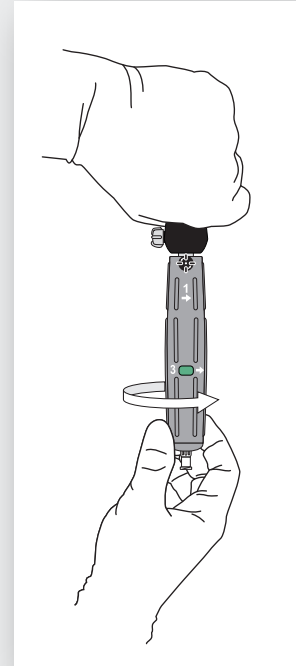
Placement of the distal component

- To release the distal bare stent, stabilize the introduction system and slide the black gripper over the gray tube and the outer sheath in a distal direction until the distal bare stent is released and it locks automatically into position next to the blue rotation handle.
- The release window on the blue rotation handle next to label 3 will turn green.



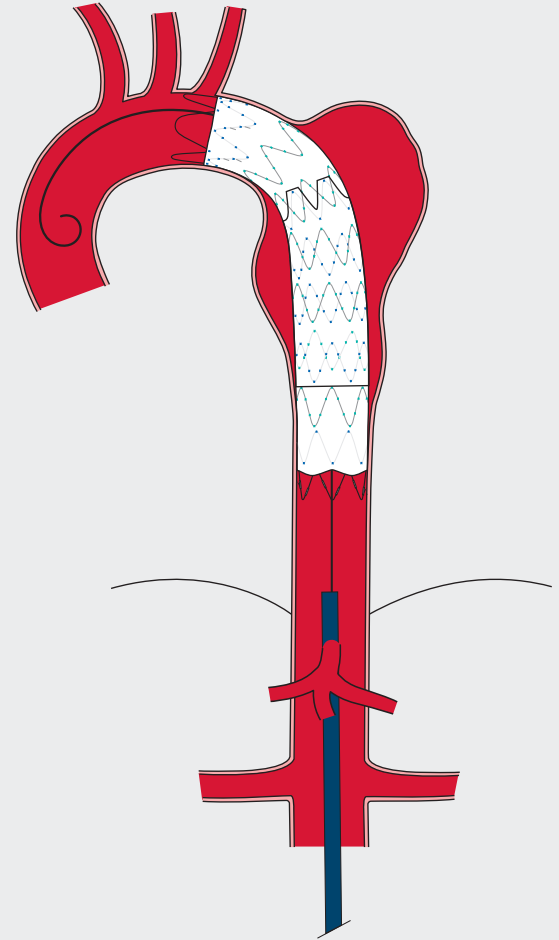
Placement of the distal component

- Turn the blue rotation handle clockwise following the directional arrow (label 3) until the handle stops and the proximal end of the graft opens.



Placement of the distal component

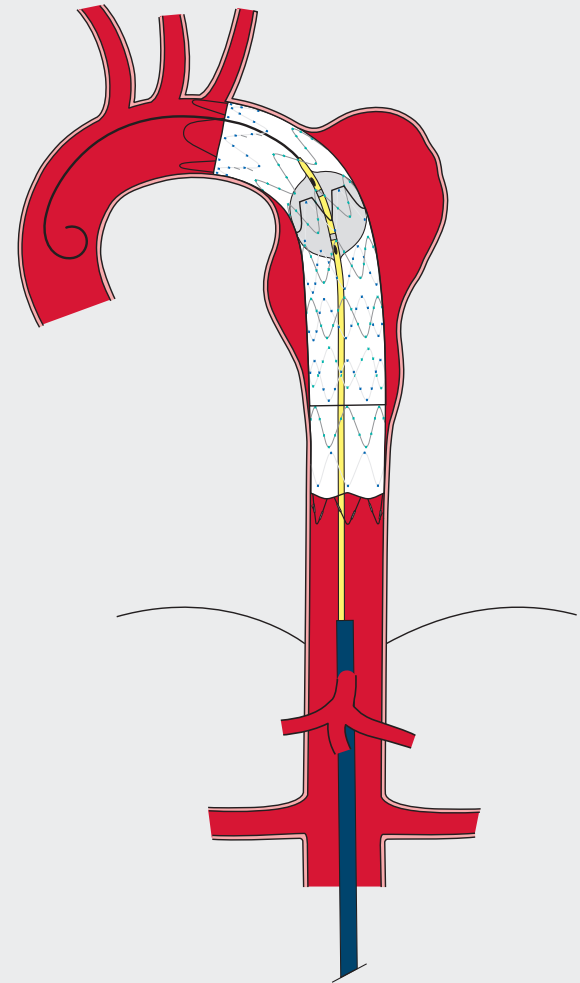
- Remove the inner introduction system entirely, leaving the sheath and wire guide in the graft. Close the Captor® Hemostatic Valve on the Flexor® Introducer Sheath.



Placement of the molding balloon

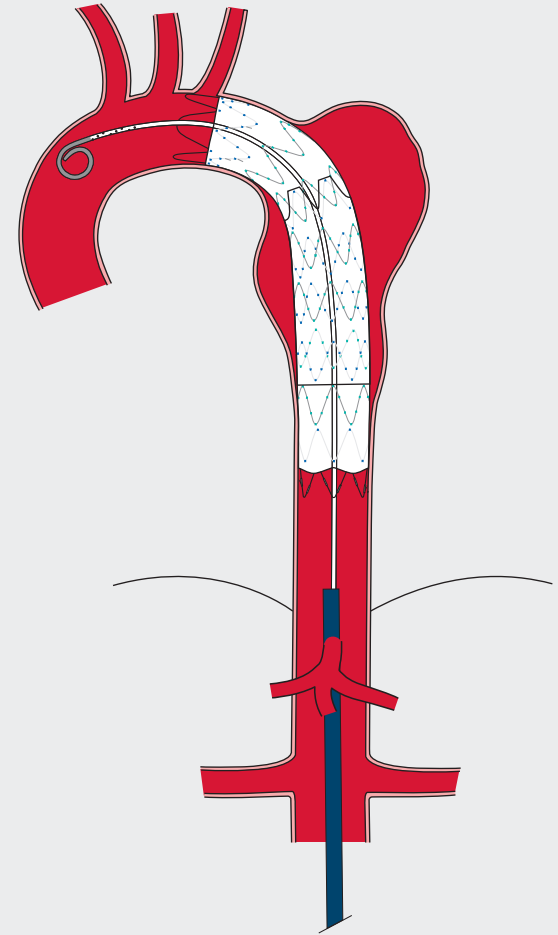
Optional

- Position the molding balloon and, using diluted contrast media (as directed by the manufacturer), expand the molding balloon in the region of the proximal covered stent, the proximal component and distal component overlap, and the distal fixation site.



Perform final flush angiography

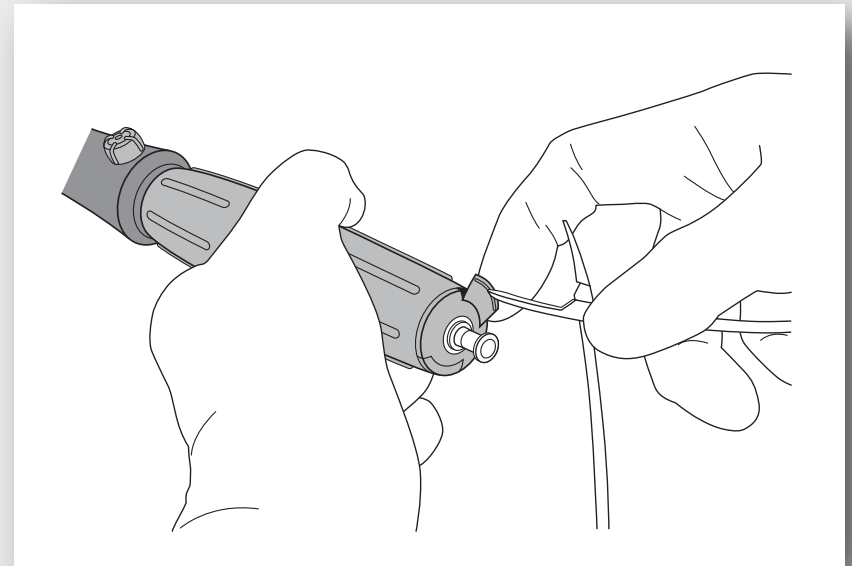
- Position a pigtail or straight catheter just above the level of the deployed endovascular graft and perform angiography to confirm the following:
 - Correct graft position
 - Patency of arch vessels and celiac plexus
 - Absence of endoleaks
 - Position of proximal and distal gold markers



Troubleshooting the component release

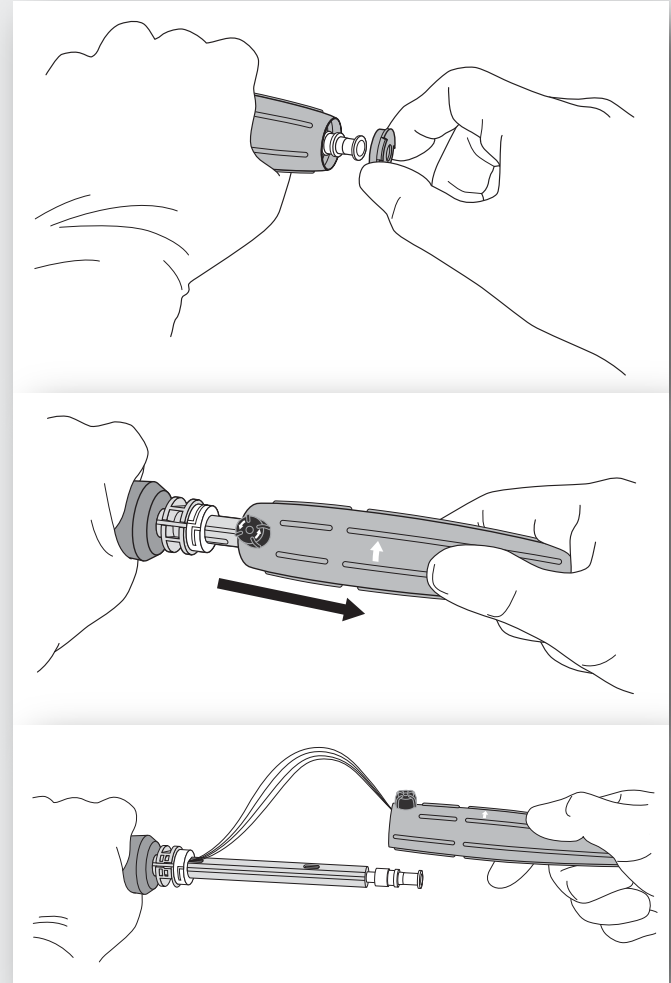
If the stent graft does not completely release as you turn the blue rotation handle, you can disassemble the rotation handle.

- Using surgical forceps, pull out the backend clips on the handle.



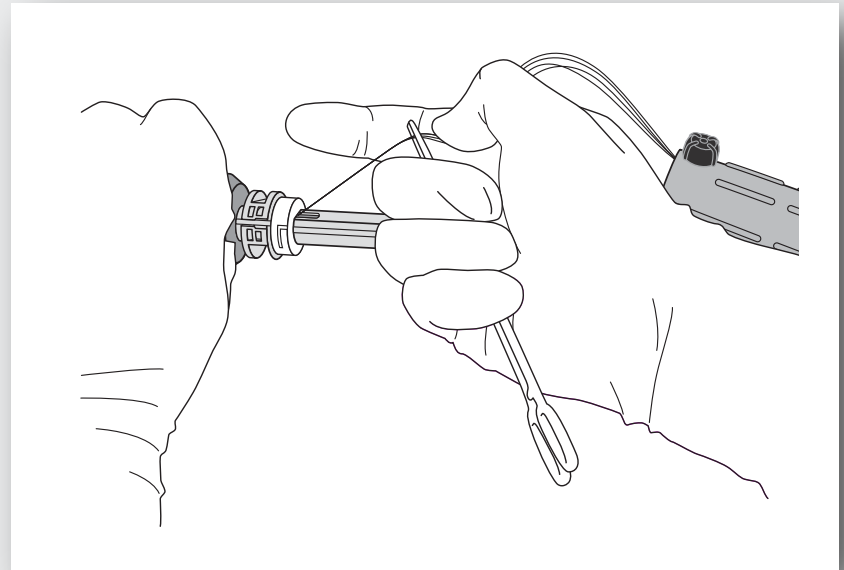
Troubleshooting the component release

- Remove the backend cap of the handle.
- Slide the rotation handle backward to pull the release wires until the graft is released. Do not pull the release wires completely out of the rotation handle.



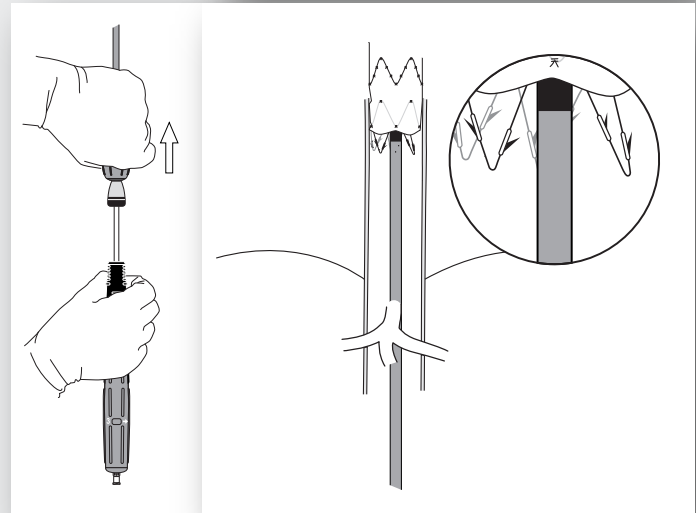
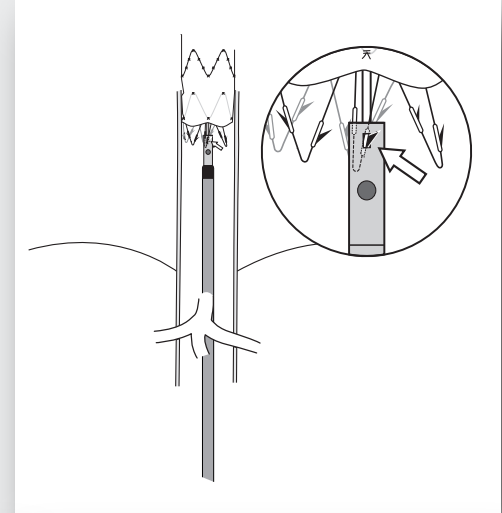
Troubleshooting the component release

- If extreme force is needed, wind the release wires around the surgical forceps.



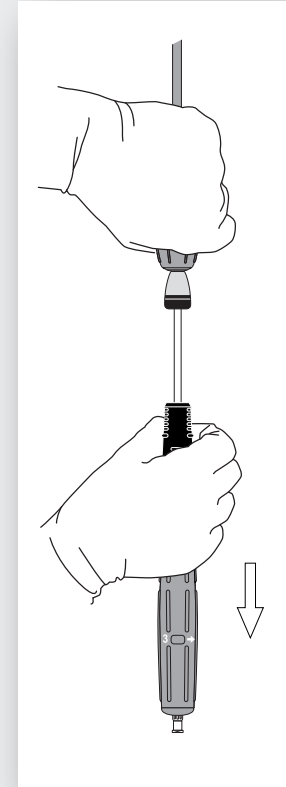
Troubleshooting the distal component release

- If the bare stent cannot be fully deployed from the cap, advance the Flexor® sheath to the distal edge of the stent graft.



Troubleshooting the distal component release

- Stabilize the Flexor® sheath and pull back the blue rotation handle. The bare stent will now be released from the cap but will still be inside the sheath.



Troubleshooting the distal component release

- Slowly withdraw the sheath with a rotating movement until the bare stent is outside the sheath.

Note: Contact your local Cook representative to obtain technical assistance from a Cook product specialist.

