Deployment sequence

Zenith Alpha™
ABDOMINAL ENDOVASCULAR GRAFT

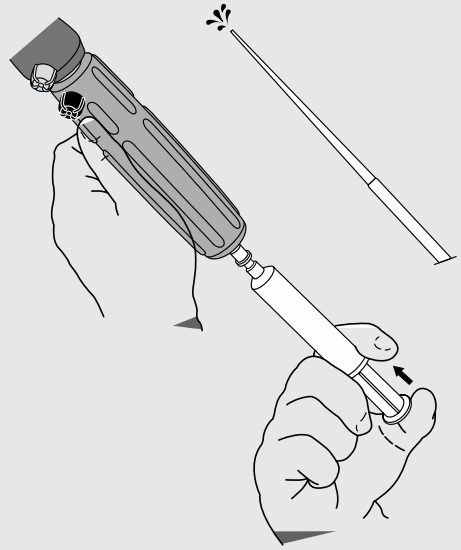
Introduction

This PowerPoint presentation is an outline highlighting the deployment process for the Zenith Alpha Abdominal Endovascular Graft. The suggested Instructions for Use booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings, and precautions.

Prepare main body and iliac leg systems

Main body

- Verify that the Captor® Sleeve is inserted in the Captor Hemostatic Valve.
- Elevate the distal tip of the system and flush through the stopcock on the Captor Hemostatic Valve until fluid emerges through the flush groove at the proximal end of the introducer sheath.
- Continue to inject 20 mL of flushing solution through the device.
- Discontinue injection and close the stopcock on the connecting tube.
- Attach a syringe with heparinized saline to the clear hub on the end of the handle.
- Flush until fluid exits the dilator tip.



Prepare main body and iliac leg systems

Iliac legs

- Remove the Peel-Away® sheath from the back of the hemostatic valve.

  Note: When removing the Peel-Away sheath from the back of the hemostatic valve, ensure that the delivery system sheath is held stationary against the dilator tip to limit possible movement.

- Elevate the distal tip of the system and flush through the stopcock on the hemostatic valve until fluid emerges through the flush groove at the proximal end of the introducer sheath.
- Continue to inject 20 mL of flushing solution through the device.
- Discontinue injection and close the stopcock on the connecting tube.
- Attach a syringe with heparinized saline to the black hub on the inner cannula.
- Flush until fluid exits the dilator tip.

Main body deployment

Orientation

Step 1

- Use fluoroscopy to orient the main-body delivery system.
- Contralateral limb:

= anterior

= posterior

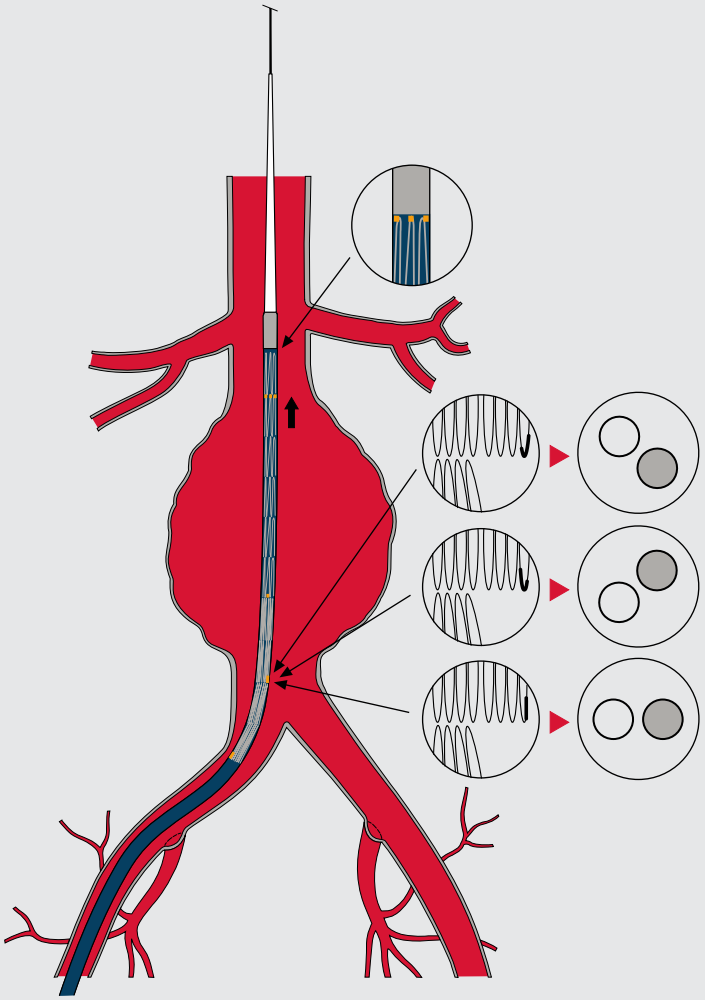
= lateral

Main body deployment

Placement

Step 2

- Introduce and position the device below the lowest renal artery and verify the device's orientation.
- Perform angiography as needed throughout the procedure.

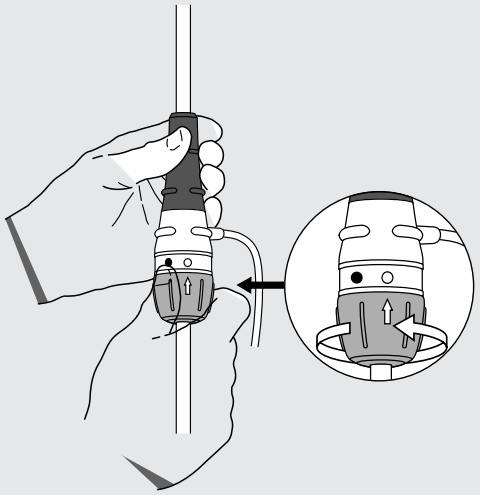


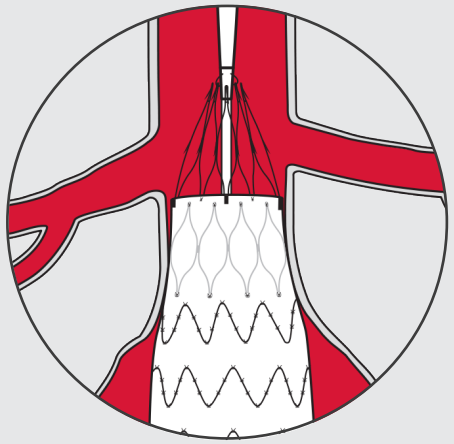
Main body deployment

Placement (continued)

Step 3

- Ensure that the Captor Hemostatic Valve is turned to the open position.
- Deploy the first two covered stents by retracting the sheath. Check the position of the device relative to the renal arteries and the aortic bifurcation.
- Use the radiopaque markers to orient the device.





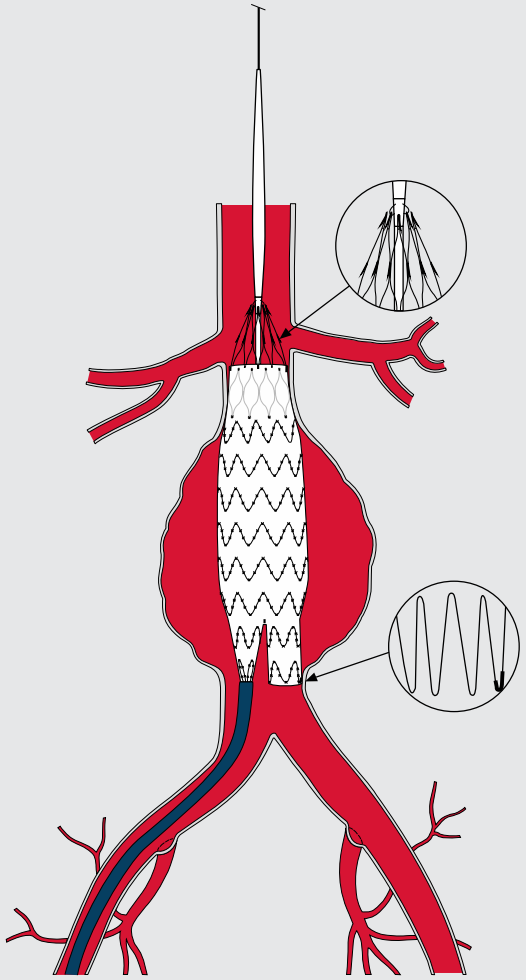
Main body deployment

Placement (continued)

Step 4

Note: Verify that the contralateral limb is at least 5 mm above the aortic bifurcation before you fully deploy the graft.

- Continue to retract the sheath until the contralateral limb is fully deployed.



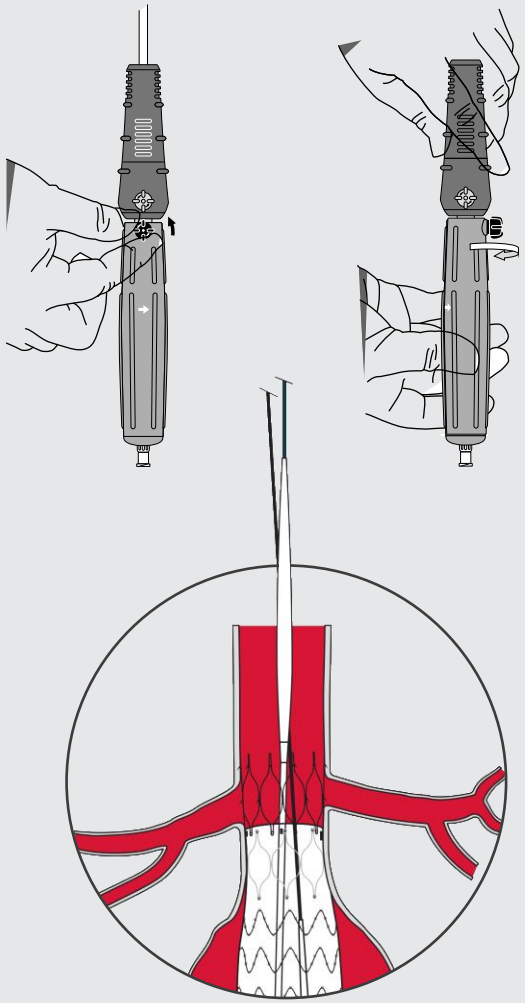
Suprarenal stent deployment

Placement (continued)

Step 5

- While holding the black gripper, turn the black safety lock knob 180 degrees in the direction of the arrows. (counterclockwise). Ensure that the black safety lock knob is secured in the unlock position. This will allow you to rotate the blue rotation handle.
- To release the suprarenal bare stent, under fluoroscopy, turn the blue rotation handle approximately two full rotations in the direction of arrow (clockwise) until a stop is felt.

  Note: If the blue rotation handle stops before completing approximately two full rotations, confirm that the black safety lock knob is in the unlock position. If it is not, unlock the black safety lock knob and complete rotation.



Contralateral iliac leg deployment

Wire guide placement

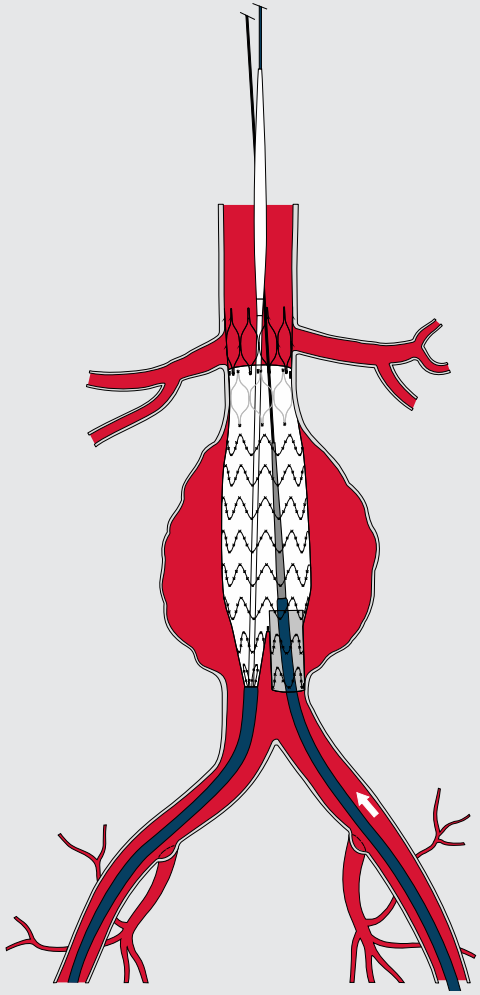
Step 6

- Using an angiographic catheter, manipulate the wire guide through the open end of the contralateral limb and into the body of the graft.
- After cannulation, advance the catheter over the wire guide into the body of the endovascular graft. Remove the wire guide and perform angiography to confirm its position.
- Through the angiographic catheter, reinsert the wire guide inside the body of the graft and into the thoracic aorta.
- Remove the angiographic catheter.

Contralateral iliac leg deployment

Step 7

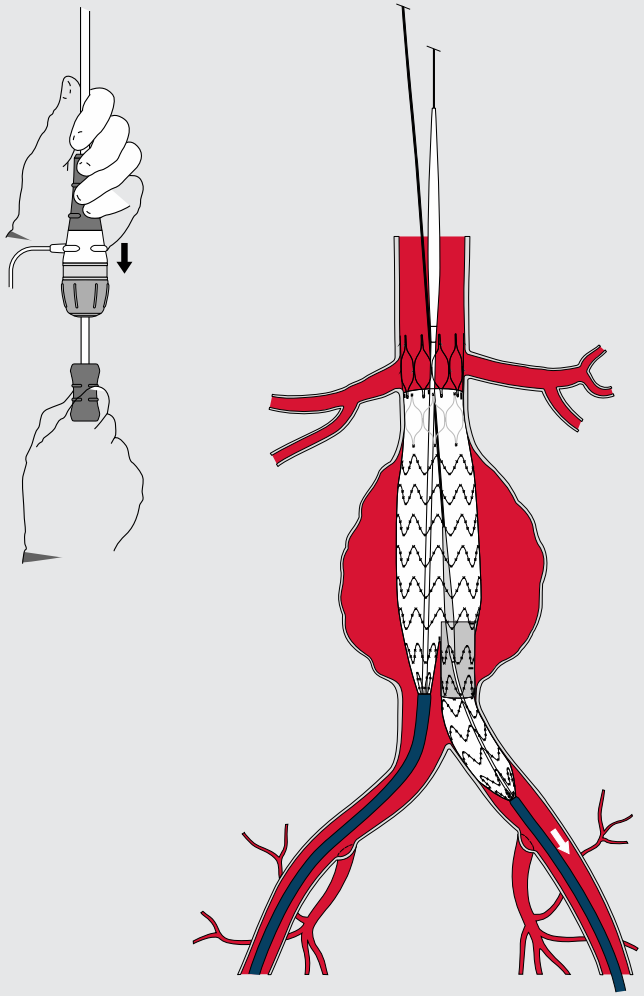
- Prior to introducing the contralateral iliac leg delivery system, inject contrast through the contralateral femoral sheath to locate the contralateral internal iliac artery.
- Remove the femoral sheath and introduce the contralateral iliac leg delivery system into the artery. Advance the delivery system slowly until the zone between the two proximal gold markers aligns with the gold radiopaque marker at the bifurcation of the main body graft. This alignment will allow between 16 mm and 32 mm of overlap between components.



Contralateral iliac leg deployment

Step 8

- To deploy the contralateral iliac leg graft, hold it in position with the gray positioner while withdrawing the sheath.
- Continue to withdraw the sheath while continuously checking the position of the graft.
- Stop withdrawing the sheath as soon as the distal end of the contralateral iliac leg graft is released.
- Under fluoroscopy and after you verify the iliac leg graft position, loosen the pin vise and retract the inner cannula to dock the tapered dilator to the positioner. Tighten the pin vise. Maintain sheath position while withdrawing the gray positioner with the secured inner cannula.



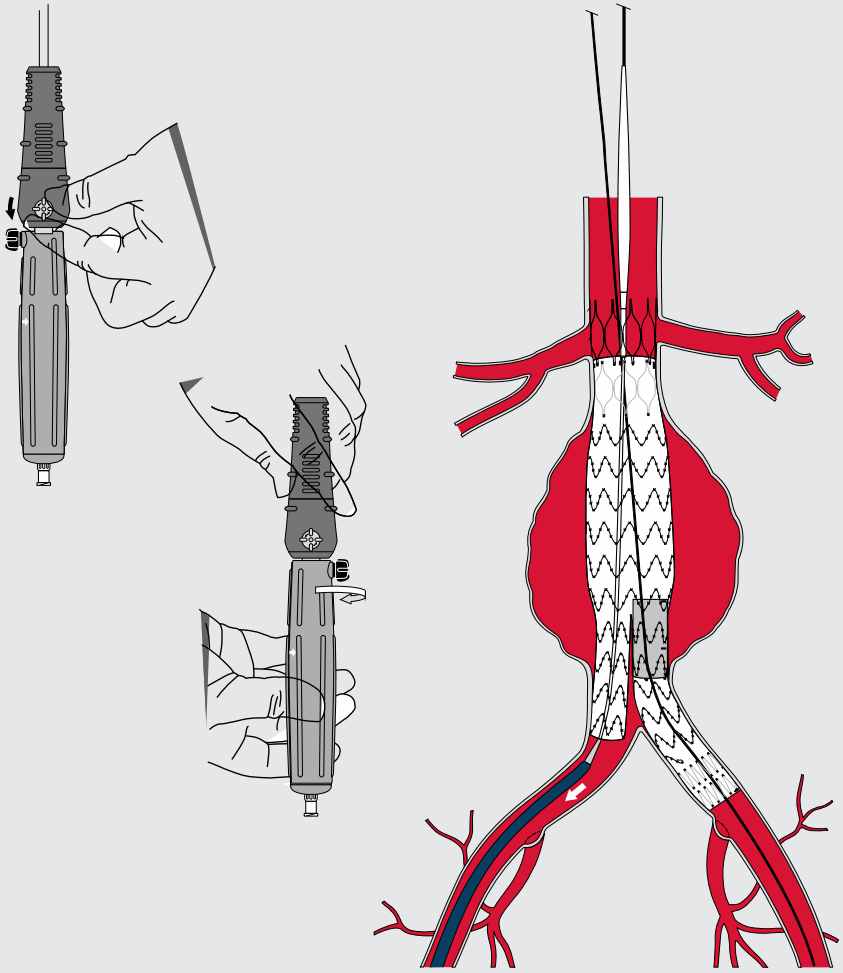
Main body distal deployment

Step 9

- Fully deploy the ipsilateral limb of the main body by withdrawing the sheath until the most distal stent has expanded. Stop withdrawing the sheath.

  Note: The distal stent is still secured to the delivery system.

- While holding the black gripper, turn the gray safety lock knob counterclockwise to engage the blue rotation handle.
- To release the wire securing the ipsilateral limb to the delivery system, turn the blue rotation handle in the direction of the arrow (clockwise) until a stop is felt.



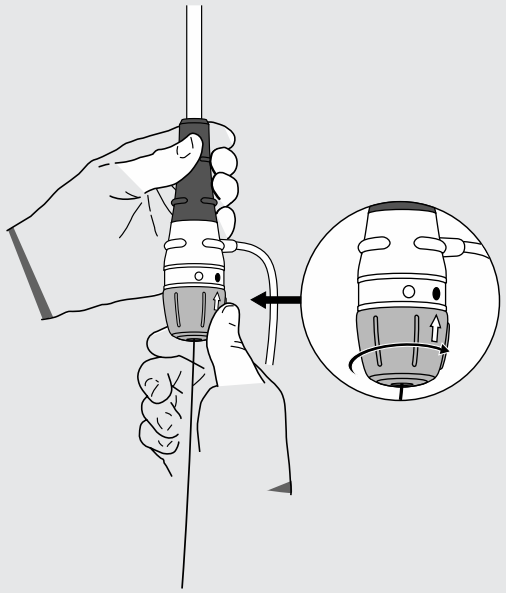
Main body distal deployment

Step 10

- Withdraw the entire inner subassembly through the sheath.

  Note: Maintain the positions of the sheath and wire guide.

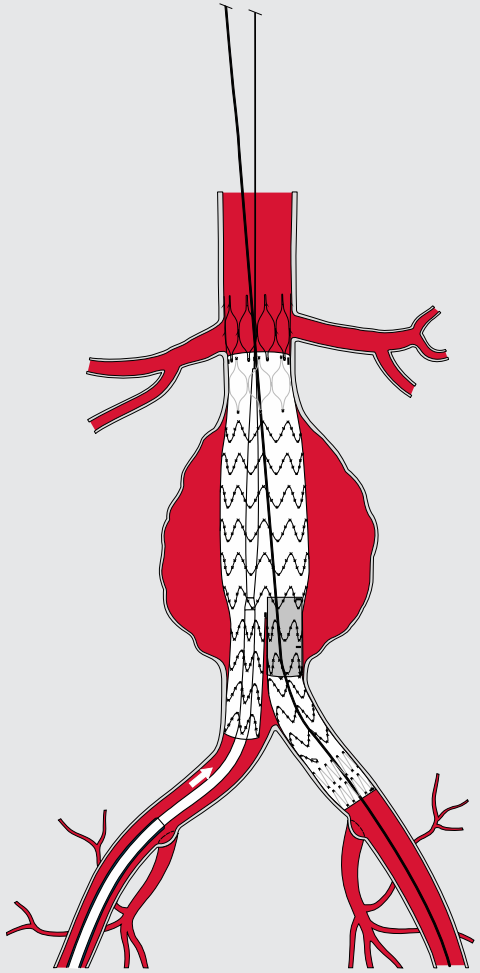
- Close the Captor Hemostatic Valve.



Ipsilateral leg deployment

Step 11

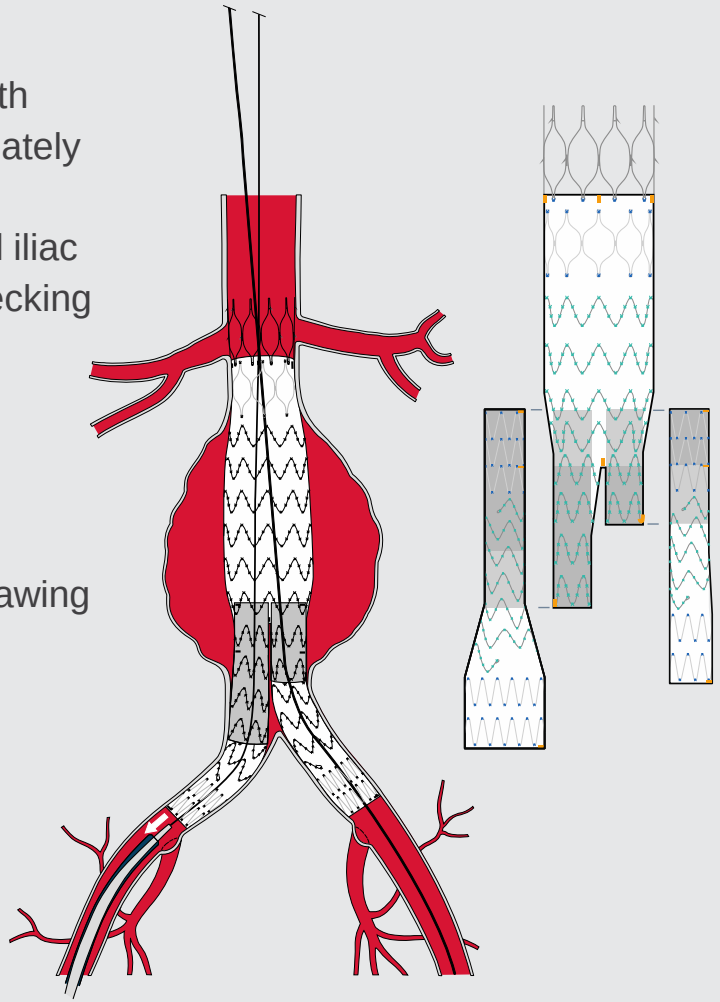
- Prior to introducing the ipsilateral iliac leg delivery system, inject contrast through the main body femoral sheath to locate the ipsilateral iliac artery.
- Use the main body graft wire and the sheath assembly to introduce the ipsilateral iliac leg graft.
- Continue advancing the delivery system slowly until the proximal edge of the ipsilateral iliac leg graft aligns with the proximal edge of the previously placed contralateral leg graft.
- Confirm the position of the distal end of the ipsilateral iliac leg graft. Reposition the ipsilateral iliac leg graft, if necessary, to ensure internal iliac patency.



Ipsilateral leg deployment

Step 12

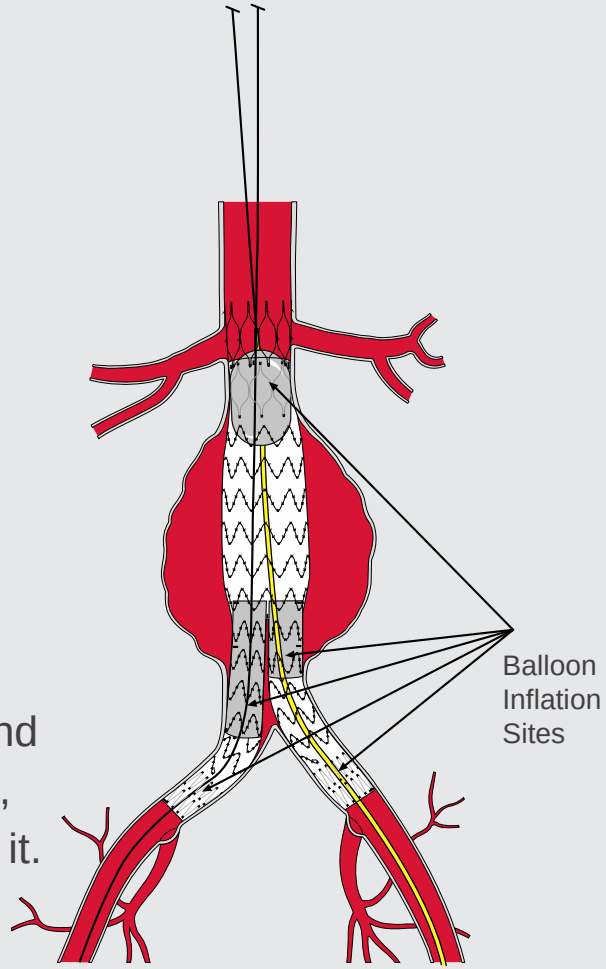
- To deploy the ipsilateral iliac leg graft, hold it in position with the gray positioner while withdrawing the sheath approximately 10 mm. Check the ipsilateral iliac leg graft's position and reposition it if necessary. Continue to deploy the ipsilateral iliac leg graft by withdrawing the sheath while continuously checking the position of the ipsilateral iliac leg graft.
- Under fluoroscopy and after you verify the ipsilateral iliac leg graft position, loosen the pin vise, and retract the inner cannula to dock the tapered dilator to the gray positioner.
- Tighten the pin vise. Maintain sheath position while withdrawing the gray positioner with the secured inner cannula.
- Close the Captor® Hemostatic Valve on the ipsilateral iliac leg introducer sheath by turning it in a clockwise direction until it stops.



Molding balloon instructions

Step 13

- Prepare the molding balloon.
- Advance the molding balloon over the wire guide.
- Expand the molding balloon with diluted contrast medium in the area of the infrarenal neck.
- Deflate the molding balloon. Reposition it at the contralateral limb overlap region and inflate it. Deflate the molding balloon, reposition it at the contralateral distal fixation site, and inflate it.
- Deflate the molding balloon and remove it.
- Advance the molding balloon into the ipsilateral iliac leg and inflate it at the overlap region. Deflate the molding balloon, reposition it at the ipsilateral distal fixation site, and inflate it.
- Deflate the molding balloon and remove it.



Final angiogram

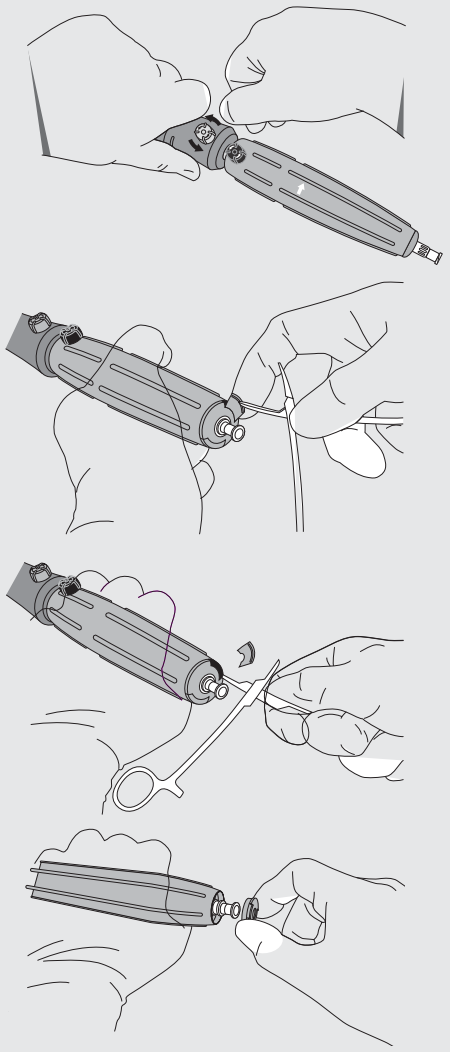
Step 14

- Position an angiographic catheter just above the level of the renal arteries. Perform angiography to verify that the renal arteries are patent and that there are no endoleaks. Verify the patency of the internal iliac arteries.
- Confirm that there are no endoleaks or kinks and verify the position of the proximal gold radiopaque markers. Remove the sheaths, wire guides, and catheters.

Main body troubleshooting

Note: Technical assistance from a Cook product specialist may be obtained by contacting your local Cook representative.

- In case of difficulty releasing the proximal bare stent and rotating the blue rotation handle, completely unsheathe the ipsilateral limb, then unlock the gray safety lock knob and secure it in the unlocked position. Continue rotating the blue rotation handle until it stops rotating (approximately two full turns), which should release the proximal bare stent and the distal ipsilateral limb. Complete the procedure. If this still does not alleviate difficulty, proceed with the main body release troubleshooting steps below to disassemble the rotation handle.
- Place surgical forceps into the slots on the backend clips and slide both clips out.
- Remove the backend cap from the blue rotation handle.

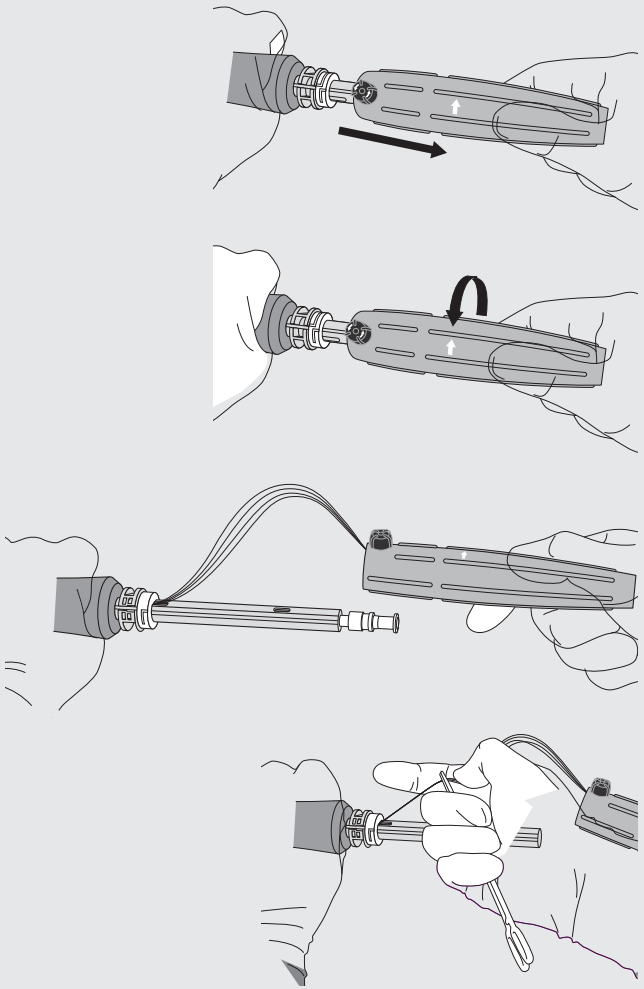


Main body troubleshooting

- While holding the black gripper, remove the blue rotation handle by sliding it straight back. If you pull the handle back and it stops, ensure that the gray safety lock knob is unlocked and secured in the unlock position (180 degree rotation) then continue to pull the handle straight back. If the handle will still not pull back, rotate it in the opposite direction of the arrows (counterclockwise) until the handle is removed.

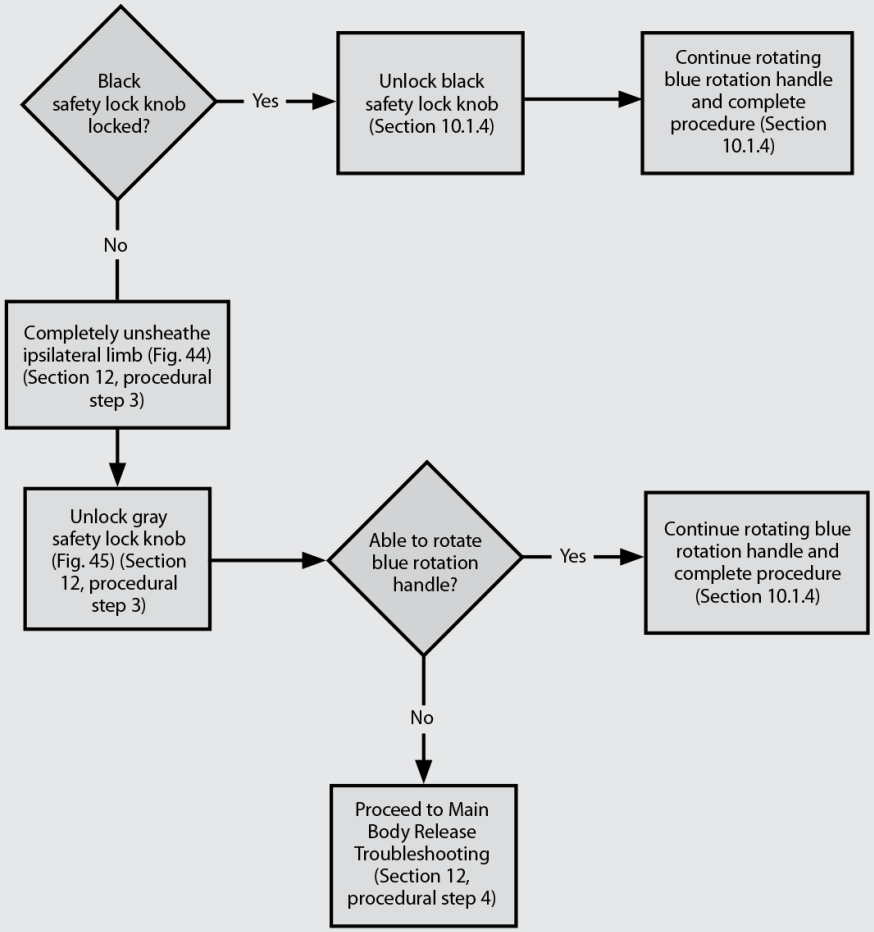
  Note: Tension will be felt during the removal of the blue rotation handle.

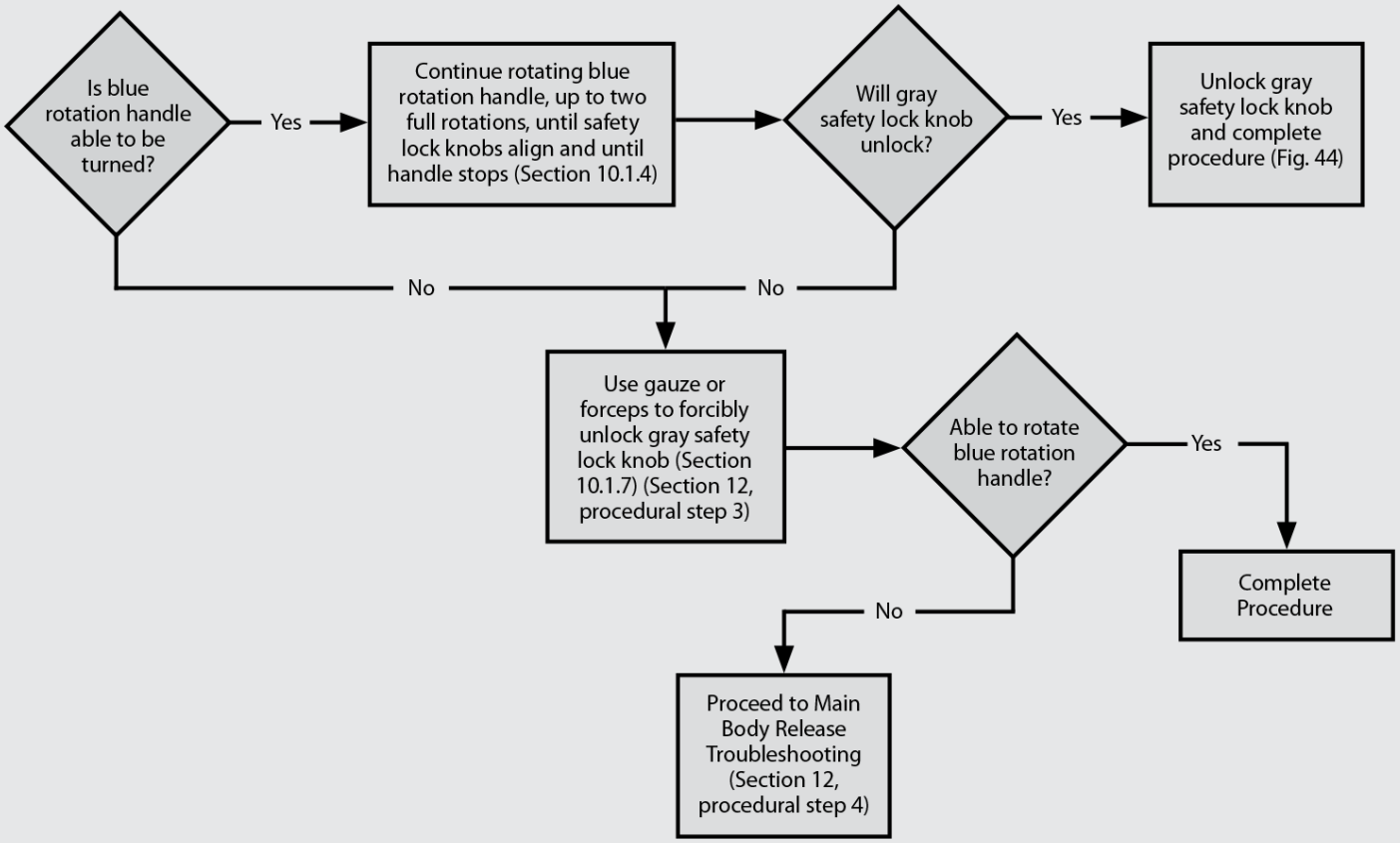
- Using forceps, grasp all the wires and withdraw them until the graft is released.



Main body troubleshooting flow chart

Flow chart 1: *Bare stent is not released and rotation handle cannot rotate.*



Main body troubleshooting flow chart

Flow chart 2: *Proximal bare stent is released and gray safety lock knob will not unlock.*