

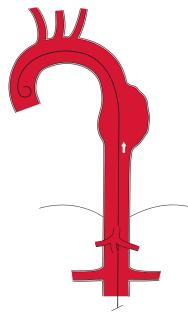
DEPLOYMENT OVERVIEW*

Pro-Form®

GENERAL CAUTIONS

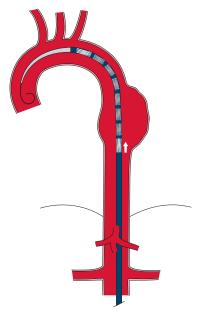
- Exercise extreme caution when manipulating interventional and angiographic devices in the region of the barbs.
- Do not advance the wire guide or delivery system if resistance is felt.
 Exercise particular care in areas of stenosis, thrombus, calcification or tortuosity.
- Unless medically indicated, do not cover arch or mesenteric arteries with the graft. If the left subclavian artery is to be covered, the clinician must be aware of the risk for compromised perfusion of cerebral, upper-limb and collateral spinal arteries.
- Use caution during manipulation of catheters, wires and sheaths within the aneurysm, as thrombus dislodgment and embolization may occur.
- Do not attempt to resheathe the graft after partial or complete deployment.
- Avoid damaging the graft or disturbing graft positioning if reinstrumentation is necessary.
- Anatomy and graft position can change with sheath removal; constantly monitor graft position, using angiography as necessary.





Through the radiopaque banded pigtail flush catheter, replace the standard wire guide with a .035 inch 260/300 cm Lunderquist Extra-Stiff DC Wire Guide. Advance the wire guide up to the level of the aortic arch and remove the pigtail flush catheter.





Introduce the delivery system for the proximal component over the Lunderquist Extra-Stiff DC Wire Guide and advance until the desired graft position is reached.

CAUTION: To avoid twisting the graft, never rotate the delivery system. Do not advance the sheath while the graft is still inside; doing so may cause the barbs to perforate the sheath.

^{*}This Deployment Overview is an outline highlighting the deployment process for the Zenith TX2 TAA Endovascular Graft with Pro-Form. The *Instructions for Use* booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings and precautions.

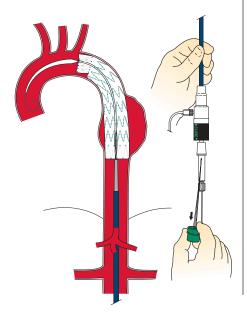
3 UNSHEATHE PROXIMAL COMPONENT



While constantly monitoring graft position, withdraw the sheath until the graft is fully expanded. Continue sheath withdrawal until the valve assembly docks with the control handle.

CAUTION: Barbs are now exposed; limited forward advancement is possible, but retracting the device may damage the aorta.

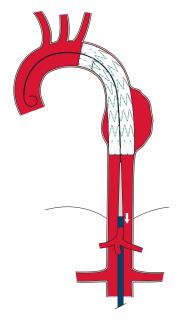




Unscrew and remove the safety lock from the green trigger-wire release mechanism. Withdraw the trigger wire slowly until the proximal end of the graft opens. Withdraw the trigger wire completely to release the distal attachment to the introducer. Make sure that all trigger wires are removed prior to withdrawal of the delivery system.

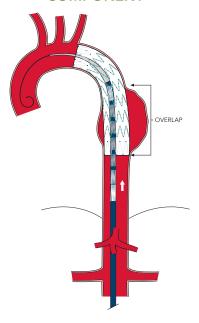
This step is enhanced with the new Pro-Form feature. The graft has an improved ability to achieve proximal neck wall apposition.

5 REMOVE INTRODUCER SHEATH FOR PROXIMAL COMPONENT



Remove the delivery system entirely, leaving the wire guide positioned in the graft.

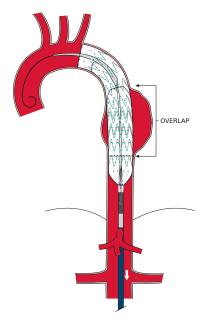
6 POSITION DISTAL COMPONENT



Introduce the delivery system for the distal component over the Lunderquist Extra-Stiff DC Wire Guide and advance until the desired position inside of the proximal component is reached. Advance the delivery system of the distal component until the collapsed stent graft inside is in its intended location, with a recommended 3-4 stent overlap (75-100 mm) with the proximal component.

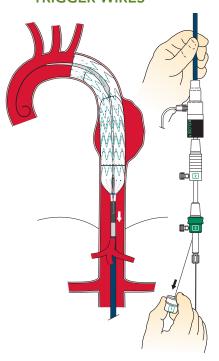
NOTE: The stainless steel stent bodies are easily visualized under fluoroscopy.

7 UNSHEATHE DISTAL COMPONENT



While constantly monitoring graft position, withdraw the sheath until the graft is fully expanded. Continue sheath withdrawal until the valve assembly docks with the control handle.

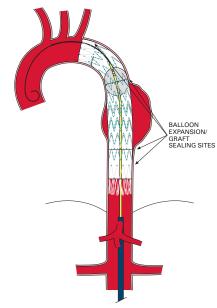
8 RELEASE DISTAL COMPONENT TRIGGER WIRES



Using the 1-2-3 deployment sequence:

- Unscrew and remove the triggerwire safety lock, then withdraw and remove the white trigger-wire release mechanism labeled #1.
- Unscrew and remove the safety lock on the telescoping handle labeled #2. Stabilize the delivery system and slide the telescoping handle together with the gray tube and outer sheath in a distal direction until it locks into position with a click.
- Unscrew and remove the safety lock from the green trigger-wire release mechanism labeled #3. Withdraw the release wires slowly until the proximal end of the graft opens, continuing withdrawal until the graft is fully opened and released.

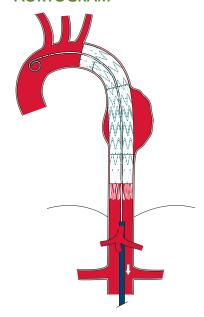
9 OPTIONAL: MOLDING BALLOON



Position molding balloon and, using diluted contrast media (as directed by manufacturer), expand it in areas of the proximal covered stent, proximal component/distal component overlap, and distal fixation site, starting proximally and working in a distal direction. Confirm complete deflation of balloon prior to repositioning.

WARNING: Do not inflate the balloon in aorta outside confines of the graft.

10 PERFORM FINAL FLUSH AORTOGRAM



Position angiographic pigtail flush catheter just above the level of the deployed endovascular graft and perform angiography to verify:

- · Correct graft position
- Patency of arch vessels and celiac plexus
- There are no endoleaks or kinks
- Position of proximal and distal gold radiopaque markers

Withdraw introducer sheath for distal component, catheters and wires. Repair vessels and close in standard surgical fashion.

WARNING: To avoid entangling any in situ catheters, rotate the delivery system during withdrawal.

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