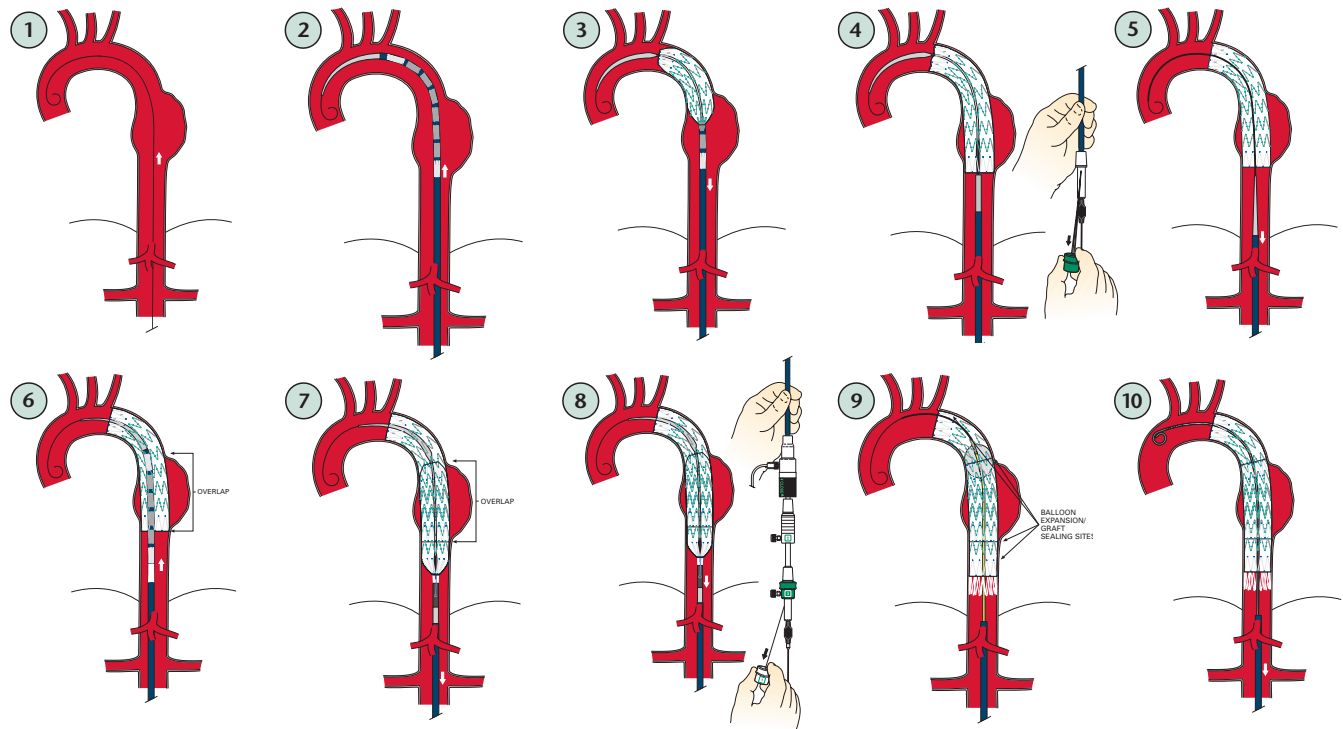


# Zenith TX2®

TAA ENDOVASCULAR GRAFT

## DEPLOYMENT OVERVIEW\*



### 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.
- With the exception of the left subclavian, do not cover arch or mesenteric arteries with the graft. If covering the subclavian, be aware of possible compromise to cerebral and upper limb perfusion.
- Use caution during manipulation of catheters, wires, and sheaths within the aneurysm, as thrombus dislodgement and embolization may occur.
- Do not attempt to re-sheath 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.

### 1 POSITION LUNDERQUIST™ EXTRA-STIFF WIRE GUIDE IN AORTIC ARCH

Through the radiopaque banded pigtail flush catheter, replace the standard wire guide with a stiff (235 inch/260 cm) Lunderquist wire guide. Advance the wire guide up to the level of the aortic arch and remove the pigtail flush catheter.

### 2 POSITION PROXIMAL COMPONENT

Introduce the delivery system for the Proximal Component over the Lunderquist Extra-Stiff 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 within; doing so may cause the barbs to perforate the sheath.

### 3 UNSHEATH THE 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 rotating the device may damage the aorta.

### 4 RELEASE PROXIMAL COMPONENT TRIGGER WIRES

Uncrew 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.

### 5 REMOVE INTRODUCER SHEATH FOR PROXIMAL COMPONENT

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

### 6 POSITION DISTAL COMPONENT

Introduce the delivery system for the Distal Component over the Lunderquist Extra-Stiff 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 made in its intended location, with a recommended 2.4-inch overlap (75-100 mm) with the Proximal Component.

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

### 7 UNSHEATH THE 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:

- Uncrew and remove the trigger-wire safety lock, then withdraw and remove the white trigger-wire release mechanism labeled #1.
- Uncrew and remove the safety lock on the telescoping handle labeled #2. Stabilize the delivery system and slide the telescoping handle together with the grip tube and outer sheath in a distal direction until it locks into position with a click.
- Uncrew and remove the safety lock from the green trigger-wire release mechanism labeled #3. Withdraw the release wire 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, utilizing diluted contrast media (as directed by manufacturer), separate 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 areas 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 vessel planes
- there are no intubations or leaks
- 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 impaling any in situ catheters, rotate the delivery system during withdrawal.**

\*This Deployment Overview is an outline highlighting the deployment process for the Zenith TX2 TAA 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.

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