Zenith Flex®

AAA Endovascular Graft

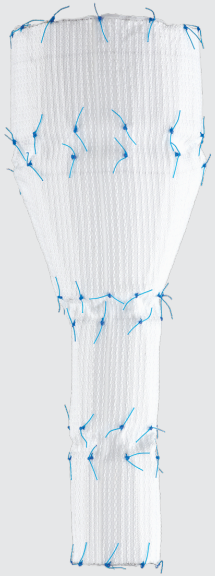
Ancillary components with Z-Trak® Introduction System

COOK® MEDICAL

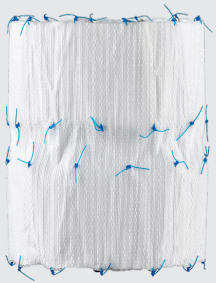
Zenith Flex® AAA Endovascular Graft

Ancillary Components

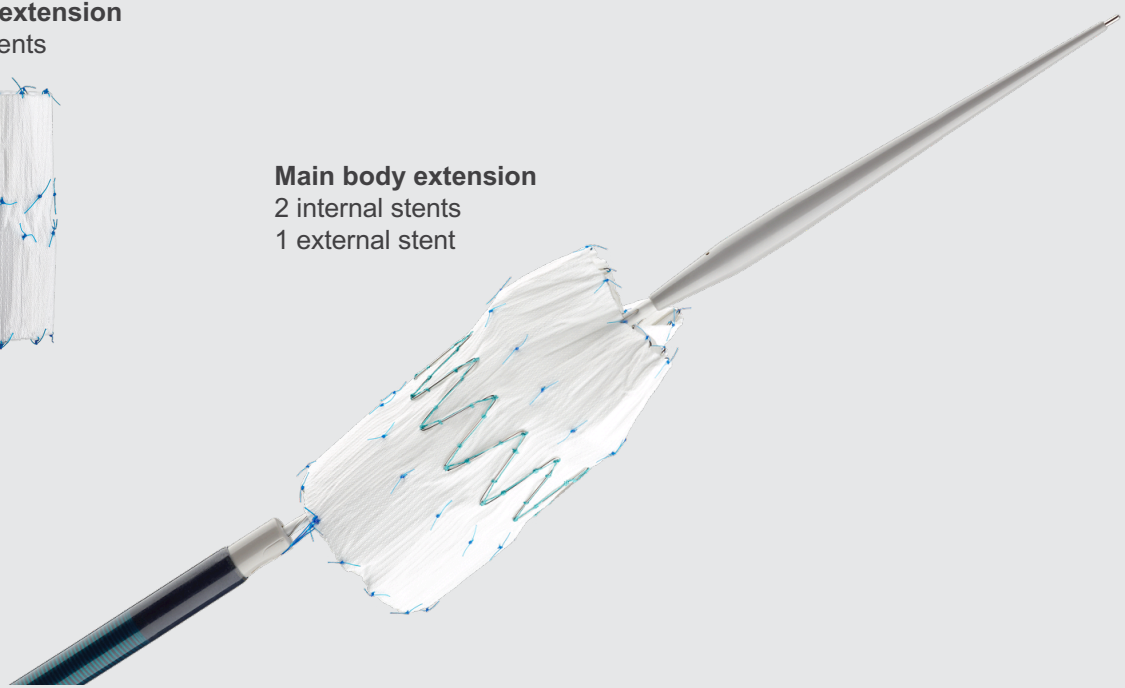
Converter



Main body extension
2 internal stents

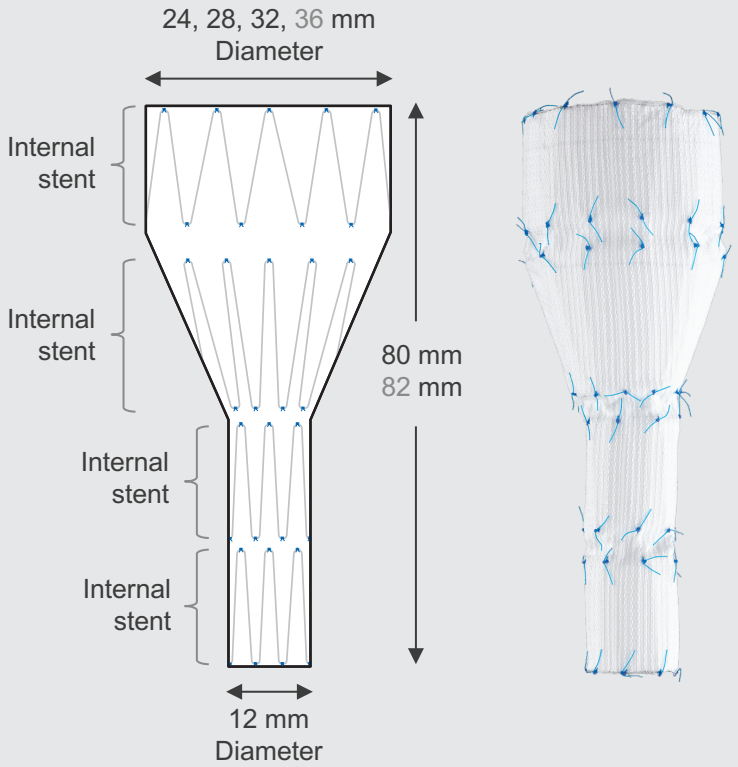


Main body extension
2 internal stents
1 external stent



Zenith Flex® AAA Endovascular Graft – Converter

- Converters can be used to turn a bifurcated graft into an aortouniiliac graft if necessary (e.g., cases of type III endoleak, limb occlusion or unattainable contralateral limb cannulation)
- The converter includes four internal z-stents
- Proximal diameters are 24, 28, 32 or 36 mm
- Distal diameter of all converters is 12 mm
- The length of the 24, 28 and 32 mm diameter converters is 80 mm
- The length of the 36 mm diameter converter is 82 mm
- The length of the sheath is 40 cm
- A converter, if used, should have a proximal diameter no smaller than that of the main body

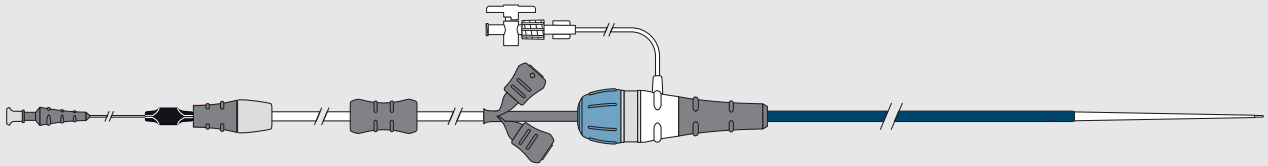


Zenith Flex® AAA Endovascular Graft – Converter

- Place the converter so that the proximal two sealing stents are positioned in the main body and the distal two stents are in the ipsilateral leg
- Converter introducer sheaths are inserted over the wire and cannot be introduced through the sheath of a main body or an iliac leg

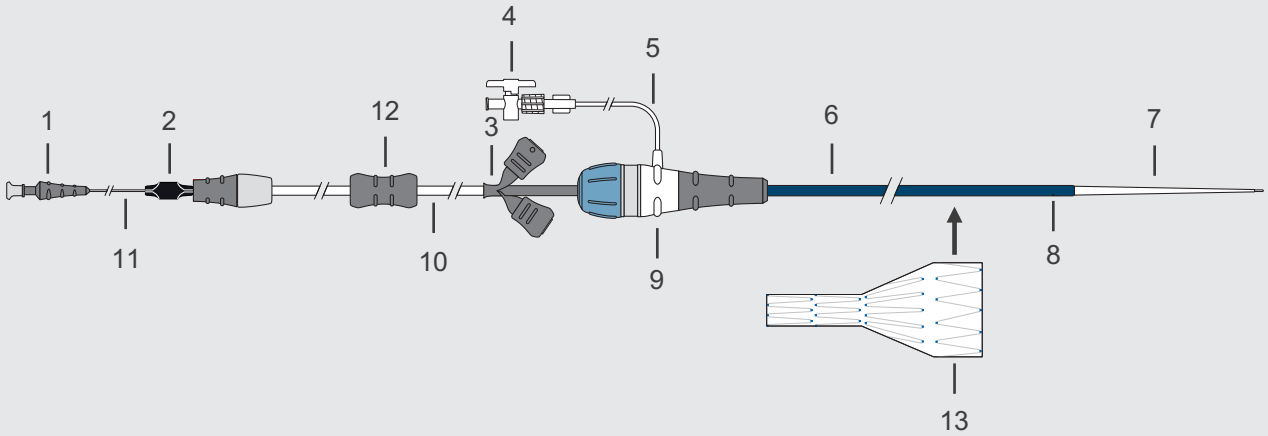
Z-Trak® Introduction System for Converters

24 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD
28-36 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Zenith Flex® AAA Endovascular Graft – Converter

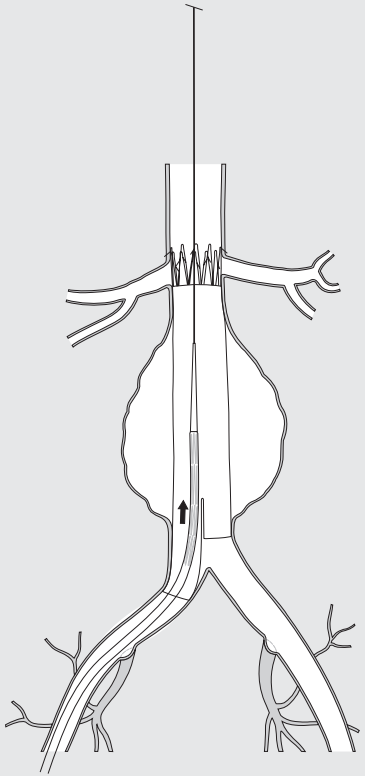
1. Hub
2. Pin vise
3. Peel-Away® Sheath
4. Stopcock
5. Connecting tube
6. Flexor® Introducer Sheath
7. Dilator tip
8. Sheath sideport
9. Captor® Hemostatic Valve
10. Gray positioner
11. Inner cannula
12. Gripper
13. Converter



Zenith Flex® AAA Endovascular Graft – Converter Deployment

Step 1

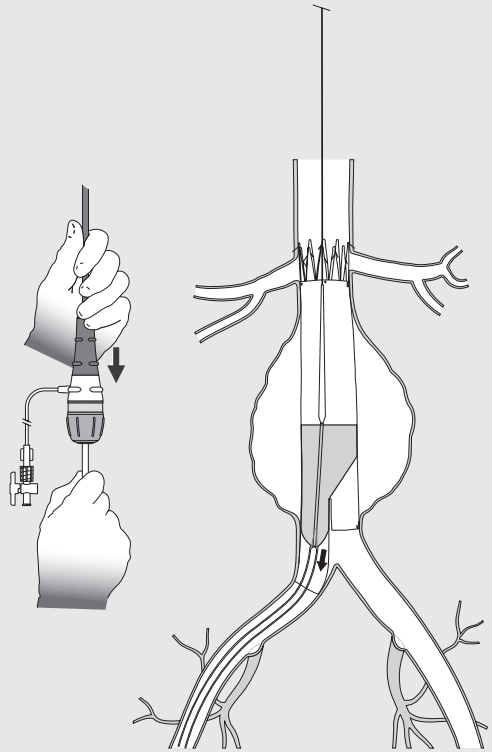
Verify appropriate position to ensure proper sealing (proximal two stents in main body, distal two stents in ipsilateral iliac limb)



Zenith Flex® AAA Endovascular Graft – Converter Deployment

Step 2

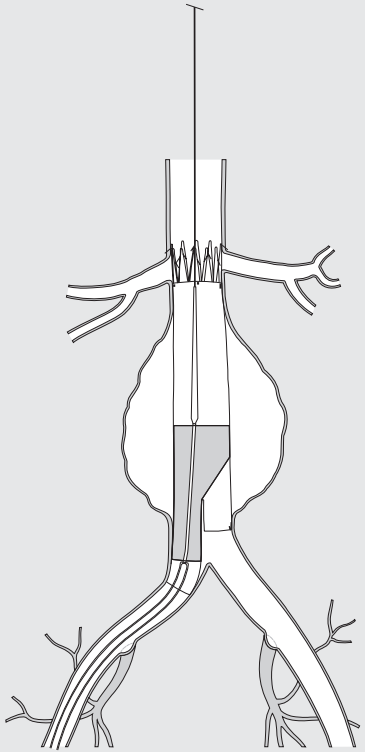
Use gripper to stabilize gray positioner and retract sheath to deploy converter



Zenith Flex® AAA Endovascular Graft – Converter Deployment

Step 3

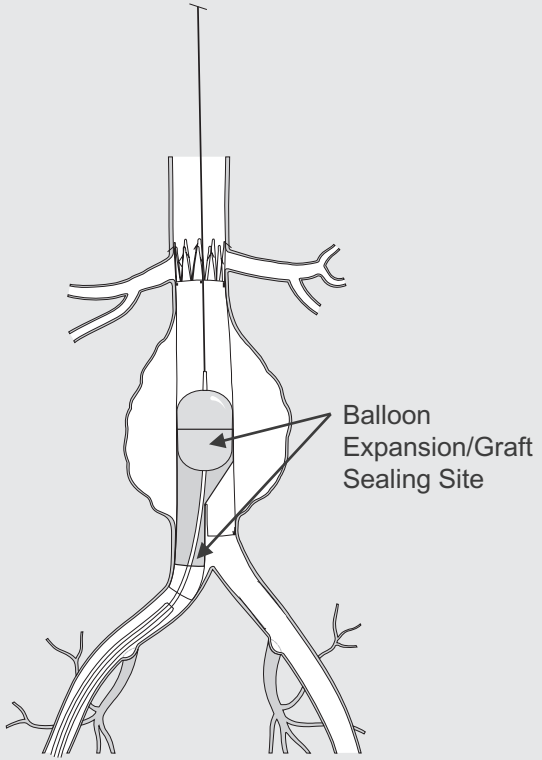
- Deploy until distal stent is uncovered
- Retract inner cannula, withdraw tapered tip of introducer through the sheath and remove gray positioner
- Close captor valve



Zenith Flex® AAA Endovascular Graft – Converter Deployment

Step 4

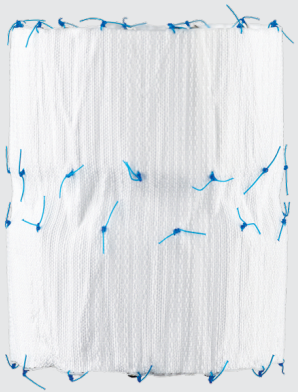
- Balloon mold the converter within the proximal segment and then the distal segment
- Perform final angiography

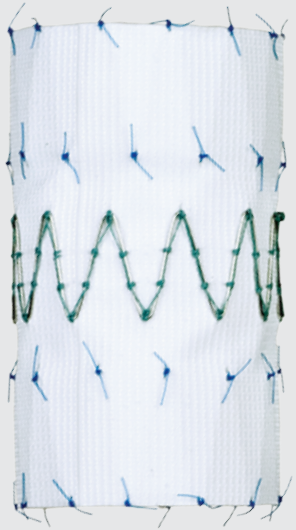


Main Body Extension (ESBE)

Used to extend the proximal body of an in situ graft. Issues causing its necessity include:

- Improper placement of the main body
- Tortuosity of the aortic neck
- Inaccurate selection of the diameter of the main body

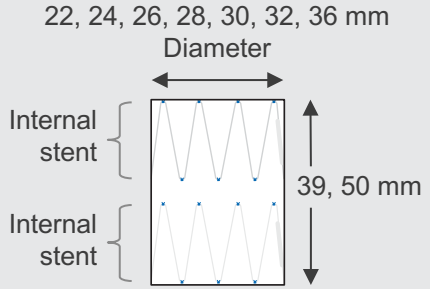


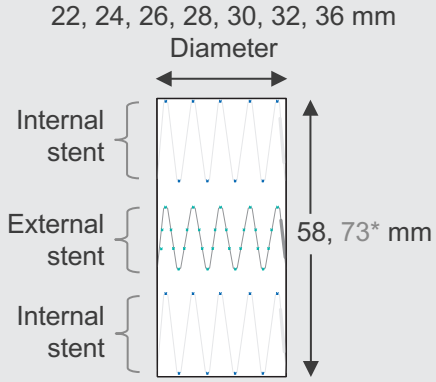


Main Body Extension (ESBE)

- Main body extensions include two or three z-stents
- Diameters include 22, 24, 26, 28, 30, 32 or 36 mm
- Main body extensions are 39, 50, 58 or 73* mm long
- The sheath length is 40 cm
- A main body extension, if used, should have a diameter no smaller than that of the main body
- In selecting the diameter of a main body extension, consider:
  - Neck shape
  - Neck angulation
  - Diameter of existing main body

*Lengths for 36 mm diameter only.



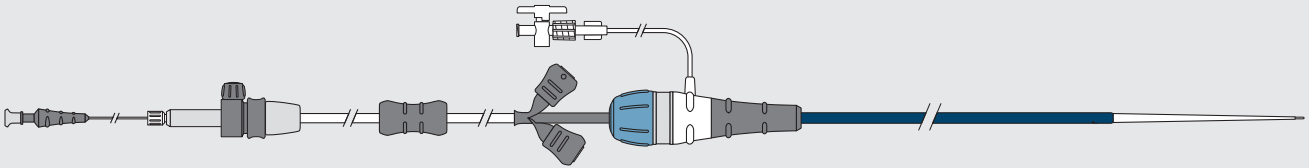


Main Body Extension (ESBE)

- The Z-Trak® Introduction System for the main body extension has a single trigger-wire release mechanism
- Do not release and remove the trigger wire until the main body extension has been deployed from the sheath
- Main body extension introduction systems are inserted over a wire and cannot be introduced through the sheath of a main body or an iliac leg

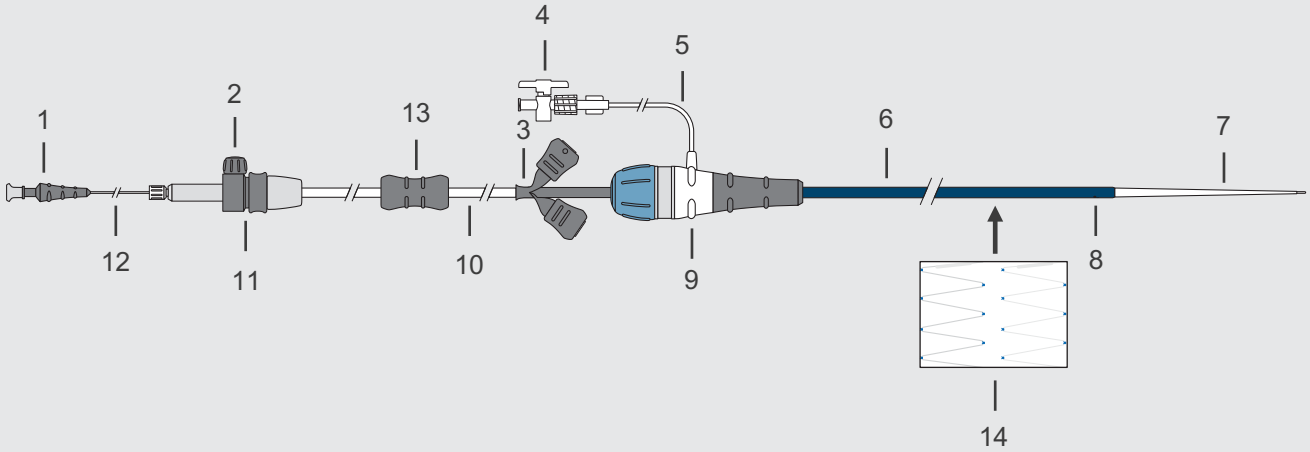
Z-Trak Introduction System for Main Body Extensions

22-26 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD
28-36 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Main Body Extension (ESBE)

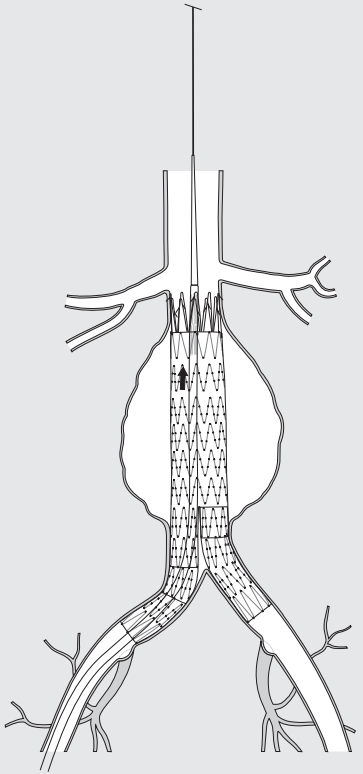
1. Hub
2. Safety lock
3. Peel-Away Sheath
4. Stopcock
5. Connecting tube
6. Flexor Introducer Sheath
7. Dilator tip
8. Sheath sideport
9. Captor Hemostatic Valve
10. Gray positioner
11. Trigger-wire release mechanism
12. Inner cannula
13. Gripper
14. Main body extension



Main Body Extension (ESBE) – Deployment

Step 1

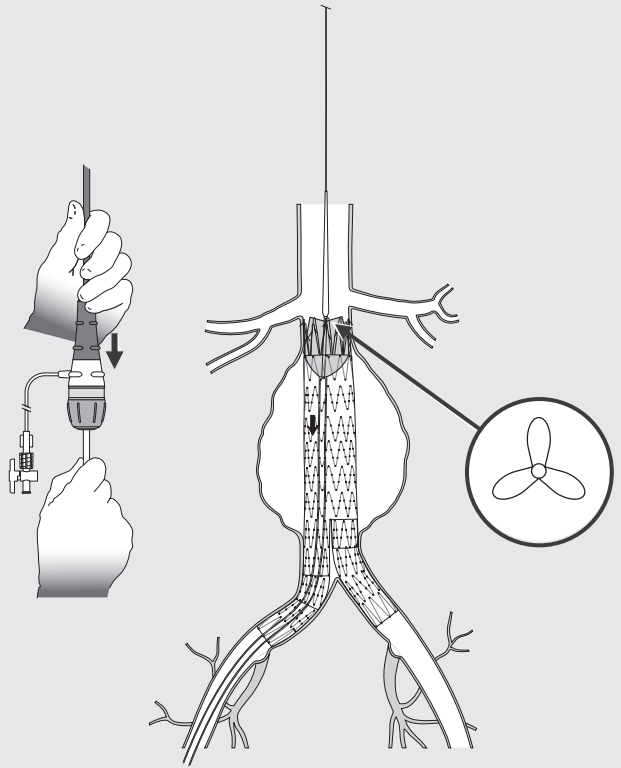
- Verify position to ensure proper sealing and resistance to migration
- Verify position with angiography to ensure renal arteries remain patent



Main Body Extension (ESBE) – Deployment

Step 2

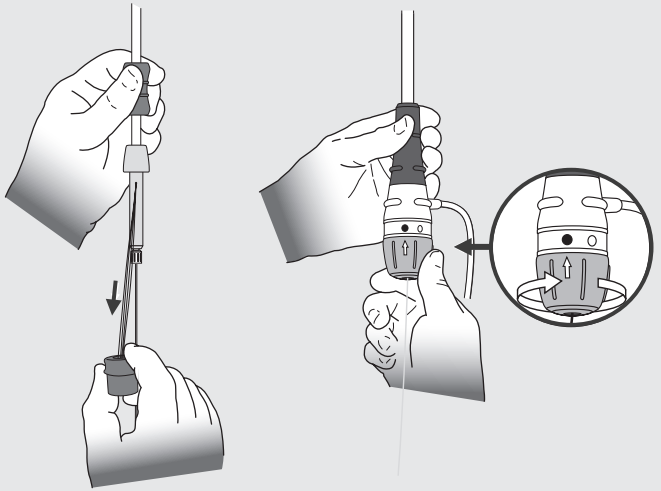
- Use gripper to stabilize gray positioner and retract sheath to deploy main body extension
- Deploy device until the most distal stent is uncovered



Main Body Extension (ESBE) – Deployment

Step 3

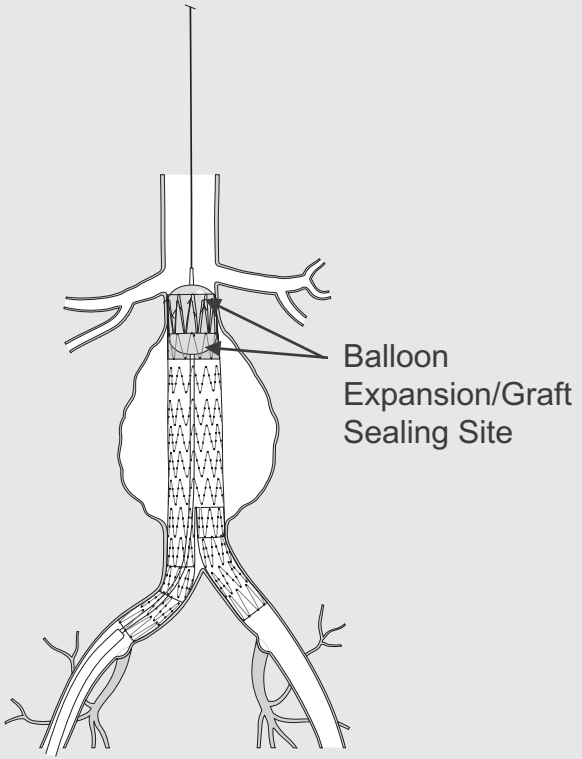
- Remove the safety lock from the trigger-wire release mechanism
- Withdraw and remove the trigger-wire release mechanism
- Retract inner cannula, withdraw tapered tip of introducer through the sheath and remove gray positioner
- Close the Captor Hemostatic Valve



Main Body Extension (ESBE) – Deployment

Step 4

- Balloon mold the main body extension within the proximal segment and then the distal segment
- Perform final angiography



Instructions for Use

Consult the Instructions for Use for a more thorough examination of the deployment protocol, MRI safety, indications for use, contraindications, warnings, and precautions.