Patient selection

View the Instructions for Use for a thorough examination of the procedural instructions, intended use, contraindications, warnings and precautions and potential adverse events.
Intended use

The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:

• Iliac/femoral anatomy that is suitable for access with the required introduction systems
  – Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer:
    • with a length of at least 20 mm, and
    • with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm
Anatomical inclusion criteria

- A proximal neck at least 20 mm long between the left common carotid artery and the thoracic lesion (aneurysm or blunt thoracic aortic injury).
  - Covering the left subclavian is acceptable except in patients with an anomalous vertebral off of the arch in the region of the subclavian or dominant vertebral off of the subclavian.
- A distal neck at least 20 mm long between the celiac artery and the aneurysm.
Anatomical inclusion criteria

• A proximal neck with a diameter between 20 mm and 42 mm measured outer wall to outer wall on a sectional image or multiplanar reconstruction (CT).

• A distal neck with a diameter between 20 mm and 42 mm measured outer wall to outer wall on a sectional image or multiplanar reconstruction (CT).

  - Estimate from a more proximal segment if the diaphragm makes identification of the outer wall difficult.
Anatomical inclusion criteria

• Adequate iliac (femoral) access compatible with the placement of the introducer sheath:
  - 16 Fr (6.0 mm OD) for 24-30 mm diameter grafts
  - 18 Fr (7.1 mm OD) for 32-38 mm diameter grafts
  - 20 Fr (7.7 mm OD) for 40-46 mm diameter grafts

• Conduits are permitted.
Anatomical exclusion criteria

- Prohibitive calcification, occlusive disease or tortuosity of intended access vessels, or intended fixation sites.
- Circumferential thrombus in the region of the intended fixation sites.
- Aneurysm or angulation in the distal thoracic aorta that would preclude advancement of the introduction system.
- Inability to preserve the left common carotid artery and the celiac artery.
Anatomical exclusion criteria

- An inverted funnel shape at the proximal fixation site or a funnel shape at the distal fixation site
- More than a 10% increase in diameter over the 20 mm intended fixation site
Anatomical exclusion criteria

- An aortic arch with a radius of less than 20 mm if the device was deployed in the arch
Anatomical inclusion criteria

- Proximal neck diameter: 20-42 mm
- Proximal neck length: ≥ 20 mm
- Distal neck diameter: 20-42 mm
- Distal neck length: ≥ 20 mm