Patient Selection

Zenith Alpha™

THORACIC ENDOVASCULAR GRAFT

COOK® MEDICAL

cookmedical.eu/aortic-intervention/

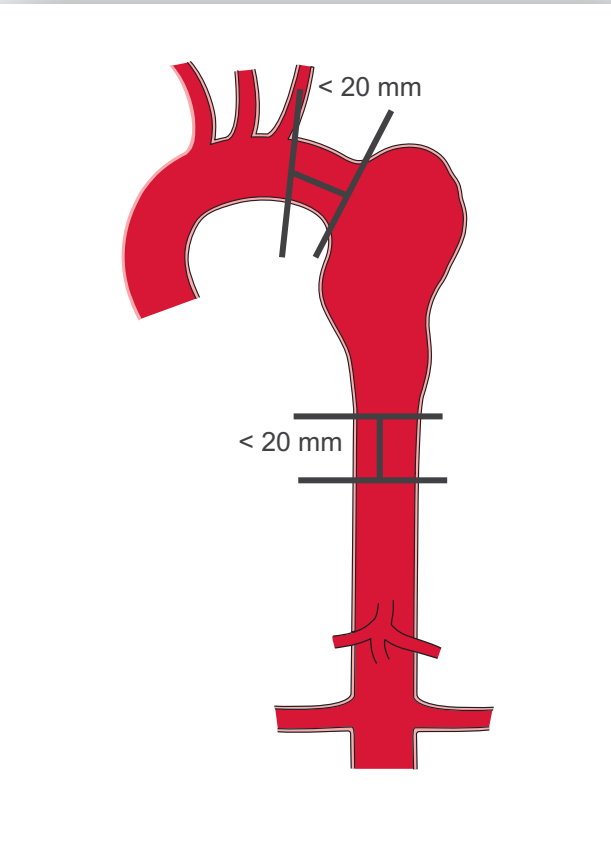
Intended use

The Zenith® Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients who have aneurysms or ulcers of the descending thoracic aorta that have vascular morphology suitable for endovascular repair.

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

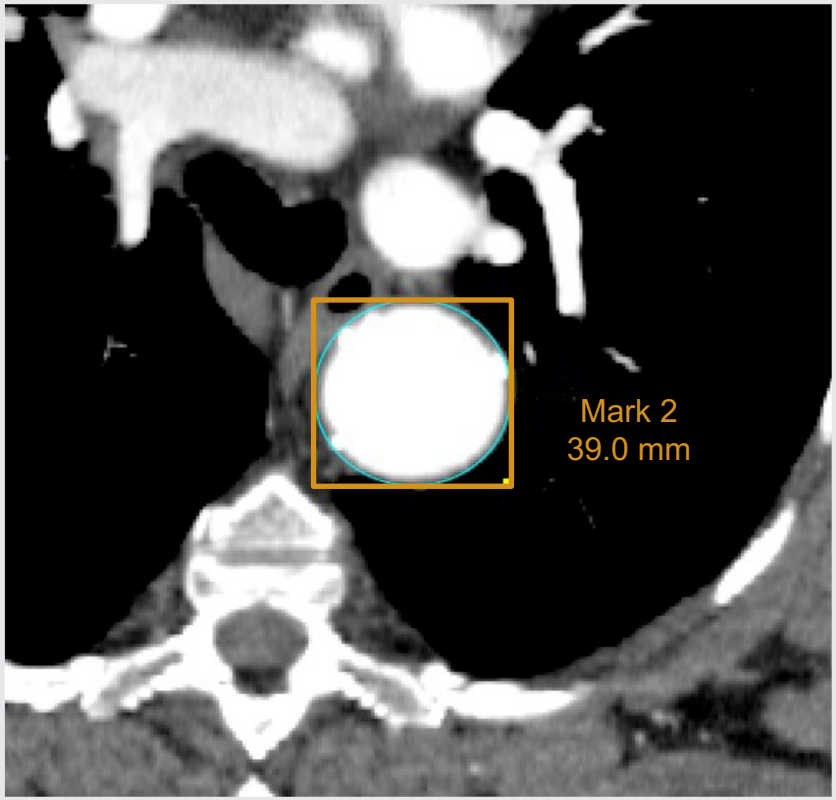
Anatomical inclusion criteria

- A proximal neck length ≥ 20 mm between the left common carotid artery and the aneurysm
  - Covering the left subclavian is acceptable, except in patients with anomalous vertebral off of the arch in the region of the subclavian or dominant vertebral off of the subclavian
- A distal neck length ≥ 20 mm between the celiac artery and the aneurysm



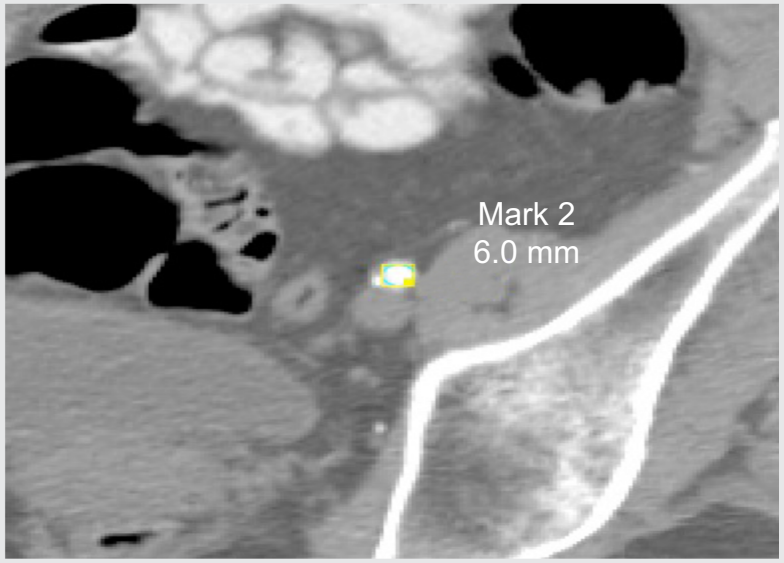
Anatomical inclusion criteria

- A proximal neck diameter ≥ 20 mm or ≤ 42 mm measured outer wall to outer wall on a sectional image or multiplanar reconstruction (CT)
- A distal neck diameter ≥ 20 mm or ≤ 42 mm measured outer wall to outer wall on a sectional image or multiplanar reconstruction (CT)
  - Estimate from a more proximal segment if diaphragm makes identification of the outer wall difficult



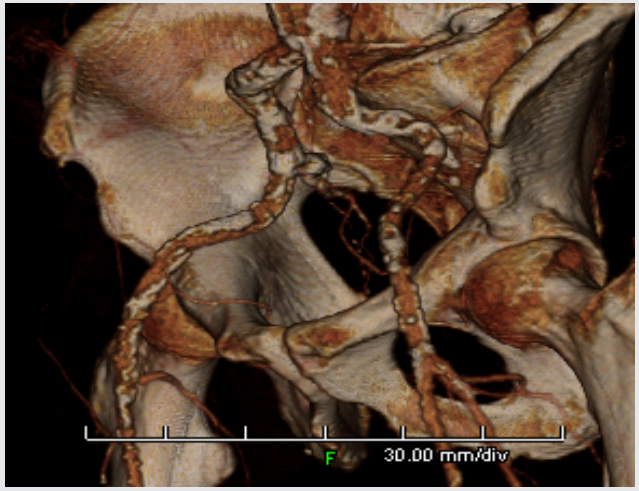
Anatomical inclusion criteria

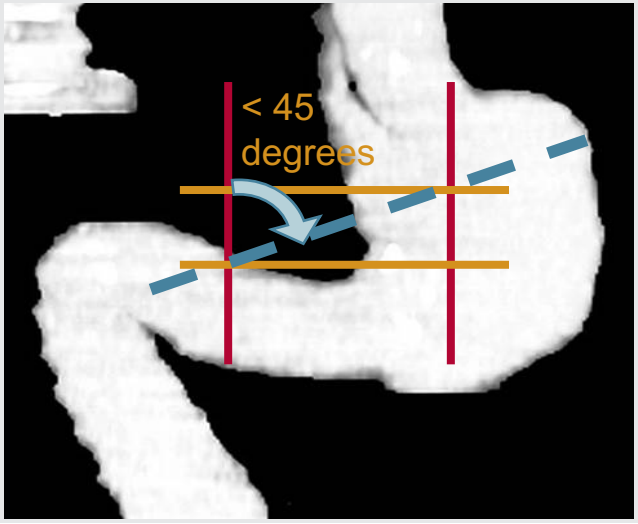
- Adequate iliac (femoral) access compatible with the placement of the introducer sheath:
  - 16 Fr (6.0 mm OD) for 24-30 mm diameter grafts
  - 18 Fr (7.1 mm OD) for 32-38 mm diameter grafts
  - 20 Fr (7.7 mm OD) for 40-46 mm diameter grafts
- Conduits are permitted.



Anatomical exclusion criteria

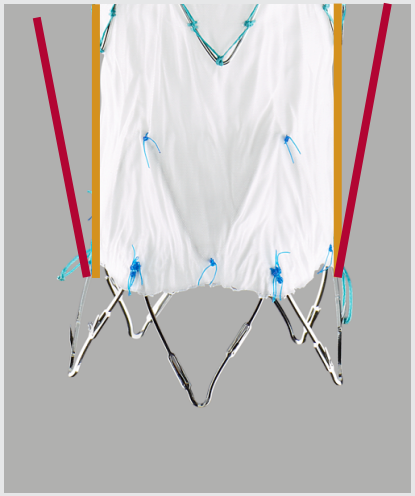
- Prohibitive calcification, occlusive disease or tortuosity of intended access vessels or intended fixation sites
- Circumferential thrombus in the region of the intended fixation sites
- Aneurysm or angulation in the distal thoracic aorta that would preclude advancement of the introduction system
-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





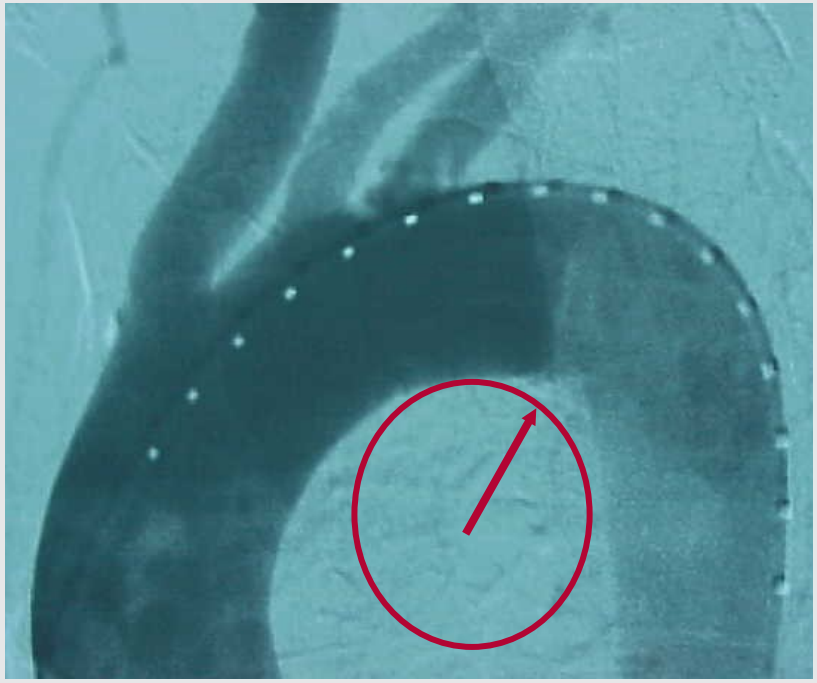
Anatomical exclusion criteria

- An inverted funnel shape at the proximal fixation site or a funnel shape at the distal fixation site
- > 10% increase in diameter over the 20 mm intended fixation site



Anatomical exclusion criteria

- An aortic arch radius ≤ 20 mm if the device was deployed in the arch



Anatomical inclusion criteria