Patient selection

Zenith Alpha™
THORACIC ENDOVASCULAR GRAFT

COOK® MEDICAL

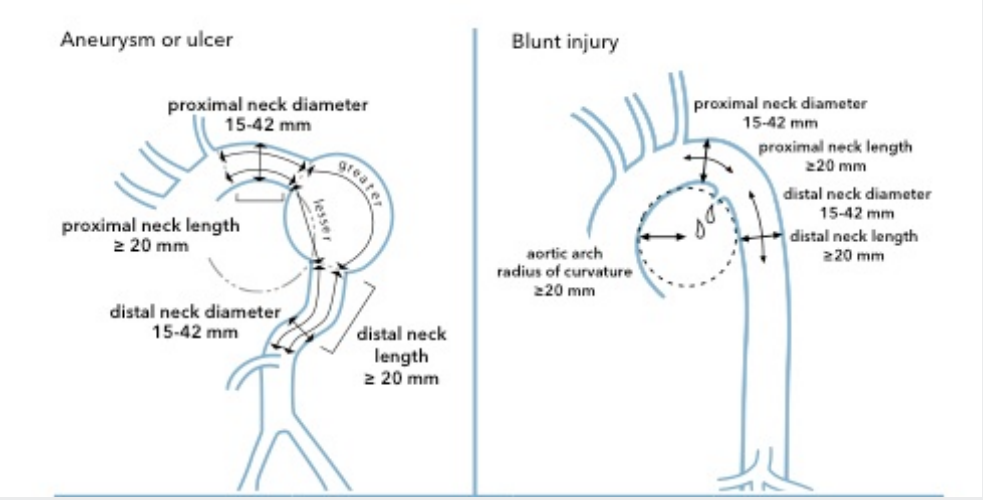
www.cookmedical.com

Intended use

The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with isolated thoracic lesions (not including dissection) having vascular anatomy suitable for endovascular repair.

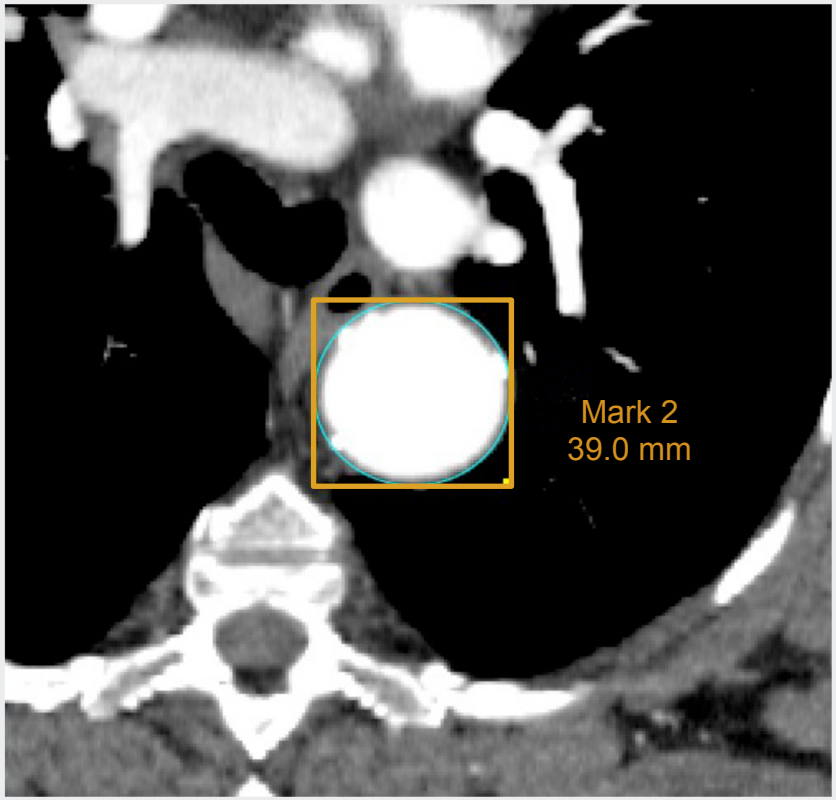
Anatomical inclusion criteria

- 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 longbetween the celiac artery and the aneurysm.



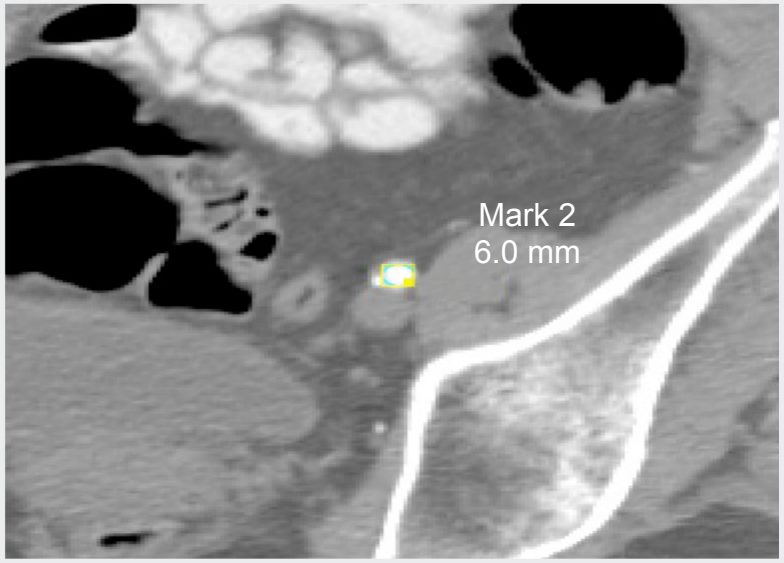
Anatomical inclusion criteria

- A proximal neck with a diameter between 15 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 15 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.



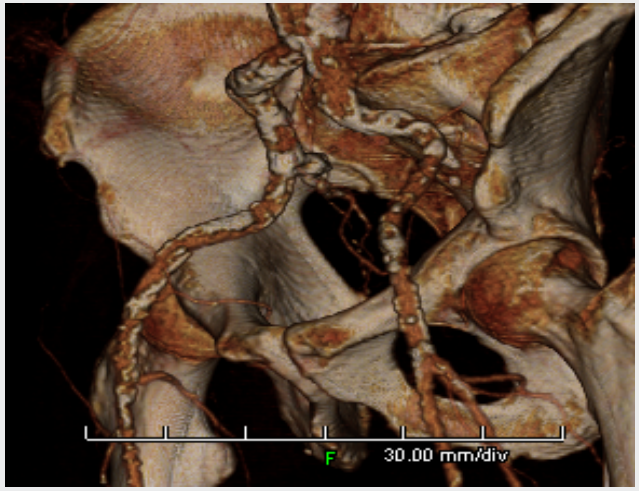
Anatomical inclusion criteria

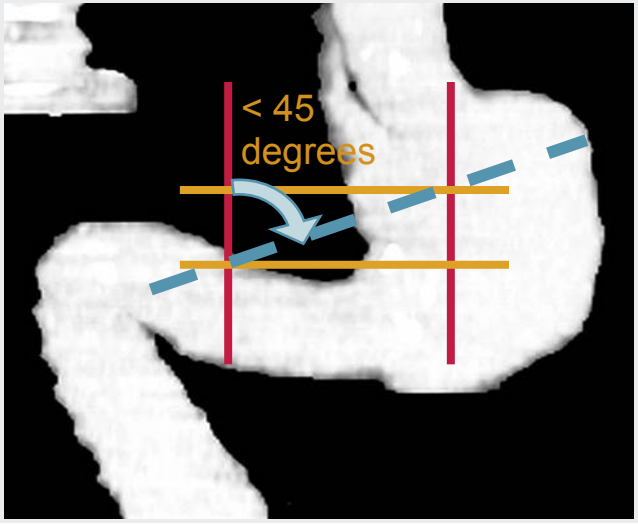
- Adequate iliac (femoral) access compatible with the placement of the introducer sheath:
  - 16 Fr (6.0 mm OD) for 18-30 mm diameter grafts
  - 18 Fr (7.1 mm OD) for 32-38 mm diameter grafts
  - 20 Fr (7.7 mm OD) for 40-46 mm diameter grafts
- Conduits are permitted.



Anatomical exclusion criteria

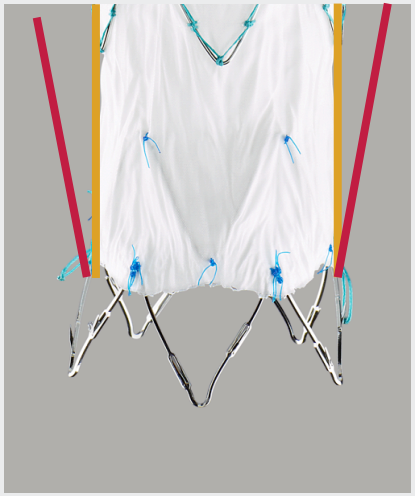
- Prohibitive calcification, occlusive disease or tortuosity of intended access vessels, or intended fixation sites
- Circumferential thrombus in the region of the intended fixation sites
- Aneurysm or angulation in the distal thoracic aorta that would preclude advancement of the introduction system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





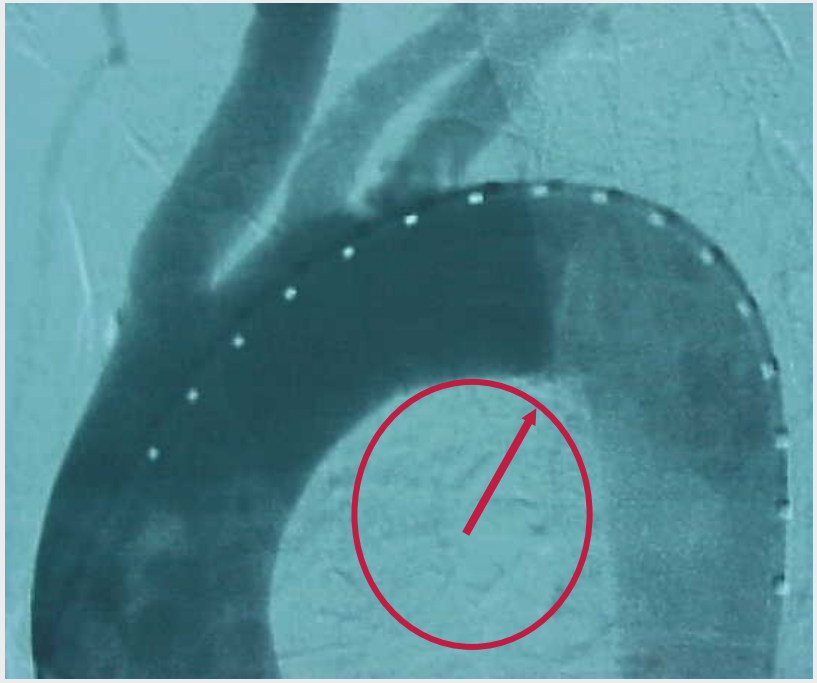
Anatomical exclusion criteria

- 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 or equal to 20 mm if the device was deployed in the arch



Anatomical inclusion criteria