

Transcend: Precision

Patient Selection

(includes Spiral-Z[™] AAA Iliac Leg and Z-Trak[®] Introduction System)

Patient Selection

The objective of patient selection is to determine if the patient is:

- A candidate for AAA repair
- A candidate for endovascular therapy
- A candidate for implantation of the Zenith Flex® AAA Endovascular Graft

Indicated Morphology as per IFU

- Adequate iliac/femoral access compatible with the required introduction systems
- Nonaneurysmal infrarenal neck proximal to the aneurysm that has:
 - -Length ≥ 15 mm
 - -Diameter of no greater than 32 mm and no less than 18 mm (measured outer wall to outer wall)
 - -Angle < 60° relative to long axis of aneurysm
 - -Angle < 45° relative to axis of suprarenal aorta

Indicated Morphology as per IFU

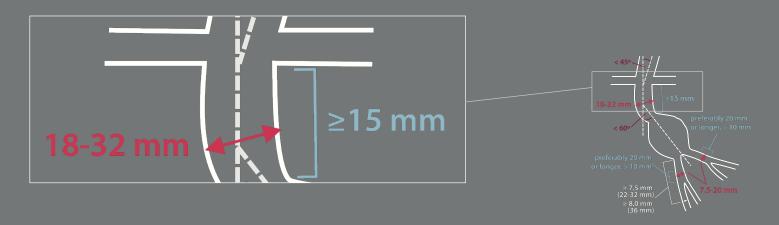
- Iliac artery distal fixation site that has:
 - -Length > 10 mm (preferably > 20 mm)
 - -Diameter 7.5-20 mm (measured outer wall to outer wall)

Proximal neck ≥ 15 mm in length

< 15 mm = inadequate seal

Proximal neck ≥ 18 mm or ≤ 32 mm in diameter

Smallest diameter of device is 22 mm; largest is 36 mm.



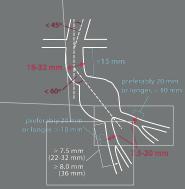
Iliac artery diameter (measured inner wall to inner wall) should be compatible with delivery systems that have the profile of a 16-22 Fr introducer sheath.



Iliac diameter 7.5-20 mm at distal fixation site (measured outer wall to outer wall)

Largest diameter leg is 24 mm.





Proximal neck with circumferential thrombus Inadequate seal

Iliac distal fixation site < 10 mm in length Inadequate seal

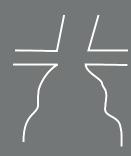
Inability to maintain at least one patent hypogastric artery Bowel ischemia, paralysis

Significant occlusive disease, tortuosity or calcification Inability to position and implant device

Unsuitable arterial anatomy

Inability to position and implant device

Proximal neck: inverted funnel shape Inadequate seal and prone to migration



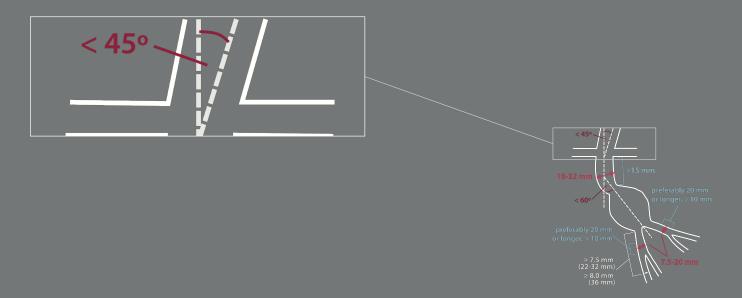
Proximal neck angle > 60 degrees relative to the long axis of the aneurysm

Inadequate seal and increased risk of migration

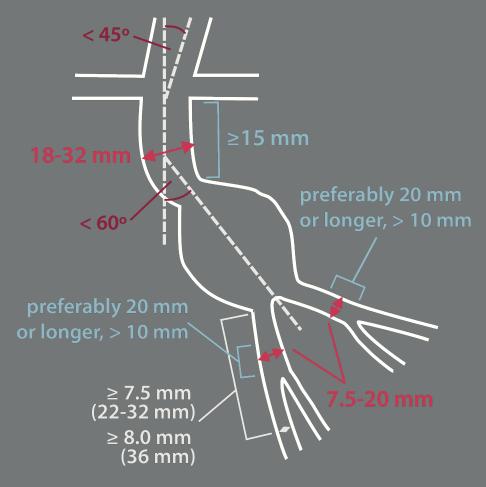


Immediate suprarenal neck angulated more than 45° relative to the immediate infrarenal neck

Inadequate seal and increased risk of migration



Patient Selection





Transcend: Precision

Going beyond. That's what it means to Transcend.

That's the essence of Zenith.