Planning and sizing

Zenith Alpha™
THORACIC ENDOVASCULAR GRAFT

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Imaging recommendations

Spiral CTA

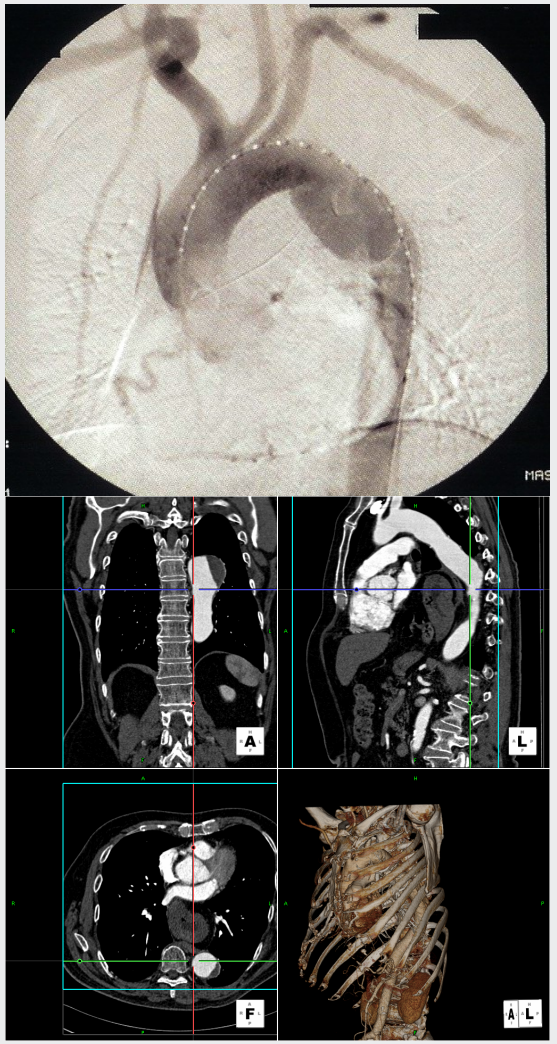
- You must perform a CT scan to show the great vessels of the aortic arch and the neck, and to scan through the femoral heads.
- The axial CT scan allows you to assess the diameters, calcium, and thrombus of the vessels.

Angiography

- You may perform angiography to assess lengths, angles, and tortuosity.

3D CTA reconstructions

- CTA reconstructions that use 3Mensio, TeraRecon, or 3D imaging help you accurately assess proximal and distal necks.



Planning

Device planning steps

- Identify the locations of proximal and distal seal zones.
- Identify the location and extent of the overlap joint (when designing the two-piece system).
- Take length measurements along the greater curvature of the aorta, including the aneurysm if present.

Adequate access

The inner diameter of the access vessel must accommodate the outer diameter of the introduction system.

How to choose seal zones

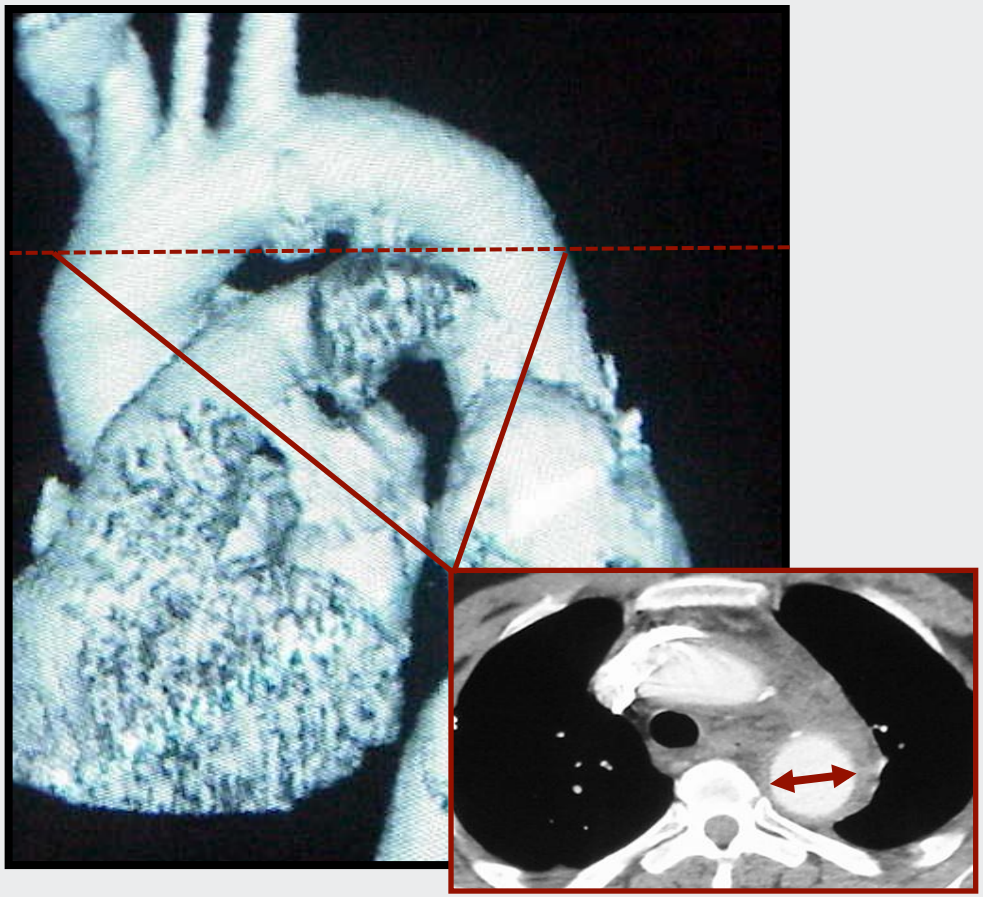
The seal zones must be conducive to good sealing between the graft and the aortic wall. The seal zones should have these characteristics:

- Minimal angulation, tortuosity, and calcification
- No circumferential thrombus
- No inverted-funnel proximal neck or funnel distal neck (more than a 10% change in diameter across 20 mm of the sealing zone)
- A length of at least 20 mm
- An outer-wall-to-outer-wall diameter between 15 and 42 mm

Identify branch vessels and plan accordingly (plan bypass of left subclavian; look for anomalous vertebrals off arch; do not cover celiac)

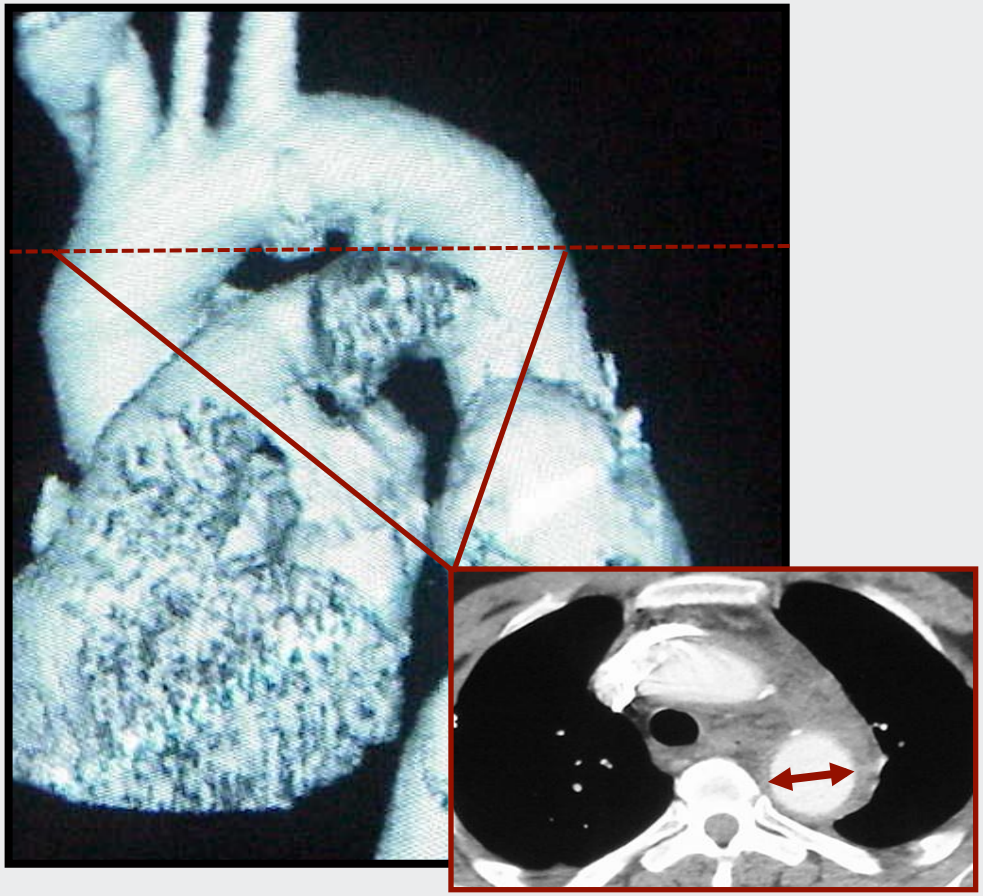
Neck diameter

- Use of 3-D reconstruction to measure neck diameter perpendicular to the centerline of flow is recommended.
- If using axial imaging, look at the **longest** measurement across the **shortest** axis of the proximal neck and distal neck.
- Measure from the outer wall to the outer wall.

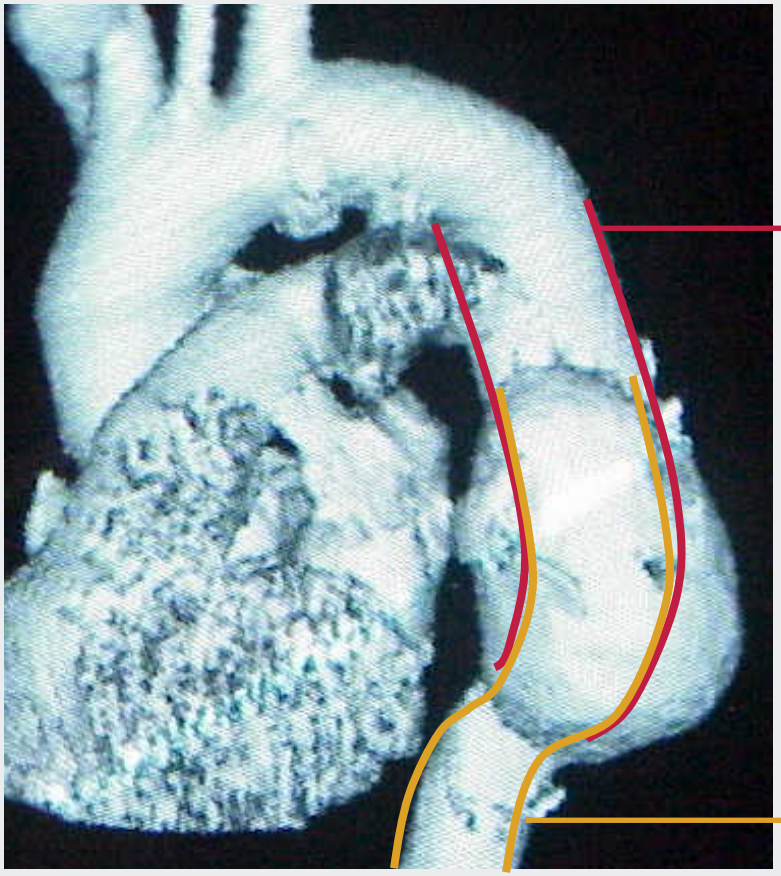


Diameter oversizing

- Oversize the components' diameters.
- Graft diameters are generally oversized 10%-25% (3-5 mm) in comparison to the anatomical measurement.
- Measurements for blunt thoracic aortic injury patients should be based on a CTA of a fully resuscitated patient.



Length of seal zones



Length of seal zones

Proximal component

- The proximal component landing zone is also referred to as the neck length.
- The neck length should be greater than or equal to 20 mm.

Why does the neck length need to be so long?

- Attachment
- Friction
- Seal

Neck shape

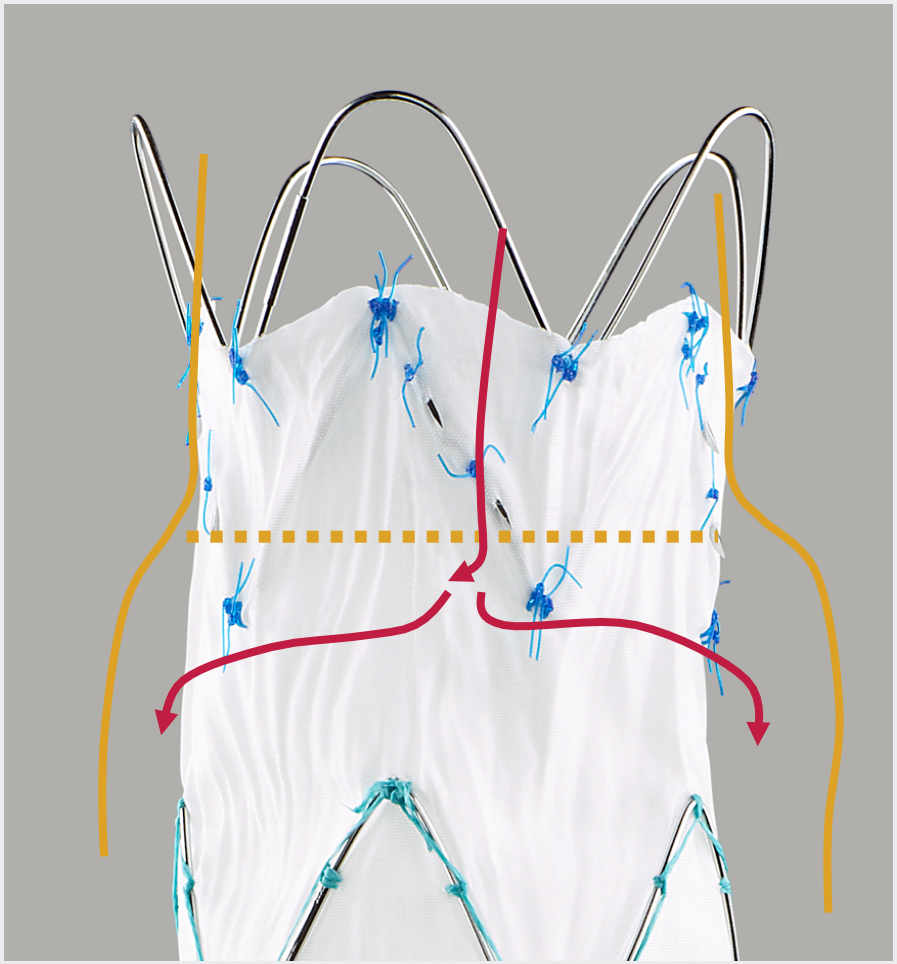
The shape of the neck must provide a parallel seal zone.

- The proximal and distal fixation sites should demonstrate less than a 10% change in diameter over the 20 mm lengths of the sites.

Seal zones shorter than 20 mm

Proximal component

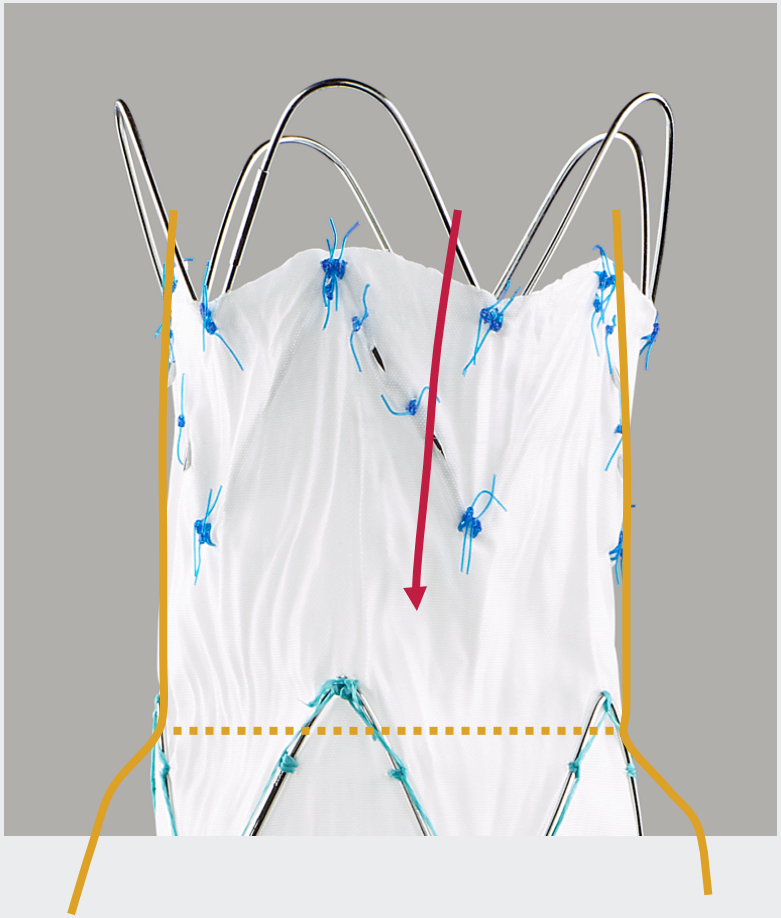
- Short landing zones can create an inadequate seal zone, which can result in a Type I endoleak.



Adequate seal-zone length

Proximal component

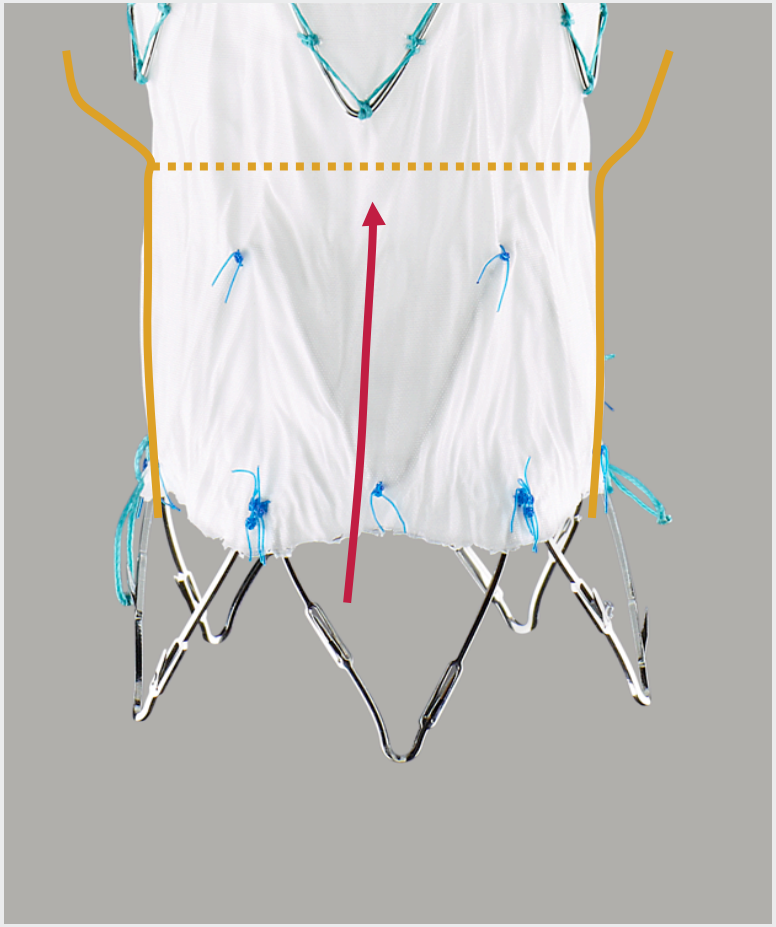
- A proximal landing zone that is greater than or equal to 20 mm long inhibits blood flow and provides an adequate seal to help prevent a Type I endoleak.



Adequate seal-zone length

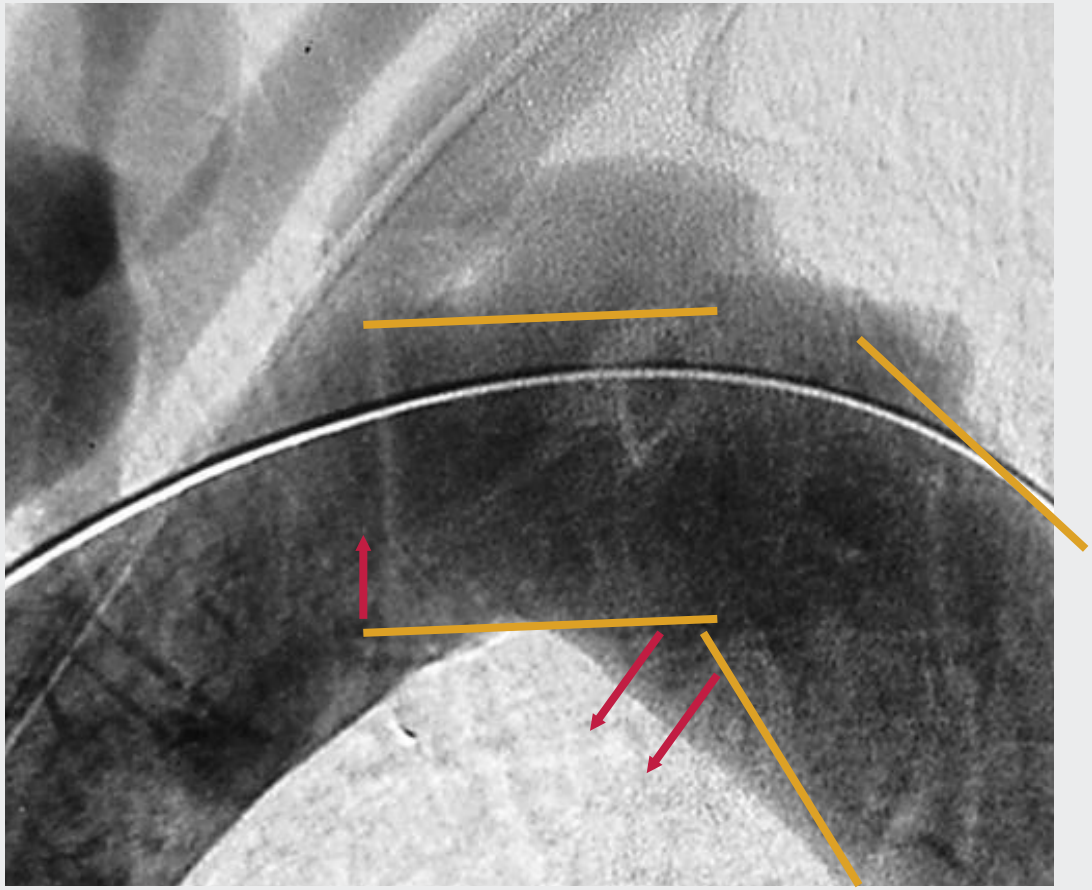
Distal component

- A distal landing zone that is greater than or equal to 20 mm long can help inhibit Type I endoleaks.



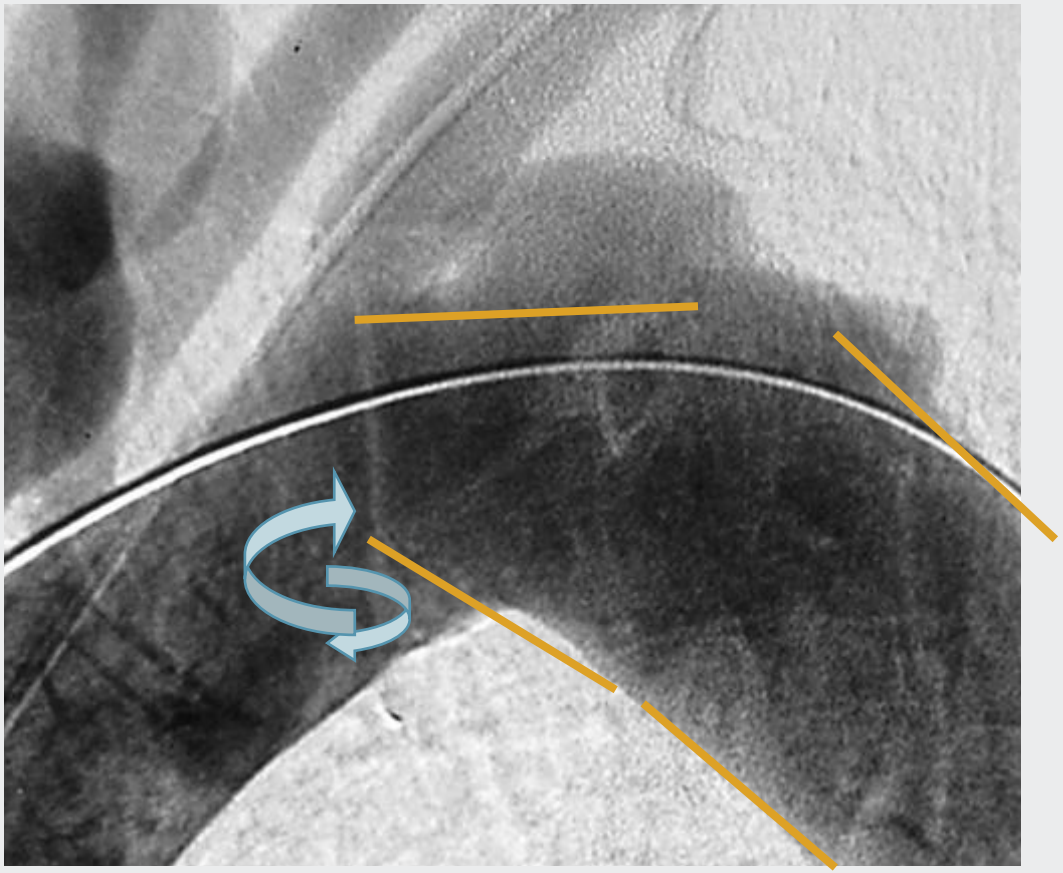
Neck shape

- This image demonstrates an inadequate, non-parallel neck shape.



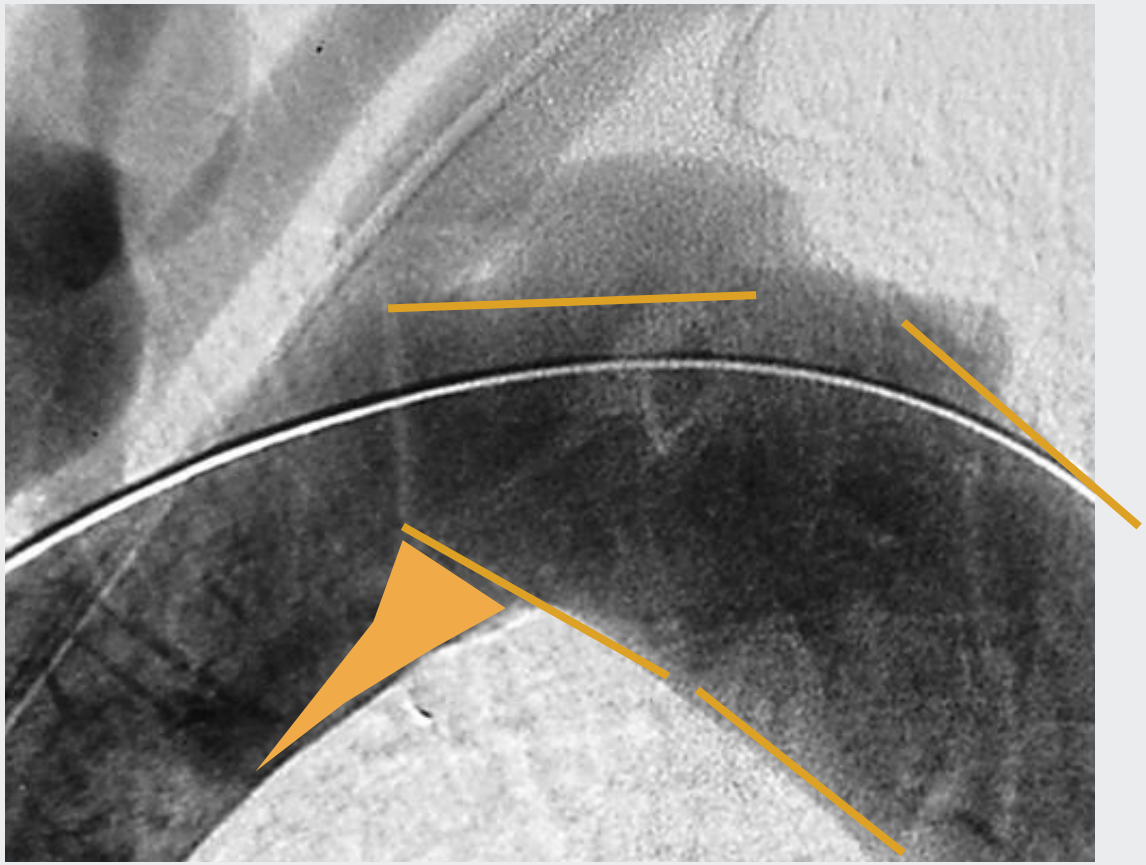
Neck shape

- Inadequate neck shape may cause the proximal component to bird beak, migrate, and/or lose seal.



Neck shape

- A thrombus may develop under the sealing stent.



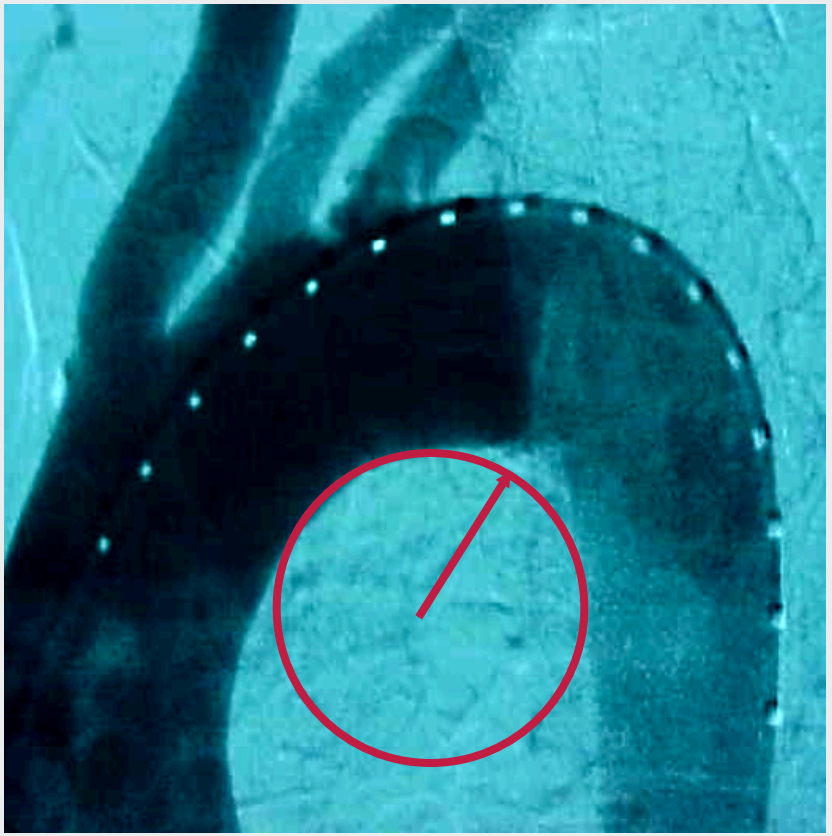
Neck shape

Parallel neck

- A landing zone in a parallel segment that is greater than or equal to 20 mm long provides adequate seal and fixation.

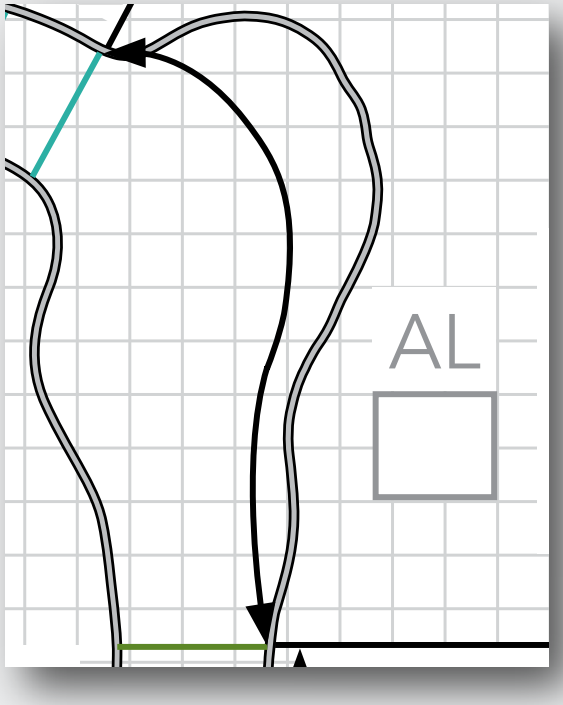
Aortic arch radius

- The inner aortic arch radius must be greater than 20 mm.



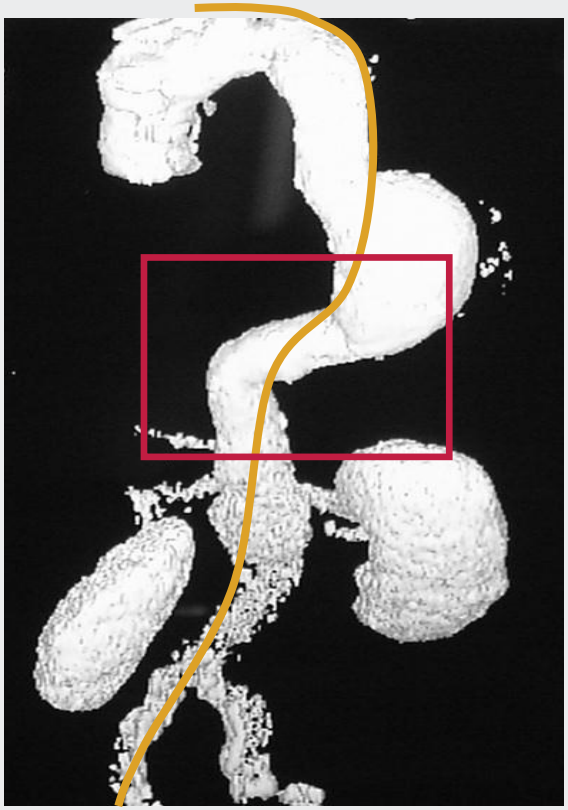
Aneurysm length

- Take the length measurements along the greater curvature of the aorta, including the aneurysm if present.
- The greater curvature of the aorta is the longest measurement following the curve of the aneurysm and may be on the outer or inner curvature of the aorta depending on the location of the aneurysm.
- A two-component (proximal and distal component) repair is recommended for aneurysms because it adapts to the length change over time if the graft settles into the greater curve and also provides active fixation at both the proximal and distal seal sites.
- If you can't implement an acceptable two-component repair, then the proximal component must be long enough to achieve and maintain the minimum 20 mm long sealing zone.



Distal aortic angle

- Successfully excluding the aneurysm if the angle through the S curve is greater than 45 degrees may be difficult.
- If you note difficulty tracking the second component through tortuous anatomy of the thoracic aorta, then you can provide extra support by using a brachio-femoral wire guide.



Device planning and sizing

Zenith Alpha™
THORACIC ENDOVASCULAR GRAFT

DEVICE PLANNING AND SIZING WORKSHEET

Date: _____ Patient ID: _____

Hospital: _____

Physician name: _____

Physician phone #: _____

Physician e-mail: _____

Physician signature: _____

Purchase order number: _____

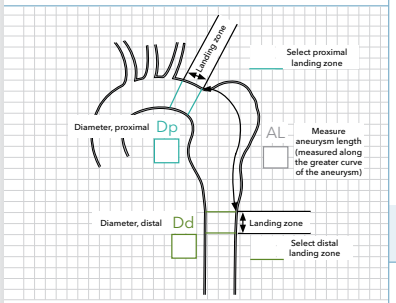
Anatomical measurements

Introduction site

❑ Right iliac — External iliac (EI) measurement _____mm

❑ Left iliac — External iliac (EI) measurement _____mm

Introduction system: 18-30 mm grafts = 6.0 mm (OD)
32-38 mm grafts = 7.1 mm (OD)
40-46 mm grafts = 7.7 mm (OD)



Aortic vessel diameters; CT diameters are outer wall to outer wall

Components

Proximal and distal components are recommended because they provide active fixation proximally and distally.
A proximal component should only be used independently for ulcer and/or saccular aneurysms.

Device overlapping

A minimum overlap of 3 stents is recommended. Ensure that the distal graft does not extend beyond the top sealing stent of the proximal graft.

Tapered anatomy

If Dp (diameter, proximal neck) is 4 mm > Dd (diameter, distal neck), then a proximal tapered graft may be used.

Proximal grafts

Proximal aortic vessel diameter (Dp) = ____

Select the graft diameter from the vessel oversizing chart below.

____ AL plus ____ Landing zone = ____ Proximal working length

Select the graft length that is closest to the working length.

Proximal Graft (ZTA-P)

Diameter mm	Length mm
18, 20, 22, 24, 26	105
28, 30, 32	109, 155, 201
34, 36	113, 161, 209
38, 40	117, 167, 217
42	121,173, 225
44, 46	125, 179, 233

Proximal Tapered Graft (ZTA-PT)

Diameter mm	Length mm
26	105
30	108
32	178, 201
34, 36	161, 209
38, 40	167, 217
42	173, 225
44, 46	179, 233

❑ Proximal graft order number = ZTA-P- ____ (Graft diameter) - ____ (Graft length) -W

❑ Proximal tapered graft order number = ZTA-PT- ____ (Graft diameter) - ____ (Graft diameter) - ____ (Graft length) -W

Distal grafts

Distal aortic vessel diameter (Dd) = ____

Select the graft diameter from the vessel oversizing chart below.

____ AL plus ____ Landing zone = ____ Distal working length

Select the graft length that is closest to the working length.

Distal Graft (ZTA-D)

Diameter mm	Length mm
28, 30, 32	160
34, 36	142, 190
38	147, 197
40	197
42	204
44, 46	211

Distal graft order number = ZTA -D - ____ (Graft diameter) - ____ (Graft length) -W

Vessel oversizing chart (10%-25%)

Aortic Vessel Outer Diameter (Dp and Dd) mm	Graft Diameter mm
15 - 16	18
17	20
18 - 19	22
20 - 21	24
22 - 23	26
24 - 25	28
26 - 27	30
28 - 29	32
30	34
31 - 32	36
33 - 34	38
35 - 36	40
37 - 38	42
39	44
40 - 42	46

When selecting a graft diameter, refer to the oversizing chart.

Additional considerations may affect the choice of diameter.

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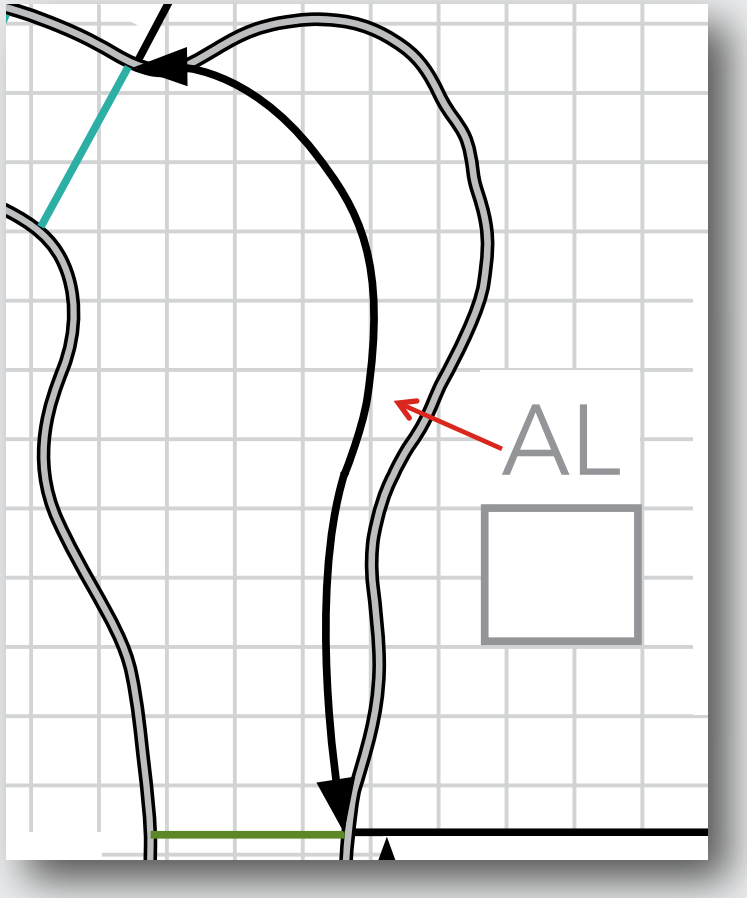
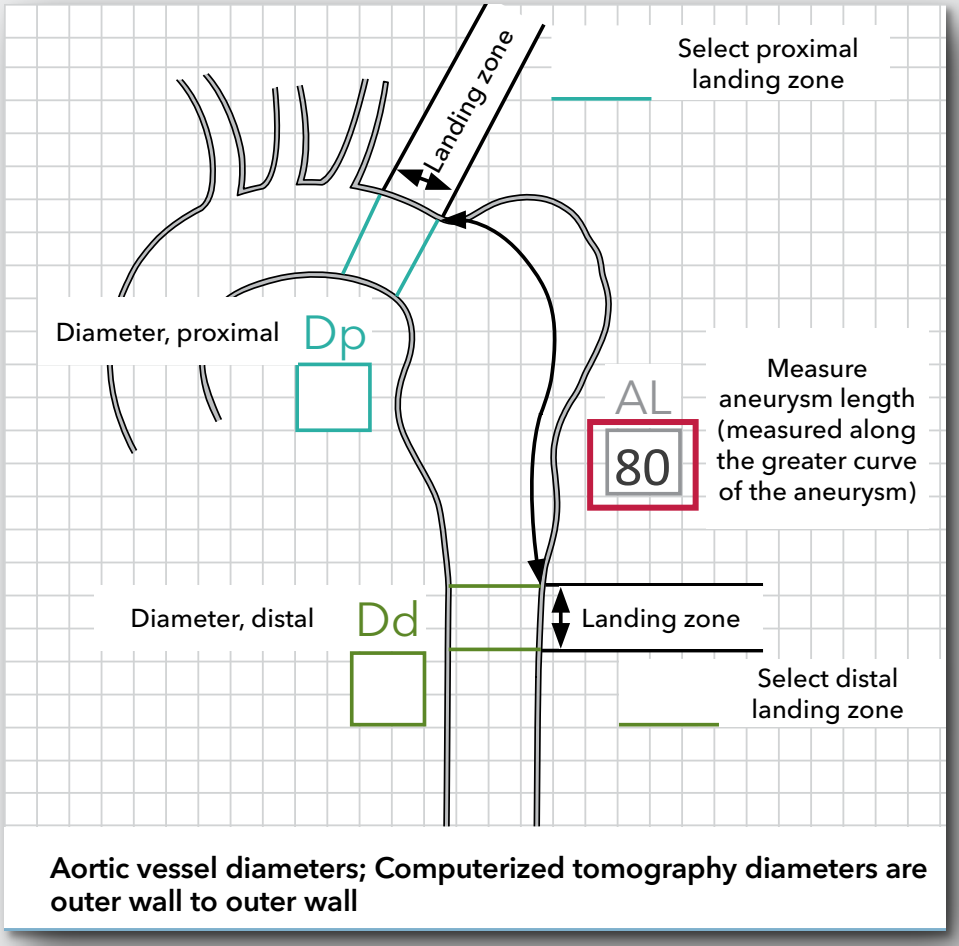
Aneurysm length (AL)

- Measure the length of the aneurysm.
- You must take the length measurements on the greater curve of the aneurysms.



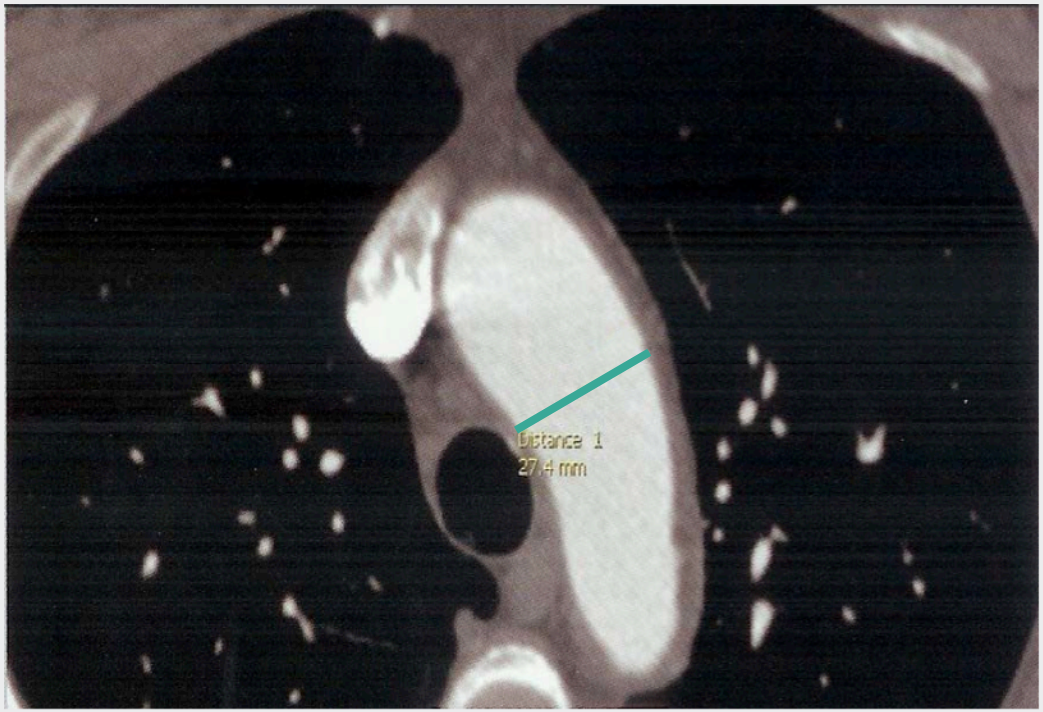
Aneurysm length (AL)

- Write the aneurysm length in the **AL** box.



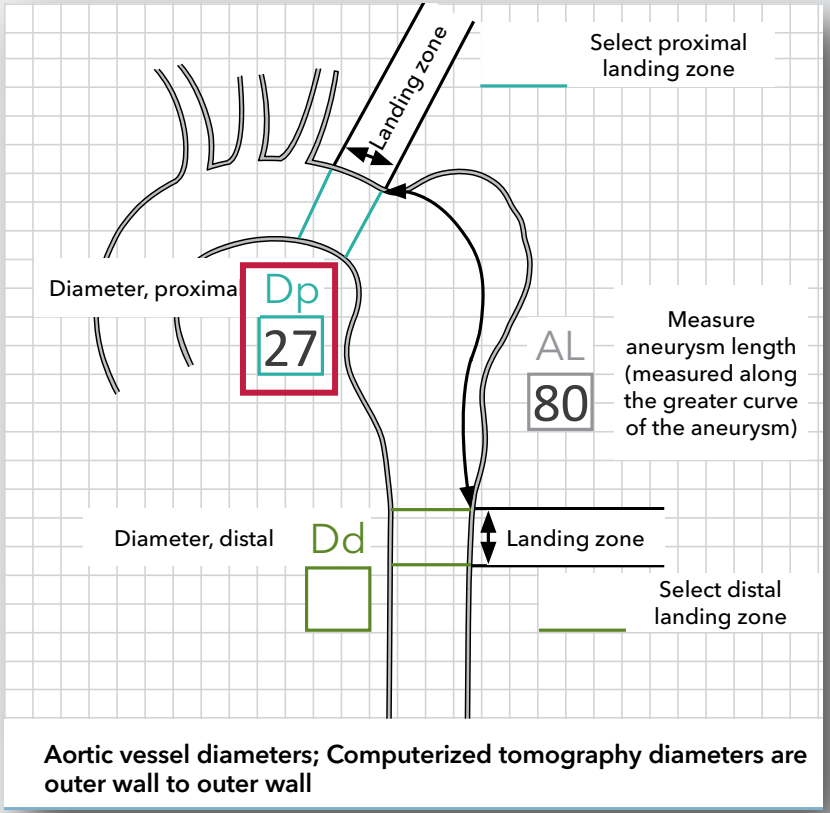
Proximal aorta anatomical diameter

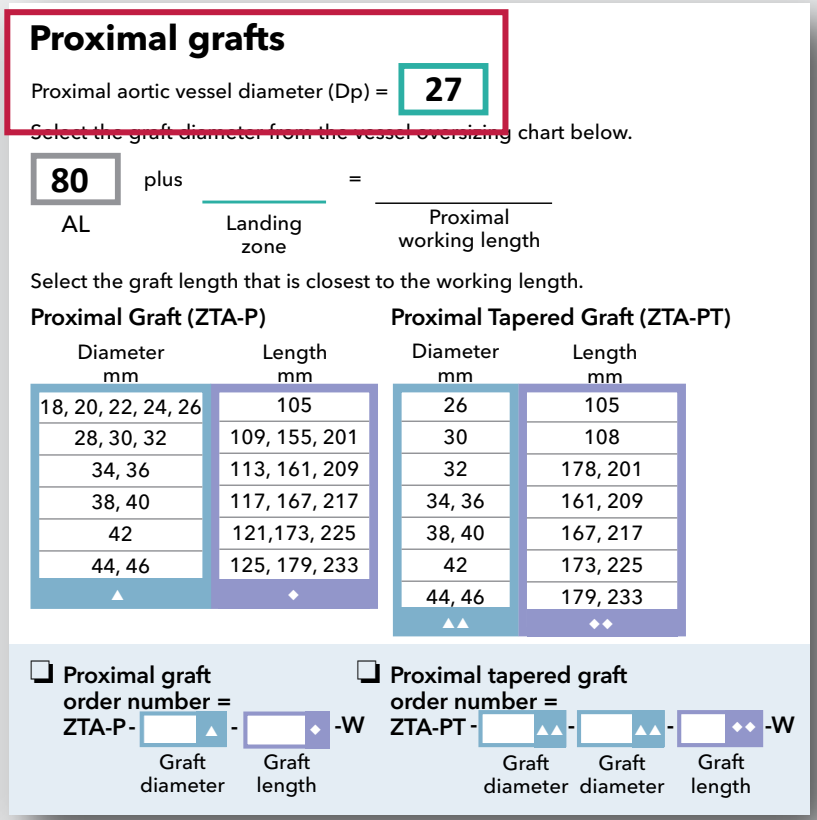
- Measure the proximal diameter of the neck outer wall to outer wall. The landing zone must be at least 20 mm long.



Proximal aorta anatomical diameter

- Write the proximal diameter measurement in the Dp box.

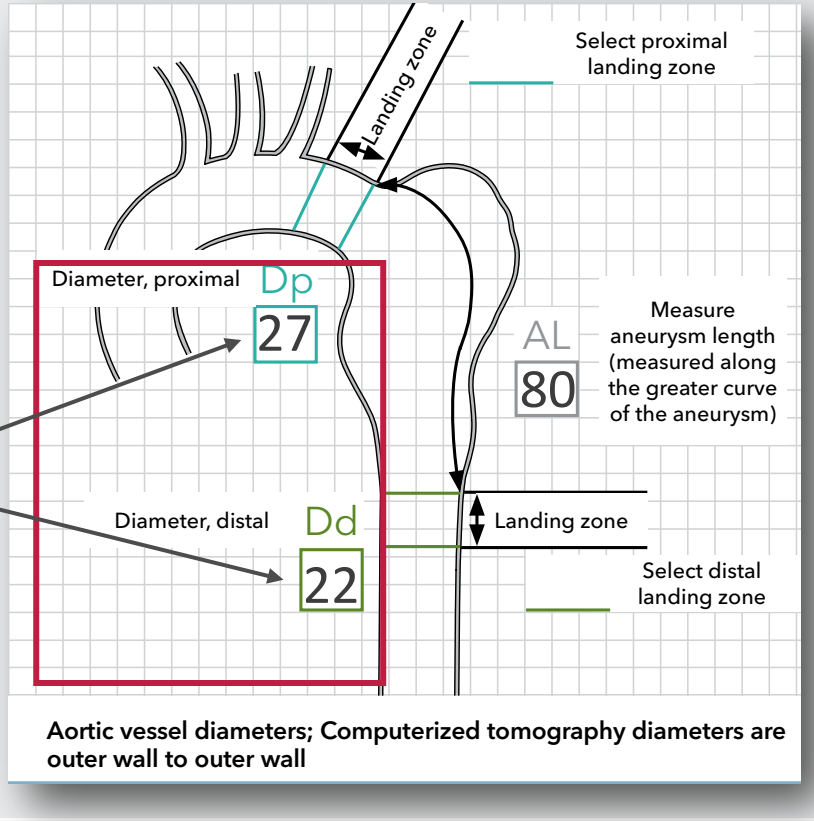




Tapering anatomy: Example

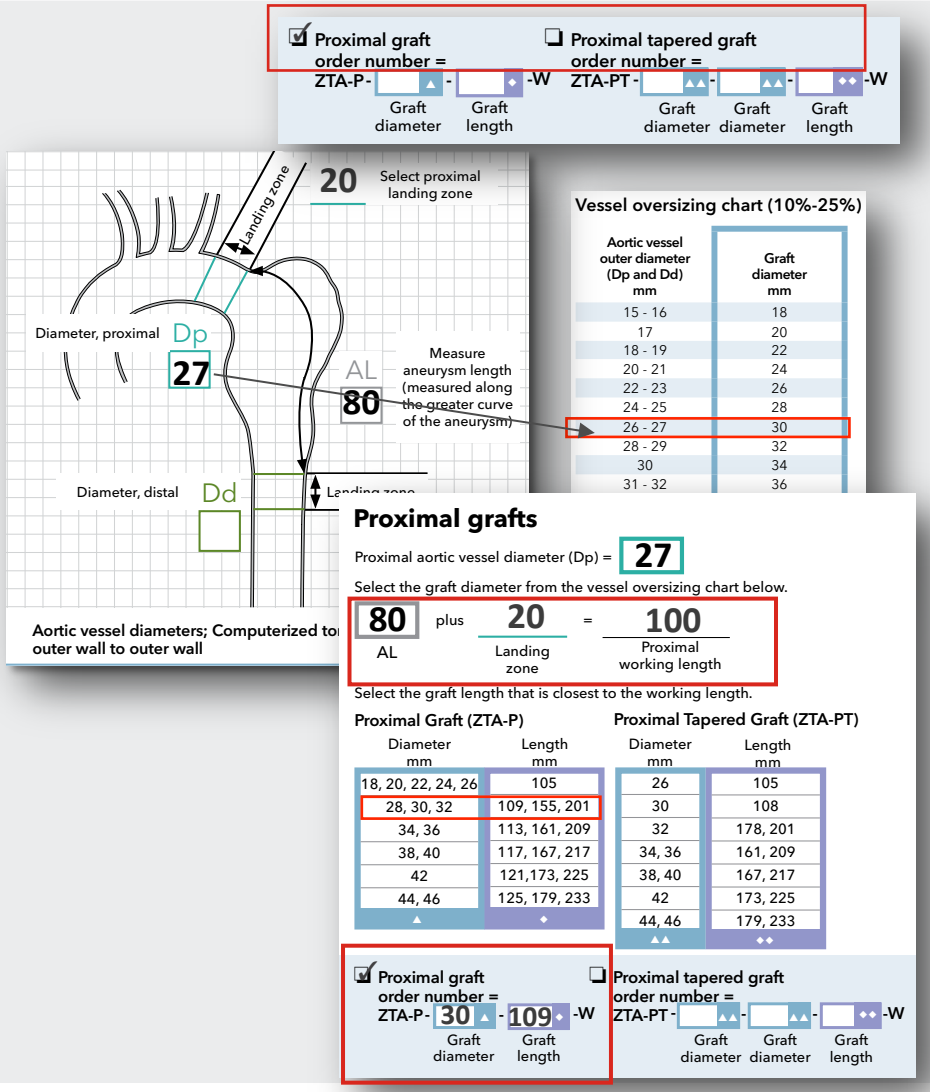
- If Dp (diameter, proximal) is 4 mm > the Dd (diameter, distal neck), then a proximal tapered graft may be used.

This difference is greater than 4 mm.



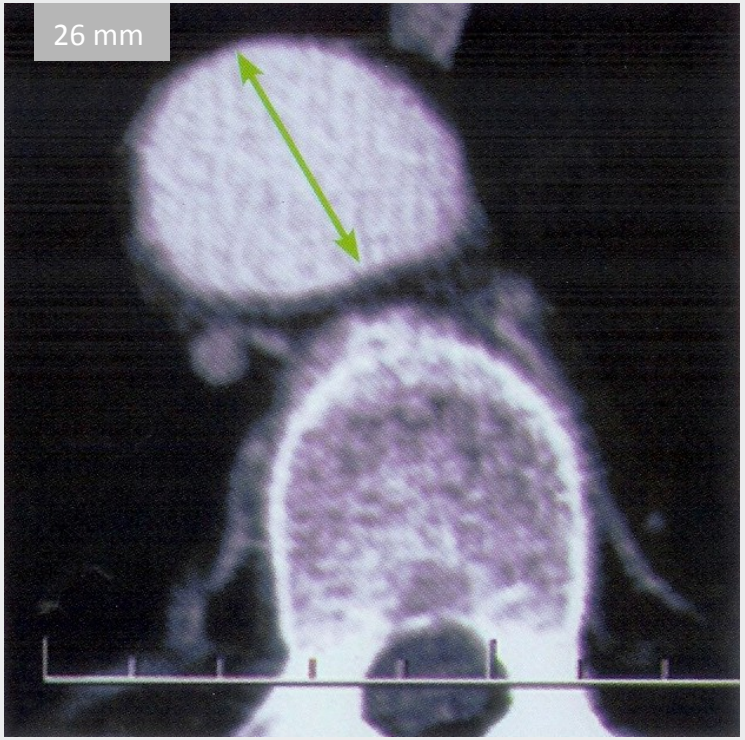
Proximal graft selection

- Select the proximal graft type.
- Select the diameter of the proximal graft from the vessel oversizing chart.
- Calculate the proximal working length by adding the aneurysm length and 20 mm.
- Select the proximal component length from the chart.



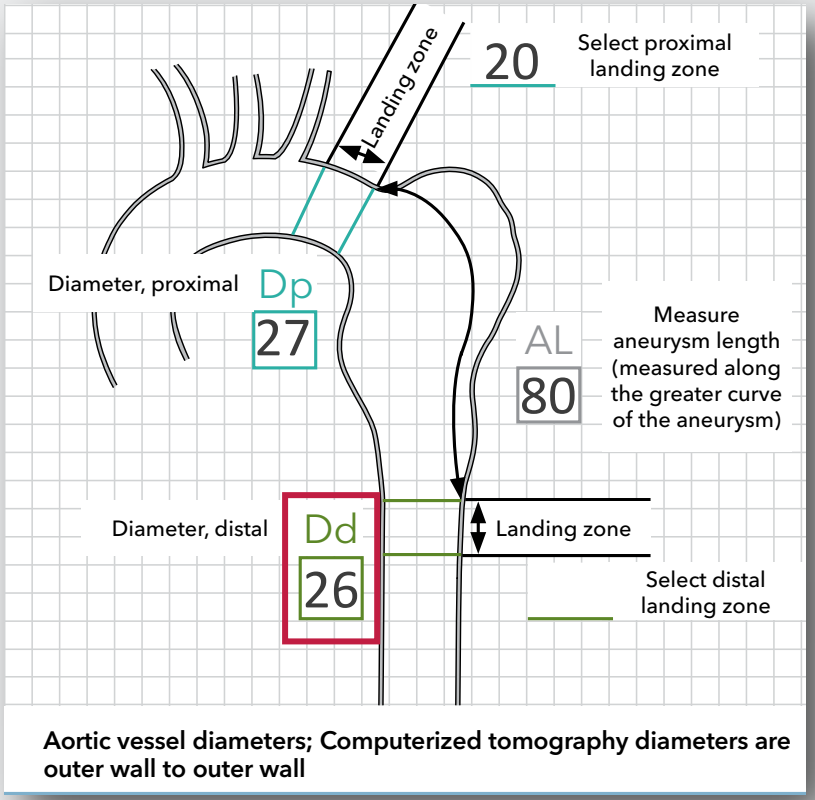
Distal aorta anatomical diameter

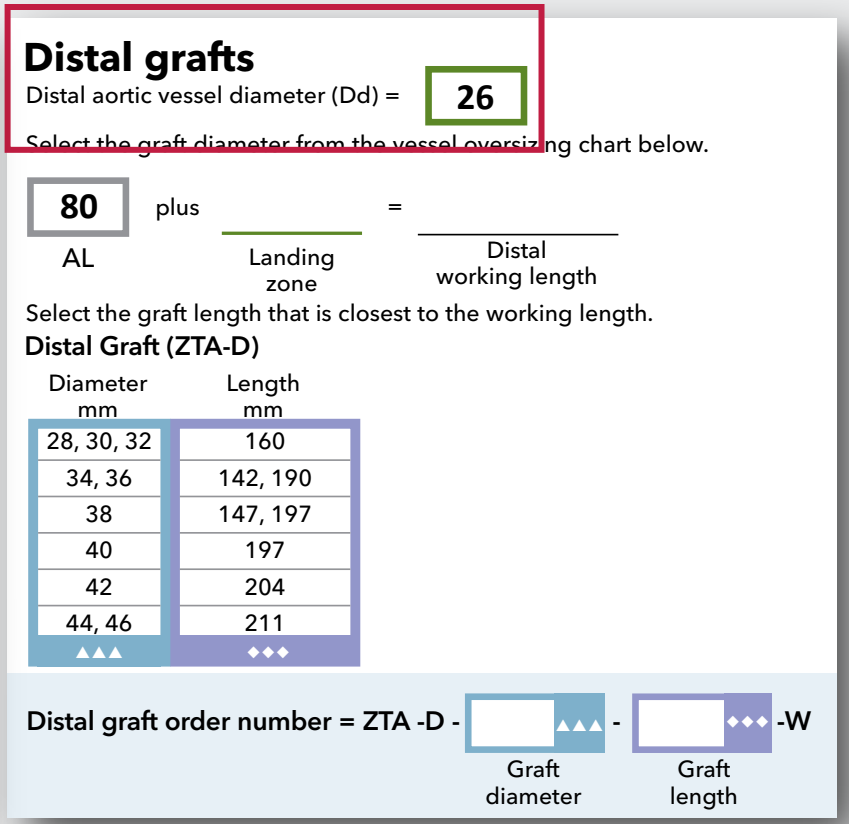
- Measure the distal diameter of the neck. The landing zone must be at least 20 mm long, measured outer wall to outer wall.



Distal aorta anatomical diameter

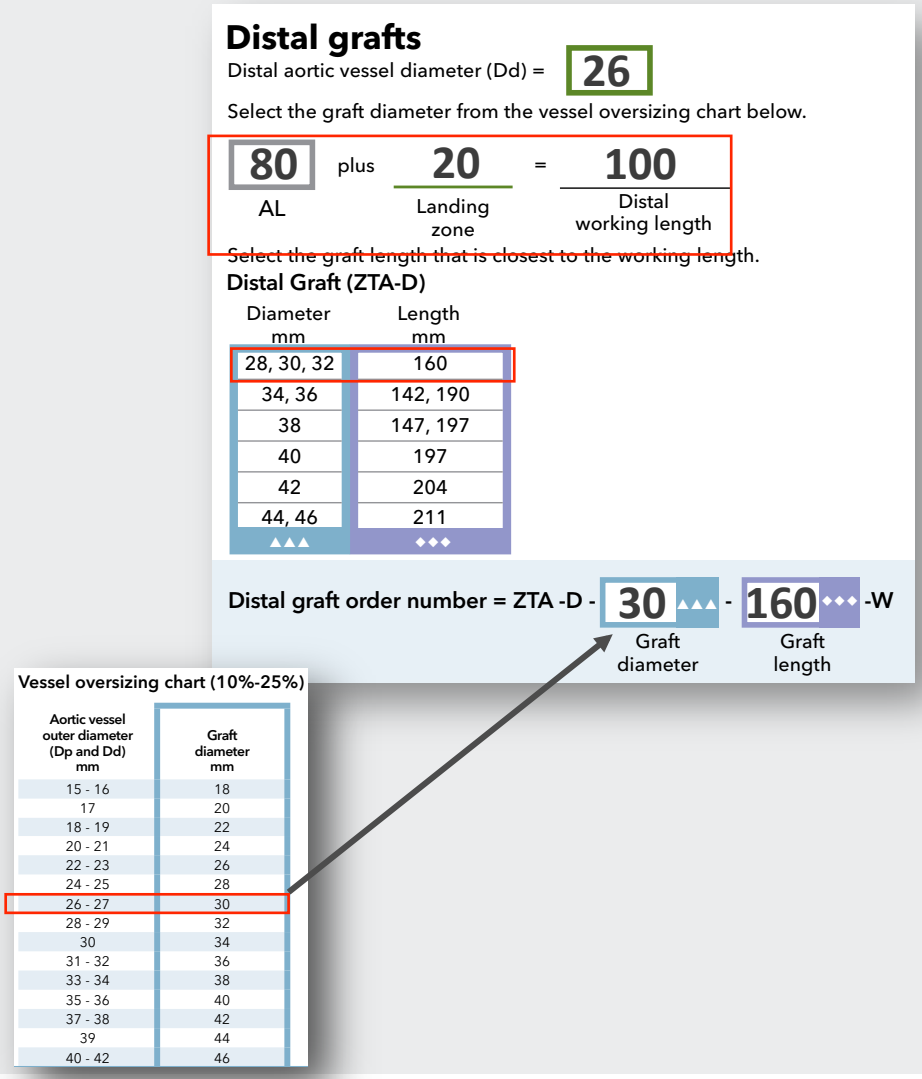
- Write the distal diameter measurement in the Dd box.





Distal graft selection

- Select the distal graft type.
- Select the diameter of the distal component from the vessel oversizing chart.
- Calculate the distal working length by adding the aneurysm length and 20 mm.
- Select the distal component length from the chart.
- A 3-4 stent (approximately 75-100 mm) overlap is recommended.



Graft order numbers

☑ **Proximal graft order number =**
ZTA-P- 30 - 109 -W

Graft diameter | Graft length

❑ **Proximal tapered graft order number =**
ZTA-PT - ___ - ___ - ___ -W

Graft diameter | Graft diameter | Graft length

Distal graft order number = ZTA -D - 30 - 160 -W

Graft diameter | Graft length