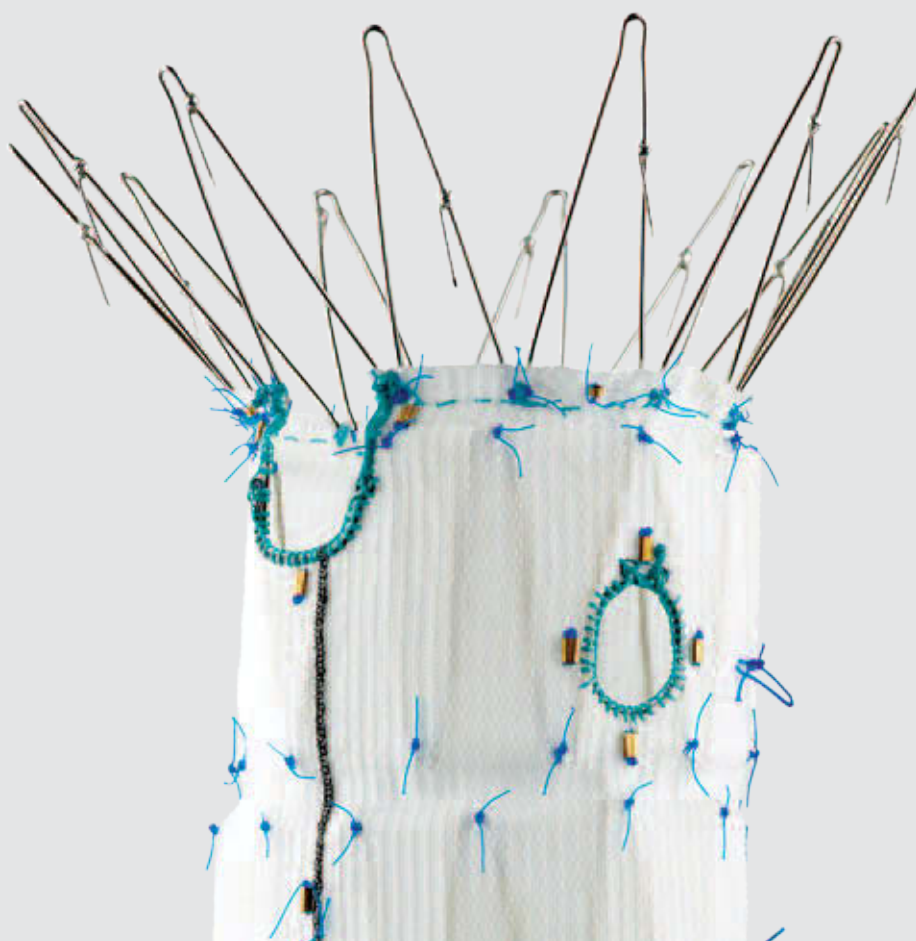


# Guidelines for Planning and Sizing a Zenith® Fenestrated Graft

Physician Handbook



Zenith® Fenestrated

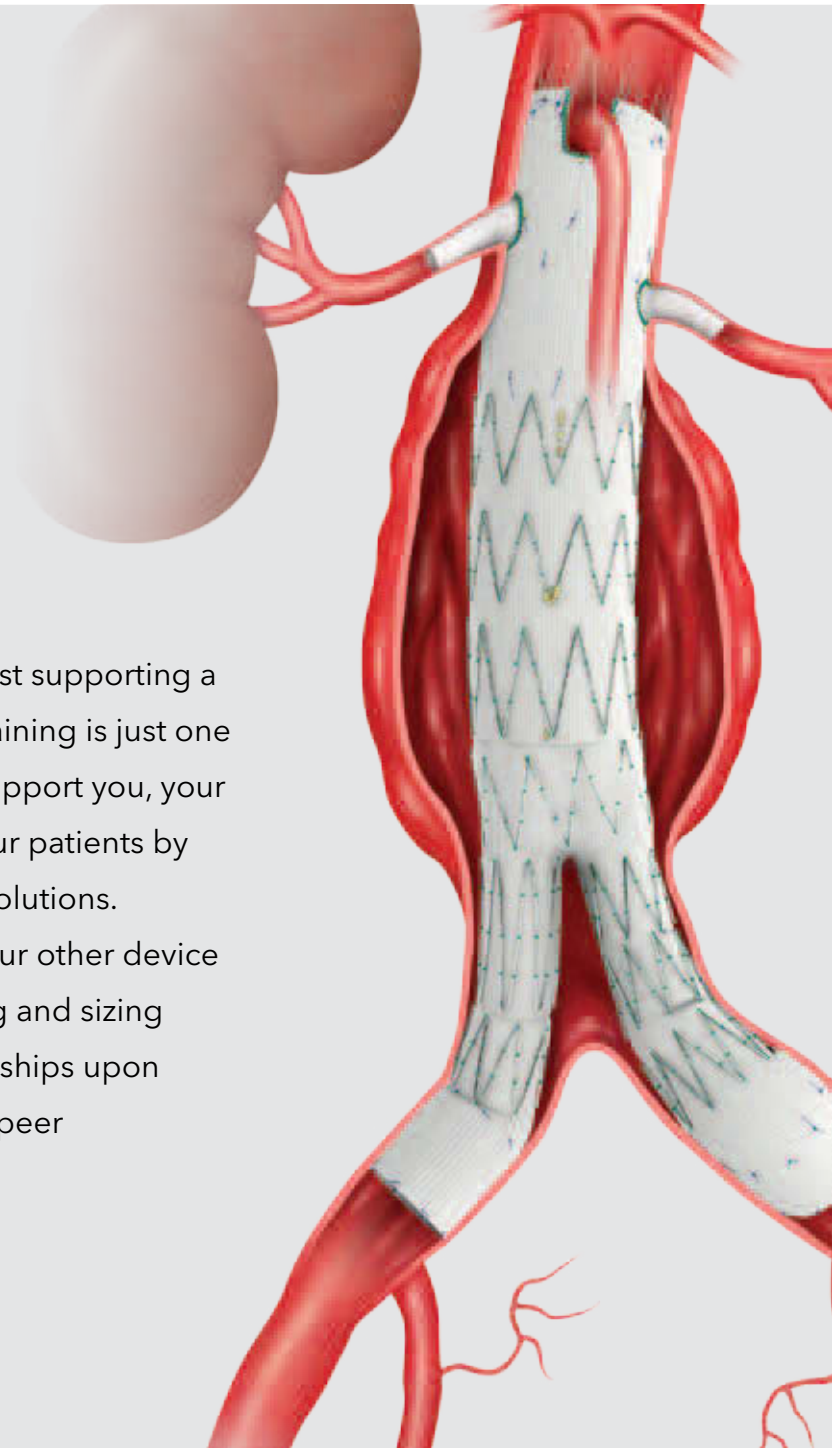
AAA ENDOVASCULAR GRAFT

## **Transcend: Support**

To us, support is about much more than just supporting a product; it's about supporting you. This training is just one example of how we continually strive to support you, your personal practice and the treatment of your patients by providing disease-specific endovascular solutions.

We encourage you to take advantage of our other device training opportunities, our global planning and sizing centres, the product development partnerships upon which Zenith is founded, and educational peer discussions worldwide.

**Going beyond. That's what it means to Transcend.  
That's the essence of Zenith.**



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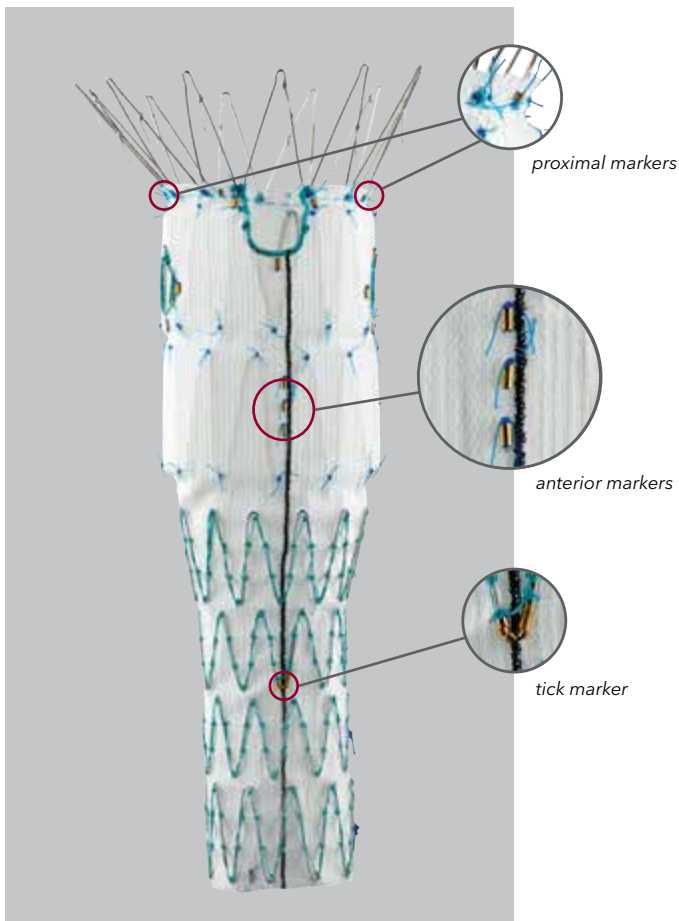
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## Device Description

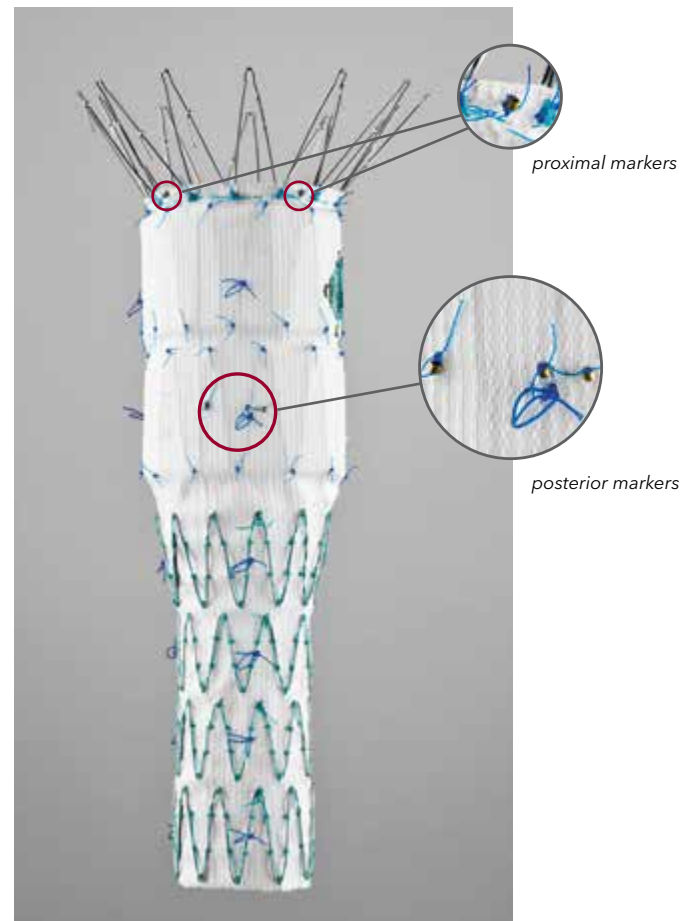
### Proximal Component

- Range of proximal diameters: 24-36 mm.
- 1 or 2 proximal internal sealing stents.
- Available in various lengths, correspondent to 1 or 2 proximal sealing stents and proximal diameter.
- All Zenith Fenestrated proximal components taper after the sealing stent(s) to a standard distal diameter of 22 mm.
- 20 Fr Flexor® Introducer Sheath for 24-34 mm grafts; 22 Fr Flexor Introducer Sheath for 36 mm graft.

Anterior View



Posterior View



- A proximal graft with 2 internal stents offers:
  - a) Maximum proximal sealing potential
  - b) A greater range of fenestration placement

Fenestration types and related criteria:



**Scallop**

Scallops along the graft's proximal edge are 10 mm wide and must be 6-12 mm in height.



**Small Fenestration**

Small fenestrations are 6 mm wide and 6 or 8 mm in height. Distance from centre of fenestration to proximal edge of graft must be  $\geq 15$  mm.



**Large Fenestration**

Large fenestrations range from 8-12 mm in diameter. Distance from centre of fenestration to proximal edge of graft must be  $\geq 10$  mm. (May have struts crossing the fenestration as pictured above.)

- Criteria for the Zenith Fenestrated graft:
  - a) Grafts may contain up to a total of 3 fenestrations.
  - b) Grafts may include no more than 2 of any one type of fenestration (small, large or scallop).
  - c) Manufacturing constraints exist regarding positions of fenestrations and scallops. **For further information, refer to Appendix A.**
- Diameter-reducing ties
  - Allow rotation/manipulation of the graft to obtain optimal alignment prior to final deployment.

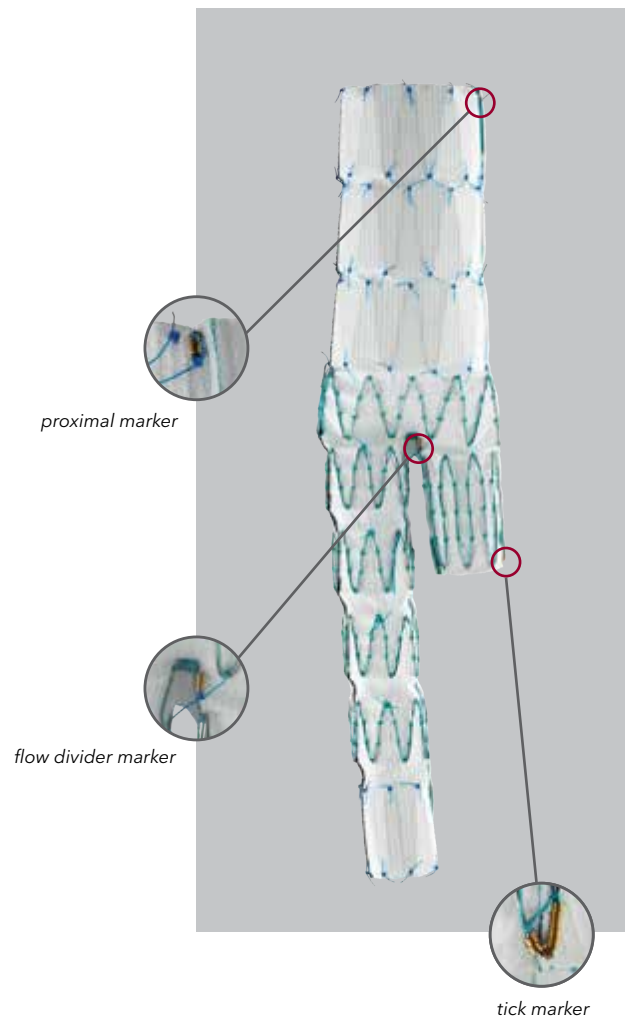


diameter-reducing ties

## Device Description (cont.)

### Distal Component

- Proximal diameter: 24 mm for interference fit.
- Proximal internal sealing stents.
- Available distal component lengths: 76, 94, 109 and 124 mm.
- Ipsilateral leg lengths (incorporated into graft): 28, 45 or 62 mm.
- Contralateral leg length is 22 mm.
- Available ipsilateral leg distal diameters: 12, 16, 20 and 24 mm.



# Procedure for Planning and Sizing the Zenith Fenestrated AAA Endovascular Graft

## 1) Image Overview

- Assess suitability of anatomy (e.g., minimal angulations, suitable landing zone, target vessels, access vessels).
- Sketch anatomy (to scale).

## 2) Sealing Zone Assessment

- Measure diameters (outer wall to outer wall) throughout proximal and distal sealing zones.
- Be aware of thrombus, calcium, diseased vessels.

## 3) Fenestration Planning

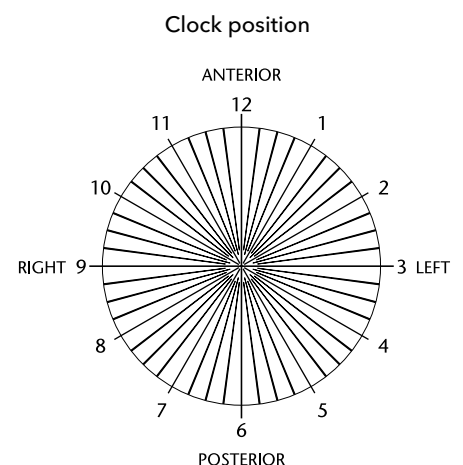
- **Centreline**
  - a) The centreline should be corrected to simulate how the graft will conform to the anatomy. For example, see images.
- **Distance Reference Line**
  - a) Select a reference point (usually the lower margin of coeliac trunk).
  - b) Measure distances to target vessels (lower margin for scallops, middle of vessel for fenestrations).
  - c) Select suitable fenestration configuration (size of fenestration/scallop). **Refer to Appendix B for examples.**
- **Clock Positions**
  - a) Use corrected imaging. Adjust magnification so that the image is the same size as the aorta.
  - b) Select clock position (15 minute increments).
  - c) Manufacturing constraints exist regarding positions of fenestrations and scallops. **For further information refer to Appendix A.**
- **IVD (Inner Vessel Diameter)**
  - a) The aortic vessel diameter (inner wall to inner wall) is taken at the level of the fenestrations – this measurement will determine the circumferential distance (in mm) of the fenestrations from the 12 o'clock position.
  - b) Incorrect IVD measurement may result in the fenestrations being misaligned with the target vessels.
  - c) Nominating an IVD that is too small may result in the fenestration being placed anterior to the target vessel.
  - d) Nominating an IVD that is too large may result in the fenestration being placed posterior to the target vessel.
  - e) Manufacturing constraints exist regarding positions of fenestrations and scallops. **For further information, refer to Appendix A.**



true centreline



corrected centreline





# Procedure for Planning and Sizing the Zenith Fenestrated AAA Endovascular Graft (cont.)

## 4) Proximal Component Diameter

- The graft should be oversized 15% or 4 mm. Excessive oversizing may result in contact with aortic wall prior to deployment.
- If the implantation site has varying diameters along its length, oversize the graft appropriately to ensure good contact with the largest diameter of the implantation site.

## 5) Proximal Component Length

- Use the distance reference line to establish where the proximal edge of the component is on multiplanar reconstruction (MPR)/centreline.
- Calculate body length.
- The distal edge of the proximal component should be planned to land 20-35 mm above the aortic bifurcation.

## 6) Distal Component Length

- Select side for introduction.
- To maximise overlap with the proximal component, plan a preferred overlap of 50 mm (more, if possible) between the proximal and distal components.
- Use corrected centreline/MPR to select the appropriate component length:
  - a) The proximal edge of the distal component should land at least 20 mm below the lowest fenestration.
  - b) Length of the distal component should position the contralateral limb 5-10 mm above the aortic bifurcation.

## 7) Ipsilateral Limb of Distal Component

- Select a 28, 45 or 62 mm limb to land in the distal common iliac artery if suitable.
- Select diameter with an appropriate degree of oversizing: 12, 16, 20 or 24 mm.
- An additional limb may be required to extend to a suitable landing zone.

## 8) Contralateral Limb Extension Length

- Select an appropriate limb extension using corrected imaging to land in the distal common iliac artery.
- Allow **1-1.5 stent overlap** for proper overlap of the contralateral leg and the distal component contralateral limb.



## Appendix A - Manufacturing Constraints

### Small Fenestrations

- 6 x 6 mm or 6 x 8 mm.
- Distance from centre of fenestration to proximal edge of graft must be  $\geq 15$  mm.
- The distal edge of large and small fenestrations must not extend beyond the lower fenestration boundary as follows:

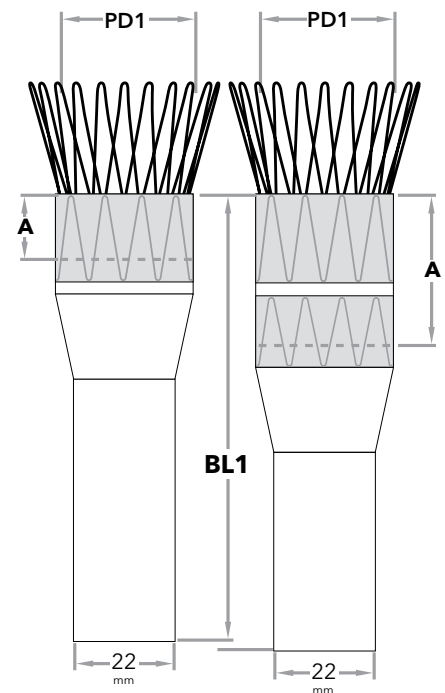
Diameter	One Internal Stent	Two Internal Stents
PD1 = 24-32 mm	$A \leq 16$ mm	$A \leq 36$ mm
PD1 = 34/36 mm	$A \leq 21$ mm	$A \leq 46$ mm

### Large Fenestrations

- Diameters range from 8-12 mm.
- Distance from centre of fenestration to proximal edge of graft must be  $\geq 10$  mm.

### Scallops

- Width = 10 mm.
- Height must range from 6-12 mm.



**Table 1**

Summary of Minimum Separation of a Combination of Small Fenestrations and Scallops

Inner Vessel Diameter	All Fenestration and Scallop Depths	
	Small Fenestration (6 x 8 mm)	Small Fenestration (6 x 6 mm)
15	2 hr 45 min	2 hr 45 min
16	2 hr 45 min	2 hr 30 min
17	2 hr 30 min	2 hr 30 min
18	2 hr 30 min	2 hr 15 min
19	2 hr 15 min	2 hr 15 min
20	2 hr 15 min	2 hr 15 min
21	2 hr	2 hr
22	2 hr	2 hr
23	2 hr	2 hr
24	1 hr 45 min	1 hr 45 min
25	1 hr 45 min	1 hr 45 min
26	1 hr 45 min	1 hr 45 min
27	1 hr 45 min	1 hr 45 min
28	1 hr 45 min	1 hr 30 min
29	1 hr 30 min	1 hr 30 min
30	1 hr 30 min	1 hr 30 min
31	1 hr 30 min	1 hr 30 min
32	1 hr 30 min	1 hr 30 min
33	1 hr 30 min	1 hr 15 min
34	1 hr 15 min	1 hr 15 min
35	1 hr 15 min	1 hr 15 min

## Appendix A - Manufacturing Constraints (cont.)

**Table 2**

Minimum Separation Between Two Small Fenestrations

Inner Vessel Diameter	Minimum Separation
15	2 hr 45 min
16	2 hr 30 min
17	2 hr 30 min
18	2 hr 15 min
19	2 hr 15 min
20	2 hr
21	2 hr
22	2 hr
23	1 hr 45 min
24	1 hr 45 min
25	1 hr 45 min
26	1 hr 45 min
27	1 hr 30 min
28	1 hr 30 min
29	1 hr 30 min
30	1 hr 30 min
31	1 hr 30 min
32	1 hr 30 min
33	1 hr 15 min
34	1 hr 15 min
35	1 hr 15 min

**Table 3**

Summary of Minimum Separation Centre of a Large Fenestration and Small Fenestration

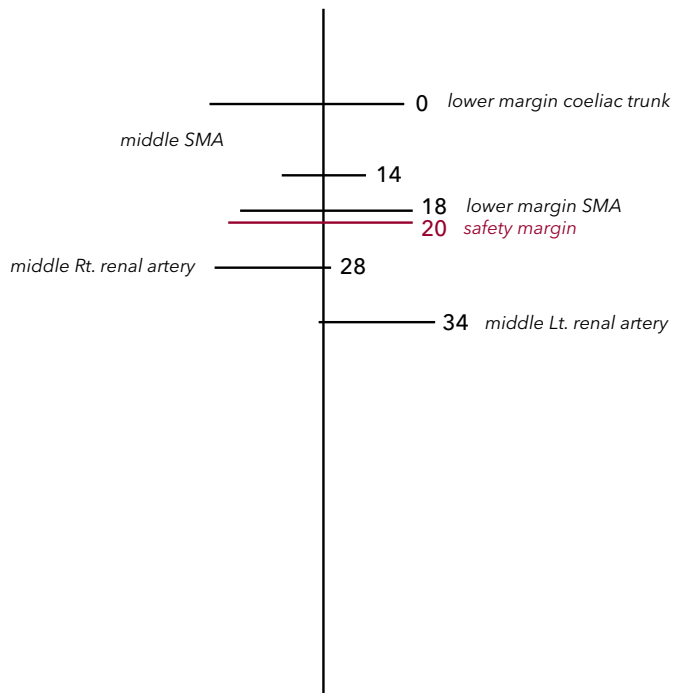
Inner Vessel Diameter	Large Fenestration Diameter		
	8	10	12
15	3 hr	3 hr 15 min	3 hr 30 min
16	2 hr 45 min	3 hr	3 hr 15 min
17	2 hr 45 min	3 hr	3 hr
18	2 hr 30 min	2 hr 45 min	3 hr
19	2 hr 30 min	2 hr 30 min	2 hr 45 min
20	2 hr 15 min	2 hr 30 min	2 hr 45 min
21	2 hr 15 min	2 hr 30 min	2 hr 30 min
22	2 hr	2 hr 15 min	2 hr 30 min
23	2 hr	2 hr 15 min	2 hr 15 min
24	2 hr	2 hr	2 hr 15 min
25	2 hr	2 hr	2 hr 15 min
26	1 hr 45 min	2 hr	2 hr
27	1 hr 45 min	2 hr	2 hr
28	1 hr 45 min	1 hr 45 min	2 hr
29	1 hr 45 min	1 hr 45 min	2 hr
30	1 hr 30 min	1 hr 45 min	1 hr 45 min
31	1 hr 30 min	1 hr 45 min	1 hr 45 min
32	1 hr 30 min	1 hr 45 min	1 hr 45 min
33	1 hr 30 min	1 hr 30 min	1 hr 45 min
34	1 hr 30 min	1 hr 30 min	1 hr 45 min
35	1 hr 30 min	1 hr 30 min	1 hr 30 min

## Appendix B - Distance Reference Line Examples

### Example 1

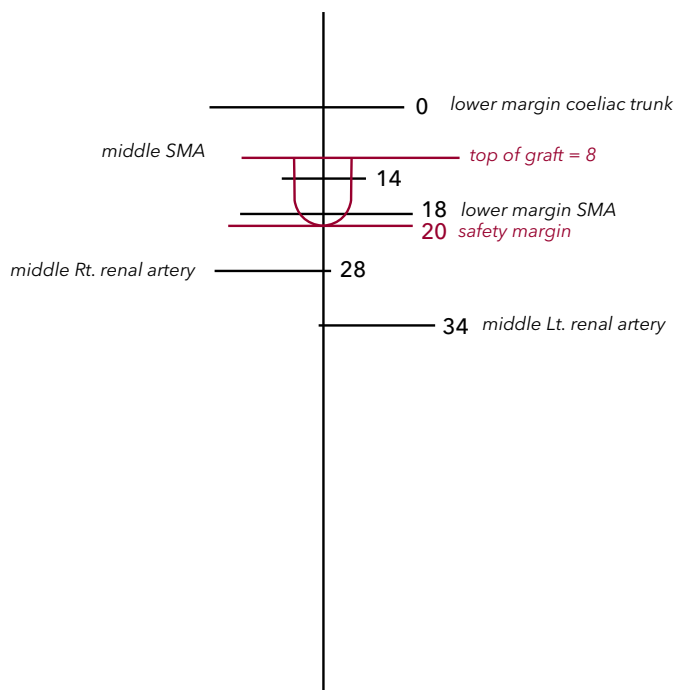
Step 1:

Measure 2 mm below the lower margin of the SMA.  
This is the safety margin.



Step 2:

Measure from the safety margin to the top of the scallop (e.g., 12 mm).  
This is the top of the graft (8 mm below the lower margin of the coeliac trunk).

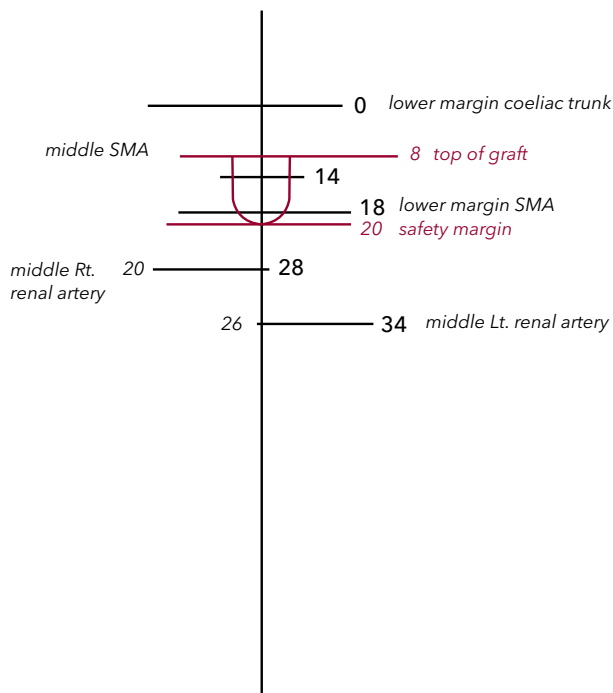


## Appendix B - Distance Reference Line Examples (cont.)

Step 3:

Measure from the top of the graft (8 mm) to the target vessels.

(Rt. =  $28 - 8 = 20$ /Lt. =  $34 - 8 = 26$ )



Step 4:

Transfer the measurements to the order form.

### REINFORCED SCALLOP FENESTRATION

All scallops are 10 mm wide.  
Height ranges from 6-12 mm.

	#1	#2
Height	12 mm	
Clock Position		

### REINFORCED LARGE FENESTRATION

Diameters are 8, 10 or 12 mm.  
Stent struts may cross large fenestration.  
Distance from centre to edge must be  $\geq 10$  mm.

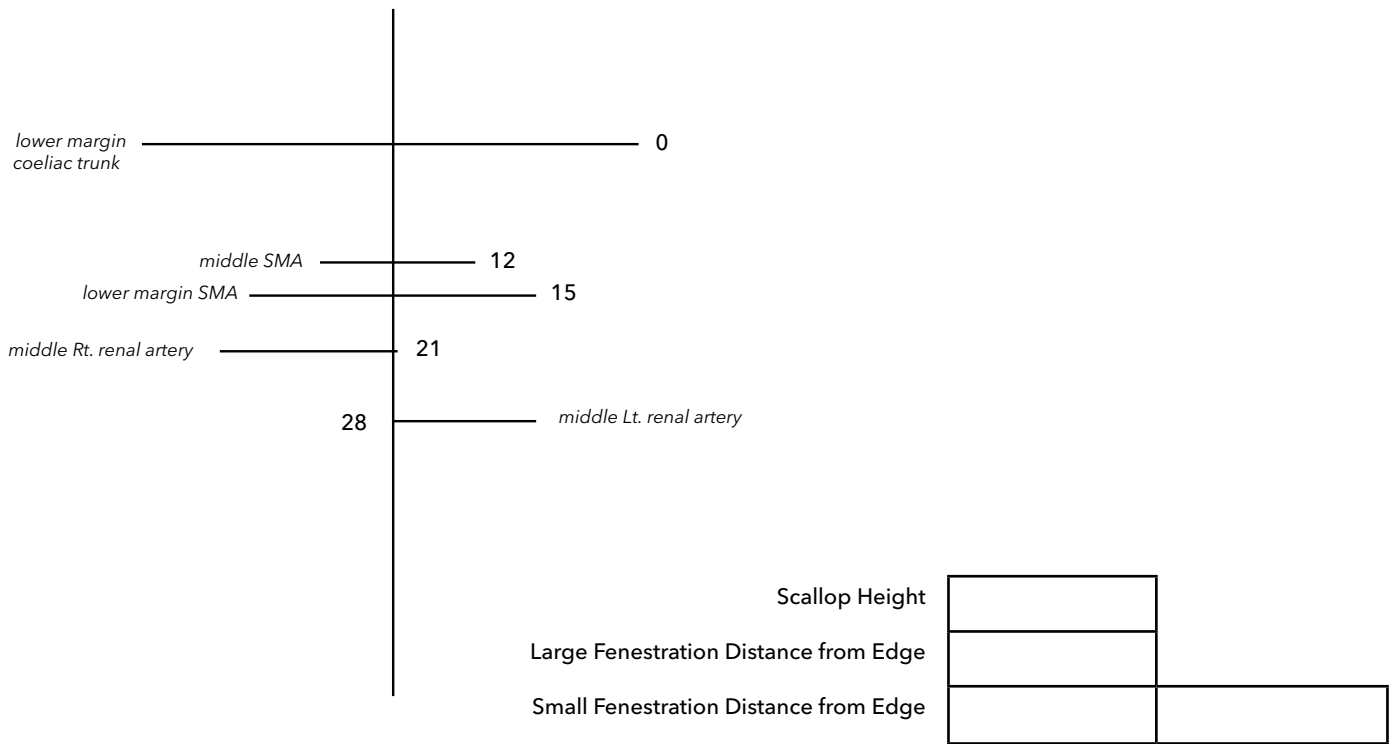
	#1	#2
Diameter		
Clock Position		
Distance from Edge		

### REINFORCED SMALL FENESTRATION

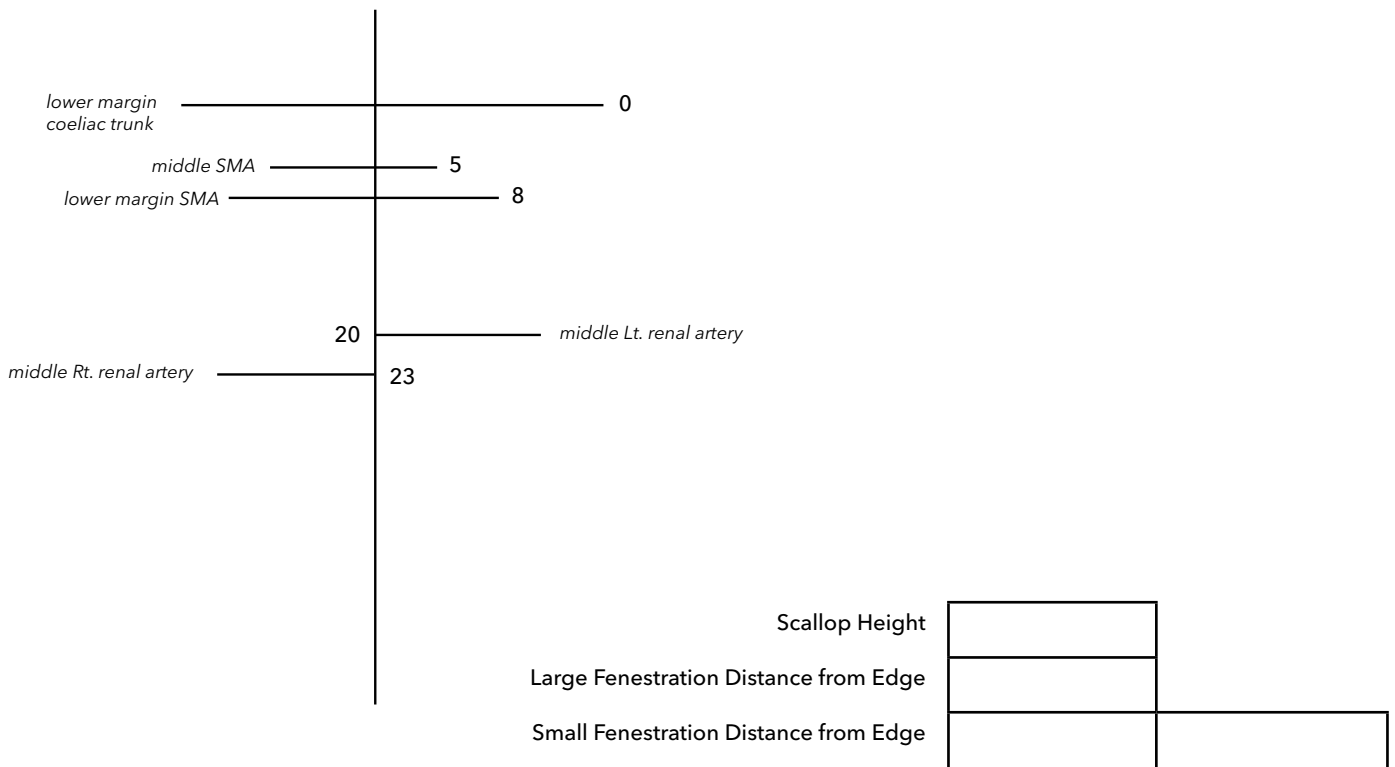
All small fenestrations are 6 mm wide.  
Heights are either 6 or 8 mm.  
Distance from centre to proximal edge must be  $\geq 15$  mm.

	#1	#2
Height		
Clock Position		
Distance from Edge	20 mm	26 mm

## Example 2

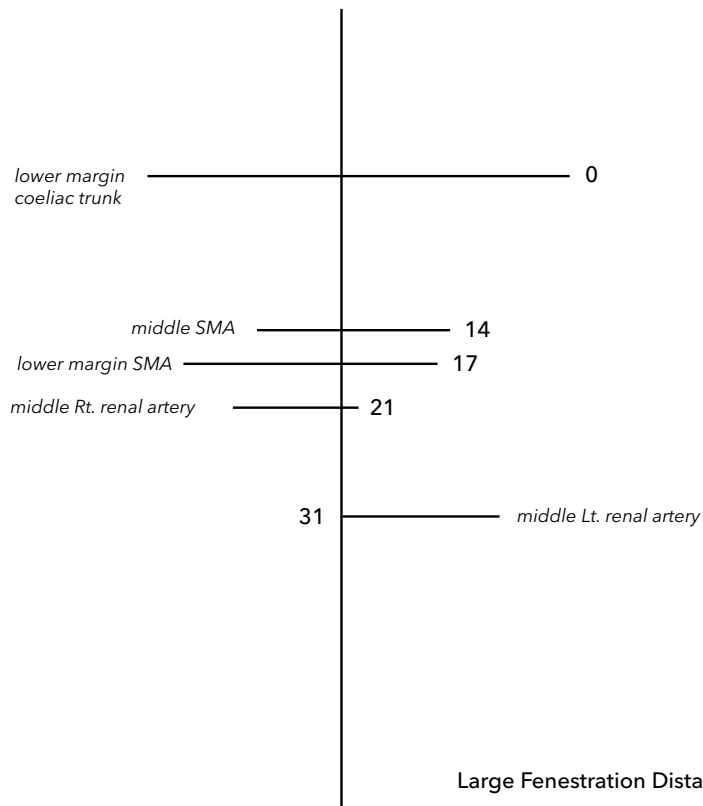


## Example 3



## Appendix B - Distance Reference Line Examples (cont.)

### Example 4



Scallop Height	
Large Fenestration Distance from Edge	
Small Fenestration Distance from Edge	

## Appendix C - IFU Guidelines for Planning & Sizing the Zenith Fenestrated AAA Endovascular Graft

### Indications for Use

Infrarenal abdominal aortic aneurysms (AAAs) in high-risk patients who are not suitable for conventional open surgical repair or who are not suitable for repair with a standard Zenith Endovascular Graft, when the aneurysmal disease extends up to the level of the renal arteries.

### Length

≥ 4 mm infrarenal (nonaneurysmal infrarenal neck)

### Aortic Fixation Site Diameter

19-31 mm (measured outer wall to outer wall)

### Angulation/Curvature

- Angle ≤ 45 degrees relative to the long axis of the aneurysm
- Angle ≤ 45 degrees relative to the axis of the suprarenal aorta

### Ipsilateral Iliac Fixation Site

Distal fixation site > 10 mm in length and 9-21 mm in diameter (measured outer wall to outer wall)

### Contralateral Iliac Fixation Site

Distal fixation site > 10 mm in length and 7-21 mm in diameter (measured outer wall to outer wall)

### Access

Adequate femoral/iliac access compatible with the required introduction systems

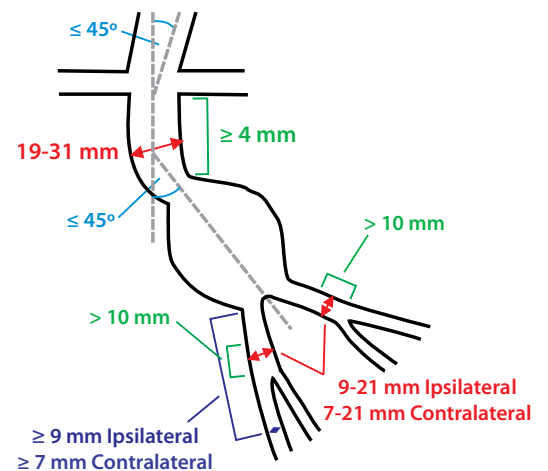
### Introducer Diameters

Proximal Body

- 24-34 mm graft = 20 Fr ID (6.9 mm), 7.8 mm OD
- 36 mm graft = 22 Fr ID (7.6 mm), 8.6 mm OD

Distal Body

- 20 Fr ID (6.9 mm), 7.8 mm OD











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