

Zenith Alpha™

ABDOMINAL ENDOVASCULAR GRAFT

DEVICE PLANNING AND SIZING WORKSHEET

Important

- Pre-existing stenosis/narrowing (< 20 mm aorta or 7 to 8 mm iliac) increases the risk of graft limb occlusion. Dilation (PTA balloon) and/or stenting of stenoses should be considered. Need for further treatment should be considered after post-procedure angiogram with stiff wire(s) removed. (Reference IFU 4.2)
- When a 42 or 59 mm leg graft is used on the ipsilateral side, contralateral leg overlap into the contralateral main body limb should be limited to 16 mm. (Reference IFU 4.1). Otherwise, an attempt to align the ipsilateral leg with the contralateral leg could result in deployment of the distal flared portion of the ipsilateral leg within the main body limb. The resulting graft compression and fabric infolding increases the risk for limb occlusion/thrombosis.
- If your leg graft diameter is 16, 20, or 24 mm and your ipsilateral vessel length is between 38-50 mm or 55-67 mm, we recommend using a shorter main body.
- Avoid excessive overlap of the leg grafts above the main body graft bifurcation. More than 12 mm of overlap (extension) above the bifurcation can increase risk of limb thrombosis. (Reference IFU 4.5)

Note: Strict adherence to the Planning and Sizing worksheet is strongly recommended when selecting the appropriate device size.

1

Date: _____ Patient ID: _____
 Hospital: _____
 Physician name: _____
 Physician phone: _____
 Physician e-mail: _____
 Physician signature: _____
 Purchase order number: _____

The plan based on the submitted data is to be taken as a suggestion only. It remains the responsibility of the physician to confirm measurements and to make the decision to proceed with this plan in whole, in part or not at all.

2

Anatomical measurements

Main body introduction site

- Right iliac External iliac (EI) measurement _____ mm
 Left iliac External iliac (EI) measurement _____ mm

(Measure the minimum diameters, measured inner wall to inner wall, from the introduction site to the aorta. Introduction system is 6 mm OD for 22-32 mm grafts and 6.5 mm OD for 36 mm grafts.)

Table position

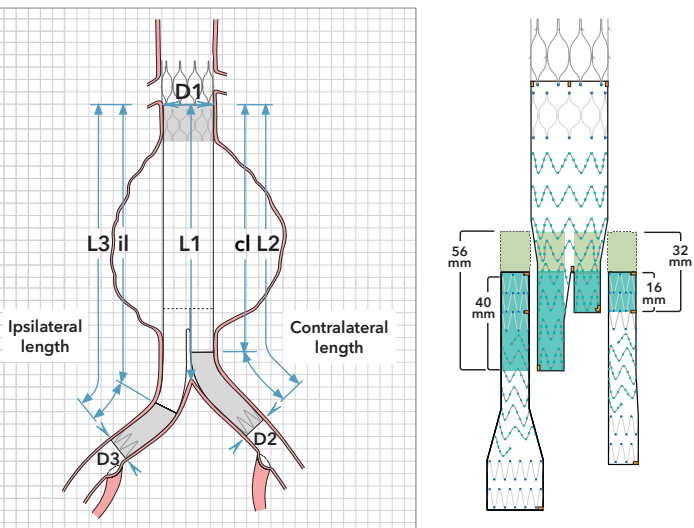
- _____ Lowest renal artery _____ Aortic bifurcation
 15 mm below the lowest renal artery; check for 10% increase in diameter. _____ Origin cl internal iliac
 _____ Origin il internal iliac

3

Diameters: D1 • D2 : D3 :

Lengths: L1 - L2 : L3 :

When using CT for length, approximate the lateral deviation (tortuosity) and add it to the difference in table position.



4

Main body (ZIMB)

Graft diameters

D1 mm	Graft diameter mm
18-19	22
20-21	24
22	26
23-24	28
25-26	30
27-28	32
29-32	36

Graft lengths

L1 mm	cl length mm	il length mm
75-88	70	94
89-102	84	108
103-112	98	122
113-122	108	132
123-132	118	142
133-142	128	152

Order number ZIMB - -
 Graft diameter cl length/graft length

5

Contralateral iliac leg (ZISL)

minus = _____
 L2 cl length Contralateral vessel length

Graft diameters

D2 mm	Graft diameter mm
8	9
9	11
10-12	13
13-15	16
16-18	20
19-20	24

16-32 mm overlap required

Graft lengths

Contralateral vessel length mm	Graft diameters mm	Label graft length mm	Total graft length mm
38-54	9-24	42	70
55-71	9-24	59	87
72-89	9-24	77	105
90-105	9-24	93	121
106-122	9-13	110	138
123-137	9-13	125	153

Order number ZISL - -
 Graft diameter Graft length

6

Ipsilateral iliac leg (ZISL)

minus = _____
 L3 cl length Ipsilateral vessel length

Graft diameters

D3 mm	Graft diameter mm
8	9
9	11
10-12	13
13-15	16
16-18	20
19-20	24

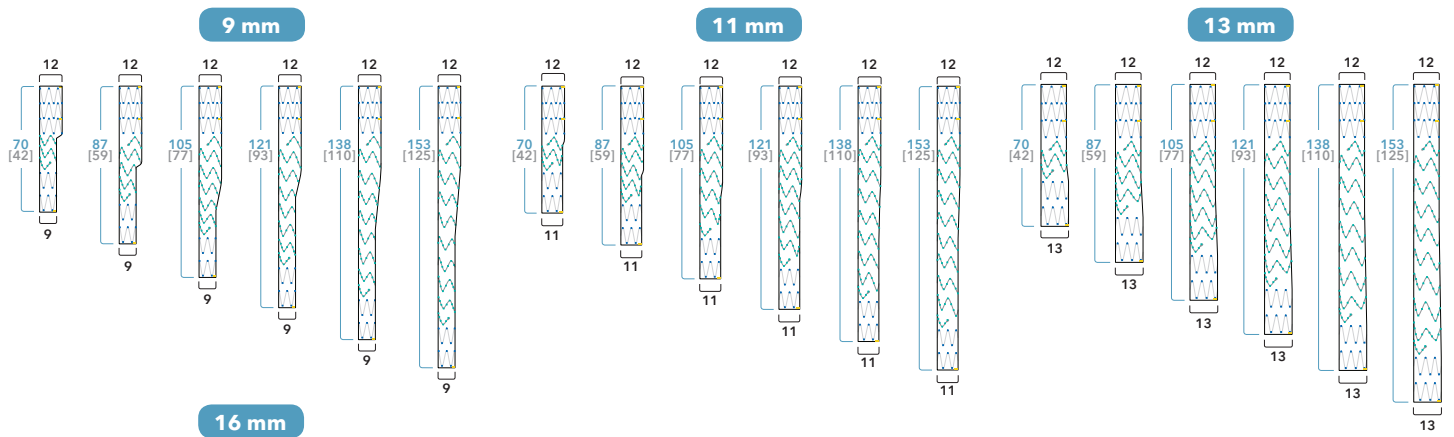
The proximal edge of the leg graft aligns closely with the proximal edge of the previously placed contralateral iliac leg graft.

Graft lengths

Ipsilateral vessel length mm	Graft diameters mm	Label graft length mm	Total graft length mm
38-54	9-13	42	70
51-54	16-24	42	70
55-71	9-13	59	87
68-71	16-24	59	87
72-89	9-24	77	105
90-105	9-24	93	121
106-122	9-13	110	138
123-137	9-13	125	153

Order number ZISL - -
 Graft diameter Graft length



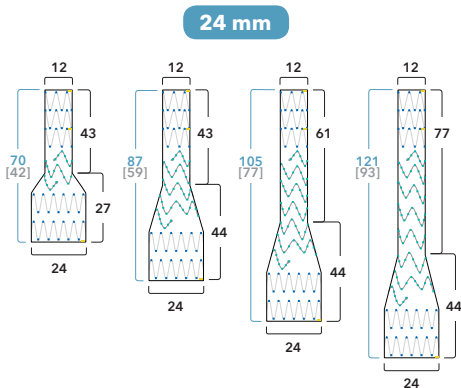
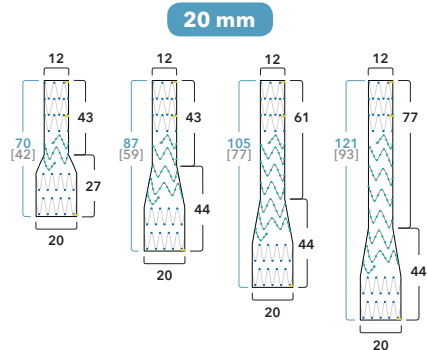
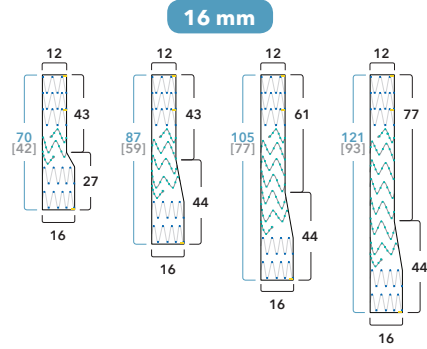
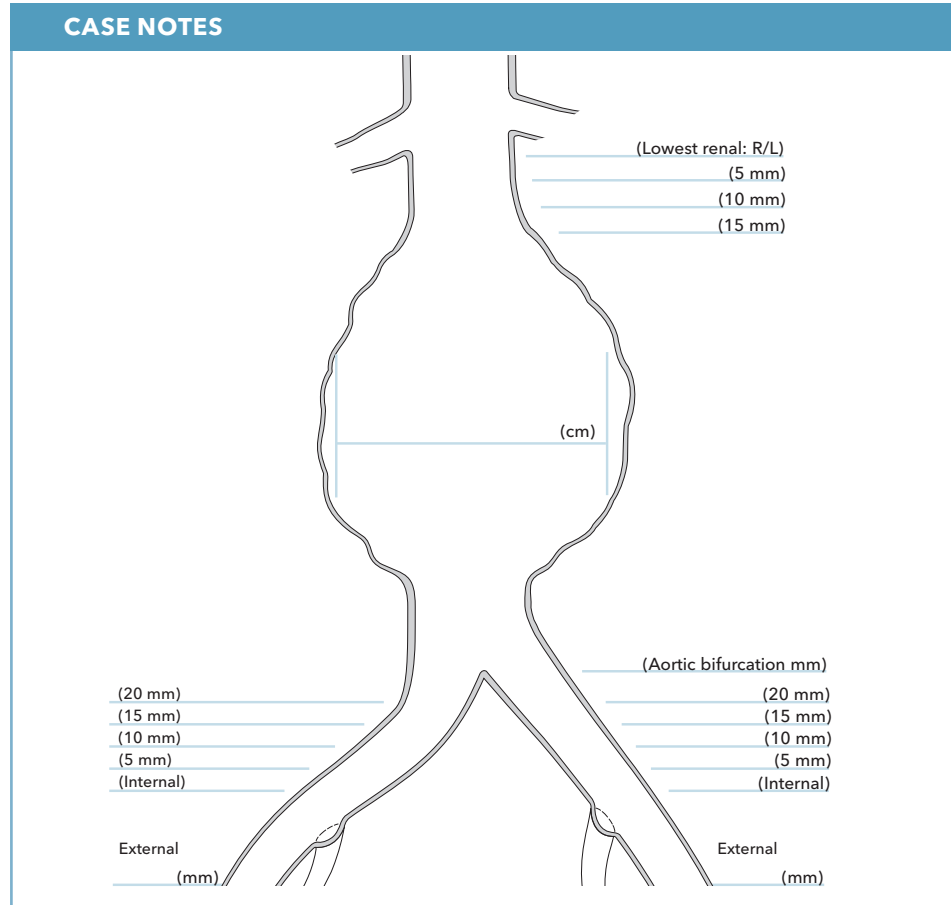


NOTE: All measurements are in millimeters. All numbers are for reference only.

NOTE: Overall graft length [label length].

Patient ID: _____

CASE NOTES



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