COOK MEDICAL

Zenith Flex®

AAA ENDOVASCULAR GRAFT

Transcend: Precision

Planning and Sizing

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

Planning and Sizing

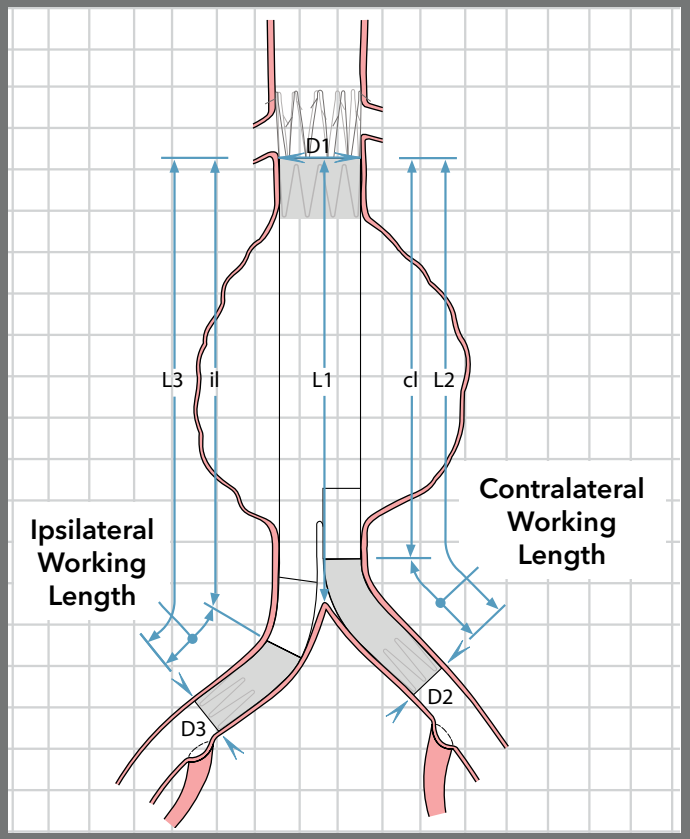
Obtain the recommended CT and angiography.

Follow these five recommended steps:

1. Select the side for main body introduction and fixation sites.
2. Obtain and note anatomical measurements on the worksheet.
3. Select the main body.
4. Select the contralateral iliac leg.
5. Select the ipsilateral iliac leg.

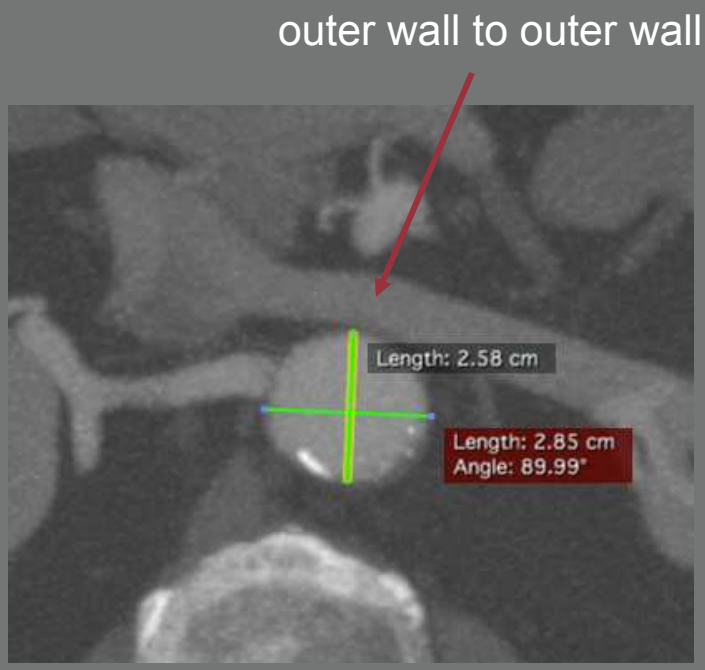
Measurements Needed

- Three diameters
  - D1, D2, D3
- Three lengths
  - L1, L2, L3



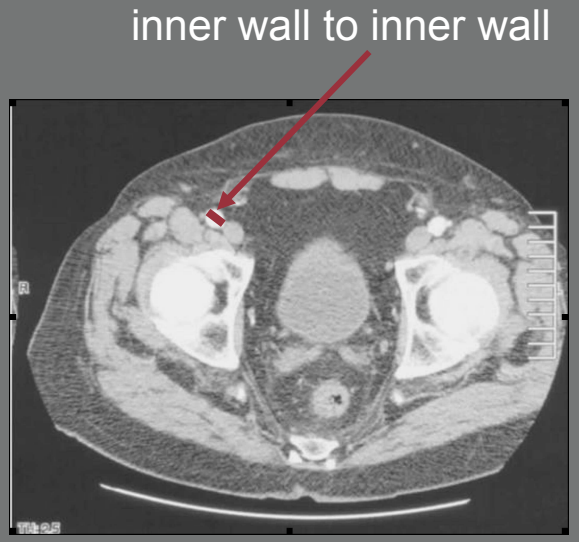
Diameter Measurements

D1, D2, D3: Proximal neck and common iliac diameters from axial CT images should be measured from outer wall to outer wall, using shortest axis.



Diameter Measurements

EI: External iliac diameters from axial CT images should be measured from inner wall to inner wall to assure delivery system access. Vessel should be compatible with delivery systems that are the profile of a 16-22 Fr introducer sheath.



Diameter Oversizing

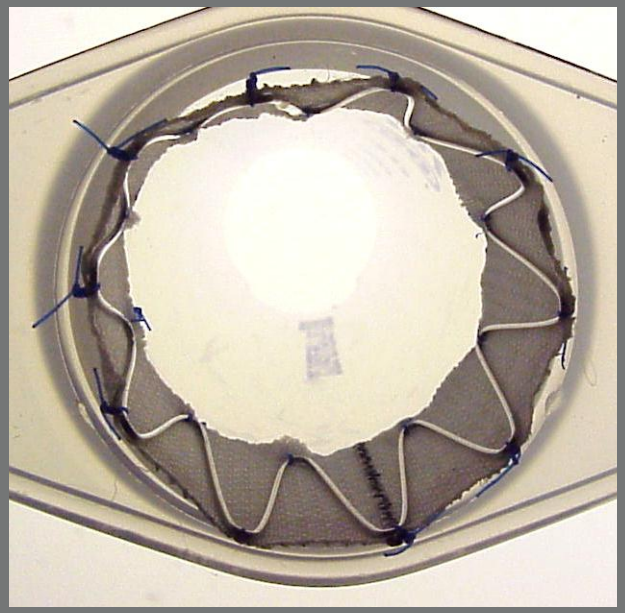
Diameters for components are oversized.

- Main body diameters are generally oversized 3-4 mm.
- Iliac leg diameters are generally oversized 1-2 mm.

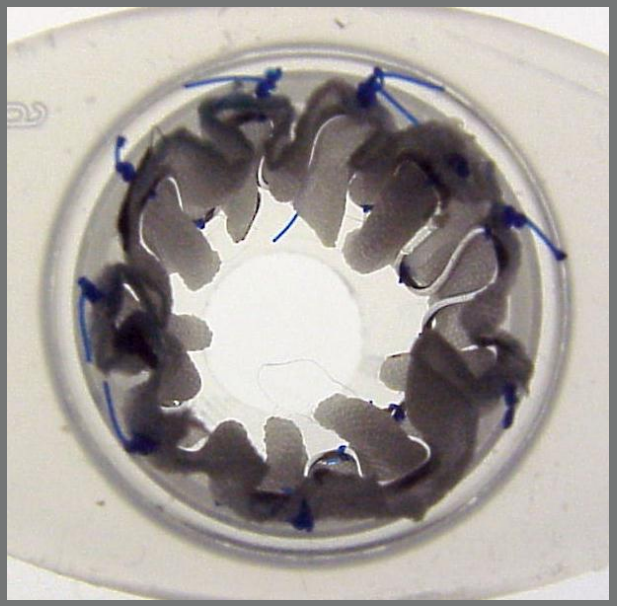
Use the sizing tables on the planning and sizing worksheet to select components with proper oversizing.

Diameter Oversizing

Undersizing



Too much oversizing



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Overlap

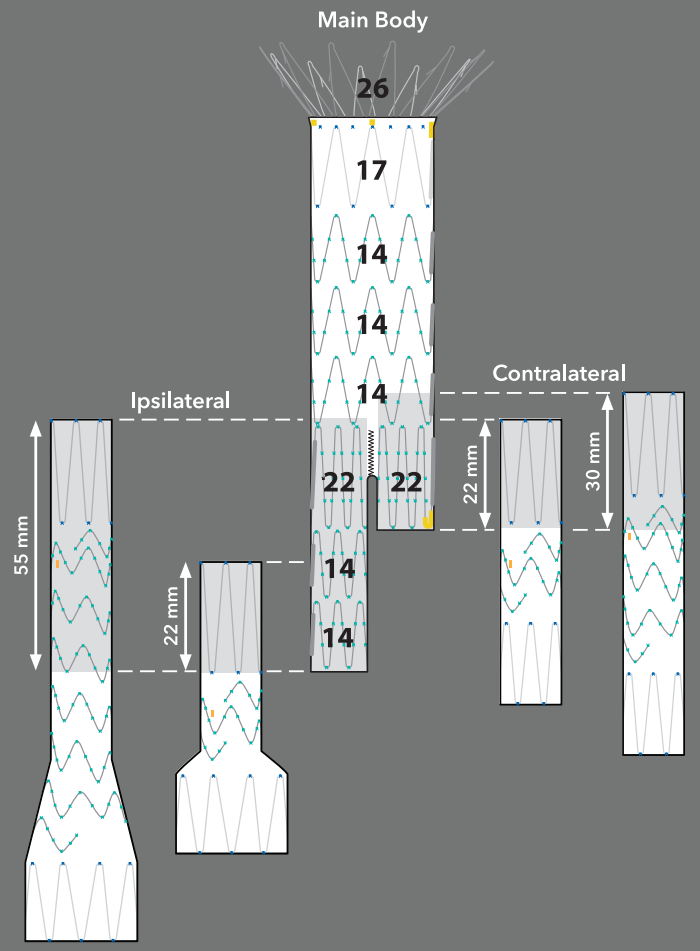
Contralateral

- 22 mm – 30 mm

Note: Maximum contralateral overlap denoted by radiopaque marker band.

Ipsilateral

- 22 mm – 30 mm (39 mm lengths)
- 22 mm – 55 mm (other lengths)



Lengths

Use CT scan and/or angiography with calibrated catheter.

Do not oversize lengths!

- Use actual lengths.
- If necessary, select shorter graft length.

Planning and Sizing Worksheet

COOK® MEDICAL **Zenith Flex®**
AAA ENDOVASCULAR GRAFT

DEVICE PLANNING AND SIZING WORKSHEET

Date: _____ Patient ID: _____
Hospital: _____
Physician Name: _____
Physician Phone #: _____
Physician E-mail: _____
Physician Signature: _____

Anatomical Measurements

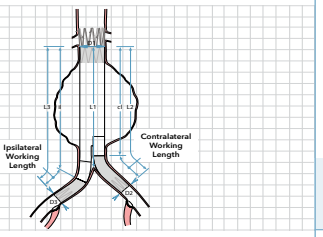
Main Body Introduction Site

❑ Right iliac — External iliac (EI) measurement _____mm
❑ Left iliac — External iliac (EI) measurement _____mm

Table Position

_____ Lowest renal artery
15 mm below lowest renal artery, check for 10% increase in diameter.

_____ Aortic bifurcation
_____ Origin cl internal iliac
_____ Origin il internal iliac



Diameters: D1 ____ D2 ____ D3 ____
Lengths: L1 ____ L2 ____ L3 ____

When using CT for length, approximate lateral deviation/tortuosity and add to difference in table position.
If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.

Main Body

Main Body 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 Diameters 22-32

L1 mm	cl Length[1] mm	il Length[2] mm
88-103	82	112
104-118	96	126
119-133	111	141
134-148	125	155
149-163	140	170
■	▪	▪▪

Graft Diameter 36

L1 mm	cl Length[1] mm	il Length[2] mm
101-120	95	125
121-139	113	143
140-158	131	161
159-177	149	179
■	▪	▪▪

[1]Main body length on contralateral side
[2]Main body length on ipsilateral side

Main Body Order Number = TFFB - ____ (Graft Diameter) - ____ (cl Length/ Graft Length) - ZT

Contralateral Spiral-Z™ AAA Iliac Leg

____ (L2) minus ____ (cl Length) = _____ (Contralateral Working Length)

Contralateral Leg (ZSLE) Diameters

D2 mm	Graft Diameter mm
≤ 8	9
9	11
10-12	13
13-15	16
16-18	20
19-20	24
●●	▲▲

Contralateral Leg (ZSLE) Lengths

Contralateral Working Length mm	Graft Length mm	Recommended Overlap mm
27-43	39[3]	22-30
44-60	56	22-30
61-77	74	22-30
78-94	90	22-30
95-111	107[4]	22-30
112-122	122[4]	22-30
	▪	

[3]Assure adequate distal fixation length.
[4]Graft lengths of 107 and 122 mm are available in 9-13 mm diameters only.

Contralateral Leg Order Number = ZSLE - ____ (Graft Diameter) - ____ (Graft Length) - ZT

Ipsilateral Spiral-Z AAA Iliac Leg

____ (L3) minus ____ (il Length) = _____ (Ipsilateral Working Length)

Ipsilateral Leg (ZSLE) Diameters

D3 mm	Graft Diameter mm
≤ 8	9
9	11
10-12	13
13-15	16
16-18	20
19-20	24
●●●	▲▲▲

Ipsilateral Leg (ZSLE) Lengths

Ipsilateral Working Length mm	Graft Length mm	Recommended Overlap mm
20-35 graft diameter 20-24	39	22-30
20-35 graft diameter 9-16	56	22-55
36-42	56	22-30
43-59	74	22-55
60-76	90	22-55
77-93	107[4]	22-55
94-122	122[4]	22-55
	▪▪	

[4]Graft lengths of 107 and 122 mm are available in 9-13 mm diameters only.

Ipsilateral Leg Order Number = ZSLE - ____ (Graft Diameter) - ____ (Graft Length) - ZT

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Step 1

- Select the side for main body introduction and fixation sites.
- Generally, place the main body through the side that has the best access vessel.
- Factors to consider (as per intended use in IFU):
  - Iliac tortuosity
  - Vessel diameter (EI)
  - Angulation of a distal neck
  - Aneurysmal sac orientation
  - Mural thrombus within the aneurysm
  - Iliofemoral disease (e.g., stenosis, calcification)
  - Iliac length (short iliac contralateral)
  - Iliac aneurysm (ipsilateral)

Zenith Worksheet

Anatomical Measurements

Main Body Introduction Site

❑ Right iliac External iliac (EI) measurement _____mm

❑ Left iliac External iliac (EI) measurement _____mm

Step 2

Obtain anatomical measurements.

- D1: Largest aortic neck diameter throughout 15 mm neck length
- D2: Largest iliac diameter throughout contralateral distal fixation site
- D3: Largest iliac diameter throughout ipsilateral distal fixation site
- L1: Lowest renal artery to aortic bifurcation, including lateral deviation
- L2: Lowest renal artery to contralateral distal fixation site, including lateral deviation
- L3: Lowest renal artery to ipsilateral distal fixation site, including lateral deviation

Zenith Worksheet

Table Position

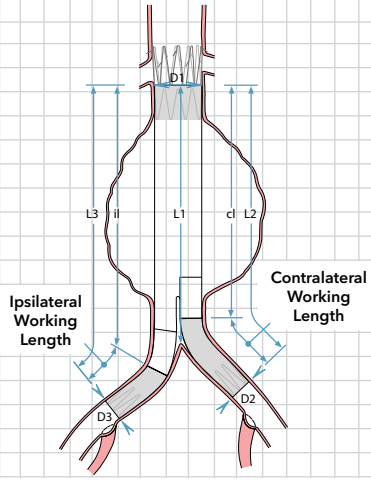
_____ Lowest renal artery

15 mm below lowest renal artery, check for 10% increase in diameter.

_____ Aortic bifurcation

_____ Origin cl internal iliac

_____ Origin il internal iliac



Diameters:	D1	22	D2	11	D3	14
Lengths:	L1	100	L2	155	L3	150

When using CT for length, approximate lateral deviation/tortuosity and add to difference in table position.

If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.

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Step 3

Select main body.

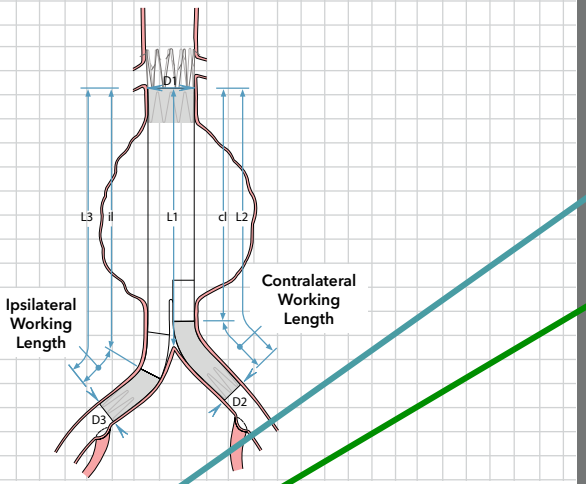
- From D1, select graft diameter. (Table includes oversizing.)
- From L1, select graft lengths. (Table provides contralateral [cl] and ipsilateral [il] lengths, and includes minimum of 5 mm clearance for cl limb.)
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly. (See manual.)

Zenith Worksheet

Table Position

_____ Lowest renal artery
15 mm below lowest renal artery, check for 10% increase in diameter.

_____ Aortic bifurcation
_____ Origin cl internal iliac
_____ Origin il internal iliac



Diameters:	D1	22	D2	11	D3	14
Lengths:	L1	100	L2	155	L3	150

When using CT for length, approximate lateral deviation/tortuosity and add to difference in table position.
If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.

Main Body

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Graft Diameters 22-32

L1 mm	cl Length[1] mm	il Length[2] mm
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104-118	96	126
119-133	111	141
134-148	125	155
149-163	140	170

Graft Diameter 36

L1 mm	cl Length[1] mm	il Length[2] mm
101-120	95	125
121-139	113	143
140-158	131	161
159-177	149	179

[1]Main body length on contralateral side
[2]Main body length on ipsilateral side

Main Body Order Number = TFFB - 26 - 82 - ZT

26 = Graft Diameter
82 = cl Length/ Graft Length

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Step 4

Select contralateral iliac leg.

- From D2, select graft diameter. (Table includes oversizing.)
- L1 − cl length = contralateral working length.
- Using contralateral working length, select graft length.
- Consider stent overlap and a secure fixation site.
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.

Zenith Worksheet

Contralateral Spiral-Z™ AAA Iliac Leg

155 (L2) minus 82 (cl Length) = 73 (Contralateral Working Length)

Contralateral Leg (ZSLE) Diameters

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

Contralateral Leg (ZSLE) Lengths

Contralateral Working Length mm	Graft Length mm	Recommended Overlap mm
27-43	39[3]	22-30
44-60	56	22-30
61-77	74	22-30
78-94	90	22-30
95-111	107[4]	22-30
112-122	122[4]	22-30

[3]Assure adequate distal fixation length.
[4]Graft lengths of 107 and 122 mm are available in 9-13 mm diameters only.

Contralateral Leg Order Number = ZSLE - 13 (Graft Diameter) - 74 (Graft Length) - ZT

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Step 5

Select ipsilateral iliac leg.

- From D3, select graft diameter. (Table includes oversizing.)
- L3 − il length = ipsilateral working length.
- Using ipsilateral working length, select graft length.
- Consider stent overlap and a secure fixation site.
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.

Zenith Worksheet

Ipsilateral Spiral-Z AAA Iliac Leg

150	minus	112	=	38
L3		il Length		Ipsilateral Working Length

Ipsilateral Leg (ZSLE) Diameters

D3 mm	Graft Diameter mm
≤ 8	9
9	11
10-12	13
13-15	16
16-18	20
19-20	24
●●●	▲▲▲

Ipsilateral Leg (ZSLE) Lengths

Ipsilateral Working Length mm	Graft Length mm	Recommended Overlap mm
20-35 graft diameter 20-24	39	22-30
20-35 graft diameter 9-16	56	22-55
36-42	56	22-30
43-59	74	22-55
60-76	90	22-55
77-93	107[4]	22-55
94-122	122[4]	22-55
	★★	

[4]Graft lengths of 107 and 122 mm are available in 9-13 mm diameters only.

Ipsilateral Leg Order Number = ZSLE - 16 (Graft Diameter) - 39 (Graft Length) - ZT

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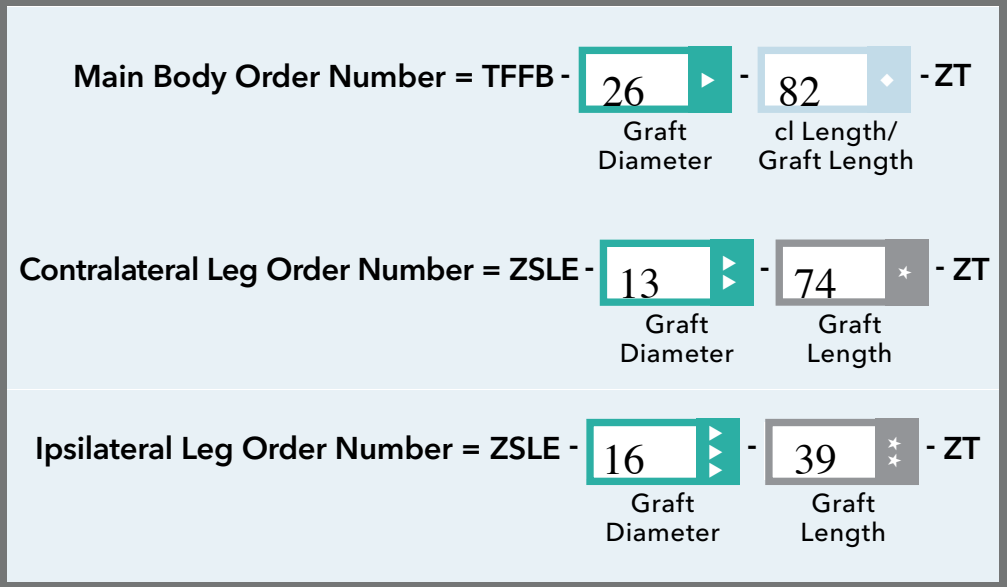
Devices to Order



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Final Step!

- Virtual “Retro-fit” on workstation
- Check landing zones, overlaps, sites of atheroma, tight curves etc.

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AAA ENDOVASCULAR GRAFT

Transcend: Precision

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