Zenith® Branch

ILIAC ENDOVASCULAR GRAFT

GUIDELINES FOR PLANNING AND SIZING

Note: These are general guidelines and should be used by physicians who have participated in the Zenith Branch Iliac Endovascular Graft Planning and Sizing Workshop. Refer to the Instructions for Use for a more thorough examination of the deployment protocol, MRI safety, indications for use, contraindications, warnings, and precautions.

Indications for Use and Patient Selection

The Zenith® Branch Iliac Endovascular Graft is indicated for the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with a 20 French (7.7 mm OD) introduction system.
- Non-aneurysmal external iliac artery fixation segment distal to the aneurysm:
  - With a length of at least 20 mm,
  - With a diameter measured outer wall to outer wall no greater than 11 mm and no less than 8 mm.
- Non-aneurysmal internal iliac artery segment distal to the aneurysm:
  - With a length of at least 10 mm (with 20-30 mm being preferred)
  - With a diameter acceptable for proper sealing.

Key anatomic elements that may affect successful exclusion of the aneurysm include tortuosity of any or all of the vessels involved, undersized or oversized iliac arteries, circumferential thrombus, aneurysm of the internal and/or external iliac artery and/or calcification of the arterial implantation sites. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites and the ability to advance the introducer systems. Diameter of the common iliac artery adjacent to the branch should be at least 16 mm. This allows for both the branch and device to open fully.[1]

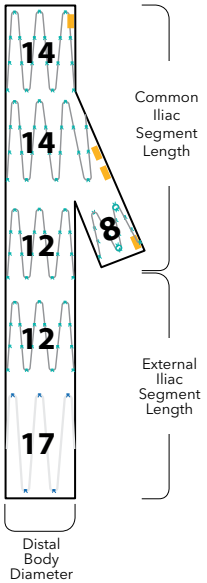
Selecting the Size of the Zenith® Branch Iliac Endovascular Graft, the Internal Iliac Covered Stent and the Bridging Stent Graft

Selecting the Size of the Zenith® Branch Iliac Endovascular Graft

There are two lengths of the common iliac segment of the graft (45 and 61 mm) and two lengths for the external iliac segment of the graft (41 and 58 mm). There are two diameters for the distal end of the device (10 mm and 12 mm).

The table below summarises the available lengths, diameters and sizes of the Zenith® Branch Iliac Endovascular Graft and delivery systems.

Order Number[1]	Reference Part Number	Proximal Body Diameter mm	Distal Body Diameter mm	Sidebranch Diameter[2] mm	Introduction Sheath ID/OD Fr(mm)/mm	Iliac Segment Length Common/External mm	Total Graft Length mm
G38612	ZBIS-10-45-41	12	10	8	20(6.7)/7.7	45/41	86
G38614	ZBIS-10-61-41	12	10	8	20(6.7)/7.7	61/41	102
G38613	ZBIS-10-45-58	12	10	8	20(6.7)/7.7	45/58	103
G38615	ZBIS-10-61-58	12	10	8	20(6.7)/7.7	61/58	119
G38616	ZBIS-12-45-41	12	12	8	20(6.7)/7.7	45/41	86
G38618	ZBIS-12-61-41	12	12	8	20(6.7)/7.7	61/41	102
G38617	ZBIS-12-45-58	12	12	8	20(6.7)/7.7	45/58	103
G38344	ZBIS-12-61-58	12	12	8	20(6.7)/7.7	61/58	119



[1]ZBIS-XX-YY-ZZ is the Zenith Branch Iliac Endovascular Graft where XX is distal diameter, YY is the Common Iliac Segment Length (length from the proximal graft edge to the tip of the sidebranch), and ZZ is the External Iliac Segment Length (length from the tip of the sidebranch to distal edge of the graft).

[2]Sidebranch contains a 6 mm diameter nitinol z-stent, but should be expanded to 8 mm during balloon-expandable covered peripheral stent deployment.

1. Common Iliac Segment Length

Choose the common iliac segment length so that the graft will not extend into the aorta over the aortic bifurcation. Please take into account that the distal end of the branch has to be placed 10 mm above origin of internal iliac artery.

2. External Iliac Segment Length

Select the external iliac segment length that will provide you the best landing zone.

1. Data on file.

Not all part numbers shown on this product information sheet may be approved for sale in all regulatory jurisdictions. Consult with your local Cook representative or customer service center for details.

3. Distal/External Diameter

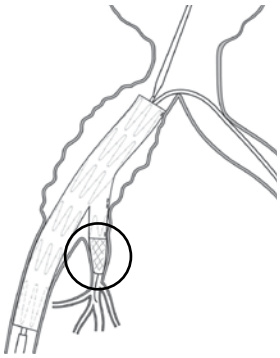
The choice of diameter should be determined from the outer wall to outer wall vessel diameter and not the lumen diameter. Undersizing or oversizing may result in incomplete sealing or compromised flow.

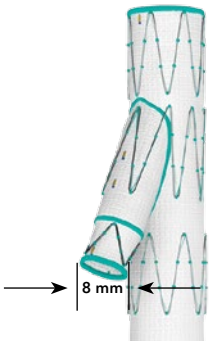
The table below indicates the appropriate diameter of the Zenith® Branch Iliac Endovascular Graft external iliac leg for the intended external iliac vessel diameter.*

Intended External Iliac Vessel Diameter[1,2] mm	Branch External Iliac Leg Diameter[3] mm	Introduction Sheath ID/OD Fr(mm)/mm
8	10	20(6.7)/7.7
9	10	20(6.7)/7.7
10	12	20(6.7)/7.7
11	12	20(6.7)/7.7

[1]Maximum diameter along the distal fixation site.
[2]Round measured iliac diameter to nearest mm.
[3]Additional considerations may affect choice of diameter.
*** All dimensions are nominal.**

Selecting the Size of the Internal Iliac Artery Balloon-Expandable Covered Peripheral Stent





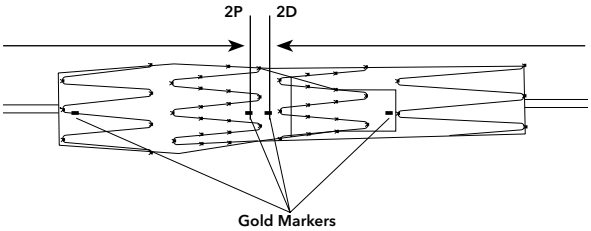
1. Diameter of the Covered Peripheral Stent

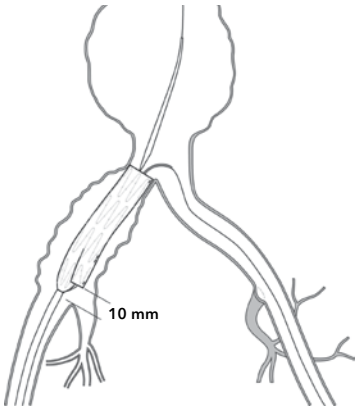
As the sidebranch diameter is 8 mm (the sidebranch contains a 6 mm nitinol z-stent) , the balloon-expandable covered peripheral stent must expand to 8 mm in the sidebranch of the Zenith® Branch Iliac Endovascular Graft, but should be sized to the internal iliac artery according to the manufacturer's instructions.

2. Length of the Covered Peripheral Stent

The length of the peripheral stent should be long enough to provide at least 10 mm overlap in the side branch device and at least 10 mm in the internal iliac artery (preferably 20-30 mm).

The peripheral stent should land no further proximally than marker 2D in the sidebranch device.

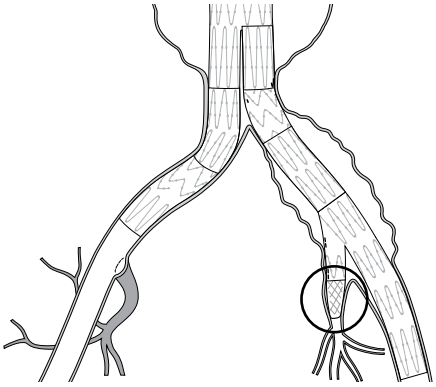


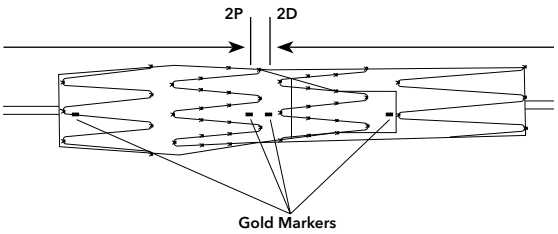


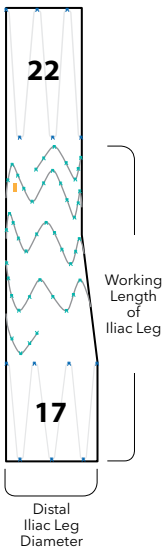
Note: The sidebranch is intended to open approximately 10 mm above origin of internal iliac artery, and this distance should be accounted for when determining the length of the internal iliac bridging stent.

Selecting the Size of the Bridging/Connecting ZSLE

The Zenith® Branch Iliac Endovascular Graft is intended to be used in conjunction with a Zenith® AAA Endovascular Graft.







The bifurcated main body device is connected to the Zenith® Branch Iliac Endovascular Graft on its contralateral side by a standard Zenith® Spiral-Z® AAA Iliac Leg Graft (ZSLE) with a distal diameter of 16 mm.

The distal landing point of the ZSLE will be at marker 2P.

For a Zenith® Branch Iliac Endovascular Graft with a:

- Common Iliac length of 45 mm, the distance to 2P is approximately 23 mm. This length needs to be subtracted from the iliac leg working length (see table below) when selecting the length of the ZSLE bridging stent graft.
- Common Iliac length of 61 mm, the distance to 2P is approximately 39 mm. This length needs to be subtracted from the iliac leg working length (see table below) when selecting the length of the ZSLE bridging stent graft.

Order Number[1]	Reference Part Number	Iliac Leg Diameter mm	Introduction Sheath ID/OD Fr(mm)/mm	Iliac Leg Working Length[2] mm
G55236	ZSLE-16-39-ZT	16	14(4.7)/5.4	39
G55237	ZSLE-16-56-ZT	16	14(4.7)/5.4	56
G55238	ZSLE-16-74-ZT	16	14(4.7)/5.4	74
G55239	ZSLE-16-90-ZT	16	14(4.7)/5.4	90

[1]ZSLE-XX-YY is the iliac leg where XX is the diameter and YY is the length.
[2]Overall leg length = working length + 22 mm docking stent.

The table below summarises the overlaps required with the bridging ZSLE stent graft, to assist in selecting the appropriate length of the ZSLE.

Overlap into the contralateral limb of the Zenith® AAA graft	Minimum 22 mm Maximum 30 mm
Overlap into the body of the Zenith® Branch Iliac Endovascular Graft	Minimum 23 mm Maximum of no further than the second marker on the proximal end of the device.

Customer Service

EU Website: cookmedical.eu
EDI: cookmedical.eu/edi
Distributors: +353 61239240, ssc.distributors@cookmedical.com
Austria: +43 179567121, oe.orders@cookmedical.com
Belgium: +32 27001633, be.orders@cookmedical.com
Denmark: +45 38487607, da.orders@cookmedical.com
Finland: +358 972519996, fi.orders@cookmedical.com
France: +33 171230269, fr.orders@cookmedical.com
Germany: +49 6950072804, de.orders@cookmedical.com
Hungary: +36 17779199, hu.orders@cookmedical.com
Ireland: +353 61239252, ie.orders@cookmedical.com
Italy: +39 0269682853, it.orders@cookmedical.com
Netherlands: +31 202013367, nl.orders@cookmedical.com
Norway: +47 23162968, no.orders@cookmedical.com
Spain: +34 912702691, es.orders@cookmedical.com
Sweden: +46 858769468, se.orders@cookmedical.com
Switzerland – French: +41 448009609, fr.orders@cookmedical.com
Switzerland – Italian: +41 448009609, it.orders@cookmedical.com
Switzerland – German: +41 448009609, de.orders@cookmedical.com
United Kingdom: +44 2073654183, uk.orders@cookmedical.com

USA Website: cookmedical.com
EDI: cookmedical.com/edi.do

Americas:
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com

Australia:
Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283
E-mail: cau.custserv@cookmedical.com-A4

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