

Zenith® Branch

ILIAC ENDOVASCULAR GRAFT

GUIDELINES FOR PLANNING AND SIZING

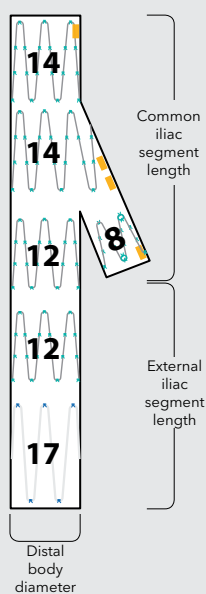
Note: These are general guidelines and should be used by physicians who have participated in the Zenith Branch Endovascular Graft - Iliac Bifurcation Planning and Sizing Workshop.

Indications for use and patient selection

The Zenith Branch Endovascular Graft - Iliac Bifurcation 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 morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with a 20 Fr (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 (The preferred length is 20-30 mm.)
 - With a diameter acceptable for proper sealing
 - The diameter of the common iliac artery adjacent to the branch should be at least 16 mm. This allows for the branch and the device to open fully.

The 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.



The table below summarises the available lengths and diameters of the Zenith Branch Endovascular Graft - Iliac Bifurcation and its delivery system.

Order Number	Reference Part Number ¹	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. Reference part numbers follow a formula of ZBIS-XX-YY-ZZ, where XX is distal body diameter, YY is the common iliac segment length (the length from the proximal graft edge to the tip of the sidebranch), and ZZ is the external iliac segment length (the length from the tip of the sidebranch to the distal edge of the graft).

2. The sidebranch contains a 6 mm diameter nitinol z-stent, but should be expanded to 8 mm during balloon-expandable covered bridging stent deployment.

Selecting the size of the Zenith Branch Endovascular Graft - Iliac Bifurcation

The common iliac segment comes in two lengths (45 and 61 mm), and the external iliac segment also comes in two lengths (41 and 58 mm). The distal body comes in two diameters (10 and 12 mm).

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 the origin of the internal iliac artery.

2. External iliac segment length

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

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

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3. Distal/external diameter

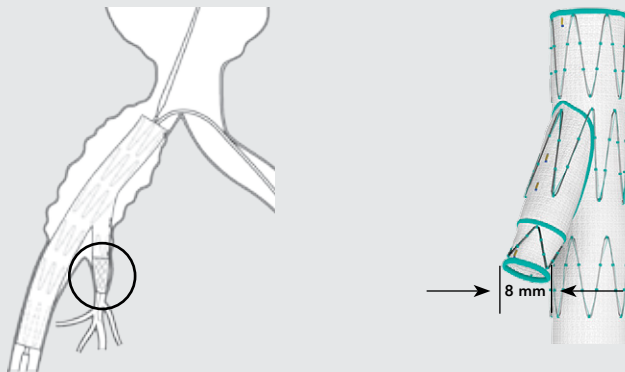
The choice of diameter should be determined by measuring vessel diameter the (outer wall to outer wall), not the lumen diameter. Undersizing or oversizing may result in an incomplete seal or compromised flow.

The table below indicates the appropriate diameter of the Zenith Branch Endovascular Graft - Iliac Bifurcation external iliac leg for the intended external iliac vessel diameter.¹

Intended External Iliac Vessel Diameter ^{2,3} mm	Branch External Iliac Leg Diameter ⁴ 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. All dimensions are nominal.
2. Use the maximum diameter along the distal fixation site.
3. Round the measured iliac diameter to the nearest mm.
4. Additional considerations may affect choice of diameter.

Selecting the size of the internal iliac artery balloon-expandable covered bridging stent



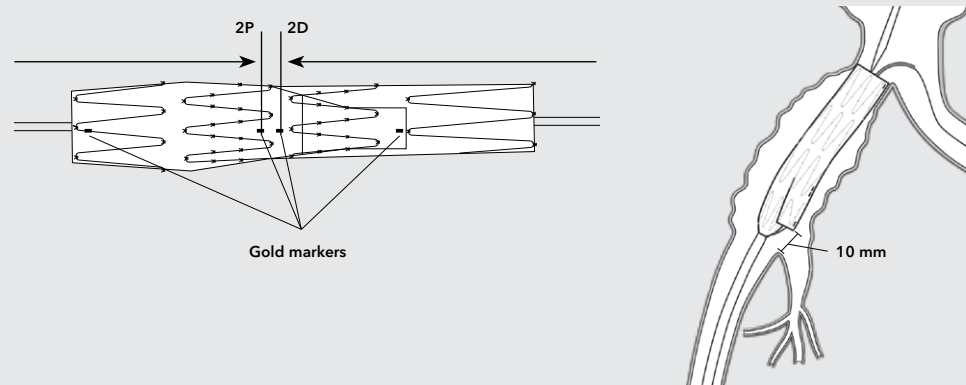
1. Diameter of the covered bridging stent

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

2. Length of the covered bridging stent

The balloon-expandable bridging stent should be long enough to provide at least 10 mm of overlap in the sidebranch device and at least 10 mm in the internal iliac artery (preferably 20-30 mm).

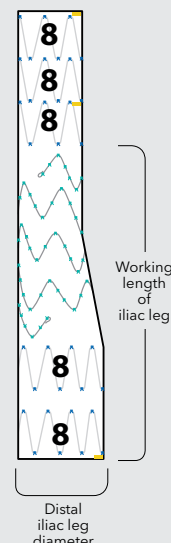
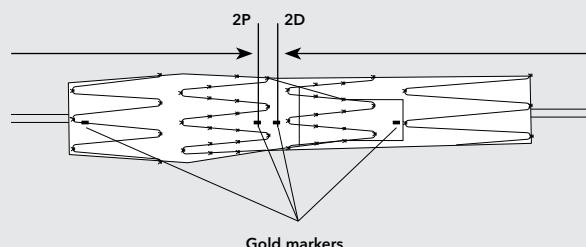
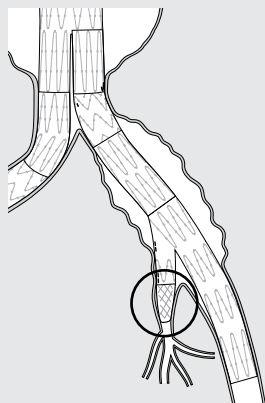
The covered bridging stent should land no further proximally than marker 2D in the sidebranch device.



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

Selecting the size of the bridging/connecting Zenith Alpha™ Spiral-Z® Endovascular Leg Graft

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



The bifurcated Zenith Alpha Abdominal Endovascular Graft (ZIMB) is connected to the contralateral side of the Zenith Branch Endovascular Graft - Iliac Bifurcation by a standard Zenith Alpha Spiral-Z Endovascular Leg Graft (ZISL) with a distal diameter of 16 mm.

The distal landing point of the ZISL in the common iliac segment length of 45 mm will be at marker 2P.

The distal landing point of the ZISL in the common iliac segment length of 61 mm will be between 23 mm and marker 2P (39 mm).

For a Zenith Branch Endovascular Graft - Iliac Bifurcation 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 the table below) when selecting the length of the ZISL.
- 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 the table below) when selecting the length of the ZISL.

Order Number	Reference Part Number ¹	Iliac Leg Diameter mm	Introduction Sheath ID/OD Fr(mm)/mm	Iliac Leg Working Length ² mm
G35971	ZISL-16-42	16	12(4.0)/4.7	42
G35972	ZISL-16-59	16	12(4.0)/4.7	59
G35973	ZISL-16-77	16	12(4.0)/4.7	77
G35975	ZISL-16-93	16	12(4.0)/4.7	93

1. Reference part numbers follow a formula of ZISL-XX-YY, where XX is the diameter and YY is the working length.

2. The overall iliac leg length is equal to the working length plus the 28 mm long docking stent.

The table below summarises the overlap lengths that are required when bridging the ZISL, in order to assist you in selecting the appropriate length of the ZISL.

Overlap into the contralateral limb of the Zenith AAA Endovascular Graft	Minimum 16 mm Maximum 32 mm
Overlap into the body of the Zenith Branch Endovascular Graft - Iliac Bifurcation	Minimum 23 mm * The ZISL should overlap no further than the second marker on the proximal end of the device.

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