

# Zenith® Iliac Branch

## GUIDELINES FOR PLANNING AND SIZING

Note: These are general guidelines. 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 Iliac Branch, when used with the necessary additional components (Zenith AAA devices and a covered bridging stent), is indicated for endovascular treatment of aortoiliac or iliac aneurysms to preserve internal iliac arterial blood flow when the distal sealing site in the common iliac artery is insufficient for the AAA device alone and when the vessel morphology is suitable for repair, including:

- Common iliac artery diameter at the level of the internal iliac artery (luminal diameter)  $\geq 16$  mm
- 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 of 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 measured outer wall to outer wall no greater than 10 mm and no less than 7 mm

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.

### Selecting the size of the Zenith Iliac Branch, the bridging/connecting Zenith Spiral-Z® AAA Iliac Leg Graft (ZSLE), and the covered stent (e.g., Getinge iCast® covered stent)

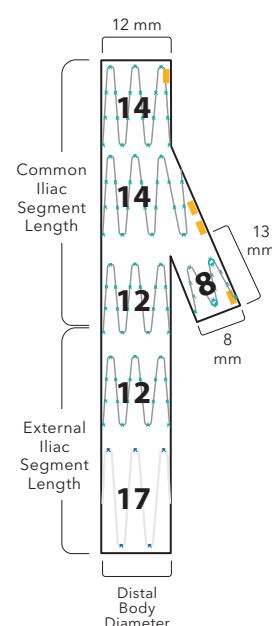
#### Selecting the size of the Zenith Iliac Branch

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 and 12 mm). The diameter of the common iliac artery adjacent to the branch should be at least 16 mm.

The table below summarizes the available lengths and diameters of the Zenith Iliac Branch and delivery systems.

Order Number	Reference Part Number <sup>1</sup>	Distal Body Diameter mm	Common Iliac Segment Length mm	External Iliac Segment Length mm	Introduction Sheath ID/OD Fr (mm)/mm	Total Graft Length mm
G60340	ZBIS-10-45-41-US	10	45	41	20(6.7)/7.7	86
G60342	ZBIS-10-61-41-US	10	61	41	20(6.7)/7.7	102
G60344	ZBIS-12-45-41-US	12	45	41	20(6.7)/7.7	86
G60345	ZBIS-12-61-41-US	12	61	41	20(6.7)/7.7	102
Nonstock						
G60341	ZBIS-10-45-58-US	10	45	58	20(6.7)/7.7	103
G60343	ZBIS-10-61-58-US	10	61	58	20(6.7)/7.7	119
G60346	ZBIS-12-45-58-US	12	45	58	20(6.7)/7.7	103
G60347	ZBIS-12-61-58-US	12	61	58	20(6.7)/7.7	119

1. ZBIS-XX-YY-ZZ-US is the Zenith Iliac Branch where XX is the distal body 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 the distal edge of the graft).



1. Distal body diameter (DBD)

The choice of diameter should be determined from the outer-wall-to-outer-wall vessel diameter of the external iliac artery (EIA) fixation segment 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 Iliac Branch external iliac leg for the intended external iliac vessel diameter.\*

External Iliac Artery Target Vessel Diameter <sup>1,2</sup> mm	Branch External Iliac Leg Graft Diameter <sup>3</sup> mm	Introduction Sheath ID/OD Fr (mm)/mm
8-9	10	20(6.7)/7.7
10-11	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.

2. Common iliac segment length

Ensure the graft system is oriented such that the distal end of the internal iliac segment (as indicated by the most distal radiopaque marker) is positioned 10 mm proximal to the proximal edge of the internal iliac artery orifice with rotational orientation to allow easy access into the internal iliac artery with minimal angulation of the bridging stent. If the radiopaque markers are not in the appropriate position, rotate the entire system until the markers are in line with the internal iliac artery orifice and/or advance or withdraw the system as necessary.

3. External iliac segment length

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

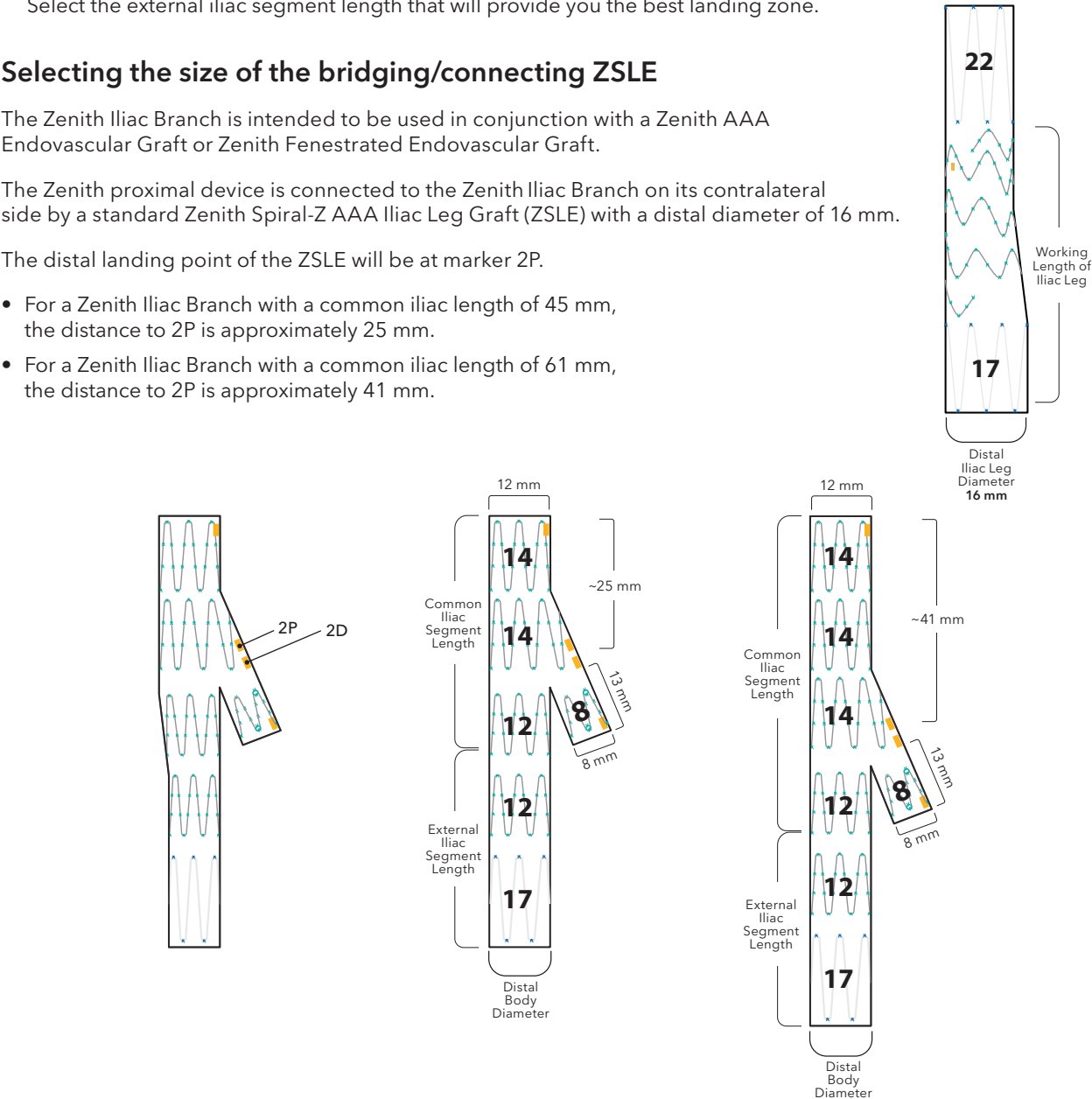
Selecting the size of the bridging/connecting ZSLE

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

The Zenith proximal device is connected to the Zenith Iliac Branch 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 Iliac Branch with a common iliac length of 45 mm, the distance to 2P is approximately 25 mm.
- For a Zenith Iliac Branch with a common iliac length of 61 mm, the distance to 2P is approximately 41 mm.



Order Number	Reference Part Number <sup>1</sup>	Iliac Leg Diameter mm	Introduction Sheath ID/OD Fr(mm)/mm	Iliac Leg Working Length <sup>2</sup> 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-ZT is the iliac leg where XX is the diameter and YY is the working length.

2. Overall leg length = working length + 22 mm docking stent.

The table below summarizes 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 proximal device	Minimum 1 ¼ stents Maximum 1 ¾ stents
Overlap into the body of the Zenith Iliac Branch	Minimum 1 ½ stents Maximum of no further than the second marker (2P) on the proximal end of the device

## Selecting the size of the covered stent

### 1. Diameter of the covered stent

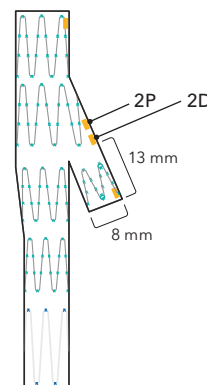
The sidebranch diameter is 8 mm. The covered stent should expand to a minimum of 8 mm in the sidebranch. The covered stent should be sized to the internal iliac artery according to the manufacturer's instructions. Additional ballooning may be required.

### 2. Length of the covered stent

The covered stent should be of sufficient length to overlap 10-14 mm with the sidebranch segment and 10 mm (with 20-30 mm being preferred) with the distal fixation site in the internal iliac artery.

The covered stent should land no further proximally than the third 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 covered stent.



## Getinge iCast® covered stent system specifications

Cook Order Number	Cook RPN/ Getinge Iliac Code	Diameter (mm)	Length (mm)	Post Nominal Pressure 8 ATM mm		Post Burst Rate Pressure 12 ATM mm		Introducer Sheath Fr
				OD	Length	OD	Length	
iCast covered stent–80 cm Catheter Length								
G60492	48838	8	38	8.1	34.7	8.5	34.7	7
G60493	48859	8	59	8.0	56.0	8.4	56.5	7
G60494	48938	9	38	8.9	33.7	9.3	32.7	7
G60495	48959	9	59	8.9	54.6	9.3	54.0	7
G60513	48038	10	38	10.0	30.8	10.4	30.9	7*
iCast covered stent–120 cm Catheter Length								
G60509	42838	8	38	8.1	34.7	8.5	34.7	7
G60510	42859	8	59	8.0	56.0	8.4	56.5	7
G60511	42938	9	38	8.9	33.7	9.3	32.7	7
G60512	42959	9	59	8.9	54.6	9.3	54.0	7
G60513	42038	10	38	10.0	30.8	10.4	30.9	7*

\*If using a 10 mm device with a Cook introducer sheath, it is recommended to use an 8 Fr sheath to minimize potential for resistance.

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