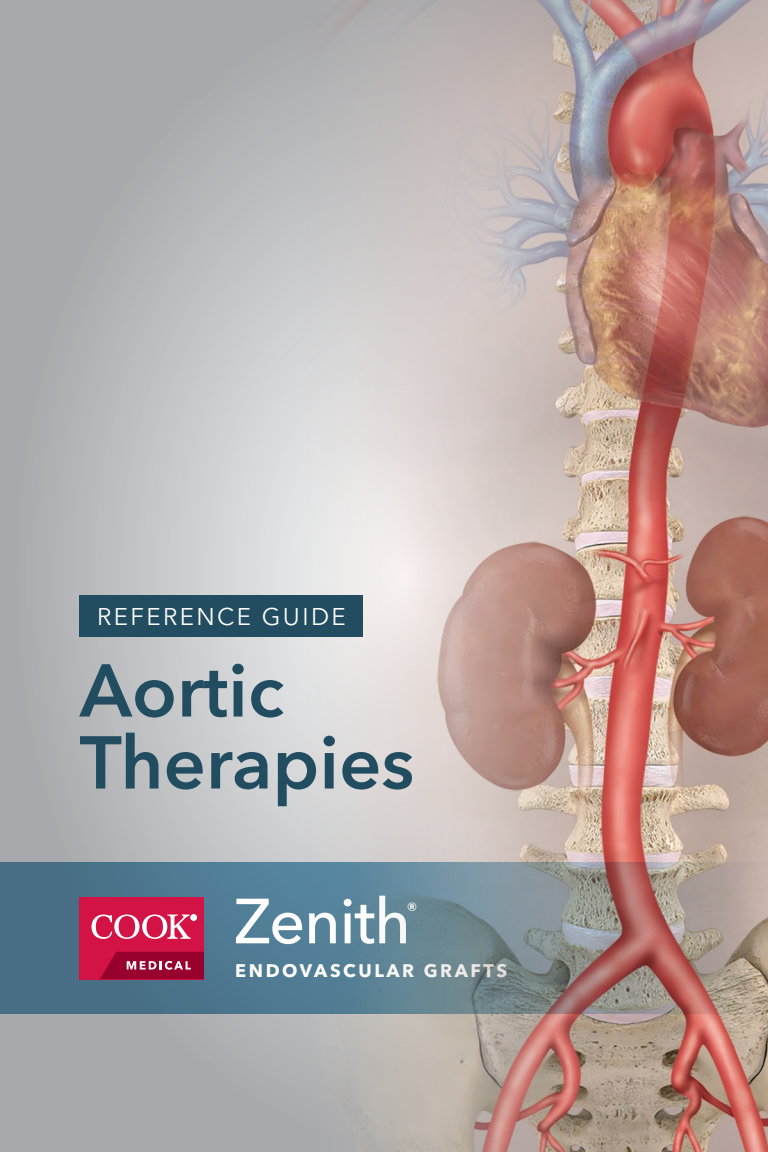




REFERENCE GUIDE

Aortic Therapies

COOK
MEDICAL

Zenith[®]
ENDOVASCULAR GRAFTS

Achieving a durable aortic repair is the foundation of the Zenith design philosophy.

View the Instructions for Use for a thorough examination of the procedural instructions, intended use, contraindications, warnings, and precautions and potential adverse events. Some products or part numbers may not be available in all markets. Contact your local representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at [cookmedical.eu](https://www.cookmedical.eu).

Additional information may be found at [cookmedical.eu/aortic-intervention](https://www.cookmedical.eu/aortic-intervention).

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Abdominal





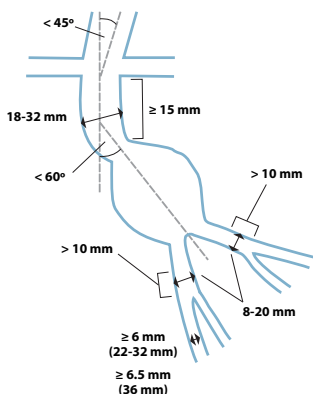
Zenith Alpha[®]

Abdominal Endovascular Graft

Abdominal



Indications for use



Indications for use	Patients with abdominal aortic or aortoiliac aneurysms having morphology suitable for endovascular repair	
Length	≥ 15 mm nonaneurysmal infrarenal neck	
Proximal fixation site diameter	18-32 mm (measured outer wall to outer wall)	
Angulation/curvature	• Angle < 60 degrees relative to the long axis of the aneurysm • Angle < 45 degrees relative to the axis of the suprarenal aorta	
Ipsilateral iliac fixation site	Distal fixation site > 10 mm in length and 8-20 mm in diameter (measured outer wall to outer wall)	
Contralateral iliac fixation site	Distal fixation site > 10 mm in length and 8-20 mm in diameter (measured outer wall to outer wall)	
Access	Adequate femoral/iliac access compatible with the required introduction systems	
Introducer diameters	22-32 mm grafts: ID 16 Fr (5.3 mm) OD 6.0 mm	36 mm grafts: ID 17 Fr (5.6 mm) OD 6.5 mm
Contraindications	• Patients with known sensitivities or allergies to nitinol, polyester, polypropylene, gold, PTFE, nylon, or urethane • Patients with a systemic infection who may be at increased risk of endovascular graft infection	

Bifurcated main body grafts

Order Number	Reference Part Number	Aortic Vessel OD mm	Main Body Diameter mm	Main Body Contralateral Length mm	Introducer Sheath ID/OD Fr (mm)/mm
22 mm Diameter					
G35986	ZIMB-22-70	18-19	22	70	16 (5.3)/6.0
G35987	ZIMB-22-84	18-19	22	84	16 (5.3)/6.0
G35988	ZIMB-22-98	18-19	22	98	16 (5.3)/6.0
G35989	ZIMB-22-108	18-19	22	108	16 (5.3)/6.0
G35990	ZIMB-22-118	18-19	22	118	16 (5.3)/6.0
G35991	ZIMB-22-128	18-19	22	128	16 (5.3)/6.0
24 mm Diameter					
G35992	ZIMB-24-70	20-21	24	70	16 (5.3)/6.0
G35993	ZIMB-24-84	20-21	24	84	16 (5.3)/6.0
G35994	ZIMB-24-98	20-21	24	98	16 (5.3)/6.0
G35995	ZIMB-24-108	20-21	24	108	16 (5.3)/6.0
G35996	ZIMB-24-118	20-21	24	118	16 (5.3)/6.0
G35997	ZIMB-24-128	20-21	24	128	16 (5.3)/6.0
26 mm Diameter					
G35998	ZIMB-26-70	22	26	70	16 (5.3)/6.0
G35999	ZIMB-26-84	22	26	84	16 (5.3)/6.0
G36030	ZIMB-26-98	22	26	98	16 (5.3)/6.0
G34381	ZIMB-26-108	22	26	108	16 (5.3)/6.0
G34382	ZIMB-26-118	22	26	118	16 (5.3)/6.0
G34383	ZIMB-26-128	22	26	128	16 (5.3)/6.0
28 mm Diameter					
G34384	ZIMB-28-70	23-24	28	70	16 (5.3)/6.0
G34385	ZIMB-28-84	23-24	28	84	16 (5.3)/6.0
G34386	ZIMB-28-98	23-24	28	98	16 (5.3)/6.0
G34387	ZIMB-28-108	23-24	28	108	16 (5.3)/6.0
G34388	ZIMB-28-118	23-24	28	118	16 (5.3)/6.0
G34389	ZIMB-28-128	23-24	28	128	16 (5.3)/6.0

Some products or part numbers may not be available in all markets.

Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

Bifurcated main body grafts (continued)

Order Number	Reference Part Number	Aortic Vessel OD mm	Main Body Diameter mm	Main Body Contralateral Length mm	Introducer Sheath ID/OD Fr (mm)/mm
30 mm Diameter					
G34390	ZIMB-30-70	25-26	30	70	16 (5.3)/6.0
G34391	ZIMB-30-84	25-26	30	84	16 (5.3)/6.0
G34392	ZIMB-30-98	25-26	30	98	16 (5.3)/6.0
G34393	ZIMB-30-108	25-26	30	108	16 (5.3)/6.0
G34394	ZIMB-30-118	25-26	30	118	16 (5.3)/6.0
G34395	ZIMB-30-128	25-26	30	128	16 (5.3)/6.0
32 mm Diameter					
G34396	ZIMB-32-70	27-28	32	70	16 (5.3)/6.0
G34397	ZIMB-32-84	27-28	32	84	16 (5.3)/6.0
G34399	ZIMB-32-98	27-28	32	98	16 (5.3)/6.0
G34400	ZIMB-32-108	27-28	32	108	16 (5.3)/6.0
G34401	ZIMB-32-118	27-28	32	118	16 (5.3)/6.0
G34402	ZIMB-32-128	27-28	32	128	16 (5.3)/6.0
36 mm Diameter					
G34403	ZIMB-36-70	29-32	36	70	17 (5.6)/6.5
G34404	ZIMB-36-84	29-32	36	84	17 (5.6)/6.5
G34405	ZIMB-36-98	29-32	36	98	17 (5.6)/6.5
G34406	ZIMB-36-108	29-32	36	108	17 (5.6)/6.5
G34407	ZIMB-36-118	29-32	36	118	17 (5.6)/6.5
G34408	ZIMB-36-128	29-32	36	128	17 (5.6)/6.5

Some products or part numbers may not be available in all markets.

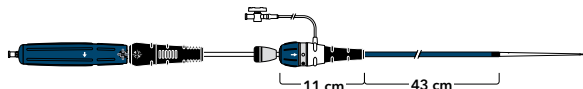
Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

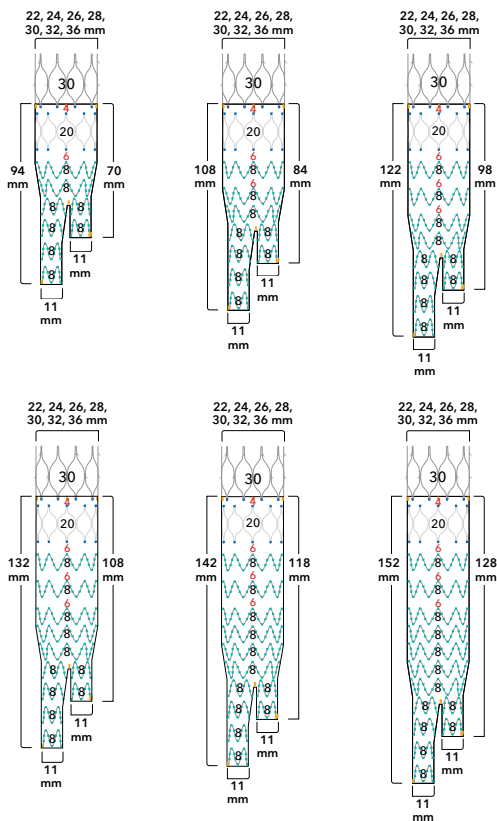
Introduction system for main body grafts

22-32 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

36 mm grafts: 17 Fr (5.6 mm) ID/6.5 mm OD



Bifurcated main body grafts



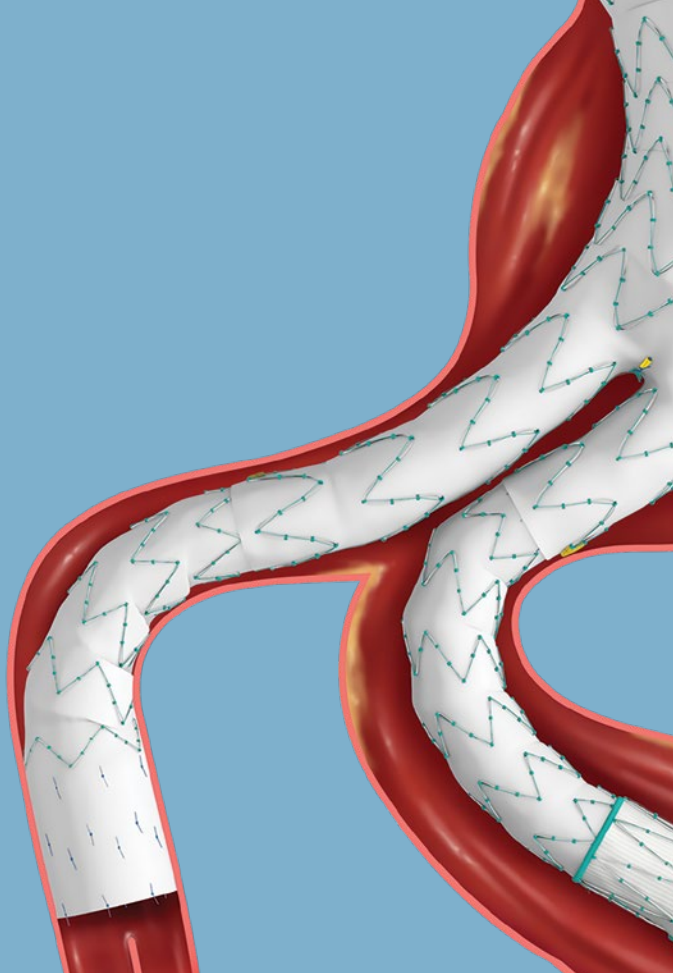
ZIMB-XX-YYY

ZIMB-(main body diameter)-(main body contralateral length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Abdominal





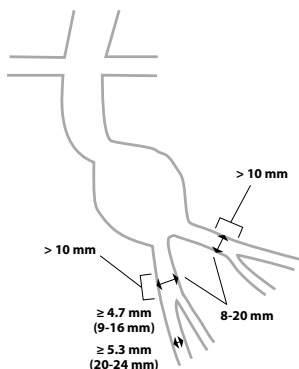
Zenith Alpha[®]

Spiral-Z[®] Endovascular Leg

Abdominal



Indications for use



Indications for use	For use with the Zenith AAA Endovascular Graft family of products, during either a primary or a secondary procedure in patients who have adequate iliac/femoral access compatible with the required introduction systems. The graft is used in combination with these products for the endovascular treatment of abdominal aortic and aortoiliac aneurysms.	
Ipsilateral iliac fixation site	Distal fixation site > 10 mm in length and 8-20 mm in diameter (measured outer wall to outer wall)	
Contralateral iliac fixation site	Distal fixation site > 10 mm in length and 8-20 mm in diameter (measured outer wall to outer wall)	
Access	Adequate femoral/iliac access compatible with the required introduction systems	
Introducer diameters	9-16 mm grafts: ID 12 Fr (4.0 mm) OD 4.7 mm	20-24 mm grafts: ID 14 Fr (4.7 mm) OD 5.3 mm
Contraindications	• Patients with known sensitivities or allergies to nitinol, polyester, polypropylene, urethane, PTFE, Nylon or gold. • Patients with a systemic infection who may be at increased risk of endovascular graft infection	

Spiral-Z endovascular leg grafts

Order Number	Reference Part Number	Iliac Leg Distal Diameter mm	Iliac Leg Label Length mm	Introducer Sheath ID/OD Fr (mm)/mm
9 mm Diameter				
G35955	ZISL-9-42	9	42	12 (4.0)/4.7
G35956	ZISL-9-59	9	59	12 (4.0)/4.7
G35957	ZISL-9-77	9	77	12 (4.0)/4.7
G34508	ZISL-9-93	9	93	12 (4.0)/4.7
G35959	ZISL-9-110	9	110	12 (4.0)/4.7
G35960	ZISL-9-125	9	125	12 (4.0)/4.7
11 mm Diameter				
G35961	ZISL-11-42	11	42	12 (4.0)/4.7
G35962	ZISL-11-59	11	59	12 (4.0)/4.7
G35963	ZISL-11-77	11	77	12 (4.0)/4.7
G35964	ZISL-11-93	11	93	12 (4.0)/4.7
G35965	ZISL-11-110	11	110	12 (4.0)/4.7
G35966	ZISL-11-125	11	125	12 (4.0)/4.7
13 mm Diameter				
G35967	ZISL-13-42	13	42	12 (4.0)/4.7
G35968	ZISL-13-59	13	59	12 (4.0)/4.7
G35969	ZISL-13-77	13	77	12 (4.0)/4.7
G35970	ZISL-13-93	13	93	12 (4.0)/4.7
G34409	ZISL-13-110	13	110	12 (4.0)/4.7
G34410	ZISL-13-125	13	125	12 (4.0)/4.7
16 mm Diameter				
G35971	ZISL-16-42	16	42	12 (4.0)/4.7
G35972	ZISL-16-59	16	59	12 (4.0)/4.7
G35973	ZISL-16-77	16	77	12 (4.0)/4.7
G35975	ZISL-16-93	16	93	12 (4.0)/4.7

Some products or part numbers may not be available in all markets.

Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

Spiral-Z endovascular leg grafts (continued)

Order Number	Reference Part Number	Iliac Leg Distal Diameter mm	Iliac Leg Label Length mm	Introducer Sheath ID/OD Fr (mm)/mm
24 mm Diameter				
G35982	ZISL-24-42	24	42	14 (4.7)/5.3
G35983	ZISL-24-59	24	59	14 (4.7)/5.3
G35984	ZISL-24-77	24	77	14 (4.7)/5.3
G35985	ZISL-24-93	24	93	14 (4.7)/5.3
20 mm Diameter				
G35977	ZISL-20-42	20	42	14 (4.7)/5.3
G35976	ZISL-20-59	20	59	14 (4.7)/5.3
G35980	ZISL-20-77	20	77	14 (4.7)/5.3
G35981	ZISL-20-93	20	93	14 (4.7)/5.3

Some products or part numbers may not be available in all markets.

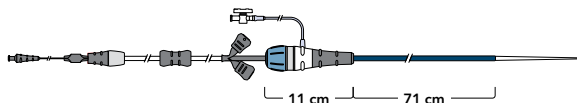
Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

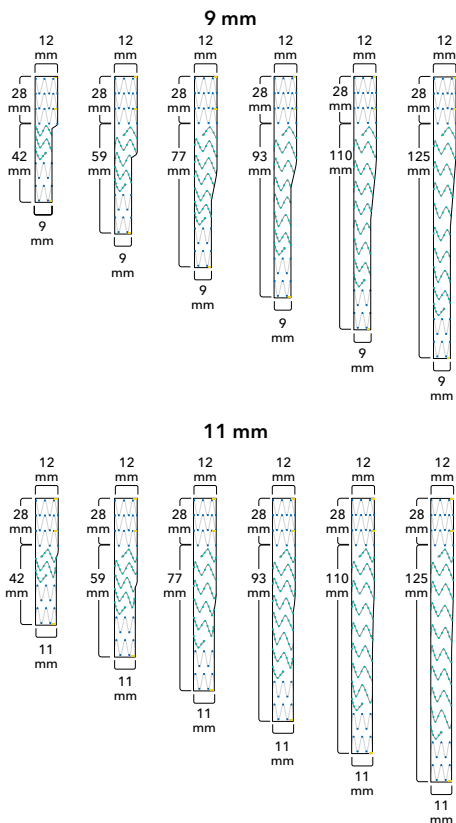
Z-Trak® Introduction System for iliac legs

9–16 mm grafts: 12 Fr (4.0 mm) ID/4.7 mm OD

20–24 mm grafts: 14 Fr (4.7 mm) ID/5.3 mm OD



Spiral-Z endovascular leg grafts



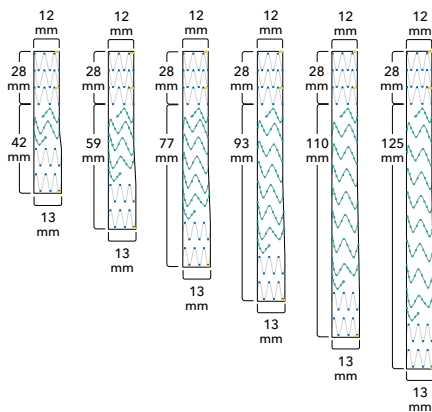
ZISL-XX-YYY

ZISL-(distal diameter)-(label length)

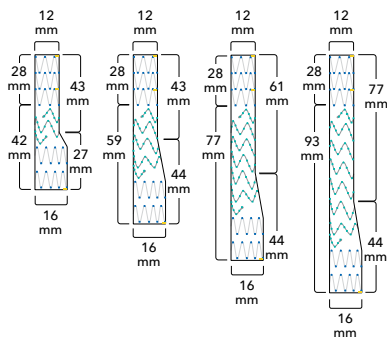
Note: All measurements are in millimetres.

Spiral-Z endovascular leg grafts (continued)

13 mm

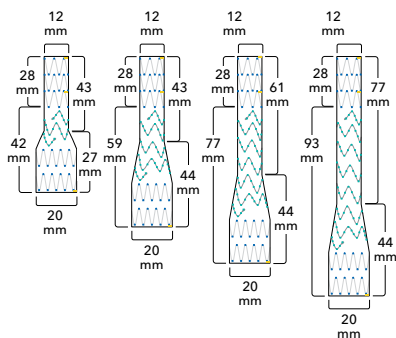


16 mm

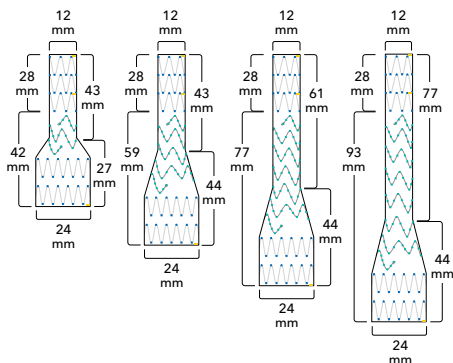


Spiral-Z endovascular leg grafts (continued)

20 mm



24 mm



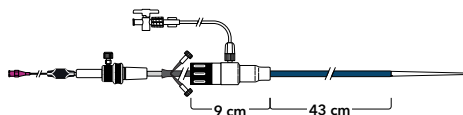
Zenith® Low Profile AAA Endovascular Graft - Main body extensions

MAIN BODY EXTENSIONS		Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
Order Number	Reference Part Number				
Main Body Extensions					
G51995	ZLBE-22-45	18-19	22	45	16 (5.3)/6.0
G51997	ZLBE-24-45	20-21	24	45	16 (5.3)/6.0
G51999	ZLBE-26-45	22	26	45	16 (5.3)/6.0
G49290	ZLBE-28-45	23-24	28	45	16 (5.3)/6.0
G52001	ZLBE-30-45	25-26	30	45	16 (5.3)/6.0
G49291	ZLBE-32-45	27-28	32	45	16 (5.3)/6.0
G53387	ZLBE-36-45	29-32	36	45	17 (5.6)/6.5
G51996	ZLBE-22-58	18-19	22	58	16 (5.3)/6.0
G51998	ZLBE-24-58	20-21	24	58	16 (5.3)/6.0
G52000	ZLBE-26-58	22	26	58	16 (5.3)/6.0
G48604	ZLBE-28-58	23-24	28	58	16 (5.3)/6.0
G52002	ZLBE-30-58	25-26	30	58	16 (5.3)/6.0
G48603	ZLBE-32-58	27-28	32	58	16 (5.3)/6.0
G53388	ZLBE-36-58	29-32	36	58	17 (5.6)/6.5

H&L-B One-Shot™ Introduction System for ancillary components

22-32 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

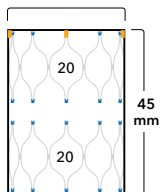
36 mm grafts: 17 Fr (5.6 mm) ID/6.5 mm OD



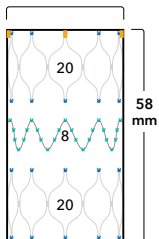
Ancillary components

Main body extensions

22, 24, 26, 28, 30, 32, 36 mm



22, 24, 26, 28, 30, 32, 36 mm



Main body extensions

ZLBE-XX-YY

ZLBE-(diameter)-(length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths.

Deployment overview*

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.

MAIN BODY PLACEMENT

- 1a** **Note:** Before insertion, position the main body delivery system on the patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb radiopaque marker.

Insert the main body delivery system over the wire and into the femoral artery. Advance the delivery system until the four gold radiopaque markers (which are positioned 2 mm from the most proximal segment of the graft material) are just inferior to the most inferior renal orifice.

- 1b** Stabilise the grey positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two covered stents by withdrawing the sheath while monitoring the device location. Check the position of the contralateral limb radiopaque marker and the location of renal arteries. Continue withdrawing the sheath until the contralateral limb is fully deployed. Stop withdrawing the sheath.

Deployment overview* (continued)

2 MAIN BODY PROXIMAL (TOP) DEPLOYMENT

While holding the black gripper, turn the black safety lock knob 180 degrees in the direction of the arrows (anticlockwise). To release the suprarenal bare stent, turn the blue rotation handle approximately two full rotations in the direction of the arrow (clockwise) until a stop is felt. The back safety lock knobs should be in alignment after rotating the blue handle.

Note: Once you deploy the barbed suprarenal stent, do not reposition the graft.

3 CONTRALATERAL ILIAC WIRE GUIDE PLACEMENT

Manipulate wire guide using an angiographic catheter through the open end of the contralateral limb into the body of the graft. Advance the wire guide inside the body of the graft and into the thoracic aorta. AP and oblique fluoroscopic views can aid in verification of device cannulation.

4 CONTRALATERAL ILIAC LEG PLACEMENT AND DEPLOYMENT

Remove the femoral sheath and introduce the contralateral iliac leg delivery system into the artery. Advance slowly until the zone between the two proximal gold markers aligns with the gold radiopaque marker at the bifurcation of the main body graft. This will allow between 16 mm and 32 mm of overlap between components.

Confirm position of the distal end of the contralateral iliac leg graft. Reposition the contralateral iliac leg graft if necessary to ensure both internal iliac patency and minimum overlap of 2 stents (16 mm) within the main body endovascular graft. To deploy, hold the contralateral iliac leg graft in position with the grey positioner while withdrawing the sheath approximately 10 mm. Check the graft position and reposition the graft if necessary. Continue to deploy the graft by withdrawing the sheath while continuously checking the graft position. Stop withdrawing the sheath as soon as the distal end of the contralateral iliac leg graft is released. Under fluoroscopy and after verification of the iliac leg graft position, loosen the pin vise and retract the inner cannula to dock the tapered dilator to the grey positioner. Tighten the pin vise. Maintain the sheath position while withdrawing the grey positioner with the secured inner cannula.

Deployment overview* (continued)

5 MAIN BODY DISTAL (BOTTOM) DEPLOYMENT

Fully deploy the ipsilateral limb of the main body by withdrawing the sheath until the most distal stent has expanded. Stop withdrawing the sheath.

Note: The distal stent is still secured to the delivery system.

While holding the black gripper, turn the grey safety lock knob anticlockwise to engage the blue rotation handle. To release the wire securing the ipsilateral limb to the delivery system, turn the blue rotation handle in the direction of the arrow (clockwise) until a stop is felt. Withdraw the entire inner subassembly through the sheath by holding the Captor® Hemostatic Valve stationary and pulling on the black gripper. Confirm that the Captor sleeve is removed along with the inner subassembly.

Note: Maintain the position of the sheath and the wire guide.

Close the Captor Hemostatic Valve on the introducer sheath by turning it in a clockwise direction until it stops.

6 IPSILATERAL ILIAC LEG PLACEMENT AND DEPLOYMENT

Utilise the main body graft wire and sheath assembly to introduce the ipsilateral iliac leg graft. Advance the dilator and sheath assembly into the main body sheath. Continue advancing it slowly until the proximal edge of the ipsilateral leg graft aligns with the proximal edge of the previously placed contralateral leg graft. Confirm the position of the distal end of the iliac leg graft. Reposition the iliac leg graft, if necessary, to ensure internal iliac patency. To deploy, hold the iliac leg graft in position with the grey positioner while withdrawing the sheath approximately 10 mm. Check the graft position and reposition if necessary. Continue to deploy the graft by withdrawing the sheath while continuously checking the position of the graft. Under fluoroscopy and after you verify the iliac leg graft position, loosen the pin vise and retract the inner cannula to dock the tapered dilator to the positioner. Tighten the pin vise. Maintain the sheath position while using the secured inner cannula to withdraw the grey positioner. Close the Captor Hemostatic Valve by turning it in a clockwise direction until it stops.

Deployment overview* (continued)

7 MOULDING BALLOON INSERTION

Advance the moulding balloon over the wire guide and through the haemostatic valve of the main body introduction system to the level of the renal arteries. Maintain proper sheath positioning. Tighten the Captor Hemostatic Valve around the moulding balloon by turning it clockwise with gentle pressure.

CAUTION: Do not inflate the balloon in the vessel outside of the graft.

Expand the moulding balloon with diluted contrast media (as directed by the manufacturer) in the area of the most proximal covered stent and the infrarenal neck, starting proximally and working in the distal direction.

CAUTION: Before you reposition the balloon, confirm that it is completely deflated.

CAUTION: The Captor Hemostatic Valve must be open before you reposition the moulding balloon.

Withdraw the moulding balloon to the ipsilateral limb overlap region and expand the balloon.

CAUTION: The Captor Hemostatic Valve must be open before you reposition the moulding balloon.

Withdraw the moulding balloon to the ipsilateral distal fixation site and expand the balloon.

CAUTION: Do not inflate the balloon in the vessel outside of the graft.

Deflate and remove the moulding balloon. Transfer the moulding balloon onto the contralateral wire guide and into the contralateral iliac leg introduction system. Advance the moulding balloon to the contralateral limb overlap region and expand the balloon.

CAUTION: Before you reposition the balloon, confirm that it is completely deflated.

Withdraw the moulding balloon to the contralateral iliac leg distal fixation site and expand the balloon.

CAUTION: Do not inflate the balloon in the vessel outside of the graft.

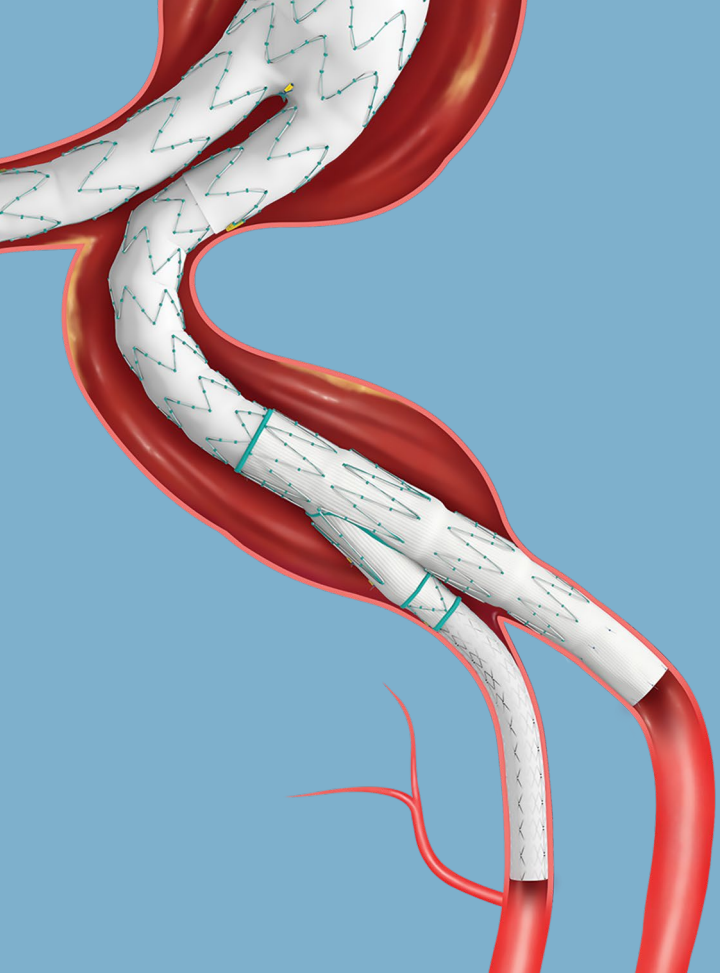
Remove the moulding balloon and replace it with an angiographic catheter to perform completion angiography.

Remove or replace all stiff wire guides to allow the iliac arteries to resume their natural position.

**This deployment overview is an outline highlighting the deployment process for the Zenith Alpha Abdominal Endovascular Graft. The Instructions for Use booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings, and precautions.*

Abdominal





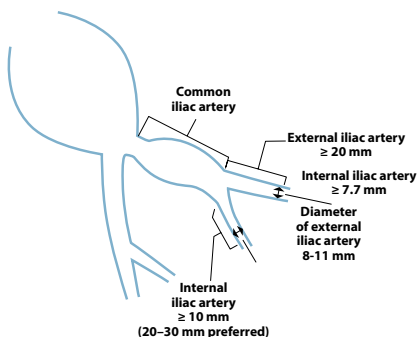
Zenith[®] Branch

Endovascular Graft -
Iliac Bifurcation

Abdominal



Indications for use



Indications for use	Patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair.
External iliac fixation site	Nonaneurysmal external iliac artery fixation segment distal to the aneurysm with: • Length ≥ 20 mm • Diameter measured outer wall to outer wall of 8-11 mm
Internal iliac fixation site	Nonaneurysmal internal iliac artery segment distal to the aneurysm with: • Length ≥ 10 mm (20-30 mm preferred) • Diameter acceptable for proper sealing
Access	Adequate femoral/iliac access compatible with the required introduction systems
Introducer diameters	ID 20 Fr (6.7 mm) OD 7.7 mm
Contraindications	There are no known contraindications for these devices

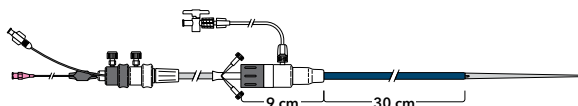
Iliac branch grafts

Order Number	Reference Part Number	Distal Body Diameter mm	Common Iliac Segment Length mm	External Iliac Segment Length mm	Introducer Sheath ID/OD Fr (mm)/mm
G38612	ZBIS-10-45-41	10	45	41	20 (6.7)/7.7
G38613	ZBIS-10-45-58	10	45	58	20 (6.7)/7.7
G38616	ZBIS-12-45-41	12	45	41	20 (6.7)/7.7
G38617	ZBIS-12-45-58	12	45	58	20 (6.7)/7.7
G38614	ZBIS-10-61-41	10	61	41	20 (6.7)/7.7
G38615	ZBIS-10-61-58	10	61	58	20 (6.7)/7.7
G38618	ZBIS-12-61-41	12	61	41	20 (6.7)/7.7
G38344	ZBIS-12-61-58	12	61	58	20 (6.7)/7.7

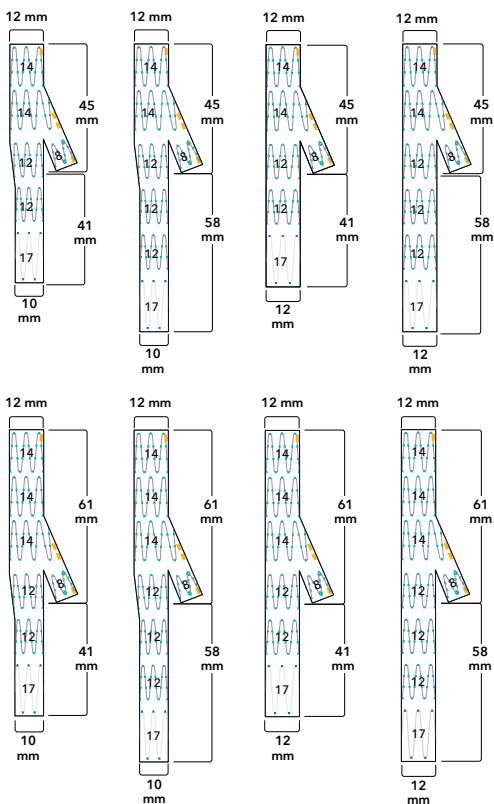
Some products or part numbers may not be available in all markets.
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Please see product risk information in the IFU at cookmedical.eu.

Introduction system for iliac bifurcation grafts

20 Fr (6.7 mm) ID/7.7 mm OD



Iliac branch grafts



ZBIS-XX-YY-ZZ

ZBIS-(distal diameter)-(common iliac segment length)-(external iliac segment length)

Refer to cookmedical.com/zenithbranch for more information.

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths.

Note: Zenith Branch Endovascular Graft-Iliac Bifurcation is compatible with 16 mm Zenith Spiral-Z legs and Zenith Alpha Spiral-Z legs.

Deployment overview*

1 PLACE THE ILIAC BRANCH

Insert the device's introduction system over the wire guide and into the iliac artery until the tip of the indwelling catheter is just above the aortic bifurcation. The distal gold marker must be at least 10 mm above the origin of the internal iliac artery.

2 POSITION THE BRANCH DEVICE

Position the device and withdraw the sheath until the indwelling catheter and hydrophilic wire guide are exposed. Advance this wire guide into the snare. Pull the snared wire through to form a through-and-through wire guide.

3 DEPLOY THE BRANCH DEVICE

Deploy the branch device until the distal end of the side branch is exposed.

4 PLACE THE UP-AND-OVER SHEATH

Advance 12 Fr sheath over the through-and-through wire guide until the tip of the sheath's dilator tip comes in contact with the tip of the pre-loaded catheter. Clamp the through-and-through wire guide at both ends to prevent wire guide displacement.

5 POSITION THE GUIDING SHEATH

Continue to advance the sheath over the secured wire guide and into the proximal opening of the device and out through the side branch.

6 PUNCTURE THE HEMOSTATIC VALVE

Remove the inner dilator. Use an 18 gauge needle to make an off-center puncture in the valve of the guiding sheath. Advance the access wire and the catheter through the sheath in order to access the internal iliac artery.

7 POSITION THE BALLOON-EXPANDABLE COVERED PERIPHERAL BRIDGING STENT

Replace the hydrophilic wire guide with a 260 cm long support wire guide. Advance the balloon-expandable covered peripheral bridging stent into position. Use the 2D gold aiming marker to ensure optimal overlap between the bridging stent and the side-branch segment. Remove the indwelling catheter and through-and-through wire guide together.

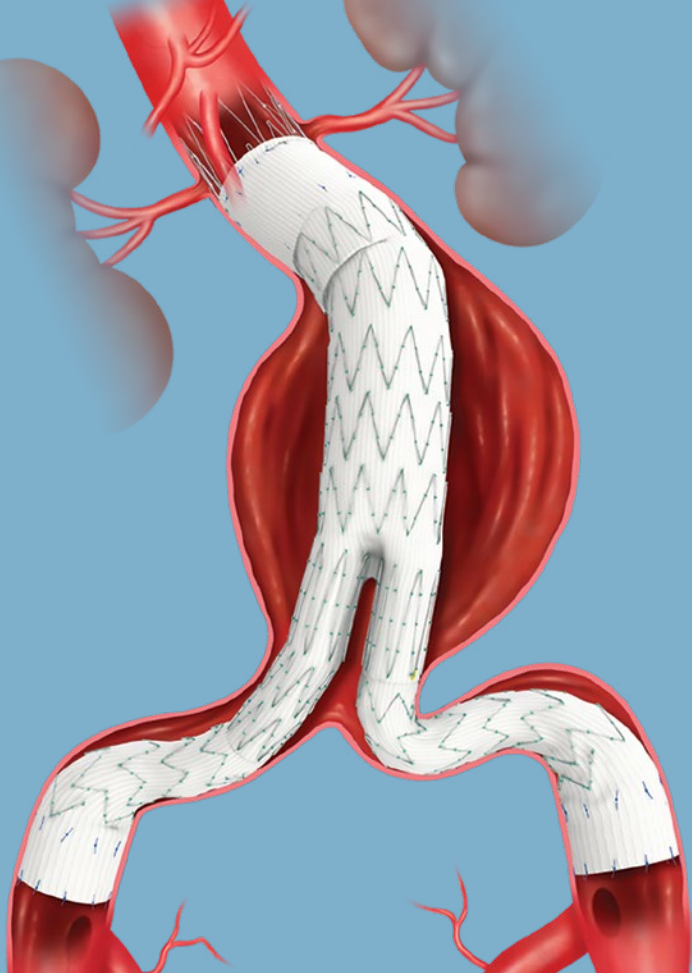
Deployment overview* (continued)

- 8 DEPLOY THE DISTAL ILIAC SEGMENT**
Withdraw the device's sheath until the external iliac segment is deployed.
- 9 REMOVE THE PROXIMAL TRIGGER WIRE**
Remove the proximal trigger wire by sliding the black trigger-wire release mechanism off of the handle.
- 10 DEPLOYING THE BALLOON-EXPANDABLE COVERED PERIPHERAL BRIDGING STENT**
Withdraw the guiding sheath until it is outside of the covered stent. Using an inflation device, deploy the covered stent
- 11 REMOVE THE DISTAL TRIGGER WIRE**
Remove the distal trigger wire.
- 12 REMOVE THE INTRODUCTION SYSTEM**
Re-inflate the balloon in the sidebranch segment and withdraw the introducer system through the graft into the introducer sheath. Prepare to place the Zenith bifurcated main body graft and iliac leg grafts.

**This deployment overview is an outline highlighting the deployment process for the Zenith Branch Endovascular Graft - Iliac Bifurcation. The Instructions for Use booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings, and precautions.*

Abdominal





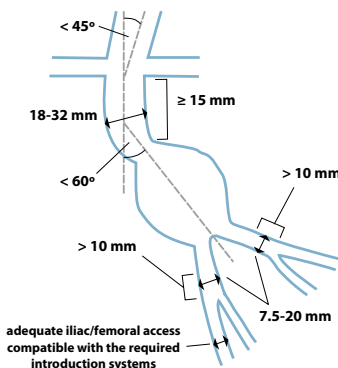
Zenith Flex[®]

AAA Endovascular Graft

Abdominal



Indications for use



Indications for use	Patients with abdominal aortic or aortoiliac aneurysms having morphology suitable for endovascular repair		
Length	≥ 15 mm nonaneurysmal infrarenal neck		
Aortic fixation site diameter	18-32 mm (measured outer wall to outer wall)		
Angulation/curvature	• Angle < 60 degrees relative to the long axis of the aneurysm • Angle < 45 degrees relative to the axis of the suprarenal aorta		
Ipsilateral iliac fixation site	Distal fixation site > 10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall)		
Contralateral iliac fixation site	Distal fixation site > 10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall)		
Access	Adequate femoral/iliac access compatible with the required introduction systems		
Introducer diameters	22-26 mm grafts: ID 18 Fr (6.0 mm) OD 7.1 mm	28-32 mm grafts: ID 20 Fr (6.7 mm) OD 7.7 mm	36 mm grafts: ID 22 Fr (7.3 mm) OD 8.5 mm
Contraindications	• Patients with known sensitivities or allergies to stainless steel, polyester, solder (tin, silver), polypropylene, or gold • Patients with a systemic infection who may be at increased risk of endovascular graft infection		

Bifurcated main body grafts

Order Number	Reference Part Number	Aortic Vessel OD mm	Main Body Diameter mm	Main Body Contralateral Length mm	Introducer Sheath ID/OD Fr (mm)/mm
22 mm Diameter					
G48402	TFFB-22-82-ZT	18-19	22	82	18 (6.0)/7.1
G48403	TFFB-22-96-ZT	18-19	22	96	18 (6.0)/7.1
G48404	TFFB-22-111-ZT	18-19	22	111	18 (6.0)/7.1
G48405	TFFB-22-125-ZT	18-19	22	125	18 (6.0)/7.1
G48406	TFFB-22-140-ZT	18-19	22	140	18 (6.0)/7.1
24 mm Diameter					
G48407	TFFB-24-82-ZT	20-21	24	82	18 (6.0)/7.1
G48408	TFFB-24-96-ZT	20-21	24	96	18 (6.0)/7.1
G48409	TFFB-24-111-ZT	20-21	24	111	18 (6.0)/7.1
G48410	TFFB-24-125-ZT	20-21	24	125	18 (6.0)/7.1
G48411	TFFB-24-140-ZT	20-21	24	140	18 (6.0)/7.1
26 mm Diameter					
G48412	TFFB-26-82-ZT	22	26	82	18 (6.0)/7.1
G48413	TFFB-26-96-ZT	22	26	96	18 (6.0)/7.1
G48414	TFFB-26-111-ZT	22	26	111	18 (6.0)/7.1
G48415	TFFB-26-125-ZT	22	26	125	18 (6.0)/7.1
G48416	TFFB-26-140-ZT	22	26	140	18 (6.0)/7.1
28 mm Diameter					
G48417	TFFB-28-82-ZT	23-24	28	82	20 (6.7)/7.7
G48418	TFFB-28-96-ZT	23-24	28	96	20 (6.7)/7.7
G48419	TFFB-28-111-ZT	23-24	28	111	20 (6.7)/7.7
G48420	TFFB-28-125-ZT	23-24	28	125	20 (6.7)/7.7
G48421	TFFB-28-140-ZT	23-24	28	140	20 (6.7)/7.7
30 mm Diameter					
G48422	TFFB-30-82-ZT	25-26	30	82	20 (6.7)/7.7
G48423	TFFB-30-96-ZT	25-26	30	96	20 (6.7)/7.7
G48424	TFFB-30-111-ZT	25-26	30	111	20 (6.7)/7.7
G48425	TFFB-30-125-ZT	25-26	30	125	20 (6.7)/7.7
G48426	TFFB-30-140-ZT	25-26	30	140	20 (6.7)/7.7

Some products or part numbers may not be available in all markets.

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Please see product risk information in the IFU at cookmedical.eu.

Bifurcated main body grafts (continued)

Order Number	Reference Part Number	Aortic Vessel OD mm	Main Body Diameter mm	Main Body Contralateral Length mm	Introducer Sheath ID/OD Fr (mm)/mm
32 mm Diameter					
G48427	TFFB-32-82-ZT	27-28	32	82	20 (6.7)/7.7
G48428	TFFB-32-96-ZT	27-28	32	96	20 (6.7)/7.7
G48429	TFFB-32-111-ZT	27-28	32	111	20 (6.7)/7.7
G48430	TFFB-32-125-ZT	27-28	32	125	20 (6.7)/7.7
G48431	TFFB-32-140-ZT	27-28	32	140	20 (6.7)/7.7
36 mm Diameter					
G48432	TFFB-36-95-ZT	29-32	36	95	22 (7.3)/8.5
G48433	TFFB-36-113-ZT	29-32	36	113	22 (7.3)/8.5
G48434	TFFB-36-131-ZT	29-32	36	131	22 (7.3)/8.5
G48435	TFFB-36-149-ZT	29-32	36	149	22 (7.3)/8.5

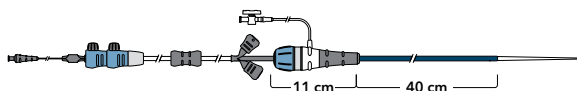
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Z-Trak Introduction System for main body grafts

22-26 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

28-32 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD

36 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Ancillary components

MAIN BODY EXTENSIONS		Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
Order Number	Reference Part Number				
Main Body Extensions					
G55204	ESBE-22-39-ZT	18-19	22	39	18 (6.0)/7.1
G55205	ESBE-24-39-ZT	20-21	24	39	18 (6.0)/7.1
G55206	ESBE-26-39-ZT	22-23	26	39	18 (6.0)/7.1
G55207	ESBE-28-39-ZT	24-25	28	39	20 (6.7)/7.7
G55208	ESBE-30-39-ZT	26-27	30	39	20 (6.7)/7.7
G55209	ESBE-32-39-ZT	28	32	39	20 (6.7)/7.7
G55210	ESBE-36-50-ZT	29-32	36	50	20 (6.7)/7.7
G55211	ESBE-22-58-ZT	18-19	22	58	18 (6.0)/7.1
G55212	ESBE-24-58-ZT	20-21	24	58	18 (6.0)/7.1
G55213	ESBE-26-58-ZT	22-23	26	58	18 (6.0)/7.1
G55214	ESBE-28-58-ZT	24-25	28	58	20 (6.7)/7.7
G55215	ESBE-30-58-ZT	26-27	30	58	20 (6.7)/7.7
G55216	ESBE-32-58-ZT	28	32	58	20 (6.7)/7.7
G55217	ESBE-36-73-ZT	29-32	36	73	20 (6.7)/7.7

Some products or part numbers may not be available in all markets.

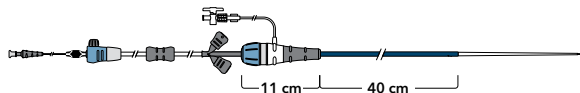
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Z-Trak Introduction System for main body extension

22-26 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

28-36 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Ancillary components (continued)

CONVERTERS

Order Number	Reference Part Number	Main Body Diameter mm	Proximal Diameter mm	Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
Converters						
G55191	ESC-24-12-80-ZT	22, 24	24	12	80	18 (6.0)/7.1
G55192	ESC-28-12-80-ZT	26, 28	28	12	80	20 (6.7)/7.7
G55193	ESC-32-12-80-ZT	30, 32	32	12	80	20 (6.7)/7.7
G55194	ESC-36-12-82-ZT	36	36	12	82	20 (6.7)/7.7

Some products or part numbers may not be available in all markets.

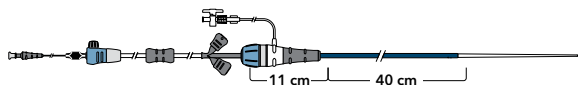
Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

Introduction System for converters

24 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

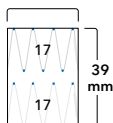
28-36 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



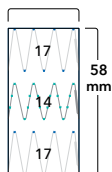
Ancillary components

Main body extensions

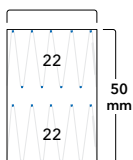
22, 24, 26, 28, 30, 32 mm



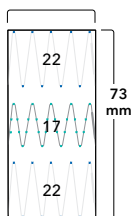
22, 24, 26, 28, 30, 32 mm



36 mm

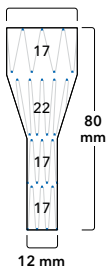


36 mm

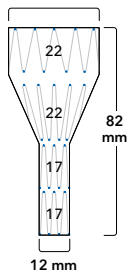


Converters

24, 28, 32 mm



36 mm



Main body extensions

ESBE-XX-YY-ZT

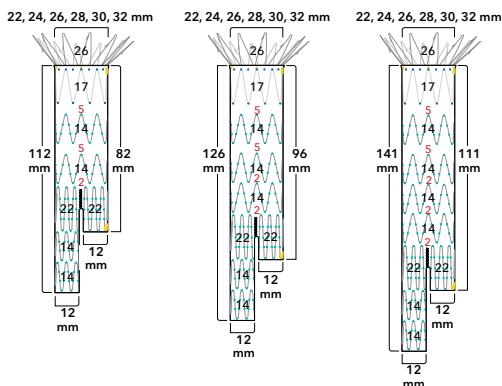
ESBE-(diameter)-(length)-ZT

Converters

ESC-XX-YY-ZZ-ZT

ESC-(proximal diameter)-(distal diameter)-(length)-ZT

Bifurcated main body grafts



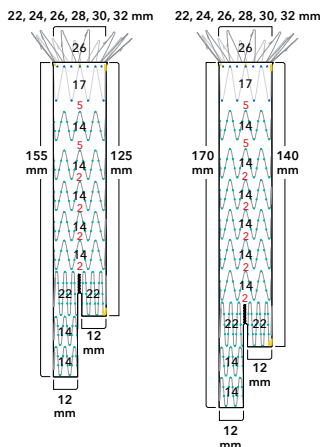
Note: Ipsilateral and contralateral limb diameters on all 22 mm diameter main body grafts are 11 mm.

TFFB-XX-YYY-ZT

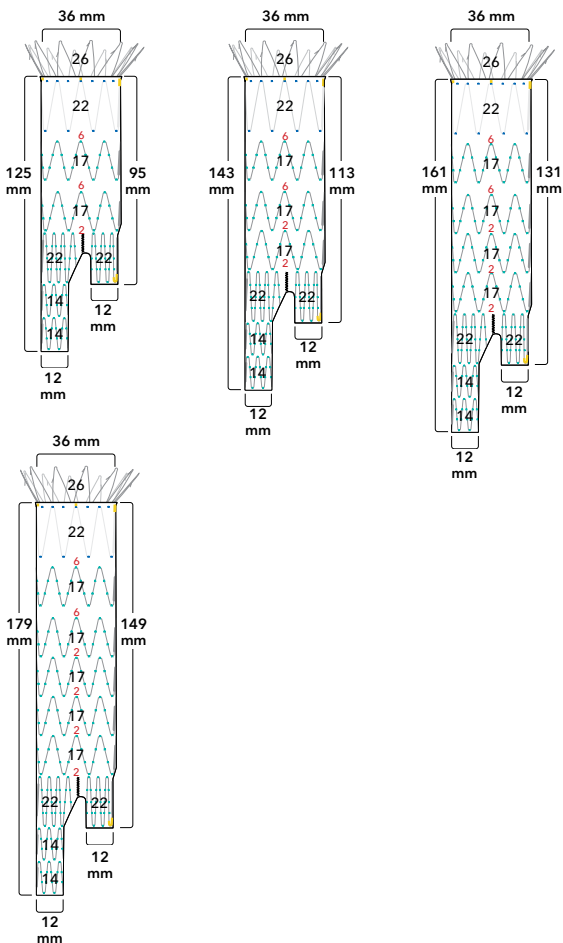
TFFB-(main body diameter)-(main body contralateral length)-ZT

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Note: Zenith Flex is compatible with Zenith Spiral-Z AAA Iliac Leg Grafts.



Bifurcated main body grafts (continued)



Deployment overview*

1a MAIN BODY PLACEMENT

Note: Before insertion, position the main body introduction system on the patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb radiopaque marker.

Insert the main body introduction system over the wire into the femoral artery. Advance the introduction system until the four gold radiopaque markers (which are positioned 2 mm from the most proximal segment of the graft material) are just inferior to the most inferior renal orifice.

1b

Deploy the first two covered stents by withdrawing the sheath while monitoring the device location. Check the position of the contralateral limb radiopaque marker and the location of renal arteries.

Note: A marker formation of √ indicates an anterior position of the short contralateral limb.

Proceed with deployment until the contralateral limb is fully deployed. Stop withdrawing the sheath.

2 CONTRALATERAL ILIAC WIRE GUIDE PLACEMENT

Manipulate the catheter and wire guide through the open end of the contralateral limb into the body of the endovascular graft. A-P and oblique fluoroscopic views aid in verification of device cannulation. Advance the angiographic catheter over the wire into the body of the endovascular graft. Perform angiography to confirm position, then advance the wire guide until it curves inside the body of the endovascular graft.

3 MAIN BODY PROXIMAL (TOP) DEPLOYMENT

Remove the safety lock from the top stent trigger-wire release mechanism. Withdraw and remove the trigger-wire release mechanism. Loosen the pin vise and deploy the suprarenal stent by advancing the top cap inner cannula 1 to 2 mm at a time until the top stent is fully deployed. Advance the top cap inner cannula an additional 1 to 2 cm and retighten the pin vise. Advance the contralateral wire guide into the thoracic aorta.

Note: Once the barbed suprarenal stent has been deployed, further attempts to reposition the graft are not recommended.

4 CONTRALATERAL ILIAC LEG PLACEMENT AND DEPLOYMENT

Introduce the contralateral iliac leg introduction system into the artery. Advance slowly until the iliac leg graft overlaps at least one full iliac leg stent inside the contralateral limb of the main body. Reposition the iliac leg graft if necessary to ensure both internal iliac patency and a minimum of one full iliac leg stent overlap (maximum overlap of 1.5 stents) within the main body endovascular graft. To deploy, hold the iliac leg graft in position with the grey positioner while withdrawing the sheath. Stop withdrawing the sheath as soon as the distal end of the iliac leg graft is released. Verify the iliac leg graft position, loosen the pin vise, and retract the inner cannula to dock the tapered dilator to the grey positioner. Tighten the pin vise and withdraw the grey positioner with the secured inner cannula.

Deployment overview* (continued)

5 MAIN BODY DISTAL (BOTTOM) DEPLOYMENT

Fully deploy the ipsilateral limb of the main body by withdrawing the sheath until the most distal stent has expanded. Stop withdrawing the sheath. Remove the safety lock from the ipsilateral limb trigger-wire release mechanism. Withdraw and remove the trigger-wire release mechanism.

6 DOCKING OF THE TOP CAP

Loosen the pin vise and advance the grey positioner over the inner cannula until it docks with the top cap. Retighten the pin vise and withdraw the entire top cap and grey positioner through the endovascular graft and through the sheath by pulling on the inner cannula.

Note: Maintain the position of the sheath and wire guide.

Close the Captor® Hemostatic Valve on the Flexor® Introducer Sheath.

7 IPSILATERAL ILIAC LEG PLACEMENT AND DEPLOYMENT

Use the main body graft wire and sheath assembly to introduce the ipsilateral iliac leg graft. Advance the dilator and sheath assembly into the main body sheath. Advance slowly until the ipsilateral iliac leg graft overlaps a minimum of one full iliac leg stent inside the ipsilateral limb of the main body. Reposition the iliac leg graft, if necessary, to ensure internal iliac patency. To deploy, stabilise the iliac leg graft with the grey positioner while withdrawing the iliac leg sheath. Verify the iliac leg graft position, loosen the pin vise, and retract the inner cannula to dock the tapered dilator to the grey positioner. Tighten the pin vise and withdraw the grey positioner with the secured inner cannula. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath.

8 MOULDING BALLOON INSERTION

Advance the moulding balloon over the wire guide and through the haemostatic valve of the main body introduction system to the level of the renal arteries. Expand the moulding balloon with diluted contrast media in the area of the most proximal covered stent and the infrarenal neck, starting proximally and working in the distal direction.

Caution: Confirm complete balloon deflation prior to repositioning.

Caution: Captor Hemostatic Valve must be open prior to repositioning of moulding balloon.

Withdraw the moulding balloon to both the ipsilateral limb overlap and the ipsilateral distal fixation site and expand. Deflate and remove the moulding balloon. Transfer the moulding balloon onto the contralateral wire guide and into the contralateral iliac leg introduction system. Advance the moulding balloon to the contralateral limb overlap and expand. Withdraw the moulding balloon to the contralateral iliac leg/vessel distal fixation and expand.

Caution: Do not inflate the balloon in the iliac vessel outside of graft.

Deflate and remove the moulding balloon and replace it with an angiographic catheter to perform completion angiography.

**This deployment overview is an outline highlighting the deployment process for the Zenith Flex AAA Endovascular Graft. The Instructions for Use booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings, and precautions.*

Abdominal





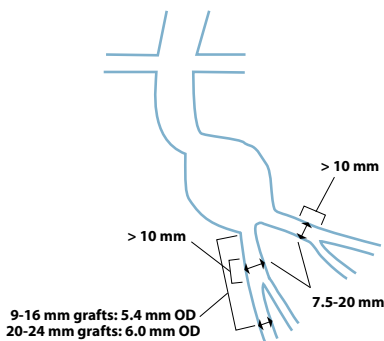
Zenith® Spiral-Z®

AAA Iliac Leg Graft

Abdominal



Indications for use



Indications for use	For use with the Zenith AAA Endovascular Graft family of products, during either a primary or a secondary procedure in patients who have adequate iliac/femoral access compatible with the required introduction systems. The graft is used in combination with these products for the endovascular treatment of abdominal aortic and aortoiliac aneurysms.	
Ipsilateral iliac fixation site	Distal fixation site > 10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall)	
Contralateral iliac fixation site	Distal fixation site > 10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall)	
Access	Adequate femoral/iliac access compatible with the required introduction systems	
Introducer diameters	9-16 mm grafts: ID 14 Fr (4.7 mm) OD 5.4 mm	20-24 mm grafts: ID 16 Fr (5.3 mm) OD 6.0 mm
Contraindications	• Patients with known sensitivities or allergies to stainless steel, nitinol, PTFE, polyester, solder (tin, silver), polypropylene, or gold • Patients with a systemic or local infection who may be at increased risk of endovascular graft infection	

Spiral-Z iliac leg grafts

Order Number	Reference Part Number	Iliac Leg Distal Diameter mm	Iliac Leg Working Length mm	Introducer Sheath ID/OD Fr (mm)/mm
9 mm Diameter				
G55218	ZSLE-9-39-ZT	9	39	14 (4.7)/5.4
G55219	ZSLE-9-56-ZT	9	56	14 (4.7)/5.4
G55220	ZSLE-9-74-ZT	9	74	14 (4.7)/5.4
G55221	ZSLE-9-90-ZT	9	90	14 (4.7)/5.4
G55222	ZSLE-9-107-ZT	9	107	14 (4.7)/5.4
G55223	ZSLE-9-122-ZT	9	122	14 (4.7)/5.4
11 mm Diameter				
G55224	ZSLE-11-39-ZT	11	39	14 (4.7)/5.4
G55225	ZSLE-11-56-ZT	11	56	14 (4.7)/5.4
G55226	ZSLE-11-74-ZT	11	74	14 (4.7)/5.4
G55227	ZSLE-11-90-ZT	11	90	14 (4.7)/5.4
G55228	ZSLE-11-107-ZT	11	107	14 (4.7)/5.4
G55229	ZSLE-11-122-ZT	11	122	14 (4.7)/5.4
13 mm Diameter				
G55230	ZSLE-13-39-ZT	13	39	14 (4.7)/5.4
G55231	ZSLE-13-56-ZT	13	56	14 (4.7)/5.4
G55232	ZSLE-13-74-ZT	13	74	14 (4.7)/5.4
G55233	ZSLE-13-90-ZT	13	90	14 (4.7)/5.4
G55234	ZSLE-13-107-ZT	13	107	14 (4.7)/5.4
G55235	ZSLE-13-122-ZT	13	122	14 (4.7)/5.4
16 mm Diameter				
G55236	ZSLE-16-39-ZT	16	39	14 (4.7)/5.4
G55237	ZSLE-16-56-ZT	16	56	14 (4.7)/5.4
G55238	ZSLE-16-74-ZT	16	74	14 (4.7)/5.4
G55239	ZSLE-16-90-ZT	16	90	14 (4.7)/5.4
20 mm Diameter				
G55240	ZSLE-20-39-ZT	20	39	16 (5.3)/6.0
G55241	ZSLE-20-56-ZT	20	56	16 (5.3)/6.0
G55242	ZSLE-20-74-ZT	20	74	16 (5.3)/6.0
G55243	ZSLE-20-90-ZT	20	90	16 (5.3)/6.0

Some products or part numbers may not be available in all markets.

Contact your local Cook representative or Customer Support & Distribution for details.

Please see product risk information in the IFU at cookmedical.eu.

Spiral-Z iliac leg grafts (continued)

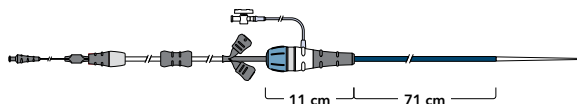
Order Number	Reference Part Number	Iliac Leg Distal Diameter mm	Iliac Leg Working Length mm	Introducer Sheath ID/OD Fr (mm)/mm
24 mm Diameter				
G55244	ZSLE-24-39-ZT	24	39	16 (5.3)/6.0
G55245	ZSLE-24-56-ZT	24	56	16 (5.3)/6.0
G55246	ZSLE-24-74-ZT	24	74	16 (5.3)/6.0
G55247	ZSLE-24-90-ZT	24	90	16 (5.3)/6.0

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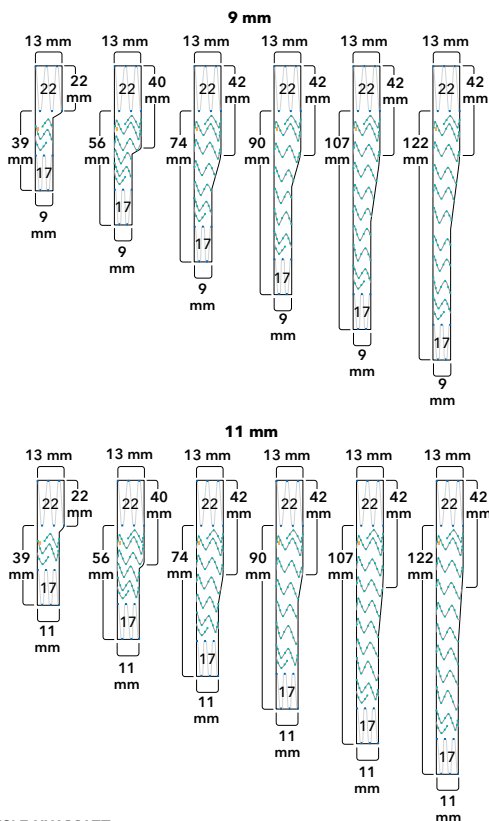
Z-Trak Introduction System for iliac legs

9-16 mm grafts: 14 Fr (4.7 mm) ID/5.4 mm OD

20-24 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD



Spiral-Z iliac leg grafts

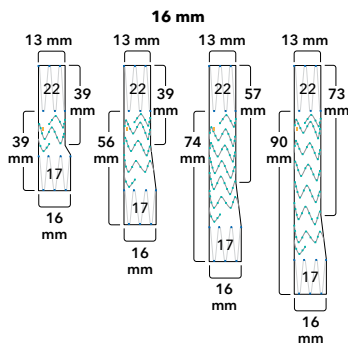
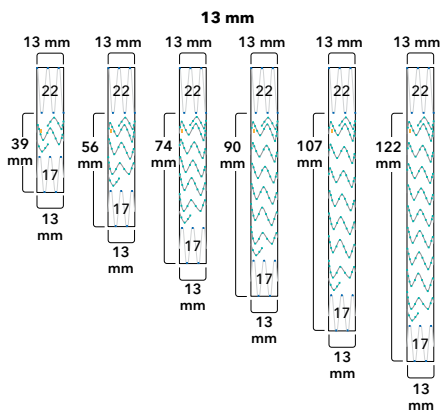


ZSLE-XX-YYY-ZT

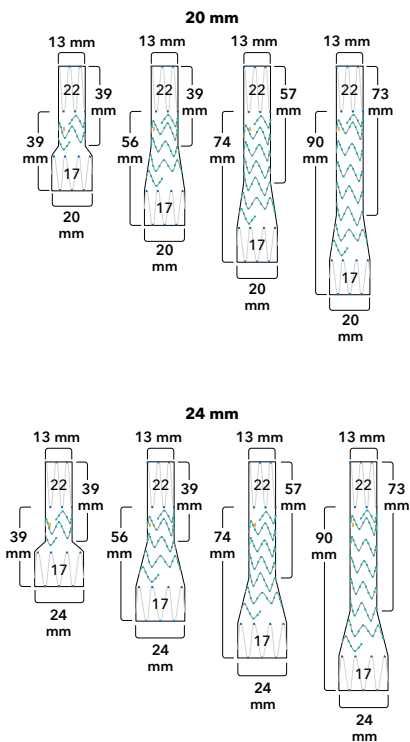
ZSLE-(distal diameter)-(working length)-ZT

Note: All measurements are in millimetres. The numbers on the illustrations indicate stent lengths.

Spiral-Z iliac leg grafts (continued)

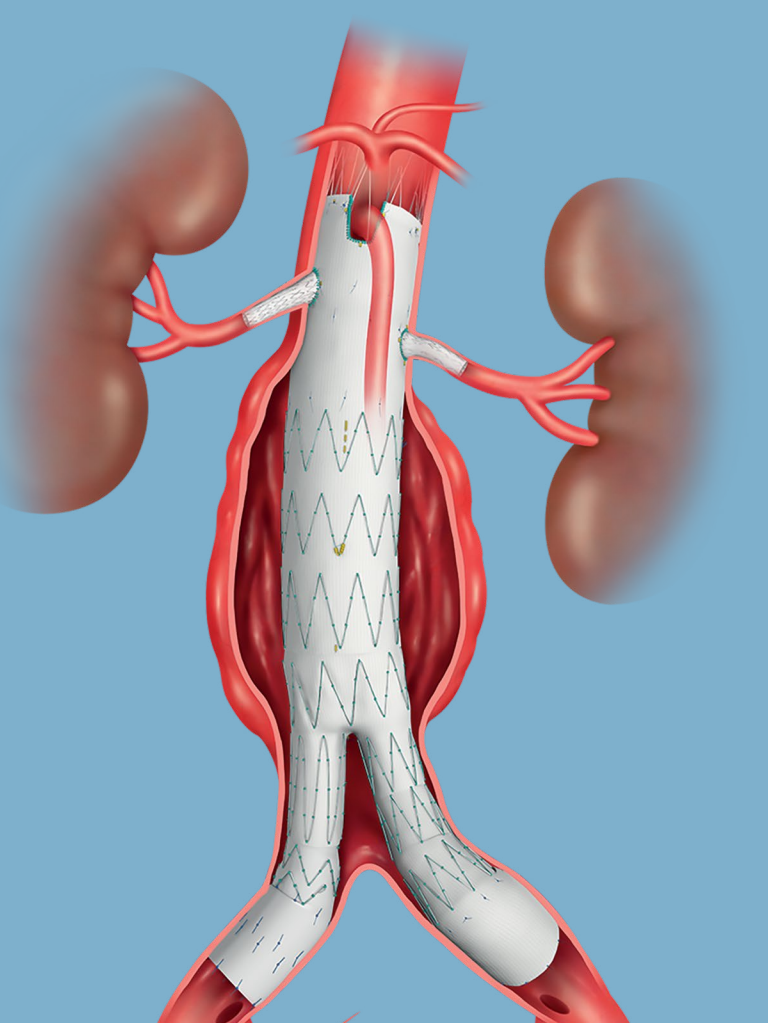


Spiral-Z iliac leg grafts (continued)



Fenestrated





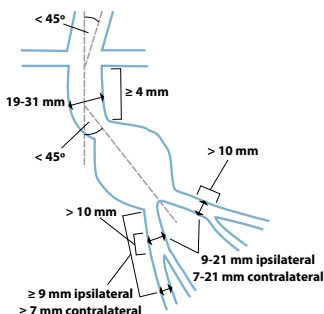
Zenith[®] Fenestrated

AAA Endovascular Graft



Fenestrated

Indications for use



Indications for use	Infrarenal abdominal aortic aneurysms (AAAs) in high-risk patients who are not suitable for conventional open surgical repair or who are not suitable for repair with a standard Zenith Endovascular Graft, when the aneurysmal disease extends up to the level of the renal arteries.	
Length	≥ 4 mm nonaneurysmal neck	
Aortic fixation site diameter	19-31 mm (measured outer wall to outer wall)	
Angulation/curvature	- Angle < 45 degrees relative to the long axis of the aneurysm - Angle < 45 degrees relative to the axis of the suprarenal aorta	
Ipsilateral iliac fixation site	Distal fixation site > 10 mm in length and 9-21 mm in diameter (measured outer wall to outer wall)	
Contralateral iliac fixation site	Distal fixation site > 10 mm in length and 7-21 mm in diameter (measured outer wall to outer wall)	
Access	Adequate femoral/iliac access compatible with the required introduction systems	
Introducer diameters	24-34 mm grafts: ID 20 Fr (6.7 mm), OD 7.7 mm	36 mm grafts: ID 22 Fr (7.3 mm), OD 8.5 mm
Contraindications	- Patients with known sensitivities or allergies to stainless steel, nitinol (nickel), polyester, solder (tin, silver), polypropylene, urethane or gold - Patients with a systemic infection may be at increased risk of endovascular graft infection. - Patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging. - Patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.	

Proximal body grafts

Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Body Diameter mm	Proximal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
One Proximal Internal Stent					
24 mm Diameter					
G38124	ZFEN-P-1-24-76	19-21	24	76	20 (6.7)/7.7
G38125	ZFEN-P-1-24-91	19-21	24	91	20 (6.7)/7.7
G38122	ZFEN-P-1-24-106	19-21	24	106	20 (6.7)/7.7
G38123	ZFEN-P-1-24-121	19-21	24	121	20 (6.7)/7.7
26 mm Diameter					
G38128	ZFEN-P-1-26-76	21-22	26	76	20 (6.7)/7.7
G38129	ZFEN-P-1-26-91	21-22	26	91	20 (6.7)/7.7
G38126	ZFEN-P-1-26-106	21-22	26	106	20 (6.7)/7.7
G38127	ZFEN-P-1-26-121	21-22	26	121	20 (6.7)/7.7
28 mm Diameter					
G38132	ZFEN-P-1-28-76	23-24	28	76	20 (6.7)/7.7
G38133	ZFEN-P-1-28-91	23-24	28	91	20 (6.7)/7.7
G38130	ZFEN-P-1-28-106	23-24	28	106	20 (6.7)/7.7
G38131	ZFEN-P-1-28-121	23-24	28	121	20 (6.7)/7.7
30 mm Diameter					
G38136	ZFEN-P-1-30-76	24-26	30	76	20 (6.7)/7.7
G38137	ZFEN-P-1-30-91	24-26	30	91	20 (6.7)/7.7
G38134	ZFEN-P-1-30-106	24-26	30	106	20 (6.7)/7.7
G38135	ZFEN-P-1-30-121	24-26	30	121	20 (6.7)/7.7
32 mm Diameter					
G38140	ZFEN-P-1-32-76	26-28	32	76	20 (6.7)/7.7
G38141	ZFEN-P-1-32-91	26-28	32	91	20 (6.7)/7.7
G38138	ZFEN-P-1-32-106	26-28	32	106	20 (6.7)/7.7
G38139	ZFEN-P-1-32-121	26-28	32	121	20 (6.7)/7.7
34 mm Diameter					
G38144	ZFEN-P-1-34-84	28-29	34	84	20 (6.7)/7.7
G38145	ZFEN-P-1-34-99	28-29	34	99	20 (6.7)/7.7
G38142	ZFEN-P-1-34-114	28-29	34	114	20 (6.7)/7.7
G38143	ZFEN-P-1-34-129	28-29	34	129	20 (6.7)/7.7
36 mm Diameter					
G38148	ZFEN-P-1-36-84	29-31	36	84	22 (7.3)/8.5
G38149	ZFEN-P-1-36-99	29-31	36	99	22 (7.3)/8.5
G38146	ZFEN-P-1-36-114	29-31	36	114	22 (7.3)/8.5
G38147	ZFEN-P-1-36-129	29-31	36	129	22 (7.3)/8.5

Some products or part numbers may not be available in all markets.
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Proximal body grafts (continued)

Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Body Diameter mm	Proximal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
Two Proximal Internal Stents					
24 mm Diameter					
G38152	ZFEN-P-2-24-94	19-21	24	94	20 (6.7)/7.7
G38150	ZFEN-P-2-24-109	19-21	24	109	20 (6.7)/7.7
G38151	ZFEN-P-2-24-124	19-21	24	124	20 (6.7)/7.7
26 mm Diameter					
G38155	ZFEN-P-2-26-94	21-22	26	94	20 (6.7)/7.7
G38153	ZFEN-P-2-26-109	21-22	26	109	20 (6.7)/7.7
G38154	ZFEN-P-2-26-124	21-22	26	124	20 (6.7)/7.7
28 mm Diameter					
G38158	ZFEN-P-2-28-94	23-24	28	94	20 (6.7)/7.7
G38156	ZFEN-P-2-28-109	23-24	28	109	20 (6.7)/7.7
G38157	ZFEN-P-2-28-124	23-24	28	124	20 (6.7)/7.7
30 mm Diameter					
G38161	ZFEN-P-2-30-94	24-26	30	94	20 (6.7)/7.7
G38159	ZFEN-P-2-30-109	24-26	30	109	20 (6.7)/7.7
G38160	ZFEN-P-2-30-124	24-26	30	124	20 (6.7)/7.7
32 mm Diameter					
G38164	ZFEN-P-2-32-94	26-28	32	94	20 (6.7)/7.7
G38162	ZFEN-P-2-32-109	26-28	32	109	20 (6.7)/7.7
G38163	ZFEN-P-2-32-124	26-28	32	124	20 (6.7)/7.7
34 mm Diameter					
G38165	ZFEN-P-2-34-107	28-29	34	107	20 (6.7)/7.7
G38166	ZFEN-P-2-34-122	28-29	34	122	20 (6.7)/7.7
G38167	ZFEN-P-2-34-137	28-29	34	137	20 (6.7)/7.7
36 mm Diameter					
G38168	ZFEN-P-2-36-107	29-31	36	107	22 (7.3)/8.5
G38169	ZFEN-P-2-36-122	29-31	36	122	22 (7.3)/8.5
G38170	ZFEN-P-2-36-137	29-31	36	137	22 (7.3)/8.5

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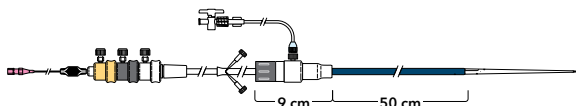
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H&L-B One-Shot Introduction System for proximal body grafts

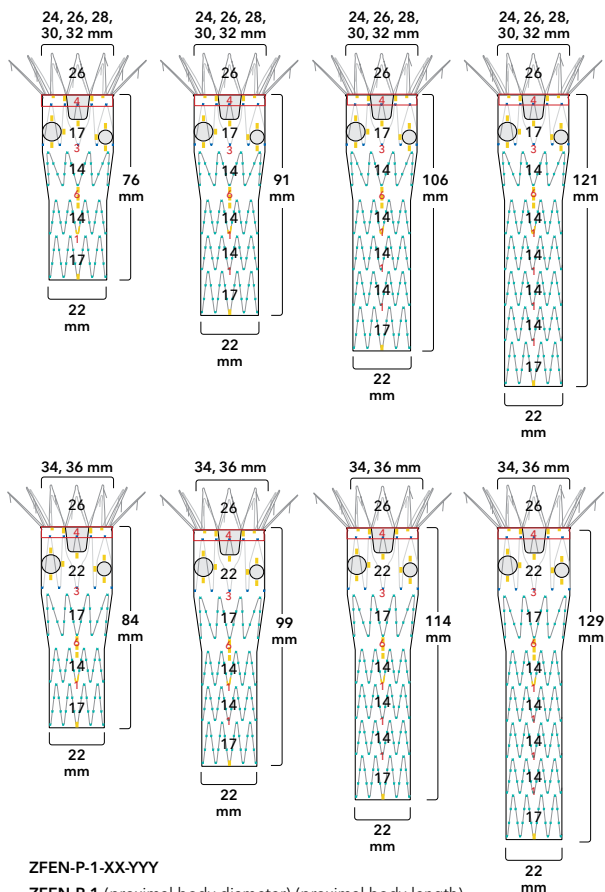
24-34 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD,

36 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Proximal body grafts

One proximal internal stent



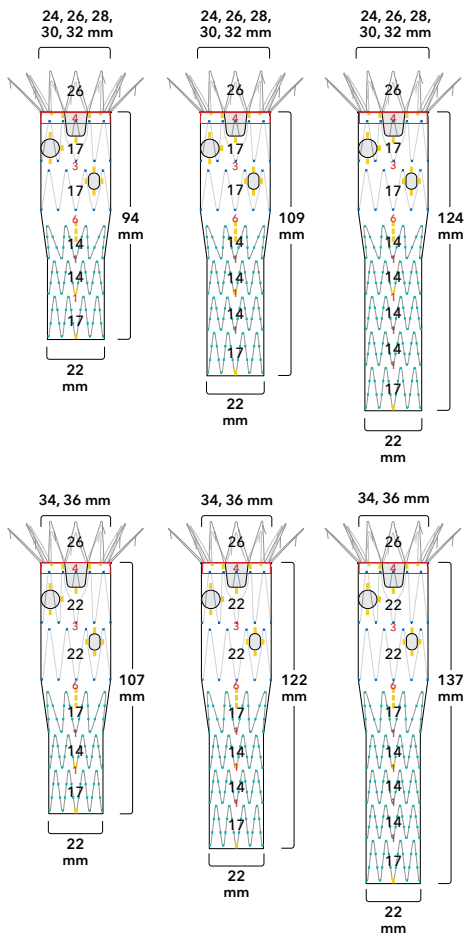
ZFEN-P-1-XX-YYY

ZFEN-P-1-(proximal body diameter)-(proximal body length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Proximal body grafts (continued)

Two proximal internal stents



ZFEN-P-2-XX-YYY

ZFEN-P-2-(proximal body diameter)-(proximal body length)

Distal bifurcated body grafts

Order Number	Reference Part Number	Ipsilateral Leg Diameter mm	Distal Ipsilateral Leg Length mm	Distal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
G38079	ZFEN-D-12-28-76	12	28	76	20 (6.7)/7.7
G38574	ZFEN-D-12-28-94	12	28	94	20 (6.7)/7.7
G38577	ZFEN-D-12-28-109	12	28	109	20 (6.7)/7.7
G38580	ZFEN-D-12-28-124	12	28	124	20 (6.7)/7.7
G38083	ZFEN-D-12-45-76	12	45	76	20 (6.7)/7.7
G38583	ZFEN-D-12-45-94	12	45	94	20 (6.7)/7.7
G38587	ZFEN-D-12-45-109	12	45	109	20 (6.7)/7.7
G38591	ZFEN-D-12-45-124	12	45	124	20 (6.7)/7.7
G38087	ZFEN-D-12-62-76	12	62	76	20 (6.7)/7.7
G38595	ZFEN-D-12-62-94	12	62	94	20 (6.7)/7.7
G38599	ZFEN-D-12-62-109	12	62	109	20 (6.7)/7.7
G38603	ZFEN-D-12-62-124	12	62	124	20 (6.7)/7.7
G38091	ZFEN-D-16-28-76	16	28	76	20 (6.7)/7.7
G38575	ZFEN-D-16-28-94	16	28	94	20 (6.7)/7.7
G38578	ZFEN-D-16-28-109	16	28	109	20 (6.7)/7.7
G38581	ZFEN-D-16-28-124	16	28	124	20 (6.7)/7.7
G38095	ZFEN-D-16-45-76	16	45	76	20 (6.7)/7.7
G38584	ZFEN-D-16-45-94	16	45	94	20 (6.7)/7.7
G38588	ZFEN-D-16-45-109	16	45	109	20 (6.7)/7.7
G38592	ZFEN-D-16-45-124	16	45	124	20 (6.7)/7.7
G38099	ZFEN-D-16-62-76	16	62	76	20 (6.7)/7.7
G38596	ZFEN-D-16-62-94	16	62	94	20 (6.7)/7.7
G38600	ZFEN-D-16-62-109	16	62	109	20 (6.7)/7.7
G38604	ZFEN-D-16-62-124	16	62	124	20 (6.7)/7.7
G38103	ZFEN-D-20-28-76	20	28	76	20 (6.7)/7.7
G38576	ZFEN-D-20-28-94	20	28	94	20 (6.7)/7.7
G38579	ZFEN-D-20-28-109	20	28	109	20 (6.7)/7.7
G38582	ZFEN-D-20-28-124	20	28	124	20 (6.7)/7.7
G38107	ZFEN-D-20-45-76	20	45	76	20 (6.7)/7.7
G38585	ZFEN-D-20-45-94	20	45	94	20 (6.7)/7.7
G38589	ZFEN-D-20-45-109	20	45	109	20 (6.7)/7.7
G38593	ZFEN-D-20-45-124	20	45	124	20 (6.7)/7.7

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Distal bifurcated body grafts (continued)

Order Number	Reference Part Number	Ipsilateral Leg Diameter mm	Distal Ipsilateral Leg Length mm	Distal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
G38111	ZFEN-D-20-62-76	20	62	76	20 (6.7)/7.7
G38597	ZFEN-D-20-62-94	20	62	94	20 (6.7)/7.7
G38601	ZFEN-D-20-62-109	20	62	109	20 (6.7)/7.7
G38605	ZFEN-D-20-62-124	20	62	124	20 (6.7)/7.7
G38115	ZFEN-D-24-45-76	24	45	76	20 (6.7)/7.7
G38586	ZFEN-D-24-45-94	24	45	94	20 (6.7)/7.7
G38590	ZFEN-D-24-45-109	24	45	109	20 (6.7)/7.7
G38594	ZFEN-D-24-45-124	24	45	124	20 (6.7)/7.7
G38119	ZFEN-D-24-62-76	24	62	76	20 (6.7)/7.7
G38598	ZFEN-D-24-62-94	24	62	94	20 (6.7)/7.7
G38602	ZFEN-D-24-62-109	24	62	109	20 (6.7)/7.7
G38606	ZFEN-D-24-62-124	24	62	124	20 (6.7)/7.7

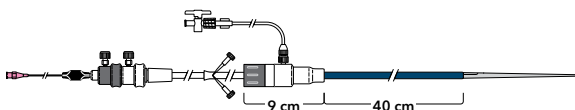
Some products or part numbers may not be available in all markets.

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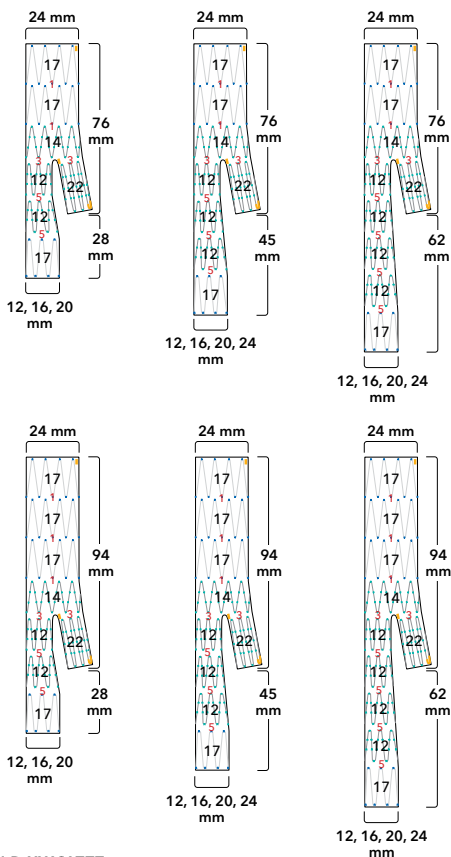
Please see product risk information in the IFU at cookmedical.eu.

H&L-B One-Shot Introduction System for distal bifurcated body grafts

20 Fr (6.7 mm) ID/7.7 mm OD



Distal bifurcated body grafts



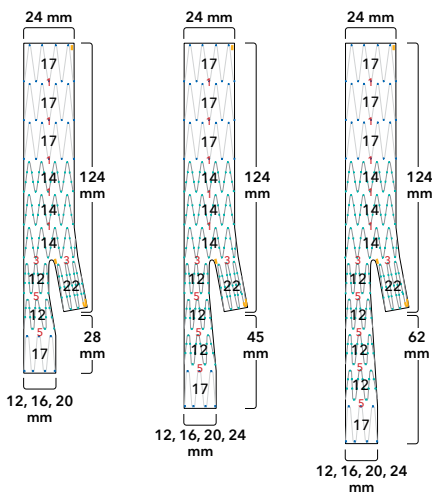
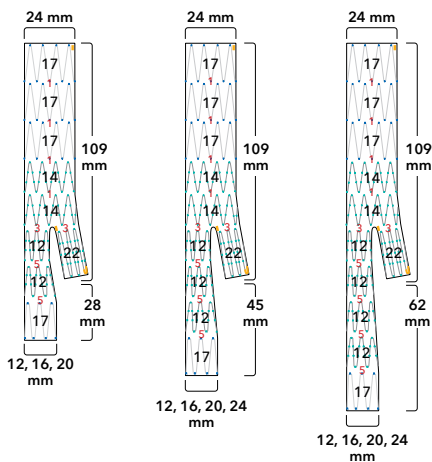
ZFEN-D-XX-YY-ZZZ

ZFEN-D-(ipsilateral leg diameter)-(distal ipsilateral leg length)-(distal body length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

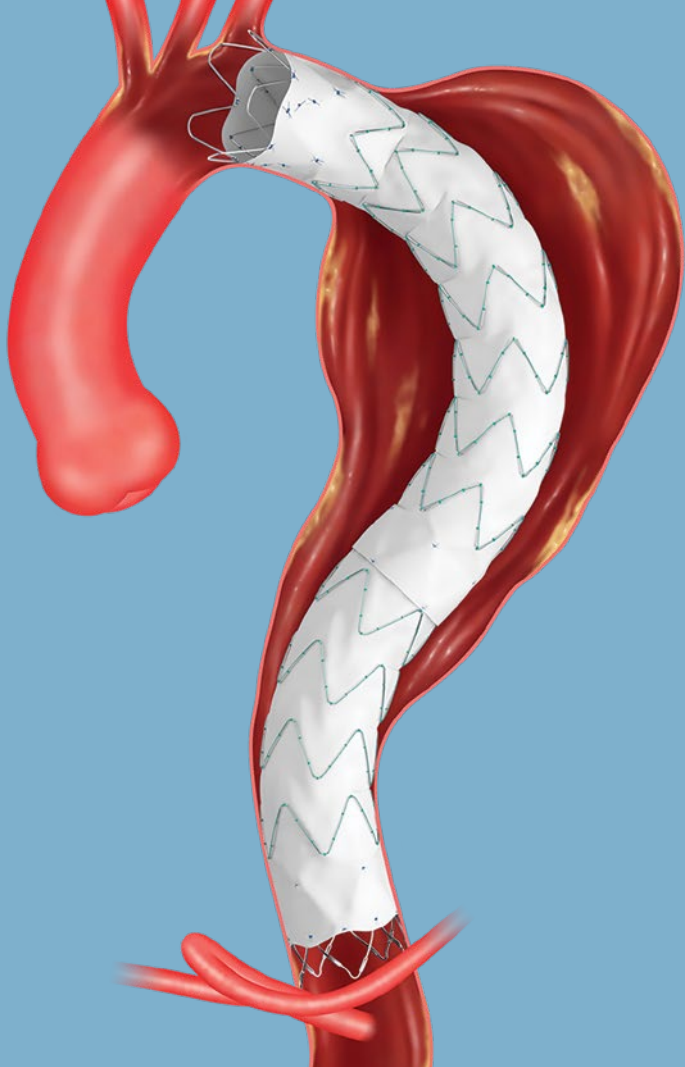
Note: Zenith® Fenestrated is compatible with Zenith Spiral-Z® legs.

Distal bifurcated body grafts (continued)



Thoracic





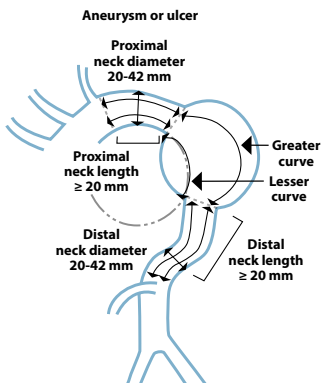
Zenith Alpha[®]

Thoracic Endovascular Graft

Thoracic



Indications for use



Indications for use	The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair including: • Iliac/femoral anatomy that is suitable for access with the required introduction systems, • Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer: - with a length of at least 20 mm, and - with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm.		
Length	Nonaneurysmal aortic necks proximal and distal to the aneurysm with a length ≥ 20 mm		
Aortic fixation site diameter	20-42 mm (measured outer wall to outer wall)		
Angulation/curvature	• Radius of curvature ≥ 20 mm for aortic arch landing zones • An angle ≤ 45 degrees (any angle in the arch or distal aorta)		
Access	Iliac/femoral anatomy that is suitable for access with the required introduction system		
Introducer diameters	24-30 mm grafts: ID 16 Fr (5.3 mm) OD 6.0 mm	32-38 mm grafts: ID 18 Fr (6.0 mm) OD 7.1 mm	40-46 mm grafts: ID 20 Fr (6.7 mm) OD 7.7 mm
Contraindications	• Patients with known sensitivities or allergies to polyester, polypropylene, nitinol, or gold. • Patients who have a condition that threatens to infect the endovascular graft.		

Proximal components

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
24 mm Diameter					
G34677	ZTA-P-24-105	20-21	24	105	16 (5.3)/6.0
26 mm Diameter					
G34679	ZTA-P-26-105	22-23	26	105	16 (5.3)/6.0
28 mm Diameter					
G34682	ZTA-P-28-109	24-25	28	109	16 (5.3)/6.0
G34683	ZTA-P-28-155	24-25	28	155	16 (5.3)/6.0
G34684	ZTA-P-28-201	24-25	28	201	16 (5.3)/6.0
30 mm Diameter					
G34685	ZTA-P-30-109	26-27	30	109	16 (5.3)/6.0
G34687	ZTA-P-30-155	26-27	30	155	16 (5.3)/6.0
G34688	ZTA-P-30-201	26-27	30	201	16 (5.3)/6.0
32 mm Diameter					
G34689	ZTA-P-32-109	28-29	32	109	18 (6.0)/7.1
G34691	ZTA-P-32-155	28-29	32	155	18 (6.0)/7.1
G34692	ZTA-P-32-201	28-29	32	201	18 (6.0)/7.1
34 mm Diameter					
G34694	ZTA-P-34-113	30	34	113	18 (6.0)/7.1
G34696	ZTA-P-34-161	30	34	161	18 (6.0)/7.1
G34697	ZTA-P-34-209	30	34	209	18 (6.0)/7.1
36 mm Diameter					
G34698	ZTA-P-36-113	31-32	36	113	18 (6.0)/7.1
G34700	ZTA-P-36-161	31-32	36	161	18 (6.0)/7.1
G34701	ZTA-P-36-209	31-32	36	209	18 (6.0)/7.1

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40 to 46 mm diameter proximal components have a Pro-Form® restraining suture to aid in conformability.

Proximal components (continued)

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
38 mm Diameter					
G34702	ZTA-P-38-117	33-34	38	117	18 (6.0)/7.1
G34704	ZTA-P-38-167	33-34	38	167	18 (6.0)/7.1
G34705	ZTA-P-38-217	33-34	38	217	18 (6.0)/7.1
40 mm Diameter					
G34706	ZTA-P-40-117	35-36	40	117	20 (6.7)/7.7
G34708	ZTA-P-40-167	35-36	40	167	20 (6.7)/7.7
G34709	ZTA-P-40-217	35-36	40	217	20 (6.7)/7.7
42 mm Diameter					
G34710	ZTA-P-42-121	37-38	42	121	20 (6.7)/7.7
G34713	ZTA-P-42-173	37-38	42	173	20 (6.7)/7.7
G34714	ZTA-P-42-225	37-38	42	225	20 (6.7)/7.7
44 mm Diameter					
G34715	ZTA-P-44-125	39	44	125	20 (6.7)/7.7
G34717	ZTA-P-44-179	39	44	179	20 (6.7)/7.7
G34718	ZTA-P-44-233	39	44	233	20 (6.7)/7.7
46 mm Diameter					
G34719	ZTA-P-46-125	40-42	46	125	20 (6.7)/7.7
G34721	ZTA-P-46-179	40-42	46	179	20 (6.7)/7.7
G34722	ZTA-P-46-233	40-42	46	233	20 (6.7)/7.7

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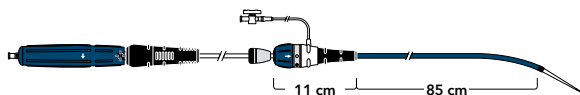
40 to 46 mm diameter proximal components have a Pro-Form restraining suture to aid in conformability.

Introduction system for proximal components

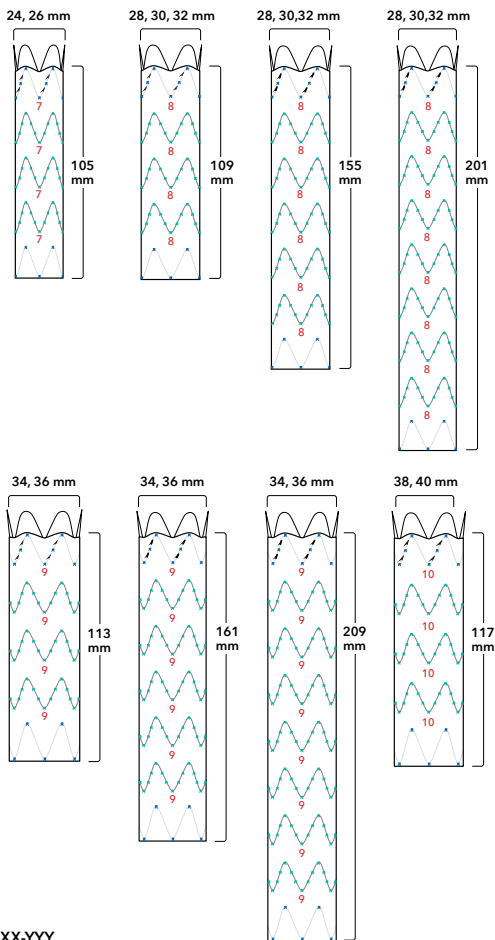
24-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

32-38 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

40-46 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Proximal components

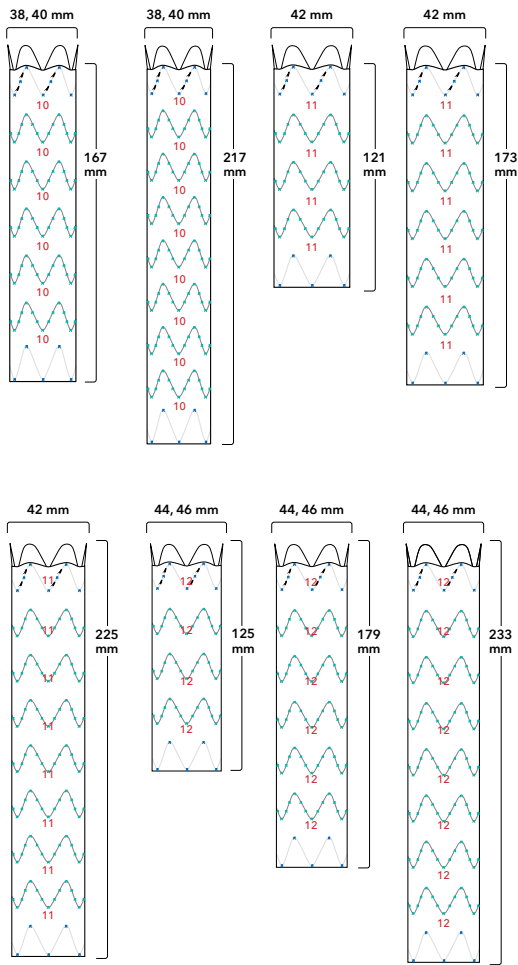


ZTA-P-XX-YYY

ZTA-P-(diameter)-(length)

Note: All measurements are in millimetres. Red numbers indicate gap lengths. Gap lengths are approximate.

Proximal components (continued)



Proximal 4 mm tapered components

Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Diameter mm	Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
30 mm Diameter						
G44446	ZTA-PT-30-26-108	26-27	30	26	108	16 (5.3)/6.0
32 mm Diameter						
G34638	ZTA-PT-32-28-178	28-29	32	28	178	18 (6.0)/7.1
G34639	ZTA-PT-32-28-201	28-29	32	28	201	18 (6.0)/7.1
34 mm Diameter						
G34640	ZTA-PT-34-30-161	30	34	30	161	18 (6.0)/7.1
G34642	ZTA-PT-34-30-209	30	34	30	209	18 (6.0)/7.1
36 mm Diameter						
G34643	ZTA-PT-36-32-161	31-32	36	32	161	18 (6.0)/7.1
G34645	ZTA-PT-36-32-209	31-32	36	32	209	18 (6.0)/7.1
38 mm Diameter						
G34646	ZTA-PT-38-34-167	33-34	38	34	167	18 (6.0)/7.1
G34648	ZTA-PT-38-34-217	33-34	38	34	217	18 (6.0)/7.1
40 mm Diameter						
G34650	ZTA-PT-40-36-167	35-36	40	36	167	20 (6.7)/7.7
G34652	ZTA-PT-40-36-217	35-36	40	36	217	20 (6.7)/7.7
42 mm Diameter						
G34653	ZTA-PT-42-38-173	37-38	42	38	173	20 (6.7)/7.7
G34655	ZTA-PT-42-38-225	37-38	42	38	225	20 (6.7)/7.7
44 mm Diameter						
G34656	ZTA-PT-44-40-179	39	44	40	179	20 (6.7)/7.7
G34657	ZTA-PT-44-40-233	39	44	40	233	20 (6.7)/7.7
46 mm Diameter						
G34659	ZTA-PT-46-42-179	40-42	46	42	179	20 (6.7)/7.7
G34661	ZTA-PT-46-42-233	40-42	46	42	233	20 (6.7)/7.7

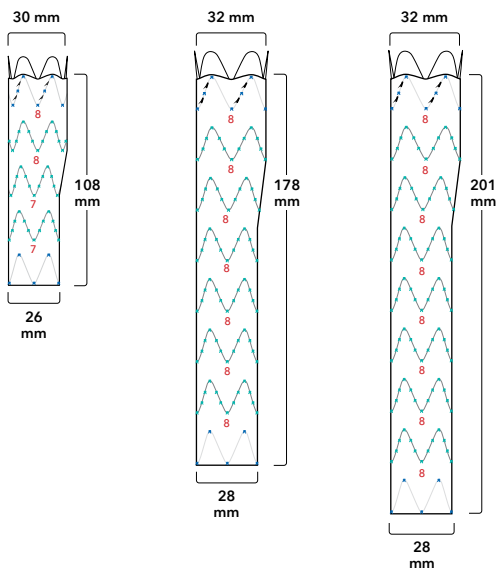
Some products or part numbers may not be available in all markets.

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40 to 46 mm diameter proximal components have a Pro-Form® restraining suture to aid in conformability.

Proximal 4 mm tapered components

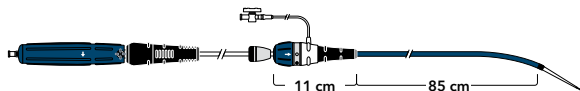


Introduction system for proximal 4 mm tapered components

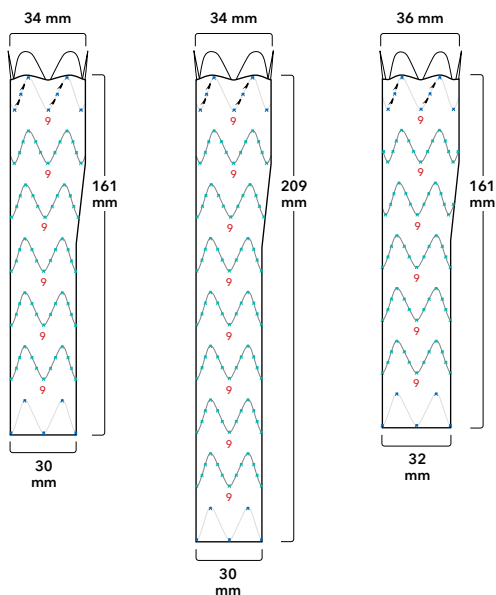
26-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

32-38 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

40-46 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Proximal 4 mm tapered components

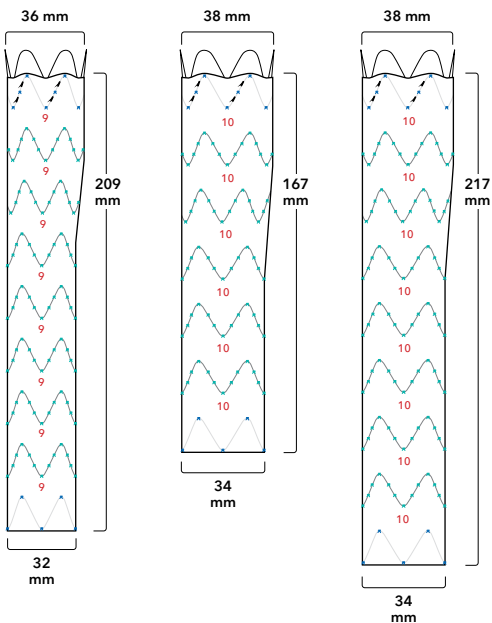


ZTA-PT-XX-YY-ZZZ

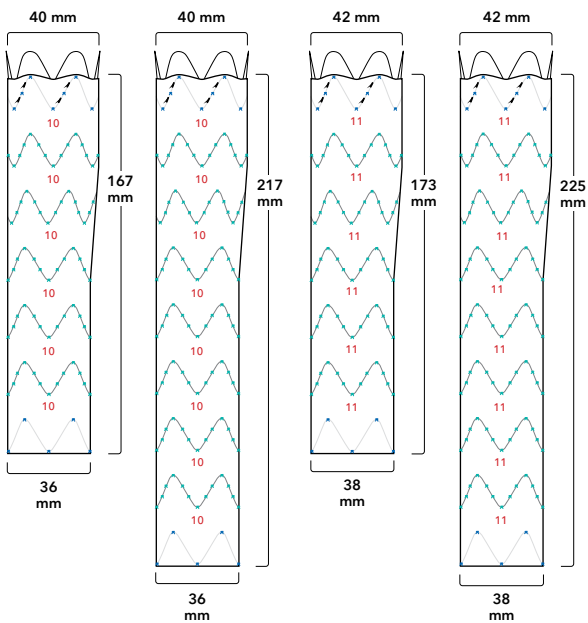
ZTA-PT-(proximal diameter)-(distal diameter)-(length)

Note: All measurements are in millimetres. Red numbers indicate gap lengths. Gap lengths are approximate.

Proximal 4 mm tapered components (continued)



Proximal 4 mm tapered components (continued)



Distal components

Order Number	Reference Part Number	Aortic Vessel OD mm	Distal Component Diameter mm	Distal Component Length mm	Introducer Sheath ID/OD Fr (mm)/mm
28 mm Diameter					
G34602	ZTA-D-28-160	24-25	28	160	16 (5.3)/6.0
30 mm Diameter					
G34610	ZTA-D-30-160	26-27	30	160	16 (5.3)/6.0
32 mm Diameter					
G34619	ZTA-D-32-160	28-29	32	160	18 (6.0)/7.1
34 mm Diameter					
G34641	ZTA-D-34-142	30	34	142	18 (6.0)/7.1
G34647	ZTA-D-34-190	30	34	190	18 (6.0)/7.1
36 mm Diameter					
G34649	ZTA-D-36-142	31-32	36	142	18 (6.0)/7.1
G34651	ZTA-D-36-190	31-32	36	190	18 (6.0)/7.1
38 mm Diameter					
G34654	ZTA-D-38-147	33-34	38	147	18 (6.0)/7.1
G34658	ZTA-D-38-197	33-34	38	197	18 (6.0)/7.1
40 mm Diameter					
G34662	ZTA-D-40-197	35-36	40	197	20 (6.7)/7.7
42 mm Diameter					
G34664	ZTA-D-42-204	37-38	42	204	20 (6.7)/7.7
44 mm Diameter					
G34667	ZTA-D-44-211	39	44	211	20 (6.7)/7.7
46 mm Diameter					
G34670	ZTA-D-46-211	40-41	46	211	20 (6.7)/7.7

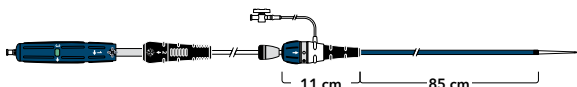
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Introduction system for distal components

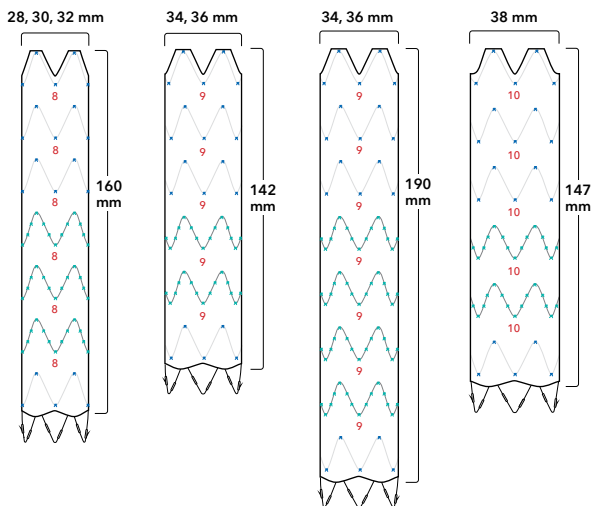
28-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

32-38 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

40-46 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Distal components

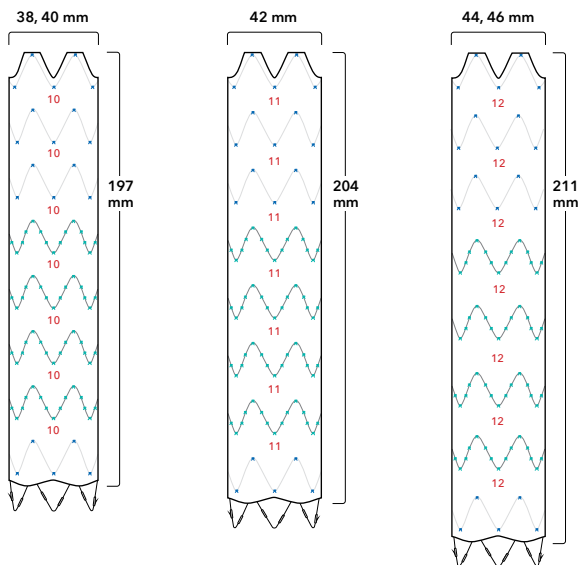


ZTA-D-XX-YYY

ZTA-D-(diameter)-(distal component length)

Note: All measurements are in millimetres. Red numbers indicate gap lengths. Gap lengths are approximate.

Distal components (continued)



Distal extensions

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
26 mm Diameter					
G34607	ZTA-DE-26-104	22-23	26	104	16 (5.3)/6.0
30 mm Diameter					
G34611	ZTA-DE-30-108	26-27	30	108	16 (5.3)/6.0
34 mm Diameter					
G34613	ZTA-DE-34-112	30	34	112	18 (6.0)/7.1
38 mm Diameter					
G34616	ZTA-DE-38-91	33-34	38	91	18 (6.0)/7.1
42 mm Diameter					
G34618	ZTA-DE-42-94	37-38	42	94	20 (6.7)/7.7
46 mm Diameter					
G34622	ZTA-DE-46-97	40-42	46	97	20 (6.7)/7.7

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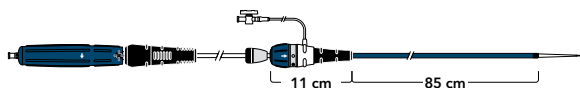
Please see product risk information in the IFU at cookmedical.eu.

Introduction system for distal extensions

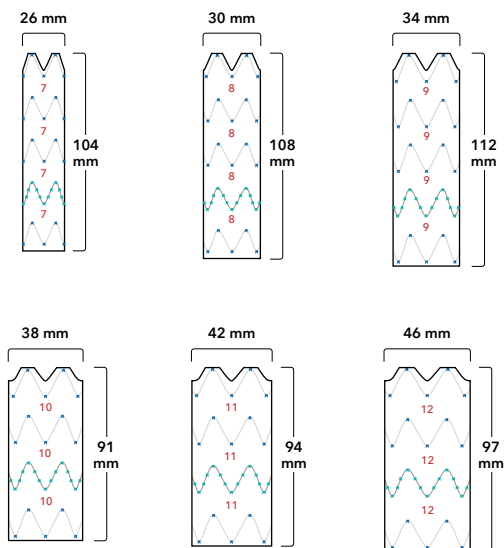
26-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

34-38 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

42-46 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



Distal extensions



ZTA-DE-XX-YYY

ZTA-DE-(diameter)-(length)

Note: All measurements are in millimetres. Red numbers indicate gap lengths. Gap lengths are approximate.

Deployment overview

1 POSITION THE LUNDERQUIST® EXTRA-STIFF DC WIRE GUIDE IN AORTIC ARCH

Through the pigtail flush catheter, replace the standard wire guide with an extra-stiff, 0.035 inch diameter, 260 or 300 cm long double-curved Lunderquist wire guide up to the level of the aortic arch and remove the pigtail.

2 POSITION THE PROXIMAL COMPONENT

Introduce the introduction system for the proximal component over the extra-stiff double-curved Lunderquist wire guide and advance until you reach the desired graft position.

Caution: To avoid twisting the graft, never rotate the introduction system during the procedure. Allow the device to conform naturally. Do not advance the sheath while the graft is still inside the sheath. Doing so may cause the barbs to perforate the introducer sheath.

3 UNSHEATHE THE PROXIMAL COMPONENT

While you constantly monitor the graft position, withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor sleeve docks with the black gripper.

4 RELEASE THE PROXIMAL COMPONENT

Hold the black gripper and loosen the black safety-lock knob on the blue rotating handle (turn in the direction of the arrows). Turn the blue rotating handle following the directional arrow next to label 1 until a stop is felt. The stop indicates that the uncovered stent and proximal end of the graft have opened and the distal attachment to the introducer has been released.

5 REMOVE THE INTRODUCTION SYSTEM FOR THE PROXIMAL COMPONENT

Remove the introduction system entirely, leaving the wire guide positioned in the graft.

6 POSITION THE DISTAL COMPONENT

Introduce the hydrated introduction system until the desired graft position has been achieved. Ensure that there is a minimum overlap of 3 stents.

7 UNSHEATHE THE DISTAL COMPONENT

Stabilise the grey postioner and withdraw the sheath until the Captor sleeve docks with the telescoping black gripper.

Deployment overview (continued)

8 RELEASE THE DISTAL COMPONENT

Use the **1-2-3** deployment sequence.

1. To release the distal attachment, hold the black sliding gripper and turn the black safety-lock knob on the blue rotating handle (turn the safety lock in the direction of the arrows). Turn the blue rotating handle following the directional arrow next to **label 1** until a stop is felt.
2. Turn the grey safety-lock knob indicated by **label 2** on the black sliding gripper (turn the safety lock in the direction of the arrows until a slight click is felt). To release the distal bare stent, stabilise the introduction system and slide the sheath together with the black telescoping gripper (by holding the Captor Valve) in a distal direction until it locks automatically into position next to the blue rotating handle (the release window on the blue rotating handle next to **label 3** will turn green).
3. Turn the blue rotating handle in the direction of the arrow (**label 3**) until a stop is felt and the proximal end of the graft opens.

9 OPTIONAL: MOULDING BALLOON

Advance the moulding balloon over the wire guide and through the haemostatic valve of the main body introduction system to the level of the proximal fixation seal site. Maintain proper sheath positioning.

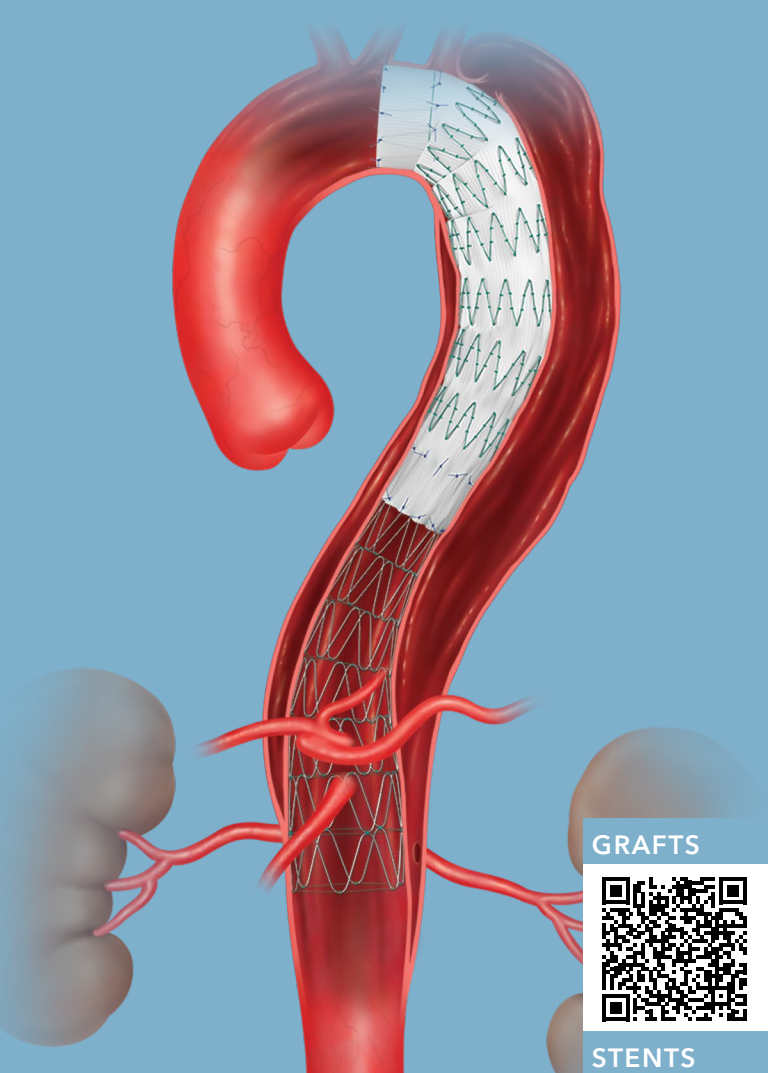
Tighten the Captor Hemostatic Valve around the moulding balloon by turning it clockwise with gentle pressure.

Caution: Do not inflate the balloon in the vessel outside of the graft.

Expand the moulding balloon with diluted contrast media (as directed by the manufacturer) in the area of the proximal covered stent, starting proximally and working in the distal direction.

Thoracic





GRAFTS



STENTS

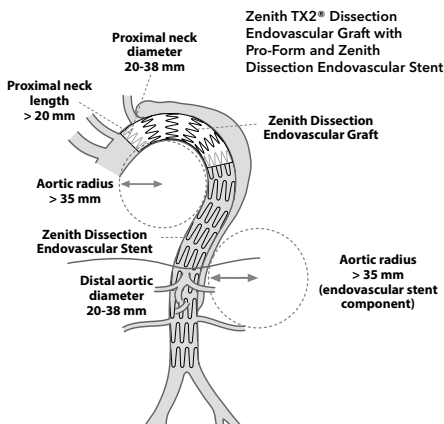


Zenith[®] Dissection

Endovascular Graft and Stent

Thoracic

Indications for use



Indications for use	Patients with symptomatic aortic dissection distal to the left subclavian artery (can be used to provide support to delaminated segments of the aorta typical in dissection) having vascular morphology suitable for endovascular repair		
Length	Dissection stent lengths 80, 120, 180, 185 used in combination with the sealing stent graft TX2 Proximal Component can potentially allow treatment of the entire descending thoracic aorta and the abdominal aorta.		
Aortic fixation site diameter	Dissection grafts: 20-38 mm (measured outer wall to outer wall) Dissection stents: 20-38 mm (measured outer wall to outer wall)		
Angulation/curvature	• Radius of curvature > 35 mm along the length of aorta that is intended to be treated (dissection graft) • Localised angulation < 45 degrees (dissection graft). • Radius of curvature > 35 mm along the length of aorta that is intended to be treated (dissection stent) • Localised angulation < 45 degrees (dissection stent).		
Access	Adequate femoral/iliac access compatible with the required introduction systems		
Introducer diameters	22-34 mm grafts: ID 20 Fr (6.7 mm) OD 7.7 mm	36-42 mm grafts: ID 22 Fr (7.3 mm) OD 8.5 mm	36, 46 mm stents: ID 16 Fr (5.3 mm) OD 6.0 mm
Contraindications	• Patients with known sensitivities or allergies to stainless steel, polyester, nitinol, polypropylene, or gold • Patients with a systemic infection who may be at increased risk of endovascular stent/graft infection		

Zenith TX2® Dissection Endovascular Graft with Pro-Form® straight components

Order Number	Reference Part Number	Component Type	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
22 mm Diameter						
G24249	ZDEG-P-22-79-PF	P	20	22	79	20 (6.7)/7.7
G24250	ZDEG-P-22-117-PF	P	20	22	117	20 (6.7)/7.7
24 mm Diameter						
G24251	ZDEG-P-24-79-PF	P	21	24	79	20 (6.7)/7.7
G24253	ZDEG-P-24-117-PF	P	21	24	117	20 (6.7)/7.7
26 mm Diameter						
G24255	ZDEG-P-26-79-PF	P	22-23	26	79	20 (6.7)/7.7
G24257	ZDEG-P-26-136-PF	P	22-23	26	136	20 (6.7)/7.7
28 mm Diameter						
G24260	ZDEG-P-28-82-PF	P	24	28	82	20 (6.7)/7.7
G24262	ZDEG-P-28-142-PF	P	24	28	142	20 (6.7)/7.7
G24265	ZDEG-P-28-202-PF	P	24	28	202	20 (6.7)/7.7
30 mm Diameter						
G24267	ZDEG-P-30-82-PF	P	25-27	30	82	20 (6.7)/7.7
G24269	ZDEG-P-30-142-PF	P	25-27	30	142	20 (6.7)/7.7
G24271	ZDEG-P-30-202-PF	P	25-27	30	202	20 (6.7)/7.7
32 mm Diameter						
G24272	ZDEG-P-32-82-PF	P	28-29	32	82	20 (6.7)/7.7
G24275	ZDEG-P-32-142-PF	P	28-29	32	142	20 (6.7)/7.7
G24276	ZDEG-P-32-202-PF	P	28-29	32	202	20 (6.7)/7.7
34 mm Diameter						
G24277	ZDEG-P-34-79-PF	P	30	34	79	20 (6.7)/7.7
G24278	ZDEG-P-34-154-PF	P	30	34	154	20 (6.7)/7.7
G24279	ZDEG-P-34-204-PF	P	30	34	204	20 (6.7)/7.7

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Zenith TX2 Dissection Endovascular Graft with Pro-Form straight components (continued)

Order Number	Reference Part Number	Component Type	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
36 mm Diameter						
G24282	ZDEG-P-36-79-PF	P	31-32	36	79	22 (7.3)/8.5
G24283	ZDEG-P-36-154-PF	P	31-32	36	154	22 (7.3)/8.5
G24284	ZDEG-P-36-204-PF	P	31-32	36	204	22 (7.3)/8.5
38 mm Diameter						
G24285	ZDEG-P-38-79-PF	P	33-34	38	79	22 (7.3)/8.5
G24286	ZDEG-P-38-154-PF	P	33-34	38	154	22 (7.3)/8.5
G24287	ZDEG-P-38-204-PF	P	33-34	38	204	22 (7.3)/8.5
40 mm Diameter						
G24288	ZDEG-P-40-83-PF	P	35-36	40	83	22 (7.3)/8.5
G24289	ZDEG-P-40-164-PF	P	35-36	40	164	22 (7.3)/8.5
G24290	ZDEG-P-40-218-PF	P	35-36	40	218	22 (7.3)/8.5
42 mm Diameter						
G24291	ZDEG-P-42-83-PF	P	37-38	42	83	22 (7.3)/8.5
G24252	ZDEG-P-42-164-PF	P	37-38	42	164	22 (7.3)/8.5
G24292	ZDEG-P-42-218-PF	P	37-38	42	218	22 (7.3)/8.5

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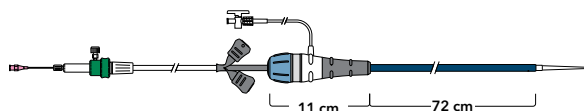
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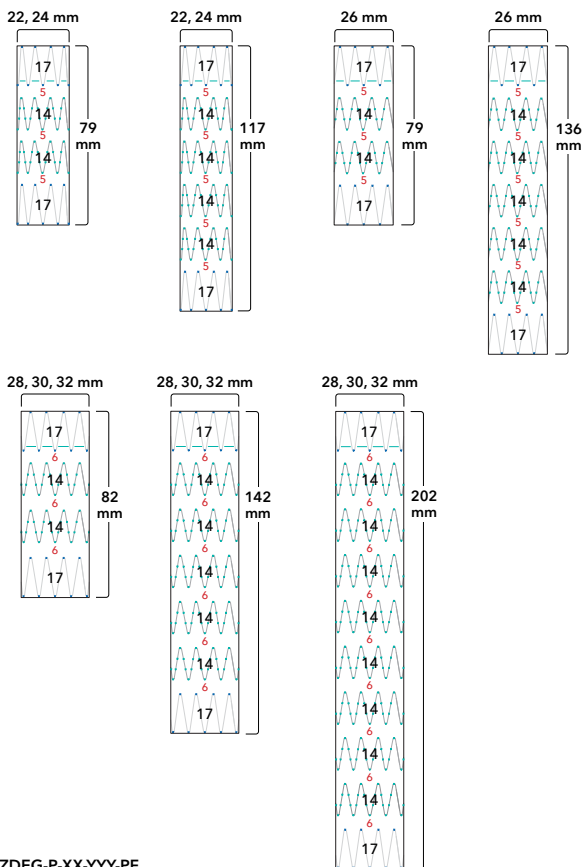
Z-Trak Plus® Introduction System for straight components

22-34 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD

36-42 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Zenith TX2 Dissection Endovascular Graft with Pro-Form straight components

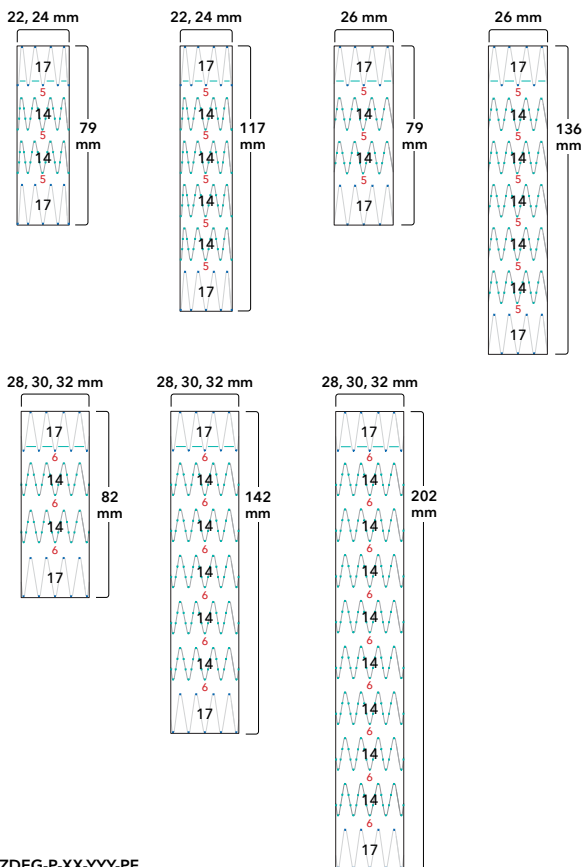


ZDEG-P-XX-YYY-PF

ZDEG-P-(diameter)-(length)-PF

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Zenith TX2 Dissection Endovascular Graft with Pro-Form straight components

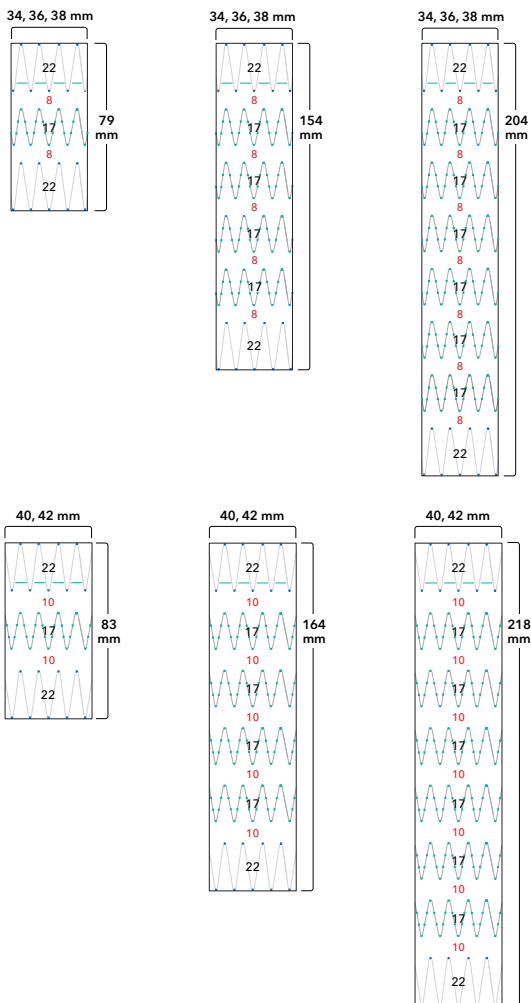


ZDEG-P-XX-YYY-PF

ZDEG-P-(diameter)-(length)-PF

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Zenith TX2 Dissection Endovascular Graft with Pro-Form straight components (continued)



Zenith TX2 Dissection Endovascular Graft with Pro-Form 4 mm tapered components

Order Number	Reference Part Number	Component Type	Aortic Vessel OD mm	Proximal Diameter mm	Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr(mm)/mm
32/28 mm Diameter							
G24254	ZDEG-PT-32-162-PF	PT	28-29	32	28	162	20(6.7)/7.7
G24256	ZDEG-PT-32-202-PF	PT	28-29	32	28	202	20(6.7)/7.7
34/30 mm Diameter							
G24258	ZDEG-PT-34-159-PF	PT	30	34	30	159	20(6.7)/7.7
G24259	ZDEG-PT-34-199-PF	PT	30	34	30	199	20(6.7)/7.7
36/32 mm Diameter							
G24261	ZDEG-PT-36-159-PF	PT	31-32	36	32	159	22(7.3)/8.5
G24263	ZDEG-PT-36-199-PF	PT	31-32	36	32	199	22(7.3)/8.5
38/34 mm Diameter							
G24264	ZDEG-PT-38-154-PF	PT	33-34	38	34	154	22(7.3)/8.5
G24266	ZDEG-PT-38-204-PF	PT	33-34	38	34	204	22(7.3)/8.5
40/36 mm Diameter							
G24268	ZDEG-PT-40-160-PF	PT	35-36	40	36	160	22(7.3)/8.5
G24270	ZDEG-PT-40-210-PF	PT	35-36	40	36	210	22(7.3)/8.5
42/38 mm Diameter							
G24273	ZDEG-PT-42-160-PF	PT	37-38	42	38	160	22(7.3)/8.5
G24274	ZDEG-PT-42-210-PF	PT	37-38	42	38	210	22(7.3)/8.5

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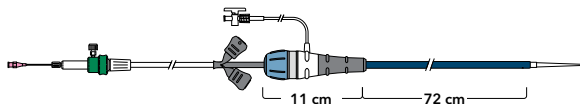
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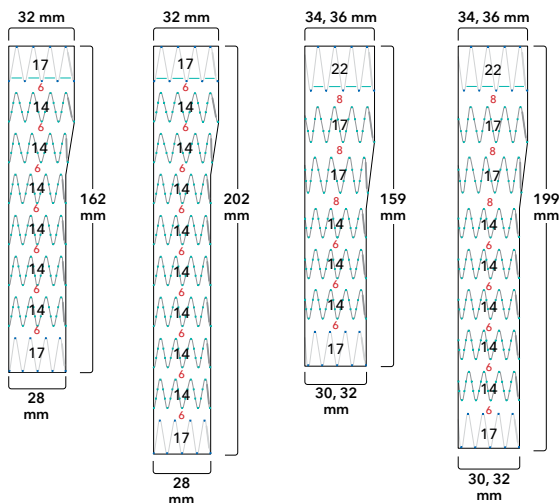
Z-Trak Plus Introduction System for 4 mm tapered components

32-34 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD

36-42 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Zenith TX2 Dissection Endovascular Graft with Pro-Form 4 mm tapered components



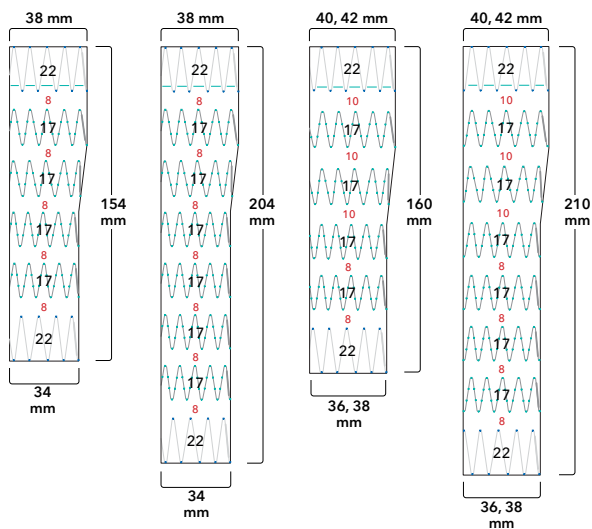
ZDEG-PT-XX-YYY-PF

ZDEG-PT-(proximal diameter)-(length)-PF

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Zenith TX2 Dissection Endovascular Graft with Pro-Form 4 mm tapered components

(continued)



Zenith TX2 Dissection Endovascular Graft with Pro-Form 8 mm tapered components

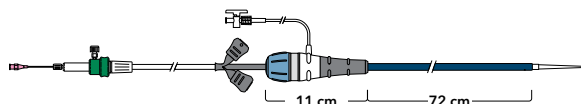
Order Number	Reference Part Number	Component Type	Aortic Vessel OD mm	Proximal Diameter mm	Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr(mm)/7.7 mm
32/24 mm Diameter							
G23172	ZDEG-PT-32-24-158-PF	PT	28-29	32	24	158	20 (6.7)/7.7
G23173	ZDEG-PT-32-24-196-PF	PT	28-29	32	24	196	20 (6.7)/7.7
34/26 mm Diameter							
G23174	ZDEG-PT-34-26-156-PF	PT	30	34	26	156	20 (6.7)/7.7
G23175	ZDEG-PT-34-26-194-PF	PT	30	34	26	194	20 (6.7)/7.7
36/28 mm Diameter							
G23176	ZDEG-PT-36-28-159-PF	PT	31-32	36	28	159	22 (7.3)/8.5
G23177	ZDEG-PT-36-28-199-PF	PT	31-32	36	28	199	22 (7.3)/8.5
38/30 mm Diameter							
G23178	ZDEG-PT-38-30-159-PF	PT	33-34	38	30	159	22 (7.3)/8.5
G23179	ZDEG-PT-38-30-199-PF	PT	33-34	38	30	199	22 (7.3)/8.5
40/32 mm Diameter							
G23180	ZDEG-PT-40-32-165-PF	PT	35-36	40	32	165	22 (7.3)/8.5
G23181	ZDEG-PT-40-32-205-PF	PT	35-36	40	32	205	22 (7.3)/8.5
42/34 mm Diameter							
G23182	ZDEG-PT-42-34-160-PF	PT	37-38	42	34	160	22 (7.3)/8.5
G23183	ZDEG-PT-42-34-210-PF	PT	37-38	42	34	210	22 (7.3)/8.5

Some products or part numbers may not be available in all markets.
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Please see product risk information in the IFU at cookmedical.eu.

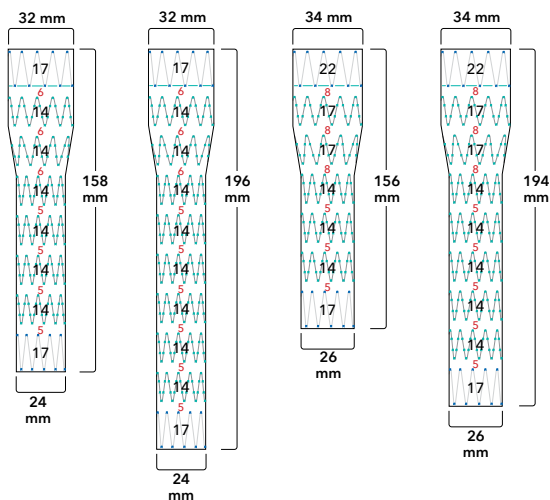
Z-Trak Plus Introduction System for 8 mm tapered component

32-34 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD

36-42 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Zenith TX2 Dissection Endovascular Graft with Pro-Form 8 mm tapered components



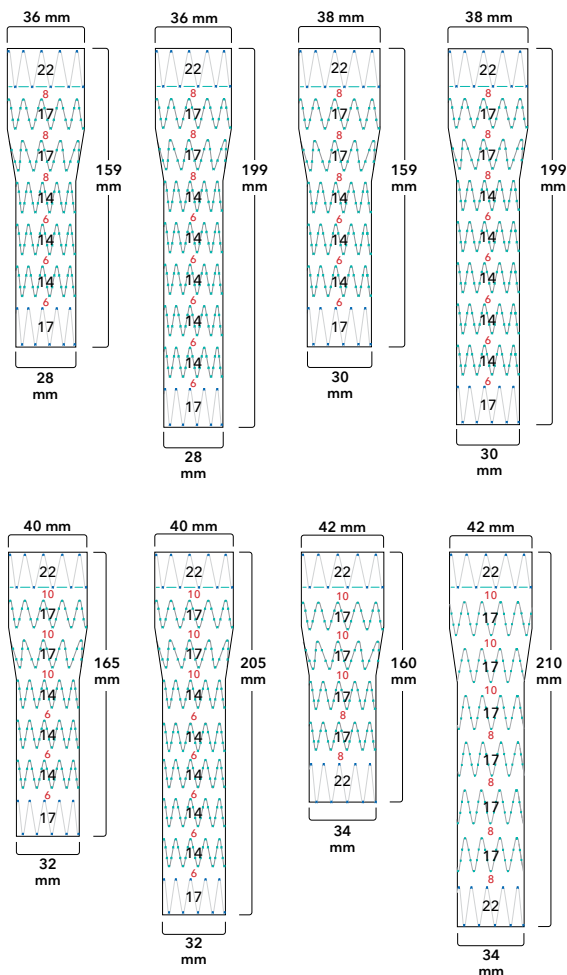
ZDEG-PT-XX-YY-ZZZ-PF

ZDEG-PT-(proximal diameter)-(distal diameter)-(length)-PF

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Zenith TX2 Dissection Endovascular Graft with Pro-Form 8 mm tapered components

(continued)



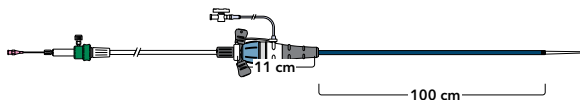
Endovascular stents

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Stents	Introducer Sheath ID/OD Fr(mm)/mm
36 mm Diameter						
G34256	ZDES-36-80	20-30	36	80	4	16 (5.3)/6.0
G34257	ZDES-36-120	20-30	36	120	6	16 (5.3)/6.0
G34258	ZDES-36-180	20-30	36	180	9	16 (5.3)/6.0
46 mm Diameter						
G34259	ZDES-46-80	31-38	46	80	4	16 (5.3)/6.0
G34260	ZDES-46-120	31-38	46	120	6	16 (5.3)/6.0
G34261	ZDES-46-185	31-38	46	185	9	16 (5.3)/6.0

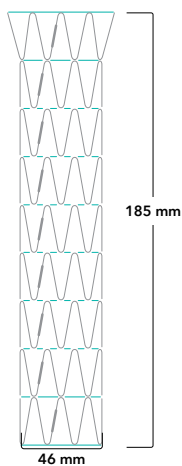
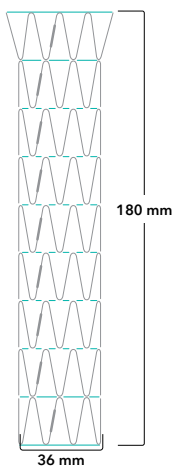
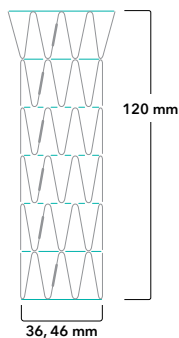
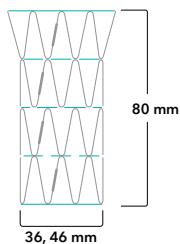
Some products or part numbers may not be available in all markets.
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Z-Trak Plus Introduction System for dissection stents

16 Fr (5.3 mm) ID/6.0 mm OD



Endovascular stents



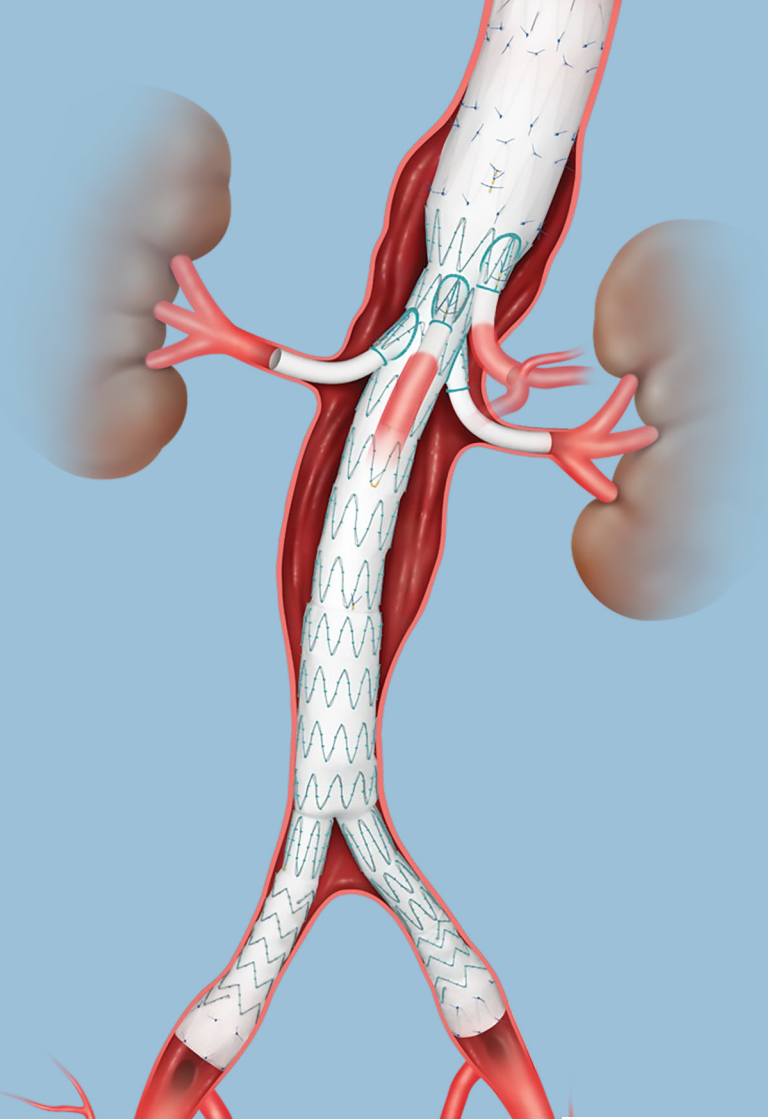
ZDES-XX-YYY

ZDES-(diameter)-(length)

Note: Proximal stent flared 9 mm to help prevent migration.

Thoracoabdominal





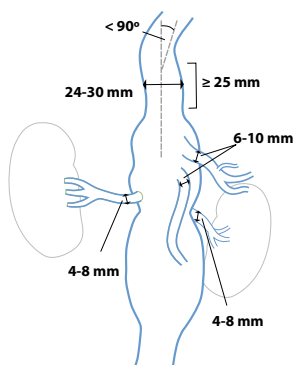
Zenith® t-Branch®

Thoracoabdominal
Endovascular Graft

Thoracoabdominal



Indications for use



Indications for use

The Zenith t-Branch Thoracoabdominal Endovascular Graft is indicated for the endovascular treatment of high-risk patients with thoracoabdominal aneurysms who are not amenable to open surgical repair. The patients must have morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with an 8.5 OD (22 Fr) introduction system,
- Nonaneurysmal thoracic aorta fixation segment proximal to the aneurysm:
 - With an angle of less than 90 degrees relative to the long axis of the aneurysm
 - With a length of at least 25 mm, (50 mm of wall contact is preferred)
 - With a diameter measured outer wall to outer wall of no greater than 30 mm and no less than 24 mm
 - Alternatively, the Zenith t-Branch graft may be attached to a pre-existing endovascular graft such as the Zenith TX2 TAA Endovascular Graft.
- Visceral vessel anatomy compatible with Zenith t-Branch, specifically:
 - Four indispensable arteries from the abdominal viscera
 - All target arteries to be accessible from an antegrade approach
 - Coeliac and superior mesenteric artery (SMA) to be 6 mm to 10 mm in diameter
 - Renal arteries to be 4 mm to 8 mm in diameter
 - The distance between each cuff and the corresponding arterial orifice is less than 50 mm
 - The line between the cuff and the arterial orifice as projected onto the vessel wall deviates by no more than 45 degrees from the long axis of the aorta.

Indications for use (continued)

Length	Nonaneurysmal thoracic aorta fixation segment proximal to the aneurysm ≥ 25 mm (50 mm of wall contact is preferred)	
Aortic fixation site diameter	24–30 mm (measured outer wall to outer wall)	
Angulation/ Curvature	An angle < 90 degrees relative to the long axis of the aneurysm	
Access	Adequate iliac/femoral access compatible with an 8.5 OD (22 Fr) introduction system	
Introducer diameters	ID 22 Fr (7.3 mm) OD 8.5 mm	
Contraindications	- Patients with known sensitivities or allergies to stainless steel, nitinol, polyester, solder (tin, silver), polypropylene, urethane, or gold - Patients with a systemic infection, as this may increase the risk of an endovascular graft infection	

Thoracoabdominal (TAAA) endovascular graft

Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Diameter mm	Distal Diameter mm	Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
G55513	TBRANCH-34-18-202	24-30	34	18	202	22 (7.3)/8.5

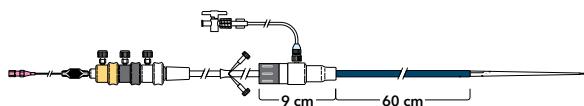
Some products or part numbers may not be available in all markets.

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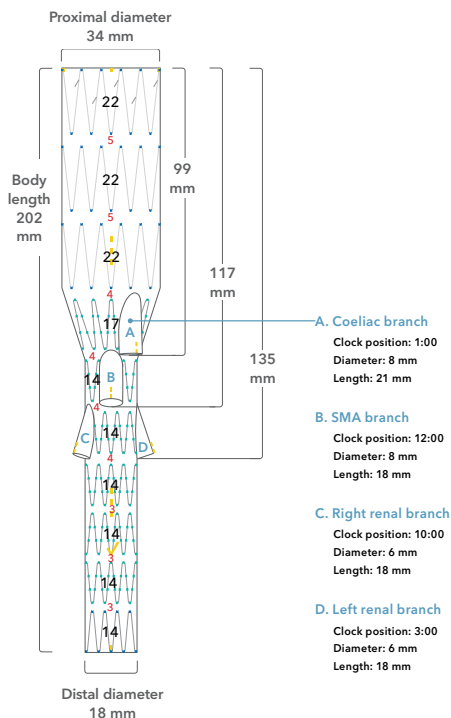
Please see product risk information in the IFU at cookmedical.eu.

H&L-B One-Shot Introduction System for t-Branch graft

22 Fr (7.3 mm) ID/8.5 mm OD



Thoracoabdominal (TAAA) endovascular graft



TBRANCH-34-18-202

TBRANCH-(proximal diameter)-(distal diameter)-(body length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Universal distal body grafts

Order Number	Reference Part Number	Proximal Diameter mm	Distal Body Length mm	Distal Limb Diameter mm	Introducer Sheath ID/OD Fr (mm)/mm
G55563	UNIBODY-22-81	22	81	11	20 (6.7)/7.7
G55564	UNIBODY-22-98	22	98	11	20 (6.7)/7.7
G55565	UNIBODY-22-115	22	115	11	20 (6.7)/7.7
G55566	UNIBODY-22-132	22	132	11	20 (6.7)/7.7
G55567	UNIBODY-24-81	24	81	12	20 (6.7)/7.7
G55568	UNIBODY-24-98	24	98	12	20 (6.7)/7.7
G55569	UNIBODY-24-115	24	115	12	20 (6.7)/7.7
G55570	UNIBODY-24-132	24	132	12	20 (6.7)/7.7

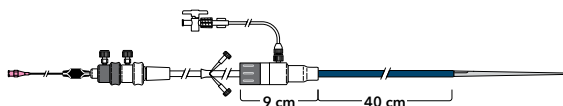
Some products or part numbers may not be available in all markets.

Contact your local Cook representative or Customer Support & Distribution for details.

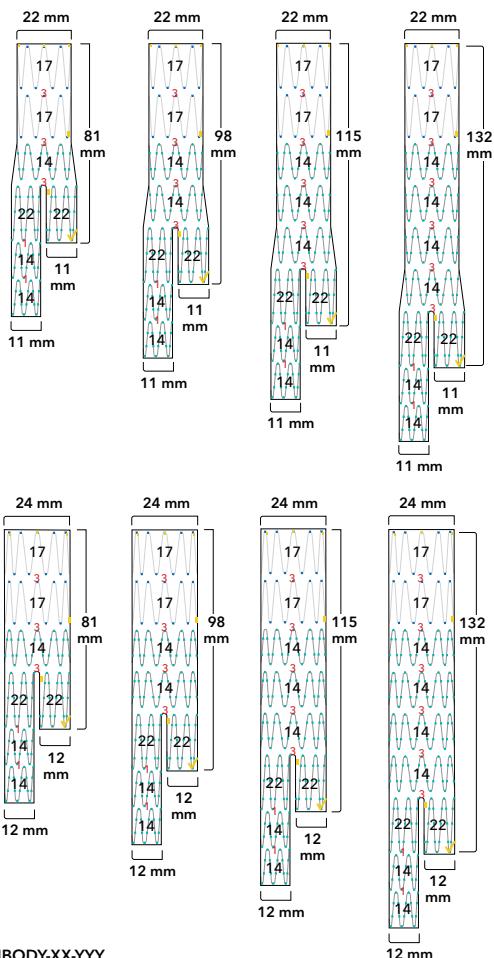
Please see product risk information in the IFU at cookmedical.eu.

H&L-B One-Shot Introduction System for universal distal body grafts

20 Fr (6.7 mm) ID/7.7 mm OD



Universal distal body grafts



UNIBODY-XX-YYY

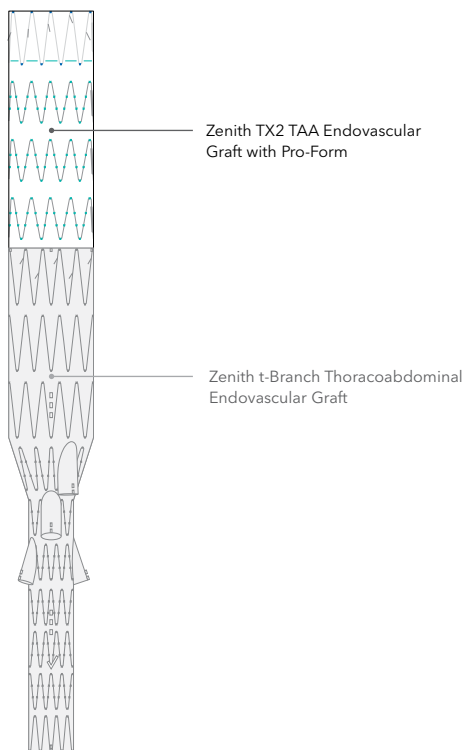
UNIBODY-(proximal diameter)-(distal body length)

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Note: Universal distal body is compatible with Zenith Spiral-Z legs.

Zenith TX2 TAA Endovascular Graft with Pro-Form

Compatible with Zenith® t-Branch® Thoracoabdominal Endovascular Graft



Zenith TX2 TAA Endovascular Graft with Pro-Form proximal 10 mm tapered components

Order Number	Reference Part Number	Component Type	Aortic Vessel OD mm	Proximal/ Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
42 mm Diameter						
G23613	ZTEG-2PT-42-32-165-PF	2PT	37-38	42/32	165	22 (7.3)/8.5
G23614	ZTEG-2PT-42-32-205-PF	2PT	37-38	42/32	205	22 (7.3)/8.5

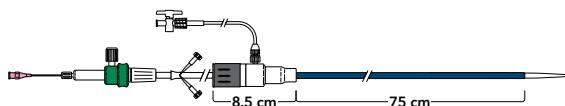
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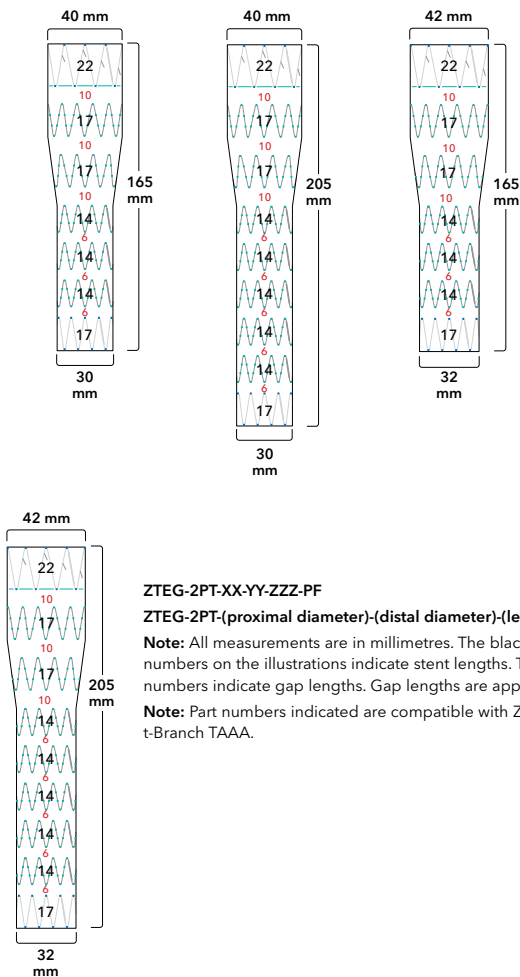
Z-Trak Plus Introduction System for proximal 10 mm tapered components

38-42 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD



Note: For straight or 4 mm tapered devices please see page 68 and 72, respectively, for required sizes.

Zenith TX2 TAA Endovascular Graft with Pro-Form proximal 10 mm tapered components



ZTEG-2PT-XX-YY-ZZZ-PF

ZTEG-2PT-(proximal diameter)-(distal diameter)-(length)-PF

Note: All measurements are in millimetres. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

Note: Part numbers indicated are compatible with Zenith t-Branch TAAA.

Patient-specific solutions

Patient-specific solutions

CUSTOM-MADE ENDOVASCULAR DEVICE PORTFOLIO

ASCENDING

Custom Ascending Arch Branch

ARCH

Custom Arch Fenestrated
Custom Arch Multi-Feature
Custom LSA Single Branch

THORACIC

Custom Thoracic Device
Custom False Lumen Endograft
Custom Thoracic SINE Device

THORACOABDOMINAL

Custom Thoracoabdominal Fenestrated
Custom Thoracoabdominal Branch
Custom Thoracoabdominal Inner Branch
Custom Thoracoabdominal Multi-Feature

VISCERAL

Custom Fenestrated

INFRARENAL

Custom Infrarenal Bifurcated
Custom Infrarenal Inverted Limb
Custom Aorto-Uni Iliac

ILIAC

Custom Iliac Branch Device
Custom Iliac Leg Extension

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