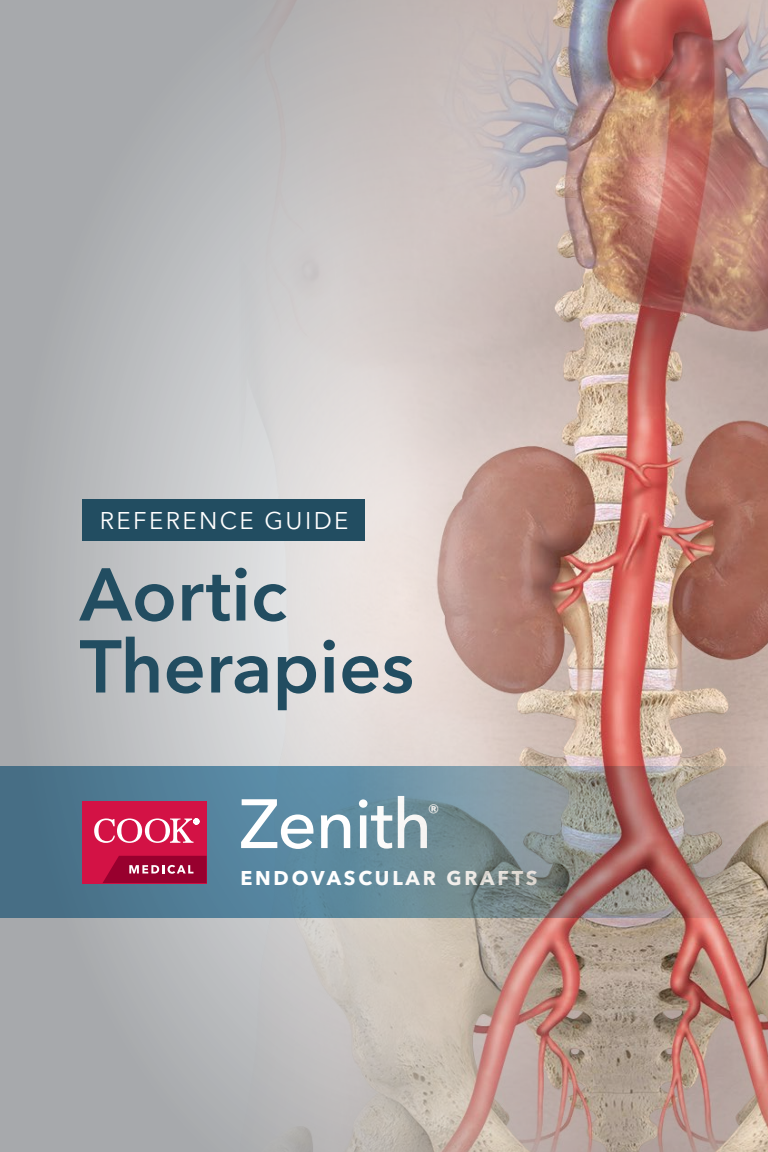




REFERENCE GUIDE

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, 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.

For complete Instructions for Use (IFUs), go to ifu.cookmedical.com.

Additional information may be found at cookmedical.com/aortic-intervention and aortic.cookmedical.com.

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ABDOMINAL

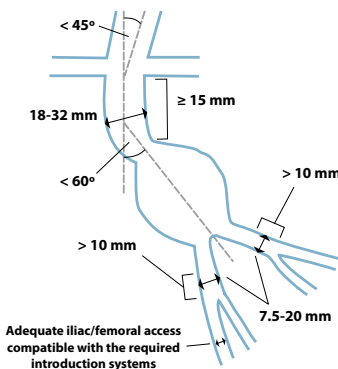




Zenith Flex[®]
AAA Endovascular Graft

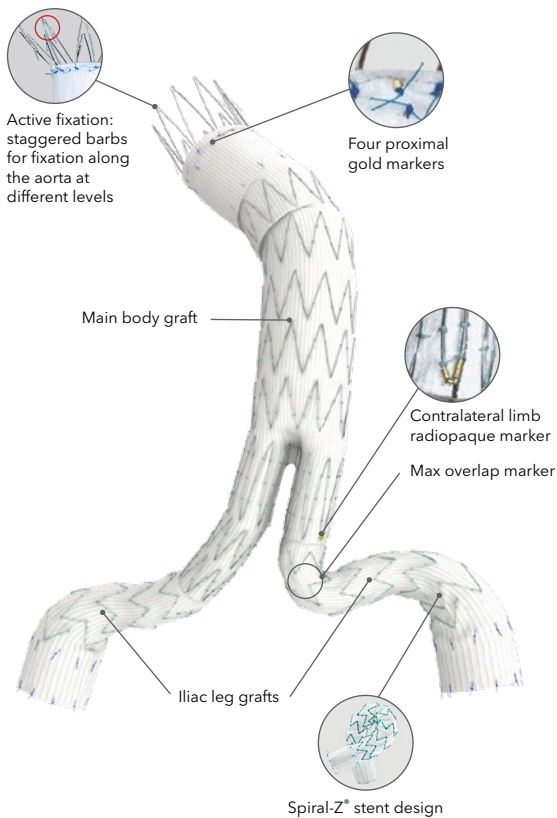


Indications for use



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		

Zenith Flex: Durable by design



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)/7.1
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. Contact your local Cook representative or Customer Support & Distribution for details.

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

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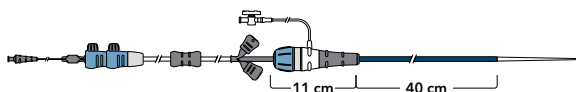
Please see product risk information in the IFU at cookmedical.com.

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

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
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

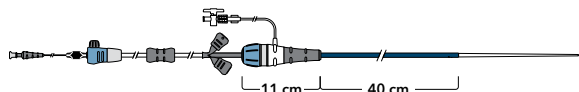
Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

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

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)

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

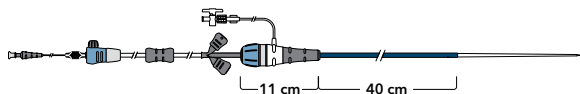
Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

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

Introduction system for converters

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

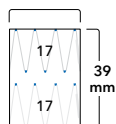
28-36 mm grafts: 20 Fr (6.7 mm) ID/7.7 mm OD



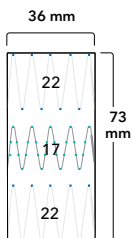
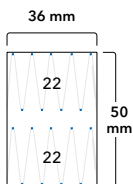
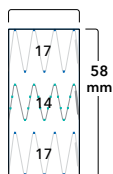
Ancillary components

Main body extensions

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

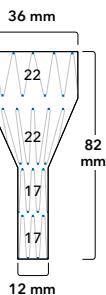
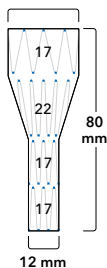


22, 24, 26, 28, 30, 32 mm



Converters

24, 28, 32 mm



Main body extensions

ESBE-XX-YY-ZT

ESBE-(diameter)-(length)-ZT

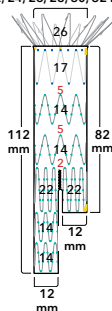
Converters

ESC-XX-YY-ZZ-ZT

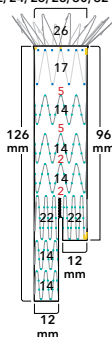
ESC-(proximal diameter)-(distal diameter)-(length)-ZT

Bifurcated main body grafts

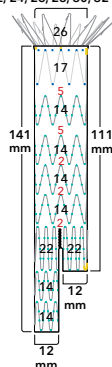
22, 24, 26, 28, 30, 32 mm



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



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



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

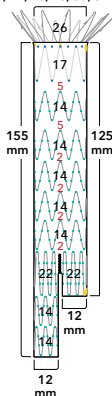
TFFB-XX-YYY-ZT

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

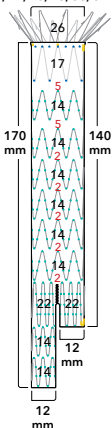
Note: All measurements are in millimeters. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

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

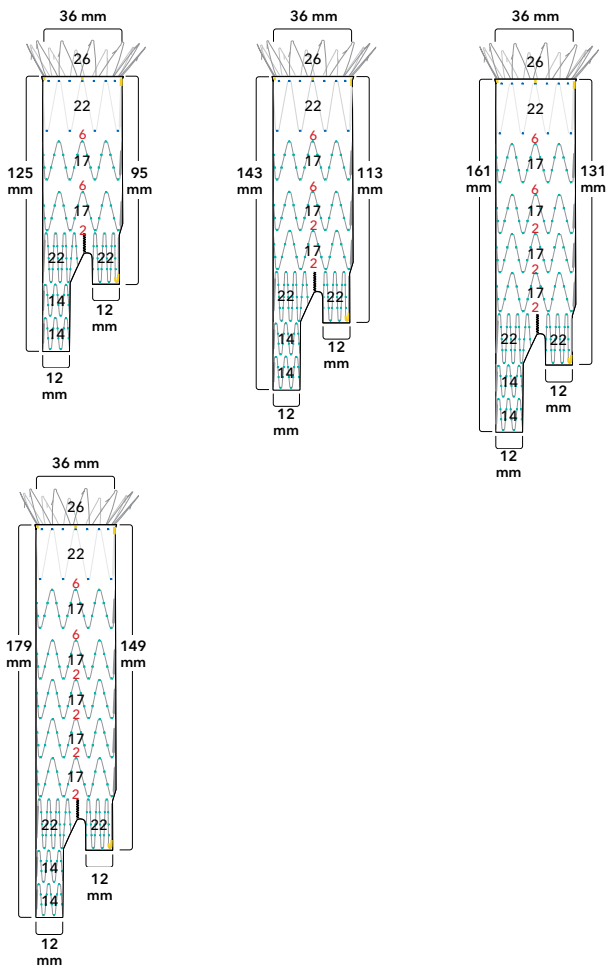
22, 24, 26, 28, 30, 32 mm



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



Bifurcated main body grafts (continued)



Deployment overview*

1 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 approximately 2 mm from the most proximal segment of the graft material) are just inferior to the most inferior renal orifice.

1a

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 gray 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 gray positioner. Tighten the pin vise and withdraw the gray positioner with the secured inner cannula.

Deployment overview* (continued)

5 MAIN BODY DISTAL 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 gray positioner over the inner cannula until it docks with the top cap. Retighten the pin vise and withdraw the entire top cap and gray 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, stabilize the iliac leg graft with the gray 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 gray positioner. Tighten the pin vise and withdraw the gray positioner with the secured inner cannula. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath.

8 MOLDING BALLOON INSERTION

Advance the molding balloon over the wire guide and through the hemostatic valve of the main body introduction system to the level of the renal arteries. Expand the molding 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 molding balloon.

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

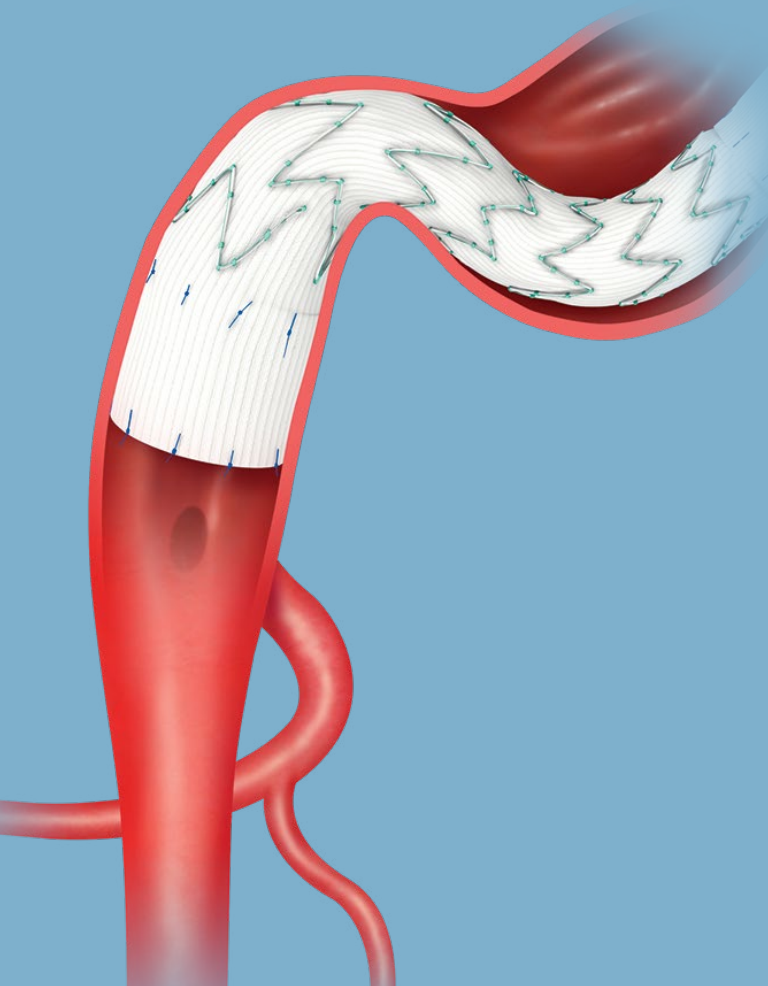
Caution: Do not inflate the balloon in the iliac vessel outside of graft.

Deflate and remove the molding 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

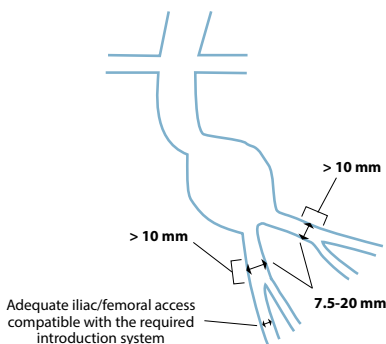




Zenith® Spiral-Z®
AAA Iliac Leg Graft



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.com.

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

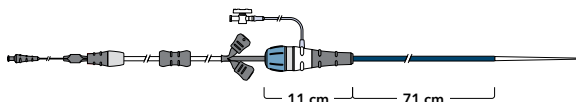
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Please see product risk information in the IFU at cookmedical.com.

Z-Trak Introduction System for iliac legs

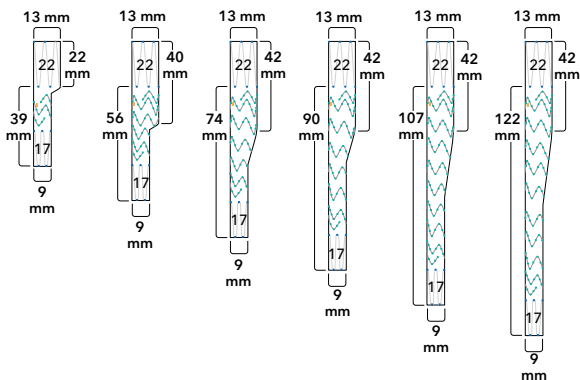
9-16 mm grafts: 14 Fr (4.7 mm) ID/5.4 mm OD

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

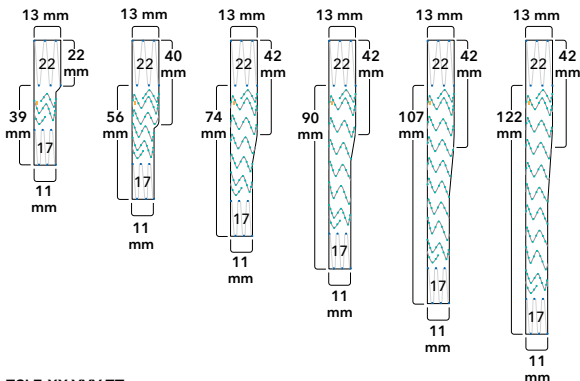


Spiral-Z iliac leg grafts

9 mm



11 mm



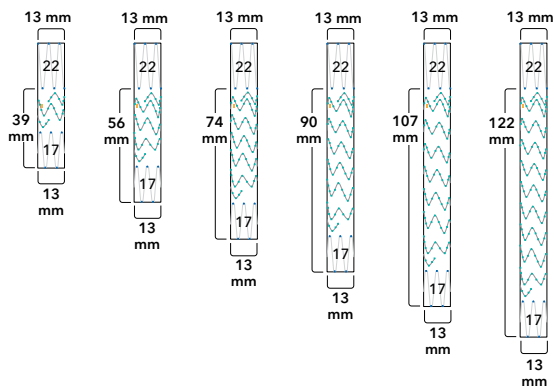
ZSLE-XX-YYY-ZT

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

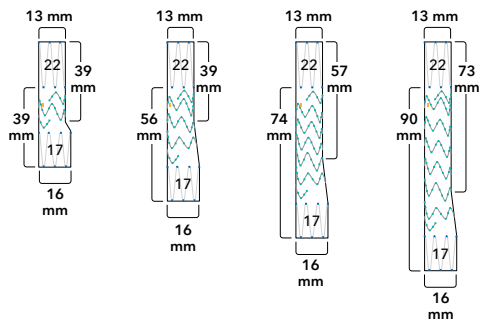
Note: All measurements are in millimeters. The numbers on the illustrations indicate stent lengths.

Spiral-Z iliac leg grafts (continued)

13 mm

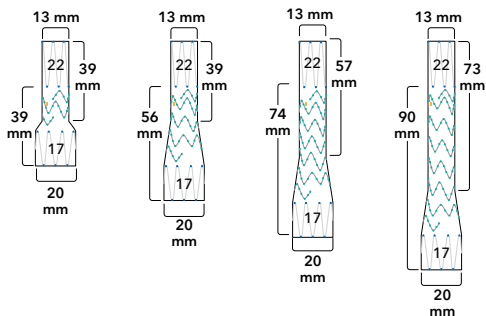


16 mm

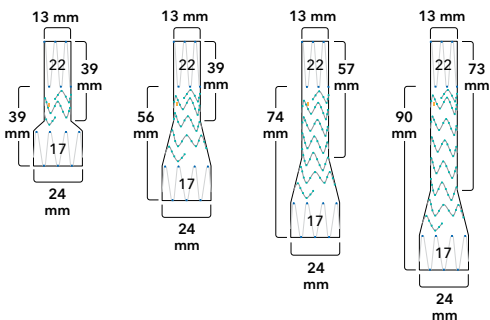


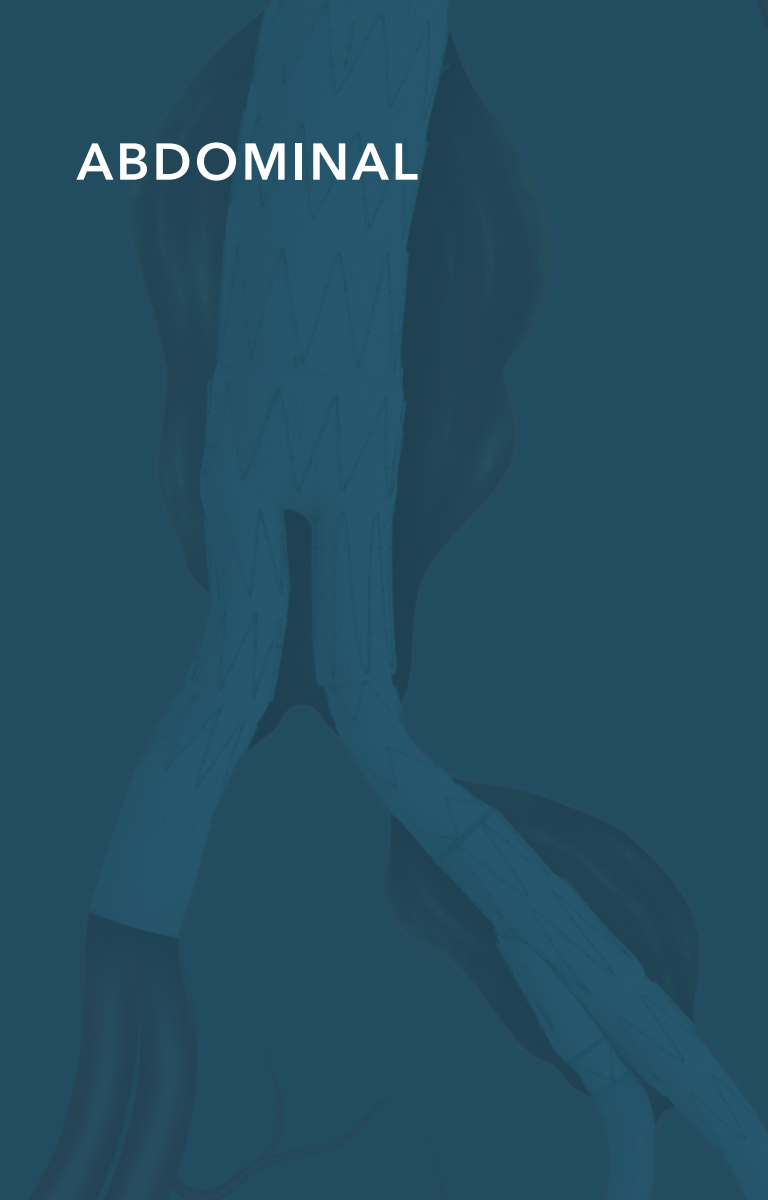
Spiral-Z iliac leg grafts (continued)

20 mm

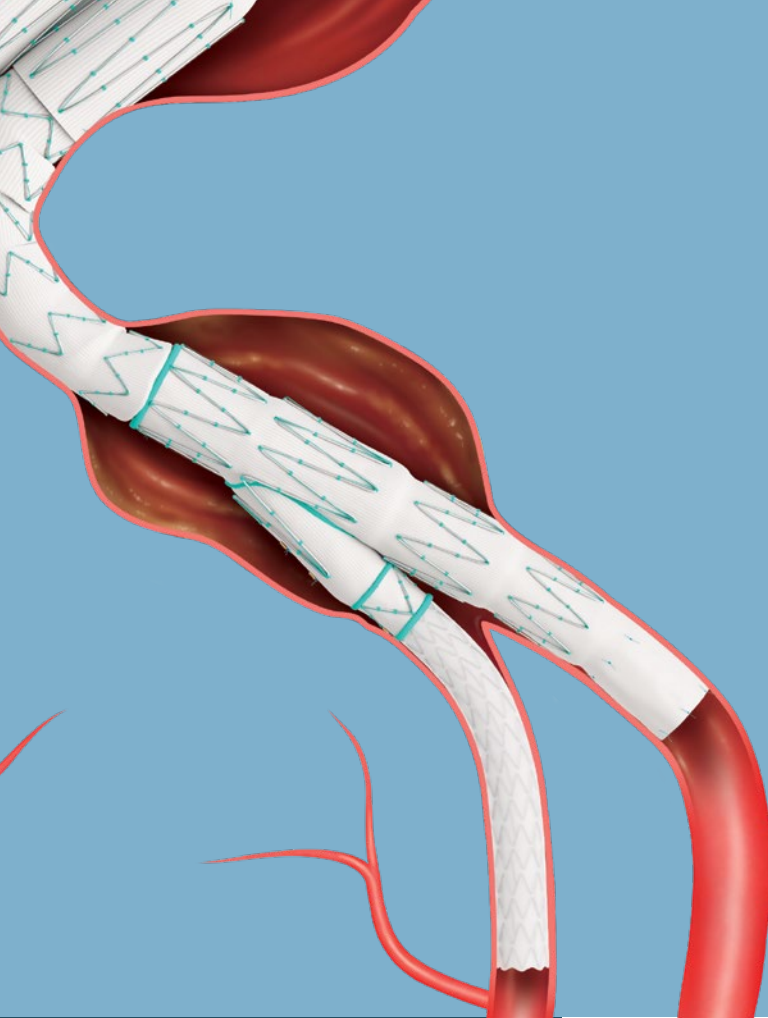


24 mm





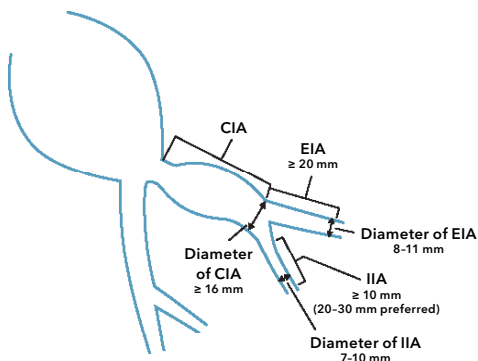
ABDOMINAL



Zenith[®] Iliac
Branch



Indications for use



Indications for use	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.
Common iliac diameter	Common iliac artery diameter ≥ 16 mm measured at the level of the internal iliac artery (luminal diameter)
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 measured outer wall to outer wall of no greater than 10 mm and no less than 7 mm
Access	Adequate femoral/iliac access compatible with the required introduction systems
Introducer diameters	ID 20 Fr (6.7 mm) OD 7.7 mm

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 Fr
G60340	ZBIS-10-45-41-US	10	45	41	20
G60342	ZBIS-10-61-41-US	10	61	41	20
G60344	ZBIS-12-45-41-US	12	45	41	20
G60345	ZBIS-12-61-41-US	12	61	41	20
G60341	ZBIS-10-45-58-US*	10	45	58	20
G60343	ZBIS-10-61-58-US*	10	61	58	20
G60346	ZBIS-12-45-58-US*	12	45	58	20
G60347	ZBIS-12-61-58-US*	12	61	58	20

*Nonstock options

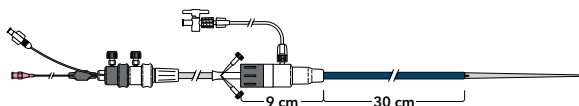
Some products or part numbers may not be available in all markets.

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

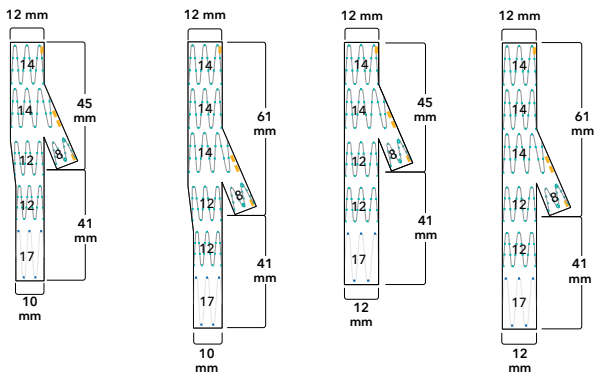
Introduction system for iliac branch grafts

20 Fr (6.7 mm) ID/7.7 mm OD

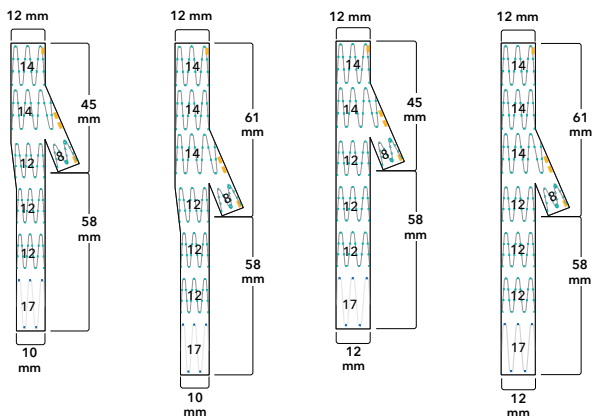


Iliac branch grafts

Stock



Nonstock



ZBIS-XX-YY-ZZ-US

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

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

Note: Zenith Iliac Branch is compatible with 16 mm Zenith Spiral-Z leg grafts.

Deployment overview*

1 PLACE THE ILIAC BRANCH GRAFT

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 ILIAC BRANCH GRAFT

Position the device and withdraw the sheath until indwelling catheter and hydrophilic wire guide are exposed. Advance this wire guide into the snare that has been placed in the opposite femoral artery to sit just above the aortic bifurcation.

Pull the snared wire through to form a through-and-through wire guide.

3 DEPLOY THE ILIAC BRANCH GRAFT

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 preloaded 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 gage 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 COVERED STENT SYSTEM

Replace the hydrophilic wire guide with a 260 cm long support wire guide. Advance the covered stent system 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 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 DEPLOY THE COVERED STENT

Withdraw the guiding sheath until it is outside of the dilation region of the covered stent balloon. Using an inflation device, deploy the covered stent.

11 REMOVE THE DISTAL TRIGGER WIRE

Remove the distal trigger wire.

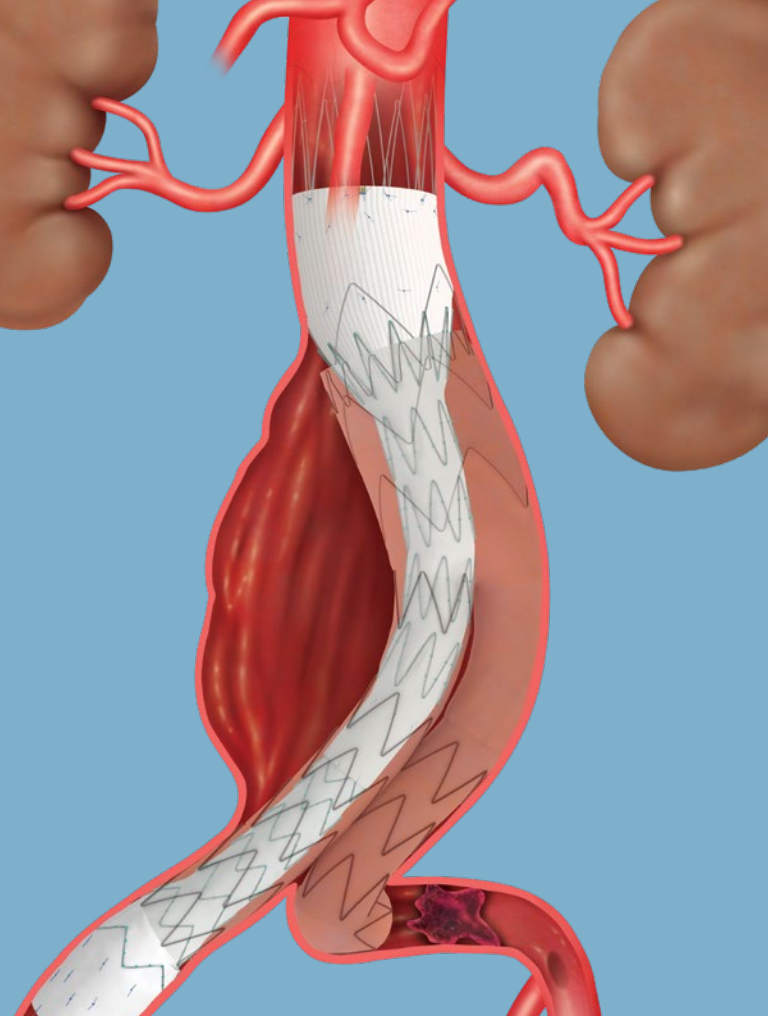
12 REMOVE THE INTRODUCTION SYSTEM

Reinflate the balloon in the side-branch 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 Iliac Branch. The Instructions for Use booklet should be consulted for a more thorough examination of the deployment protocol, indications, contraindications, warnings, and precautions.*

ABDOMINAL

A stylized anatomical illustration of the human digestive system, rendered in various shades of blue. The esophagus is shown as a thick, curved tube entering the stomach, which is depicted as a large, sac-like structure. The small intestine is shown as a long, coiled tube, and the large intestine is depicted as a wider, more segmented tube. The illustration is set against a dark blue background, with the word "ABDOMINAL" in white, bold, uppercase letters in the upper left corner.

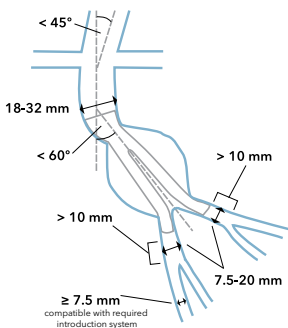


Zenith Renu[®]
AAA Ancillary Graft Converter

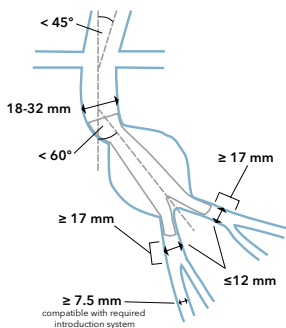


Indications for use

Utilizing iliac leg



Without iliac leg



Indications for use	Secondary endovascular intervention in patients having received prior endovascular repair of infrarenal abdominal aortic or aortoiliac aneurysms in which there is inadequate proximal fixation or seal.		
Length	Lowest renal artery to bifurcation of previously placed graft of > 43 mm for the main body extension and > 37 mm for the converter.		
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		
Converter distal fixation site	For the converter used without an iliac leg, distal fixation site within a graft segment of ≤ 12 mm in diameter and ≥ 17 mm (one Cook-Z® stent) in length, with more overlap length being preferred. For the converter used in combination with the iliac leg, distal fixation site 7.5-20 mm in diameter (measured outer wall to outer wall) and > 10 mm in length with 20 to 30 mm being preferred.		
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.		

Indications for use *(continued)*

Patient treatment and selection

Use of the Zenith Renu AAA converter typically requires occlusion of the contralateral iliac artery in conjunction with a standard femoral-to-femoral bypass procedure.

The final treatment decision is at the discretion of the physician and patient.

Converters

Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal/ Distal Diameter mm	Proximal/ Distal Length mm	Total Length mm	Introducer Sheath ID/OD Fr (mm)/mm
22 mm Diameter						
G55357	AX1-2-22-113-ZT	18-19	22/12	59/54	113	18 (6.0)/7.1
24 mm Diameter						
G55363	AX1-2-24-113-ZT	20-21	24/12	59/54	113	18 (6.0)/7.1
26 mm Diameter						
G55369	AX1-2-26-113-ZT	22	26/12	59/54	113	18 (6.0)/7.1
28 mm Diameter						
G55376	AX1-2-28-113-ZT	23-24	28/12	59/54	113	20 (6.7)/7.7
30 mm Diameter						
G55382	AX1-2-30-113-ZT	25-26	30/12	59/54	113	20 (6.7)/7.7
32 mm Diameter						
G55388	AX1-2-32-113-ZT	27-28	32/12	59/54	113	20 (6.7)/7.7
36 mm Diameter						
G55394	AX1-2-36-127-ZT	29-32	36/12	80/47	127	22 (7.3)/8.5

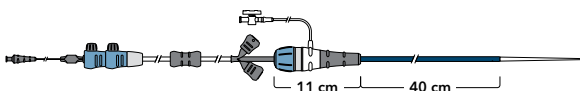
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Please see product risk information in the IFU at cookmedical.com.

Z-Trak Introduction System for Renu Converters

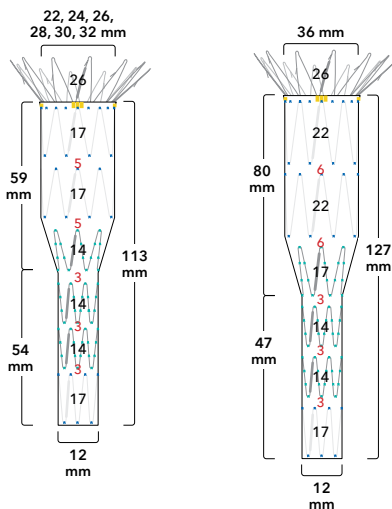
22-26 mm grafts: 18 Fr (6.0 mm) ID/7.1 mm OD

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



Converters



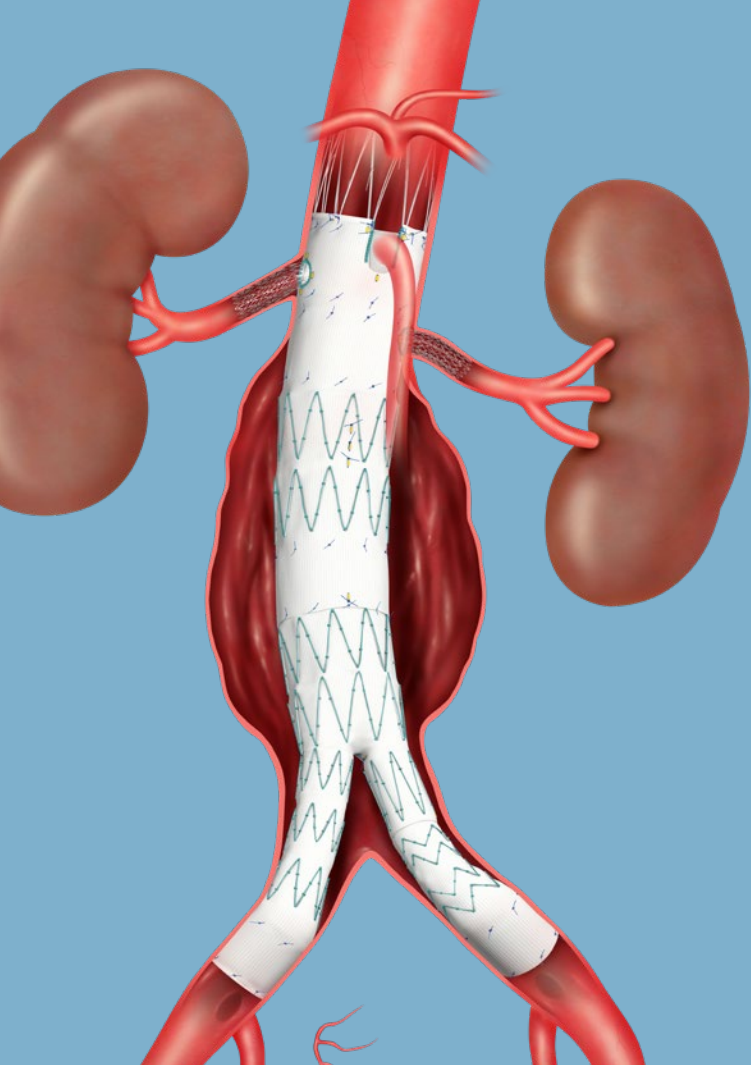
AX1-2-XX-YY-ZT

AX1-2-(proximal diameter)-(total length)-ZT

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

FENESTRATED

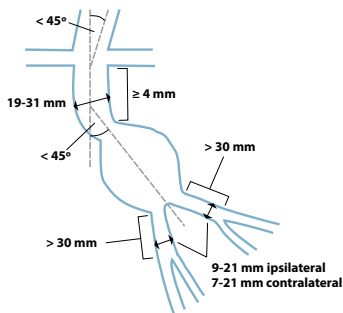




Zenith[®] Fenestrated
AAA Endovascular Graft



Indications for use



Indications for use	Endovascular treatment of patients with abdominal aortic or aortoiliac aneurysms having morphology suitable for endovascular repair.	
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 > 30 mm in length and 9-21 mm in diameter (measured outer wall to outer wall)	
Contralateral iliac fixation site	Distal fixation site > 30 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, or gold. • Patients with a systemic or local infection that may increase the risk of endovascular graft infection.	

Zenith Fenestrated:

Durable by design with precision in mind



Scallop

Width: 10 mm
Depth: 6-12 mm



Small fenestration

Width: 6 mm
Height: 6 or 8 mm*



Large fenestration

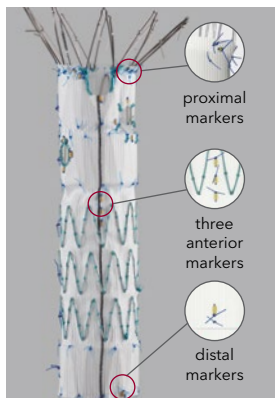
Diameter:
8, 10, 12 mm**

*At least 15 mm from the top of the graft to the center of the fenestration
Strut free: recommended to be stented

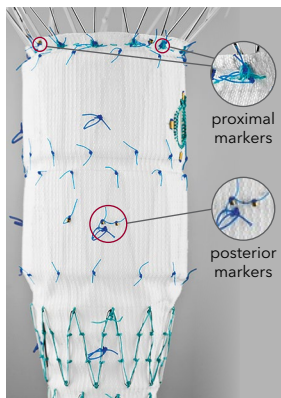
**At least 10 mm from the top of the graft to the center of the fenestration

Proximal body graft

Anterior view



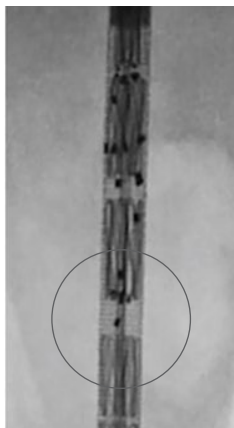
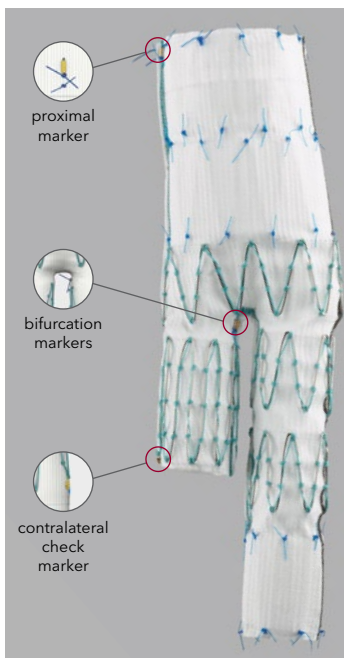
Posterior view



Zenith Fenestrated:

Durable by design with precision in mind

Distal bifurcated body graft



Angiographic view of anterior and posterior markers aligned



Contralateral check marker



Criteria for the Zenith Fenestrated graft:

- a) Grafts may contain up to a total of 3 fenestrations
- b) Grafts may include no more than 2 of any one type of fenestration (small, large, or scallop)
- c) Verify the design at <https://fenccheck.cookmedical.com>.

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					
G32502	ZFEN-P-1-24-76-R	19-21	24	76	20 (6.7)/7.7
G32507	ZFEN-P-1-24-91-R	19-21	24	91	20 (6.7)/7.7
G32512	ZFEN-P-1-24-106-R	19-21	24	106	20 (6.7)/7.7
G32517	ZFEN-P-1-24-121-R	19-21	24	121	20 (6.7)/7.7
26 mm Diameter					
G32503	ZFEN-P-1-26-76-R	21-22	26	76	20 (6.7)/7.7
G32508	ZFEN-P-1-26-91-R	21-22	26	91	20 (6.7)/7.7
G32513	ZFEN-P-1-26-106-R	21-22	26	106	20 (6.7)/7.7
G32518	ZFEN-P-1-26-121-R	21-22	26	121	20 (6.7)/7.7
28 mm Diameter					
G32504	ZFEN-P-1-28-76-R	23-24	28	76	20 (6.7)/7.7
G32509	ZFEN-P-1-28-91-R	23-24	28	91	20 (6.7)/7.7
G32514	ZFEN-P-1-28-106-R	23-24	28	106	20 (6.7)/7.7
G32519	ZFEN-P-1-28-121-R	23-24	28	121	20 (6.7)/7.7
30 mm Diameter					
G32505	ZFEN-P-1-30-76-R	24-26	30	76	20 (6.7)/7.7
G32510	ZFEN-P-1-30-91-R	24-26	30	91	20 (6.7)/7.7
G32515	ZFEN-P-1-30-106-R	24-26	30	106	20 (6.7)/7.7
G32520	ZFEN-P-1-30-121-R	24-26	30	121	20 (6.7)/7.7
32 mm Diameter					
G32506	ZFEN-P-1-32-76-R	26-28	32	76	20 (6.7)/7.7
G32511	ZFEN-P-1-32-91-R	26-28	32	91	20 (6.7)/7.7
G32516	ZFEN-P-1-32-106-R	26-28	32	106	20 (6.7)/7.7
G32521	ZFEN-P-1-32-121-R	26-28	32	121	20 (6.7)/7.7
34 mm Diameter					
G32522	ZFEN-P-1-34-84-R	28-29	34	84	20 (6.7)/7.7
G32524	ZFEN-P-1-34-99-R	28-29	34	99	20 (6.7)/7.7
G32526	ZFEN-P-1-34-114-R	28-29	34	114	20 (6.7)/7.7
G32528	ZFEN-P-1-34-129-R	28-29	34	129	20 (6.7)/7.7
36 mm Diameter					
G32523	ZFEN-P-1-36-84-R	29-31	36	84	22 (7.3)/8.5
G32525	ZFEN-P-1-36-99-R	29-31	36	99	22 (7.3)/8.5
G32527	ZFEN-P-1-36-114-R	29-31	36	114	22 (7.3)/8.5
G32529	ZFEN-P-1-36-129-R	29-31	36	129	22 (7.3)/8.5

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Proximal body grafts (continued)

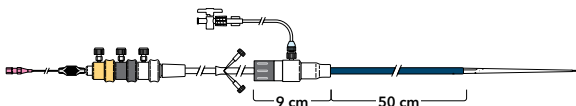
Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Body Diameter mm	Proximal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
Two Proximal Internal Stents					
24 mm Diameter					
G32530	ZFEN-P-2-24-94-R	19-21	24	94	20 (6.7)/7.7
G32535	ZFEN-P-2-24-109-R	19-21	24	109	20 (6.7)/7.7
G32540	ZFEN-P-2-24-124-R	19-21	24	124	20 (6.7)/7.7
26 mm Diameter					
G32531	ZFEN-P-2-26-94-R	21-22	26	94	20 (6.7)/7.7
G32536	ZFEN-P-2-26-109-R	21-22	26	109	20 (6.7)/7.7
G32541	ZFEN-P-2-26-124-R	21-22	26	124	20 (6.7)/7.7
28 mm Diameter					
G32532	ZFEN-P-2-28-94-R	23-24	28	94	20 (6.7)/7.7
G32537	ZFEN-P-2-28-109-R	23-24	28	109	20 (6.7)/7.7
G32542	ZFEN-P-2-28-124-R	23-24	28	124	20 (6.7)/7.7
30 mm Diameter					
G32533	ZFEN-P-2-30-94-R	24-26	30	94	20 (6.7)/7.7
G32538	ZFEN-P-2-30-109-R	24-26	30	109	20 (6.7)/7.7
G32543	ZFEN-P-2-30-124-R	24-26	30	124	20 (6.7)/7.7
32 mm Diameter					
G32534	ZFEN-P-2-32-94-R	26-28	32	94	20 (6.7)/7.7
G32539	ZFEN-P-2-32-109-R	26-28	32	109	20 (6.7)/7.7
G32544	ZFEN-P-2-32-124-R	26-28	32	124	20 (6.7)/7.7
34 mm Diameter					
G32545	ZFEN-P-2-34-107-R	28-29	34	107	20 (6.7)/7.7
G32547	ZFEN-P-2-34-122-R	28-29	34	122	20 (6.7)/7.7
G32549	ZFEN-P-2-34-137-R	28-29	34	137	20 (6.7)/7.7
36 mm Diameter					
G32546	ZFEN-P-2-36-107-R	29-31	36	107	22 (7.3)/8.5
G32548	ZFEN-P-2-36-122-R	29-31	36	122	22 (7.3)/8.5
G32550	ZFEN-P-2-36-137-R	29-31	36	137	22 (7.3)/8.5

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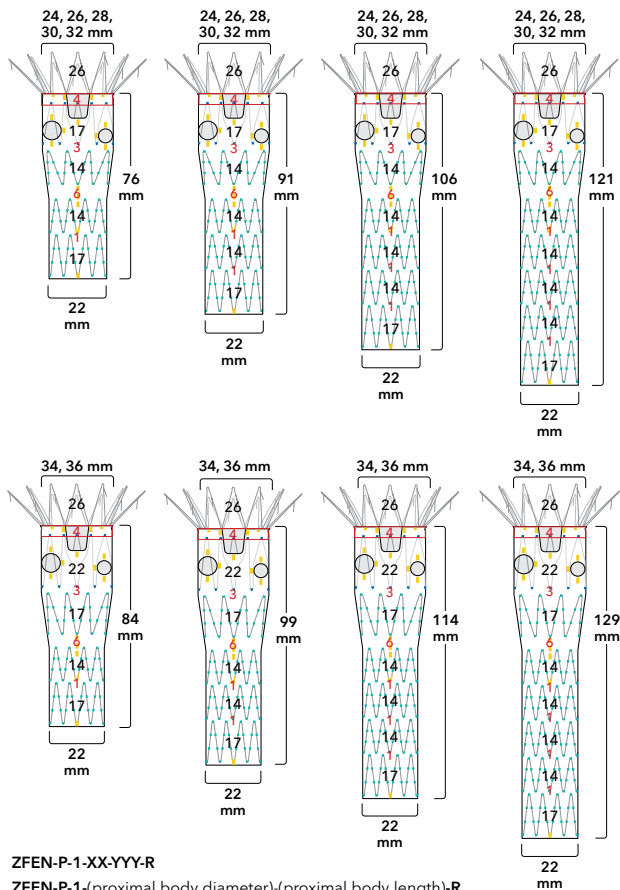
H&L-B One-Shot™ Introduction System for proximal body grafts

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



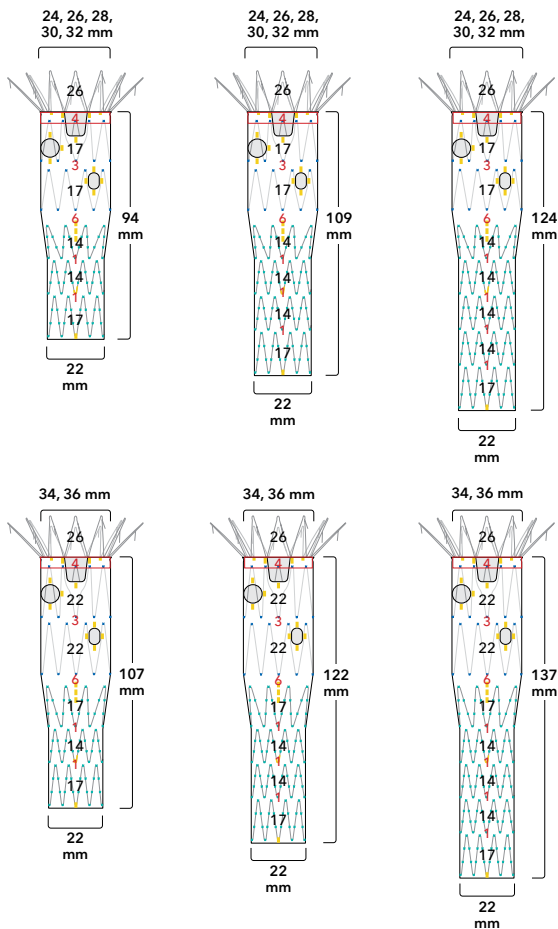
ZFEN-P-1-XX-YYY-R

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

Note: All measurements are in millimeters. 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-R

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

Distal bifurcated body grafts

Order Number	Reference Part Number	Ipsilateral Leg Diameter mm	Distal Leg Length mm	Distal Body Length mm	Introducer Sheath ID/OD Fr (mm)/7.7
G32551	ZFEN-D-12-28-76-C	12	28	76	20 (6.7)/7.7
G32554	ZFEN-D-12-28-91	12	28	91	20 (6.7)/7.7
G32500	ZFEN-D-12-28-106-C	12	28	121	20 (6.7)/7.7
G32501	ZFEN-D-12-28-121-C	12	28	121	20 (6.7)/7.7
G32561	ZFEN-D-12-45-76-C	12	45	76	20 (6.7)/7.7
G32565	ZFEN-D-12-45-91	12	45	91	20 (6.7)/7.7
G32569	ZFEN-D-12-45-106-C	12	45	106	20 (6.7)/7.7
G32573	ZFEN-D-12-45-121-C	12	45	121	20 (6.7)/7.7
G32577	ZFEN-D-12-62-76-C	12	62	76	20 (6.7)/7.7
G32580	ZFEN-D-12-62-91-C	12	62	91	20 (6.7)/7.7
G32584	ZFEN-D-12-62-106-C	12	62	106	20 (6.7)/7.7
G32588	ZFEN-D-12-62-121-C	12	62	121	20 (6.7)/7.7
G32552	ZFEN-D-16-28-76-C	16	28	76	20 (6.7)/7.7
G32555	ZFEN-D-16-28-91-C	16	28	91	20 (6.7)/7.7
G32557	ZFEN-D-16-28-106-C	16	28	106	20 (6.7)/7.7
G32559	ZFEN-D-16-28-121-C	16	28	121	20 (6.7)/7.7
G32562	ZFEN-D-16-45-76-C	16	45	76	20 (6.7)/7.7
G32566	ZFEN-D-16-45-91-C	16	45	91	20 (6.7)/7.7
G32570	ZFEN-D-16-45-106-C	16	45	106	20 (6.7)/7.7
G32574	ZFEN-D-16-45-121-C	16	45	121	20 (6.7)/7.7
G32592	ZFEN-D-16-62-76-C	16	62	76	20 (6.7)/7.7
G32581	ZFEN-D-16-62-91-C	16	62	91	20 (6.7)/7.7
G32585	ZFEN-D-16-62-106-C	16	62	106	20 (6.7)/7.7
G32589	ZFEN-D-16-62-121-C	16	62	121	20 (6.7)/7.7
G32553	ZFEN-D-20-28-76-C	20	28	76	20 (6.7)/7.7
G32556	ZFEN-D-20-28-91-C	20	28	91	20 (6.7)/7.7
G32558	ZFEN-D-20-28-106-C	20	28	106	20 (6.7)/7.7
G32560	ZFEN-D-20-28-121-C	20	28	121	20 (6.7)/7.7
G32563	ZFEN-D-20-45-76-C	20	45	76	20 (6.7)/7.7
G32567	ZFEN-D-20-45-91-C	20	45	91	20 (6.7)/7.7
G32571	ZFEN-D-20-45-106-C	20	45	106	20 (6.7)/7.7
G32575	ZFEN-D-20-45-121-C	20	45	121	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.com.

Distal bifurcated body grafts (continued)

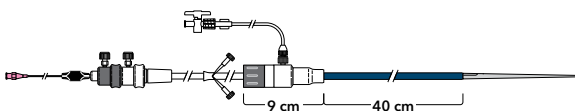
Order Number	Reference Part Number	Ipsilateral Leg Diameter mm	Distal Leg Length mm	Distal Body Length mm	Introducer Sheath ID/OD Fr (mm)/mm
G32578	ZFEN-D-20-62-76-C	20	62	76	20 (6.7)/7.7
G32582	ZFEN-D-20-62-91-C	20	62	91	20 (6.7)/7.7
G32586	ZFEN-D-20-62-106-C	20	62	106	20 (6.7)/7.7
G32590	ZFEN-D-20-62-121-C	20	62	121	20 (6.7)/7.7
G32564	ZFEN-D-24-45-76-C	24	45	76	20 (6.7)/7.7
G32568	ZFEN-D-24-45-91-C	24	45	91	20 (6.7)/7.7
G32572	ZFEN-D-24-45-106-C	24	45	106	20 (6.7)/7.7
G32576	ZFEN-D-24-45-121-C	24	45	121	20 (6.7)/7.7
G32579	ZFEN-D-24-62-76-C	24	62	76	20 (6.7)/7.7
G32583	ZFEN-D-24-62-91-C	24	62	91	20 (6.7)/7.7
G32587	ZFEN-D-24-62-106-C	24	62	106	20 (6.7)/7.7
G32591	ZFEN-D-24-62-121-C	24	62	121	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.

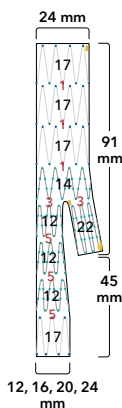
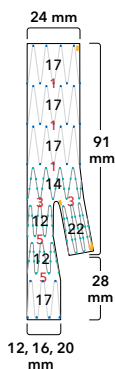
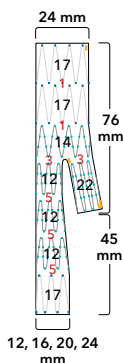
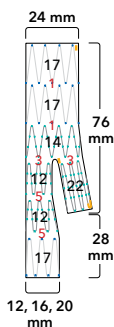
Please see product risk information in the IFU at cookmedical.com.

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



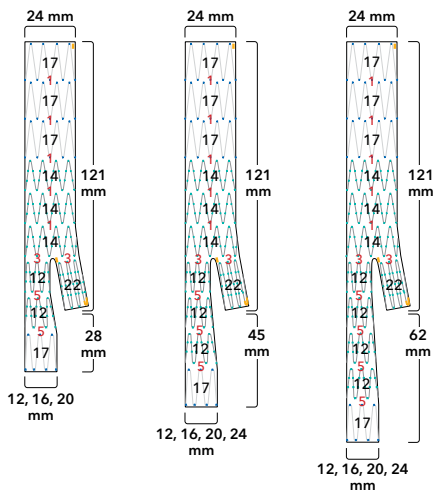
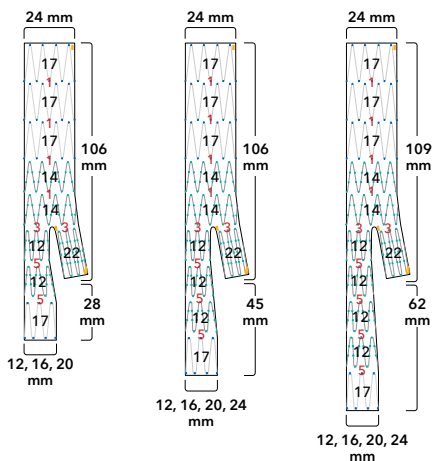
ZFEN-D-XX-YY-ZZZ-C

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

Note: All measurements are in millimeters. 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)



Deployment overview

1 PROXIMAL BODY PLACEMENT

Note: Before insertion, position proximal body delivery system on patient's abdomen under fluoroscopy to assist with orientation and positioning. Rotate to a position where the anterior markers are situated in the most anterior (12:00 o'clock) position.

Advance the delivery system until the radiopaque markers indicating the fenestration(s) and/or scallop(s) are at the level of the appropriate arteries. Check that the distal end of the graft is in a satisfactory position above the aortic bifurcation and that the anterior and posterior markers indicate that the graft is in satisfactory orientation.

Note: The vertical anterior markers, and the horizontal posterior markers should form a cross, on the fluoroscopic image, when correctly oriented.

Stabilize the gray positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location.

Perform angiography, and adjust graft placement as necessary. Continue to withdraw the sheath making positional adjustments as necessary.

Proceed with deployment until the graft has been fully unsheathed.

When a satisfactory graft position has been achieved, exchange the contralateral angiographic catheter and wire guide with a selective wire guide/selective catheter positioned just below the level of the proximal body. Cannulate the partially deployed proximal main body. Advance the selective catheter over the selective wire guide into the renal artery. Exchange the selective wire with a Rosen wire or equivalent wire guide.

Utilizing contralateral access sheath and wire guide, advance a guiding catheter into each small fenestration and its respective vessel.

Note: Cannulation of the scallop and its respective vessel may also be achieved using similar techniques.

Note: It is not recommended to use balloons or guiding catheters to guide final placement of large fenestrations as stent struts across fenestration may interfere.

Verify proper position of proximal body. Remove the safety lock from the first (distal) gold trigger-wire release mechanism. Withdraw and remove the trigger-wire by sliding the gold trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula.

2 POSITION BODY (TOP) DEPLOYMENT

Remove the safety lock from the top stent trigger-wire release mechanism. Under fluoroscopy, withdraw and remove the trigger wire to unlock the suprarenal stent from the top cap by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula.

Loosen the pin vise. Control the position of the graft by stabilizing the gray positioner of the introducer.

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 then retighten the pin vise to avoid contact with the deployed suprarenal stent.

Deployment overview (continued)

Remove the safety lock from the second (proximal) white trigger-wire release mechanism. Withdraw and remove the trigger wire to detach the distal end of the endovascular graft from the delivery system by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula.

3 DOCKING OF TOP CAP

Loosen pin vise. Secure sheath and inner cannula to avoid any movement of these components. Advance the gray positioner over the inner cannula until it docks with the top cap. Retighten pin vise and withdraw the entire top cap and gray positioner through the graft and through the sheath by pulling on the pink hub of the inner cannula. Leave the sheath and wire guide in place. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath.

4 FENESTRATION STENT PLACEMENT AND DEPLOYMENT

In the event that small fenestrations are being utilized, stents may be placed to secure positive alignment.

Return to the guide catheter and wire guide which cannulated the small fenestration and respective vessel.

Introduce appropriately sized balloon expandable stent and advance to the ostium of the fenestration/vessel. Advance stent partially into the vessel, leaving approximately 4-5 mm of stent in the aorta.

Note: Fluoroscopic views tangential to the fenestration will optimize visualization of the stent position relative to the stent graft. Expand stent.

Remove the balloon and replace with an oversized angioplasty balloon. Advance the balloon until the proximal tip is positioned at the ostium.

Inflate the balloon to flare the intra-aortic segment of the stent. Remove the angioplasty balloon. Withdraw renal access sheaths, catheters and wire guides in the contralateral side to a level just above the aortic bifurcation.

Note: In the event that there is more than one fenestration, repeat preceding steps for each additional small fenestration.

5 DISTAL BIFURCATED BODY PLACEMENT

Before insertion, position distal bifurcated body delivery system on patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb. The side arm of the hemostatic valve may serve as an external reference to the contralateral limb radiopaque marker.

Note: Distal bifurcated body delivery system will not pass through the sheath used to deliver the proximal body.

Insert distal bifurcated delivery system over the wire into the femoral artery with attention to sidearm reference. Advance delivery system until the contralateral limb is positioned in suitable orientation above and anterior to the origin of the contralateral iliac. If the contralateral limb radiopaque marker is not properly aligned, rotate the entire system until it is.

Repeat angiogram to verify the degree of overlap with proximal body (no less than 2 stents), the position of the contralateral limb and the position of the ipsilateral iliac limb with respect to the common iliac bifurcation.

Stabilize the gray positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location. Proceed with deployment until contralateral limb is fully deployed.

Deployment overview (continued)

6 CONTRALATERAL ILIAC WIRE GUIDE PLACEMENT

Manipulate catheter and wire guide from the contralateral side and into the contralateral limb and into the distal bifurcated body. A-P and oblique fluoroscopic views aid in verification of device cannulation. Advance the angiographic catheter over the wire into the body of the graft. Perform angiography to confirm position inside the distal bifurcated body. Advance the catheter to where the proximal end of the distal bifurcated body is attached to the introducer.

7 DISTAL BIFURCATED BODY DEPLOYMENT

Perform angiography to confirm proper position of the ipsilateral iliac leg with respect to the internal iliac (hypogastric) artery. Adjust position if necessary. Withdraw sheath until the iliac leg is fully deployed.

Remove the safety lock from the black trigger-wire release mechanism. Withdraw and remove the trigger wire by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula.

Advance the contralateral catheter to above the level of the proximal graft and pass a supportive wire guide (AUS or LES) through it to the level of the arch. Remove catheter.

8 CONTRALATERAL ILIAC LEG PLACEMENT AND DEPLOYMENT

Introduce the contralateral iliac leg delivery system over a stiff wire into the femoral 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 30 mm) within the main body endovascular graft. To deploy, hold the iliac leg graft in position with the gray positioner while withdrawing the sheath. Stop withdrawing the sheath as soon as the distal end of the iliac leg graft is released. Verify iliac leg graft position, loosen pin vise and retract inner cannula to dock tapered dilator to gray positioner. Tighten pin vise and withdraw gray positioner with secured inner cannula. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath.

9 DISTAL BIFURCATED BODY DEPLOYMENT

Remove the safety lock from the white trigger-wire release mechanism. Withdraw and remove the trigger wire by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula. Under fluoroscopy and after verification of iliac leg graft position, withdraw gray positioner with secured inner cannula.

10 MOLDING BALLOON INSERTION

Advance the molding balloon over the wire guide and through the Captor Hemostatic Valve of the distal bifurcated body introduction system to the level of the renal arteries. Expand the molding balloon with diluted contrast media in the area of the suprarenal stent and the infrarenal neck, starting proximally and working in the distal direction.

Deployment overview (continued)

Caution: Prior to molding in the vicinity of any fenestration(s) confirm that the aortic section of the stent has been flared.

Caution: Confirm complete deflation of balloon prior to repositioning.

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

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

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

11 FINAL ANGIOGRAM

Position angiographic catheter just above the level of the branch vessel(s) accommodated by a fenestration/scallop. Perform angiography to verify branch vessel (e.g., renal artery, superior mesenteric artery) patency and that there are no endoleaks. Verify patency of internal iliac arteries.

Confirm there are no endoleaks or kinks and verify position of proximal gold radiopaque markers. Remove the sheaths, wires, and catheters.

**This deployment overview is an outline highlighting the deployment process for the Zenith Fenestrated 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.*

THORACIC



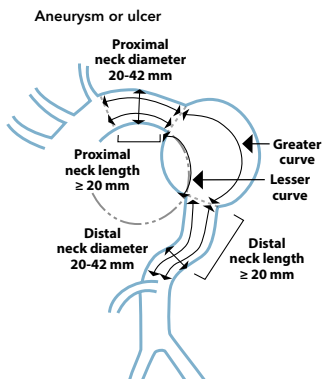


Zenith Alpha[®] 2

Thoracic Endovascular Graft



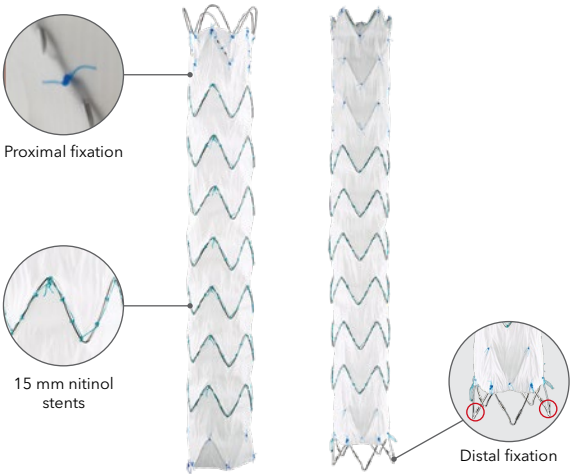
Indications for use



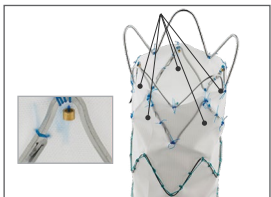
Indications for use	The Zenith Alpha 2 Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair including: • Iliac/femoral anatomy that is suitable for access with the required introduction systems • Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic lesion: - 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 with a systemic infection who may be at increased risk of endovascular graft infection.		

Zenith Alpha® 2 Thoracic Endovascular Graft:

Treat more patients with a durable repair



Diameters (mm)	# of Gold Markers
24-30	5
32-38	6
40-42	7
44-46	8



Gold proximal and distal markers 1 mm from the edge of the graft material

Graft diameters	Introducer sheath diameters	
24 - 30 mm	16 Fr ID	6.0 mm OD
32 - 38 mm	18 Fr ID	7.1 mm OD
40 - 46 mm	20 Fr ID	7.7 mm OD

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					
G59956	ZTA2-P-24-105-W	20-21	24	105	16 (5.3)/6.0
26 mm Diameter					
G59960	ZTA2-P-26-105-W	22-23	26	105	16 (5.3)/6.0
28 mm Diameter					
G59965	ZTA2-P-28-109-W	24-25	28	109	16 (5.3)/6.0
G59972	ZTA2-P-28-155-W	24-25	28	155	16 (5.3)/6.0
G59975	ZTA2-P-28-201-W	24-25	28	201	16 (5.3)/6.0
30 mm Diameter					
G59978	ZTA2-P-30-109-W	26-27	30	109	16 (5.3)/6.0
G59984	ZTA2-P-30-155-W	26-27	30	155	16 (5.3)/6.0
G59987	ZTA2-P-30-201-W	26-27	30	201	16 (5.3)/6.0
32 mm Diameter					
G59990	ZTA2-P-32-109-W	28-29	32	109	18 (6.0)/7.1
G59996	ZTA2-P-32-155-W	28-29	32	155	18 (6.0)/7.1
G59999	ZTA2-P-32-201-W	28-29	32	201	18 (6.0)/7.1
34 mm Diameter					
G60002	ZTA2-P-34-113-W	30	34	113	18 (6.0)/7.1
G60008	ZTA2-P-34-161-W	30	34	161	18 (6.0)/7.1
G60011	ZTA2-P-34-209-W	30	34	209	18 (6.0)/7.1
36 mm Diameter					
G60014	ZTA2-P-36-113-W	31-32	36	113	18 (6.0)/7.1
G60020	ZTA2-P-36-161-W	31-32	36	161	18 (6.0)/7.1
G60023	ZTA2-P-36-209-W	31-32	36	209	18 (6.0)/7.1
38 mm Diameter					
G60026	ZTA2-P-38-117-W	33-34	38	117	18 (6.0)/7.1
G60032	ZTA2-P-38-167-W	33-34	38	167	18 (6.0)/7.1
G60035	ZTA2-P-38-217-W	33-34	38	217	18 (6.0)/7.1

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.com.

Proximal components (continued)

Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
40 mm Diameter					
G59915	ZTA2-P-40-117-W	35-36	40	117	20 (6.7)/7.7
G59921	ZTA2-P-40-167-W	35-36	40	167	20 (6.7)/7.7
G59923	ZTA2-P-40-217-W	35-36	40	217	20 (6.7)/7.7
42 mm Diameter					
G59926	ZTA2-P-42-121-W	37-38	42	121	20 (6.7)/7.7
G59932	ZTA2-P-42-173-W	37-38	42	173	20 (6.7)/7.7
G59935	ZTA2-P-42-225-W	37-38	42	225	20 (6.7)/7.7
44 mm Diameter					
G59938	ZTA2-P-44-125-W	39	44	125	20 (6.7)/7.7
G59944	ZTA2-P-44-179-W	39	44	179	20 (6.7)/7.7
G59947	ZTA2-P-44-233-W	39	44	233	20 (6.7)/7.7
46 mm Diameter					
G59950	ZTA2-P-46-125-W	40-42	46	125	20 (6.7)/7.7
G59910	ZTA2-P-46-179-W	40-42	46	179	20 (6.7)/7.7
G59912	ZTA2-P-46-233-W	40-42	46	233	20 (6.7)/7.7

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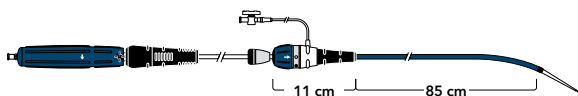
40 to 46 mm diameter proximal components have a Proximal Reducing Tie to aid in conformability.

Introduction system for proximal components

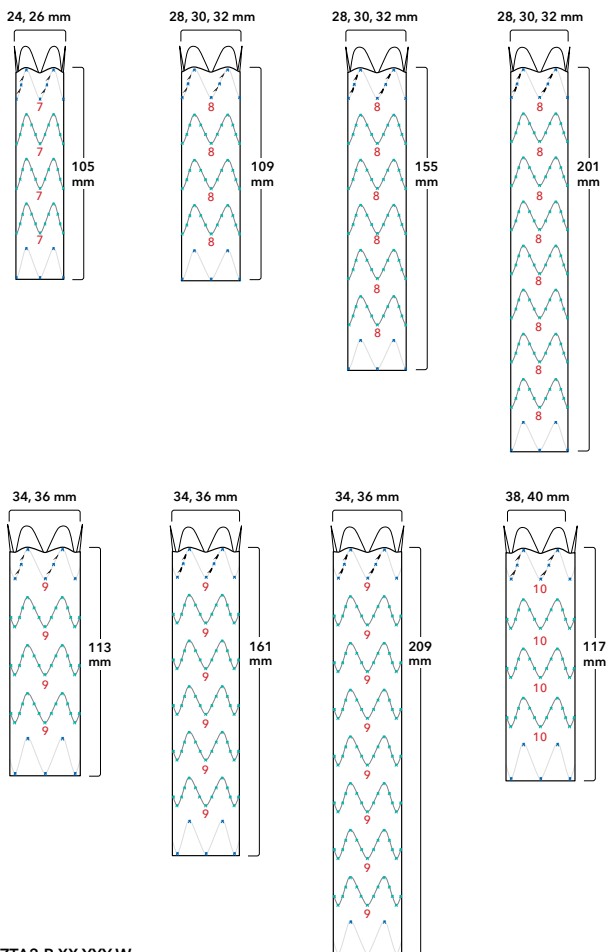
24-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

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 (continued)

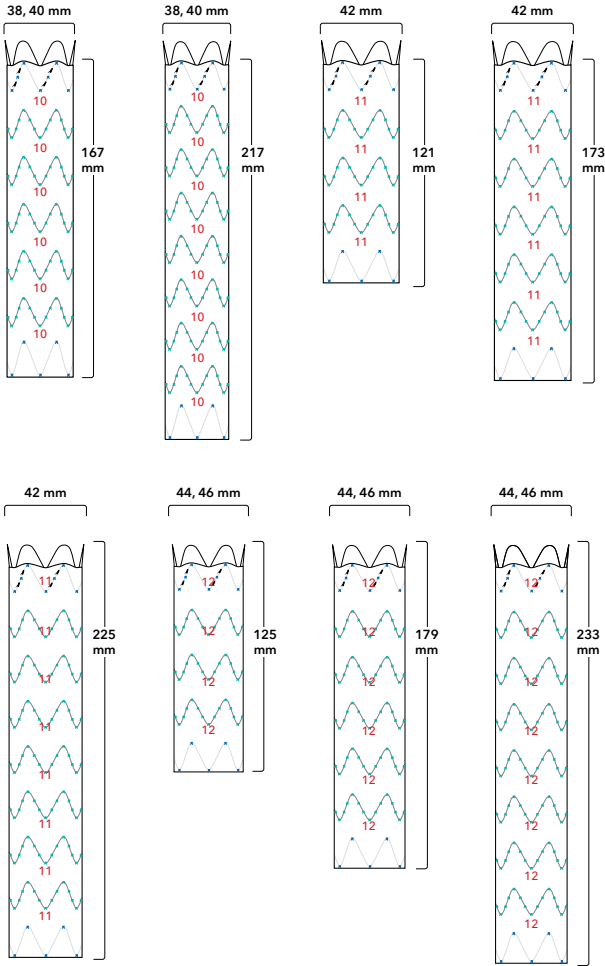


ZTA2-P-XX-YYY-W

ZTA2-P-(diameter)-(length)-W

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

Proximal components (continued)



Proximal 4 mm tapered components

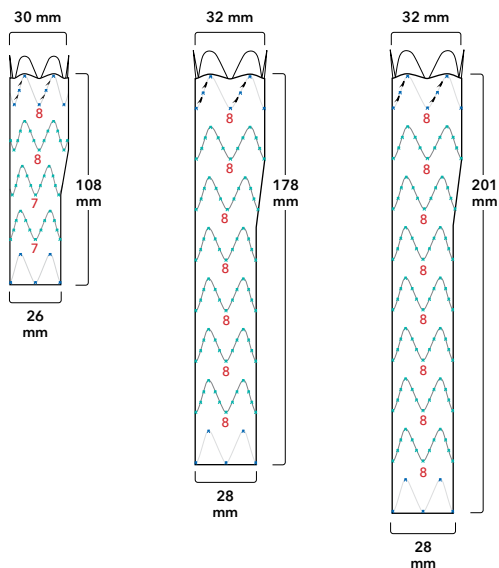
Order Number	Reference Part Number	Aortic Vessel OD mm	Proximal Diameter mm	Distal Diameter mm	Length mm	Introducer Sheath ID/OD Fr (mm)/mm
30 mm Diameter						
G60040	ZTA2-PT-30-26-108-W	26-27	30	26	108	16 (5.3)/6.0
32 mm Diameter						
G60039	ZTA2-PT-32-28-178-W	28-29	32	28	178	18 (6.0)/7.1
G60043	ZTA2-PT-32-28-201-W	28-29	32	28	201	18 (6.0)/7.1
34 mm Diameter						
G60046	ZTA2-PT-34-30-161-W	30	34	30	161	18 (6.0)/7.1
G60049	ZTA2-PT-34-30-209-W	30	34	30	209	18 (6.0)/7.1
36 mm Diameter						
G60052	ZTA2-PT-36-32-161-W	31-32	36	32	161	18 (6.0)/7.1
G60055	ZTA2-PT-36-32-209-W	31-32	36	32	209	18 (6.0)/7.1
38 mm Diameter						
G60058	ZTA2-PT-38-34-167-W	33-34	38	34	167	18 (6.0)/7.1
G60061	ZTA2-PT-38-34-217-W	33-34	38	34	217	18 (6.0)/7.1
40 mm Diameter						
G60064	ZTA2-PT-40-36-167-W	35-36	40	36	167	20 (6.7)/7.7
G60067	ZTA2-PT-40-36-217-W	35-36	40	36	217	20 (6.7)/7.7
42 mm Diameter						
G60070	ZTA2-PT-42-38-173-W	37-38	42	38	173	20 (6.7)/7.7
G60073	ZTA2-PT-42-38-225-W	37-38	42	38	225	20 (6.7)/7.7
44 mm Diameter						
G60076	ZTA2-PT-44-40-179-W	39	44	40	179	20 (6.7)/7.7
G60084	ZTA2-PT-44-40-233-W	39	44	40	233	20 (6.7)/7.7
46 mm Diameter						
G60079	ZTA2-PT-46-42-179-W	40-42	46	42	179	20 (6.7)/7.7
G60082	ZTA2-PT-46-42-233-W	40-42	46	42	233	20 (6.7)/7.7

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40 to 46 mm diameter proximal components have a Proximal Reducing Tie to aid in conformability.

Proximal 4 mm tapered components (continued)

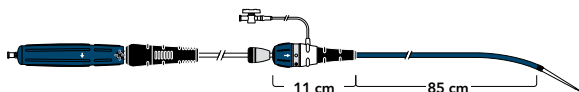


Introduction system for proximal 4 mm tapered components

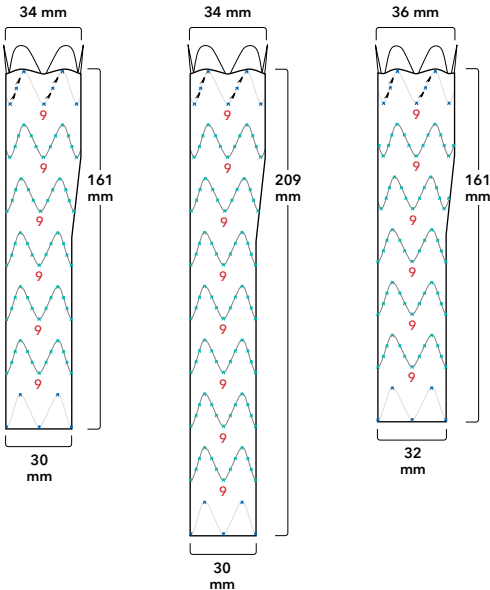
26-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

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 (continued)

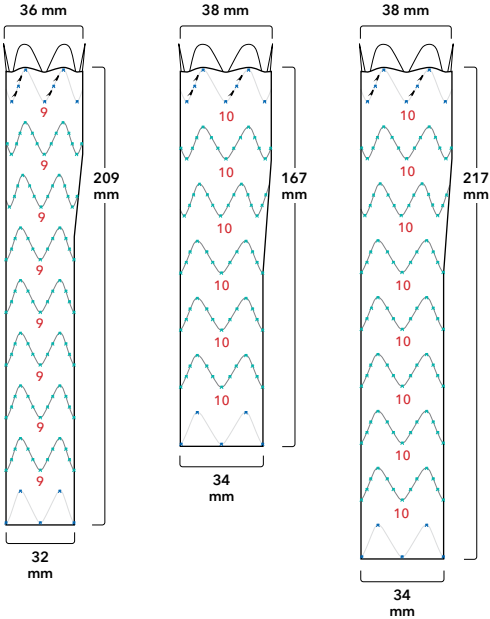


ZTA2-PT-XX-YY-ZZZ-W

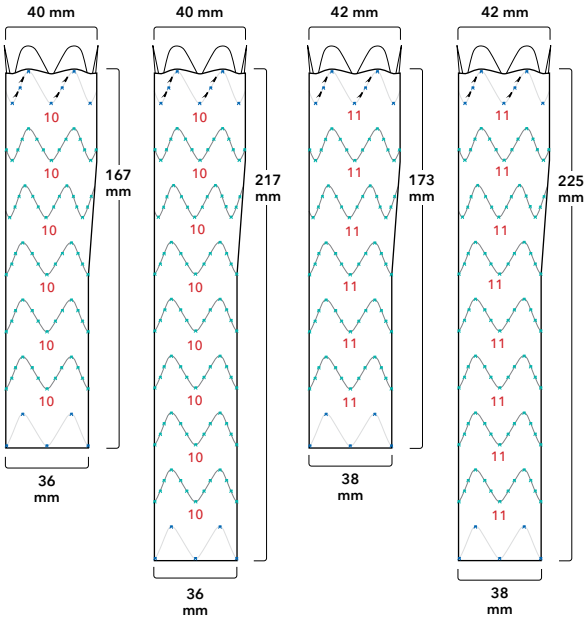
ZTA2-PT-(proximal diameter)-(distal diameter)-(length)-W

Note: All measurements are in millimeters. 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					
G60159	ZTA2-D-28-160-W	24-25	28	160	16 (5.3)/6.0
30 mm Diameter					
G60165	ZTA2-D-30-160-W	26-27	30	160	16 (5.3)/6.0
32 mm Diameter					
G60171	ZTA2-D-32-160-W	28-29	32	160	18 (6.0)/7.1
34 mm Diameter					
G60177	ZTA2-D-34-142-W	30	34	142	18 (6.0)/7.1
G60180	ZTA2-D-34-190-W	30	34	190	18 (6.0)/7.1
36 mm Diameter					
G60183	ZTA2-D-36-142-W	31-32	36	142	18 (6.0)/7.1
G60186	ZTA2-D-36-190-W	31-32	36	190	18 (6.0)/7.1
38 mm Diameter					
G60189	ZTA2-D-38-147-W	33-34	38	147	18 (6.0)/7.1
G60192	ZTA2-D-38-197-W	33-34	38	197	18 (6.0)/7.1
40 mm Diameter					
G60195	ZTA2-D-40-147-W	35-36	40	147	20(6.7)/7.7
G60198	ZTA2-D-40-197-W	35-36	40	197	20(6.7)/7.7
42 mm Diameter					
G60204	ZTA2-D-42-204-W	37-38	42	204	20(6.7)/7.7
44 mm Diameter					
G60210	ZTA2-D-44-211-W	39	44	211	20(6.7)/7.7
46 mm Diameter					
G60212	ZTA2-D-46-211-W	40-42	46	211	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.

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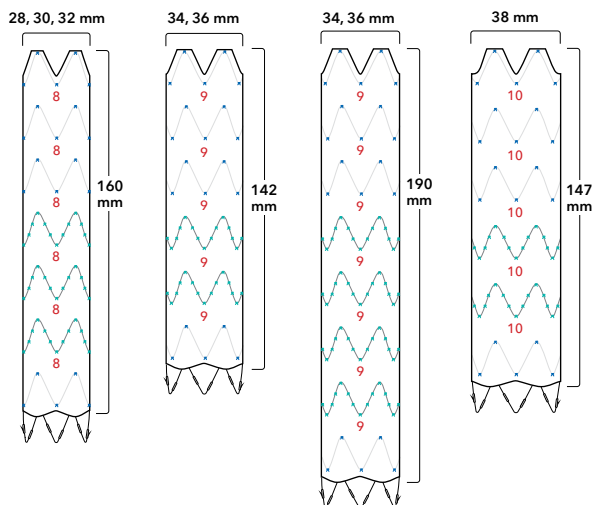
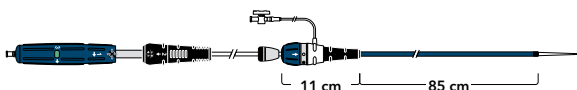
Distal components (continued)

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

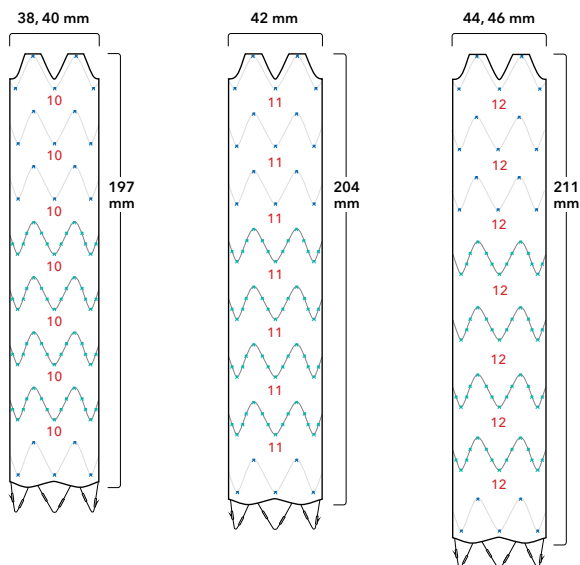


ZTA2-D-XX-YYY-W

ZTA2-D-(distal component diameter)-(distal component length)-W

Note: All measurements are in millimeters. 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					
G60093	ZTA2-DE-26-104-W	22-23	26	104	16(5.3)/6.0
30 mm Diameter					
G60105	ZTA2-DE-30-108-W	26-27	30	108	16(5.3)/6.0
34 mm Diameter					
G60116	ZTA2-DE-34-112-W	30	34	112	18(6.0)/7.1
38 mm Diameter					
G60130	ZTA2-DE-38-91-W	33-34	38	91	18(6.0)/7.1
42 mm Diameter					
G60142	ZTA2-DE-42-94-W	37-38	42	94	20(6.7)/7.7
46 mm Diameter					
G60154	ZTA2-DE-46-97-W	40-42	46	97	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.

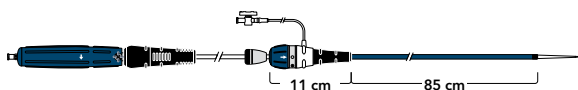
Please see product risk information in the IFU at cookmedical.com.

Introduction system for distal extensions

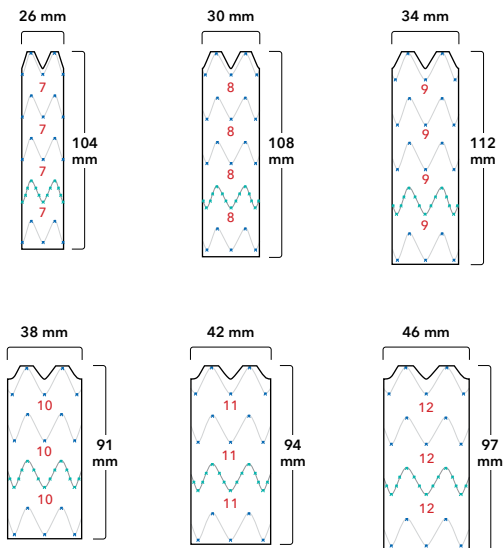
26-30 mm grafts: 16 Fr (5.3 mm) ID/6.0 mm OD

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 (continued)



ZTA2-DE-XX-YYY-W

ZTA2-DE-(diameter)-(length)-W

Note: All measurements are in millimeters. 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

Stabilize the gray positioner 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 gray 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, stabilize 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: MOLDING BALLOON

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

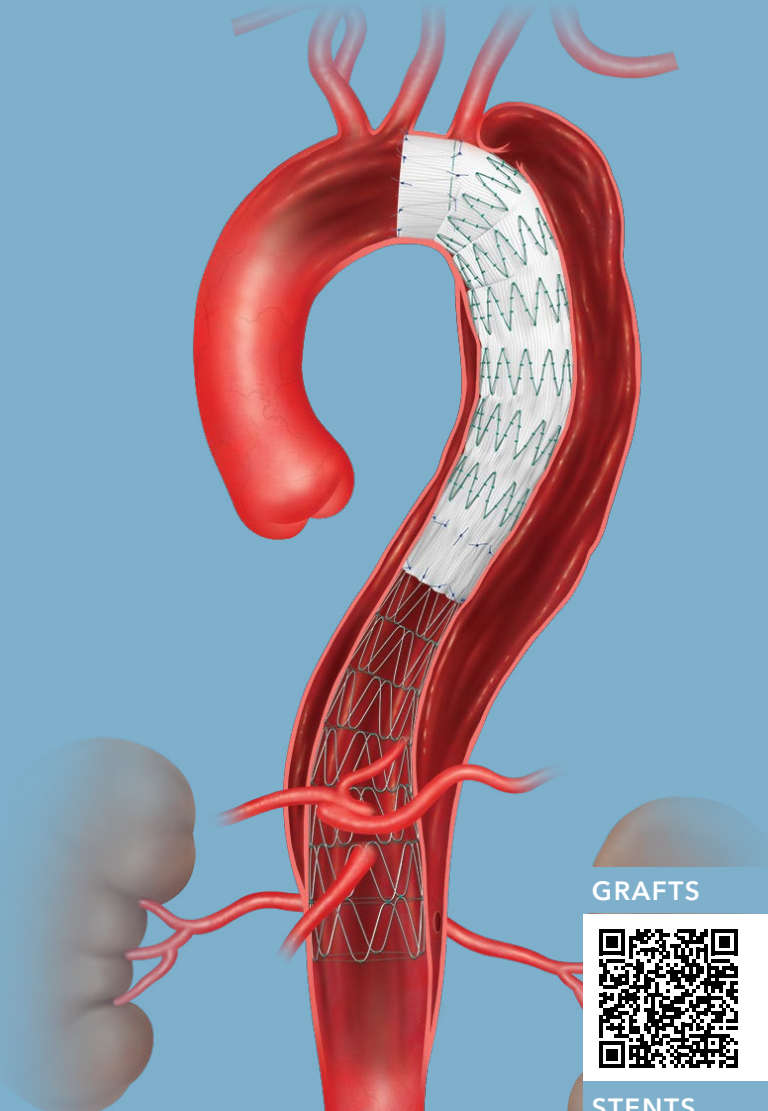
Tighten the Captor Hemostatic Valve around the molding balloon by turning it clockwise with gentle pressure.

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

Expand the molding 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

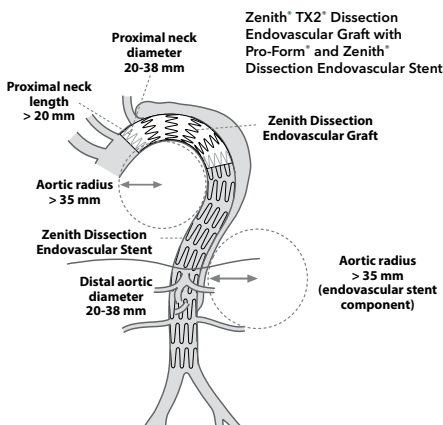


STENTS



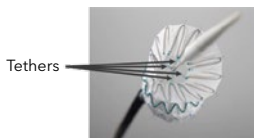
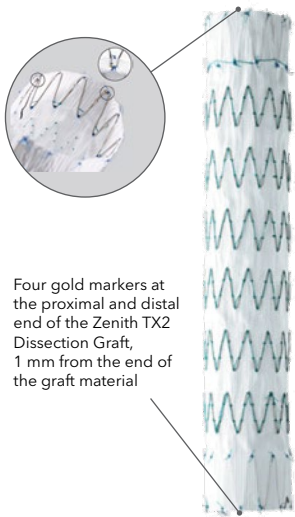
Zenith[®] Dissection
Endovascular System

Indications for use

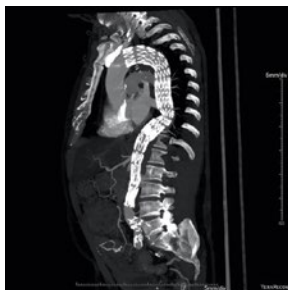
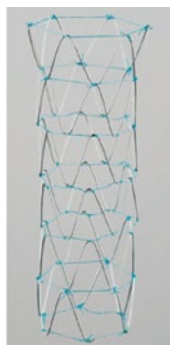


Indications for use	Endovascular treatment of patients with Type B aortic dissection. The Zenith TX2 Dissection Endovascular Graft with Pro-Form is intended to seal the entry tears and to exclude aneurysms associated with chronic dissections. The Zenith Dissection Endovascular Stent is intended to be used as a distal component to provide support to delaminated segments of non-aneurysmal aorta with dissection distal to a Zenith TX2 Dissection Endovascular Graft.		
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) • Localized angulation < 45 degrees (dissection graft) • Radius of curvature > 35 mm along the length of aorta that is intended to be treated (dissection stent) • Localized 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 Dissection Endovascular System: Disease-specific solution



Pro-Form tethers the distal end of the proximal sealing stent, allowing for better conformity



Ability to treat a Type B dissection all the way down to the aortic bifurcation

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						
G47437	ZDEG-P-22-79-PF-US	P	20	22	79	20 (6.7)/7.7
G47436	ZDEG-P-22-117-PF-US	P	20	22	117	20 (6.7)/7.7
24 mm Diameter						
G47439	ZDEG-P-24-79-PF-US	P	21	24	79	20 (6.7)/7.7
G47438	ZDEG-P-24-117-PF-US	P	21	24	117	20 (6.7)/7.7
26 mm Diameter						
G47441	ZDEG-P-26-79-PF-US	P	22-23	26	79	20 (6.7)/7.7
G47440	ZDEG-P-26-136-PF-US	P	22-23	26	136	20 (6.7)/7.7
28 mm Diameter						
G47444	ZDEG-P-28-82-PF-US	P	24	28	82	20 (6.7)/7.7
G47442	ZDEG-P-28-142-PF-US	P	24	28	142	20 (6.7)/7.7
G47443	ZDEG-P-28-202-PF-US	P	24	28	202	20 (6.7)/7.7
30 mm Diameter						
G47447	ZDEG-P-30-82-PF-US	P	25-27	30	82	20 (6.7)/7.7
G47445	ZDEG-P-30-142-PF-US	P	25-27	30	142	20 (6.7)/7.7
G47446	ZDEG-P-30-202-PF-US	P	25-27	30	202	20 (6.7)/7.7
32 mm Diameter						
G47450	ZDEG-P-32-82-PF-US	P	28-29	32	82	20 (6.7)/7.7
G47448	ZDEG-P-32-142-PF-US	P	28-29	32	142	20 (6.7)/7.7
G47449	ZDEG-P-32-202-PF-US	P	28-29	32	202	20 (6.7)/7.7
34 mm Diameter						
G47453	ZDEG-P-34-79-PF-US	P	30	34	79	20 (6.7)/7.7
G47451	ZDEG-P-34-154-PF-US	P	30	34	154	20 (6.7)/7.7
G47452	ZDEG-P-34-204-PF-US	P	30	34	204	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.com.

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						
G47456	ZDEG-P-36-79-PF-US	P	31-32	36	79	22 (7.3)/8.5
G47454	ZDEG-P-36-154-PF-US	P	31-32	36	154	22 (7.3)/8.5
G47455	ZDEG-P-36-204-PF-US	P	31-32	36	204	22 (7.3)/8.5
38 mm Diameter						
G47459	ZDEG-P-38-79-PF-US	P	33-34	38	79	22 (7.3)/8.5
G47457	ZDEG-P-38-154-PF-US	P	33-34	38	154	22 (7.3)/8.5
G47458	ZDEG-P-38-204-PF-US	P	33-34	38	204	22 (7.3)/8.5
40 mm Diameter						
G47462	ZDEG-P-40-83-PF-US	P	35-36	40	83	22 (7.3)/8.5
G47460	ZDEG-P-40-164-PF-US	P	35-36	40	164	22 (7.3)/8.5
G47461	ZDEG-P-40-218-PF-US	P	35-36	40	218	22 (7.3)/8.5
42 mm Diameter						
G47465	ZDEG-P-42-83-PF-US	P	37-38	42	83	22 (7.3)/8.5
G47463	ZDEG-P-42-164-PF-US	P	37-38	42	164	22 (7.3)/8.5
G47464	ZDEG-P-42-218-PF-US	P	37-38	42	218	22 (7.3)/8.5

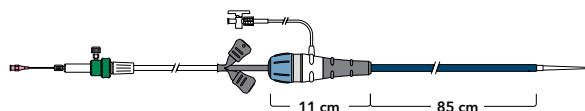
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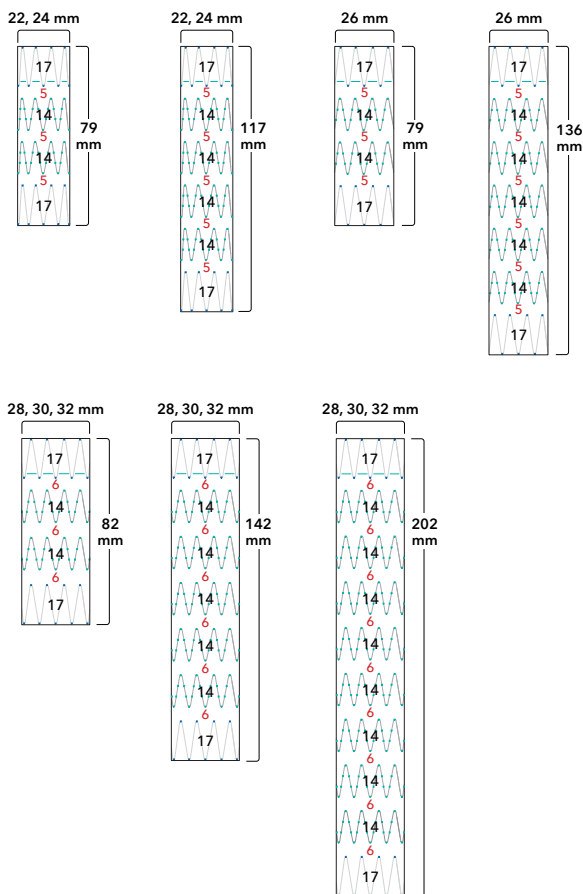
Z-Trak® Plus Introduction System for straight components

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

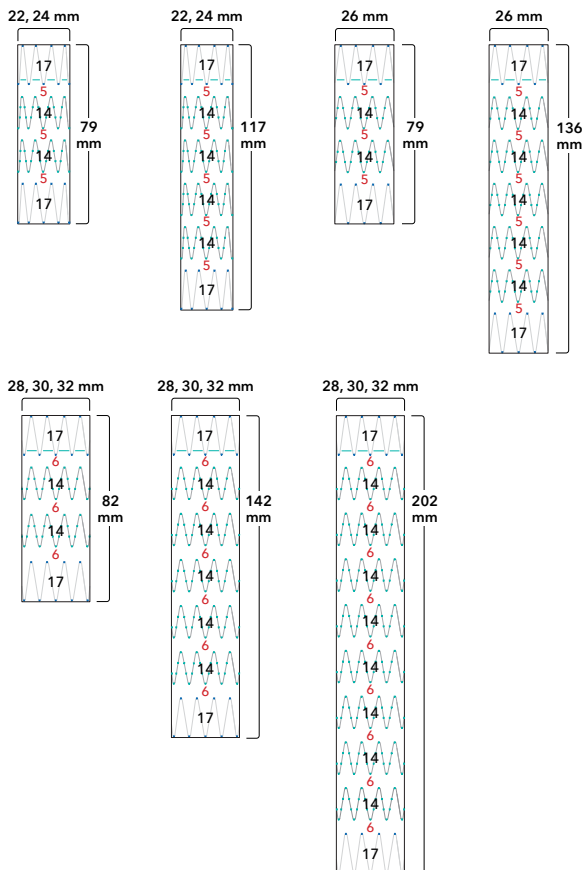


ZDEG-P-XX-YYY-PF-US

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

Note: All measurements are in millimeters. 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)



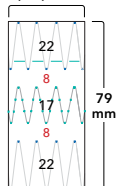
ZDEG-P-XX-YYY-PF-US

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

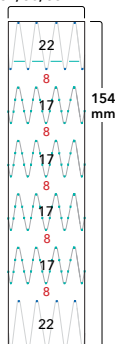
Note: All measurements are in millimeters. The black numbers on the illustrations indicate stent lengths. The red numbers indicate gap lengths. Gap lengths are approximate.

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

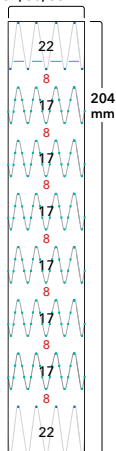
34, 36, 38 mm



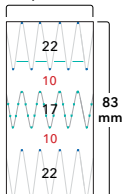
34, 36, 38 mm



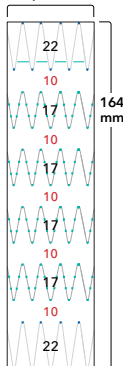
34, 36, 38 mm



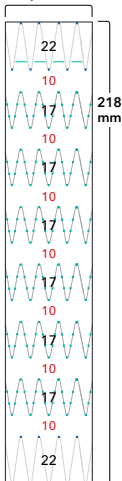
40, 42 mm



40, 42 mm



40, 42 mm



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							
G47466	ZDEG-PT-32-162-PF-US	PT	28-29	32	28	162	20(6.7)/7.7
G47467	ZDEG-PT-32-202-PF-US	PT	28-29	32	28	202	20(6.7)/7.7
34/30 mm Diameter							
G47470	ZDEG-PT-34-159-PF-US	PT	30	34	30	159	20(6.7)/7.7
G47471	ZDEG-PT-34-199-PF-US	PT	30	34	30	199	20(6.7)/7.7
36/32 mm Diameter							
G47474	ZDEG-PT-36-159-PF-US	PT	31-32	36	32	159	22(7.3)/8.5
G47475	ZDEG-PT-36-199-PF-US	PT	31-32	36	32	199	22(7.3)/8.5
38/34 mm Diameter							
G47478	ZDEG-PT-38-154-PF-US	PT	33-34	38	34	154	22(7.3)/8.5
G47479	ZDEG-PT-38-204-PF-US	PT	33-34	38	34	204	22(7.3)/8.5
40/36 mm Diameter							
G47482	ZDEG-PT-40-160-PF-US	PT	35-36	40	36	160	22(7.3)/8.5
G47483	ZDEG-PT-40-210-PF-US	PT	35-36	40	36	210	22(7.3)/8.5
42/38 mm Diameter							
G47486	ZDEG-PT-42-160-PF-US	PT	37-38	42	38	160	22(7.3)/8.5
G47487	ZDEG-PT-42-210-PF-US	PT	37-38	42	38	210	22(7.3)/8.5

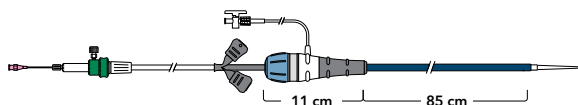
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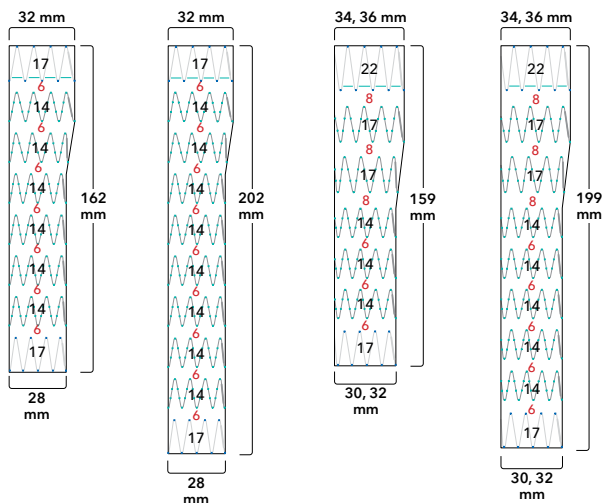
Z-Trak Plus Introduction System for 4 mm tapered components

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



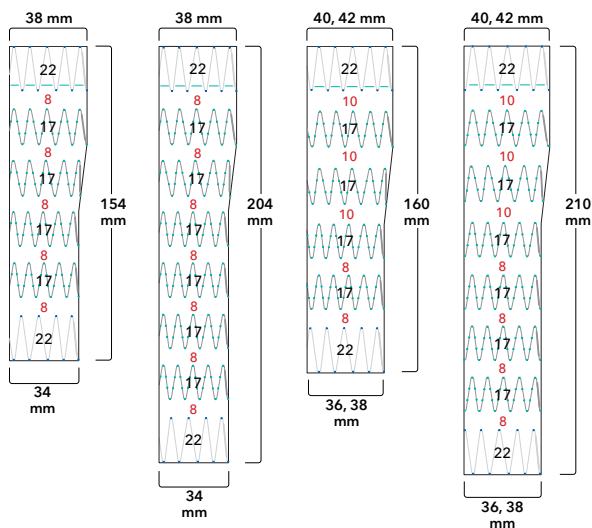
ZDEG-PT-XX-YYY-PF-US

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

Note: All measurements are in millimeters. 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)/mm
32/24 mm Diameter							
G47468	ZDEG-PT-32-24-158-PF-US	PT	28-29	32	24	158	20 (6.7)/7.7
G47469	ZDEG-PT-32-24-196-PF-US	PT	28-29	32	24	196	20 (6.7)/7.7
34/26 mm Diameter							
G47472	ZDEG-PT-34-26-156-PF-US	PT	30	34	26	156	20 (6.7)/7.7
G47473	ZDEG-PT-34-26-194-PF-US	PT	30	34	26	194	20 (6.7)/7.7
36/28 mm Diameter							
G47476	ZDEG-PT-36-28-159-PF-US	PT	31-32	36	28	159	22 (7.3)/8.5
G47477	ZDEG-PT-36-28-199-PF-US	PT	31-32	36	28	199	22 (7.3)/8.5
38/30 mm Diameter							
G47480	ZDEG-PT-38-30-159-PF-US	PT	33-34	38	30	159	22 (7.3)/8.5
G47481	ZDEG-PT-38-30-199-PF-US	PT	33-34	38	30	199	22 (7.3)/8.5
40/32 mm Diameter							
G47485	ZDEG-PT-40-32-165-PF-US	PT	35-36	40	32	165	22 (7.3)/8.5
G47484	ZDEG-PT-40-32-205-PF-US	PT	35-36	40	32	205	22 (7.3)/8.5
42/34 mm Diameter							
G47488	ZDEG-PT-42-34-160-PF-US	PT	37-38	42	34	160	22 (7.3)/8.5
G47489	ZDEG-PT-42-34-210-PF-US	PT	37-38	42	34	210	22 (7.3)/8.5

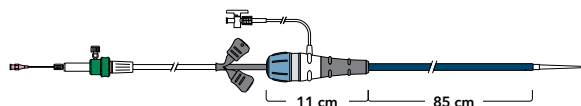
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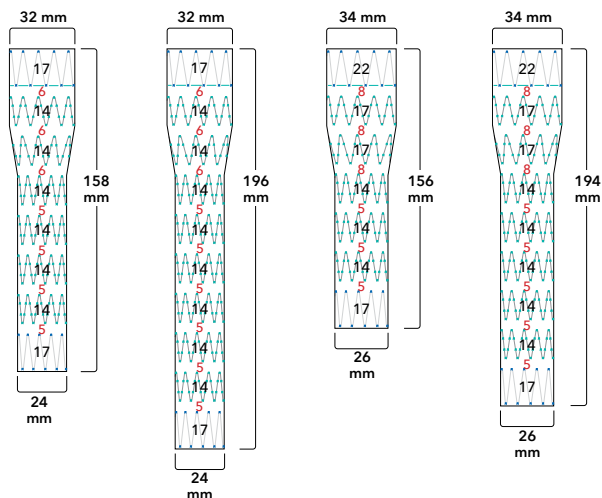
Z-Trak Plus Introduction System for 8 mm tapered component

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



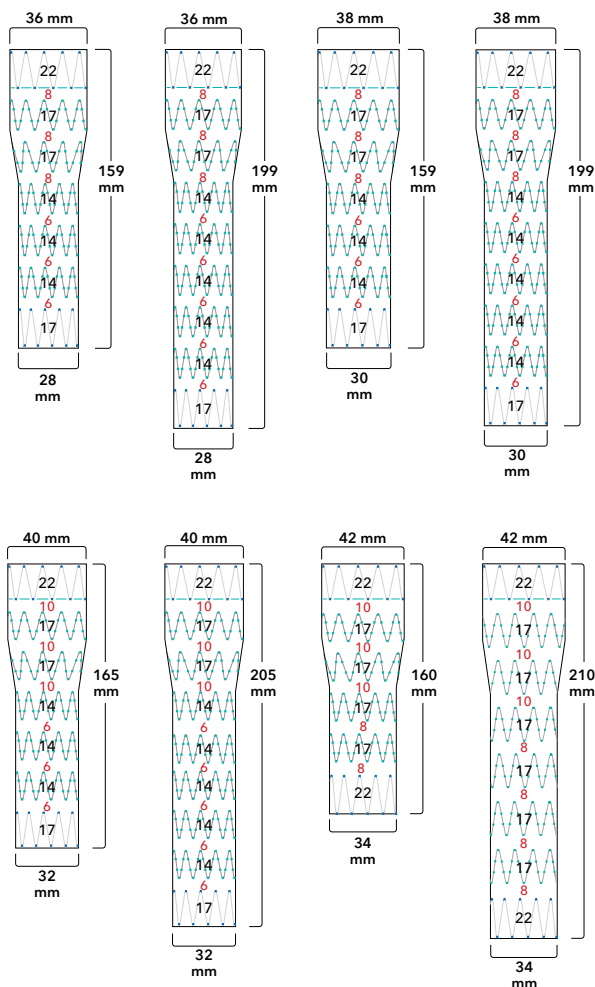
ZDEG-PT-XX-YY-ZZZ-PF-US

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

Note: All measurements are in millimeters. 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

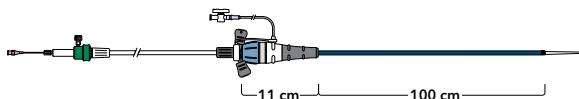
Order Number	Reference Part Number	Aortic Vessel OD mm	Diameter mm	Length mm	Stents	Introducer Sheath ID/OD Fr(mm)/mm
36 mm Diameter						
G47491	ZDES-36-80-US	20-30	36	80	4	16 (5.3)/6.0
G47492	ZDES-36-120-US	20-30	36	120	6	16 (5.3)/6.0
G47493	ZDES-36-180-US	20-30	36	180	9	16 (5.3)/6.0
46 mm Diameter						
G47494	ZDES-46-80-US	31-38	46	80	4	16 (5.3)/6.0
G47495	ZDES-46-120-US	31-38	46	120	6	16 (5.3)/6.0
G47496	ZDES-46-185-US	31-38	46	185	9	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.

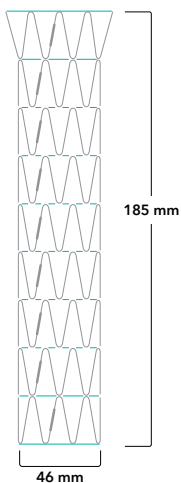
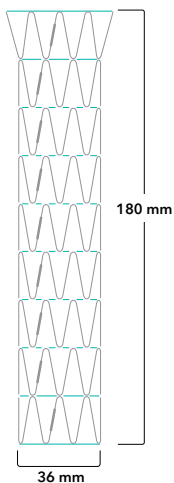
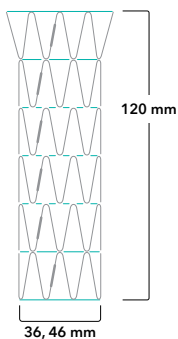
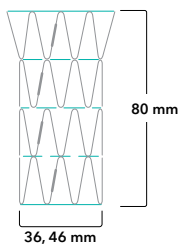
Please see product risk information in the IFU at cookmedical.com.

Z-Trak Plus Introduction System for dissection stents

16 Fr (5.3 mm) ID/6.0 mm OD



Endovascular stents



ZDES-XX-YYY-US

ZDES-(diameter)-(length)-US

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

Essentials for endovascular procedures





**MANAGING AORTIC DISEASE REQUIRES
MORE THAN JUST PRODUCTS.**



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