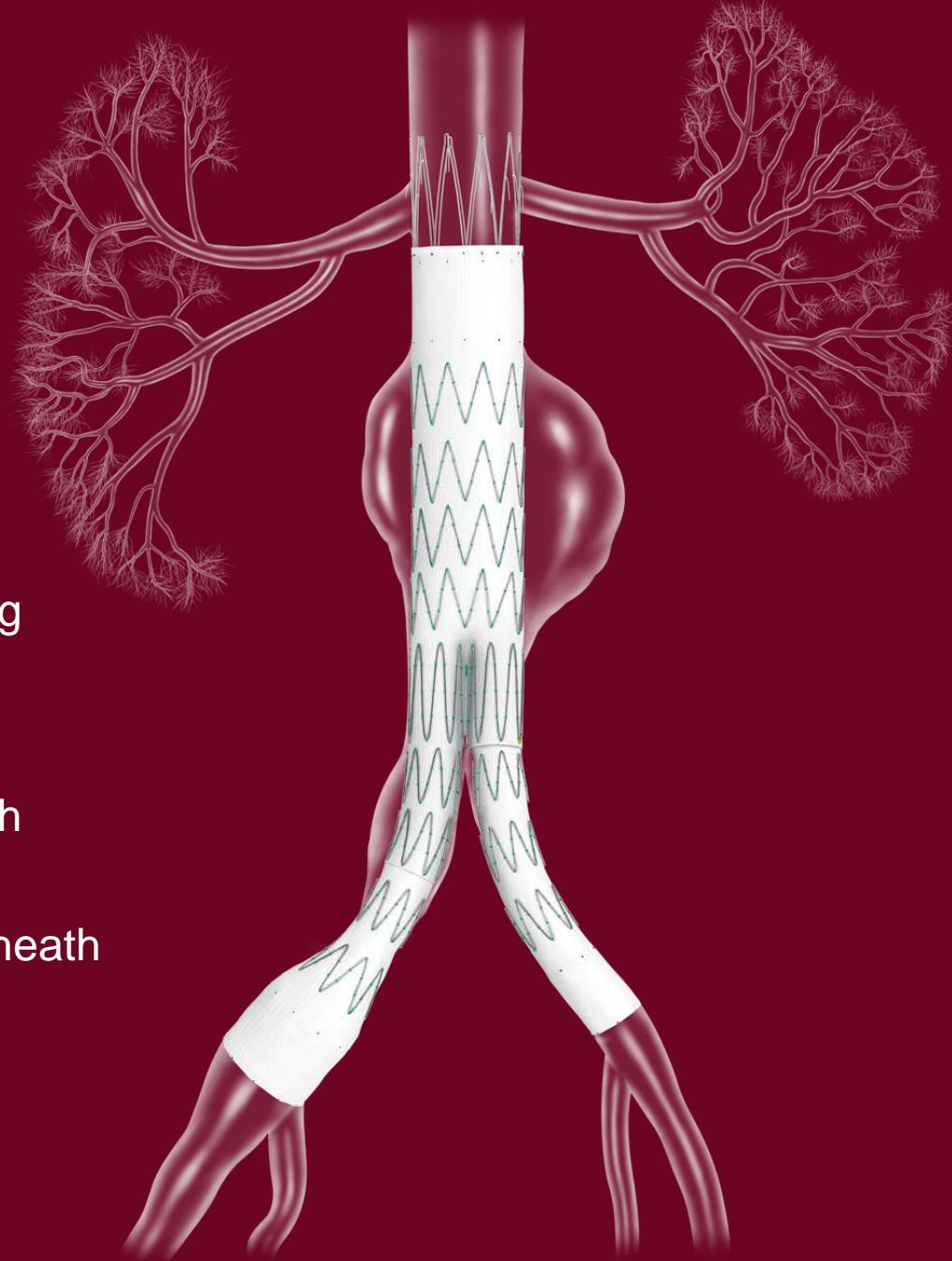


Cook Medical

*Zenith Flex® AAA Endovascular Graft
with Z-Trak™ Introduction System
Physician Training*



- Bifurcated system
- Proximal suprarenal stent
- Modular (aortic main body and two iliac legs)
- Full-thickness, woven polyester graft material
- Fully supported by self-expanding z-stents
- Z-Trak™ Introduction System
- Flex design, increased gap length provide greater conformability
- Hydrophilic Flexor® Introducer Sheath (main body graft only)
- Captor® Hemostatic Valve



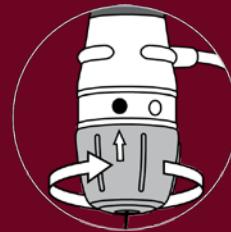
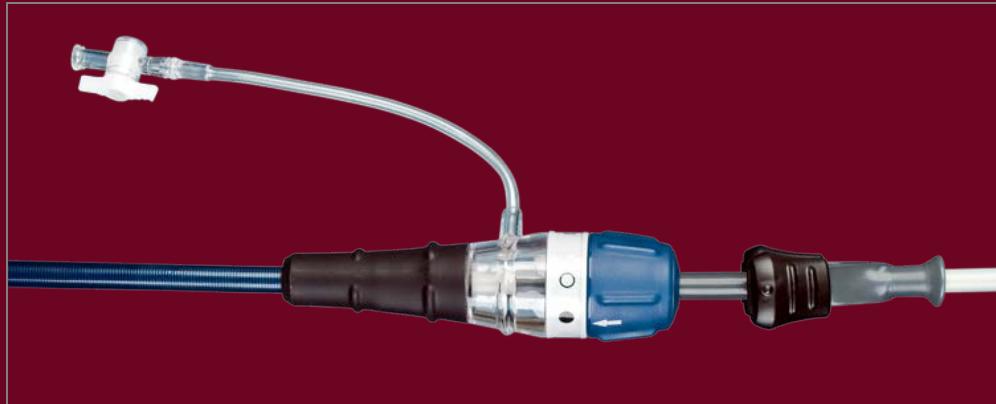
Development

- 1993 Aorto-aortic, uncovered proximal fixation stent
- 1994 Bifurcated two-piece prosthesis, fully stented; transfer capsule, top cap
- 1995 External stents, running suture attachment
- 1996 H&L-B One-Shot™ Introduction System; longer overlap zone
- 1997 Bifurcated, 3-piece prosthesis with current proximal fixation stent
- 1999 Shorter stents in limbs, longer gaps between limb stents
- 2000 Pivotal U.S. trial began
- 2003 FDA approval for commercial release (May 23, 2003)
- 2006 Addition of 36 mm diameter main body
- 2007 Introduction of Zenith Flex®
- 2008 Introduction of the Z-Trak™ Introduction System and Flex legs

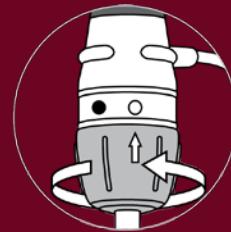
Hydrophilic Flexor® Introducer Sheath



Captor® Hemostatic Valve



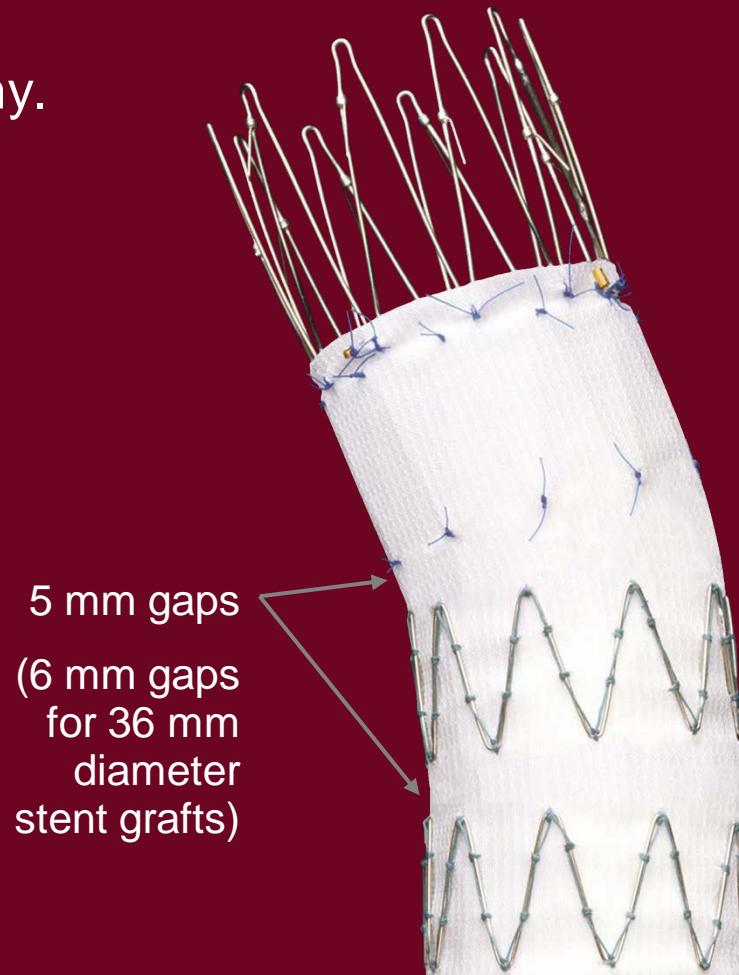
Indicates
valve closed
position



Indicates
valve open
position

Design

Increased gap length incorporated into the proximal segment of the main body provides greater conformance to angulated anatomy.

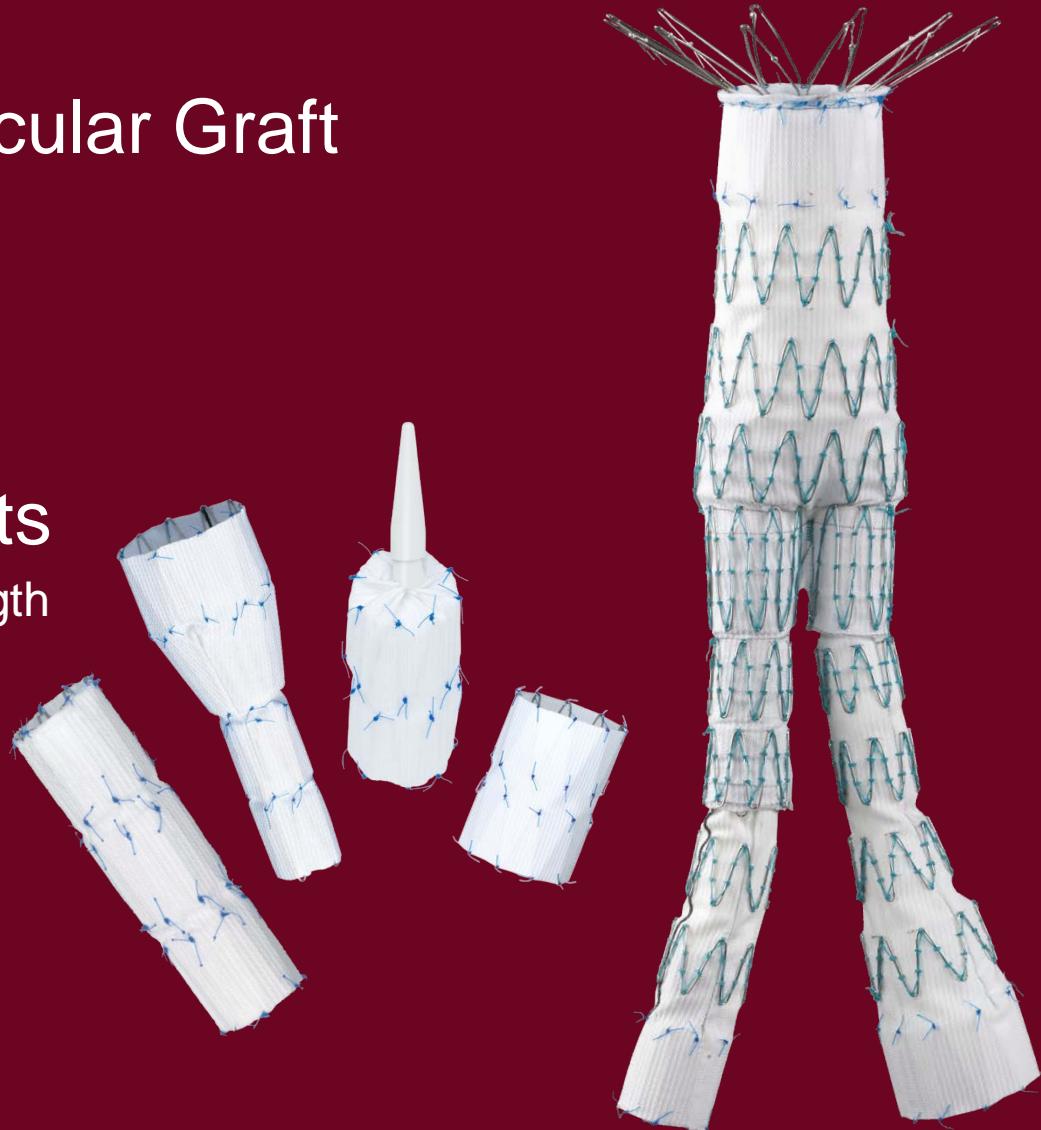


Main Body Endovascular Graft

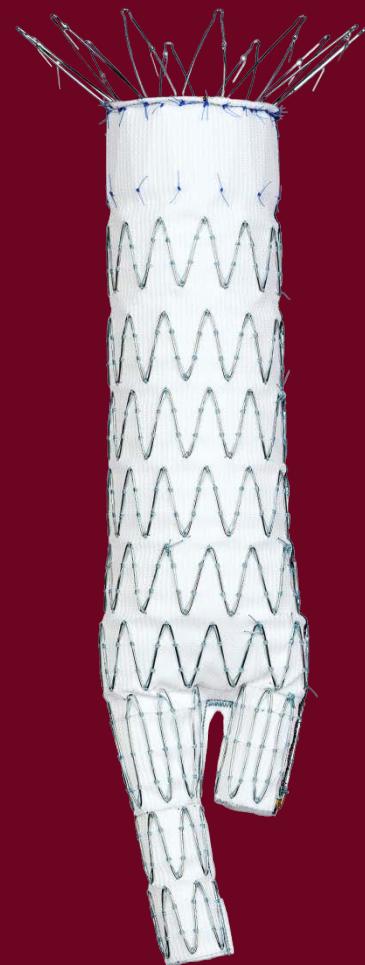
- TFFB-diameter-length-ZT
- TFLE-diameter-length-ZT

Ancillary Components

- ESC-diameter-diameter-length
- ZIP-diameter-length
- ESBE-diameter-length
- ESLE-diameter-length



Main Body	cl Length (mm)				
	82	96	111	125	140
Diameter (mm)					
22					
24	18 Fr ID (6.0 mm ID/7.1 mm OD) Z-Trak™ Introduction System				
26					
28					
30	20 Fr ID (6.7 mm ID/7.7 mm OD) Z-Trak Introduction System				
32					
	95	113	131	149	
36	22 Fr ID (7.3 mm ID/8.5 mm OD) Z-Trak Introduction System				

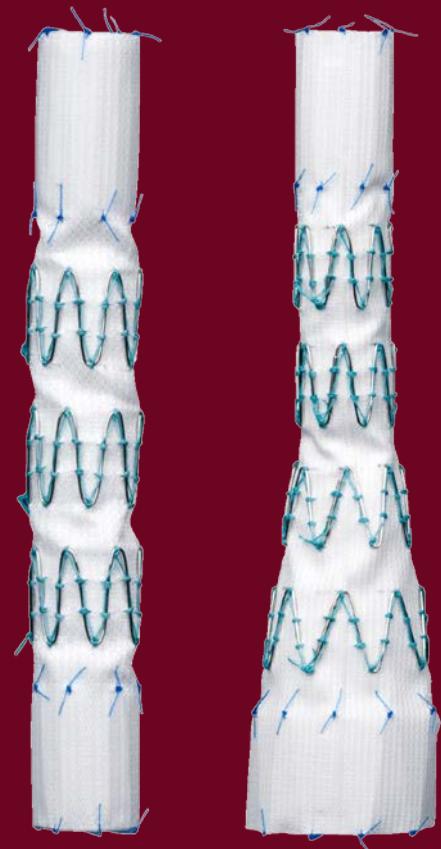


4 or 5 lengths + 7 diameters = 34 main body sizes

Sheath length = 40 cm

Sheath + valve length = 51 cm

Iliac Legs	Length (mm)					
	37	54	71	88	105	122
Diameter (mm)						
8	14 Fr ID (4.7 mm ID/5.3 mm OD) Z-Trak™ Introduction System					
10	39	56	73	90	107	124
12						
14						
16	16 Fr ID (5.3 mm ID/6.0 mm OD) Z-Trak Introduction System					
18	X	X				
20	X	X				
22	X	X				
24	X	X				



9 diameters + 4 or 6 lengths = 44 iliac leg sizes

Sheath length = 71 cm

Sheath + valve length = 82 cm

Features of the Zenith Flex® AAA Endovascular Graft

Unique Stent Graft Design

Independent, self-expanding stainless steel z-stent configuration provides:

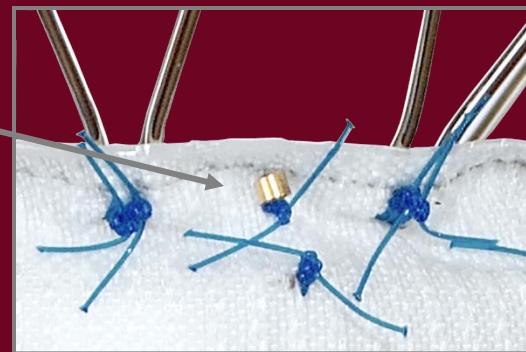
- graft flexibility
- secure graft/vessel apposition
- dimensional stability



Features of the Zenith Flex® AAA Endovascular Graft

Four Gold Proximal Markers

2 mm from most proximal segment of graft material



Contralateral Limb Gold Marker

Contralateral limb “check mark”



Stent Lengths – Main Body

Suprarenal stent

Proximal sealing stent

External stents

First stent after bifurcation

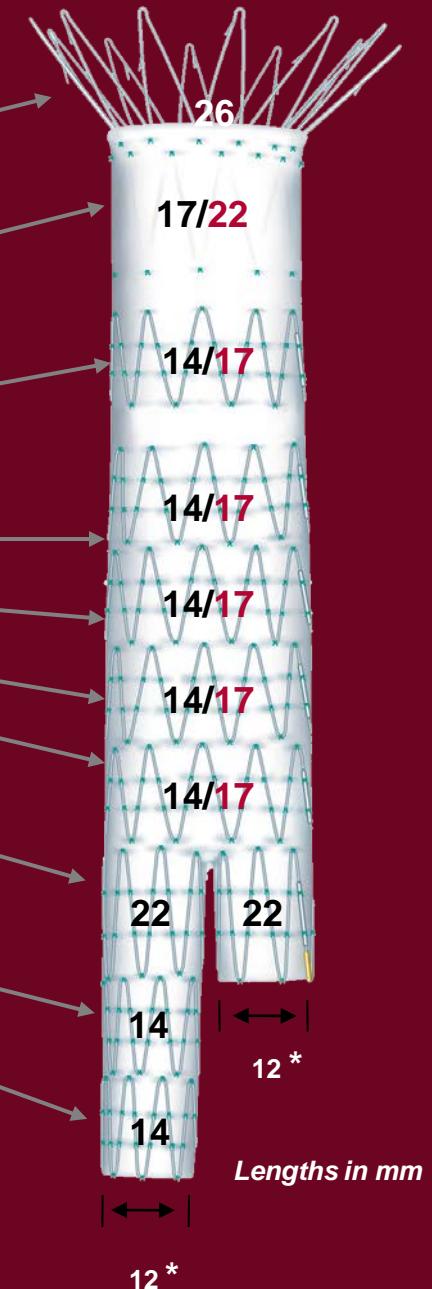
Distal limb stents

2-5 mm gaps between stents throughout graft for 22-32 mm diameters

2-6 mm gaps between stents throughout graft for 36 mm diameters

NOTE: Measurements specific to the 36 mm diameter stent graft are in red.

* 11 mm for stent grafts with a 22 mm proximal diameter.



Stent Lengths – Iliac Leg

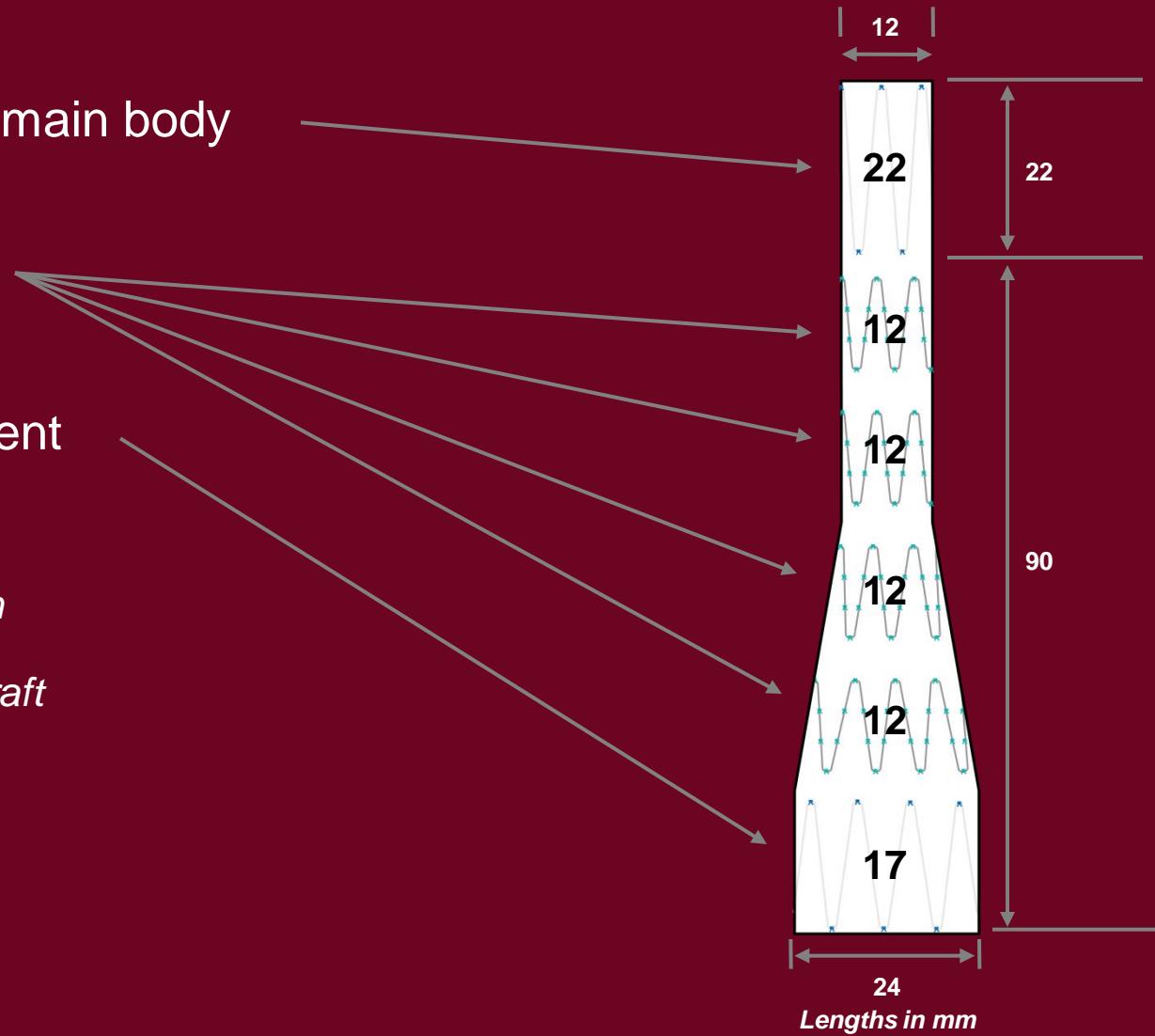
Sealing stent to main body

External stents

Distal sealing stent

5 mm gaps between

stents throughout graft



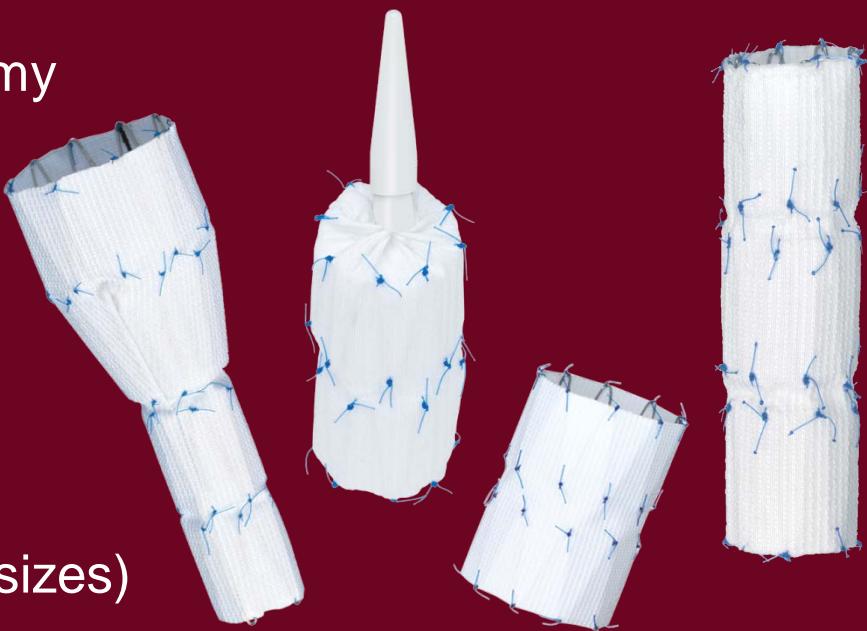
Ancillary Components

Uses

- To correct inaccuracies during device size selection
- To compensate for difficult anatomy encountered during procedure

Types

- Converter (ESC, four sizes)
- Iliac Plug (ZIP, four sizes)
- Main Body Extension (ESBE, 14 sizes)
- Iliac Leg Extension (ESLE, 9 sizes)



Deployment Sequence

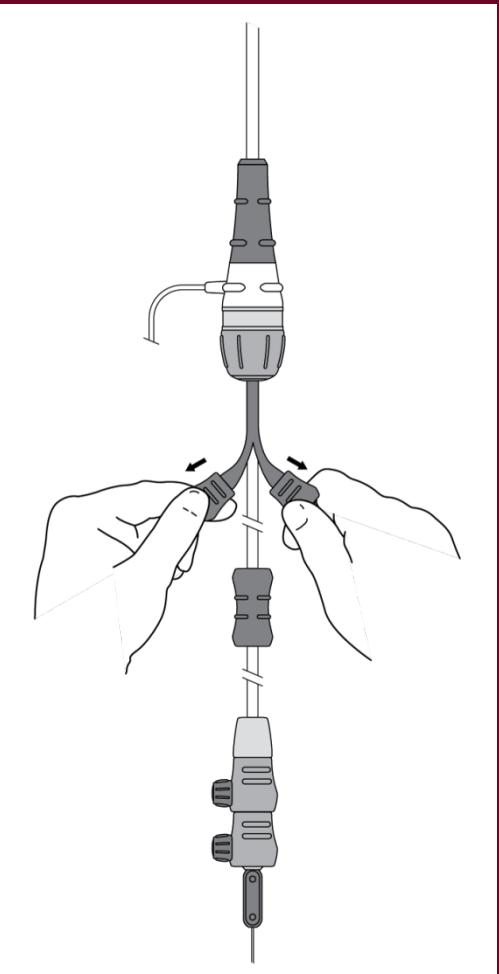
Prior to Use

- Inspect device and packaging for shipping damage. Do not use if damage has occurred or sterilization barrier has been broken.
- Verify that correct devices (quantity and size) have been supplied for the patient. Match the device to the prescribed order for each patient.
- Prepare systems for insertion.

Prepare Main Body and Iliac Leg Systems

Remove the three shipping protectors.

- Hubbed shipping stylet
- Dilator tip protector
- Peel-Away® sheath

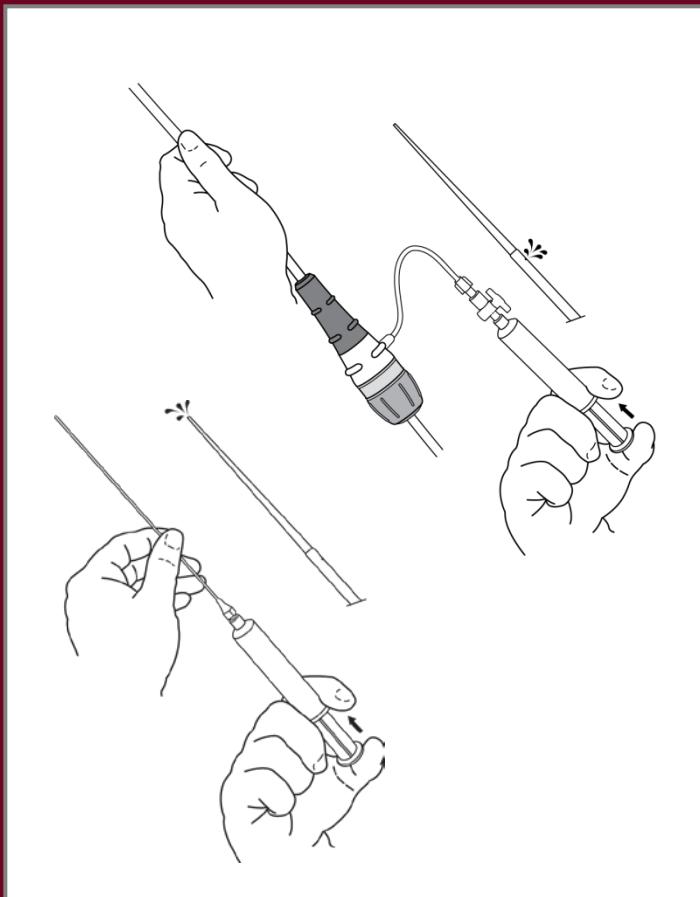


Prepare Main Body and Iliac Leg Systems (cont.)

Elevate distal tip of system and flush:

- wire lumen through hub
- sheath through stopcock

Wipe Flexor® Introducer Sheath to activate hydrophilic coating on the main body delivery system



Step 1

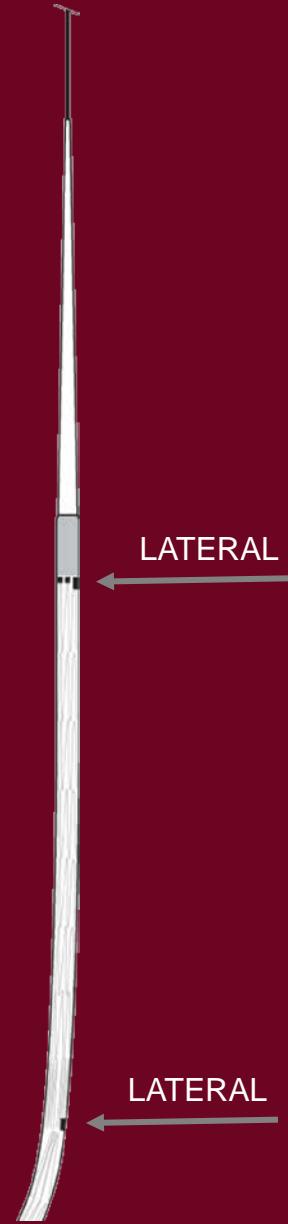
Orient main body delivery system
using fluoroscopy.

Contralateral limb

✓ = anterior

↖ = posterior

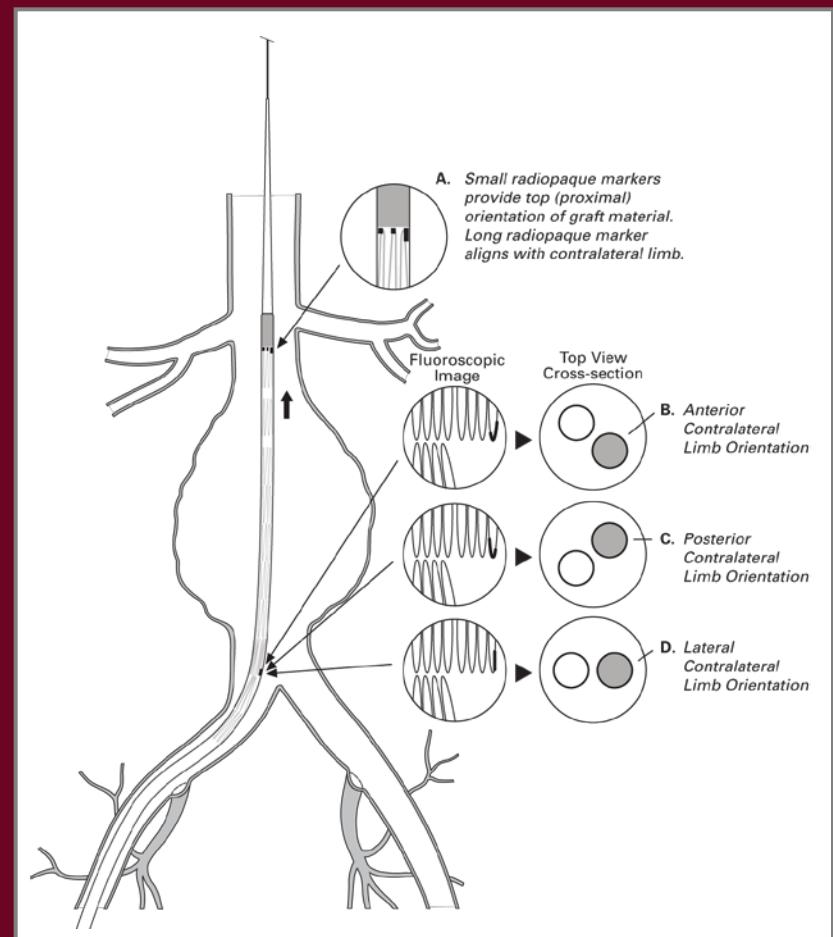
| = lateral



Step 2

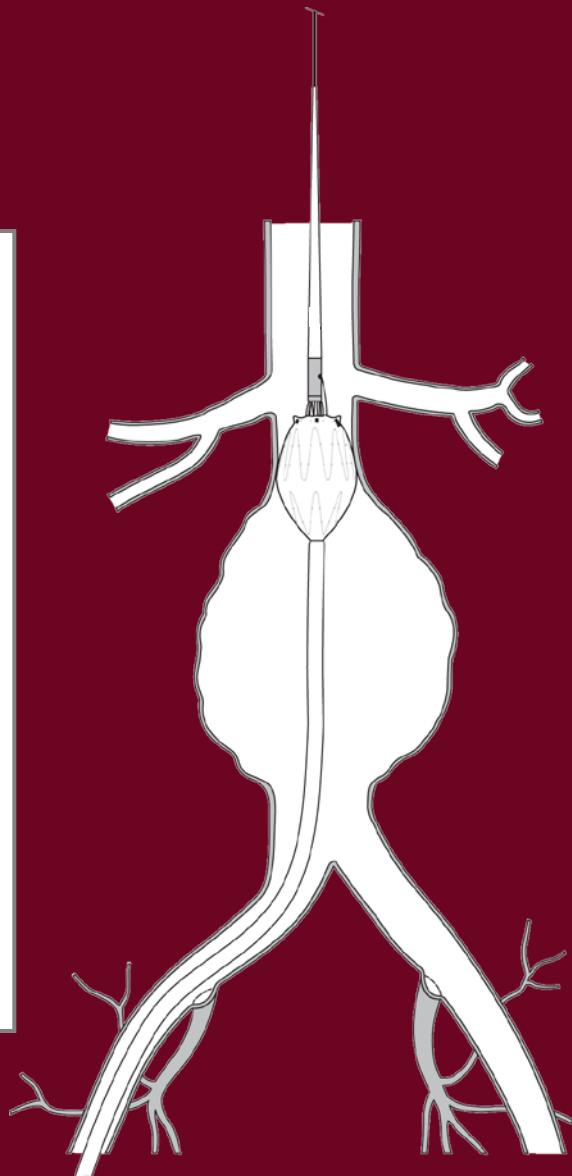
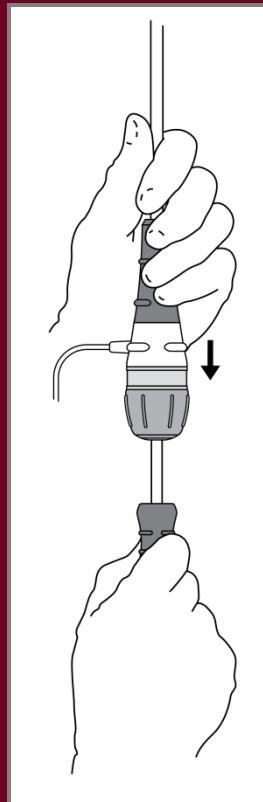
Introduce and position device below the lowest renal artery and verify orientation.*

* Perform angiograms as needed throughout procedure.



Step 3

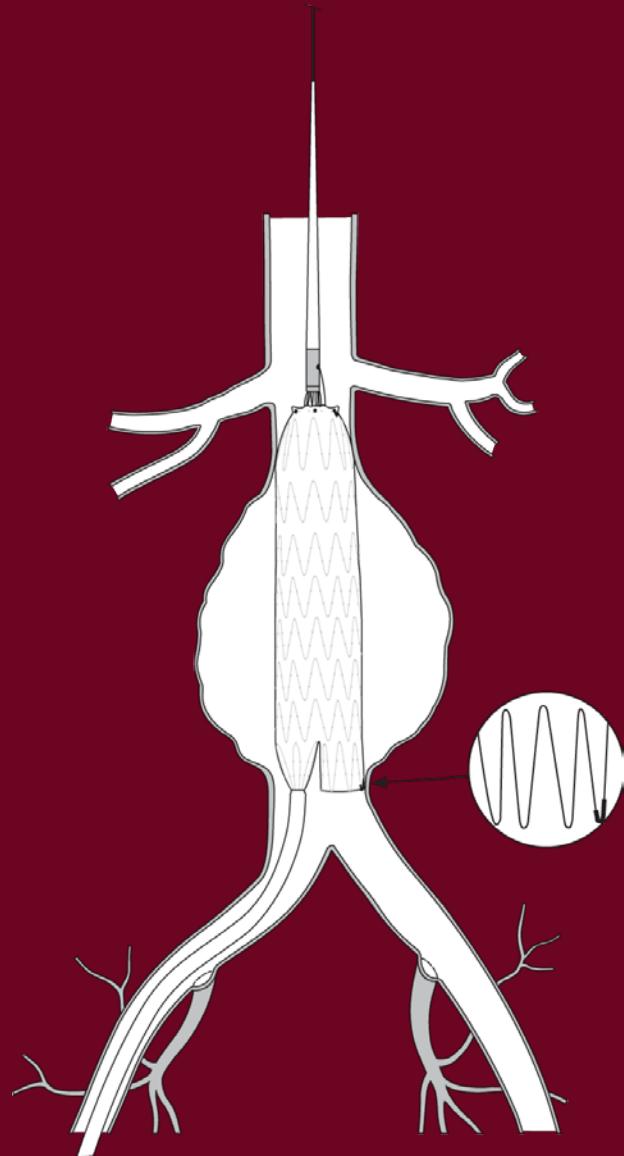
- Deploy first two covered stents by retracting sheath.
- Check position relative to renal arteries and aortic bifurcation.
- Orient using stent markers.



Step 4

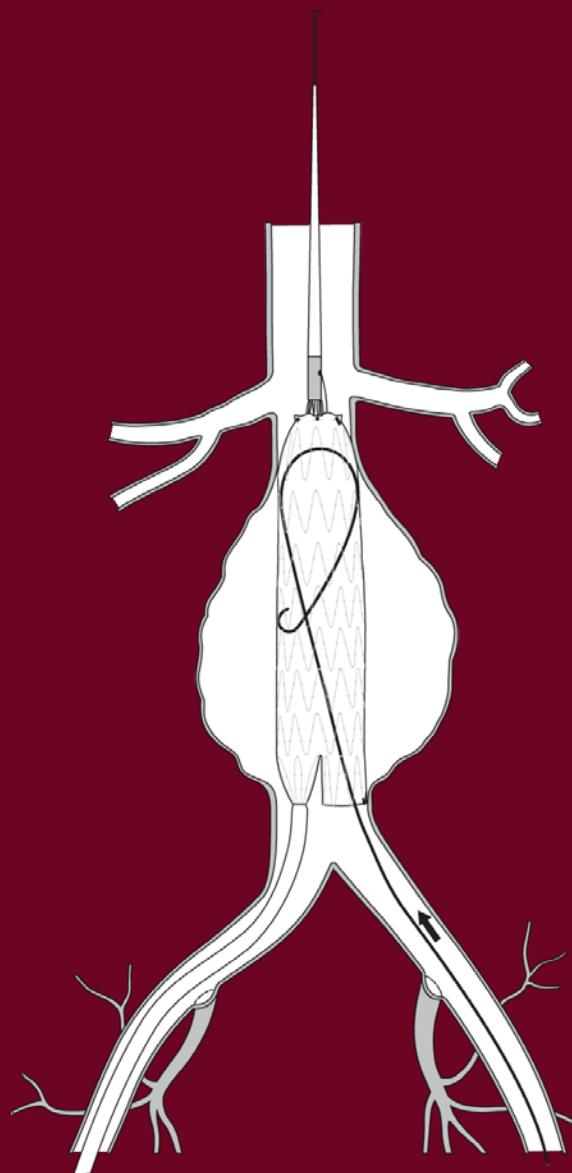
Continue sheath retraction until contralateral limb is fully deployed.

NOTE: Flexor® Introducer Sheath must be stabilized at all times.



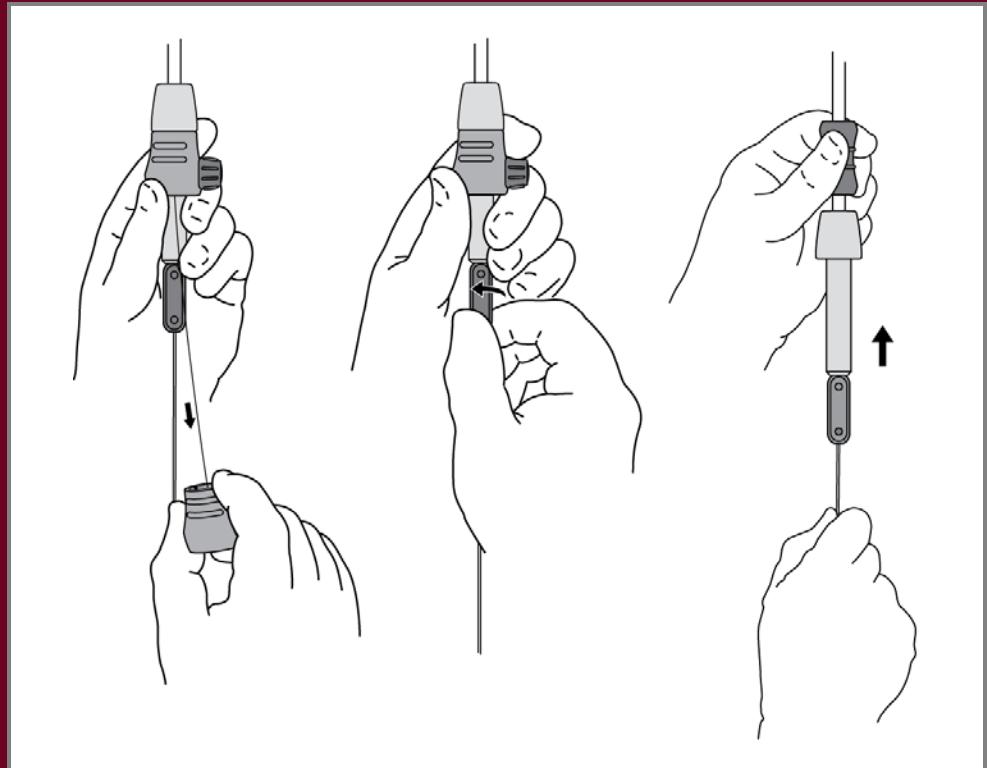
Step 5

- Cannulate contralateral limb.
- Perform angiogram with catheter tip at proximal orifice.
- Locate renal arteries.
- Verify catheter position (within graft).
- Check wire guide position.



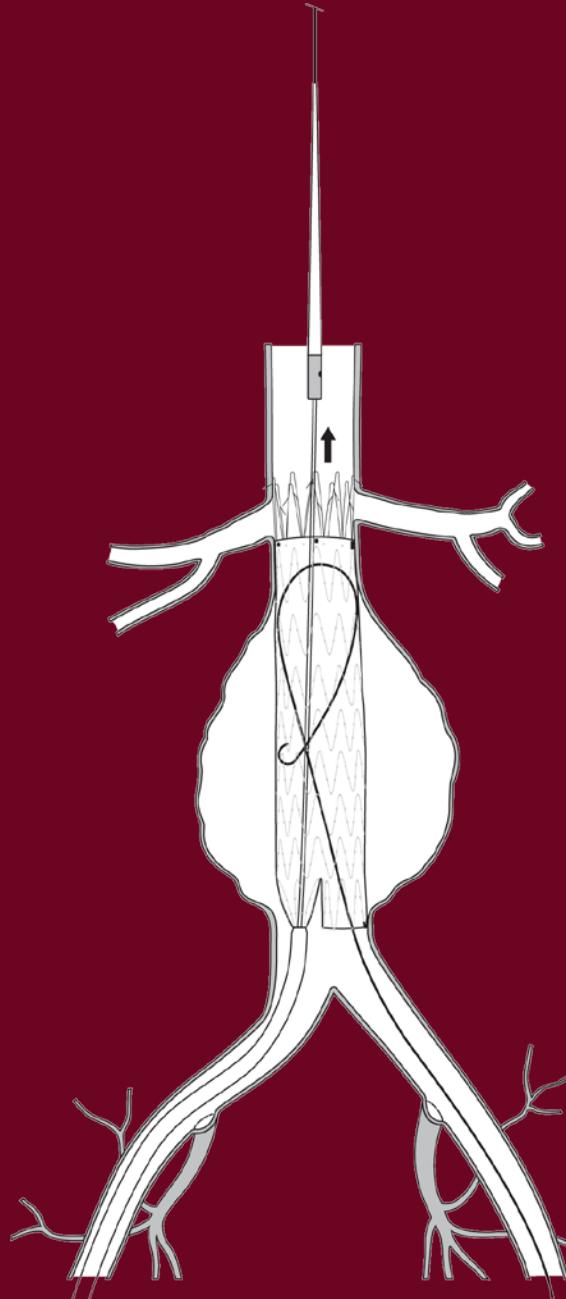
Step 6

- Remove top stent trigger wire.
- Deploy suprarenal stent (loosen pin vise and advance inner cannula, retighten pin vise).



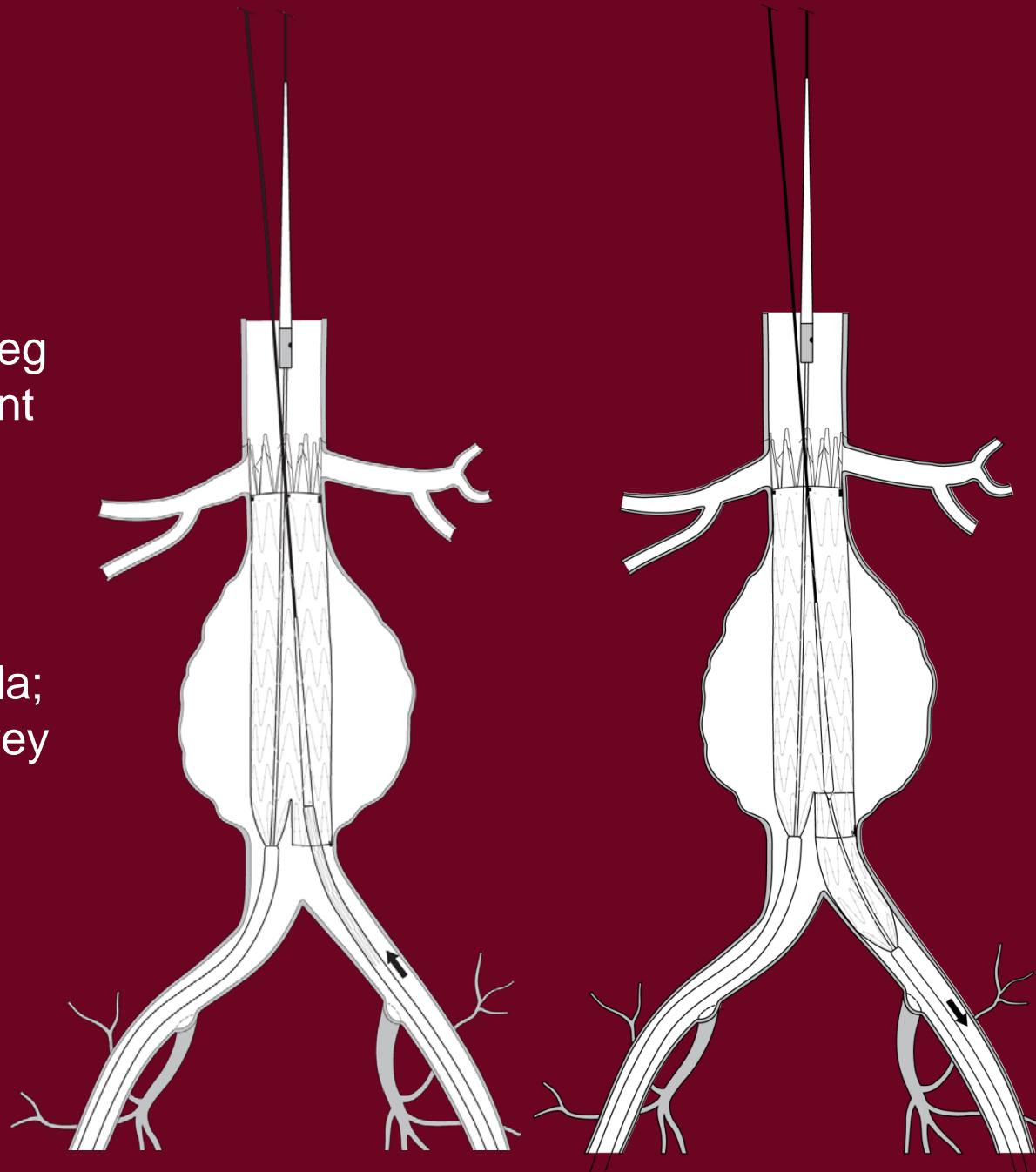
Step 7

- Withdraw catheter into body of graft.
- Advance wire guide through catheter.
- Perform angiogram to locate contralateral internal iliac artery.



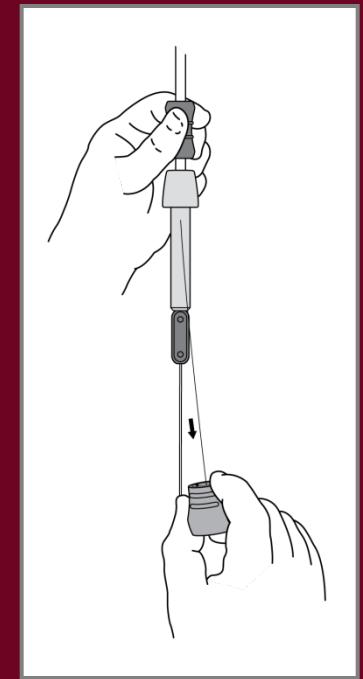
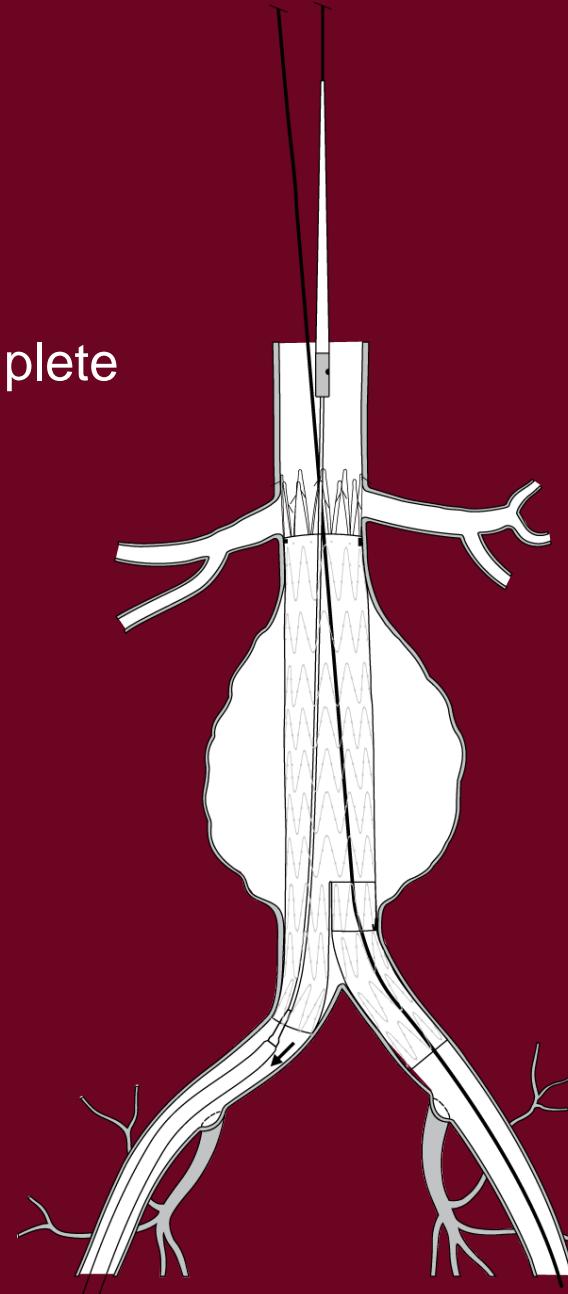
Step 8

- Introduce/advance leg to achieve 1-1.5 stent overlap.
- Check distal position/deploy.
- Retract inner cannula; dock and remove grey positioner.



Step 9

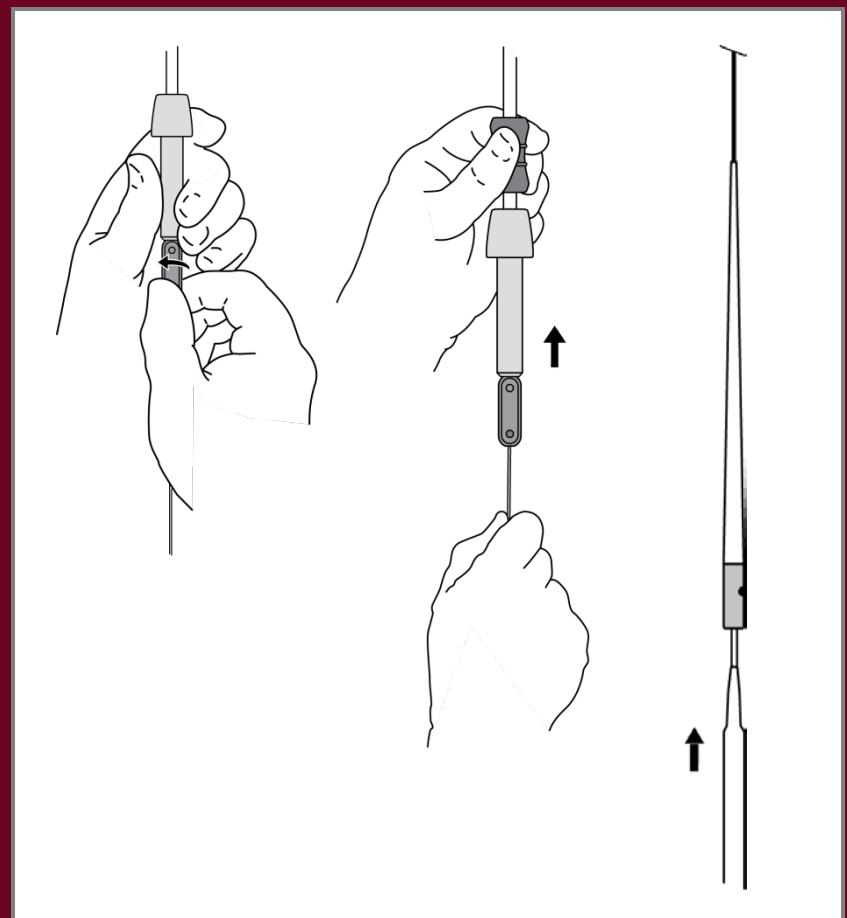
- Fully deploy main body (complete retraction of sheath).
- Remove ipsilateral limb trigger wire.



Step 10

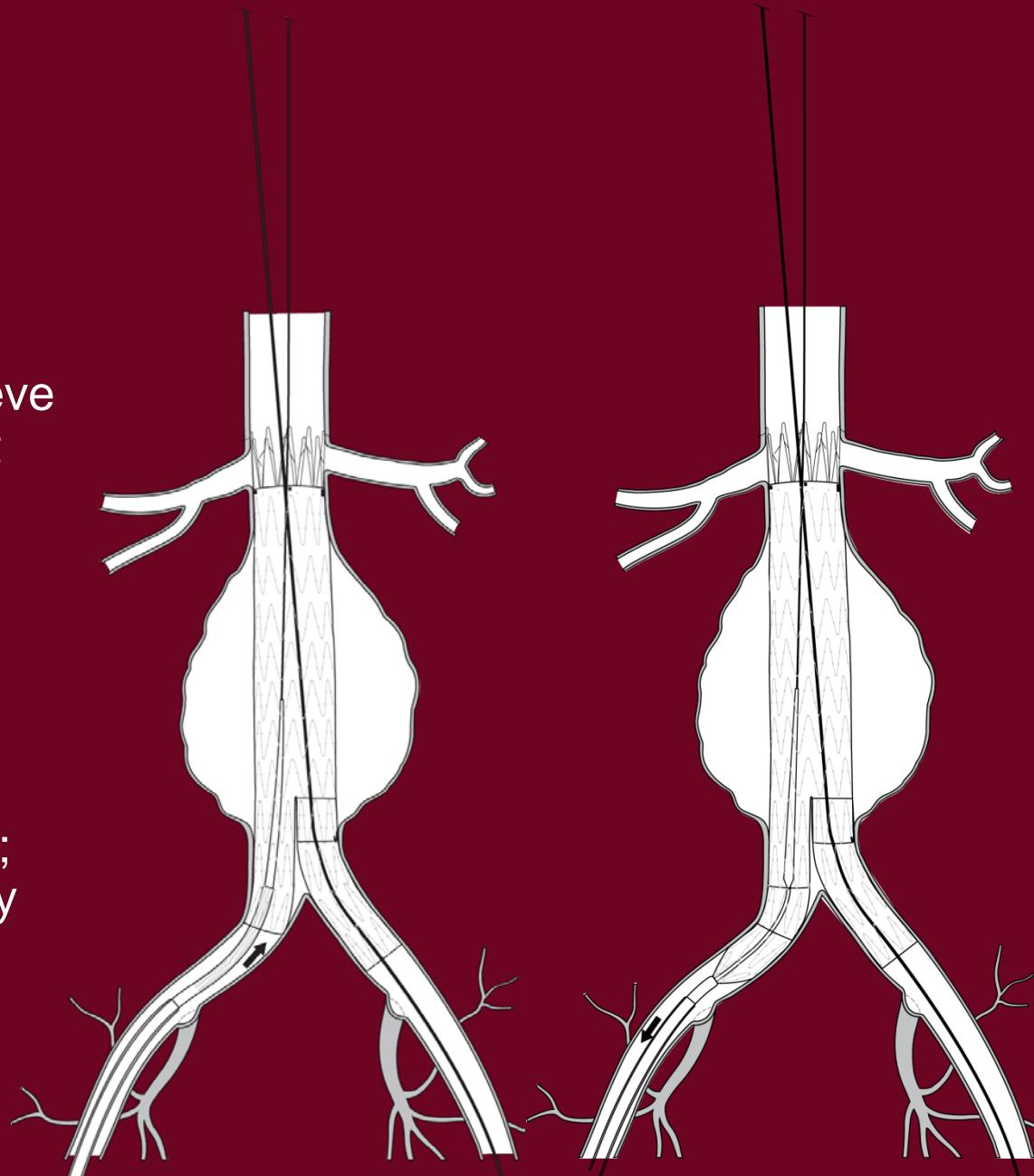
Dock top cap

- Loosen pin vise and secure both the inner cannula and sheath.
- Advance and dock grey positioner with top cap.
- Tighten pin vise.
- Remove main body delivery system.



Step 11

- Introduce/advance ipsilateral leg to achieve minimum of one stent overlap.
- Perform angiogram through large sheath.
- Check distal position/deploy.
- Retract inner cannula; dock and remove grey positioner.

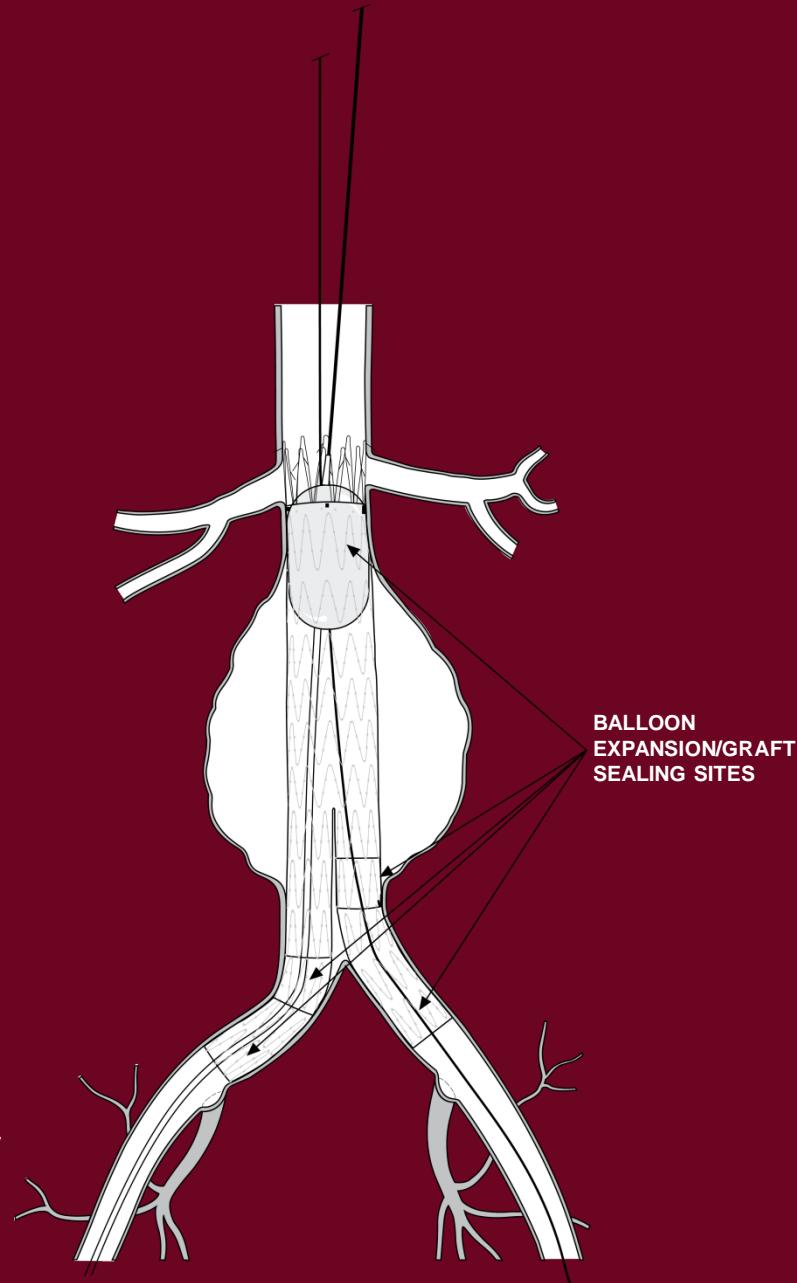


Step 12

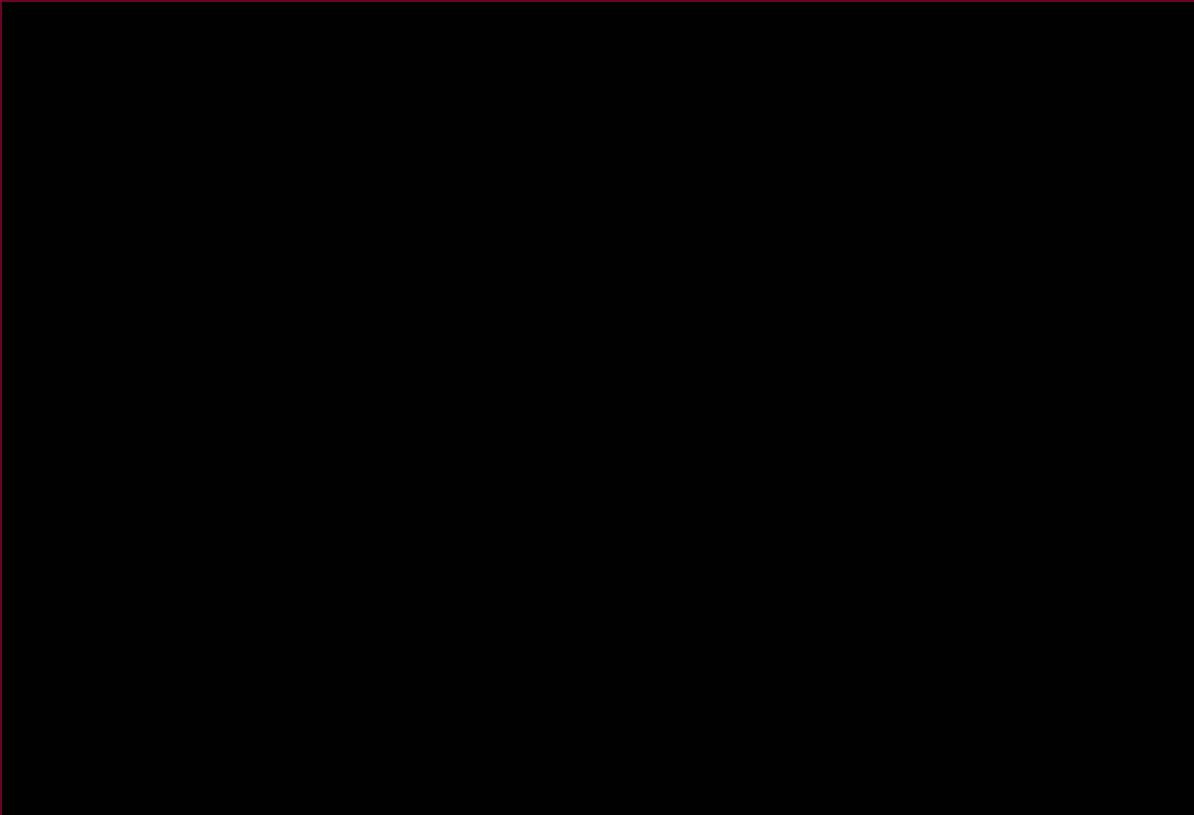
- Balloon-mold the graft at vessel seal sites and component overlap sites.
- Perform final angiogram.
- Do not inflate the balloon in vessel outside of the graft, as doing so may cause damage to the vessel.
- Use care in inflating the balloon within the graft in the presence of calcification, as excessive inflation may cause damage to the vessel.

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

NOTE: Confirm there are no endoleaks or kinks and verify position of proximal gold radiopaque markers.



Deployment Animation



Patient Selection

Patient Selection

The objective of patient selection is to determine if the patient is:

- a candidate for AAA repair
- a candidate for endovascular therapy
- a candidate for implantation of the Zenith Flex® AAA Endovascular Graft

Contraindications

The Zenith Flex AAA Endovascular Graft with the Z-Trak™ Introduction System is contraindicated in:

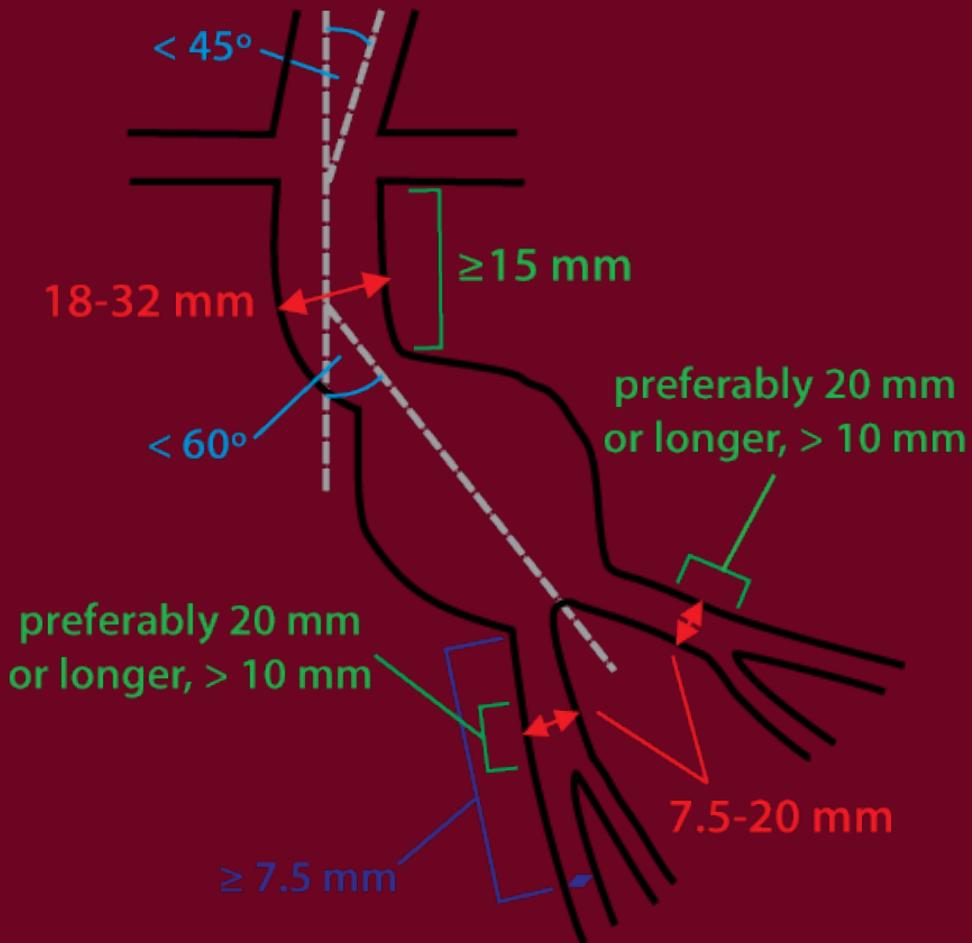
- patients with known sensitivities or allergies to stainless steel, polyester, solder (tin, silver), polypropylene or gold
- patients with a systemic infection who may be at increased risk of endovascular graft infection

Patient Selection

Ideal Morphology

- Adequate iliac/femoral access compatible with the required introduction systems
- Nonaneurysmal infrarenal neck that has:
 - length \geq 15 mm
 - diameter, measured outer wall to outer wall, of no greater than 32 mm and no less than 18 mm
 - angle $< 60^\circ$ relative to long axis of aneurysm
 - angle $< 45^\circ$ relative to axis of suprarenal aorta
- Iliac artery distal fixation site that has:
 - length $>$ 10 mm (preferably $>$ 20 mm)
 - diameter 7.5-20 mm (outer wall to outer wall)

Patient Selection



Device Planning

Device Planning

- Obtain recommended CT and angiography.
- Follow five recommended steps:
 1. Select the side for main body introduction and fixation sites.
 2. Obtain and insert anatomical measurements on the worksheet.
 3. Select the main body.
 4. Select the contralateral iliac leg.
 5. Select the ipsilateral iliac leg.

Device Planning

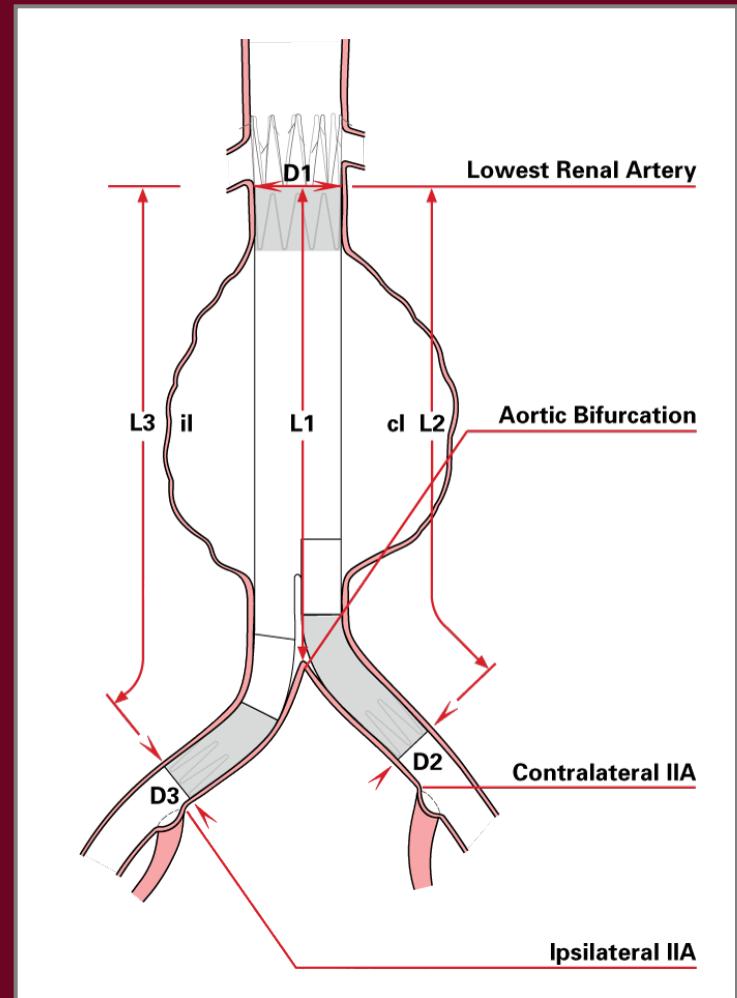
Measurements needed:

3 diameters

(D1, D2, D3)

3 lengths

(L1, L2, L3)



Device Planning

Diameter Measurements

D1, D2, D3

Proximal neck and common iliac diameters from axial CT images should be measured from outer wall to outer wall, using shortest axis.

EI

External iliac diameters from axial CT images should be measured from inner wall to inner wall to assure delivery system access.

Vessel size must be compatible with the required introduction systems.

outer wall to outer wall



Device Planning

Diameter Oversizing

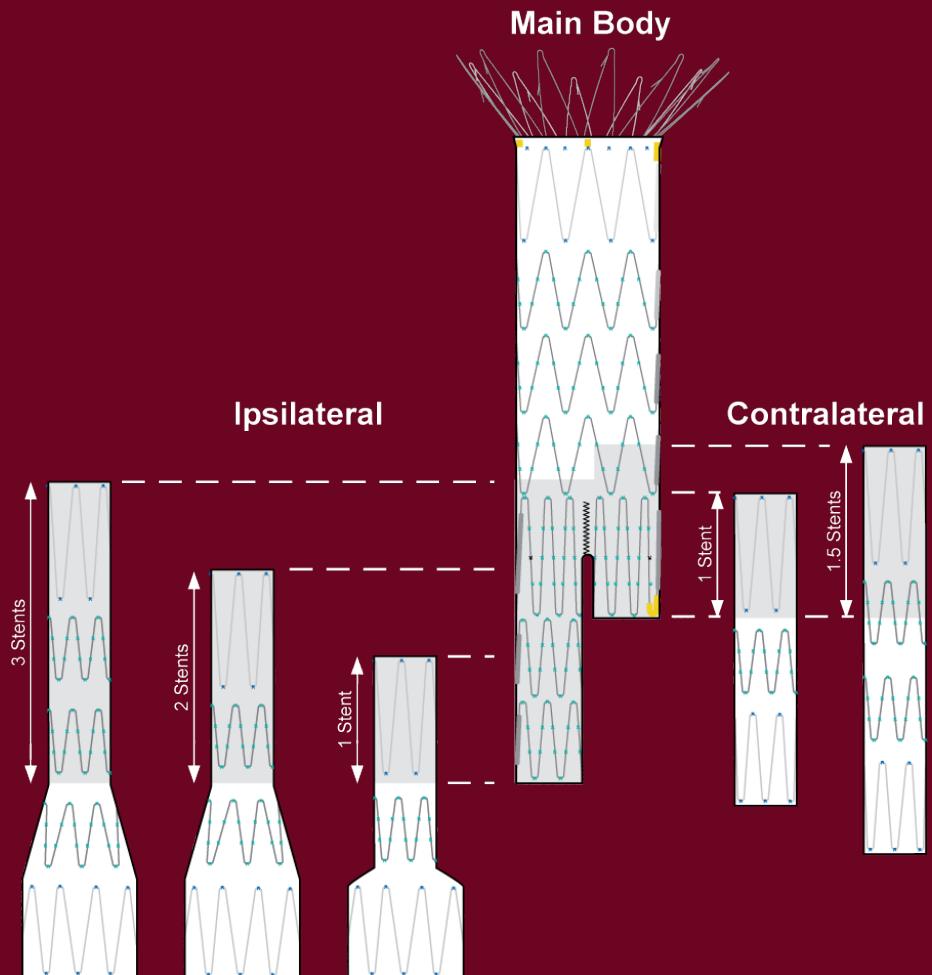
- Diameters for components are oversized.
 - Main body diameters are generally oversized 3-4 mm.
 - Iliac leg diameters are generally oversized 1-2 mm.
- Use the sizing tables on the Device Planning and Ordering Worksheet to select components with proper oversizing.

Device Planning

Overlap

Contralateral
1-1.5 leg stents

Ipsilateral
1-2 stents
(37, 39, 54 or 56 mm)
or
1-3 stents (others)



Device Planning

Lengths

- Use CT scan and/or angiography with calibrated catheter.
- Do not oversize lengths.
 - Use actual lengths.
 - If necessary, select shorter graft length.

Device Planning and Ordering Worksheet

Device Planning and Ordering Worksheet

ZENITH FLEX®
AAA ENDOVASCULAR GRAFT

DEVICE PLANNING AND SIZING WORKSHEET

Select Side of Main Body Introduction and Fixation Sites

Right iliac Left iliac
 External iliac (EI) measurement _____ mm
(Minimum diameter, inner wall to inner wall, from introduction site to aorta.)

Anatomical Measurements

CT table position at:
 - lowest renal artery
 15 mm below lowest renal artery,
 check for 10% increase

— aortic bifurcation
 — origin cl internal iliac
 — origin il internal iliac

• When using CT for length, approximate lateral deviation/tortuosity and add to difference in table position.

Diameters:	D1	D2	D3
Lengths:	L1	L2	L3

D1: Largest aortic neck diameter throughout 15 mm neck length
 D2: Largest iliac diameter throughout contralateral distal fixation site
 D3: Largest iliac diameter throughout ipsilateral distal fixation site

L1: Lowest renal artery to aortic bifurcation + lateral deviation/tortuosity
 L2: Lowest renal artery to contralateral distal fixation site + lateral deviation/tortuosity
 L3: Lowest renal artery to ipsilateral distal fixation site + lateral deviation/tortuosity

Main Body

- From D1, select graft diameter.
- From L1, select the graft lengths.
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.
- Using graft diameter and cl length, complete the Main Body Order Number.

Diameter 22-32		
L1	cl Length*	il Length**
88-103	82	112
104-118	96	126
119-133	111	141
134-148	125	155
149-163	140	170
Main Body Order Number = TFFB - - - - ZT		

*main body length on contralateral side
**main body length on ipsilateral side

Main Body Order Number = TFFB - - - - ZT

ALL information must be complete:

Date: _____ Patient ID: _____
 Hospital: _____
 Physician Name: _____
 Physician Signature: _____
 Physician Phone #: _____
 Physician E-mail: _____

Contralateral Iliac Leg

- From D2, select graft diameter.
- Using L2 and cl length, complete the following equation:

- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.
- 8 and 10 mm graft diameters are also available.

Contralateral Leg (TFLE) Graft Diameters	
D2 mm	Graft Diameter mm
10-11	12
12-13	14
14-15	16
16-17	18
18	20
19	22
20	24
**	**
**	**

Contralateral Leg (TFLE) Graft Lengths (mm)

Contralateral Working Length mm	Graft Length mm	Recommended Overlap stents
27-43	39*	1-1.5
44-60	56	1-1.5
61-77	73	1-1.5
78-94	90	1-1.5
95-111	107**	1-1.5
112-124	124**	1-1.5

*Assure adequate distal fixation length
**Graft lengths 107 and 124 mm are available in 12 and 14 mm diameters only.

Contralateral Leg Order Number = TFLE - - - ZT

Ipsilateral Iliac Leg

- From D3, select graft diameter.
- Using L3 and il length, complete the following equation:

- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.
- 8 and 10 mm graft diameters are also available.

Ipsilateral Leg (TFLE) Graft Diameters	
D3 mm	Graft Diameter mm
10-11	12
12-13	14
14-15	16
16-17	18
18	20
19	22
20	24
***	***
***	***

Ipsilateral Leg (TFLE) Graft Lengths (mm)

Ipsilateral Working Length mm	Graft Length mm	Recommended Overlap stents
20-35 graft diameter 18-24	39	1-2
20-35 graft diameter 19-26	56	1-3
26-42	56	1-2
43-59	73	1-3
60-76	90	1-3
77-93	107*	1-3
94-124	124*	1-3
***	***	***

*Graft lengths 107 and 124 mm are available in 12 and 14 mm diameters only.

Ipsilateral Leg Order Number = TFLE - - - - ZT

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Device Planning and Ordering Worksheet

Step 1

Select the side for main body introduction and fixation sites.

- Generally, place the main body through the side that has the best access vessel.
- Factors to consider:
 - Iliac tortuosity
 - Angulation of a distal neck
 - Mural thrombus within the aneurysm
 - Iliac length (short iliac contralateral)
 - Vessel diameter (EI)
 - Mural thrombus within Iliofemoral disease (e.g., stenosis, calcium)
 - Iliac aneurysm (ipsilateral)

Device Planning and Ordering Worksheet

Step 1

A large, empty white rectangular box with a thin black border, positioned below the "Step 1" text. It is intended for the user to fill in their device planning and ordering information.

Device Planning and Ordering Worksheet

Step 2

Obtain anatomical measurements

Diameters

D1 - Largest aortic neck diameter throughout 15 mm neck length

D2 - Largest iliac diameter throughout contralateral distal fixation site

D3 - Largest iliac diameter throughout ipsilateral distal fixation site

Lengths

L1 - Lowest renal artery to aortic bifurcation + lateral deviation/tortuosity

L2 - Lowest renal artery to contralateral distal fixation site + lateral deviation/tortuosity

L3 - Lowest renal artery to ipsilateral distal fixation site + lateral deviation/tortuosity

Device Planning and Ordering Worksheet

Step 2

A large, empty white rectangular box centered on the page, intended for the user to fill in their device planning and ordering information.

Device Planning and Ordering Worksheet

Step 3

Select main body

- From D1, select graft diameter. Table includes oversizing.
- From L1, select graft lengths. Table provides cl and il lengths, and includes minimum of 5 mm clearance for cl limb.
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly (see manual).

Device Planning and Ordering Worksheet

Step 3

Main Body

- From D1, select graft diameter.
- From L1, select the graft lengths.
- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.
- Using graft diameter and cl length, complete the Main Body Order Number.

Main Body Graft Diameters

D1 mm	Graft Diameter mm
18-19	22
20-21	24
22	26
23-24	28
25-26	30
27-28	32
29-32	36

Diameter 22-32

L1	cl Length*	il Length**
88-103	82	112
104-118	96	126
119-133	111	141
134-148	125	155
149-163	140	170

*main body length on contralateral side

**main body length on ipsilateral side

Diameter 36

L1	cl Length*	il Length**
101-120	95	125
121-139	113	143
140-158	131	161
159-177	149	179

Main Body Order Number = TFFB - [] - [] - ZT

Graft
Diameter

cl Length/
Graft Length

Device Planning and Ordering Worksheet

Step 4

Select contralateral iliac leg

- From D2, select graft diameter. Table includes oversizing.
- $L_2 - cl$ length = contralateral working length.
- Using contralateral working length, select graft length.
- Consider stent overlap and a secure fixation site.
- If choice is affected by other considerations, adjust accordingly.

Device Planning and Ordering Worksheet

Step 4

Contralateral Leg (TFLE) Graft Diameters

D2 mm	Graft Diameter mm
----------	-------------------------

Contralateral Iliac Leg

- From D2, select graft diameter.
- Using L2 and cl length, complete

Device Planning and Ordering Worksheet

Step 5

Select ipsilateral iliac leg

- From D3, select graft diameter. Table includes oversizing.
- $L3 - il$ length = ipsilateral working length.
- Using ipsilateral working length, select graft length.
- Consider stent overlap and a secure fixation site.
- If choice is affected by other considerations, adjust accordingly.

Device Planning and Ordering Worksheet

Step 5

Ipsilateral Iliac Leg

- From D3, select graft diameter.
- Using L3 and il length, complete the following equation.

$$\boxed{\text{L3}} \text{ minus } \boxed{\text{il Length}} : = \text{Ipsilateral Working Length}$$

- If choice of graft diameter or graft length is affected by other considerations, adjust accordingly.
- 8 and 10 mm graft diameters are also available.

Ipsilateral Leg (TFLE) Graft Diameters

D3 mm	Graft Diameter mm
10-11	12
12-13	14
14-15	16
16-17	18
18	20
19	22
20	24
•••	▲▲▲

Ipsilateral Leg (TFLE) Graft Lengths (mm)

Ipsilateral Working Length mm	Graft Length mm	Recommended Overlap stents
20-35 graft diameter 18-24	39	1-2
20-35 graft diameter 12-16	56	1-3
36-42	56	1-2
43-59	73	1-3
60-76	90	1-3
77-93	107*	1-3
94-124	124*	1-3
**		

*Graft lengths 107 and 124 mm are available in 12 and 14 mm diameters only.

Ipsilateral Leg Order Number = TFLE -  -  - ZT

Graft Diameter Graft Length

Device Planning and Ordering Worksheet

Devices to Order

Main Body Order Number = TFFB - ▶ - ◆ - ZT

▶

- ZT

Graft Diameter

cl Length/
Graft Length

Contralateral Leg Order Number = TFLE - [red box] - [green box] * - ZT

1

★

Ipsilateral Leg Order Number = TFLE - [redacted] - [redacted] - ZT

3

2

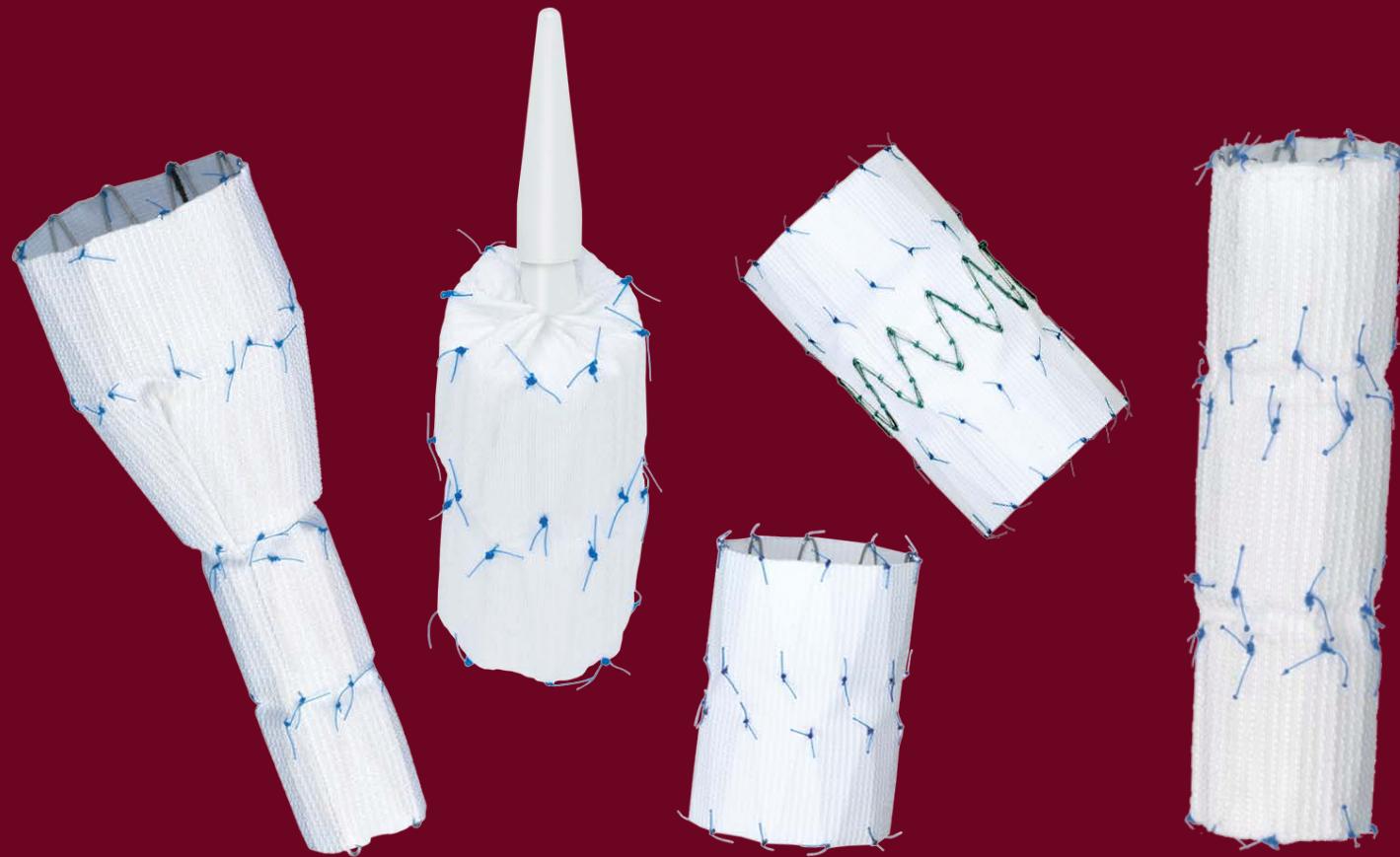
Graft Diameter

Graft Length

Ancillary Components

Zenith Flex® Endovascular Graft

Ancillary Components



Converter



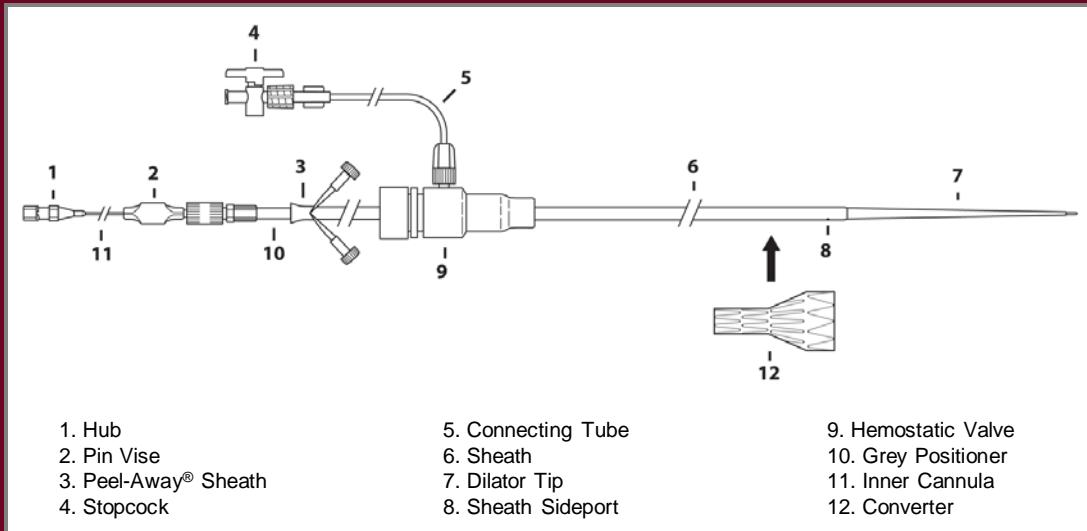
Converter

- Converters can be used to convert a bifurcated graft into an aorto-uniiliac graft, if necessary (e.g., cases of Type III endoleak, limb occlusion or unattainable contralateral limb cannulation).
- The converter includes four internal z-stents.
- The length of the 24, 28 and 32 mm diameter converters is 80 mm.
- The length of the 36 mm diameter converter is 82 mm.
- Distal diameter of all converters is 12 mm.
- Proximal diameters are 24, 28, 32 or 36 mm.
- A converter, if used, should have a proximal diameter no smaller than that of the main body.



Converter (cont.)

- Place the converter sealing stent exactly within the main body to assure adequate graft-to-graft seal. If implanted properly, the two distal stents on the converter should land within the ipsilateral iliac limb of the main body.
- Converter introducer sheaths are inserted over the wire and cannot be introduced through the sheath of a main body or an iliac leg.

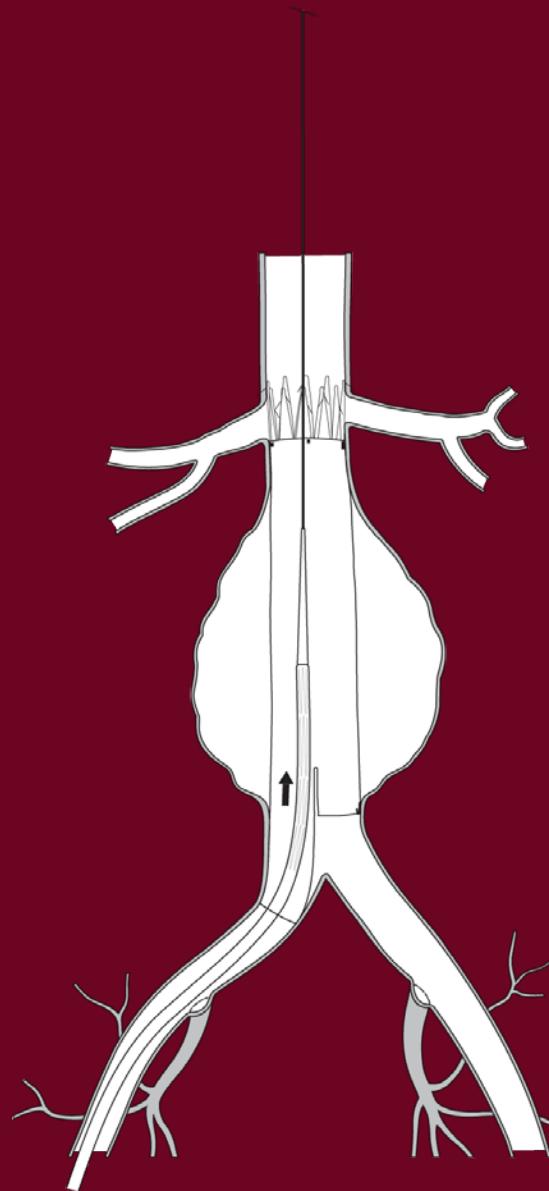


Converter (cont.)

Deployment

Step 1

Verify appropriate position to ensure proper sealing (proximal two stents in main body, distal two stents in ipsilateral iliac limb).

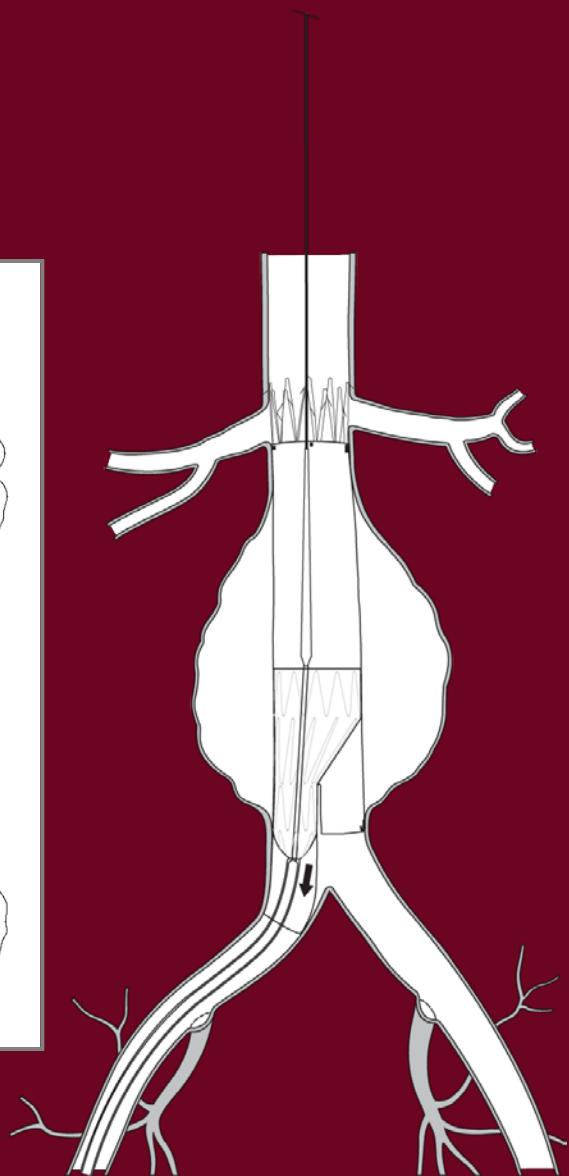
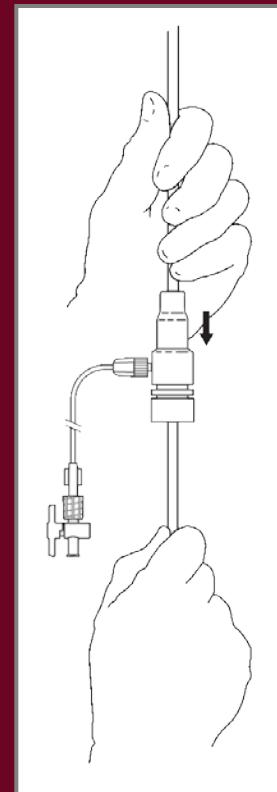


Converter (cont.)

Deployment

Step 2

Stabilize grey positioner and retract sheath to deploy converter.

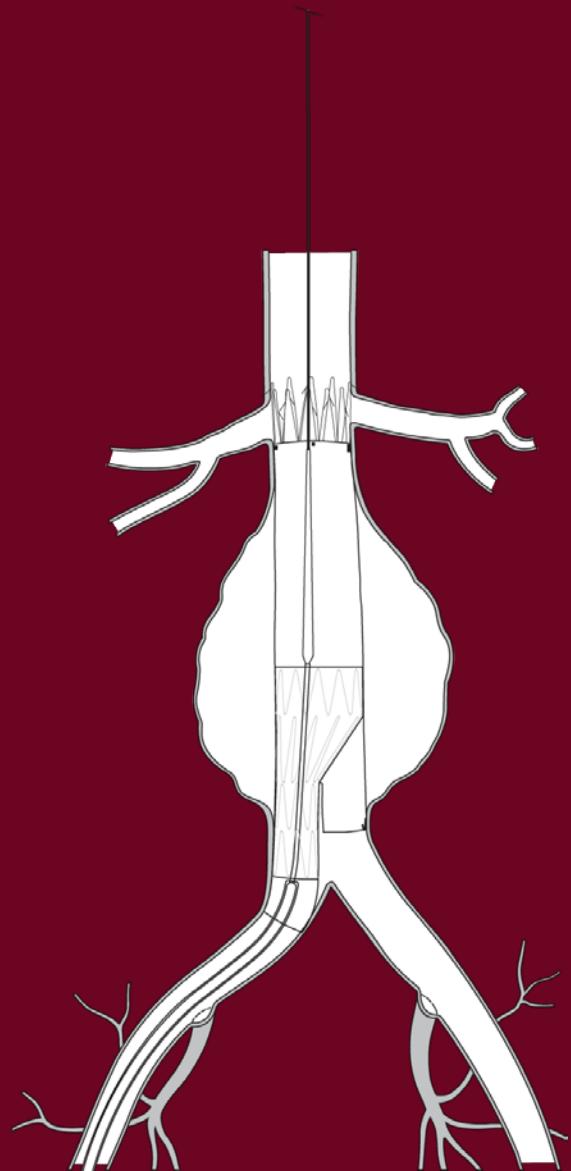


Converter (cont.)

Deployment

Step 3

- Deploy until distal stent is uncovered.
- Retract inner cannula; dock and remove grey positioner.

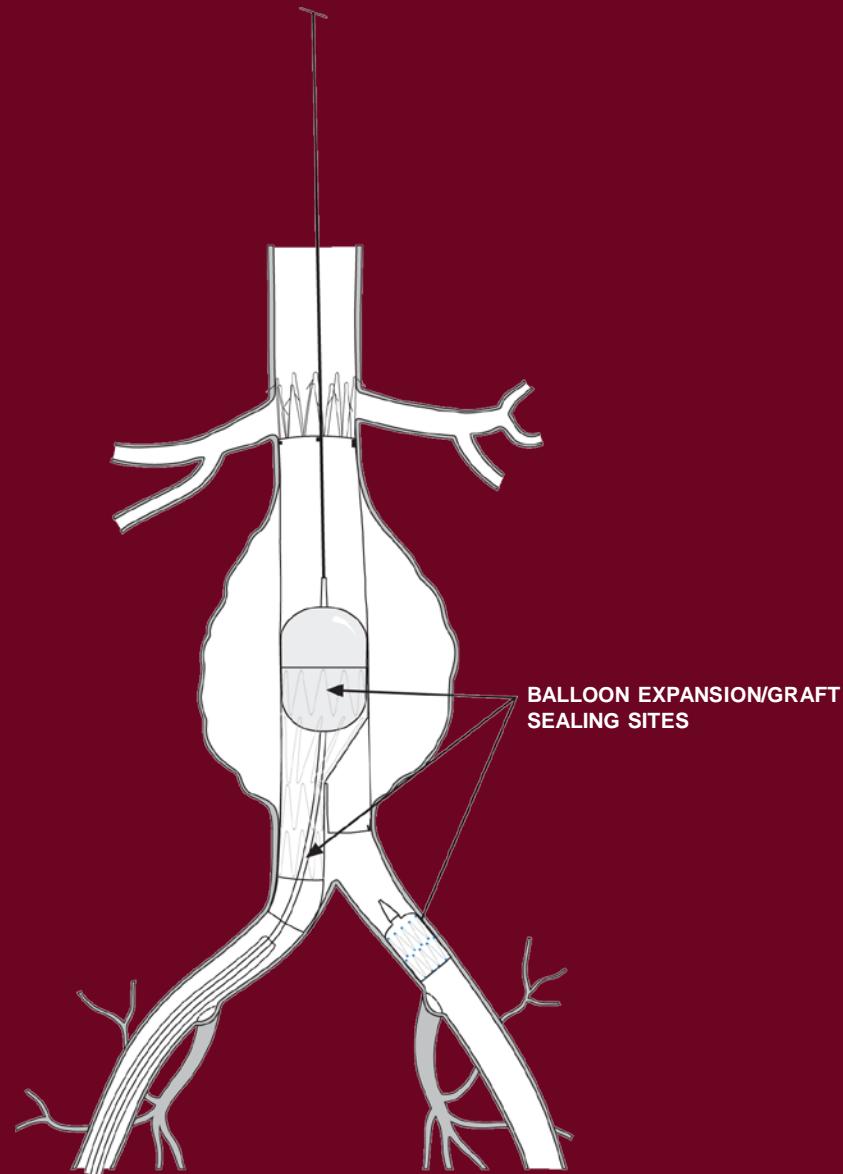


Converter (cont.)

Deployment

Step 4

- Balloon-mold the converter within the proximal segment and then the distal segment.
- Perform final angiogram.



Iliac Plug



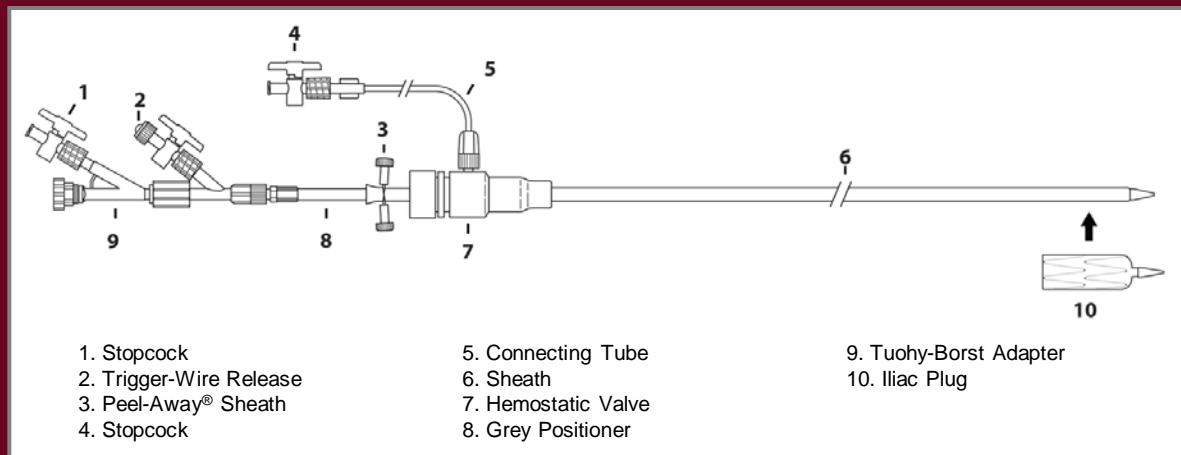
Iliac Plug

- The iliac plug is used to occlude an iliac artery when the converter system has been placed and/or is in conjunction with a femoral-to-femoral crossover procedure.
- The length of all iliac plugs is 30 mm.
- Available diameters are 14, 16, 20 and 24 mm.
- Iliac plug diameter should be determined from diameter of the intended fixation site (outer wall to outer wall) and the next larger-sized component selected.
- An iliac plug should generally have a diameter at least 2 mm larger than that of the iliac artery.



Iliac Plug (cont.)

- The iliac plug is preloaded into 14 or 16 Fr H&L-B One-Shot Introduction Systems.
- The H&L-B One-Shot™ Introduction System for the iliac plug has a single trigger-wire release mechanism.
- Iliac plug introduction systems are inserted over a wire.
- Do not release and remove the trigger wire until the iliac plug has been deployed from the sheath.

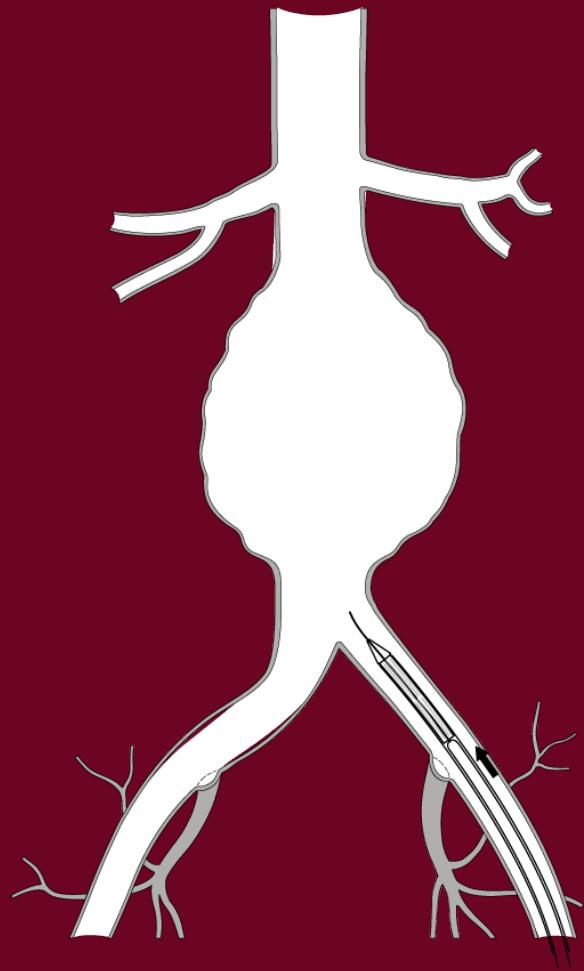


Iliac Plug (cont.)

Deployment

Step 1

- Verify position with angiography to determine proper placement.
- Advance the delivery system over the wire to the intended position in the common iliac artery.

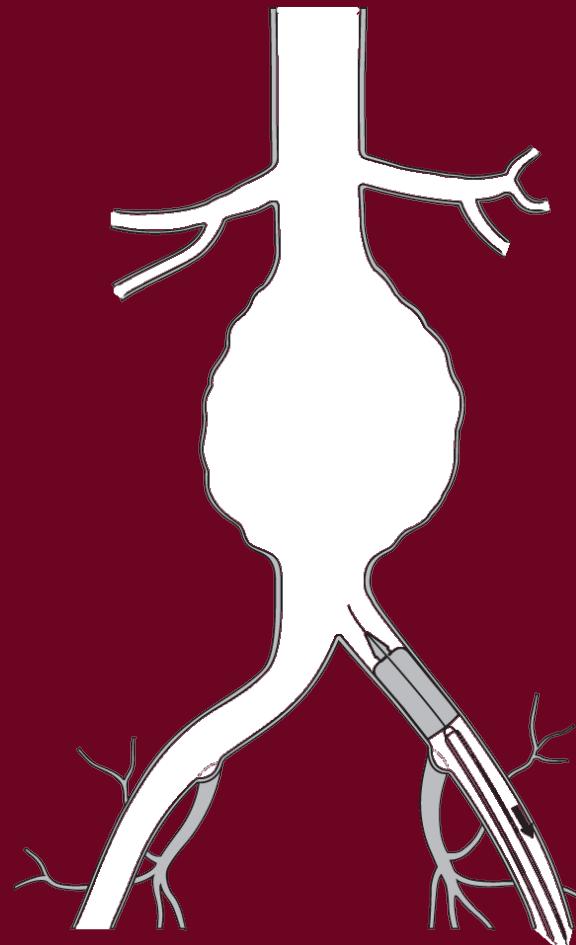
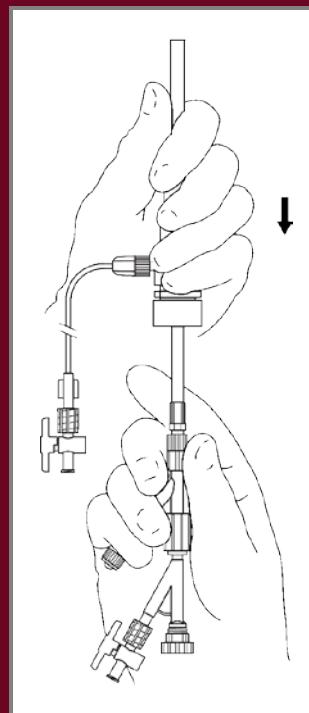


Iliac Plug (cont.)

Deployment

Step 2

- Stabilize grey positioner and retract sheath to deploy the iliac plug.
- Withdraw the sheath until the iliac plug is uncovered.

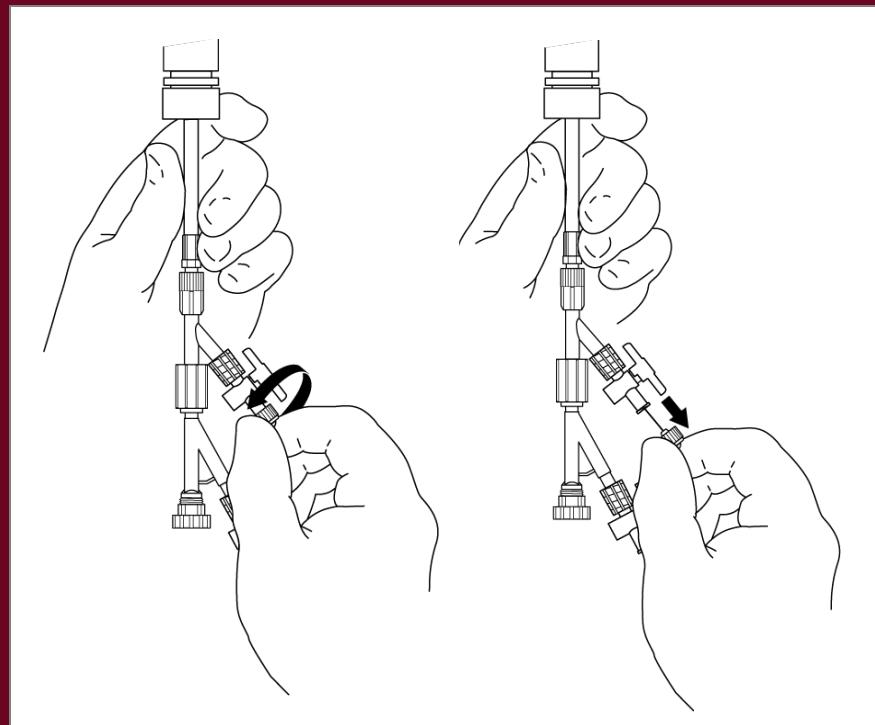


Iliac Plug (cont.)

Deployment

Step 3

- Unscrew the trigger-wire release knob.
- Withdraw the wire completely.

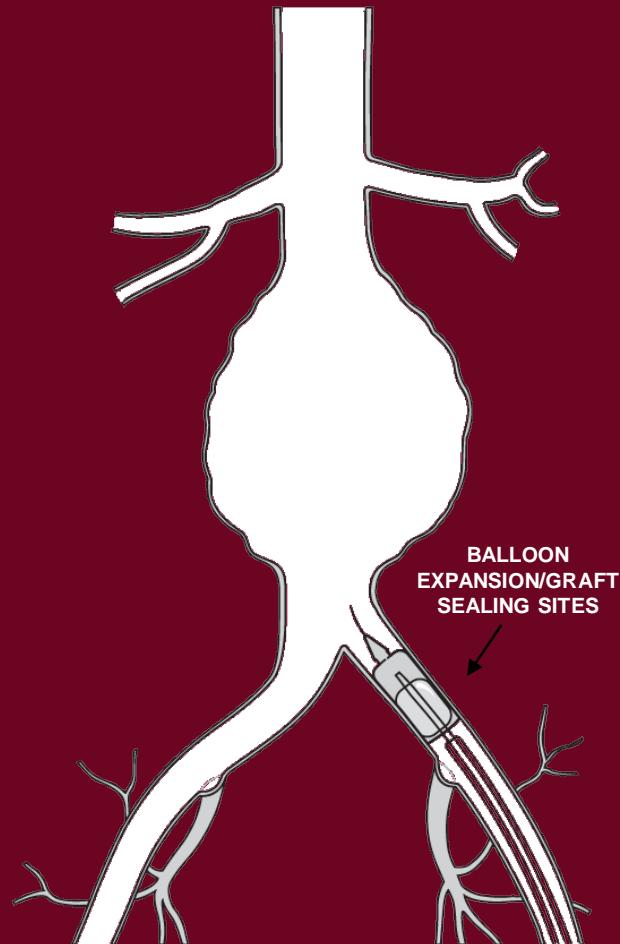
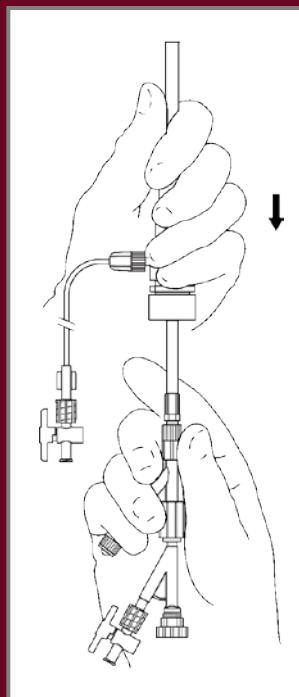


Iliac Plug (cont.)

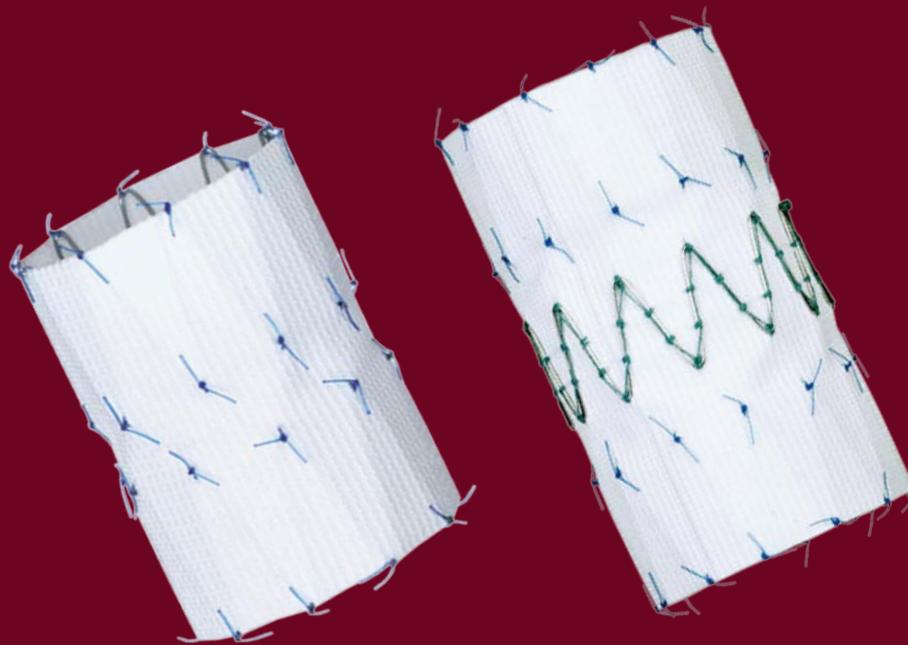
Deployment

Step 4

- Remove wire guide. Ensure graft is not displaced during withdrawal.
- Remove grey positioner. Ensure graft is not displaced during withdrawal.
- (Optional) Balloon-mold the expandable length of the iliac plug.
- Perform final angiogram.



Main Body Extension (ESBE)



Main Body Extension

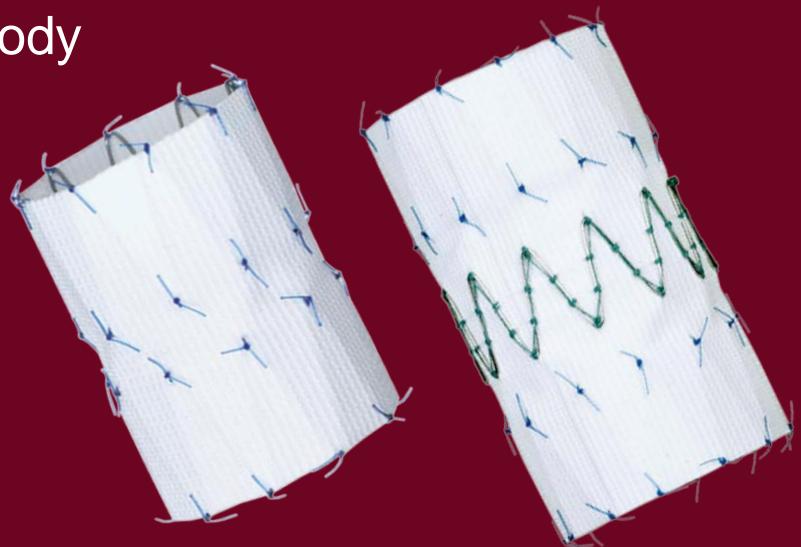
Used to treat a Type I endoleak, which may be caused by:

- Improper placement of the main body
- Tortuosity of the aortic neck
- Inaccurate selection of main body diameter

Main Body Extension (cont.)

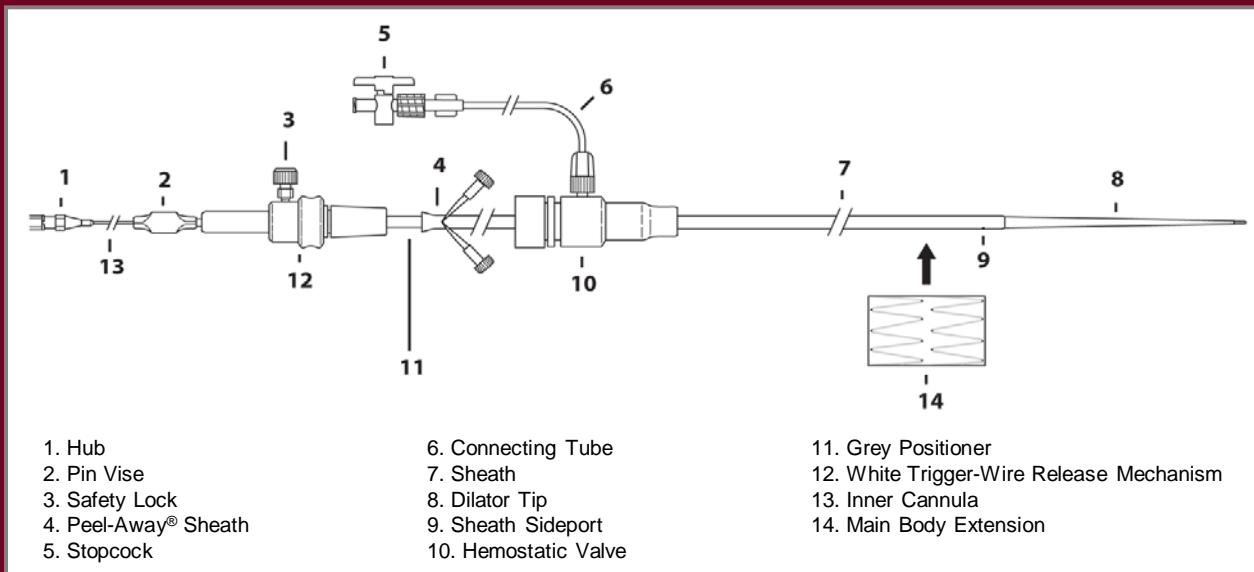
- Main body extensions include two or three z-stents.
- Main body extensions are 39, 50*, 58 or 73* mm long.
- Diameters include 22, 24, 26, 28, 30, 32 or 36 mm.
- A main body extension, if used, should have a diameter no smaller than that of the main body.
- In selecting the diameter of a main body extension, consider:
 - neck shape
 - neck angulation
 - diameter of existing main body

*Lengths for 36 mm diameter only.



Main Body Extension (cont.)

- The H&L-B One-Shot™ Introduction System for the main body extension has a single trigger-wire release mechanism.
- Do not release and remove the trigger wire until the main body extension has been deployed from the sheath.
- Main body extension introduction systems are inserted over a wire and cannot be introduced through the sheath of a main body or an iliac leg.

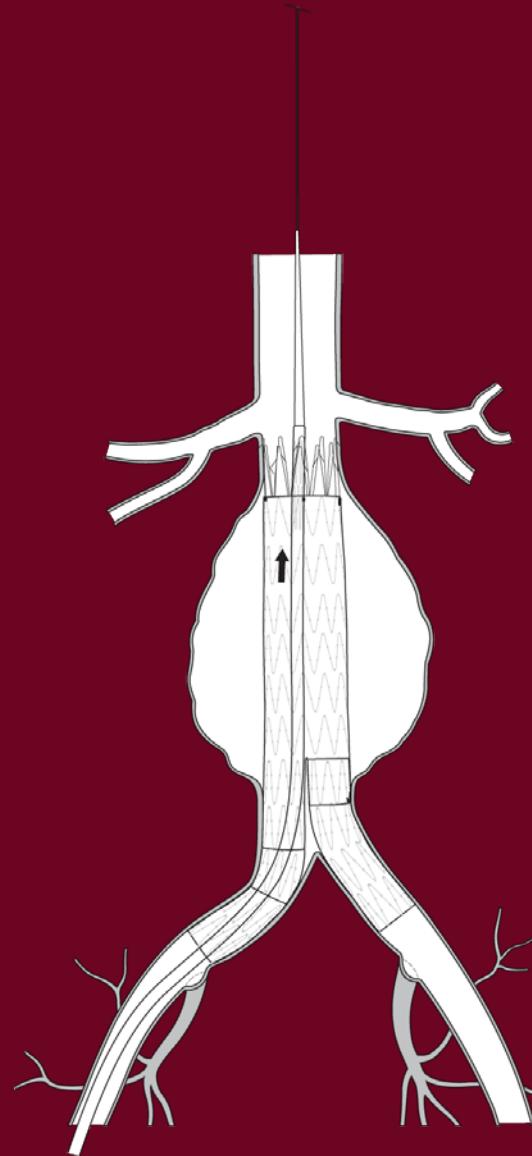


Main Body Extension (cont.)

Deployment

Step 1

- Verify position to ensure proper sealing and resistance to migration.
- Verify position with angiography to ensure renal arteries remain patent.

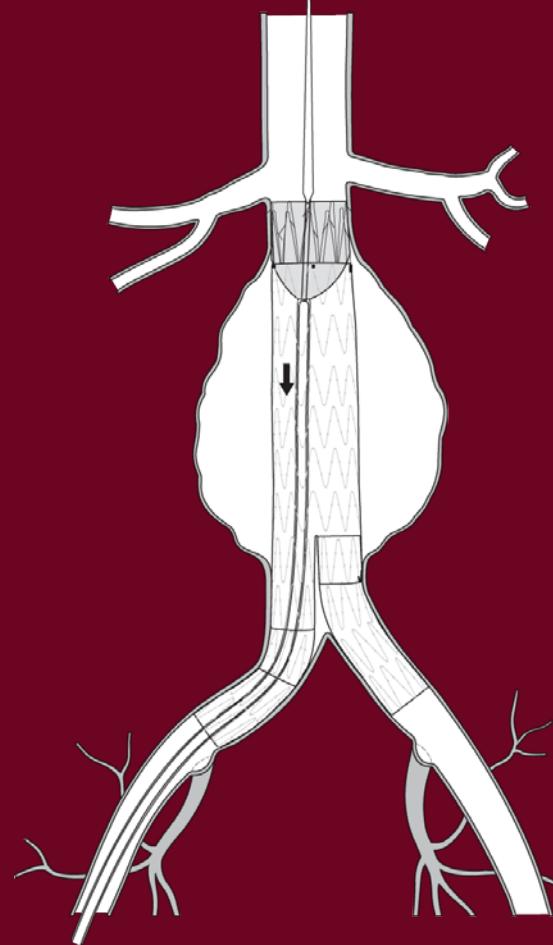
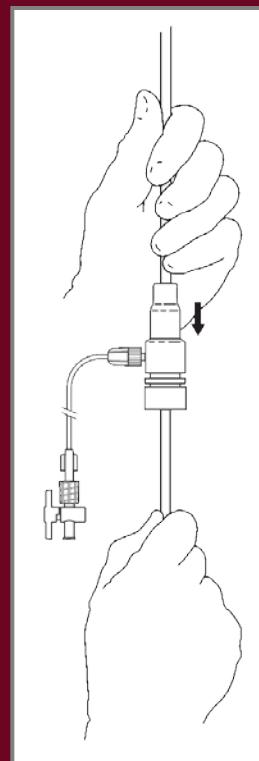


Main Body Extension (cont.)

Deployment

Step 2

- Stabilize grey positioner and retract sheath to deploy main body extension.
- Deploy device until the most distal stent is uncovered.

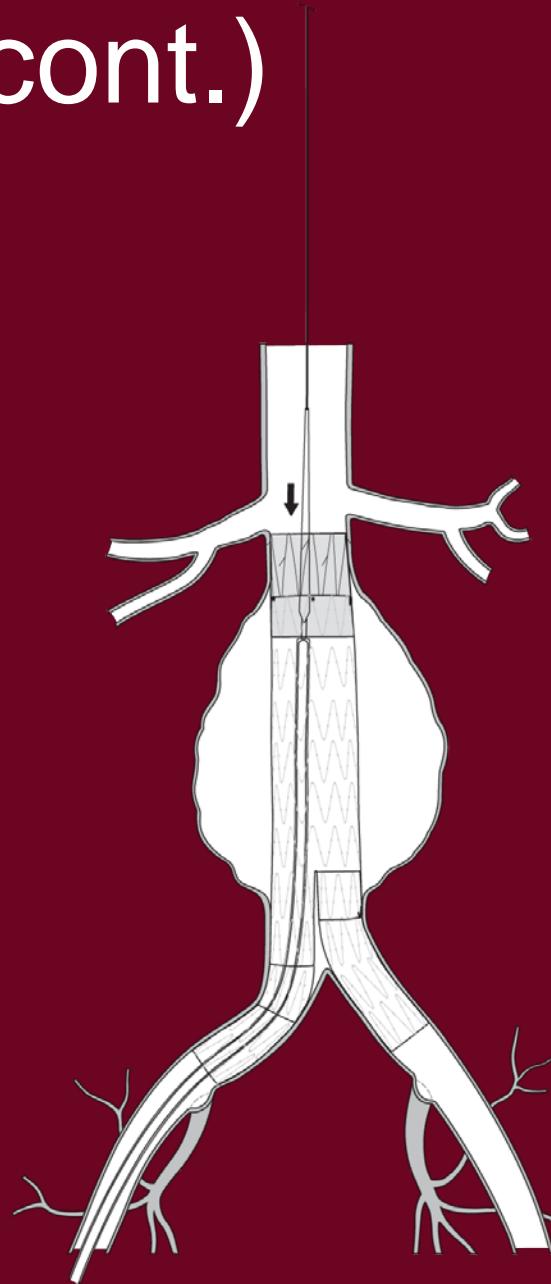
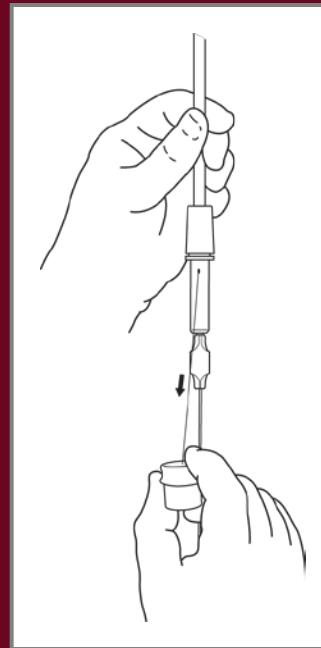


Main Body Extension (cont.)

Deployment

Step 3

- Remove white trigger wire.
- Retract inner cannula; dock and remove grey positioner.

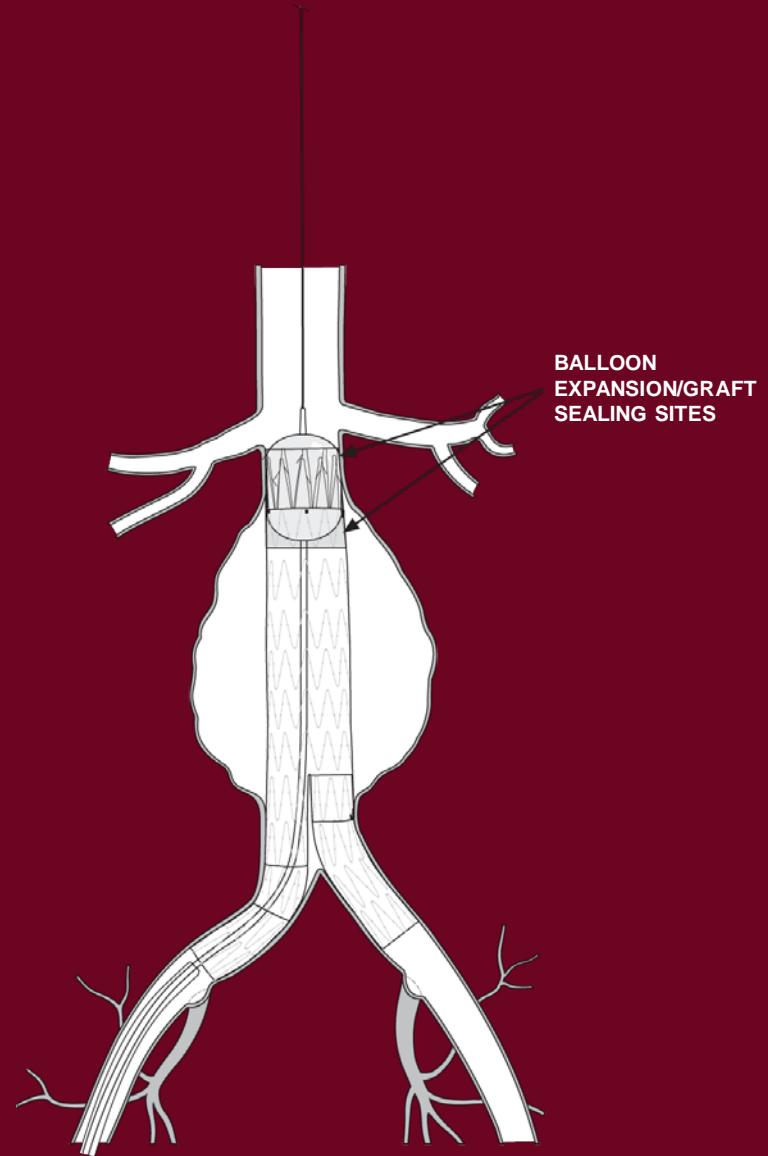


Main Body Extension (cont.)

Deployment

Step 4

- Balloon-mold the main body extension within the proximal segment and then the distal segment.
- Perform final angiogram.



Iliac Leg Extension (ESLE)



Iliac Leg Extension

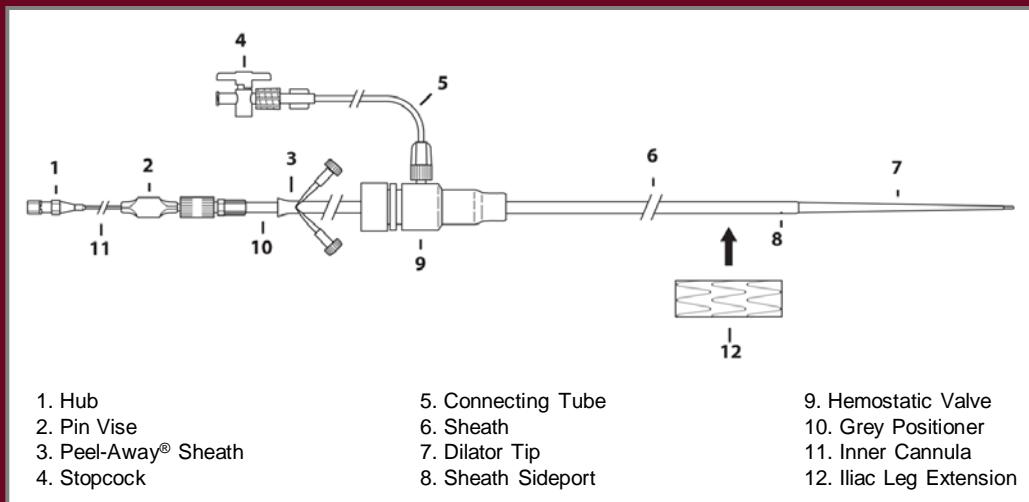
Used to lengthen and/or bridge the iliac leg(s) of an in situ endovascular graft.

- Iliac leg extensions include three internal z-stents.
- Diameters include 8, 10, 12, 14, 16, 18, 20, 22 or 24 mm.
- An iliac leg extension, if used, should have a diameter no smaller than that of the in situ iliac leg graft.

If an iliac leg extension is not available, an iliac leg can be used.

Iliac Leg Extension (cont.)

- Iliac leg extensions are preloaded into an H&L-B One-Shot™ Introduction System.
- 8-20 mm iliac leg extension introducer sheaths can be inserted either through an in situ main body introducer sheath or directly into the vessel.
- The 22 and 24 mm iliac leg extension introducer sheaths should not be inserted into a main body introducer sheath.

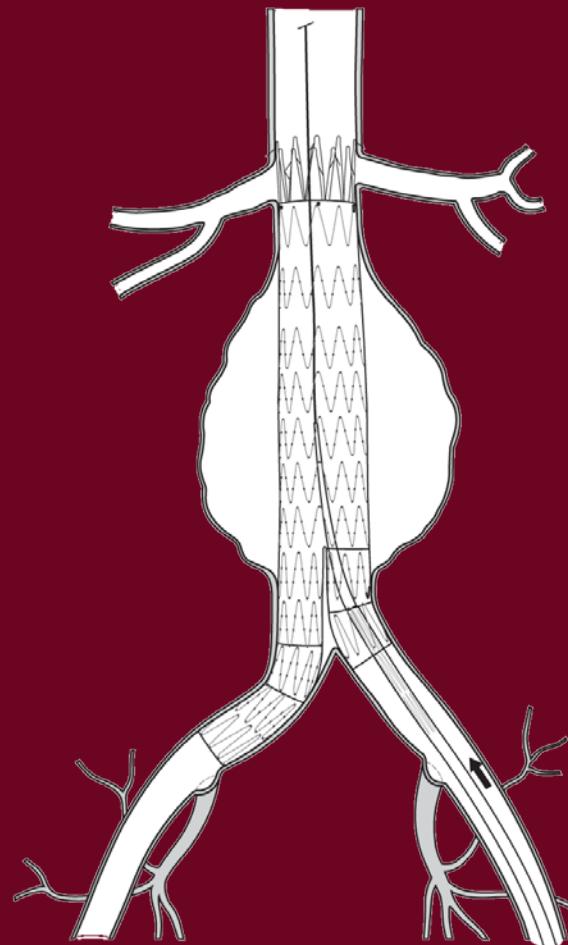


Iliac Leg Extension (cont.)

Deployment

Step 1

- Verify appropriate stent graft overlap to ensure proper sealing and resistance to migration.
- Verify placement with angiography to ensure the internal iliacs will remain patent.

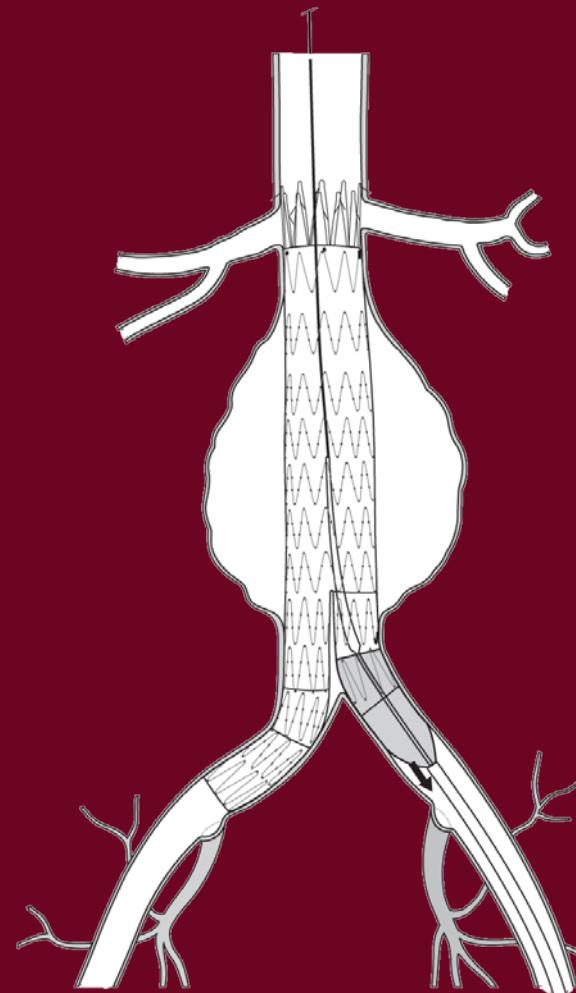


Iliac Leg Extension (cont.)

Deployment

Step 2

Stabilize grey positioner and retract sheath to deploy iliac leg extension.

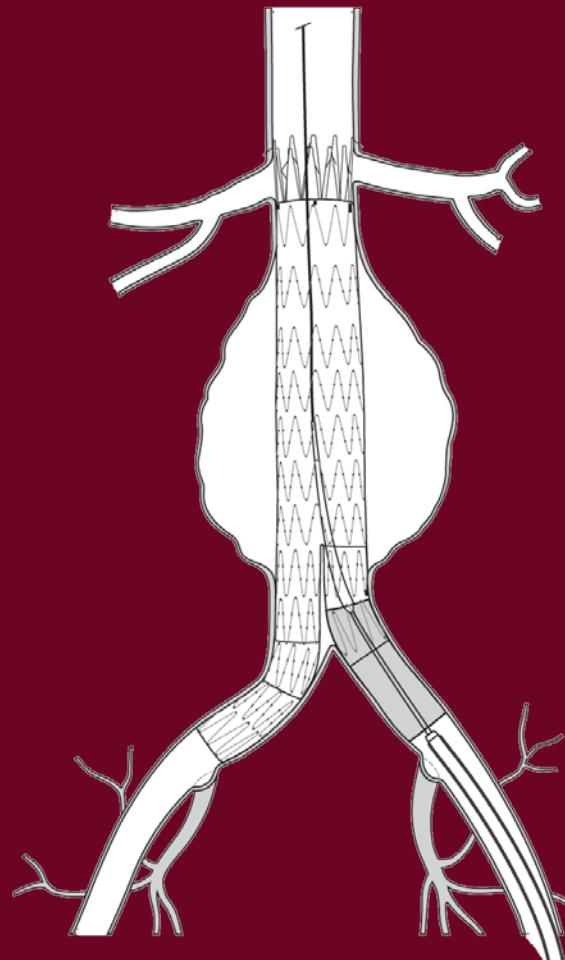


Iliac Leg Extension (cont.)

Deployment

Step 3

- Continue to deploy the device until the distal stent is uncovered.
- Retract inner cannula; dock and remove grey positioner.

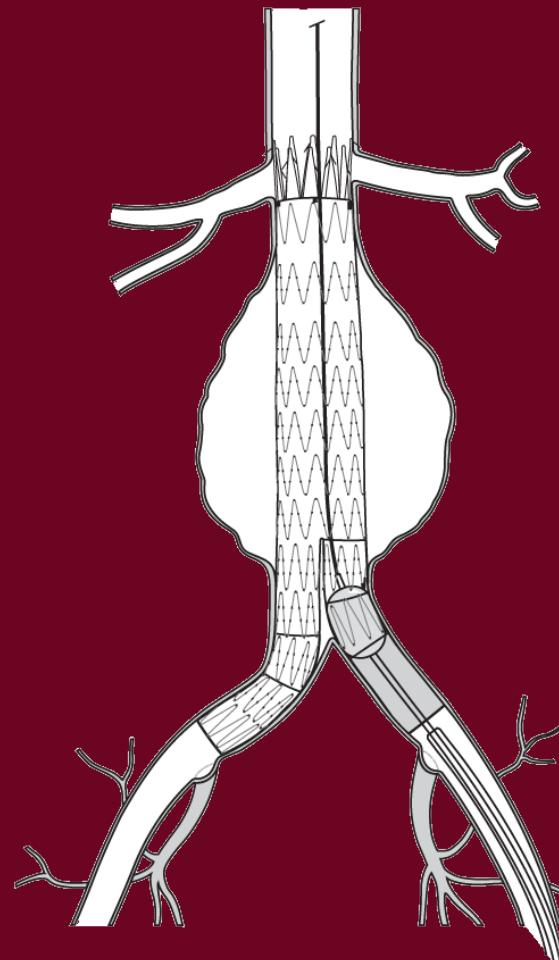


Iliac Leg Extension (cont.)

Deployment

Step 4

- Balloon-mold the iliac leg extension within the most proximal segment and then the most distal segment.
- Perform final angiogram.



Postoperative Information

Follow-up Imaging Guidelines

All patients should be advised that:

- endovascular treatment requires lifelong, regular follow-up to assess performance
- adhering to the follow-up schedule is critical in ensuring the ongoing safety and effectiveness of endovascular treatment
- subsequent reinterventions, including catheter-based and open surgical conversion, are possible following endograft placement

Minimum Follow-up Imaging Recommendations

	CT (Contrast and noncontrast)*	Abdominal Radiographs
Predischarge (within 7 days)	X	X
1 month	X	X
3 months	X if endoleak at previous CT	
6 months	X	X
12 months (annually thereafter)	X	X

* *Duplex ultrasound and noncontrast CT may be used for patients who have renal failure or are otherwise unable to have contrast-enhanced CT.*

* *If Type I or III endoleak, prompt intervention and additional postintervention follow-up recommended.*