

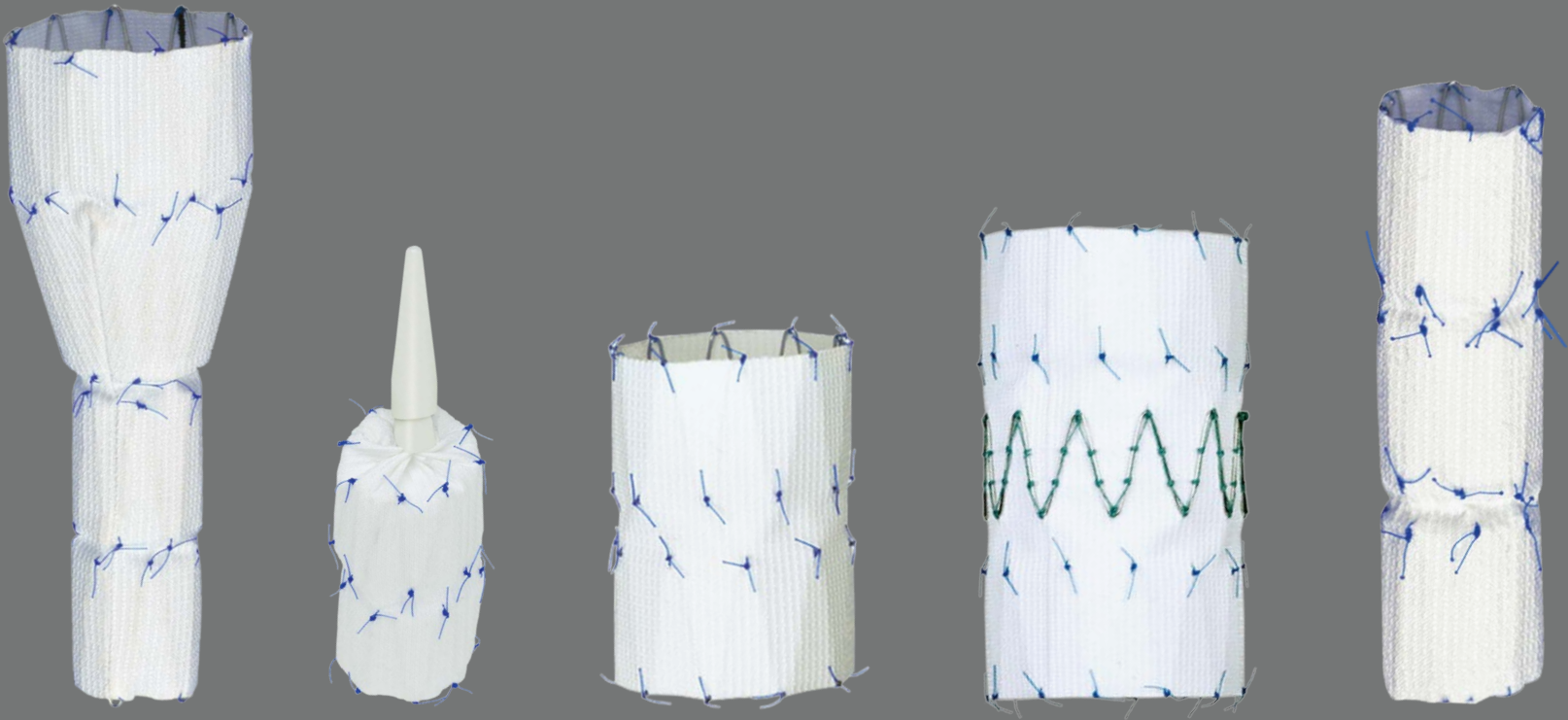


Zenith Flex[®]
AAA ENDOVASCULAR GRAFT

Ancillary Components
with Z-Trak[®] Introduction System

Zenith Flex[®] AAA Endovascular Graft

Ancillary Components



Zenith Flex[®] — Insist on precise placement and unrivaled migration resistance.

Converter

- Converters can be used to convert a bifurcated graft into an aortouniiliac 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.
- **The length of the sheath is 40 cm.**



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Converter

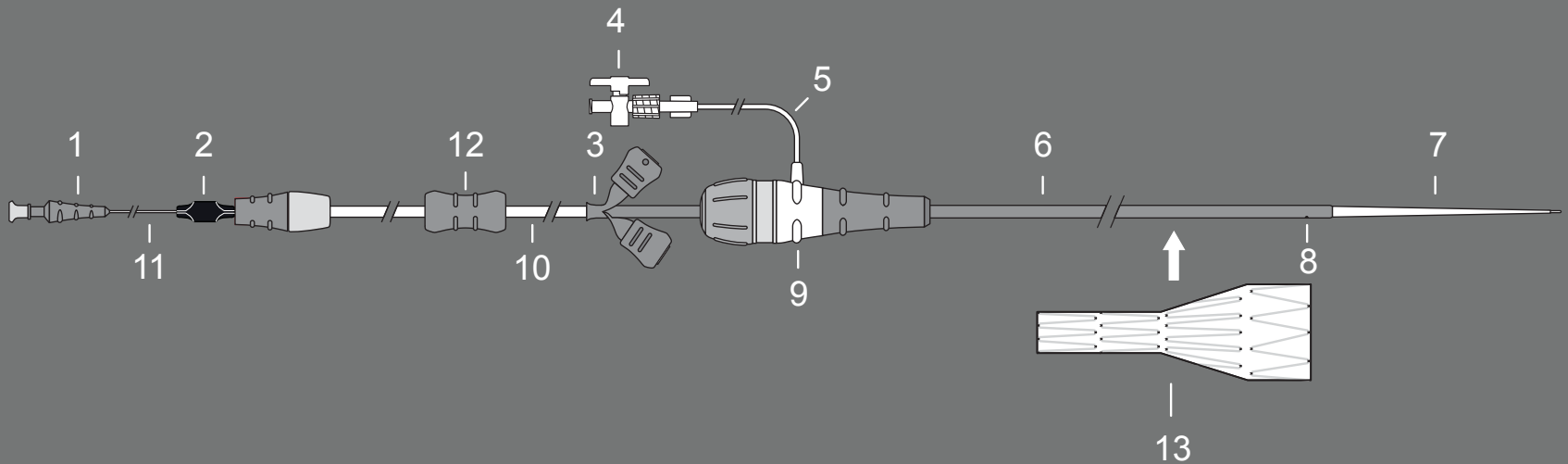
- Distal diameter of all converters is 12 mm.
- Proximal diameters are 24, 28, 32 or 36 mm.
- A converter, if used, should have a proximal diameter no smaller than that of the main body.

Converter

- Place the converter so that the proximal two sealing stents are positioned in the main body and the distal two stents are in the ipsilateral leg.
- Converter introducer sheaths are inserted over the wire and cannot be introduced through the sheath of a main body or an iliac leg.

Converter

1. Hub
2. Pin vise
3. Peel-Away® Sheath
4. Stopcock
5. Connecting tube
6. Flexor® Introducer Sheath
7. Dilator tip
8. Sheath sideport
9. Captor® Hemostatic Valve
10. Gray positioner
11. Inner cannula
12. Gripper
13. Converter



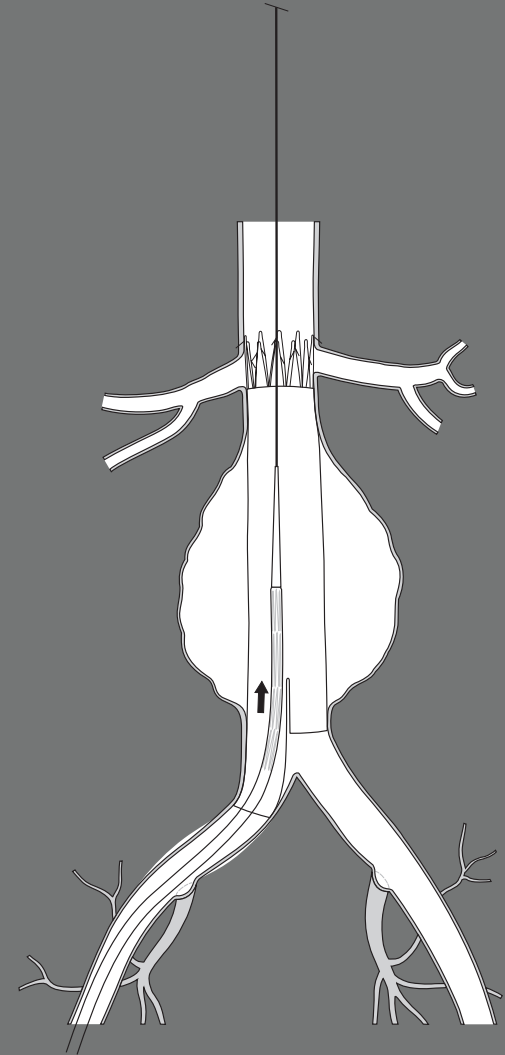
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Converter

Deployment

Step 1

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



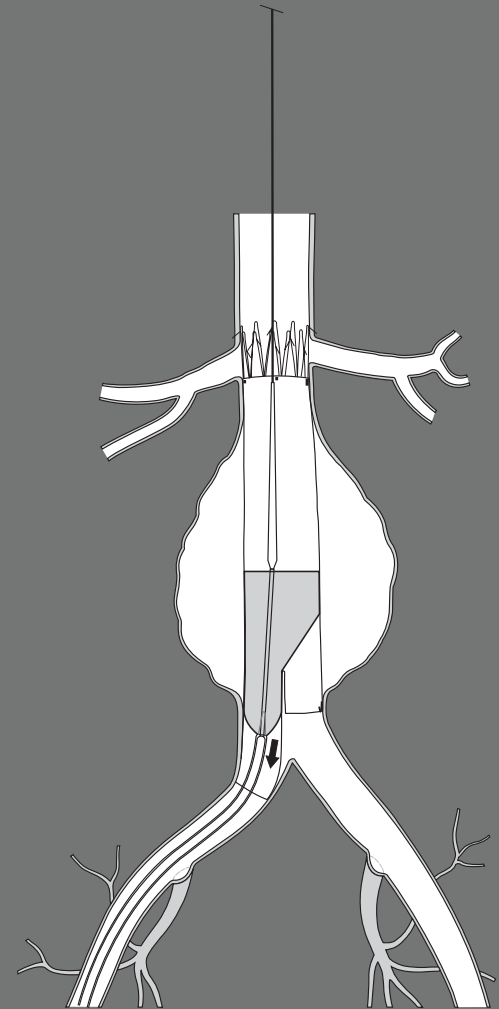
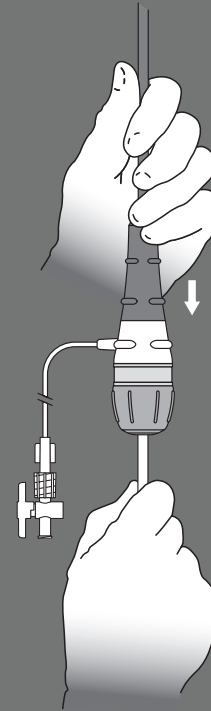
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Converter

Deployment

Step 2

- Use gripper to stabilize gray positioner and retract sheath to deploy converter.



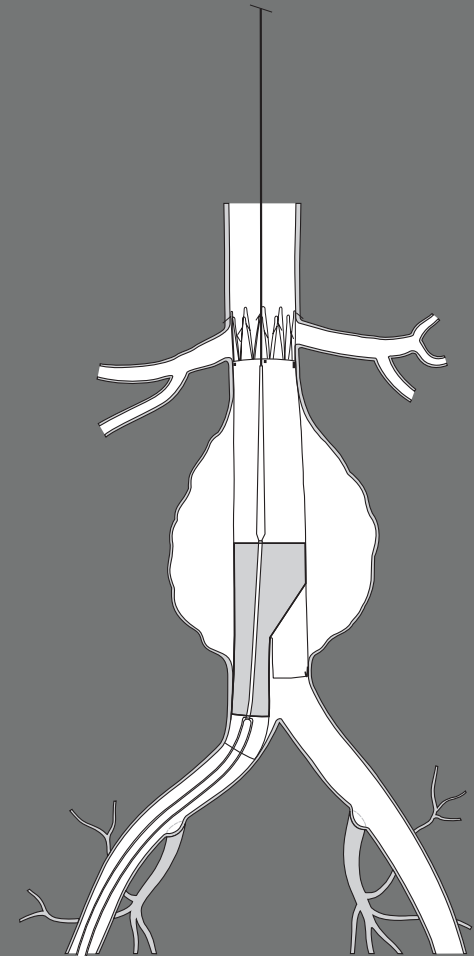
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Converter

Deployment

Step 3

- Deploy until distal stent is uncovered.
- Retract inner cannula, dock and remove gray positioner.



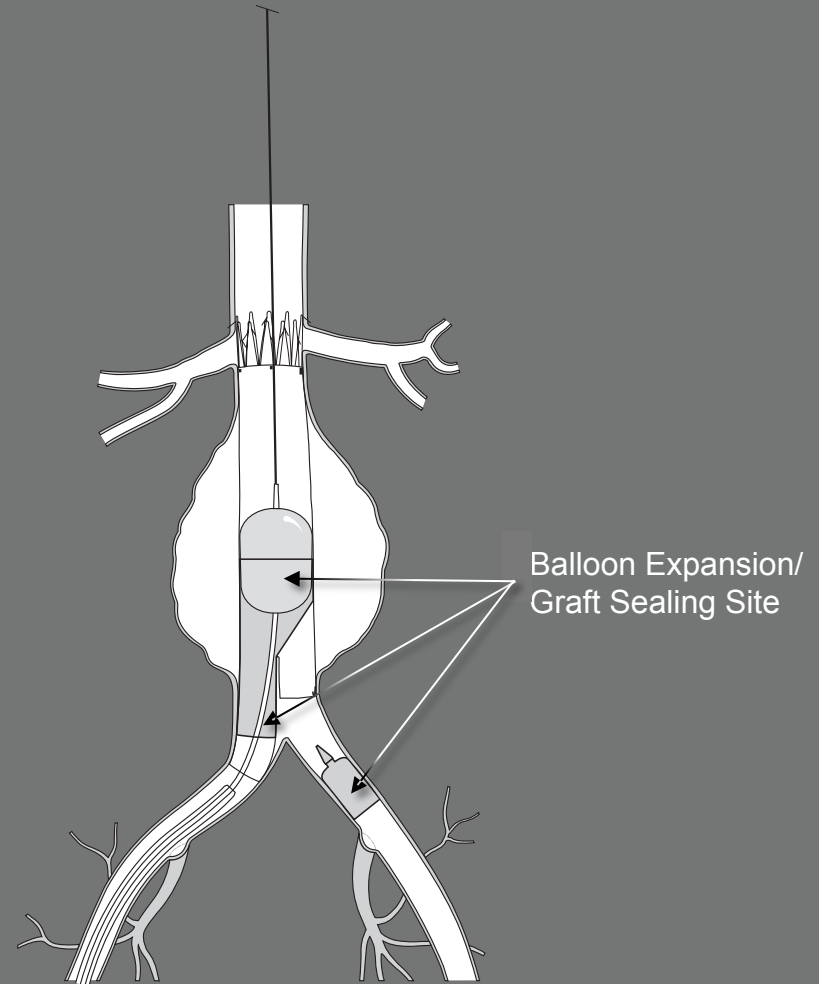
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Converter

Deployment

Step 4

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



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Iliac Plug

- The iliac plug is used to occlude an iliac artery when the converter system has been placed and/or 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.
- **The sheath length is 30 cm.**
- Iliac plug diameter should be determined from the diameter of the intended fixation site (outer wall to outer wall) and the next larger sized component should be selected.
- An iliac plug should generally have a diameter at least 2 mm larger than that of the iliac artery.



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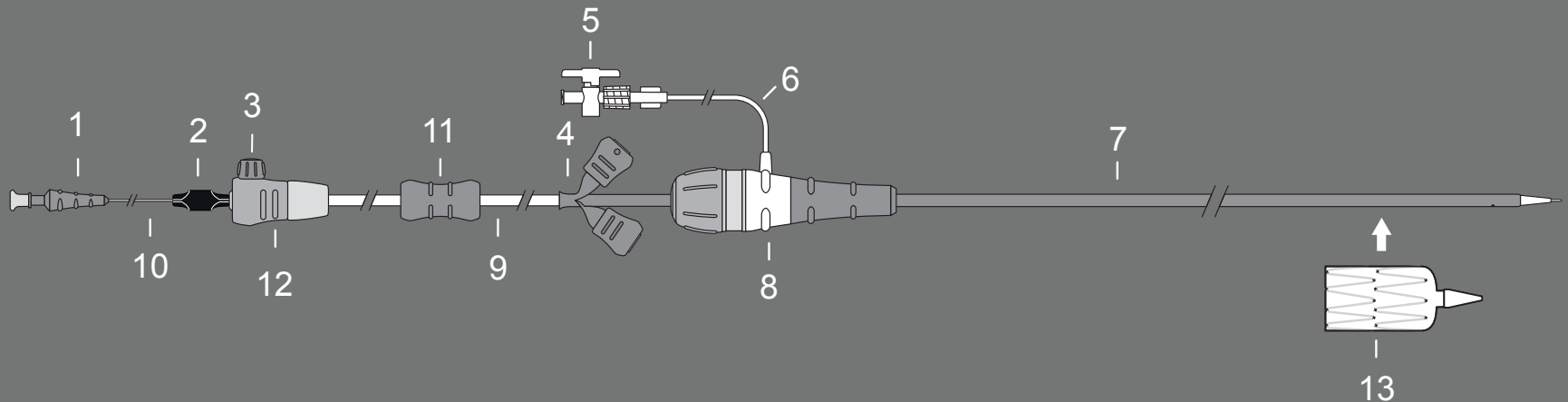
Iliac Plug

- The iliac plug is preloaded into a 14 or 16 Fr Z-Trak Introduction System.
- The Z-Trak 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.

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Iliac Plug

1. Hub
2. Pin vise
3. Peel-Away Sheath
4. Safety lock
5. Stopcock
6. Connecting tube
7. Flexor Introducer Sheath
8. Captor Hemostatic Valve
9. Gray positioner
10. Inner cannula
11. Gripper
12. Trigger-wire release mechanism
13. Iliac plug



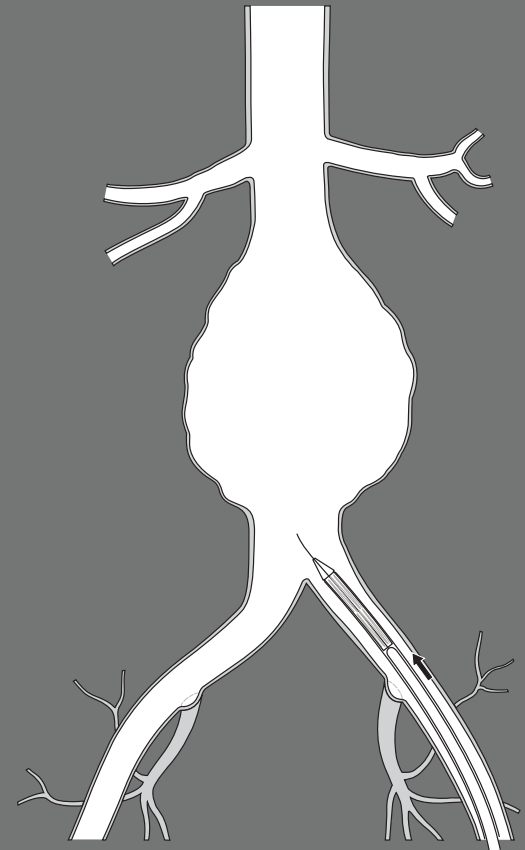
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Iliac Plug

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.



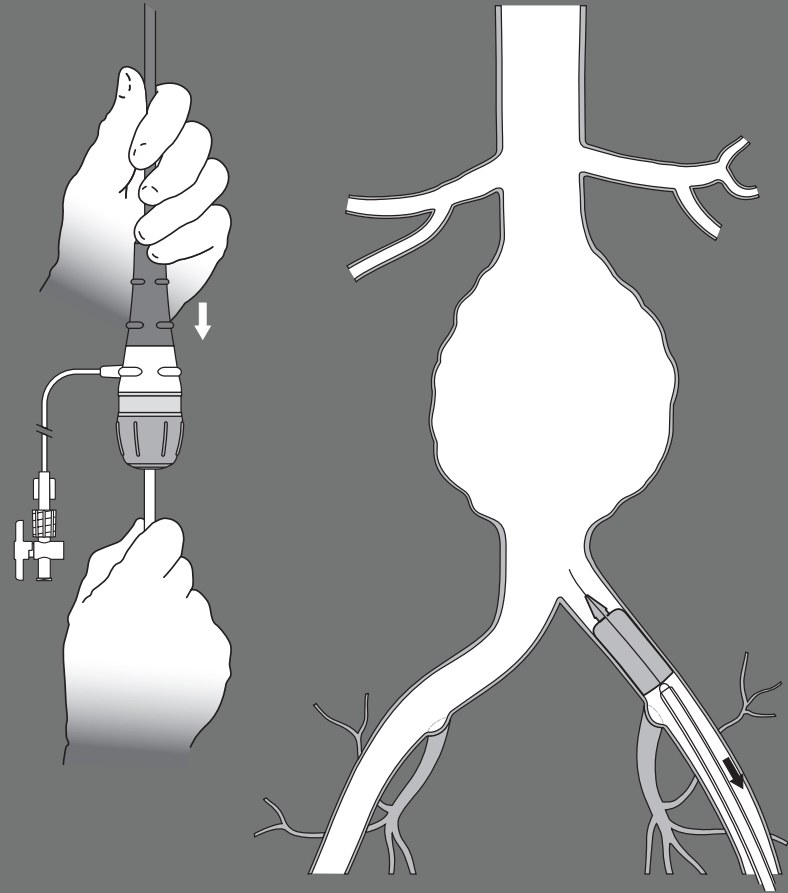
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Iliac Plug

Deployment

Step 2

- Use gripper to stabilize gray positioner and retract sheath to deploy the iliac plug.
- Withdraw the sheath until the iliac plug is uncovered.



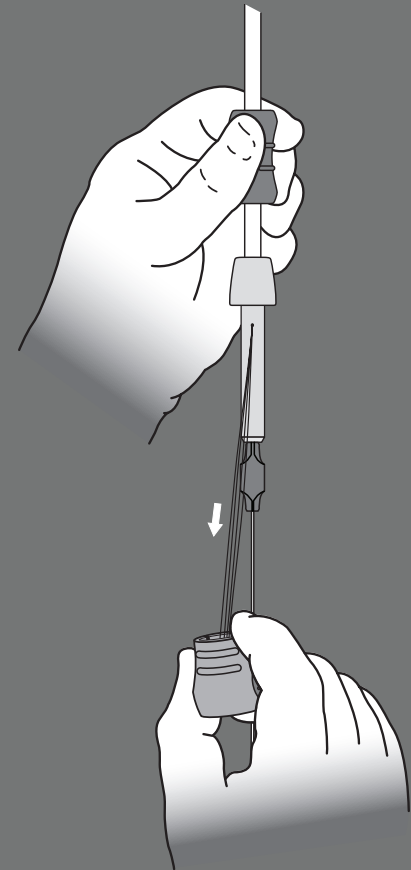
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Iliac Plug

Deployment

Step 3

- Remove the safety lock from the trigger-wire mechanism.
- Withdraw and remove the trigger-wire release mechanism.



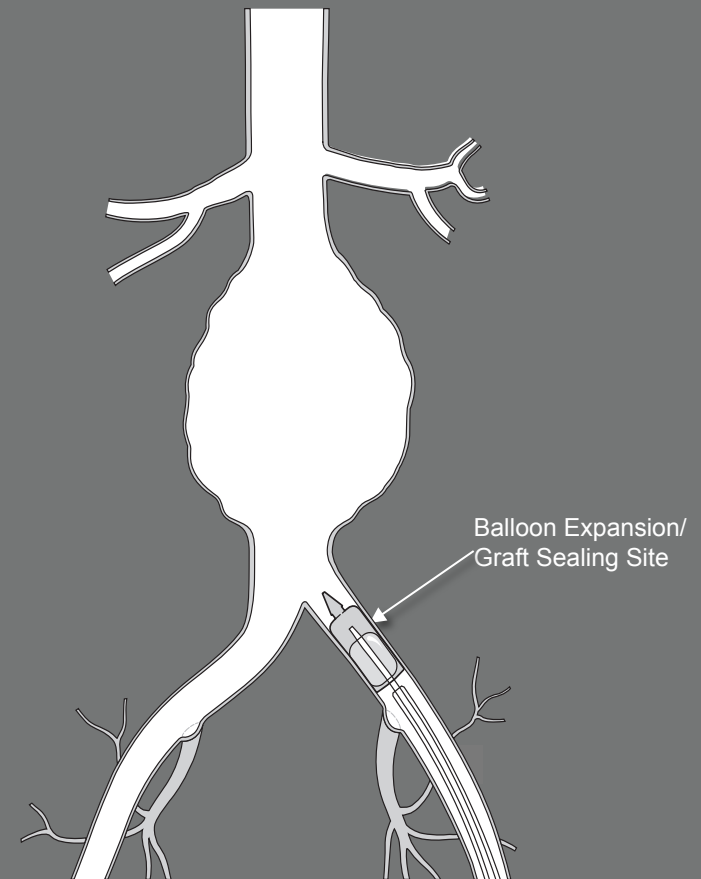
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Iliac Plug

Deployment

Step 4

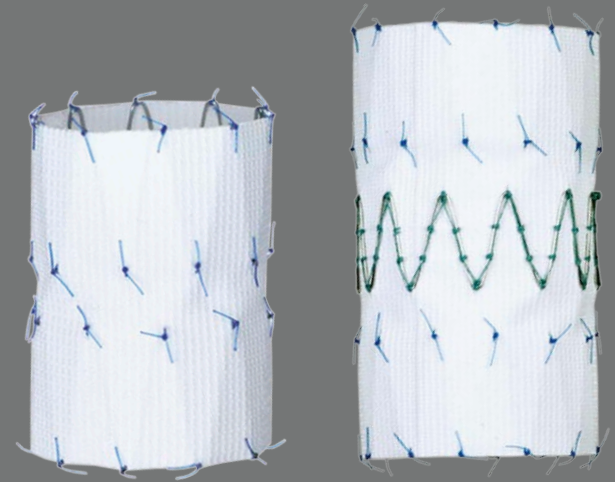
- Remove wire guide. (Ensure graft is not displaced during withdrawal.)
- Remove gray positioner. (Ensure graft is not displaced during withdrawal.)
- Balloon mold the expandable length of the iliac plug (optional).
- Perform final angiography.
- **CAUTION:** Keep the balloon inside the graft.



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Main Body Extension (ESBE)

- Used to extend the proximal body of an in situ graft. Issues causing its necessity include:
 - Improper placement of the main body
 - Tortuosity of the aortic neck
 - Inaccurate selection of the diameter of the main body



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Main Body Extension

- 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.
- **The sheath length is 40 cm.**
- 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.*

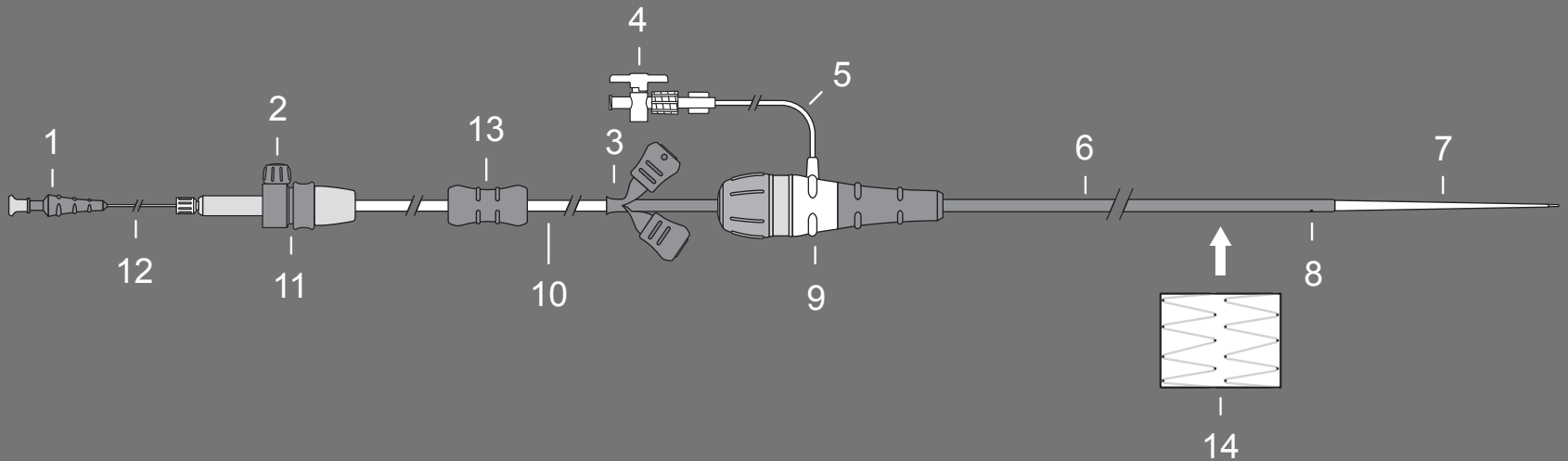
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Main Body Extension

- The Z-Trak 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

1. Hub
2. Safety lock
3. Peel-Away Sheath
4. Stopcock
5. Connecting tube
6. Flexor Introducer Sheath
7. Dilator tip
8. Sheath sideport
9. Captor Hemostatic Valve
10. Gray positioner
11. Trigger-wire release mechanism
12. Inner cannula
13. Gripper
14. Main body extension



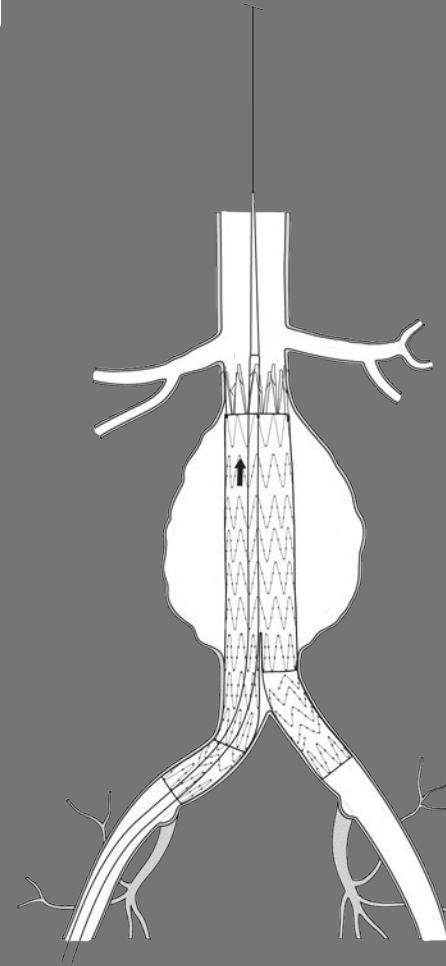
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Main Body Extension

Deployment

Step 1

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



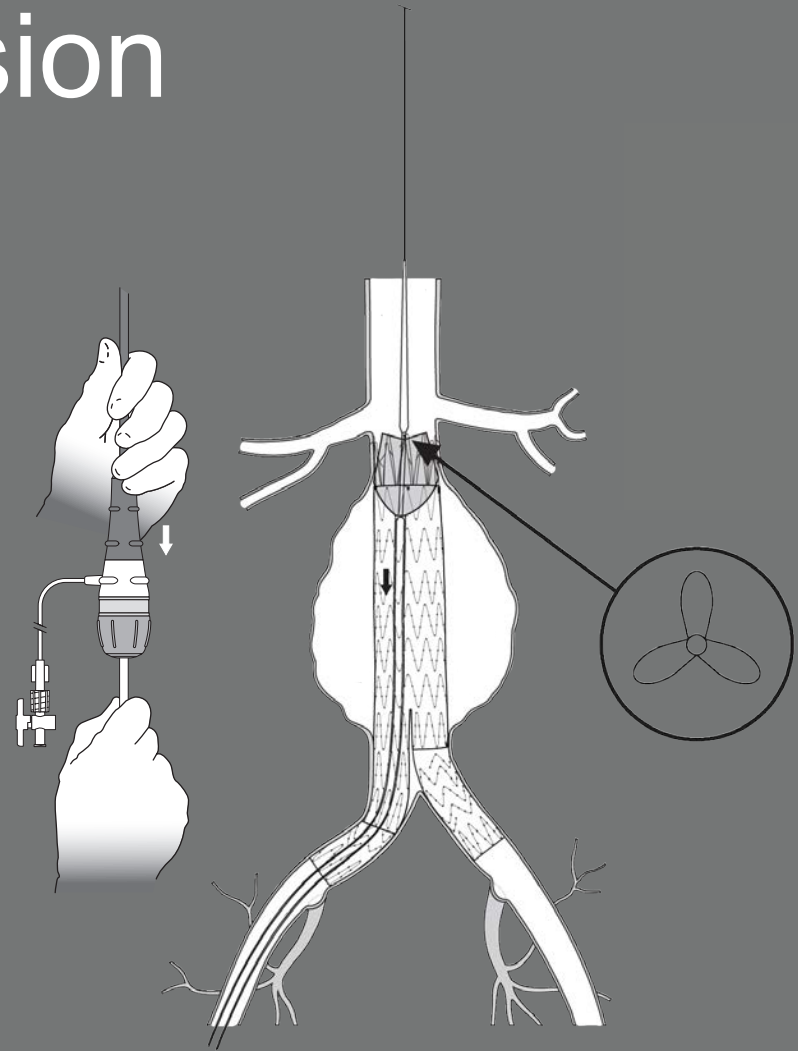
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Main Body Extension

Deployment

Step 2

- Use gripper to stabilize gray positioner and retract sheath to deploy main body extension.
- Deploy device until the most distal stent is uncovered.



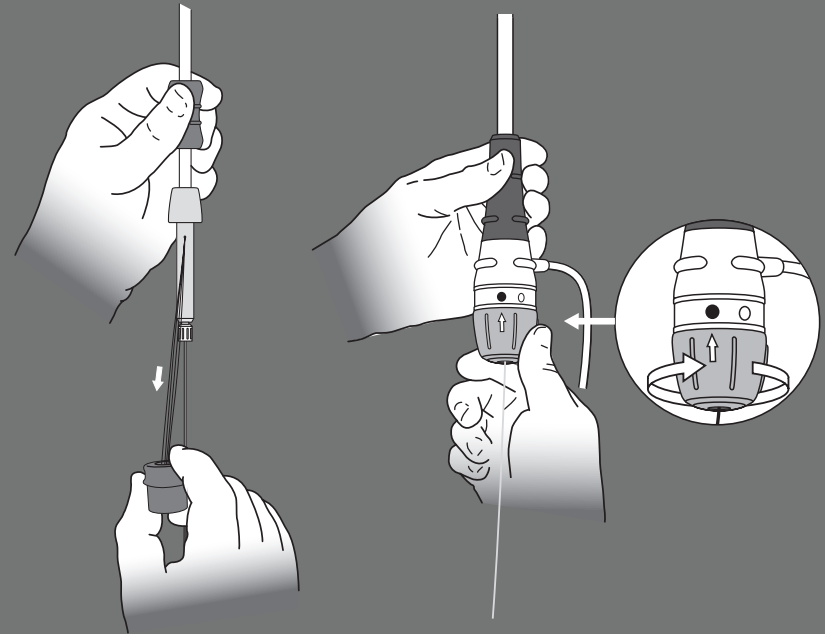
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Main Body Extension

Deployment

Step 3

- Remove the safety lock from the trigger-wire release mechanism.
- Withdraw and remove the trigger-wire release mechanism.
- Retract inner cannula, dock and remove gray positioner.
- Close the Captor Hemostatic Valve.



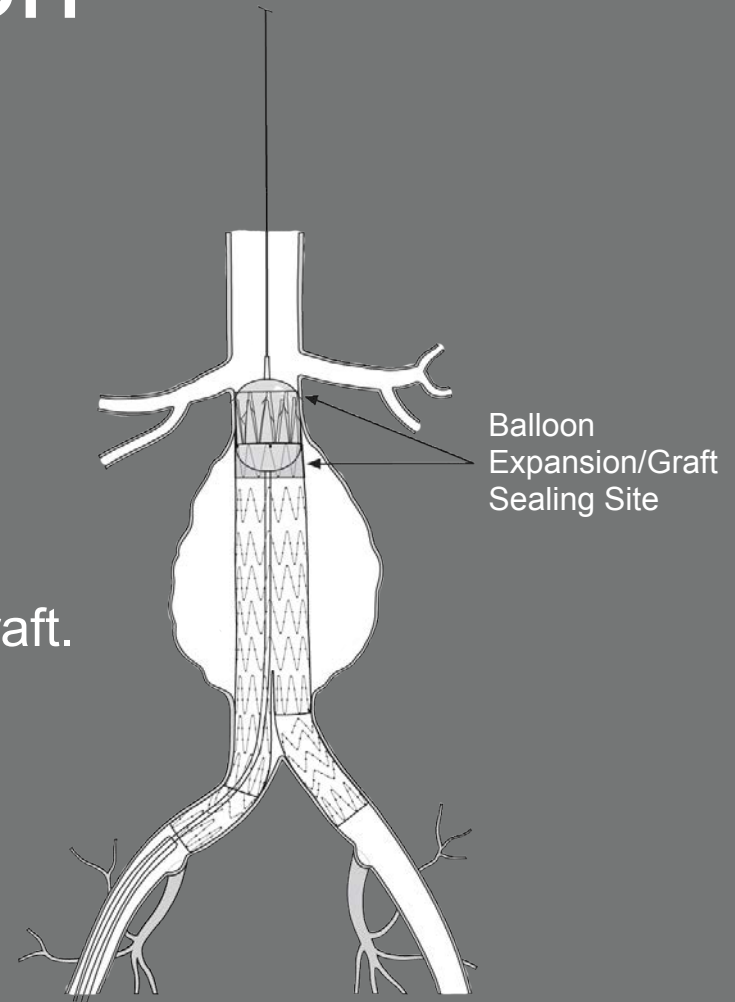
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Main Body Extension

Deployment

Step 4

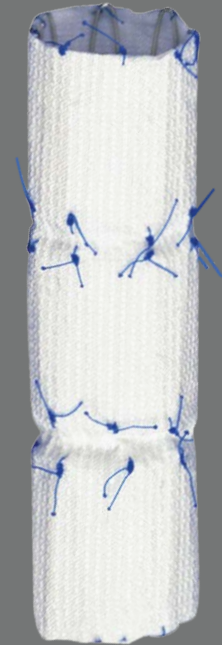
- Balloon mold the main body extension within the proximal segment and then the distal segment.
- Perform final angiography.
- **CAUTION:** Keep the balloon inside the graft.



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Iliac Leg Extension (ESLE)

- 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.
 - All iliac leg extensions (ESLE) are 55 mm in length.
 - **The sheath length is 71 cm.**
- If an iliac leg extension is not available, an iliac leg can be used.



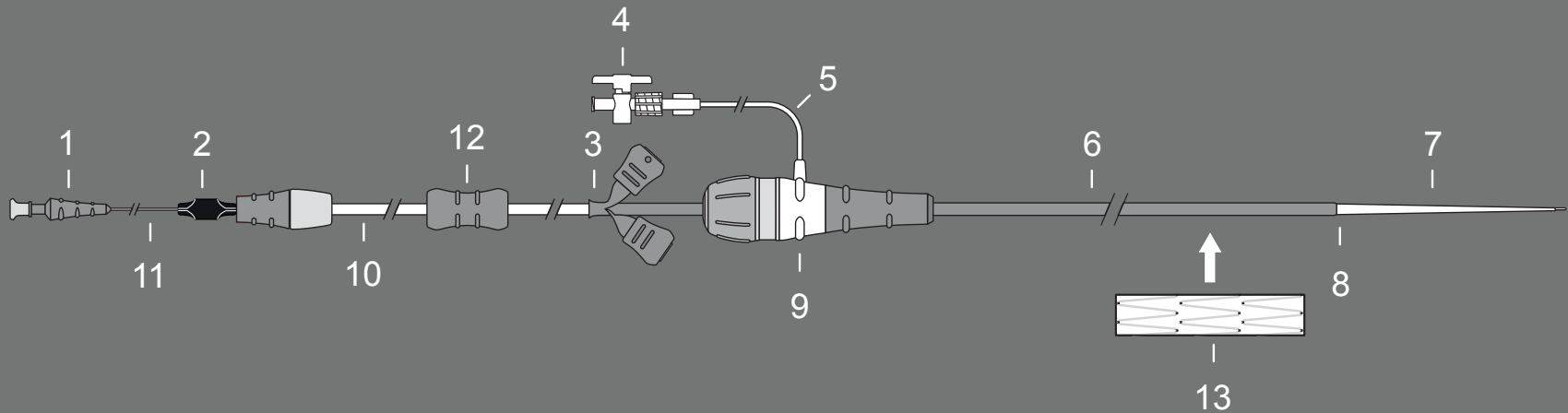
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Iliac Leg Extension

- Iliac leg extensions are preloaded in a Z-Trak Introduction System.
- The 8-24 mm iliac leg extension introducer sheaths can be inserted either through an in situ main body introducer sheath or directly into the vessel over a wire.

Iliac Leg Extension

1. Hub
2. Pin vise
3. Peel-Away Sheath
4. Stopcock
5. Connecting tube
6. Flexor Introducer Sheath
7. Dilator tip
8. Flushing groove
9. Captor Hemostatic Valve
10. Gray positioner
11. Inner cannula
12. Gripper
13. Iliac leg extension



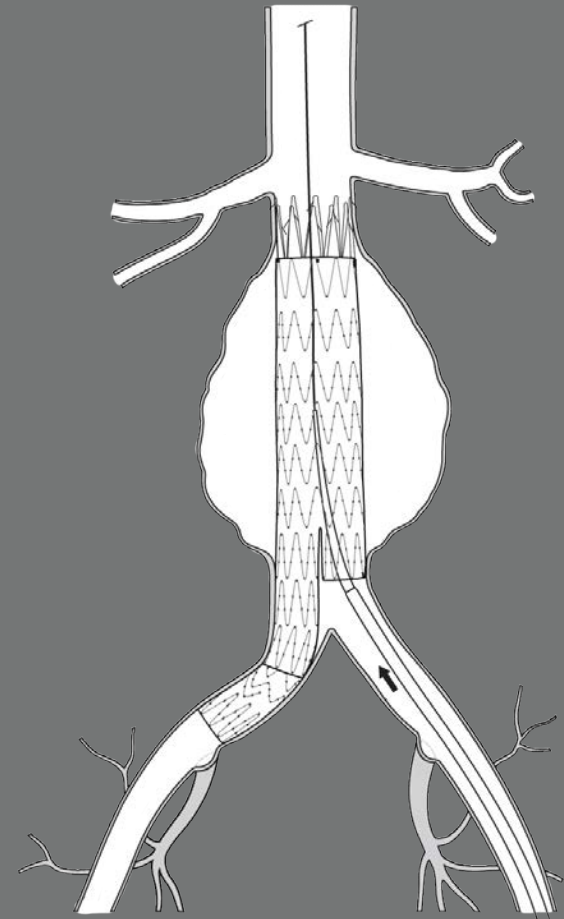
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Iliac Leg Extension

Deployment

Step 1

- Verify appropriate stent-graft overlap to ensure proper sealing and resistance to migration.
- Verify placement with angiography.



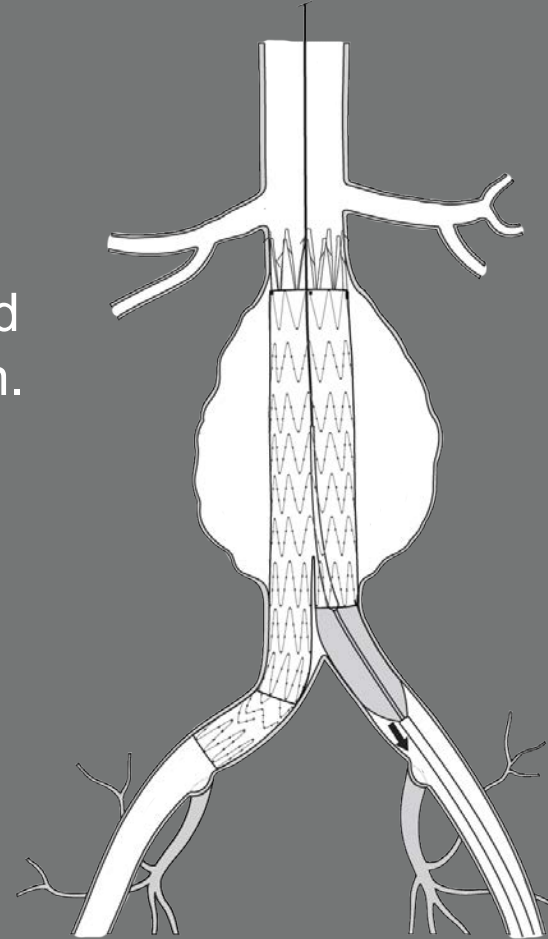
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Iliac Leg Extension

Deployment

Step 2

- Use gripper to stabilize gray positioner and retract sheath to deploy iliac leg extension.



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Iliac Leg Extension

Deployment

Step 3

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



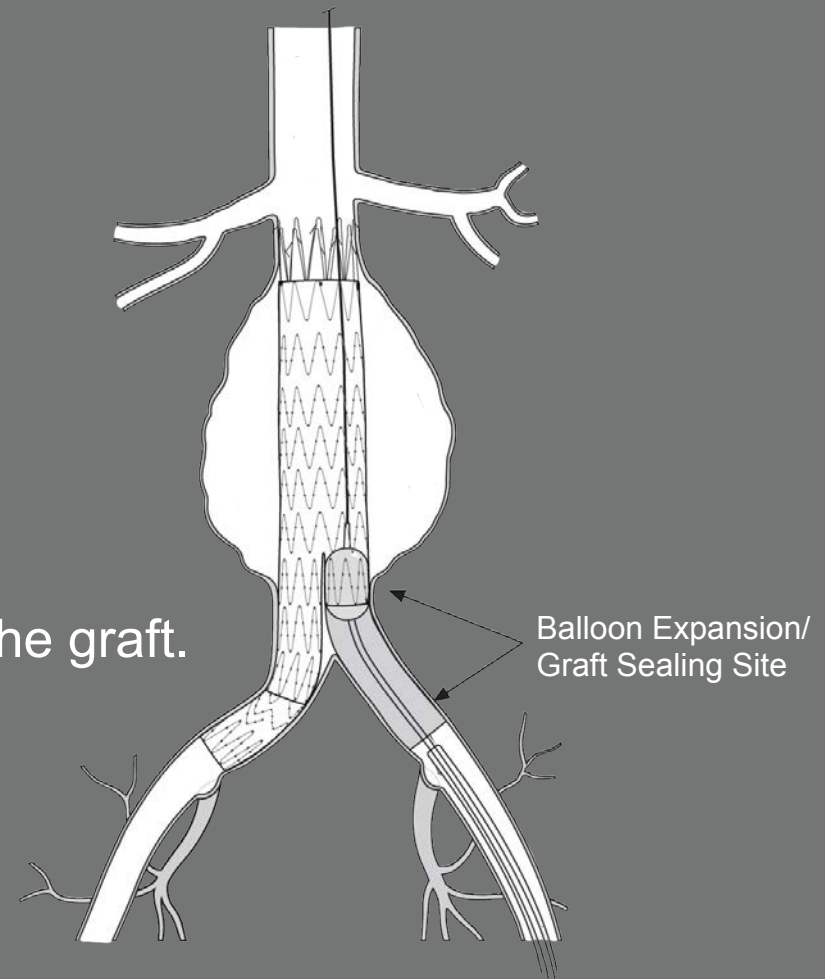
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Iliac Leg Extension

Deployment

Step 4

- Balloon mold the iliac leg extension within the most proximal segment and then the most distal segment.
- Perform final angiography.
- **CAUTION:** Keep the balloon inside the graft.



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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 to ensure the ongoing safety and effectiveness of endovascular treatment.
- Subsequent reinterventions, including catheter-based and open surgical conversion, are possible following endovascular graft placement.

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Minimum Follow-Up Imaging Requirements

	CT (Contrast and Noncontrast)	Abdominal Radiographs
Predischarge (within 7 days)	X ^{1,2,3}	X
1 month		X
3 months	X ^{1,3,4}	
6 months	X ^{1,3}	X
12 months (annually thereafter)	X ^{1,3}	X

¹ Duplex ultrasound and noncontrast CT may be used for patients who have renal failure or are otherwise unable to have contrast-enhanced CT.

² Either predischarge or 1 month CT recommended.

³ If type I or III endoleak, prompt intervention and additional postintervention follow-up recommended.

⁴ Recommended if endoleak reported at predischarge or 1 month.

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