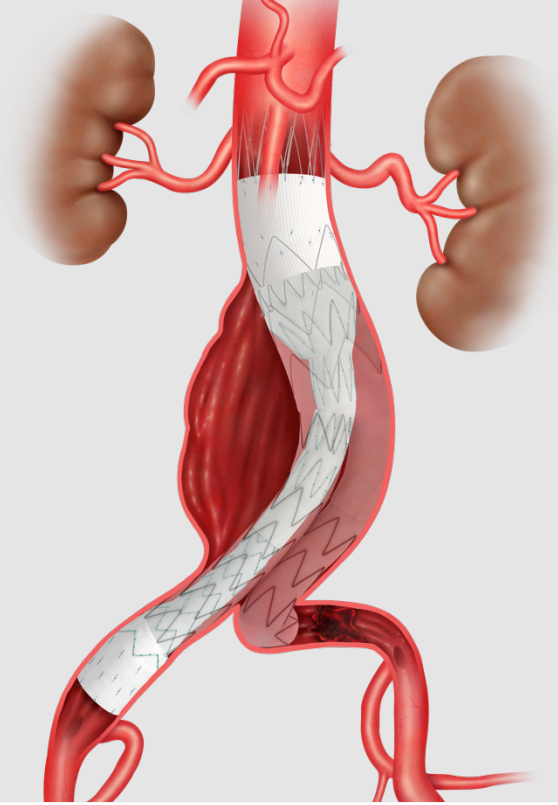


# Zenith Renu<sup>®</sup>

## AAA Converter Graft

- Device Description
- Planning and Sizing
- Deployment Sequence
- Patient Follow-Up



## Device description: Device indications

The Zenith Renu<sup>®</sup> AAA Converter Graft with Z-Trak<sup>®</sup> Introduction System is indicated for 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

# Device description: Zenith Renu AAA Converter Graft

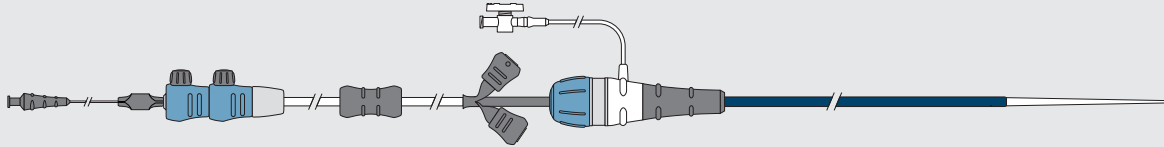
The Zenith Renu AAA Converter a long, tapered graft

Converter



# Device description: Flexor® Introducer Sheath

- The Zenith Renu Converters are preloaded into 18, 20 and 22 Fr delivery sheaths



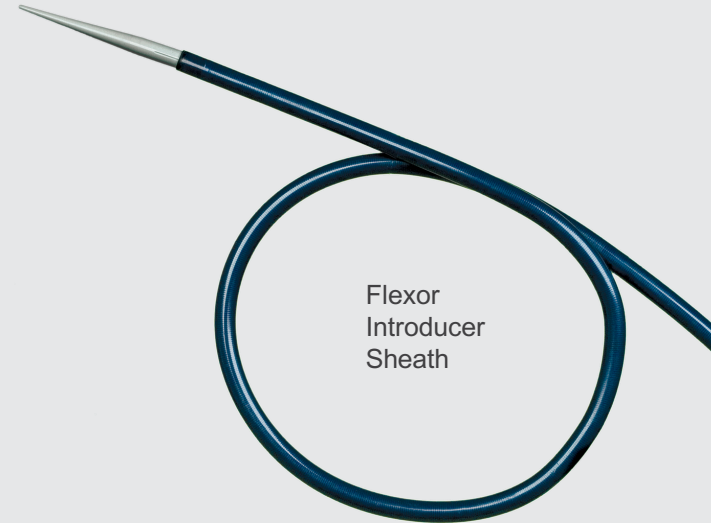
## Z-Trak® Introduction System for Renu Converters

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

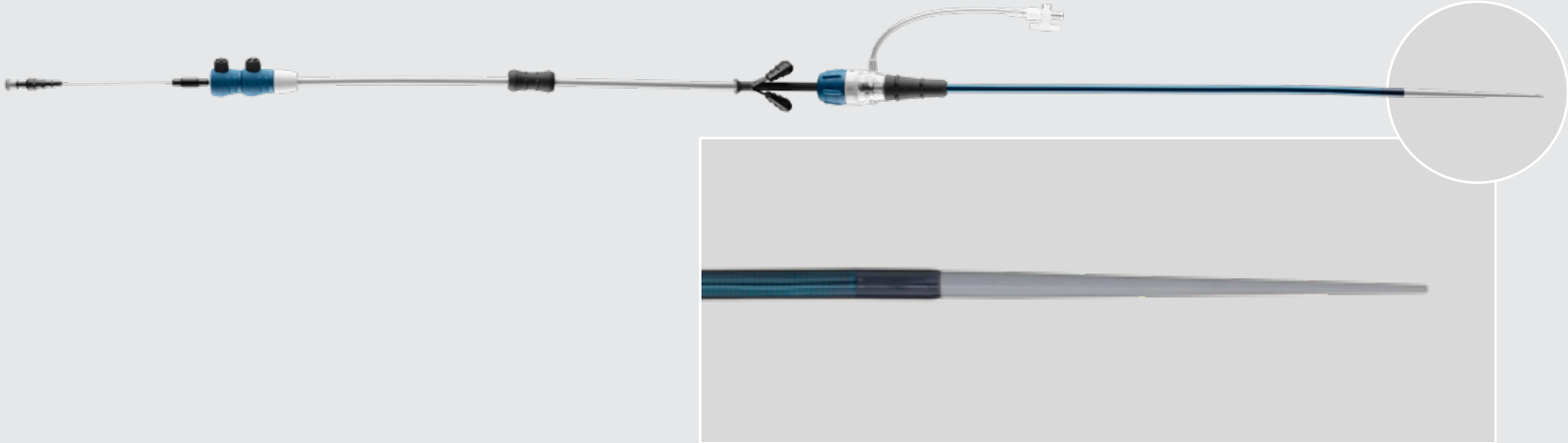
36 mm grafts: 22 Fr (7.3 mm) ID/8.5 mm OD

- Radiolucent sheath enables graft visualization during delivery of the system
- Uniquely fabricated sheath design provides maximum flexibility without kinking or compression
- Hydrophilic coating



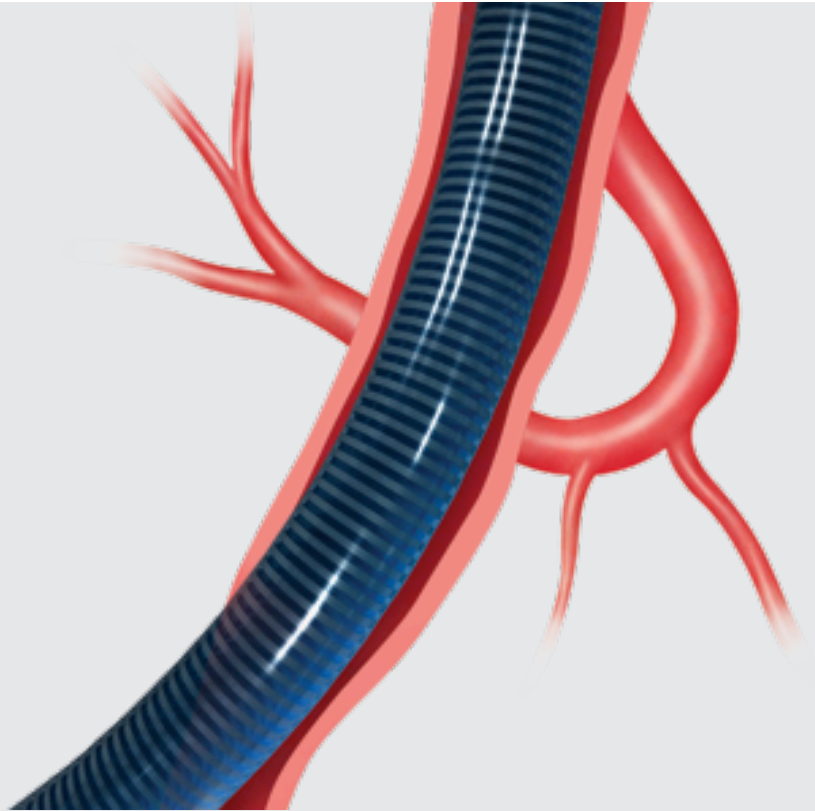
# Device description: Dilator tip

Long, tapered tip minimizes vessel trauma and offers excellent trackability



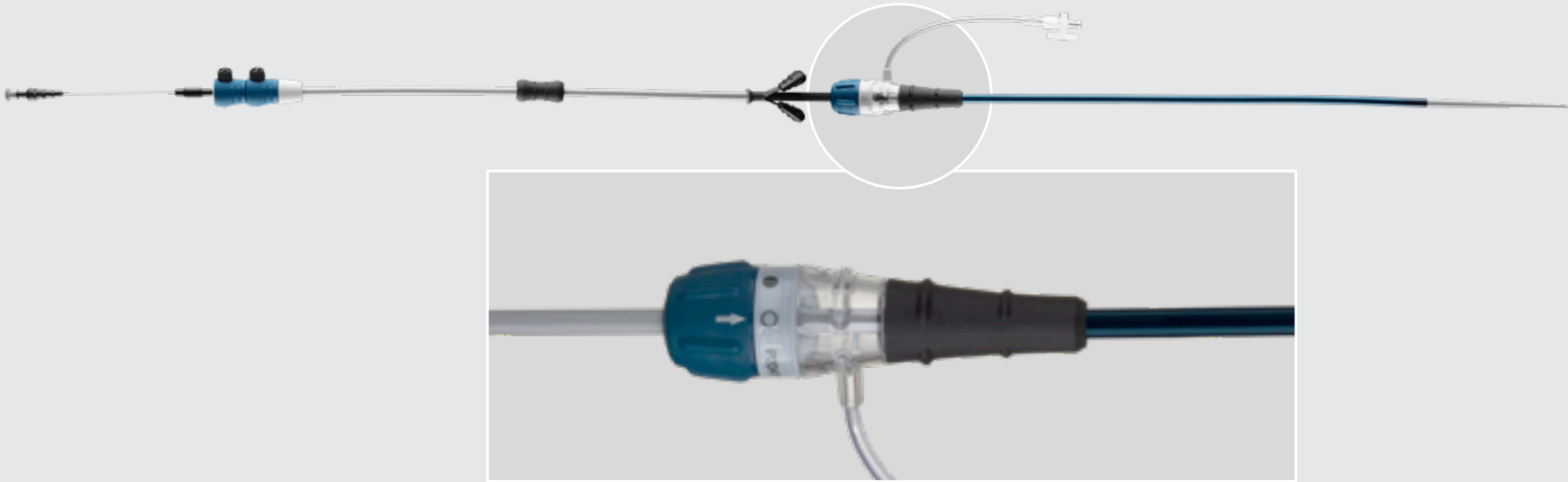
## Device description: Hydrophilic coating

AQ<sup>®</sup> hydrophilic coating dramatically reduces friction to enhance deliverability, while Flexor's large, low-friction, PTFE-coated lumen facilitates device delivery



# Device description: Captor® Hemostatic Valve

Unique design inhibits blood reflux



# Device description: Zenith Renu AAA Converter Graft

<b>Cook Reorder Number Prefix</b>	<b>Graft Diameter mm</b>	<b>Graft Length mm</b>	<b>Introducer Sheath Fr</b>
AX1-2	22, 24, 26	113	18
AX1-2	28, 30, 32	113	20
AX1-2	36	127	22



# Planning and sizing: General component selection

## From Instructions for Use, considerations for selection include:

- Amount of preexisting graft migration
- Condition of preexisting graft
- Working length from lowest renal artery orifice to preexisting graft bifurcation (flow divider)
- Diameter of preexisting graft and diameter at intended proximal fixation site

**Note:** Refer to the Zenith Renu AAA Ancillary Graft Instructions for Use for more information on device selection

# Planning and sizing: General Indications for Use

**The Zenith Renu AAA Converter Graft with Z-Trak Introduction System is indicated for 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 with:**

- Adequate iliac/femoral access compatible with the required introduction systems
- Adequate proximal fixation site:
  - With an angle less than 60 degrees relative to the long axis of the aneurysm
  - With an angle less than 45 degrees relative to the axis of the suprarenal aorta

# Planning and sizing: Additional anatomical considerations

## Patients should also have a proximal seal site with the following anatomy:

- Proximal neck length of at least 10 mm from the lowest renal artery to the top of the preexisting graft
- Less than a 15% change in diameter over the 10 mm proximal seal zone, i.e., the length from the lowest renal artery to the top of the preexisting graft

**Note:** In patients with less favorable anatomy, the likelihood of resolving preexisting type I endoleaks may be reduced. The benefits and risks of endovascular therapy should be considered relative to the risks of open surgical repair in determining the best therapy for the patient

# Planning and sizing: Additional anatomical considerations

## Obtain recommended imaging:

- 3 mm slice thickness axial CT images
- Record appropriate information on Zenith Renu device order sheet
- Preexisting graft type (note material)
- Preexisting graft dimensions
- Distance from lowest renal artery orifice to preexisting graft bifurcation (flow divider)
- Aortic neck diameter
- Diameter of distal sealing zone

# Planning and sizing: Zenith Renu AAA Converter Graft planning and sizing

## Diameters

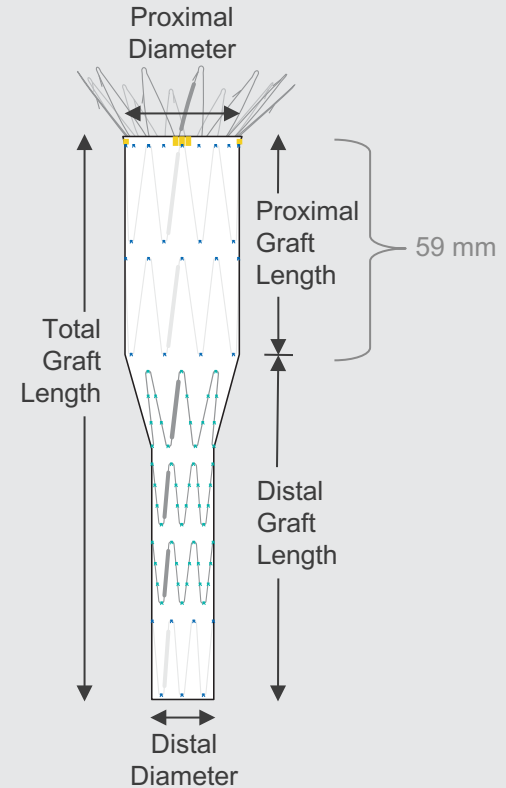
- Obtain aortic diameter measurements above existing graft and up until the existing graft is seen full round
- Measure existing graft diameters and both body and limb diameters throughout, including uncovered common iliac arteries

## Lengths

- Distance to where top of graft is visualized
- Distance to where existing graft is seen full round
- Distance to existing graft flow divider
- Distance from lowest renal to distal graft limbs and internal iliac arteries

# Planning and sizing: Zenith Renu AAA Converter Graft selection

- The shortest proximal graft length available is 59 mm; therefore, Cook Medical recommends that the length from the lowest renal artery to the bifurcation of the preexisting graft be at least 59 mm, preferably longer
- Aortic diameter of proximal fixation site must be  $\geq 18$  mm and  $\leq 32$  mm (measured outer wall to outer wall)



## Planning and sizing: Zenith Renu AAA Converter Graft selection

The Zenith Renu AAA Converter Graft should be selected and may be used in combination with an iliac leg graft when the preexisting graft has any of the following characteristics:

- Composed of PTFE graft material (recommended use with iliac leg graft)
- Body length (top of graft-to-graft bifurcation) is  $\leq 17$  mm
- Proximal graft diameter is  $> 34$  mm
- Appropriate oversizing for both the preexisting graft and aortic neck is not possible because of significant diameter differences
- Preexisting graft is unstable

## Planning and sizing: Zenith Renu AAA Converter Graft selection

- When using the converter in combination with an iliac leg, the distal fixation site should be:
  - 7.5-20 mm in diameter (measured outer wall to outer wall)
  - > 10 mm in length, with 20-30 mm being preferred
- When using the converter without an iliac leg, the distal fixation site should be:
  - At least one Cook-Z stent (17 mm) in length with more overlap length being preferred
  - ≤ 12 mm in diameter within the preexisting graft leg



# Planning and sizing: Zenith Renu AAA Converter Graft

<b>Intended Aortic Vessel Diameter<sup>1,2,3</sup> mm</b>	<b>Proximal Graft Diameter mm</b>	<b>Distal Graft Diameter mm</b>	<b>Graft Length (nonstock) mm</b>
18-19	22	12	113
20-21	24	12	113
22	26	12	113
23-24	28	12	113
25-26	30	12	113
27-28	32	12	113
29-32	36	12	127

- 1. Maximum diameter along the proximal fixation site
- 2. Round measured aortic diameter to nearest mm
- 3. Additional considerations may affect choice of diameter

# Deployment sequence: Zenith Renu AAA Converter Graft

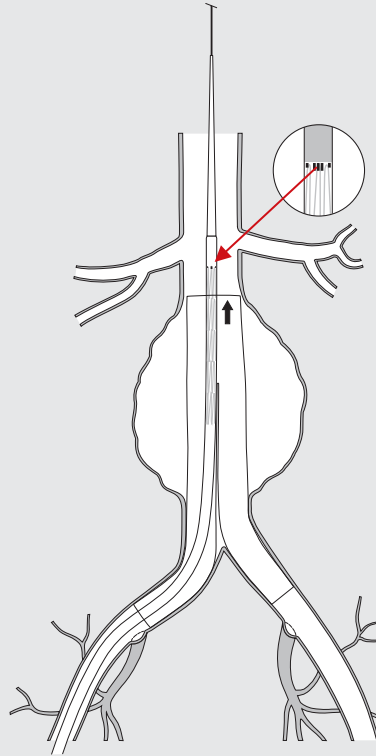
## Prior to use:

- Verify correct devices (quantity and size) have been supplied for the patient. Match the device to the prescribed order for each particular patient
- Preparation for use is the same as the preparation for other Zenith components with which you are familiar
- Activate hydrophilic coating on the Flexor Introducer Sheath

# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 1

- Introduce and position device below the lowest renal artery
- Verify the proximal gold markers are just inferior to the most inferior renal orifice

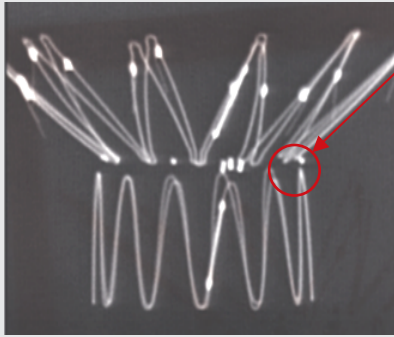


Radiopaque markers provide visibility of graft material position in relation to renal arteries

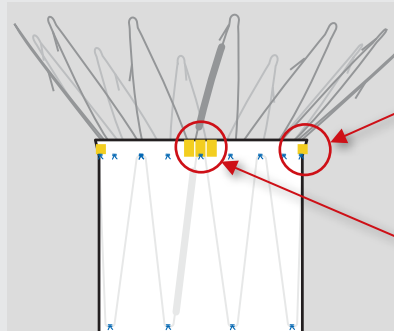
**Note:** To ensure patency of renal arteries, recognize that the proximal graft markers are 2 mm below the proximal edge of the graft material

# Deployment sequence: Radiographic appearance

## Four positions of gold proximal markers



2 mm from most proximal edge of graft material



Three positions have a single marker

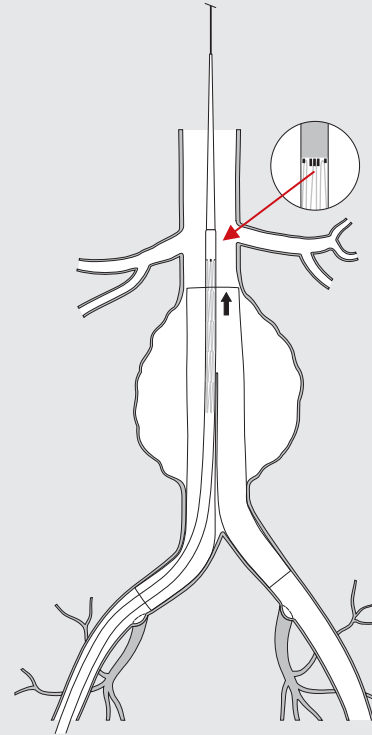
One position has a cluster of three markers to differentiate it from other components

# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 2

- Verify position to ensure proper placement, sealing and overlap
- Confirm the distal end of the Zenith Renu AAA Converter Graft will provide at least one Cook-Z stent (17 mm) overlap in the iliac portion of the preexisting stent graft

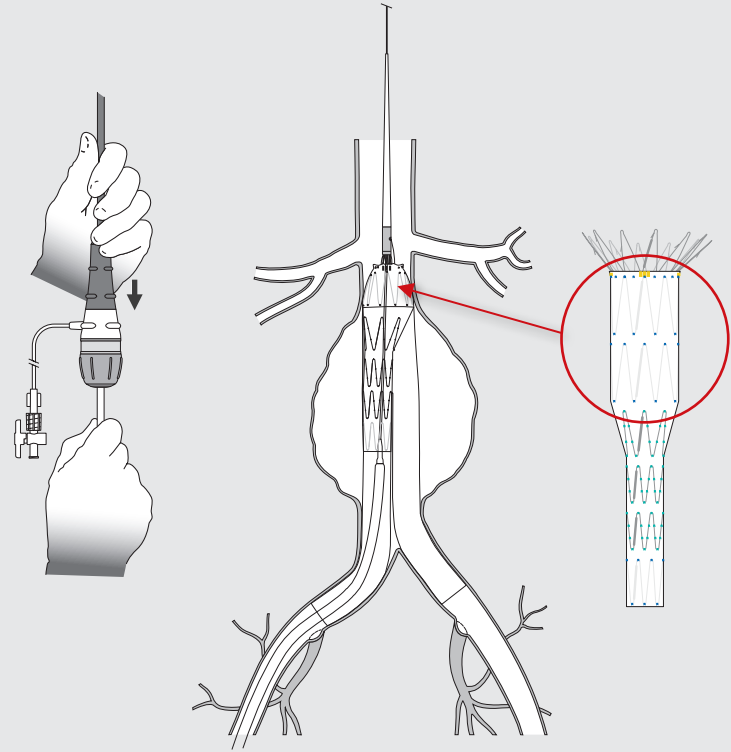
**Note:** A one-stent overlap in the iliac portion of the preexisting graft is not necessary when the Zenith Renu AAA Converter Graft is used with an iliac leg graft



# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 3

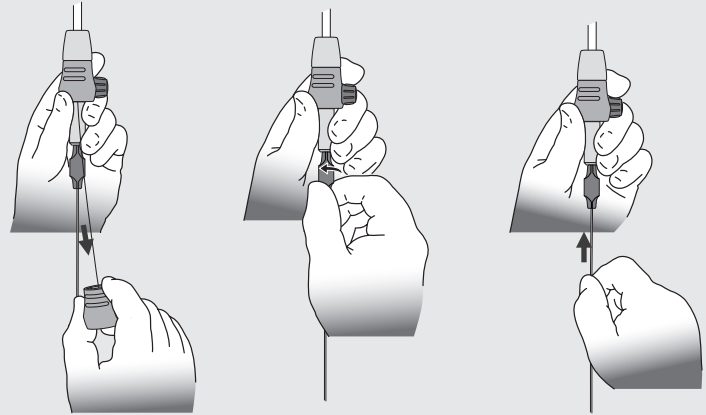
- Stabilize gray positioner and retract sheath to deploy the Zenith Renu AAA Converter Graft
- Deploy device until the most distal stent is uncovered



# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 4

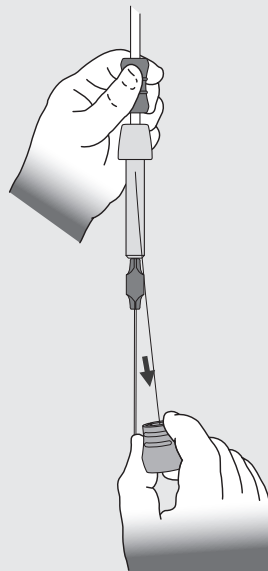
- Remove proximal trigger-wire release mechanism
- Deploy suprarenal stent (loosen pin vise and advance inner cannula; retighten pin vise)



# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 5

- Remove distal trigger-wire release mechanism

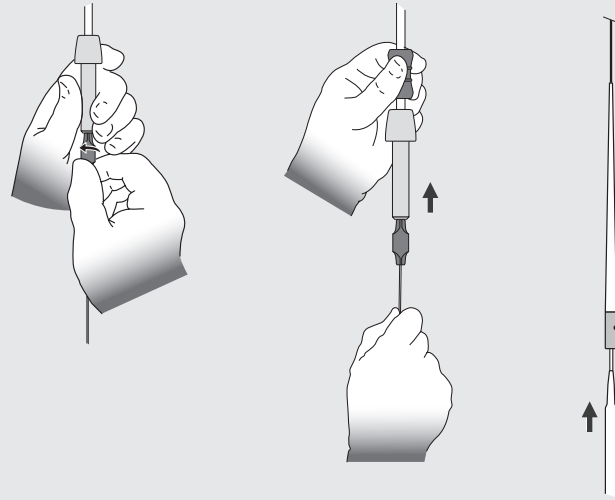




# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 6

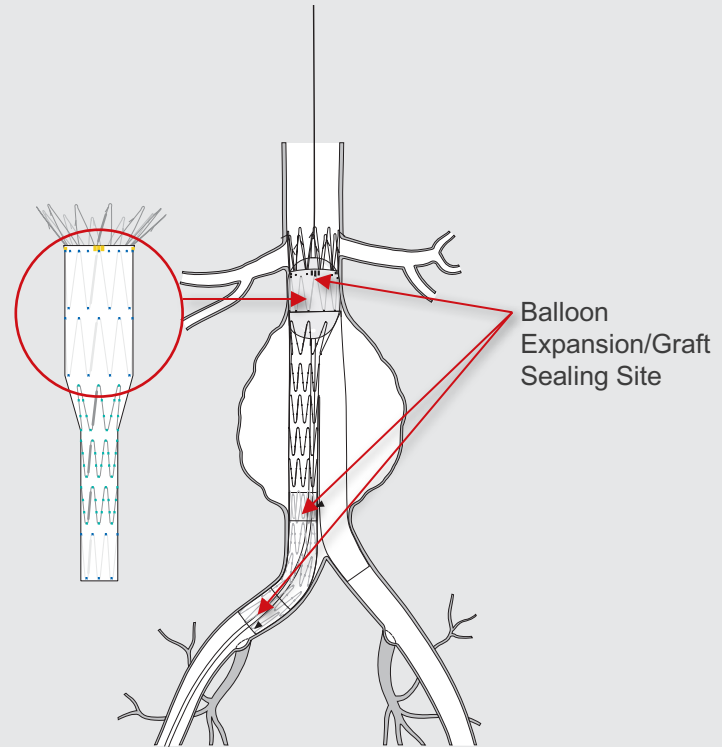
- Dock top cap
- Loosen pin vise and secure both the inner cannula and sheath
- Advance and dock gray positioner with top cap
- Tighten pin vise. Remove converter delivery system



# Deployment sequence: Zenith Renu AAA Converter Graft

## Step 7

- Balloon molds the graft at vessel seal site and component overlap site
- Perform final angiography



# Deployment sequence: Zenith Renu AAA Converter Graft

- To aid in graft sealing, an iliac leg may be used to extend the Zenith Renu AAA Converter Graft
- Typically an occluder is used on the contralateral side



# Instructions for Use

Consult the Instructions for Use for a more thorough examination of the deployment protocol, MRI safety, indications for use, contraindications, warnings, and precautions.