COOK® MEDICAL

Zenith Renu®

AAA ANCILLARY GRAFT

Transcend: Precision

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

Device Description

Zenith Renu® — Restore graft-to-vessel fixation and seal.

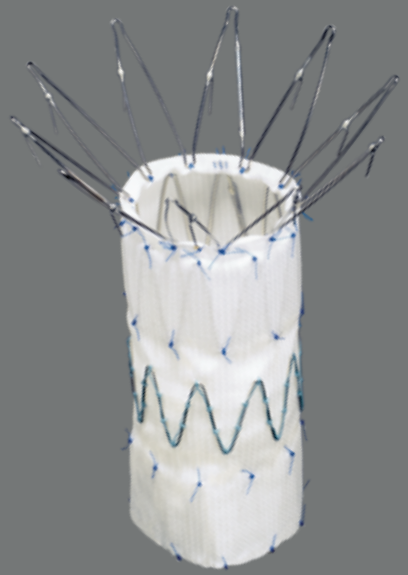
Device Indications

The Zenith Renu® AAA Ancillary 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.

Please refer to the printed Instructions for Use for complete warnings and precautions as well as additional important details.

AAA Ancillary Graft

Zenith Renu is available as either a straight component (Renu main body extension) or a longer, tapered component (Renu converter).



Renu
Main Body
Extension

Renu
Converter

Zenith Renu® — Restore graft-to-vessel fixation and seal.

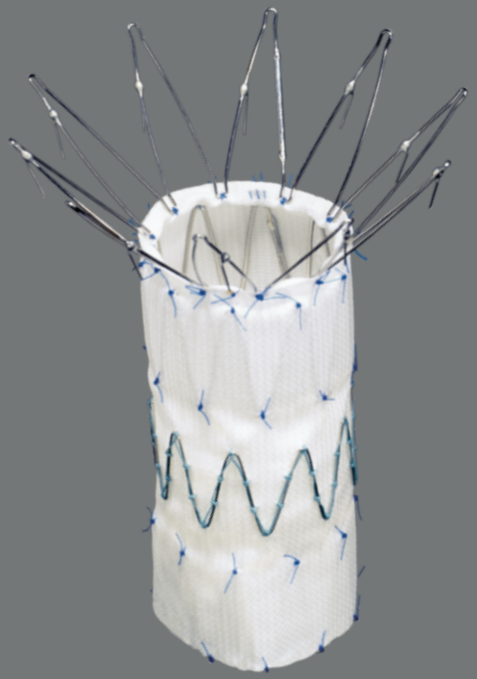
Converter

Unique design provides multiple size options for conversion of in situ endovascular grafts.

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Main Body Extension

Various diameters and lengths are offered to extend proximal bodies of in situ endovascular grafts.



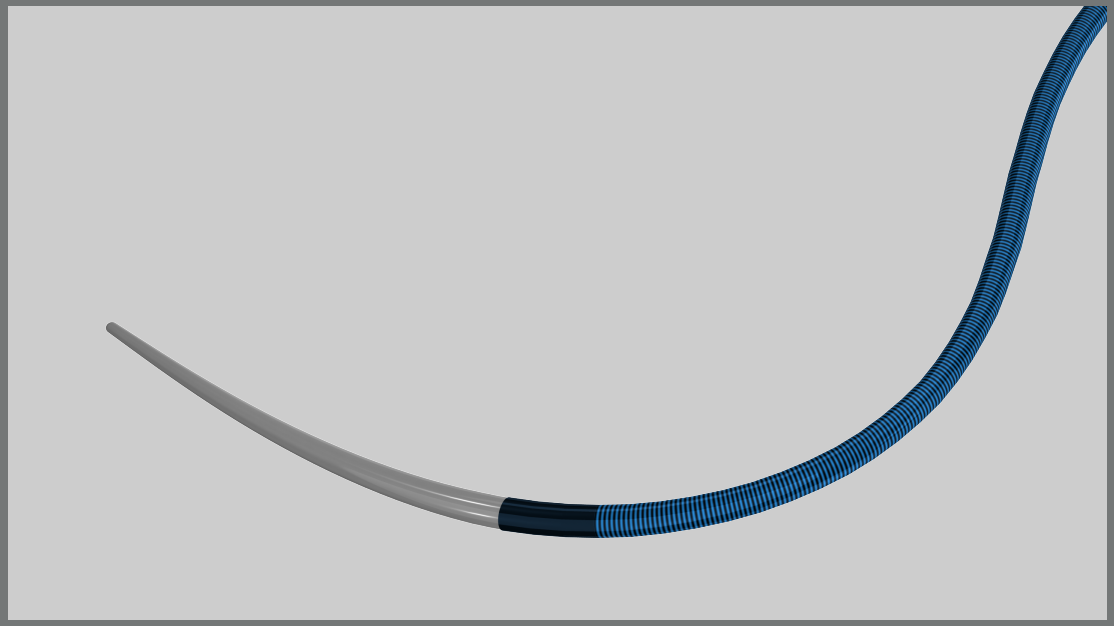
Zenith Renu® — Restore graft-to-vessel fixation and seal.

Flexor® Introducer Sheath

- Renu components are preloaded into 18, 20 and 22 Fr delivery sheaths.
  - 22-26 mm = 18 Fr
  - 28-32 mm = 20 Fr
  - 36 mm = 22 Fr
- Radiolucent sheath enables graft visualization during delivery of the system.
- Uniquely fabricated sheath design provides maximum flexibility without kinking or compression.
- Hydrophilic coating.

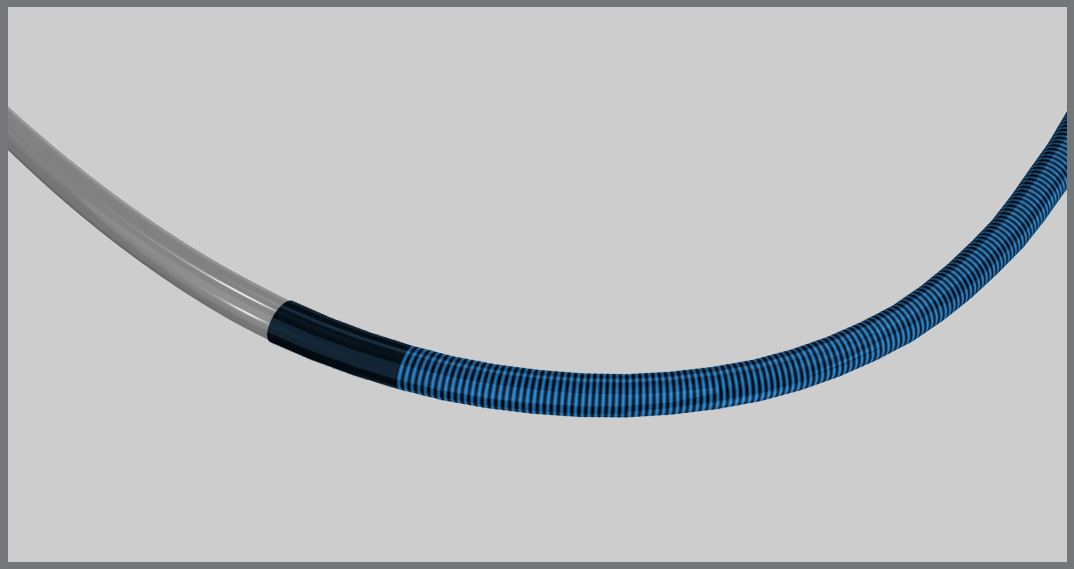
Dilator Tip

Long, tapered tip minimizes vessel trauma and offers excellent trackability.



Hydrophilic Coating

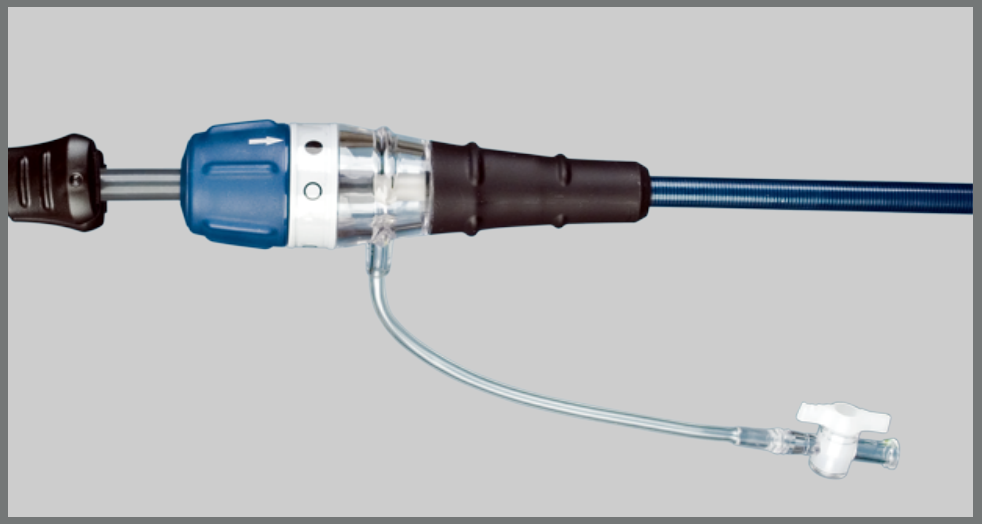
AQ® hydrophilic coating dramatically reduces friction to enhance deliverability, while Flexor's large, low-friction, PTFE-coated lumen facilitates device delivery.



Zenith Renu® — Restore graft-to-vessel fixation and seal.

Captor® Hemostatic Valve

Unique design inhibits blood reflux.



Zenith Renu® — Restore graft-to-vessel fixation and seal.

Main Body Extension

Cook Reorder Number Prefix	Graft Diameter mm	Graft Length mm	Introducer Sheath Fr
RX1	22, 24, 26	43, 62	18
RX1	28, 30, 32	43, 62	20
RX1	36	54, 77	22

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Converter

Cook Reorder Number Prefix	Graft Diameter mm	Graft Length mm	Introducer Sheath Fr
AX1-1	22, 24, 26	108, 125	18
AX1-1	28, 30, 32	108, 125	20
AX-1-1	36	116	22

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Converter

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

Note: Product not available in all markets. Contact your Cook representative for more information.

Zenith Flex® AAA Iliac Legs

Iliac Legs

14 Fr Z-Trak Introduction System						
Diameter mm	Length mm					
8	37	54	71	88	105	122
10	37	54	71	88	105	122
16 Fr Z-Trak Introduction System						
12	39	56	73	90	107	124
14	39	56	73	90	107	124
16	39	56	73	90	X	X
18	39	56	73	90	X	X
20	39	56	73	90	X	X
22	39	56	73	90	X	X
24	39	56	73	90	X	X

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Zenith® Spiral-Z™ AAA Iliac Legs

Iliac Legs

14 Fr Z-Trak Introduction System						
Diameter mm	Length mm					
9	39	56	74	90	107	122
11	39	56	74	90	107	122
13	39	56	74	90	107	122
16	39	56	74	90	107	122
16 Fr Z-Trak Introduction System						
20	39	56	74	90	X	X
24	39	56	74	90	X	X

Zenith Renu® — Restore graft-to-vessel fixation and seal.

General Component Selection

From Instructions for Use, considerations for selection include:

- Preexisting graft material (for grafts made of PTFE, a Renu converter is recommended)
- 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.

Considerations for Planning and Sizing

General Indications for Use

The Zenith Renu AAA Ancillary Graft with 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

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.

General Planning and Sizing

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

Zenith Renu Planning and Sizing

Obtain aortic diameter measurements

- Above existing graft and up until the existing graft is seen full round

Measure existing graft diameters

- Both body and limb diameters throughout, including uncovered common iliac arteries

Determine distance measurements (note the following):

- 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

Main Body Extension Selection

Considerations from approved indications for use include:

- Working length be at least 43 mm in length (shortest main body extension available is 43 mm), preferably longer
- Graft-to-graft seal of at least one Cook-Z® stent (17 or 22 mm) in length
- Preexisting graft diameter ≤ 34 mm
- Aortic diameter of proximal seal site measured outer wall to outer wall of ≥ 18 mm and ≤ 32 mm

Note: There should be a minimum of 2 mm oversizing with respect to the preexisting graft.

Main Body Extension

Intended Aortic Vessel Diameter[1,2,3] mm	Graft Diameter mm	Graft Length (nonstock) mm
18-19	22	43, 62, (81)
20-21	24	43, 62, (81)
22	26	43, 62, (81)
23-24	28	43, 62, (81)
25-26	30	43, 62, (81)
27-28	32	43, 62, (81)
29-32	36	54, 77, (100)

[1]Maximum diameter along the proximal fixation site.

[2]Round measured aortic diameter to nearest mm.

[3]Additional considerations may affect choice of diameter.

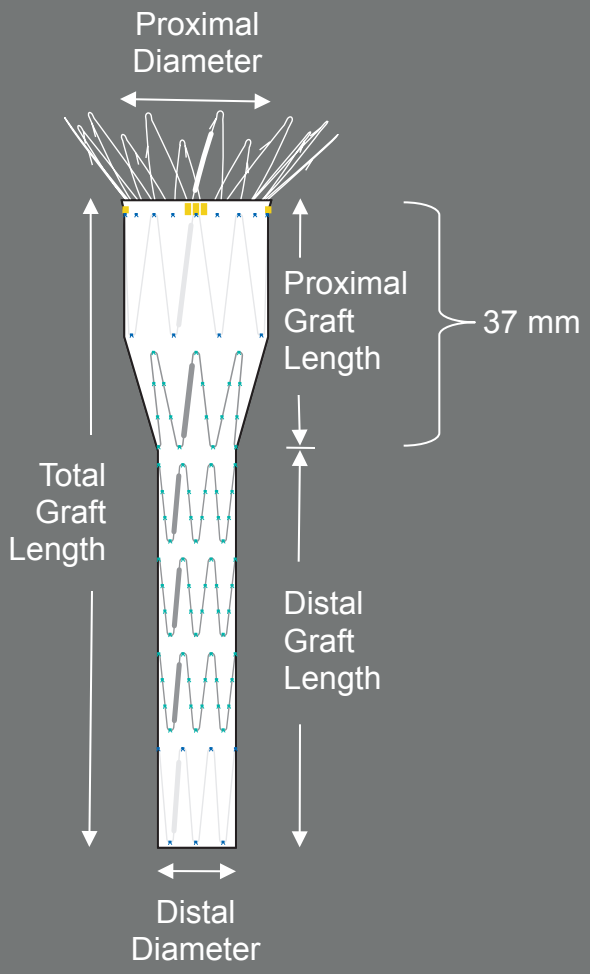
Note: Preexisting graft diameter no larger than 34 mm.

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Converter Selection

- The shortest proximal graft length available is 37 mm; therefore, Cook Medical recommends that the length from the lowest renal artery to the bifurcation of the preexisting graft be at least 37 mm, preferably longer.
- Aortic diameter of proximal fixation site must be ≥ 18 mm and ≤ 32 mm (measured outer wall to outer wall).

The two-seal stent converter AX1-2-XX-XXX requires a minimum distance of 59 mm from lowest renal to existing graft bifurcation.



Converter Selection

The Zenith Renu converter 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 ≤ 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

Converter 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

Converter

Intended Aortic Vessel Diameter[1,2,3] mm	Proximal Graft Diameter mm	Distal Graft Diameter mm	Graft Length (nonstock) mm
18-19	22	12	(91), 108, 113,* 125, (130,* 147*)
20-21	24	12	(91), 108, 113,* 125, (130,* 147*)
22	26	12	(91), 108, 113,* 125, (130,* 147*)
23-24	28	12	(91), 108, 113,* 125, (130,* 147*)
25-26	30	12	(91), 108, 113,* 125, (130,* 147*)
27-28	32	12	(91), 108, 113,* 125, (130,* 147*)
29-32	36	12	99,116, 127,* (133, 144,* 161*)

[1]Maximum diameter along the proximal fixation site.

[2]Round measured aortic diameter to nearest mm.

[3]Additional considerations may affect choice of diameter.

*Two-seal stent converter only.

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Component Selection

After considering component selection criteria, record component type (converter or body extension) and component size (diameter and length) to complete Renu Device Order Sheet.

Deployment Sequence

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Deployment

Main Body Extension

Prior to use:

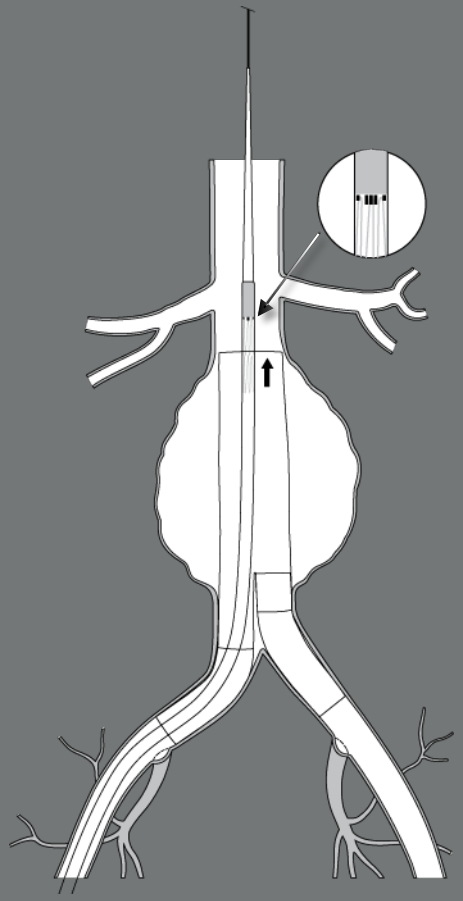
- Verify correct devices (quantity and size) have been supplied for the patient. Match the device to the prescribed order for each particular patient.
- Preparation for use is the same as preparation for the other Zenith components with which you are familiar.
- Activate hydrophilic coating on the Flexor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

Deployment

Main Body Extension

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.

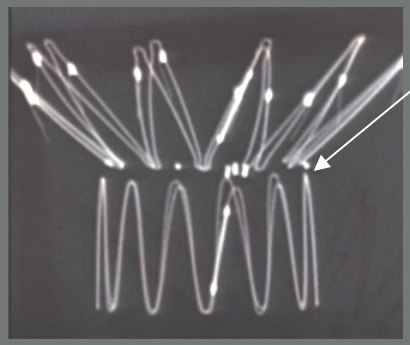


Radiopaque markers provide visibility of graft material position in relation to renal arteries.

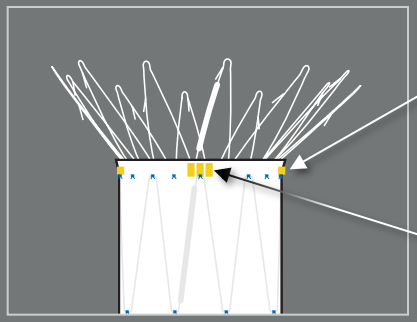
Note: To ensure patency of renal arteries, recognize that the proximal graft markers are 2 mm below the proximal edge of the graft material.

Radiographic Appearance

Four Positions of Gold Proximal Markers



2 mm from most proximal edge of graft material



Three positions have a single marker

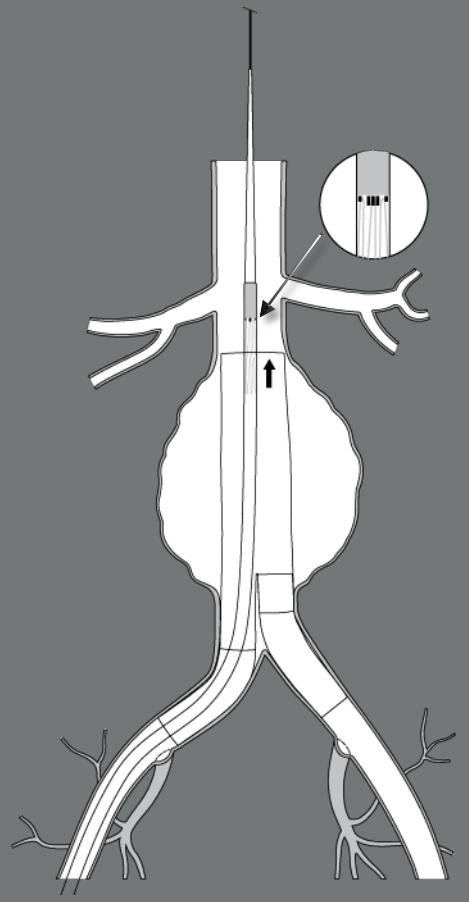
One position has a cluster of three markers to differentiate it from other components

Deployment

Main Body Extension

Step 2

- Verify position to ensure proper placement, sealing and overlap.
- Confirm the distal end of the Renu main body extension will provide at least one Cook-Z stent (17 or 22 mm) overlap in the aortic portion of the preexisting stent graft.

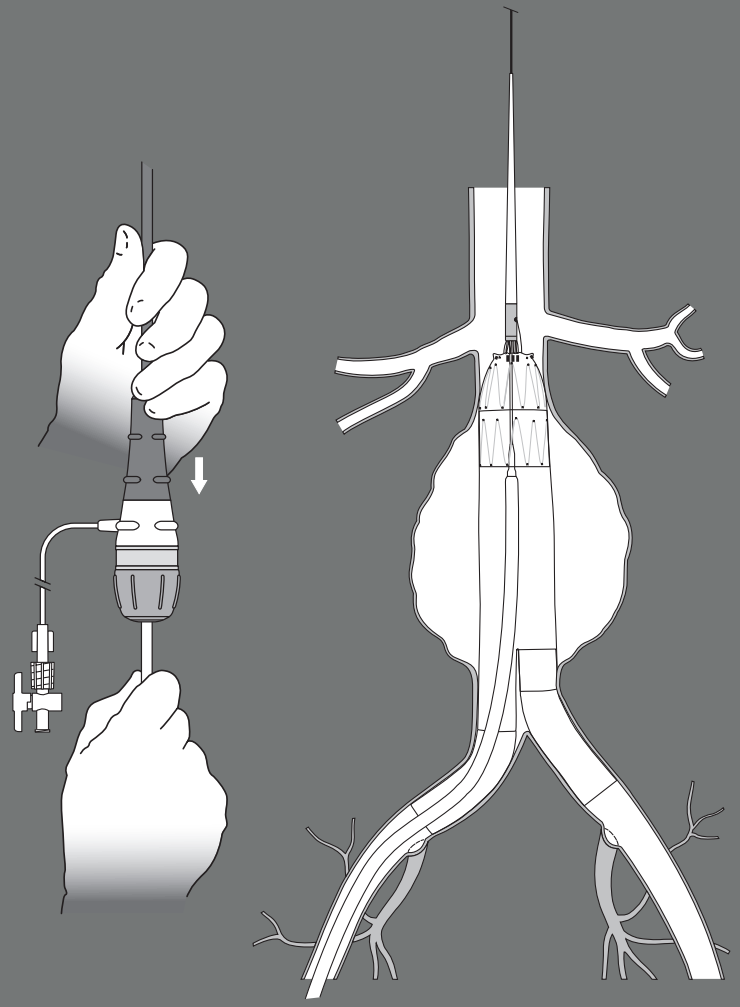


Deployment

Main Body Extension

Step 3

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

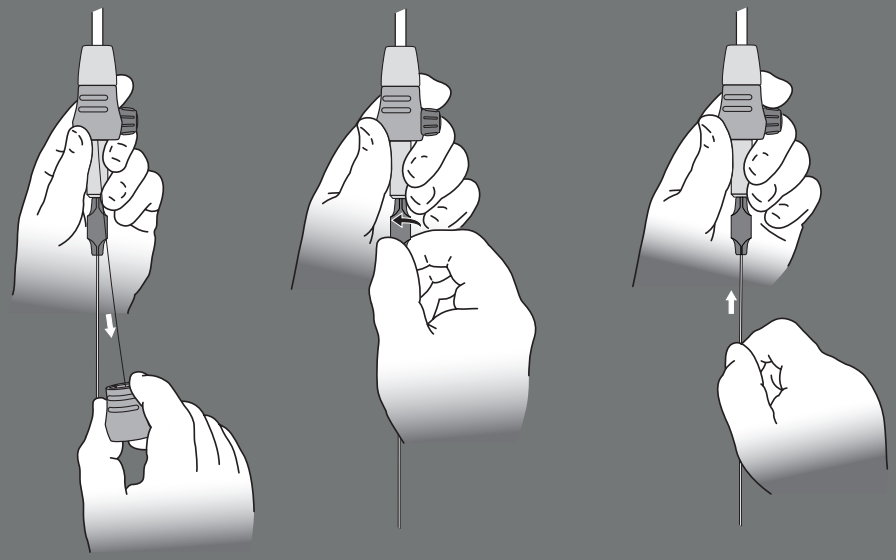


Deployment

Main Body Extension

Step 4

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

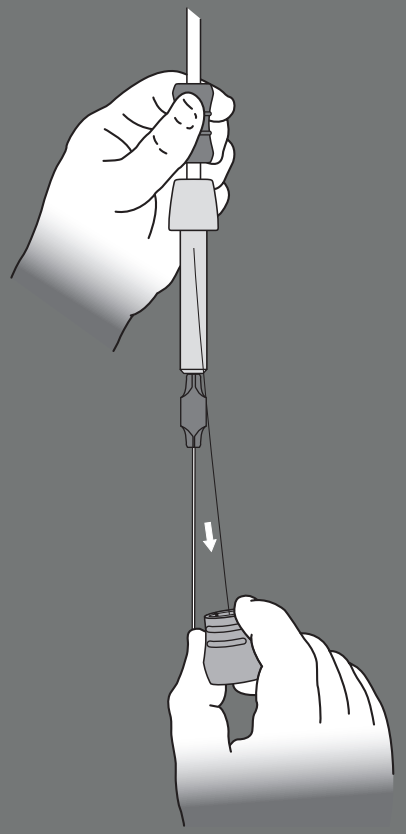


Deployment

Main Body Extension

Step 5

- Remove distal trigger-wire release mechanism.

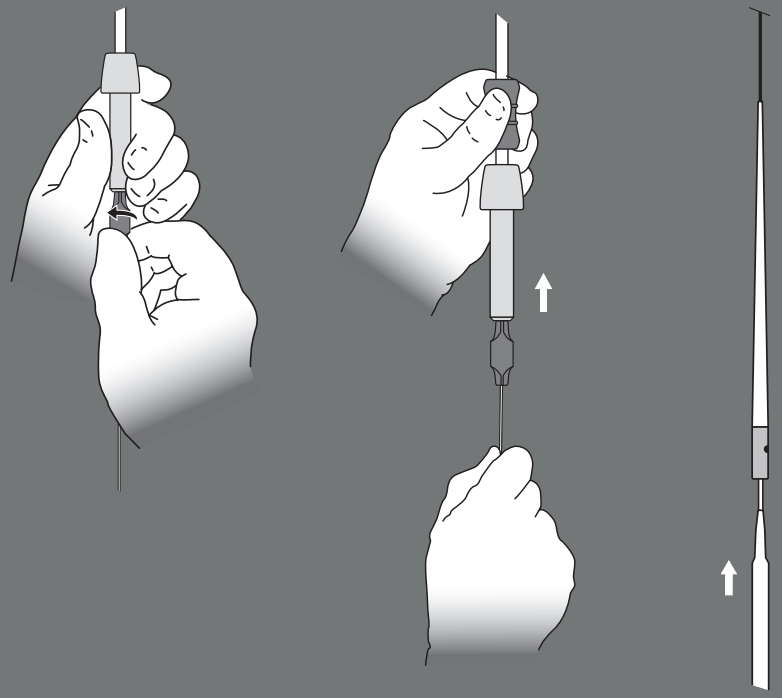


Deployment

Main Body Extension

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 main body extension delivery system.

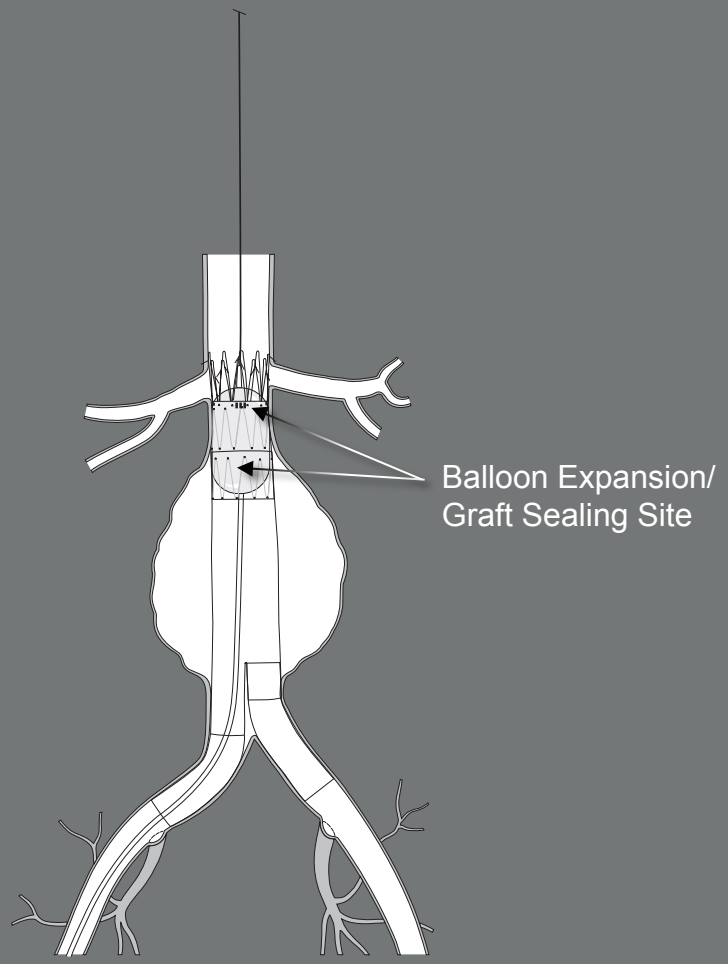


Deployment

Main Body Extension

Step 7

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



Deployment

Converter

Prior to use:

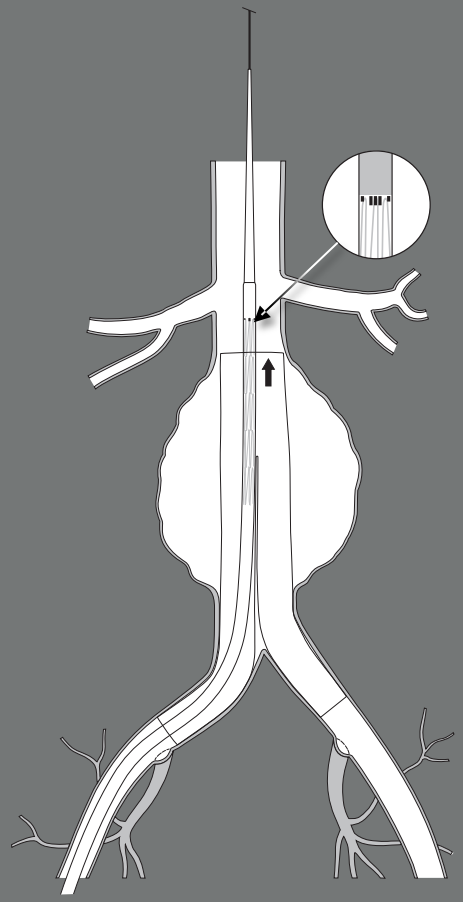
- Verify correct devices (quantity and size) have been supplied for the patient. Match the device to the prescribed order for each particular patient.
- Preparation for use is the same as the preparation for other Zenith components with which you are familiar.
- Activate hydrophilic coating on the Flexor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

Deployment

Converter

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.

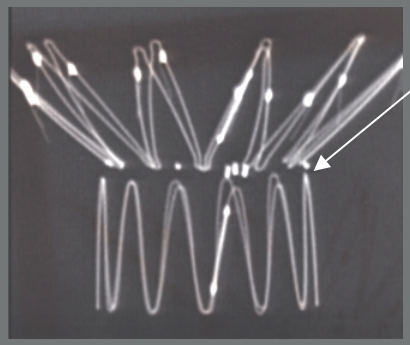


Radiopaque markers provide visibility of graft material position in relation to renal arteries.

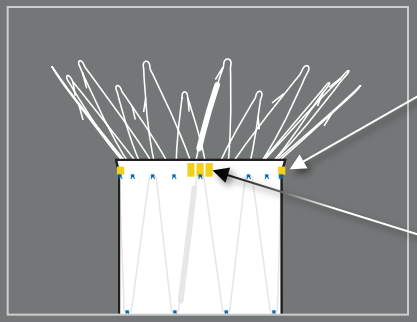
Note: To ensure patency of renal arteries, recognize that the proximal graft markers are 2 mm below the proximal edge of the graft material.

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

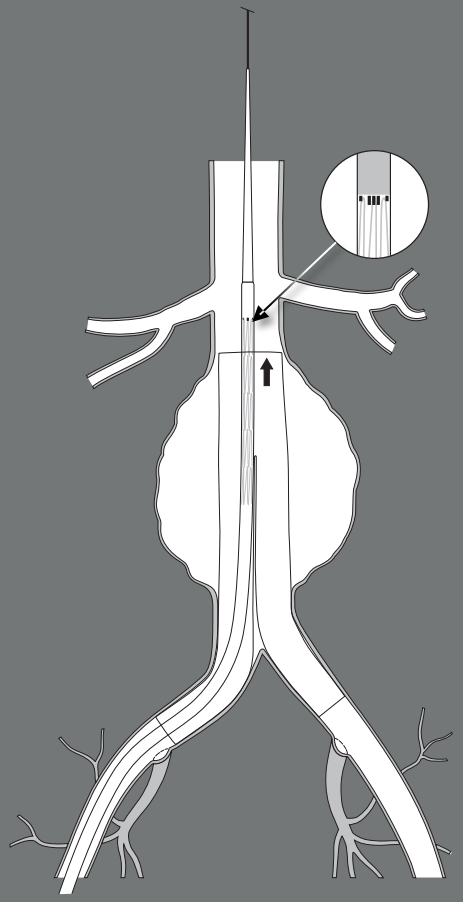
Deployment

Converter

Step 2

- Verify position to ensure proper placement, sealing and overlap.
- Confirm the distal end of the Renu converter 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 Renu converter is used with an iliac leg graft.

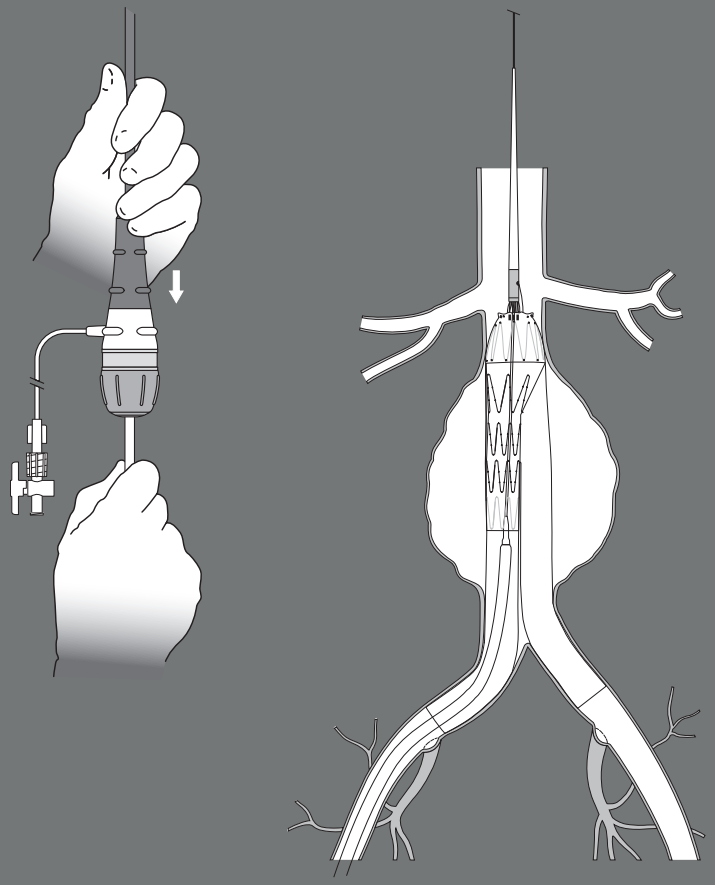


Deployment

Converter

Step 3

- Stabilize gray positioner and retract sheath to deploy the Renu converter.
- Deploy device until the most distal stent is uncovered.

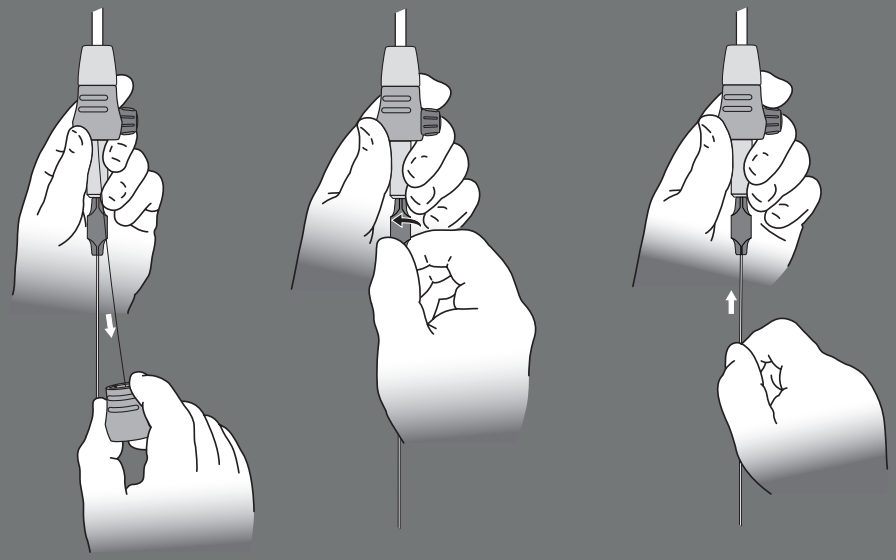


Deployment

Converter

Step 4

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

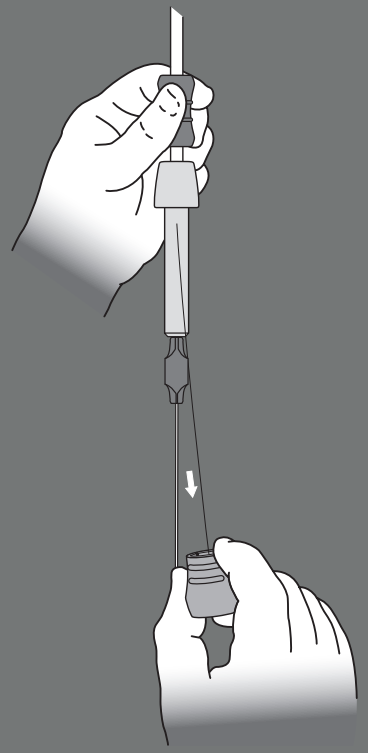


Deployment

Converter

Step 5

- Remove distal trigger-wire release mechanism.

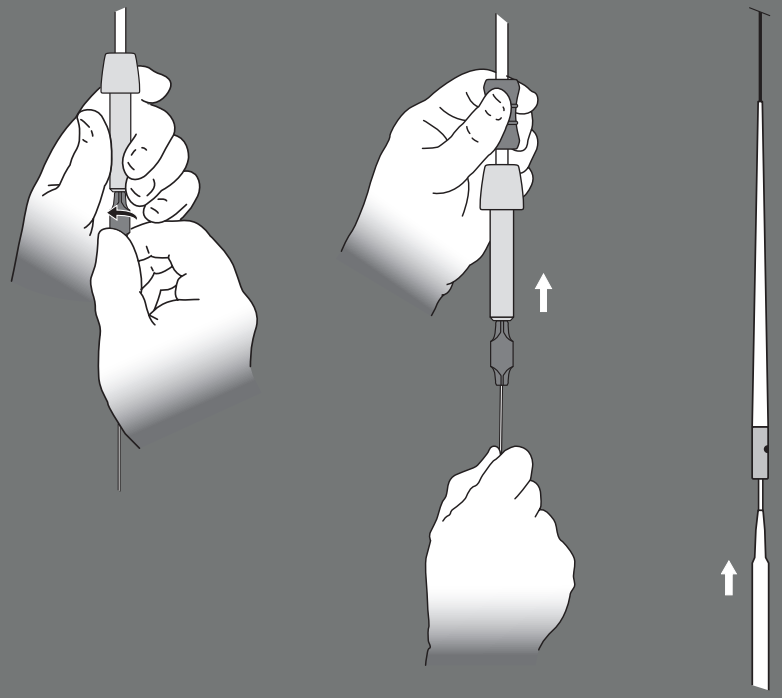


Deployment

Converter

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.

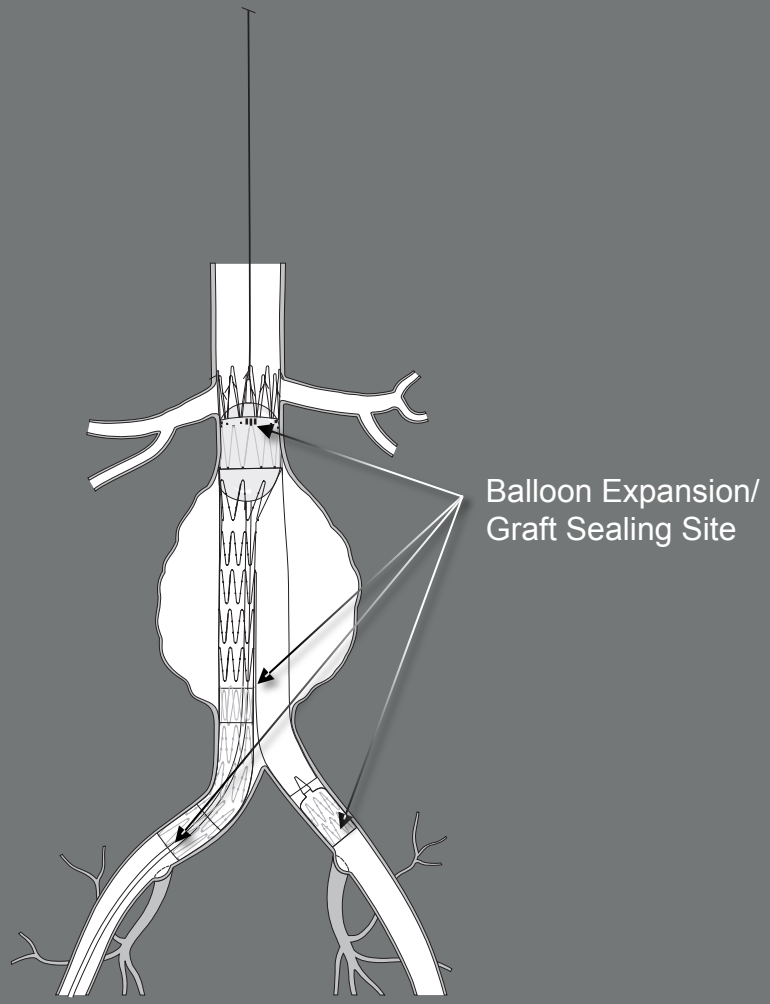


Deployment

Converter

Step 7

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

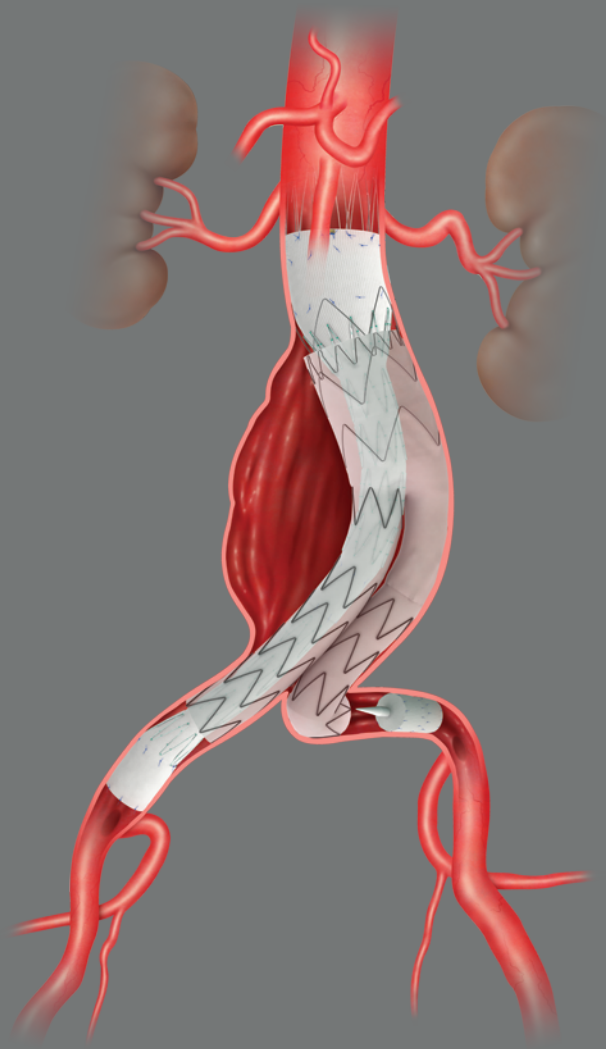


Deployment

Converter

- To aid in graft sealing, an iliac leg may be used to extend the Renu converter.
- Typically an occluder is used on the contralateral side.

For more information, please refer to the Zenith Renu AAA Ancillary Graft Instructions for Use.

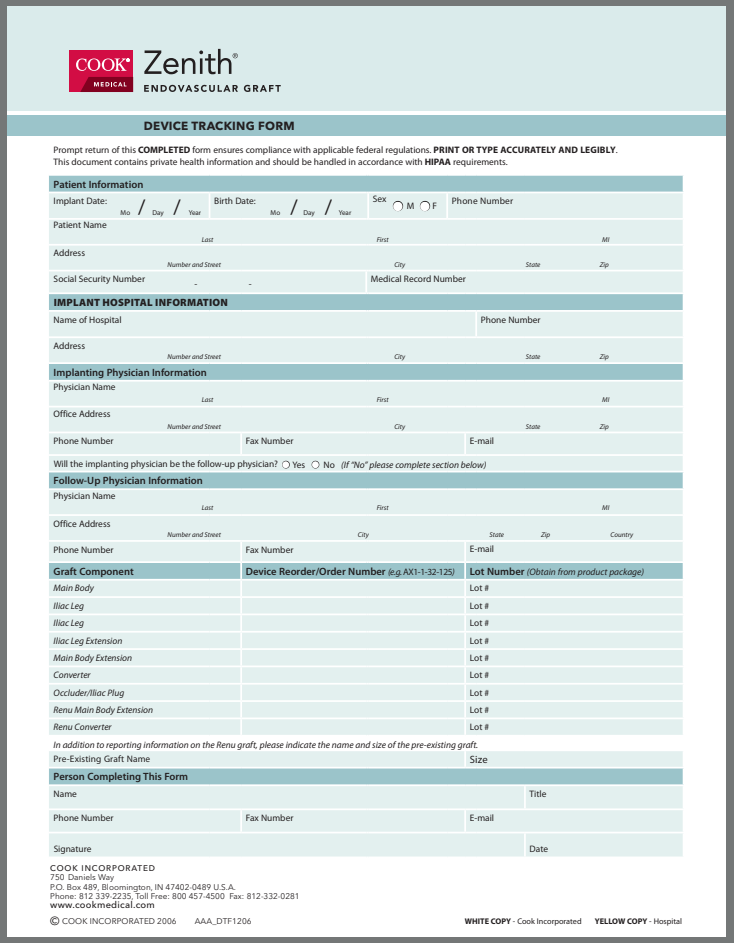


Patient Follow-Up

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Patient Tracking Information

- The Zenith Renu® AAA Ancillary Graft is packaged with a Device Tracking Form.
- As required by law, the hospital staff is to complete the form and return it to Cook Incorporated in the envelope provided.



COOK MEDICAL Zenith® ENDOVASCULAR GRAFT

DEVICE TRACKING FORM

Prompt return of this **COMPLETED** form ensures compliance with applicable federal regulations. **PRINT OR TYPE ACCURATELY AND LEGIBLY.**
This document contains private health information and should be handled in accordance with **HIPAA** requirements.

Patient Information

Implant Date: Mo / Day / Year | Birth Date: Mo / Day / Year | Sex ○ M ○ F | Phone Number

Patient Name: Last, First, MI

Address: Number and Street, City, State, Zip

Social Security Number - - | Medical Record Number

IMPLANT HOSPITAL INFORMATION

Name of Hospital | Phone Number

Address: Number and Street, City, State, Zip

Implanting Physician Information

Physician Name: Last, First, MI

Office Address: Number and Street, City, State, Zip

Phone Number | Fax Number | E-mail

Will the implanting physician be the follow-up physician? ○ Yes ○ No *(If "No" please complete section below)*

Follow-Up Physician Information

Physician Name: Last, First, MI

Office Address: Number and Street, City, State, Zip, Country

Phone Number | Fax Number | E-mail

Graft Component	Device Reorder/Order Number *(e.g. AX1-1-32-125)*	Lot Number *(Obtain from product package)*
Main Body		Lot #
Iliac Leg		Lot #
Iliac Leg		Lot #
Iliac Leg Extension		Lot #
Main Body Extension		Lot #
Converter		Lot #
Occluder/Iliac Plug		Lot #
Renu Main Body Extension		Lot #
Renu Converter		Lot #

In addition to reporting information on the Renu graft, please indicate the name and size of the pre-existing graft.

Pre-Existing Graft Name | Size

Person Completing This Form

Name | Title

Phone Number | Fax Number | E-mail

Signature | Date

COOK INCORPORATED
750 Daniels Way
P.O. Box 489, Bloomington, IN 47402-0489 U.S.A.
Phone: 812 339-2235, Toll Free: 800 457-4500 Fax: 812-332-0281
www.cookmedical.com

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WHITE COPY - Cook Incorporated **YELLOW COPY** - Hospital

Zenith Renu® — Restore graft-to-vessel fixation and seal.

Patient Identification Card

- The Zenith Renu AAA Ancillary Graft Instructions for Use include a Patient ID Card that should be completed and given to the patient.
- The completed card provides information concerning:
  - Type of device implanted
  - Date of implant
  - Implanting physician
  - Follow-up physician
  - MRI information
- Patients should be instructed to keep the card available at all times, to tell all of their healthcare providers that they have the graft, and to show them the card.

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 helping ensure the ongoing safety and effectiveness of endovascular treatment.
- Subsequent reinterventions, including catheter-based and open surgical conversion, are possible following endovascular graft placement.
- Patients receiving the Zenith Renu AAA Ancillary Graft should receive enhanced follow-up.

Recommended Imaging Schedule

	CT (Contrast and Noncontrast)	Abdominal Radiographs
Predischarge (within 7 days)	X[1,2,3]	X
1 month		X
3 month	X[1,2,3] if endoleak at previous CT	
6 month	X[1,3]	X
12 month (annually thereafter)	X[1,3]	X

[1]Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast-enhanced CT scan. With ultrasound, noncontrast CT still recommended.

[2]Either predischarge or 1 month CT recommended.

[3]If type I or III endoleak, prompt intervention and additional follow-up post intervention recommended. (See Section 12.6 of Instructions for Use.)

COOK® MEDICAL

Zenith Renu®

AAA ANCILLARY GRAFT

Transcend: Precision

Going beyond. That’s what it means to Transcend.
That’s the essence of Zenith.