COOK® MEDICAL

Zenith Flex®

AAA ENDOVASCULAR GRAFT

Transcend: Precision

Device Description

(includes Spiral-Z™ AAA Iliac Leg and Z-Trak® Introduction System)

Flex Design

Increased gap length between the z-stents on the proximal segment of the main body designed to provide greater conformance to angulated anatomy.

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

Unique Stent-Graft Design

Graft flexibility

- 5 mm gaps between the first and second stent and second and third stent on main body
  - Diameters 22-32 mm
- 6 mm gaps between the first and second stent and second and third stent on main body
  - Diameters 36 mm
- Secure graft-to-vessel apposition
- Dimensional stability

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Unique Stent-Graft Design

- Independent z-stent configuration provides graft flexibility.
- Modular stent-graft construction allows unique adaptability to individual anatomy.
- Varied z-stent lengths and gage diameters promote secure graft-to-vessel apposition, columnar strength and graft flexibility.

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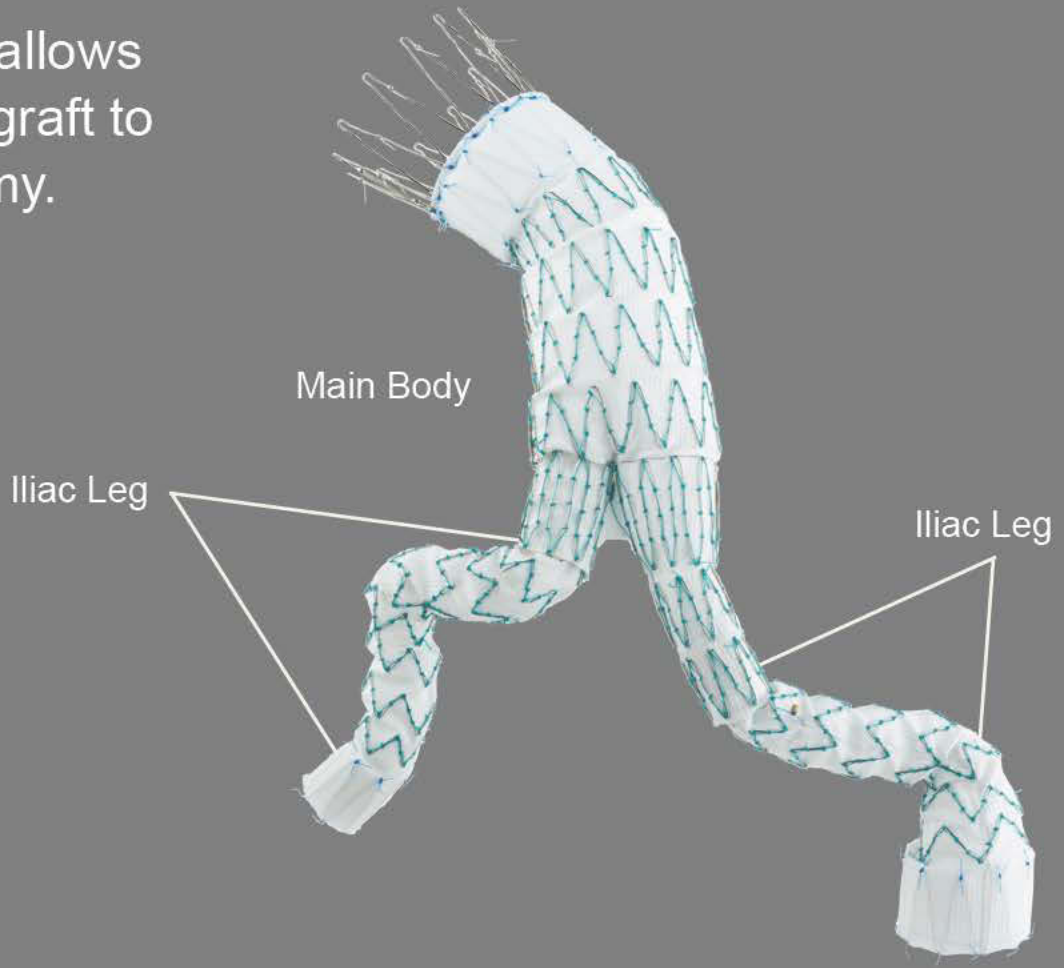
Modular Design

Three-piece modular system allows the physician to customize a graft to the patient's individual anatomy.



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

A Name with Built-In Meaning

- ARC Technology™ is the name for Zenith® AAA's unrivaled systemic migration resistance:

  Active fixation,

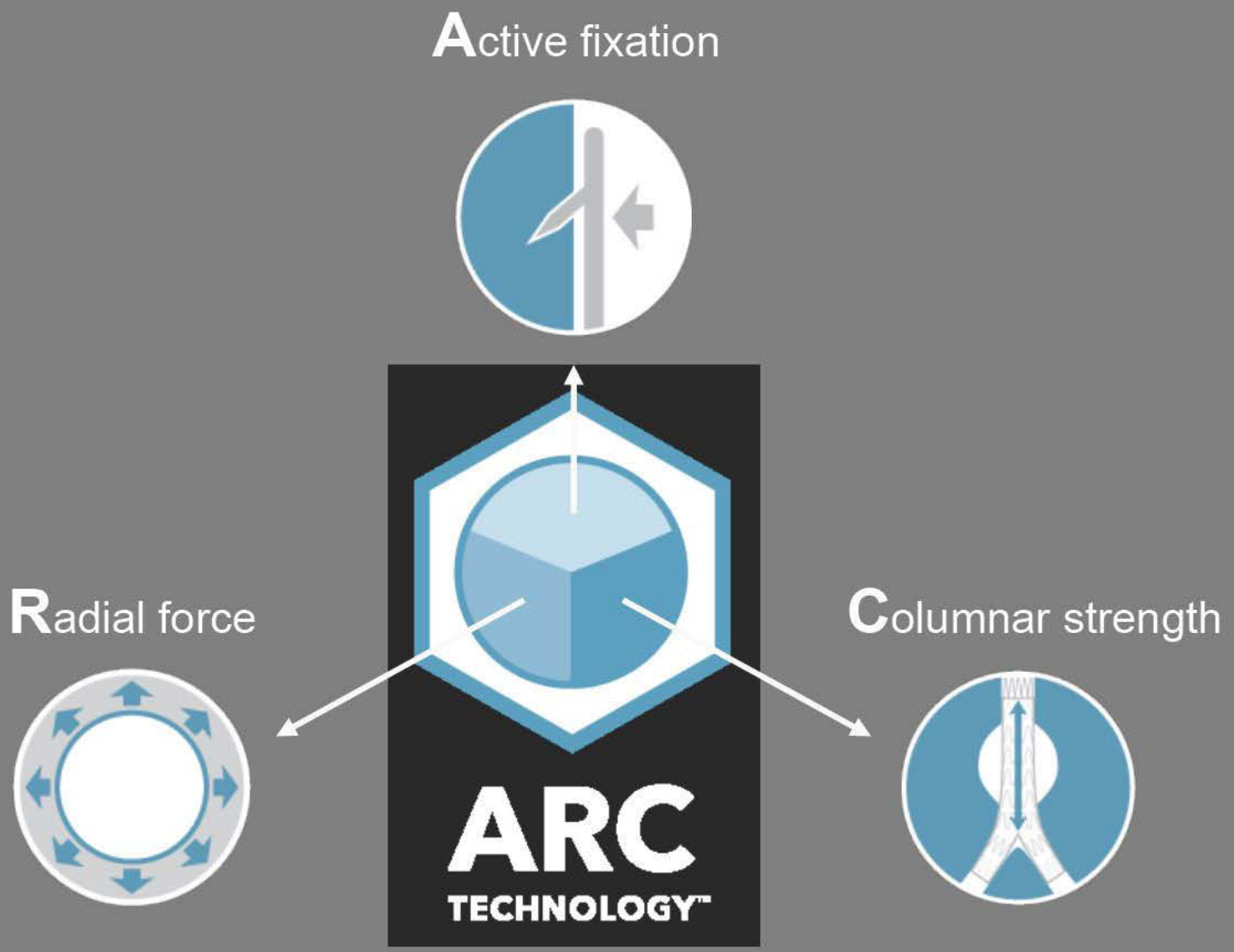
  Radial force and

  Columnar strength…working in unison.

- Only Zenith AAA grafts have ARC Technology.
- Another example of Zenith AAA *precision*.

ARC TECHNOLOGY™

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



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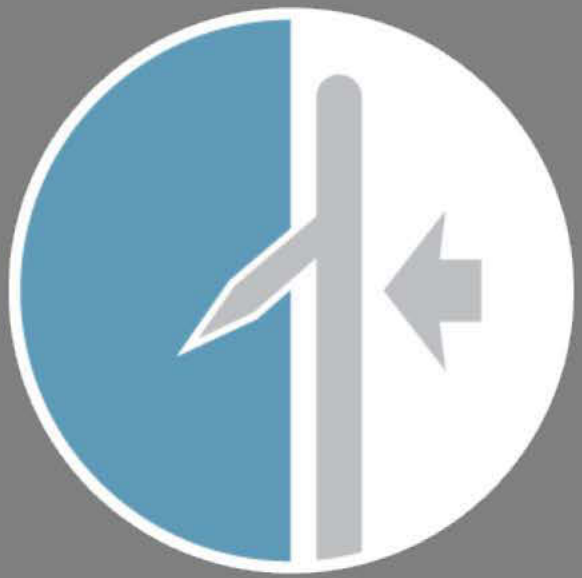
Active Fixation

Anchoring Barbs

The angle, staggered configuration and beveled tip of our barbs make them the industry standard for design and migration resistance.



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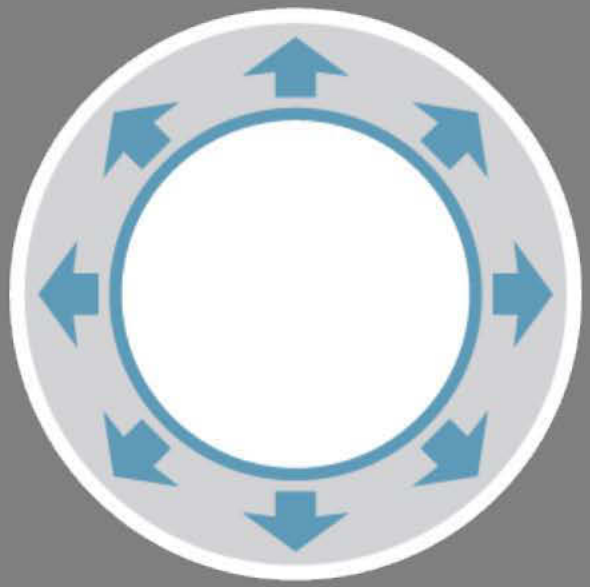
Radial Force

Self-Expanding Internal Z-Stents

Provide continuous radial force, added stability and optimal graft-to-vessel apposition.



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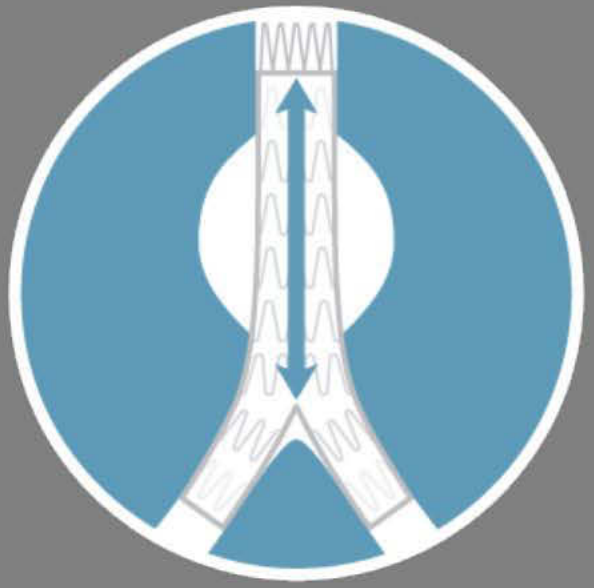
Columnar Strength

Long Main-Body Design

Mimics natural anatomy and features a time-tested balance of length, stability and flexibility.



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

Woven Polyester

- A lightweight, strong, shrink- and stretch-resistant synthetic polymer used in both plastics and fibers.
- This material is also used for open surgical AAA procedures.

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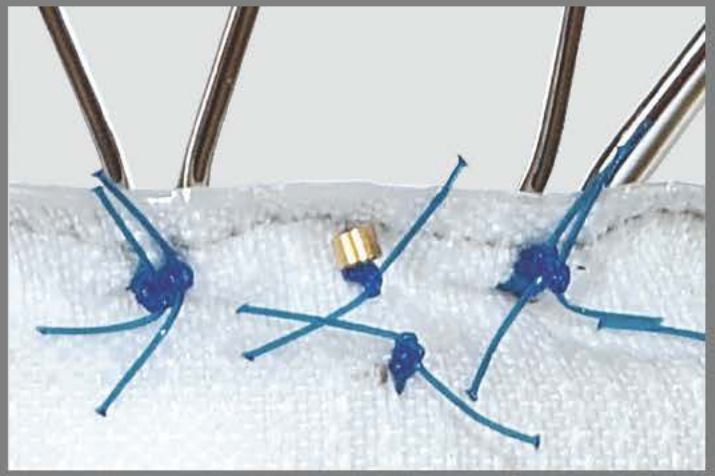
Proximal Gold Radiopaque Markers

- Four gold markers (2 mm from the most proximal segment of the graft material) identify the most proximal segment of the graft material.



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

Contralateral Limb Gold Radiopaque Marker

- Gold check mark (✓) identifies proper contralateral limb orientation, simplifying contralateral limb wire-guide access.

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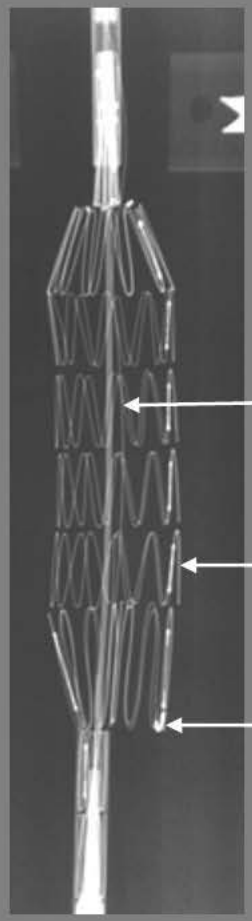
Precise Placement

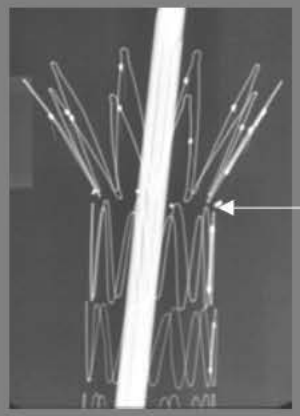


Highly Visible Z-Stents

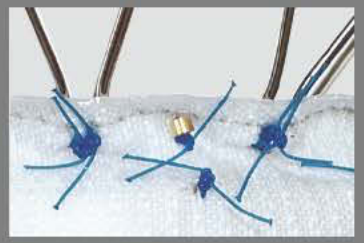
Radiopaque Cannulas

Contralateral Limb Gold Marker

Contralateral limb "check mark"



4 Gold Proximal Markers
2 mm from most proximal segment of graft material



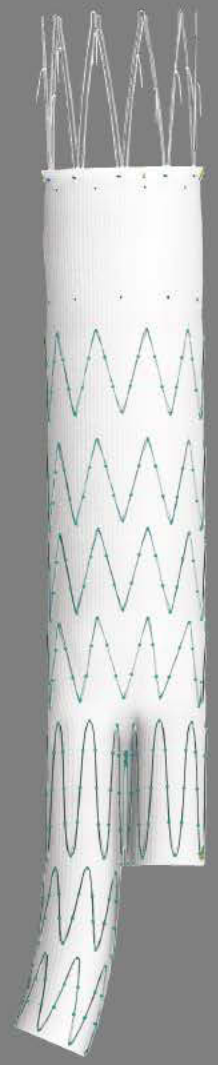
Zenith Flex® — Insist on precise placement and unrivaled migration resistance.

Low Iliac Attachment

- Extended main body with low iliac graft bifurcation provides longitudinal/columnar strength and simplifies cannulation of the contralateral limb.

Bifurcated Main Body Dimensions

- Graft Diameters: 22-36 mm
- Graft Lengths (Contralateral): 82-149 mm



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

Z-Trak® Introduction System with Flexor® Introducer Sheath

- Unique sheath construction provides optimal flexibility and maximum resistance to kinking and compression.
- Radiopaque band incorporated within sheath material identifies precise location of sheath's distal tip for positioning accuracy.
- Hydrophilic coating allows precise delivery by dramatically reducing surface friction.

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

Captor® Hemostatic Valve

- The Captor Hemostatic Valve is incorporated into all main-body and iliac-leg introducer systems.
- Unique design inhibits blood reflux.

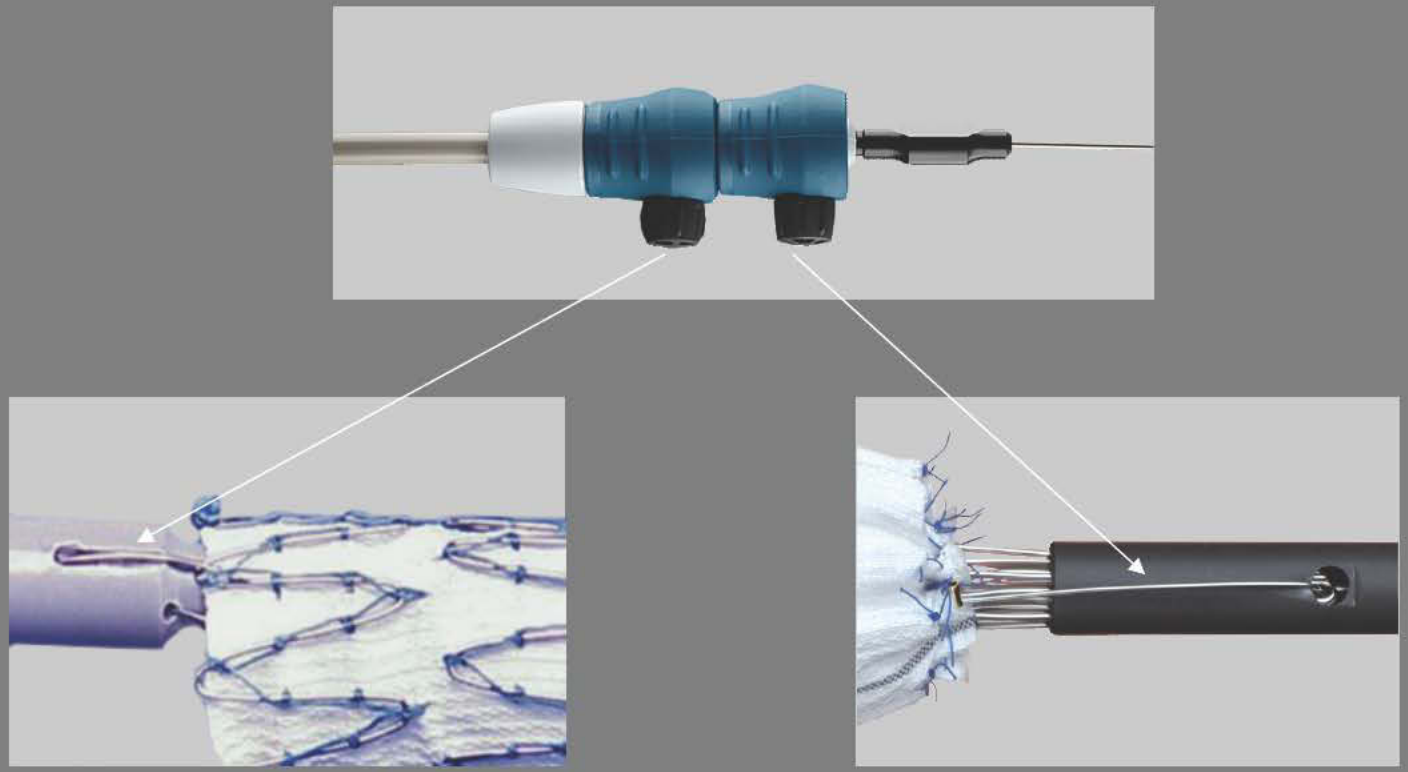
Zenith Flex® — Insist on precise placement and unrivaled migration resistance.

Trigger-Wire Release Mechanisms

- The top stent and ipsilateral limb release knobs are attached to their respective trigger wires and are used when the device is ready to be released from the delivery system. Sequential release knob positioning simplifies the deployment process.

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

Trigger Wires: The Secret to Precision Deployment



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Dilator Tip

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

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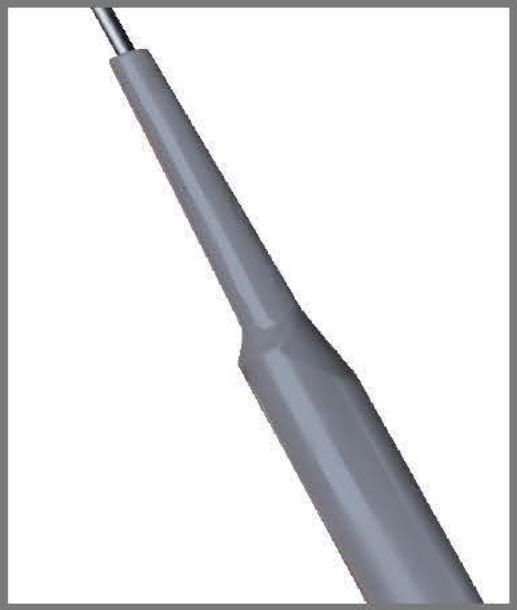
Gray Positioner

- The proximal tip of the gray positioner is tapered, which facilitates postdeployment retrieval of the top cap.
- The ipsilateral limb is attached to the proximal tip of the gray positioner and can only be released after it has been unsheathed and the distal trigger-wire release mechanism has been removed.



Inner Cannula

Inner cannula provides
over-the-wire trackability.

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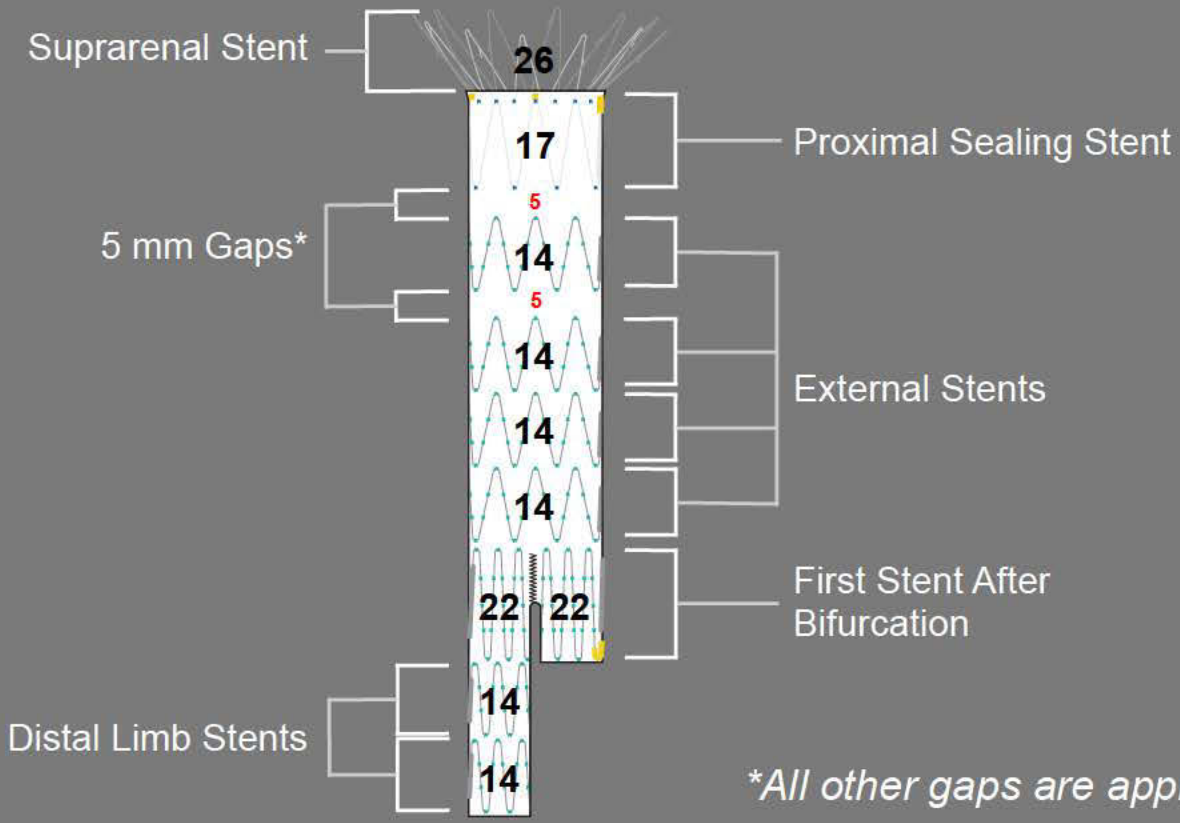
Trigger-Wire Attachment

The proximal uncovered z-stent is housed within the top cap of the introduction system and secured with the trigger wire.

The trigger wire facilitates:

- Stabilization of the endovascular graft during deployment
- Controlled release of the graft from the delivery system
- Graft manipulation even when the graft is semi-deployed

Stent Lengths – Main Body 22-32 mm



**All other gaps are approximately 2-3 mm.*

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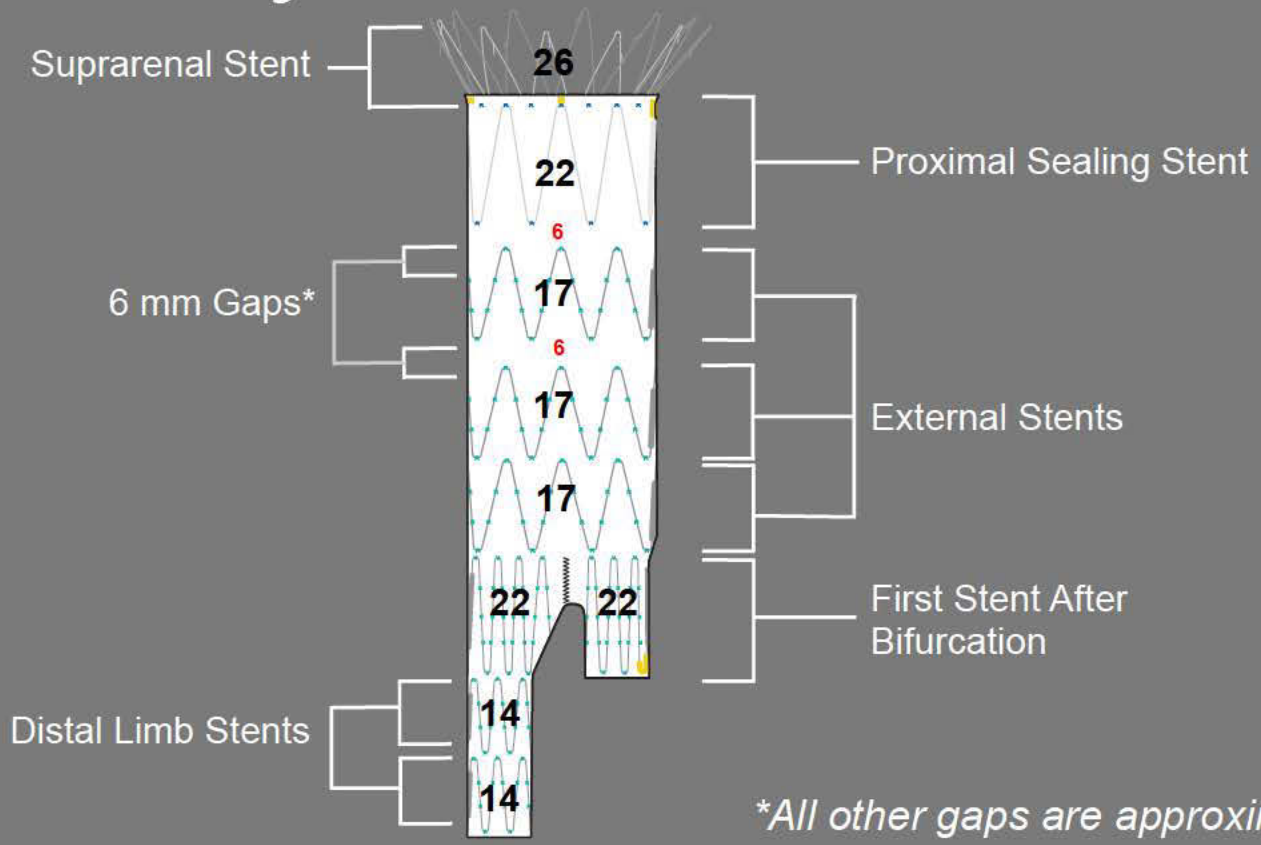
Stent Lengths – Main Body 36 mm



*All other gaps are approximately 2-3 mm.

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Zenith Spiral-Z™ AAA Iliac Leg

- Increased leg flexibility and kink resistance*
- Enhanced delivery system
- Increased radial force at proximal sealing site*
- External stent made of a continuous nitinol wire

**Data on file*

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Spiral-Z AAA Iliac Leg Dimensions

- Leg Diameters: 9-24 mm
- Leg Lengths: 39-122 mm

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Flexor Introducer Sheath

Spiral-Z

- The Flexor Introducer Sheath has a hydrophilic coating to enhance system trackability.

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Flexor Introducer Sheath

- Introducer sheath for iliac legs is 71 cm
- Introducer sheath plus valve length for iliac legs is 82 cm
- Iliac leg diameter 9-16 mm in 14 Fr sheath
- Iliac leg diameter 20-24 mm in 16 Fr sheath

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Spiral-Z External Stent Lengths and Gaps

- The strut lengths in the external spiral stent vary from 7.5-9.5 mm
- Gapping can vary from 4-8 mm over the length of the leg graft
- Both internal sealing stents are made of stainless steel

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Spiral-Z Stent Overlaps

Contralateral Iliac Leg (cl)

- Overlap into the *main body* should be a minimum of one stent and a maximum of 30 mm, designated by the gold radiopaque marker.

Ipsilateral Iliac Leg

- Overlap into the *main body* should be a minimum of one stent and a maximum of 55 mm.

Diameters 22-32 mm

Main Body

cl Length (mm)

82, 96, 111, 125, 140

18 Fr Z-Trak Introduction System

Diameter (mm)

22, 24, 26

20 Fr Z-Trak Introduction System

Diameter (mm)

28, 30, 32

5 lengths, 6 diameters, 30 sizes of main bodies

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36 mm Device

Main Body

cl Length (mm)

95, 113, 131, 149

22 Fr Z-Trak Introduction System

Diameter (mm)

36

36 mm *main body* is available in 4 lengths.

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Spiral-Z Legs Sizing Guide

Intended Iliac Vessel Diameter mm	Iliac Leg Diameter mm	Iliac Leg Working Length mm	Introducer Sheath Fr
≤ 8	9	39,56,74,90,107,122	14
9	11	39,56,74,90,107,122	14
10-12	13	39,56,74,90,107,122	14
13-15	16	39,56,74,90	14
16-18	20	39,56,74,90	16
19-20	24	39,56,74,90	16

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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 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 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 non-contrast 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 followup recommended.

4 Recommended if endoleak reported at predischarge or 1 month.

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Transcend: Precision

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