# Device description

## Zenith® Dissection

ENDOVASCULAR GRAFT AND STENT

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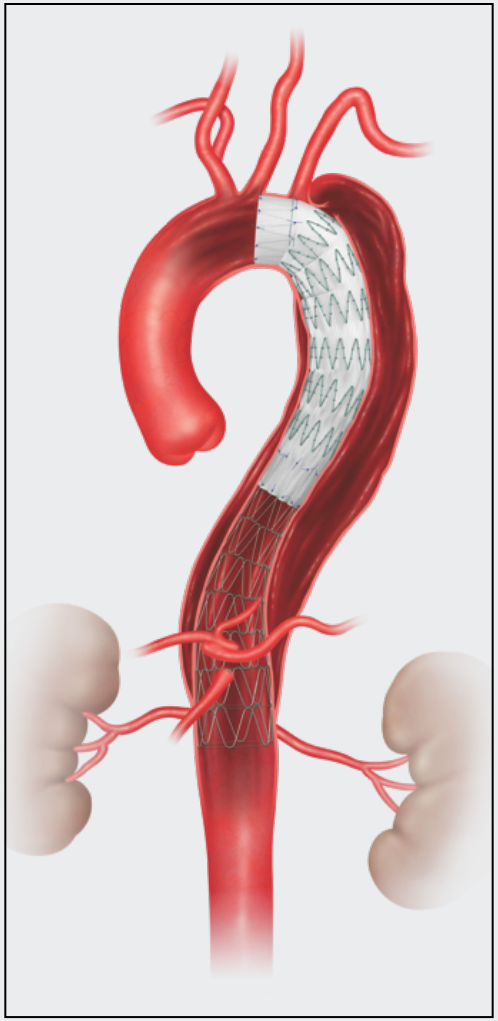
# Zenith® Dissection

Zenith® TX2® Dissection Endovascular Graft with Pro-Form® (ZDEG) and Z-Trak Plus Introduction System

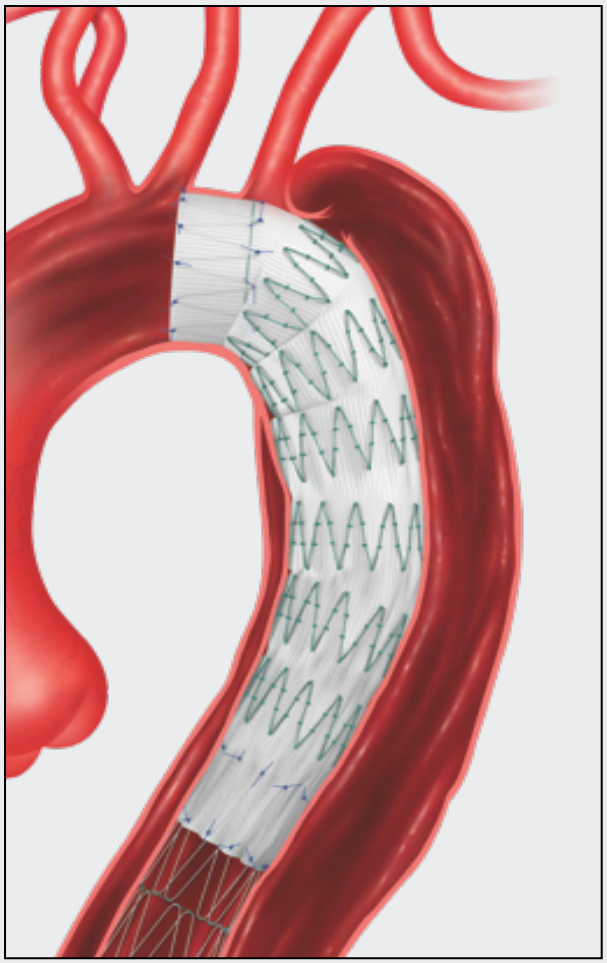
Zenith® TX2® Dissection Endovascular Stent (ZDES) and Z-Trak Plus Introduction System



# Control procedure

TX2 Dissection Graft

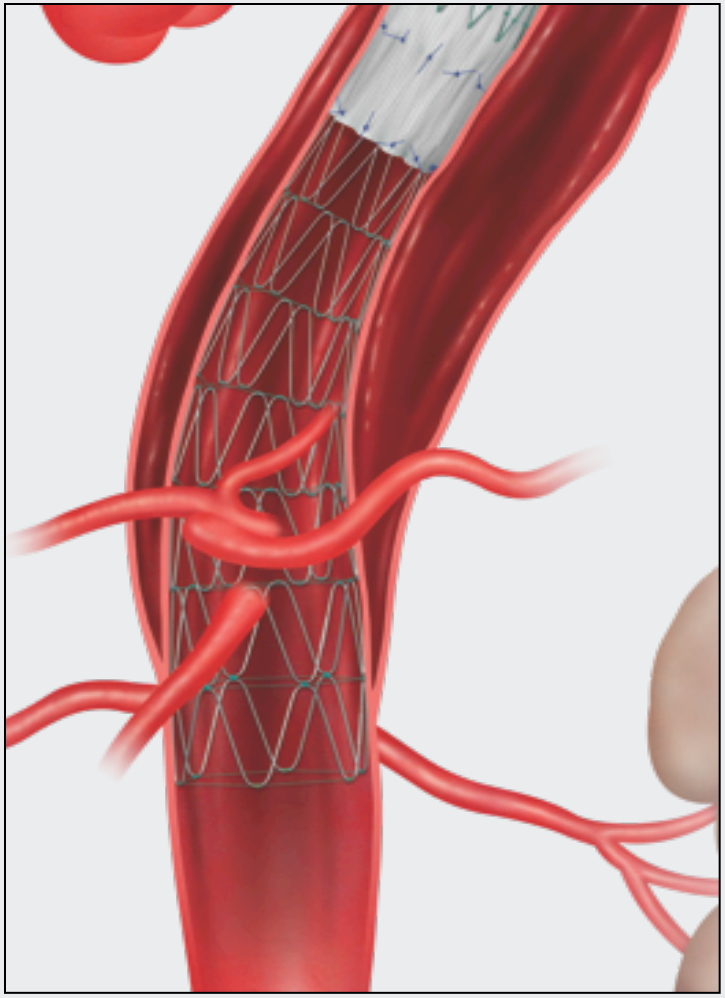
- Designed to:
  - Seal a primary entry tear
  - Depressurize the false lumen and induce false-lumen thrombosis



# Control procedure

Zenith Dissection Stent

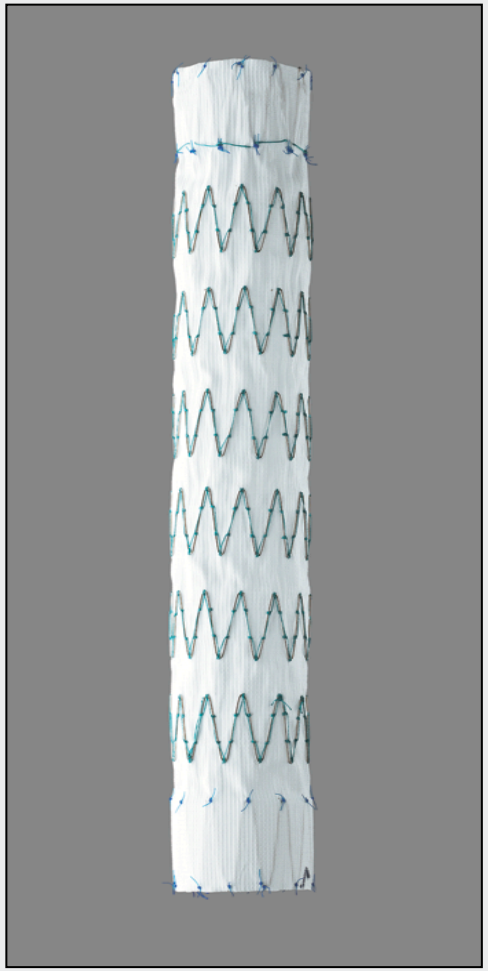
- Designed To:
  - Reinforce the true lumen
  - Maintain perfusion of the branch vessels



# Control design

Nontapered component

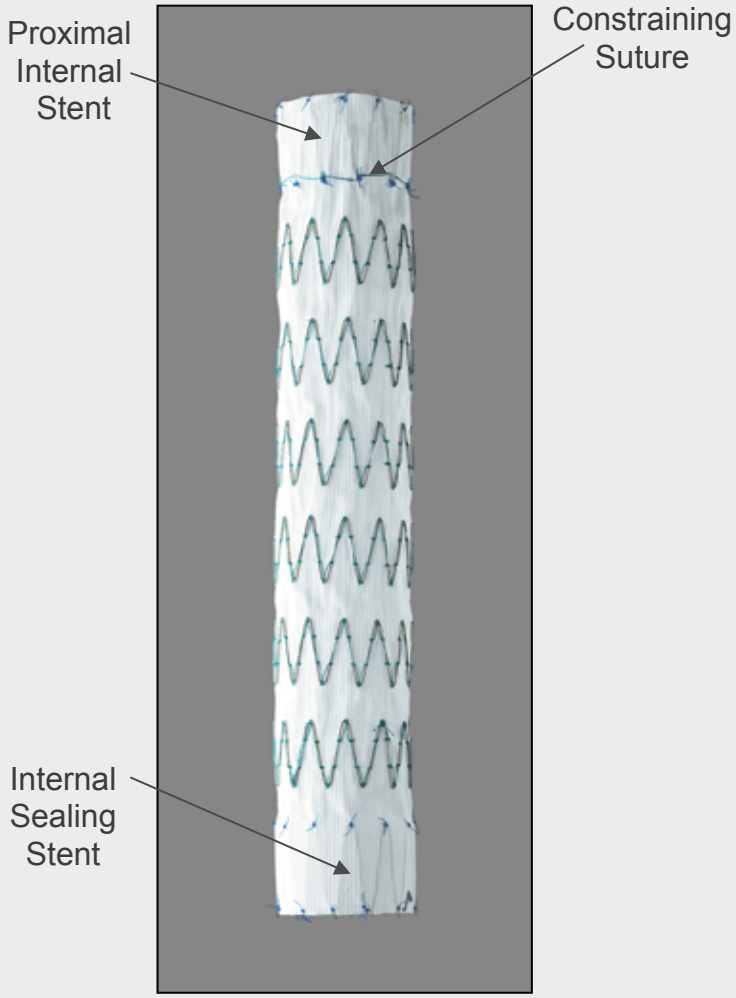
- Proximal sealing stent with no barbs
- Sealing stent dimensions
  - .018 and .020 inch diameter wire guides
  - 17 and 22 mm length, respectively
- Body stents
  - .014 and .016 inch diameter wire guides
  - 14 and 17 mm length, respectively



# Control design

Nontapered component

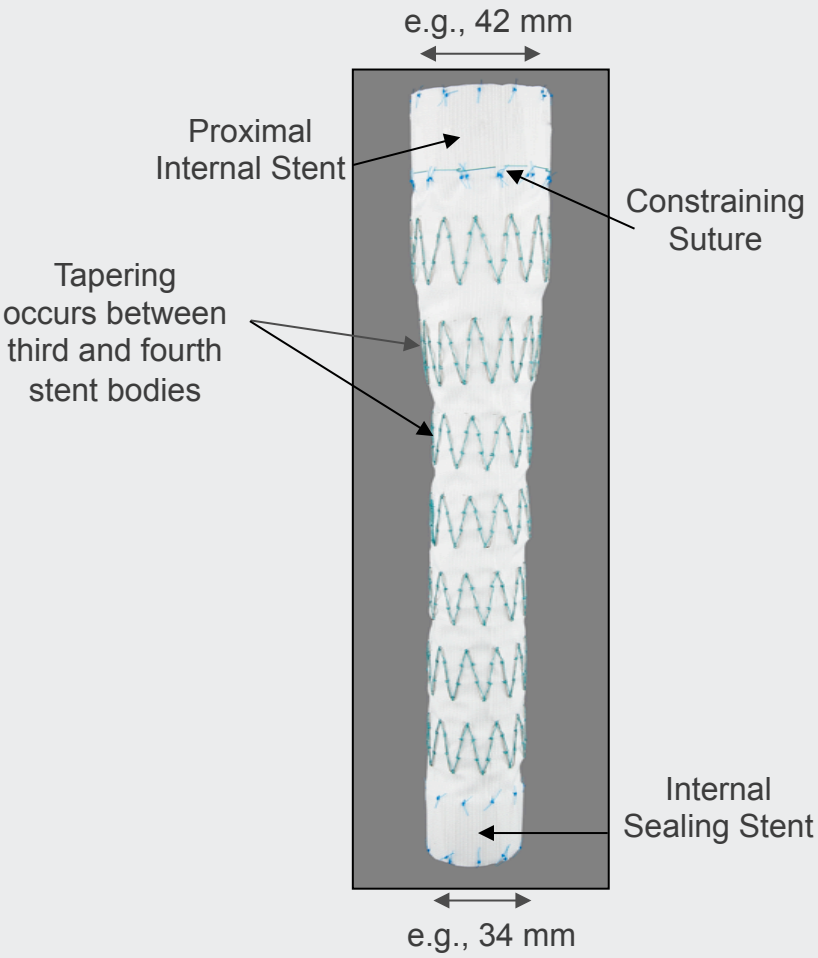
| Lengths mm | Diameters mm |
|---|---|
| 22, 24 | 79, 117 |
| 26 | 79, 136 |
| 28, 30, 32 | 82, 142, 202 |
| 34, 36, 38 | 79, 154, 204 |
| 40, 42 | 83, 164, 218 |



# Control design

Proximal tapered component

| Lengths mm | Diameters mm |
|---|---|
| 8 mm taper | |
| 158, 196 | 32/24 |
| 156, 194 | 34/26 |
| 159, 199 | 36/28, 38/30 |
| 165, 205 | 40/32 |
| 160, 210 | 42/34 |

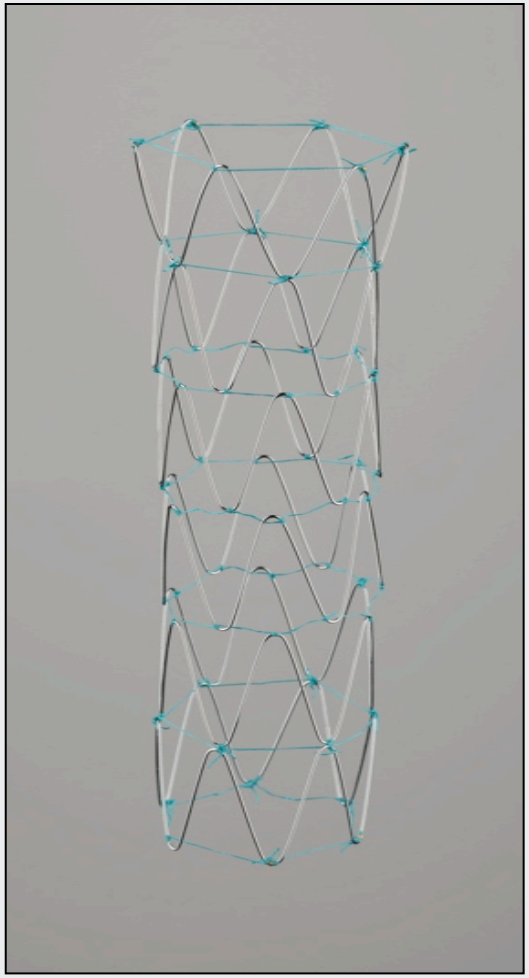


# Control design

Zenith Dissection Endovascular Stent

- Nitinol Z-stents
- Monofilament sutures

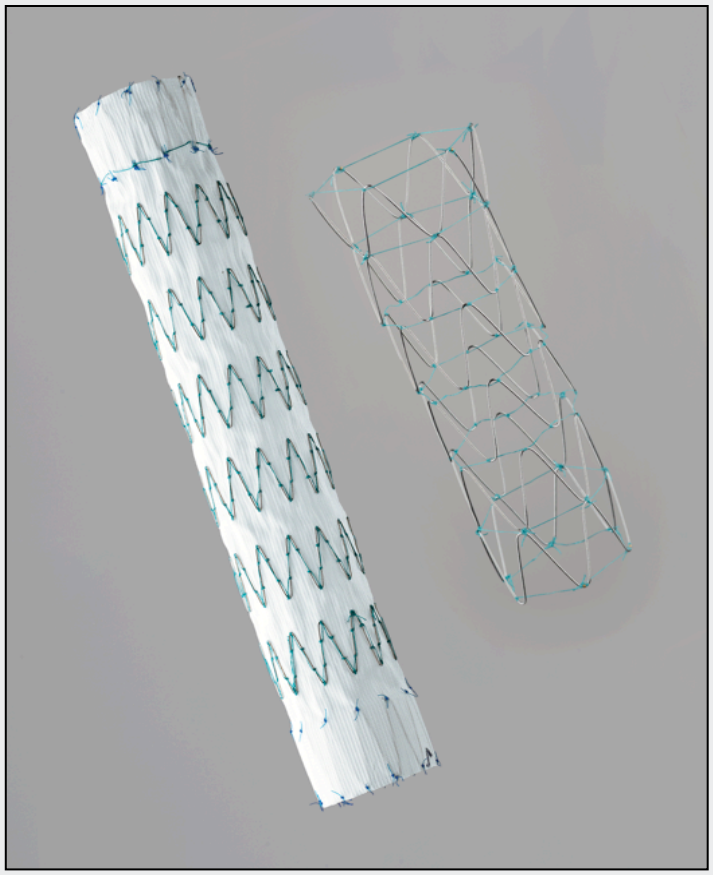
| Lengths mm | Diameters mm |
|---|---|
| 80, 120, 180 | 36 |
| 80, 120, 185 | 46 |



# Control design

Zenith Dissection Endovascular Stent

- 36 mm stent compliments the Zenith 22-34 mm proximal component
- 46 mm stent compliments the Zenith 36-42 mm proximal component



# Control design

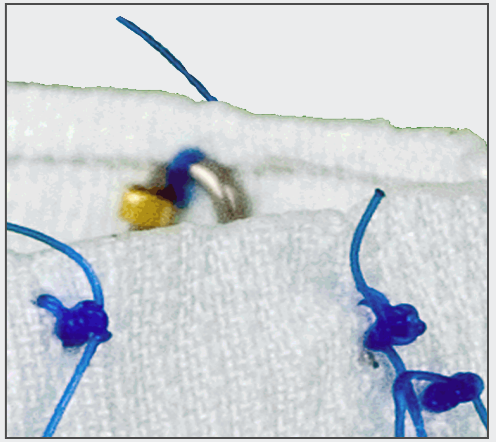
Woven polyester

- Lightweight, strong, shrink-/stretch-resistant woven polyester is used in both the plastics and fibers.
- Porosity is 350 mL/min/$cm^2$
- Historically used for open surgical, TAA, and AAA repairs
- Suture material
  - Green, braided polyester
  - Blue, monofilament polypropylene

# Control design

Radiopaque markers

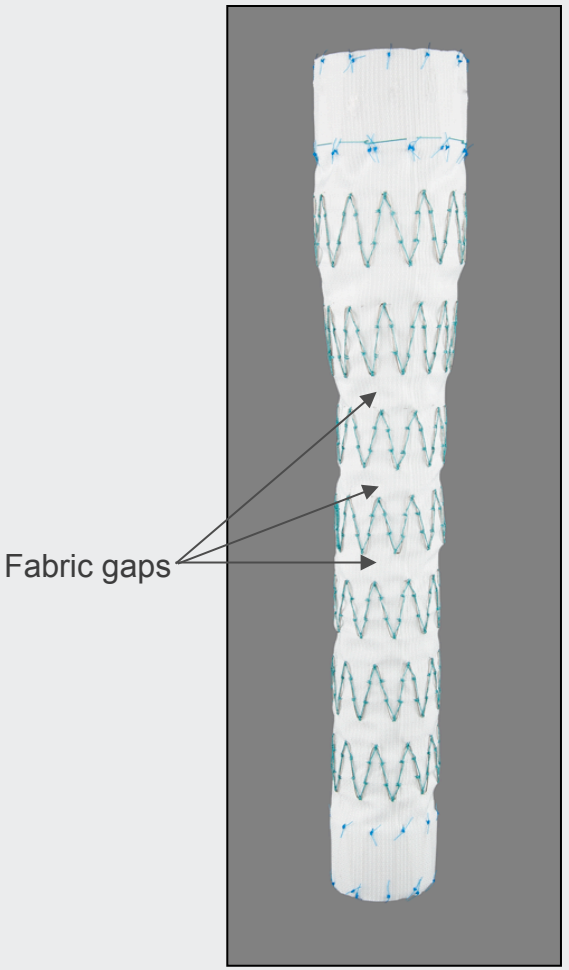
- Four gold markers, placed 1 mm from all proximal and distal aspects of the graft.
- Denotes the edges of the graft material to assist in deployment accuracy.



# Control design

Fabric gaps

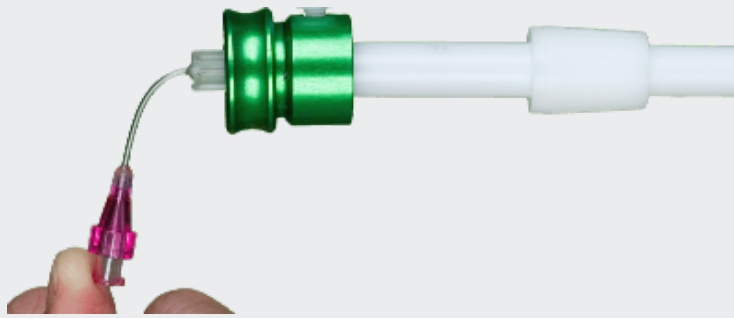
- 5 mm
  - Graft diameters of 22-26 mm
- 6 mm
  - Graft diameters of 28-32 mm
- 8 mm
  - Graft diameters of 34-38 mm
- 10 mm
  - Graft diameters of 40-42 mm



# Control delivery

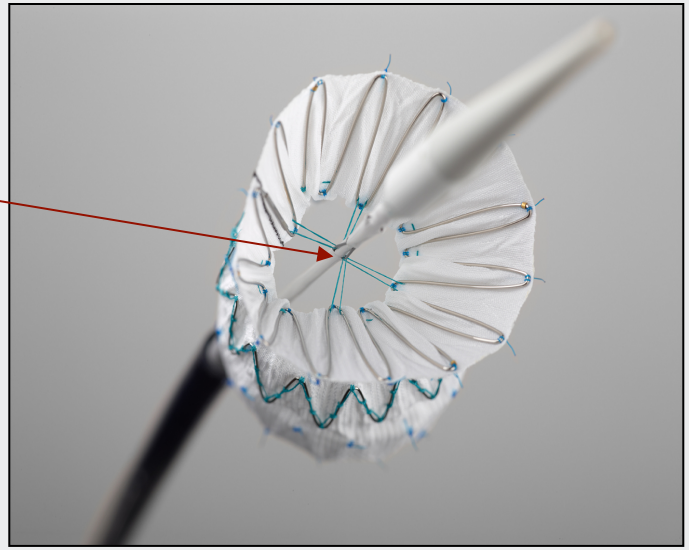
Z-Trak Plus® Introduction System

- Flexor® sheath with hydrophilic coating and radiopaque band
  - 22-34 mm = 20 Fr (7.7 mm) OD
  - 36-42 mm = 22 Fr (8.5 mm) OD
  - 72 cm usable length
- Inner cannula made of a superelastic alloy
- Captor® Hemostatic Valve



# Control delivery

- The Pro-Form® tethers on the distal end of the proximal sealing stent allow for better proximal conformity



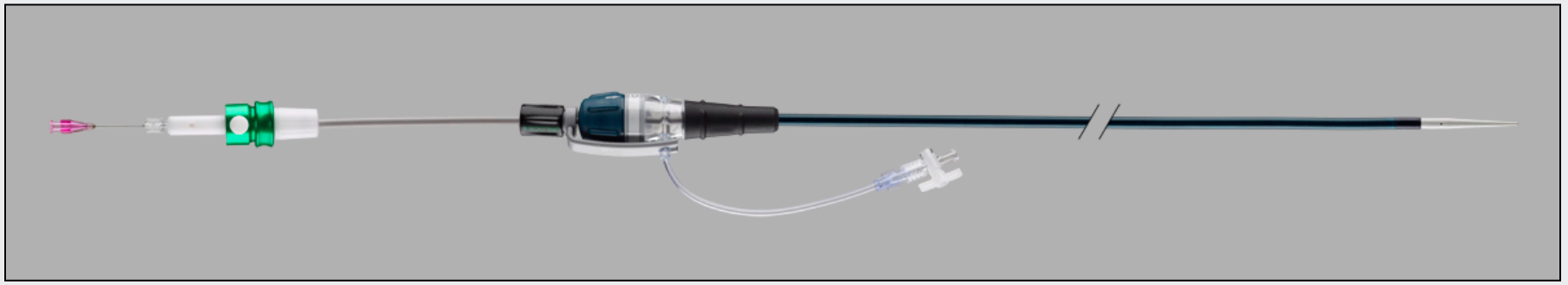
# Control delivery

Safety trigger wires

- Three trigger wires hold the proximal end closed. All are connected to a single green knob or trigger-wire release mechanism.
- One trigger wire holds the distal end (it releases when pulled completely out) and is also connected to the green trigger-wire release mechanism.

# Zenith Dissection Endovascular Stent

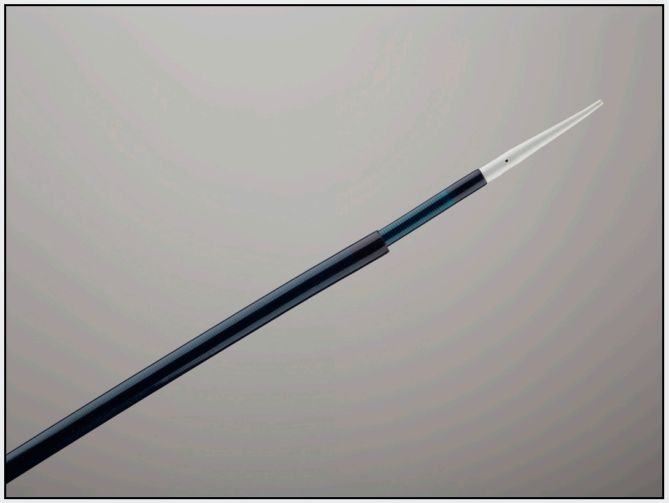
- Flexor® sheath with hydrophilic coating and radiopaque band
  - 16 Fr (5.3mm) ID/6mm OD, 100 cm long
  - Inner cannula made of a superelastic alloy
  - Captor® Hemostatic Valve
  - Anti-torque device

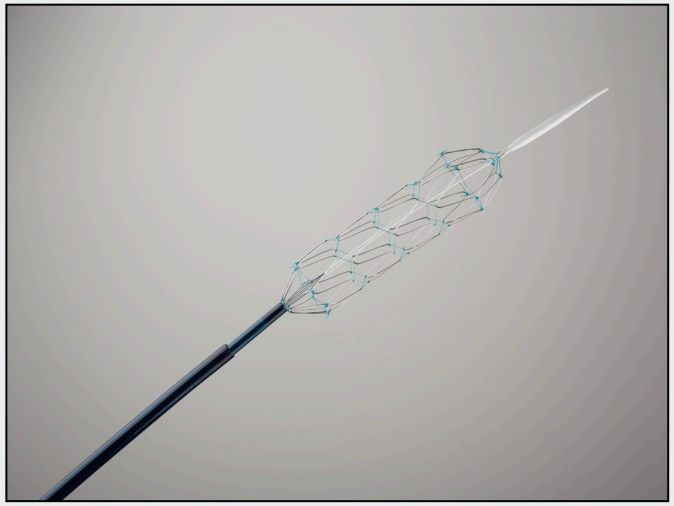


# Control delivery

Coaxial introduction

- Once deployed, the sheath from the Zenith® TX2® Dissection Endovascular graft with Pro-Form® allows coaxial advancement and delivery of the Zenith® Dissection Endovascular Stent(s).

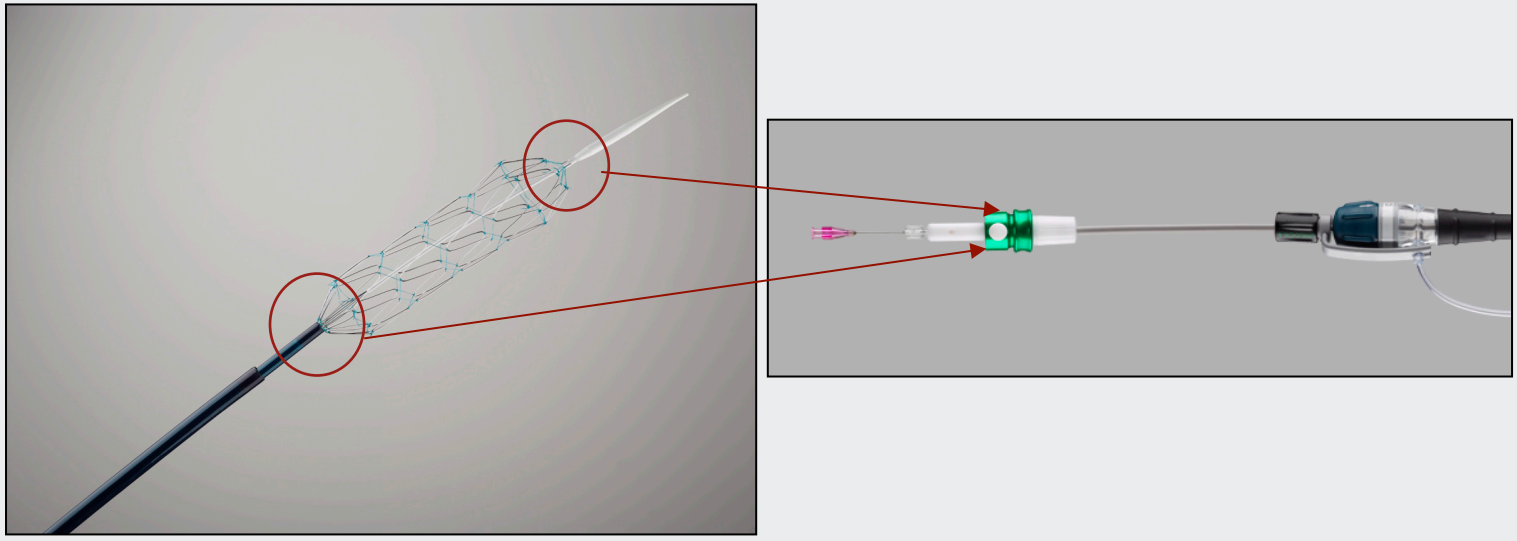




# Control delivery

Safety trigger wire

- With the sheath withdrawn, both the graft and stent are tethered to the introduction system for accurate positioning.



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