

Device description

Zenith AlphaTM
THORACIC ENDOVASCULAR GRAFT



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Modular design

- The two-piece modular system allows the physician to customize a graft system to fit each patient's individual anatomy.
- Graft length should be selected to cover the lesion as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.
- A two-component (proximal and distal component) is recommended, as it provides the ability to adapt to the length change over time.
- A two-component (proximal and distal component) also provides active fixation at both the proximal and distal seal sites.



Unique stent-graft design

- The configuration of independent nitinol z-stents provides graft flexibility.
- The range of graft lengths and diameters promotes secure graft-to-vessel apposition, columnar strength, and graft flexibility.



Alpha: nitinol

Proximal component

- There is an uncovered stent at the proximal end
- The internal sealing stent has fixation barbs that protrude through the graft material
- Fixation barbs are 3.5 mm long and protrude through the fabric.
- All sizes have release wires.
- 40 to 46 mm diameter proximal components have a Pro-Form[®] restraining suture to aid in conformability.



Alpha: nitinol

Distal component

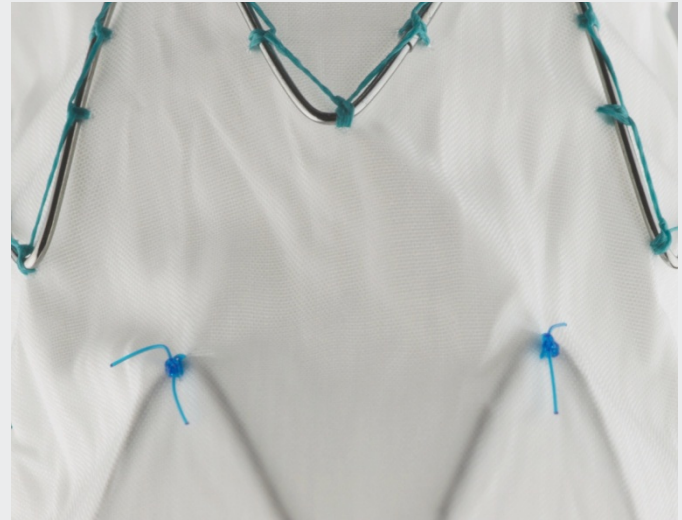
- There are three internal sealing stents at the top
- The distal uncovered stent has barbs
 - The barbs are 3.5 mm long



Graft fabric

Woven polyester

- Lightweight, strong, shrink-and-stretch-resistant, woven polyester is used in both plastics and fibers
- Woven polyester has historically been used for open surgical TAA and AAA repairs
- Two types of suture material are used:
 - Green, braided polyester
 - Blue, monofilament polypropylene



Radiopaque markers

Radiopaque markers

- Gold markers are placed 1 mm from the edge of the graft material on the proximal and distal stents of the graft
- The number of gold markers varies according to graft diameter (there is one gold marker in each apex of the sealing stent):

<i>Diameters (mm)</i>	<i># of Gold Markers</i>
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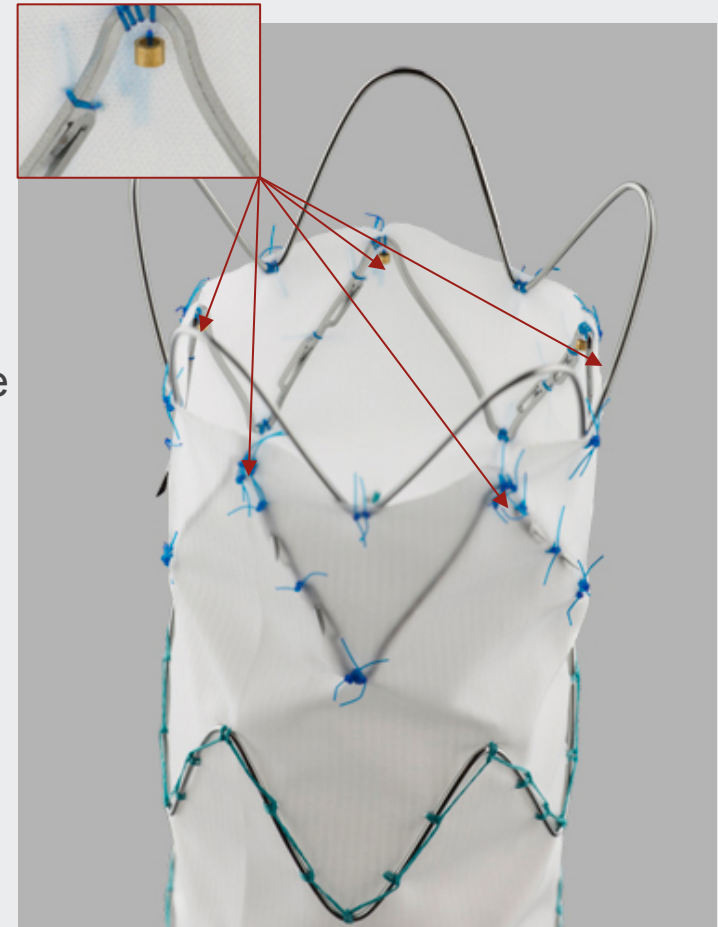
18-30	5
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32-38	6
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40-42	7
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44-46	8
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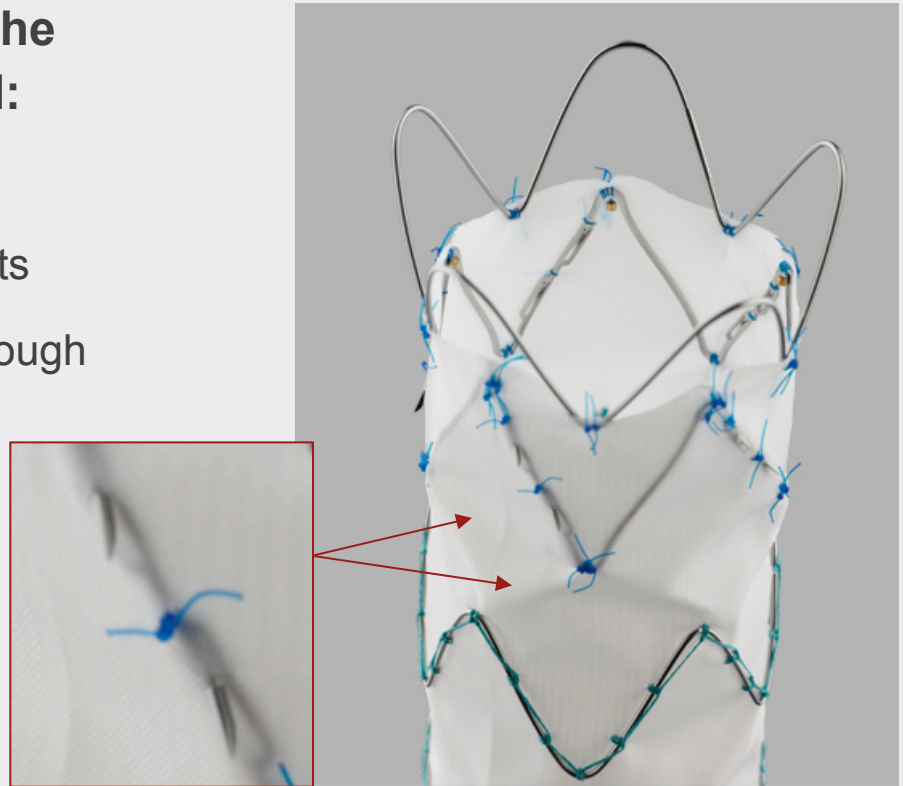
- Gold markers denote the edges of the graft material (1 mm) to assist in deployment accuracy



Control design

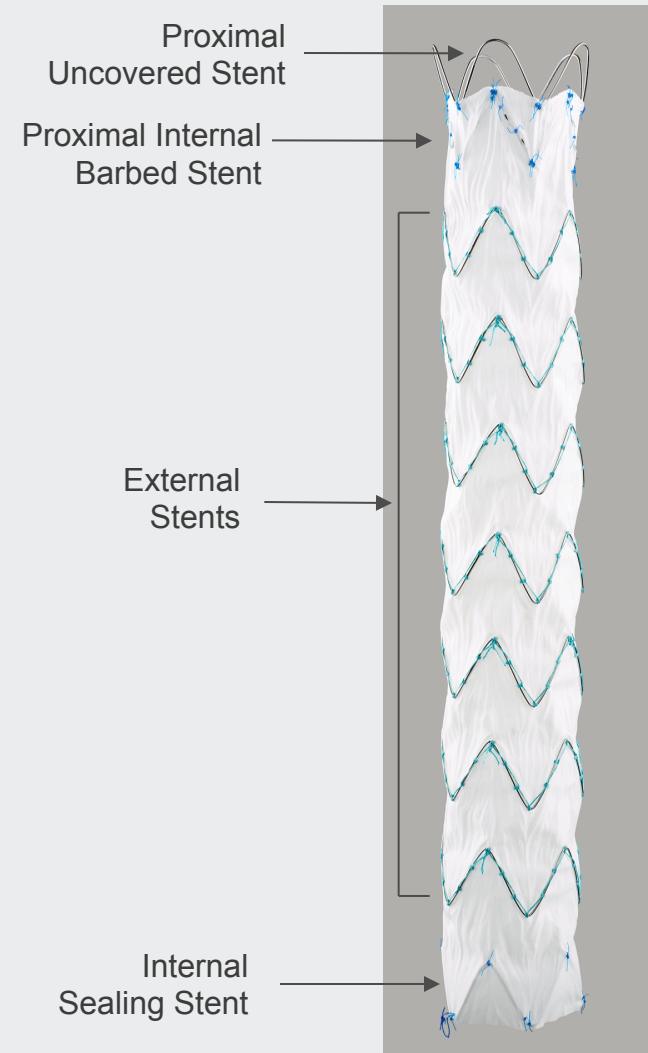
For alignment and added fixation, the following features are incorporated:

- An uncovered proximal stent
- Proximal and distal internal sealing stents
- Proximal fixation barbs that protrude through the graft material



The proximal component

- The range of proximal component diameters and lengths allows optimal vessel coverage. You can fit the graft to each patient's specific anatomical requirements.
 - Available dimensions
 - Diameters of 18-46 mm
 - Lengths of 105-233 mm
- Graft length should be selected to cover the lesion as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.



Alpha: fixation

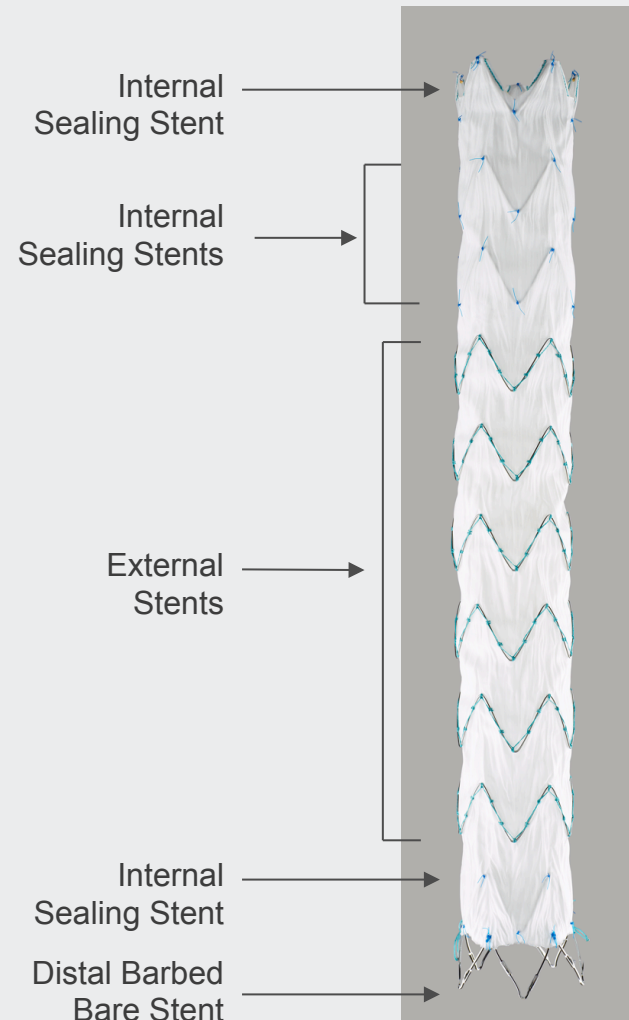
Proximal-component fixation

- There is a 15-mm-long uncovered stent on the proximal end
- The internal sealing stent's barbs protrude through the fabric
- The barbs are 3.5 mm long
- The stent is inside the graft material for sealing



The distal component

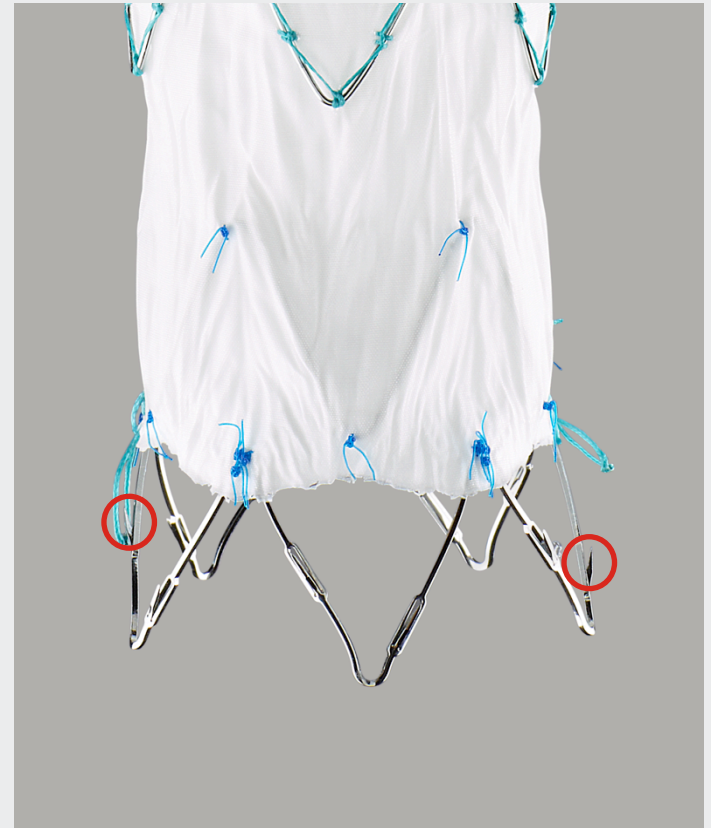
- The range of distal component diameters and lengths allows optimal vessel coverage. You can fit the grafts to each patient's specific anatomical requirements and provide maximum overlap with proximal components.
- Available dimensions
 - Diameters of 28-46 mm
 - Distal components can have diameters up to 8 mm bigger than proximal components.
 - Lengths of 142-211 mm



Alpha: fixation

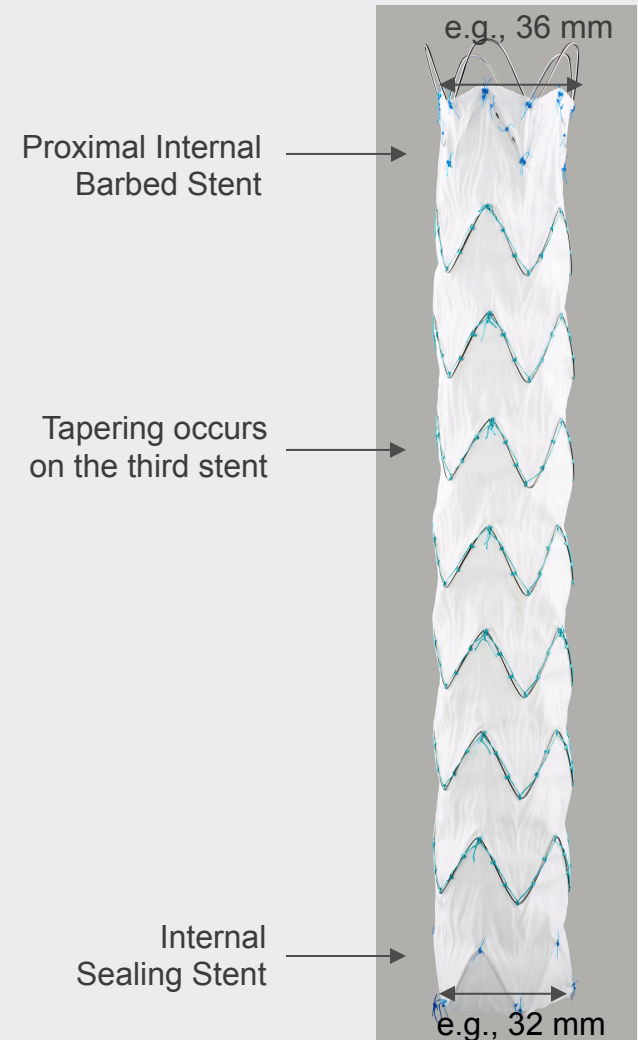
Distal-component fixation

- The 15-mm-long bare stent has barbs
- The barbs are 3.5 mm long
- The bare stent is secured in the bottom cap with a release wire



The proximal tapered component

- Accommodates aortic anatomy where proximal necks measure 4 mm or larger in diameter than distal necks.
- Available dimensions
 - Proximal diameters of 26-46 mm
 - Distal diameters of 22-42 mm
 - Lengths of 105-233 mm

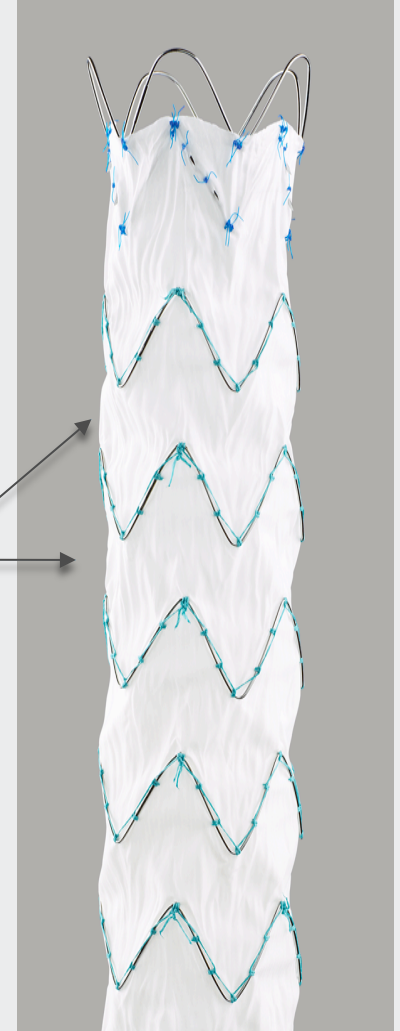


Alpha: fit

Fabric gaps

- Graft diameters of 18-26 mm: 7 mm
- Graft diameters of 28-32 mm: 8 mm
- Graft diameters of 34-36 mm: 9 mm
- Graft diameters of 38-40 mm: 10 mm
- Graft diameters of 42 mm: 11 mm
- Graft diameters of 44-46 mm: 12 mm

Fabric gaps



Distal extensions

Available dimensions

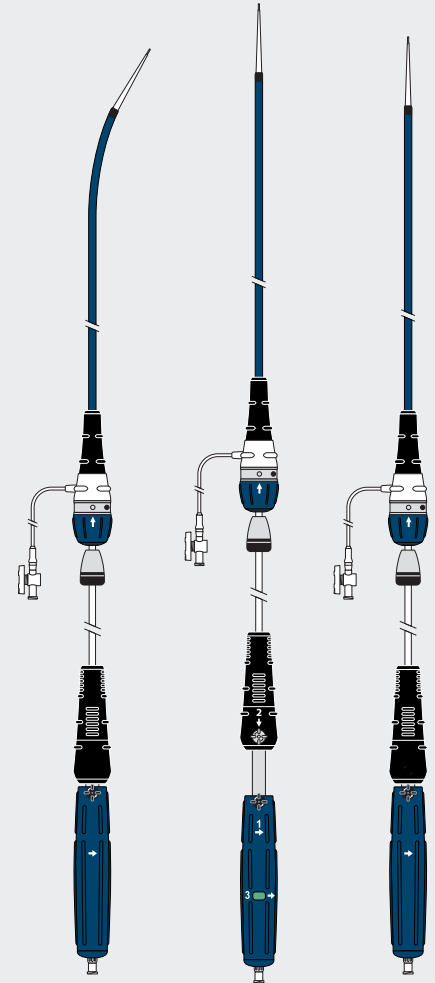
- Diameters of 22, 26, 30, 34, 38, 42, 46 mm
- Lengths of 91-112 mm



Distal
Extension

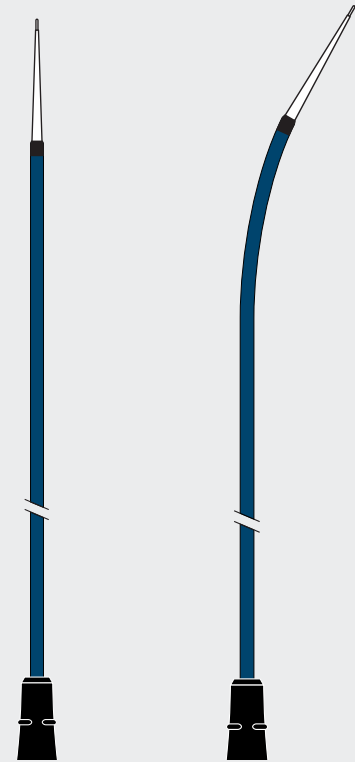
Introduction system

- Flexor[®] sheath with hydrophilic coating
 - 18-30 mm grafts = 16 Fr (6.0 mm) sheath OD
 - 32-38 mm grafts = 18 Fr (7.1 mm) sheath OD
 - 40-46 mm grafts = 20 Fr (7.7 mm) sheath OD
- Inner cannula: super-elastic alloy (nitinol)
- 85 cm usable length
- Soft, flexible dilator tip
- Radiopaque band so you can precisely locate the sheath's distal tip



Flexor sheath and dilator tip

- The short, tapered, hydrophilic-coated dilator tip minimizes vessel trauma and provides increased trackability over the wire guide.
- The kink-resistant Flexor sheath allows controlled delivery, even in the aortic arch.
- The proximal-component introduction system uses a pre-curved inner cannula that assists in proximal inner curvature wall apposition.



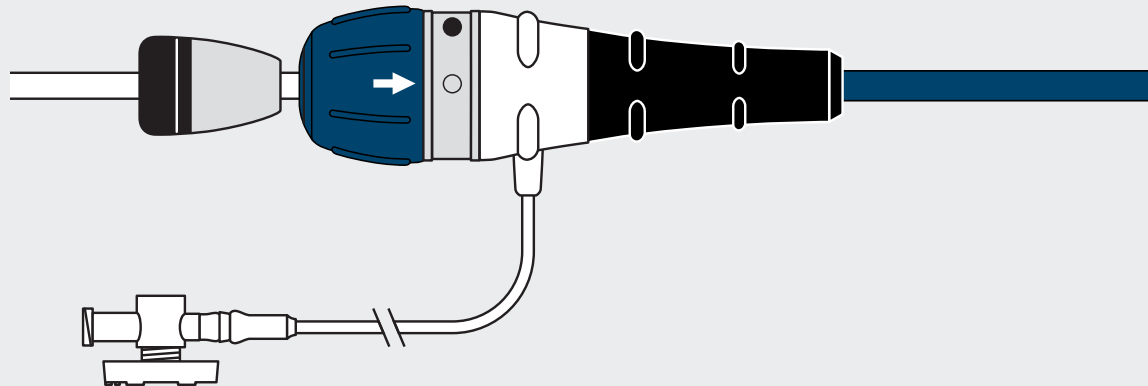
The sheath's hemostatic valve

Captor[®] Hemostatic Valve

- The valve can be manually opened and closed
- Turn the valve counterclockwise to open it
- Turn the valve clockwise to close it

Captor sleeve

- The captor sleeve allows for smoother unsheathing of the device



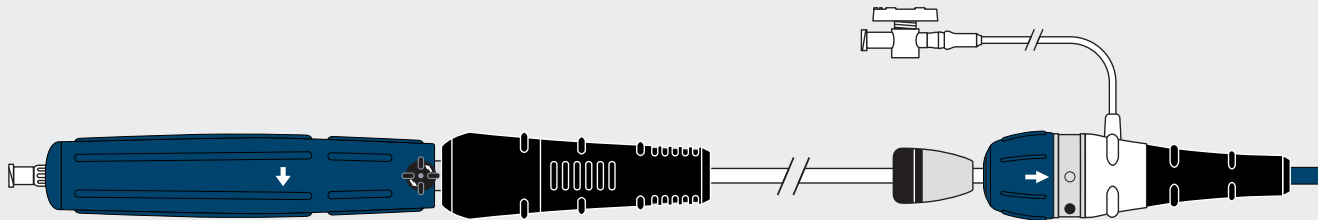
Single locking mechanism

Proximal component

The single locking mechanism is attached to nitinol wires. When the rotation handle is rotated, the graft is released from the introduction system.

The wires that run inside of the introducer and tether to the stent graft provide:

- Endovascular graft stability during deployment
- Controlled release of the graft from the introduction system
- Graft manipulation when the graft is semi-deployed



Dual locking mechanism

Distal component

Black and gray safety locks secure the graft onto the introduction system until the graft is released.

1. The rotation handle releases the distal attachment
2. The black sliding gripper releases the distal attachment stent
3. The rotation handle releases the proximal end of the graft

