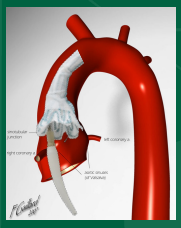
THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Current Status of the Relay Ascending Aortic PS-IDE: What makes it different?



Adam W. Beck, MD
Veith Symposium
November 2024
NY, New York

Disclosures

All proceeds to UAB

Consultant for:

Artivion, Cook Medical, Philips, Medtronic, Terumo Aortic

Research support: Cook Medical, Endospan, Medtronic, Philips, Terumo, W.L. Gore & Associates

Additional Disclosures

- A PS-IDE using the Modified RelayPro Ascending Device is being reviewed by FDA through a pre-submission
- The Modified RelayPro Ascending Device is currently not available in the United States.
- An Ascending Relay Device is available in Europe through the custom-made program
- (Custom made devices are specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications; which gives (1) specific design characteristics provided under that person's responsibility and (2) is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. Custom made devices are not available in the US and availability is subject to local regulatory approval.)

Relay® Pro Platform

Low Profile
- 21FR-23FR OD

Appropriate Usable Length
- Long outer sheath (90cm working length)
- Ability to reach Zone 0

Relay® Pro Platform

Dual Sheath Technology
- Nitinol pre-curved inner catheter
- Inner sheath
- Outer sheath

Core Technologies
- Flared constraining sleeve
- Proximal clasping (allows re-positioning)
- Deployment sequence

Mechanical Advantage
- Controlled stent-graft expansion

Relay® Pro: Flexible Inner Sheath

Atraumatic navigation through the aortic arch
- Reduces potential trauma
- Staged deployment

Pre-curved inner catheter facilitates self-alignment to primary curve of the aorta
- Conforms to the ascending aorta

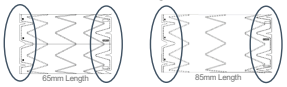
Enhanced constraining sleeve
- Optimized weave pattern allows for a reduction in profile
- Expands **9mm** when exiting the outer sheath

Inner Sheath Flared End (V-patch)
- Allows for stent-graft expansion towards the inner curve for a correct apposition on the inner curve

Modified Relay® Pro Platform

- **Landing zone requirements:** The stent-graft must land 10mm proximal to the entry tear without compromising the function of the aortic root anatomy
- Non-bare stent proximally & distally
- 65mm & 85mm length
- Diameters from 32mm – 46mm
- **No S-bar**

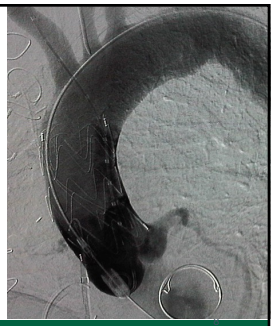
Non-Bare Stent Configuration



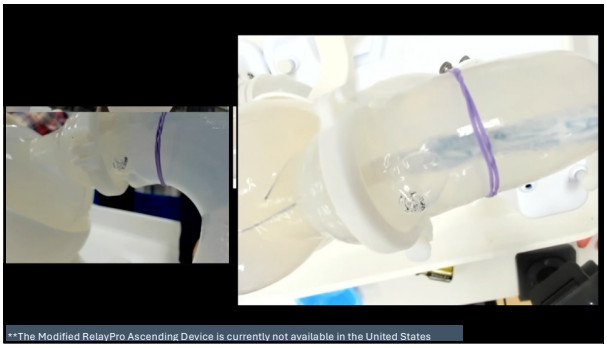
Stent-Graft Diameter (mm)	Thoracic Proximal Vessel Diameter (mm)	Delivery System French Size (O.D.)	
		65cm Length	85cm Length
32	28-29	21	21
34	30-31	21	21
36	32-33	22	22
38	34	22	22
40	35-36	22	22
42	37-38	23	23
44	39-40	23	23
46	41-42	23	23

Study Description

- Aortic Team:
  (Vascular + Cardiac Surgery + Cardiac Anesthesia)
- High and Prohibitive Risk for Open Surgery
- Zone 0 – Zone 0 deployment zone
- Indications:
  - Acute and Chronic Ascending Aortic Dissection
  - Pseudoaneurysm
  - PAU/IMH



**The Modified RelayPro Ascending Device is currently not available in the United States



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Thank You

- awbeck@uabmc.edu
- https://www.uab.edu/medicine/surgery/vascular-endovascular