Valiant Navion device enhancements:
a case-based approach to Navion’s clinical value

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I have the following potential conflicts of interest to report:

Clinical investigator in Medtronic pre-market Valiant Navion clinical trial
## Valiant Navion Device Enhancements

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<th>Clinical Scenario</th>
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<td><em>Increased accessibility/Trackability</em></td>
<td><em>More complex anatomy</em></td>
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<td><em>Enhanced conformability</em></td>
<td><em>More complex aortic disease</em></td>
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<td><em>Accurate deployment</em></td>
<td><em>Severe tortuosity</em></td>
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<td><em>More stent-graft size and configuration options</em></td>
<td><em>Difficult vascular access</em></td>
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<td><em>Short aortic neck</em></td>
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Valiant Navion: a new low profile thoracic device

- Valiant Captivia: Length ≥ 80cm
  - Working Length = 93cm

- Valiant Navion: Reduced tapered tip length
  - Hydrophilic coating length increase: 10cm
  - Different packaging system: reduced tension forces accumulation

Wider applicability: percutaneous

Better trackability: less friction effects, easier SG progression through difficult anatomies

Minimize aortic wall stress and potential damage

Working length increase

Reduced tapered tip length

Hydrophilic coating length increase: 10cm

Different packaging system: reduced tension forces accumulation
Valiant Navion: Enhanced conformability

From peak to valley config and connection bar absence..

To shortened stent struts, increased stent spacing and graft microarchitecture

Better adaptability to the aortic anatomies

Valiant Navion:
- Multi-filament (from Endurant)
- Thoracic adapted

Valiant Captivia:
- Mono-filament Valiant graft material

Higher trackability

More durable results
Case 1

- 80 Year old male
- Multiple PAU on a severely (shaggy) atherosclerotic aorta
- Key point: limited distal neck (2cm)
- Need for very stable and precise SG release
Case Planning

Considerations:

Long coverage, neck discrepancy and severe atheromasy

- Free flo configuration is not the first choice
- 2 **Navion CoveredSeal Devices** Implanted by bottom up approach,
- Ultratapered device is an option

Hybrid room
- General Anesthesia (usual practice)
- 17 min fluoroscopy time

- Distal piece VNMC2828C175CE  **First**
- Proximal piece VNMC3434C100CE

Ancillary equipment as usual: Lunderquist wire, Pigtail catheter, Reliant Balloon
- Surgical Vascular Access
- Use of TEE in the DTA
- No Rapid-Pacing. Blood pressure kept around 90 mmHg during stent graft deployment phase
TEE monitoring
Stent Graft Insertion
Angiography
Stent Graft Deployment
Graft loading significantly impacts Stent Graft Deployment
Tip Capture Release
Partial intimal dislodgement before proximal device deployment
Valiant Navion Stent Graft System is an investigational device
Final result:
Enhanced conformability

40 days control CT scan

1 year control CT scan
A case-based approach to Navion’s clinical value

Case 2

- Female 72 yy, history of smoking, Hypertension
- Ascending aorta and arch aneurysm treated with Elephant trunk technique
- Progressive diffuse aneurysmatic dilation of thoraco-abdominal aorta (max diameter 57mm)
- Diameter increase >1 cm in the last year
2 steps approach

1. TEVAR – elephant trunk distal extension

2. Three options
   - Total endovascular final treatment (BEVAR)
   - Thoracobdominal OS
   - Hybrid approach (Aabd OS + TEVAR)

- Minimizing the risk of paraplegia
- Procedure time reduction
  (Lower complications)
Anatomy challenges

- Severe angulation
- ET prosthesis: limited elasticity
- Neck discrepancy (ET prosthesis 28mm)
- Calcified and small diameter vascular access

TEVAR needs

- Higher device conformability and trackability
- Controlled deployment with no free flo configuration
- More sizing and configurations options
Case Planning

- 72 Year old female
- General Anesthesia (usual practice)
- 20 min fluoroscopy time
- Neck discrepancy (proximal 28mm-distal 35mm)
- 2 Navion Covered Seal Devices
  - Proximal piece (VNMC3434C182CE)
  - Distal piece (VNMC4040C175CE)
  - Ancillary equipment as usual: Lunderquist wire, Pigtail catheter, Reliant Balloon
- Percutaneous access (future procedures)
- No Rapid-Pacing. Blood pressure kept around 85 mmHg during stent graft deployment

Valiant Navion: low profile thoracic device: expanded opportunities
First device advancement
VNMC3434C182TE
 Deployment

 Capture tip release
System retrieval
Second device deployment
VNMC4040C175TE
Higher device conformability

Final result

- Optimal sealing effect
- No distal endoleak waiting for 2 step

Optimal S-G aortic curves adaptability
Final considerations

• New generation low profile graft Valiant Navion is more easy to use and seems to adapt very well to different anatomical and even more challenging scenarios.

• The enhanced conformability is promising for more durable results.

• Trackability is excellent in tortuous DTA.

Reduced nn of peaks
Shortened stent struts
Increased stent spacing
Graft microarchitecture
Final considerations

• Valiant Navion offers a broader range of applications in TEVAR

• Covered Seal version with the tip capture mechanism combines a very precise proximal deployment with an expanded clinical use (surgical procedure extension)

• Wider range of configurations/sizing and low profile may cover almost all TEVAR needs

Ultratapered devices 5-6mm from proximal to distal caliber
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