The new Medtronic Valiant Navion TEVAR device: How this new low-profile device can impact TEVAR

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Disclosure

Speaker name:

...............Fabio Verzini...............................................

I have the following potential conflicts of interest to report:

- Consulting for Cook, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Low Profile Design

Minimized profile

*up to 4 Fr reduction in profile*

Valiant Captivia
- 25 Fr
- 24 Fr
- 22 Fr

Valiant Navion
- 22 Fr
- 20 Fr
- 18 Fr

Proximal configuration with tip capture

Multi-filament (same as Endurant) vs. Mono-filament Valiant graft material

Valiant Captivia
- 46-40mm
- 37-28mm
- 25-20mm
Broad size matrix

- Treat wide range of anatomies
  - Increased length (225 mm)
  - Smaller diameter (20 mm)
  - Refined tapering (5 & 6 mm)
- Tailored pieces for specific use (increased tapering, cuff, sizing changes)

<table>
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<tr>
<th>Fr</th>
<th>SG Size (mm)</th>
<th>Covered Length (mm)*</th>
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<tbody>
<tr>
<td></td>
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<td>60</td>
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<td>18 Fr</td>
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<td>22 Fr</td>
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DELIVERY SYSTEM MODIFICATIONS VS. VALIANT CAPTIVIA

Tapered Tip

- Length reduced by ~1cm versus Valiant Captivia system (22Fr)
- Length proportionally sized to maintain taper

Working Length and Hydrophilic coating Length

- Working length increase: 10cm
  - Valiant Captivia WL = 83cm;
  - Navion WL = 93cm
- Hydrophilic coating length increase: ~10cm
  - Valiant Captivia HCL ~ 70cm;
  - Navion HCL ≥ 80cm
Stent graft design overview

CoveredSeal

FreeFlo
**Valiant EVO Global clinical trial**

**Enrollment**
- 37 sites worldwide (In North America & EU)
- 100 subjects
- First patient in: April 2016

**Design**
- Prospective, multi-center, pre-market, non-randomized, single-arm trial

**Endpoints**
- **Safety**: Major Adverse Events (MAEs) within 30-days post-implantation
- **Effectiveness**: Technical success at index procedure and treatment success at 12-months

**US (22 Centers)**
PI: Prof. A. Azizzadeh

**OUS (15 Centers)**
PI: Prof. F. Verzini
- Female, 83 y.o.
- Hypertension
- Hypercholesterolemia
- Type 2 diabetes mellitus
- Persistent atrial fibrillation under anticoagulant and antiarrhythmic therapy
- COPD

Left vocal cord paralysis

Persistent coughing and dysphonia
Distal aortic arch penetrating aortic ulcer
1 stage: L carotid-subclavian bypass, 2 stage: TEVAR w Rapid pacing

right common vein access for Cardiac rapid pacing

Right femoral surgical cut-down

Percutaneous Left brachial access

Percutaneous left femoral access
Prevertebral subclavian embolization

Amplatzer Vascular Plug II 10 mm
Post-procedural angiogram

30 days post-op CTA
- Male, 59 y.o.
- Hypertension
- Hypercholesterolemia
- Type 2 diabetes mellitus
- Obesity
- COPD
- Renal Insufficiency

- 6 cm Thoracic Aneurysm
Navion
40-40-175 FreeFlo+
43-43-175 CoveredSeal
1 stage: L carotid-subclavian bypass, Amplatzer LSA embolization

2 stage: TEVAR w Rapid pacing

Right femoral surgical cut-down

Left percutaneous fem:
- vein access for Cardiac rapid pacing
- Artery for Angio
Conclusion

• New, Low Profile Navion, based on the solid design of the Valiant device, offers multiple options in size and 2 different prox graft-configurations

• In trial

• Results expected soon
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