New Features Associated with Valiant Navion™ CoveredSeal that Tailor Fragile Aorta Treatment

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Historically, TEVAR devices have been designed for aneurysmal disease and used for all aortic pathologies.
What is a Fragile Aorta?

**Acute dissection, IMH, PAU**

**Pts. at ↑ risk of aortic adverse events**
- Increased inflammatory state
  - Hypertension
  - Aortic wall stress
  - Challenging anatomy

**Females:**
- Tissue composition predisposed to fragile state

**CLINICAL NEED FOR ENDOGRAFT WITH SPECIFIC FEATURES TO TREAT BROAD AORTIC PATHOLOGIES & FRAGILE AORTAS**
Factors Influencing Overall Therapy Success of TEVAR

Simplified Access Low OD Crossing Profile

Valiant Navion™ Delivery System

- **18 Fr OD**
  - 20-25 mm
- **20 Fr OD**
  - 28-37 mm
- **22 Fr OD**
  - 40-46 mm

In Global IDE Trial

- **49% Perc Access** (72% US; 23% OUS)
- **40% Female Patients**
- **0% Access Failures**

External iliac arteries \( \varnothing \leq 5 \text{mm} \)

Valiant Navion™ Thoracic Stent Graft System IFU; 2018 Valiant Evo APR, Version 1.0, 5/DEC/2018
Factors Influencing Overall Therapy Success of TEVAR

DEVICE TRACKABILITY Managing Tortuous Access and Aortic Anatomy

Global IDE Trial, Valiant Navion™ Stent Graft System

Valiant Navion™ Thoracic Stent Graft System IFU, 2018 Valiant Evo APR, Version 1.0, 5/DEC/2018
VALIANT NAVION™ Freeflow and COVEREDSEAL

CoveredSeal: No proximal bare metal

- Internal Seal Stent
- W Stent
- Flush cut
Slightly Lower Outward Radial Pressure
Tailored for Fragile Aortic Pathologies

Circumferentially Distributed Radial Force

Dissection Oversizing

Data on file at Medtronic
Navion™ Platforms: Gemelli Hospital Series
IMH with ulcer-like projection (♂, 75 yrs, Chest Pain)
IMH with ulcer-like projection (♂, 75 yrs, Chest Pain)
Zone 2 Landing (Prior LCCA → LSA Bypass Graft)

- D1 37 mm
- D2 31 mm
- L 207 mm
Hybrid Room
First case in Rome
Penetrating Aortic Ulcer (♂, 54 yrs, Marfan Syndrome)
Subacute Dissecting TAAA (♀, 46 yrs, Marfan Syndrome)
Postoperative CT Angiography

One month after TEVAR
Two months later...
Open Repair of Visceral Aorta
Open Repair of Visceral Aorta
Open Repair of Visceral Aorta
Coeliac Trunk Direct Reimplant
PAU (♂, 86 yrs, Chest Pain, Calcified Shaggy Aorta)
Postoperative CTA (Navion CovereSeal)
Conclusions

✓ The Navion Platform with the option of a fully covered proximal edge: Good advancement to provide a “softer touch” to the aortic wall
Conclusions

✓ The new features such as profile reduction are helpful to reduce vessel trauma, especially in acute phase with high inflammatory degree.

✓ Ongoing dedicated studies will clarify performance of Navion in Fragile aorta especially in terms of RTAD.

✓ Continuous improvement of technology is welcome to provide a curative solution to Fragile aorta patients.
Thank You!
Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement(s)/reference statement(s) below to review applicable indications, safety and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1.763.514.4000 and/or consult the Medtronic website at www.medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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