The DISSECT-N Trial:
Valiant Navion™ in Type B Aortic Dissection

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Disclosure

Speaker name: Robin H. Heijmen

I have the following potential conflicts of interest to report:

- Consulting for 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
Medtronic’s history of TBAD clinical expertise

1998

TALENT THORACIC
CE MARK

2005

VALIANT CAPTIVIA
CE MARK

2009

VALIANT NAVION
CE MARK AND FDA BROAD DTA INDICATION

2013

INSTEAD 2YR
140 PATIENTS. UNCOMPLICATED TBAD. OMT VS TEVAR + OMT

2014

VIRTUE REGISTRY 3YR
100 PATIENTS. COMPLICATED. ACUTE, SUB-ACUTE AND CHRONIC TBAD

2018

DISSECTION 5YR
50 PATIENTS. VALIANT CAPTIVA. COMPLICATED. ACUTE TBAD.

2020

INSTEAD XL 5YR
140 PATIENTS. UNCOMPLICATED TBAD. OMT VS TEVAR + OMT


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140 PATIENTS.
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BROAD DTA INDICATION

1998
2005
2009
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2020

Five-year outcomes of endovascular repair of complicated acute type B aortic dissections

Valiant Navion™ stentgraft system leverages 20+ yrs of clinical experience

Goal: Create a TEVAR system that

- Simplifies access and delivery
- Has a broad labeled indication
- Allows for a tailored therapeutic approach to patients’ anatomy and pathology
- Improves key clinical outcomes

Data on file at Medtronic
Valiant Navion™ stentgraft system leverages 20+ yrs of clinical experience

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LOWER radial force

CoveredSeal
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DISSECT-N Registry
Prospective, Observational, Global, Multi-center, Post-market
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Prospective, Observational, Global, Multi-center, Post-market

**Study Purpose**

To assess real-world safety and effectiveness of the Valiant Navion™ Thoracic Stent Graft System in routine clinical practice in subjects diagnosed with a dissection of the thoracic aorta.

- At least 200 subjects enrolled globally
- Minimum of 50 subjects with an acute (1-14 days) dissection
- Approximately 45 sites: 20 US, 18 Europe, 4 APAC, 1 NZ, 2 Canada
- Subjects will be followed for 3 years post index procedure
**Primary Endpoint**

The primary endpoint is a composite safety and effectiveness, including technical procedures success and freedom from major adverse events (MAEs) reported up to one month following the index procedures.

<table>
<thead>
<tr>
<th><strong>Primary Safety</strong></th>
<th><strong>Primary Effectiveness</strong></th>
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<tbody>
<tr>
<td>MAEs defined as:</td>
<td>Technical success defined as:</td>
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<tr>
<td>• All Cause Mortality</td>
<td>the ability to advance, deploy and position</td>
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<tr>
<td>• Retrograde Type A Dissection</td>
<td>the Valiant Navion Thoracic Stent Graft</td>
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<td>• Aortic Rupture</td>
<td>at the target site with successful coverage and</td>
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<td>• Permanent Paraplegia and Paraparesis</td>
<td>sealing of the proximal entry tear and</td>
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<td>• Stent Induced New Entry Tear</td>
<td>removal of the delivery system.</td>
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<td>• Conversion to Open Repair</td>
<td></td>
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<td>• Disabling Stroke</td>
<td></td>
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<tr>
<td>• Non-preexisting Renal Failure</td>
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</table>
DISSECT-N Registry
Prospective, Observational, Global, Multi-center, Post-market

Inclusion / Exclusion Criteria

All subjects diagnosed with a dissection of the thoracic aorta who have been treated, or are intended to be treated, with the Valiant Navion™ Thoracic Stent Graft System.

**Inclusion Criteria**

- Subject is ≥18 years old
- Subject was treated in the last 7 days, or is intended to be treated, with the Valiant Navion Thoracic Stent Graft System for a dissection in the thoracic aorta
- Subject is willing to comply with standard of care clinical follow-up
- Subject or legal representative has consented for study participation and signed the approved Informed Consent

**Exclusion Criteria**

- Subject is participating in an investigational drug or device study which may bias or interfere with the endpoints and follow-up of this study
- Subject is pregnant
  - Not an exclusion if allowed per local regulatory requirements, pregnancy test to be performed where required
DISSECT-N Registry
Prospective, Observational, Global, Multi-center, Post-market

US (20) and Canadian (2) site list
DISSECT-N Registry
Prospective, Observational, Global, Multi-center, Post-market

Europe (18) site list
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Prospective, Observational, Global, Multi-center, Post-market

APAC (5) site list
M, 69-yrs

Aug 5th, 2020
Acute interscapular pain
M, 69-yrs

Aug 5th, 2020
Acute interscapular pain

Small intimal entry

Retrograde IMH (‘Type A’)
No PE
M, 69-yrs

Aug 5th, 2020
Acute interscapular pain

MAX diameter TL + FL = 45mm

HIGH-RISK RADIOGRAPHIC PREDICTOR (> 4cm) for adverse outcome

Retrograde IMH (‘Type A’)
No PE
M, 69-yrs

Aug 5th, 2020
Acute interscapular pain

MAX diameter TL + FL = 45mm

HIGH-RISK RADIOGRAPHIC PREDICTOR (> 4cm) for adverse outcome

RETROGRADE IMH TYPE A is a predictor for TEVAR-related procedural complications ....

Retrograde IMH (‘Type A’)
No PE
M, 69-yrs

Aug 5th, 2020
Aug 12th, 2020:

Reduced thickness IMH
M, 69-yrs

Aug 5th, 2020
Aug 12th, 2020:

Reduced thickness IMH

PREEMPTIVE TEVAR
IN
SUBACUTE PHASE

IN A FRAGILE AORTA!
M, 69-yrs

Aug 5th, 2020
Aug 12th, 2020:

**SIZING:**
- LZ proximal: 31 mm (IMH*)
- LZ distal: 34 mm

![Valiant Navion™](image)
M, 69-yrs

Aug 5th, 2020
Aug 12th, 2020

SIZING:
LZ proximal 31 mm (IMH*)
LZ distal 34 mm

Valiant Navion™

whole descending thoracic aorta
M, 69-yrs

Aug 5th, 2020
Aug 12th, 2020
Aug 19th, 2020:

TOE guided

Angiography

Proximal stentgraft.

Distal stentgraft
The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

Lower descending Ao

Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month
The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

Lower descending Ao

Valiant Navion™ in TBAD

preop @ 1 week @ 1 month
The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

Lower descending Ao

Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month

[Images of CT scans showing progressive remodeling in IMH, Upper descending Ao, and Lower descending Ao at preoperative and postoperative stages.]
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Valiant Navion™ in TBAD

preop  @ 1 week  @ 1 month