

The DISSECT-N Trial :

Valiant Navion™ in Type B Aortic Dissection

R.H. (Robin) Heijmen, MD PhD

**Department of Cardiothoracic Surgery
St Antonius Hospital, Nieuwegein
The Netherlands**



Disclosure

Speaker name:

Robin H. Heijmen

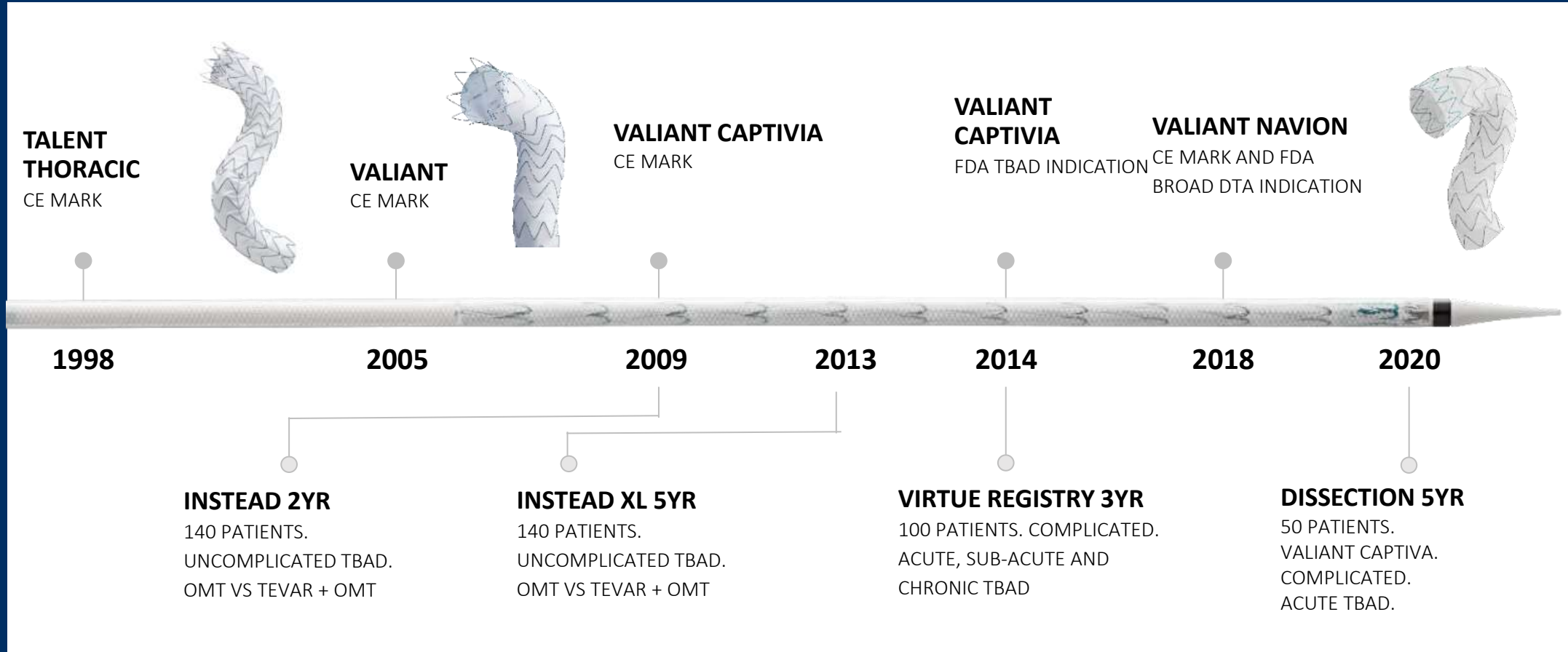
I have the following potential conflicts of interest to report:

- 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



INSTEAD: Circulation 2009 Dec 22;120(25):2519-28.

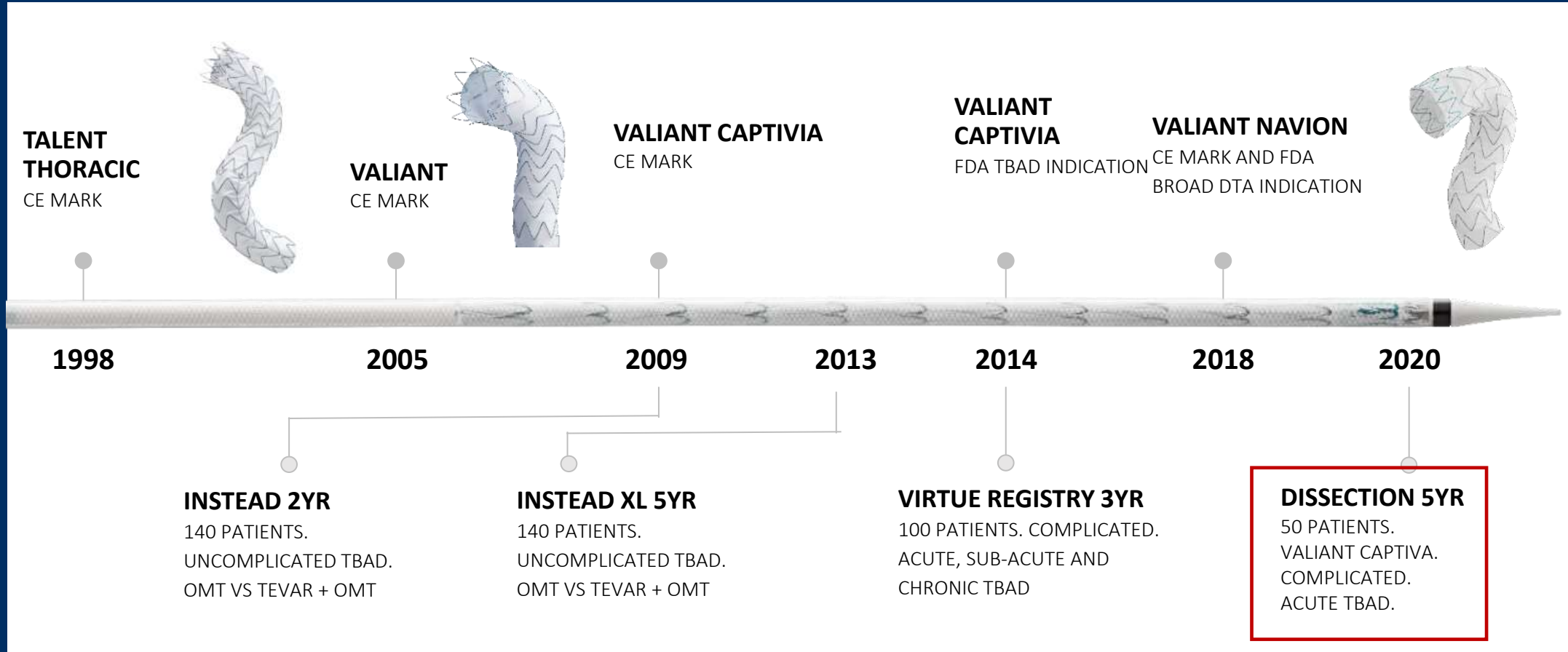
INSTEAD XL: Circ Cardiovasc Interv. 2013 Aug;6(4):407-16.

VIRTUE 3YR: Eur J Vasc Endovasc Surg. 2014 Oct;48(4):363-71.

Dissection: J Thorac Cardiovasc Surg 2020 May 13;S0022-5223(20)31092-8.



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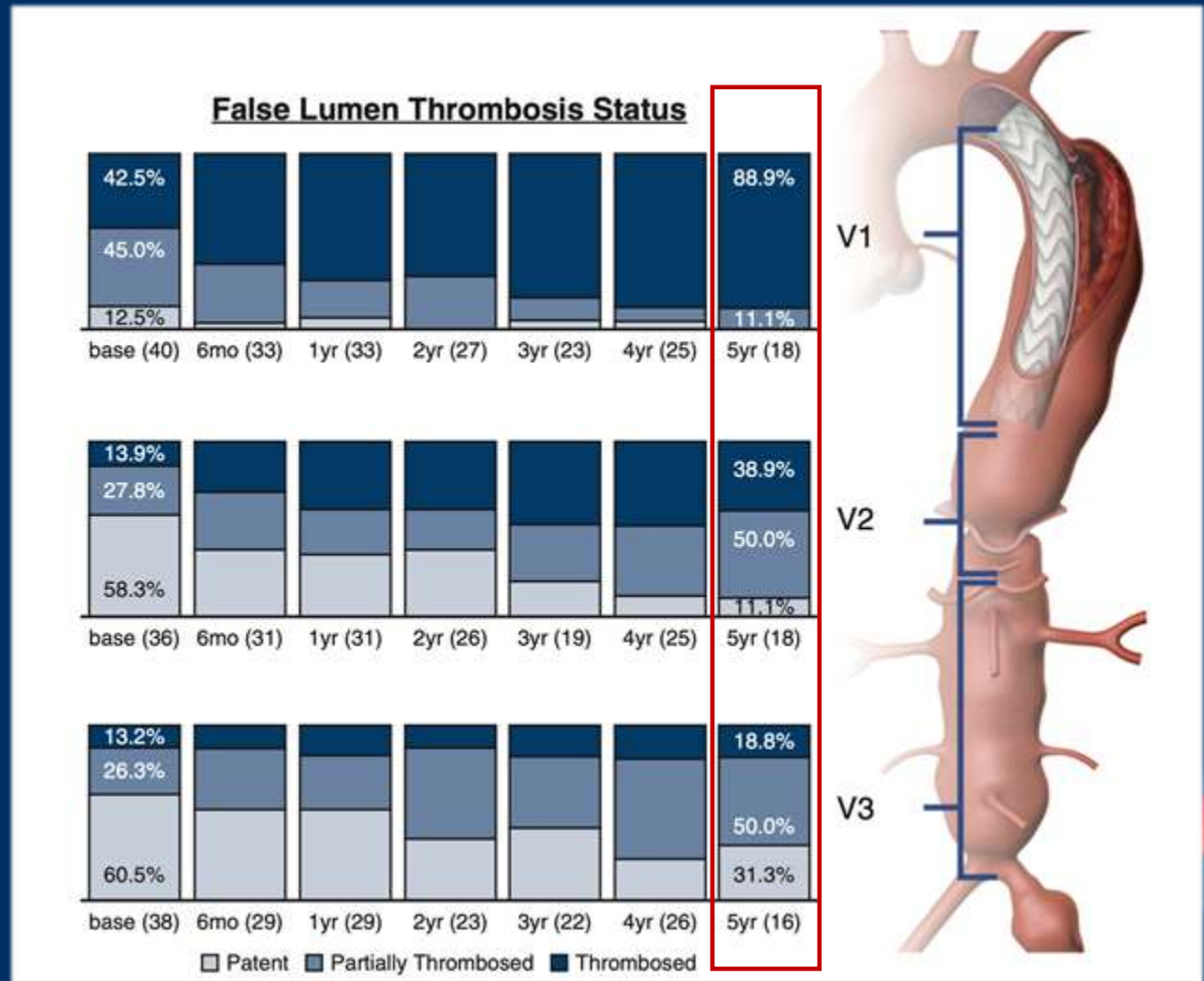
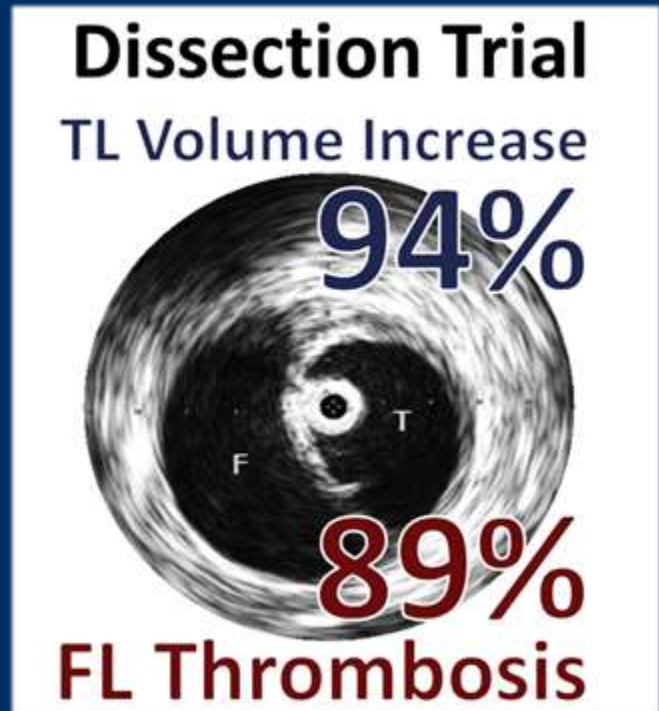
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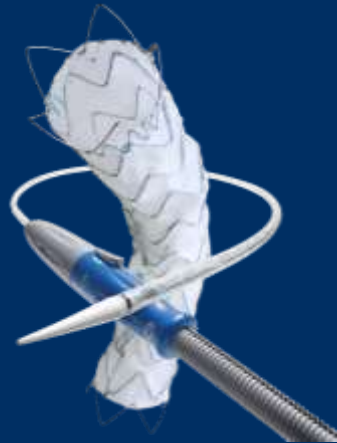
Five-year outcomes of endovascular repair of complicated acute type B aortic dissections



J Thorac Cardiovasc Surg 2020 May 13;
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Valiant Navion™ stentgraft system leverages 20+ yrs of clinical experience

Talent Thoracic
Stent Graft System



+

Valiant Captivia™
Stent Graft System



>150,000 Patients of Experience

Data on file at Medtronic

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

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

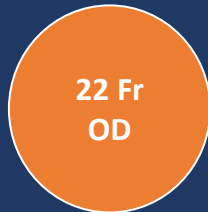
Valiant Navion™ Delivery System



20-25 mm



28-37 mm



40-46 mm

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

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



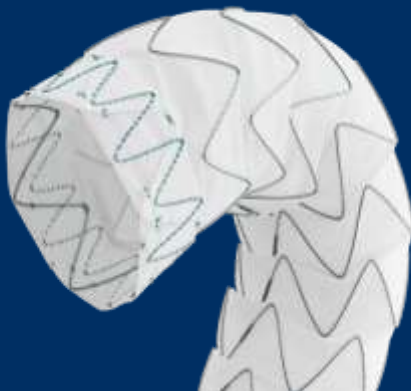
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FreeFlo

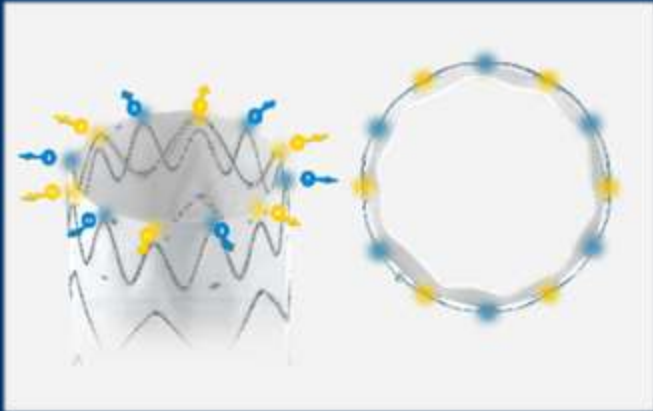


CoveredSeal

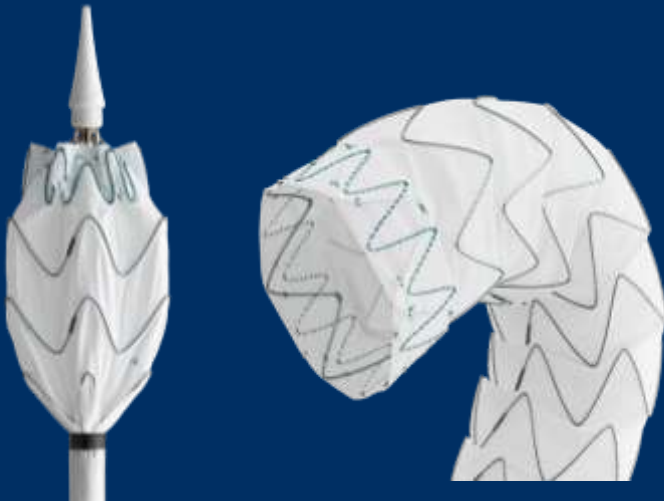
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Valiant Navion™ stentgraft system leverages 20+ yrs of clinical experience



LOWER radial force



CoveredSeal

Goal: Create a TEVAR system that

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

DISSECT-N Registry

Prospective, Observational, Global, Multi-center,
Post-market

Goal: Create a TEVAR system that

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DISSECT-N Registry

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

DISSECT-N Registry

Prospective, Observational, Global, Multi-center, Post-market

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

Primary Safety

MAEs defined as:

- All Cause Mortality
- Retrograde Type A Dissection
- Aortic Rupture
- Permanent Paraplegia and Paraparesis
- Stent Induced New Entry Tear
- Conversion to Open Repair
- Disabling Stroke
- Non-preexisting Renal Failure

Primary Effectiveness

Technical success defined as:

the ability to advance, deploy and position the Valiant Navion Thoracic Stent Graft at the target site with successful coverage and sealing of the proximal entry tear and removal of the delivery system.

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

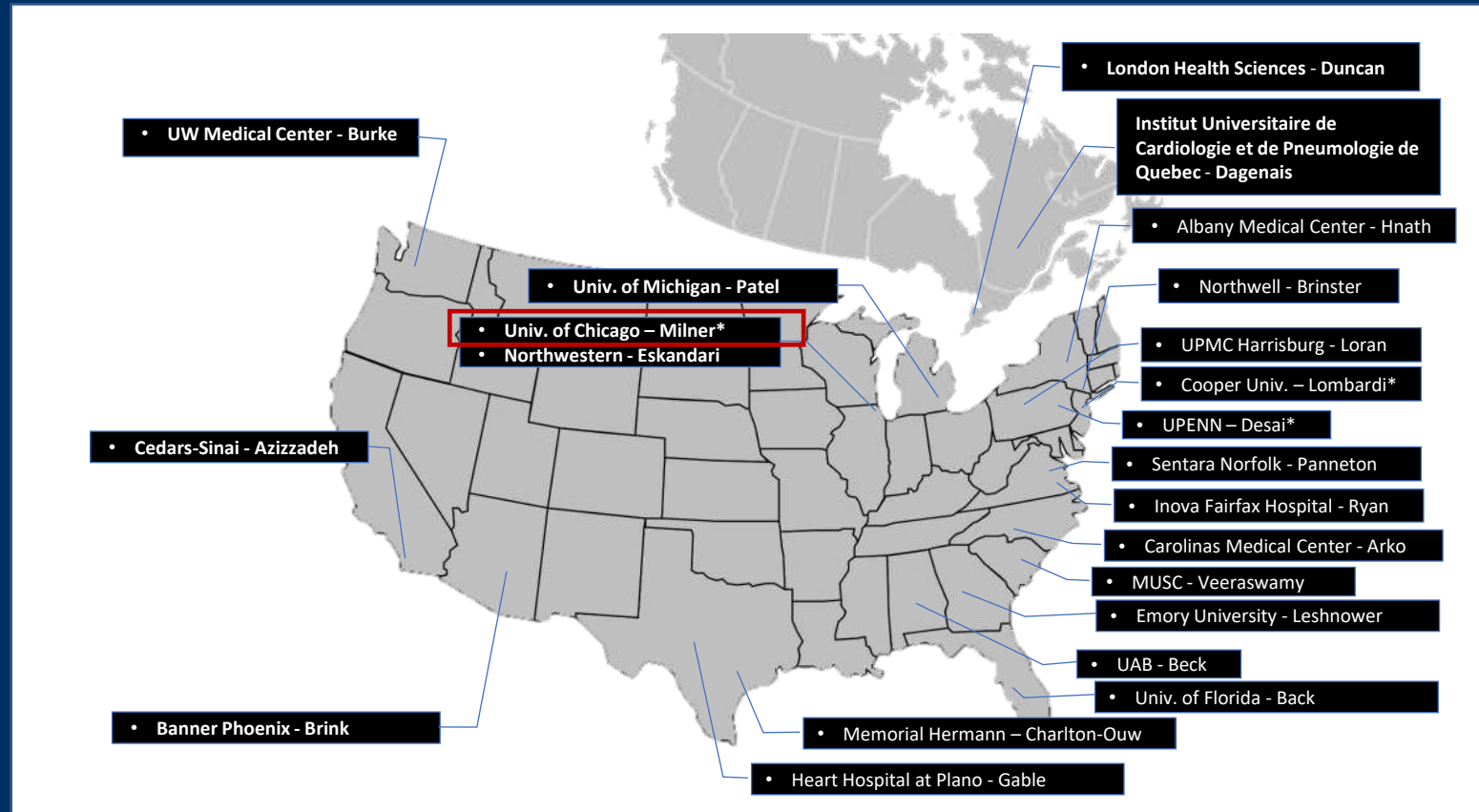
Exclusion Criteria

- 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

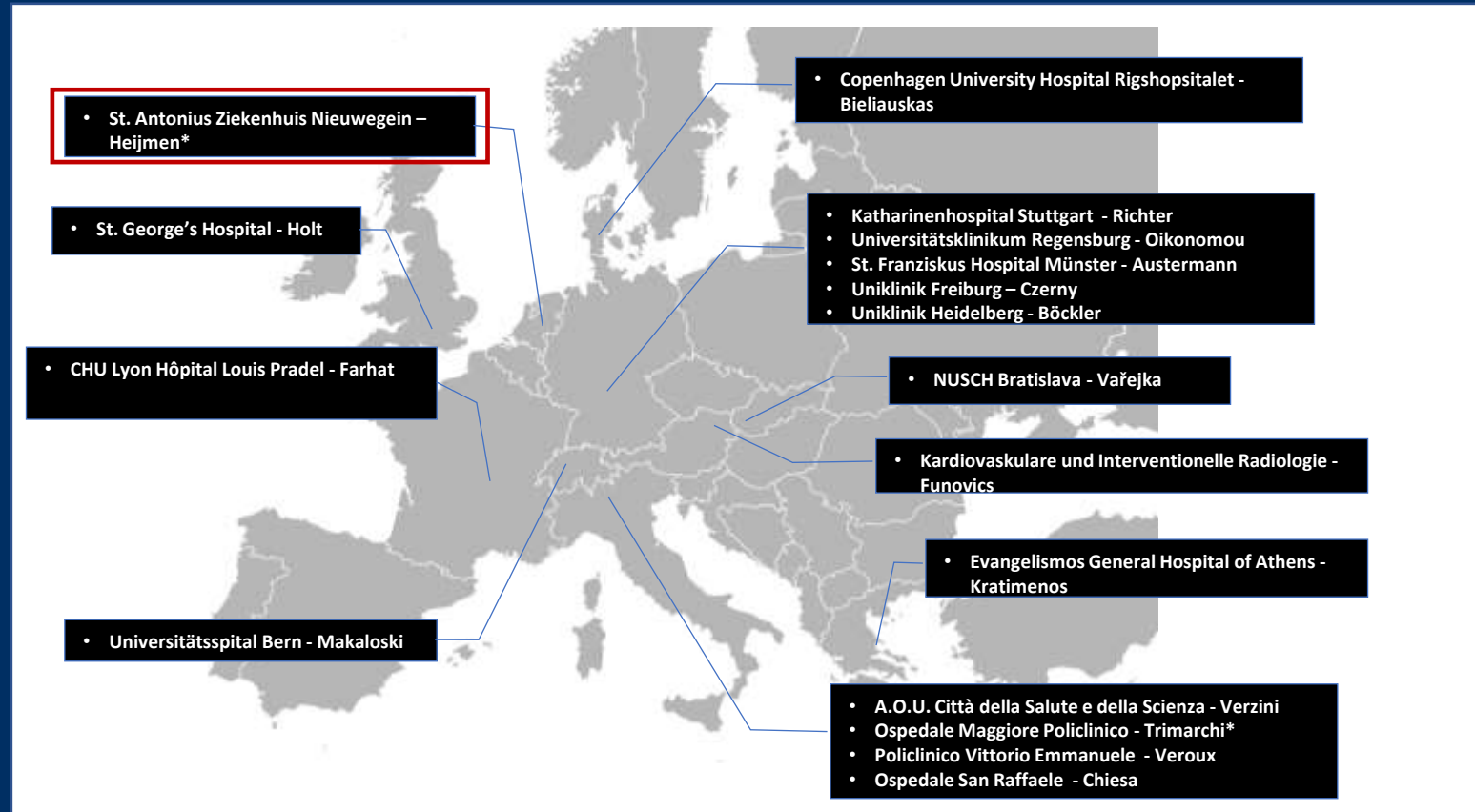
US (20) and Canadian (2) site list



DISSECT-N Registry

Prospective, Observational, Global, Multi-center, Post-market

Europe (18) site list



DISSECT-N Registry

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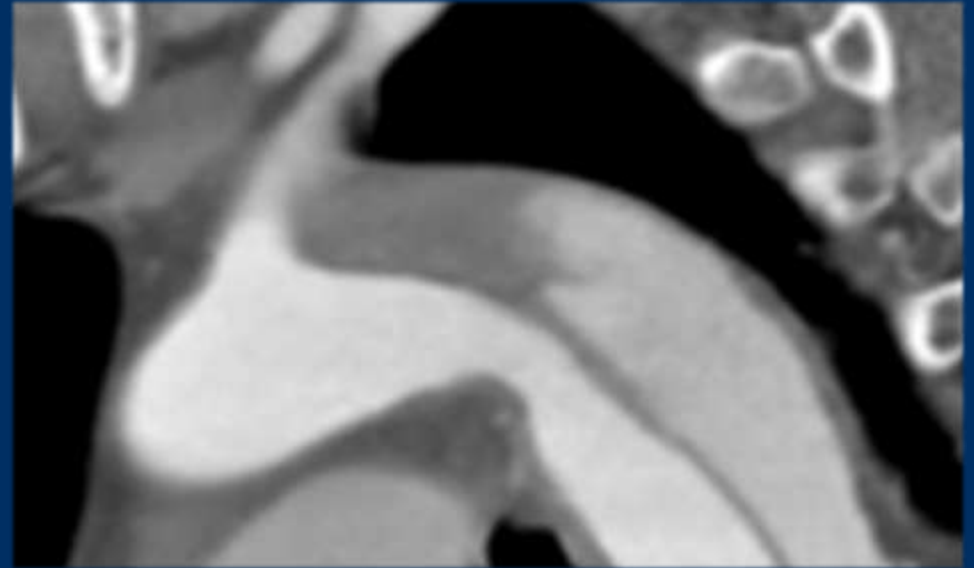
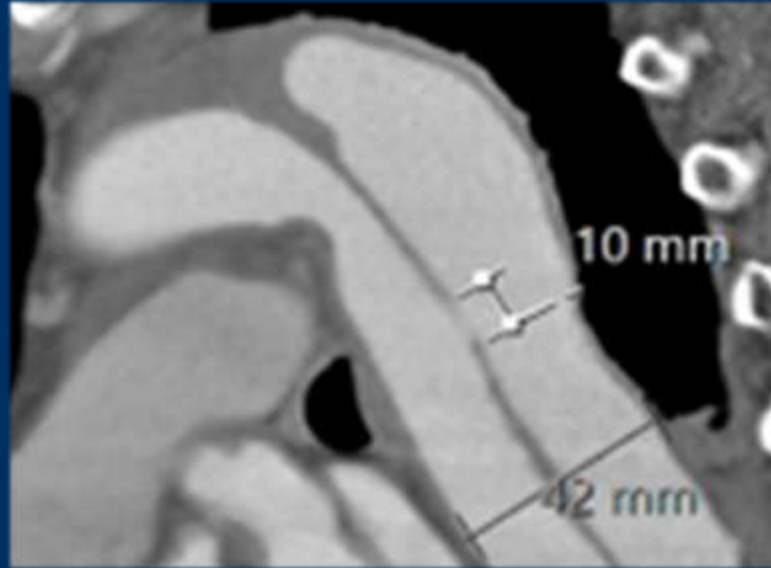
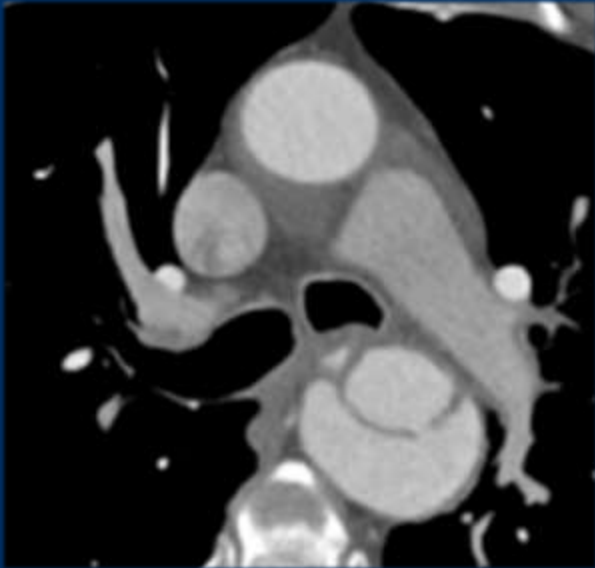
APAC (5) site list



M, 69-yrs

Aug 5th, 2020

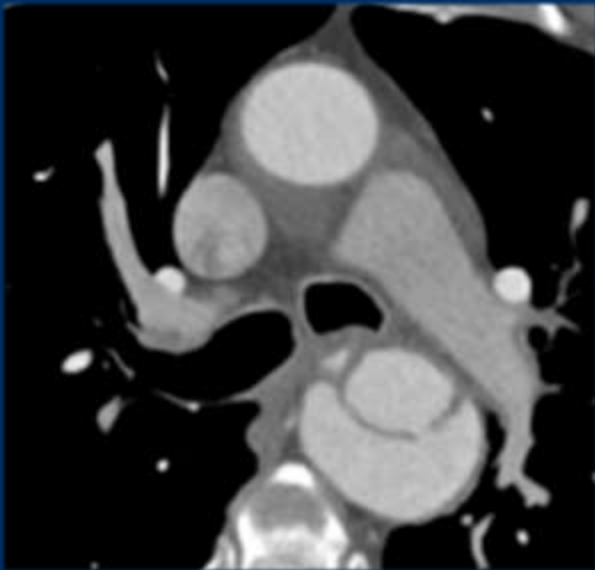
Acute interscapular pain



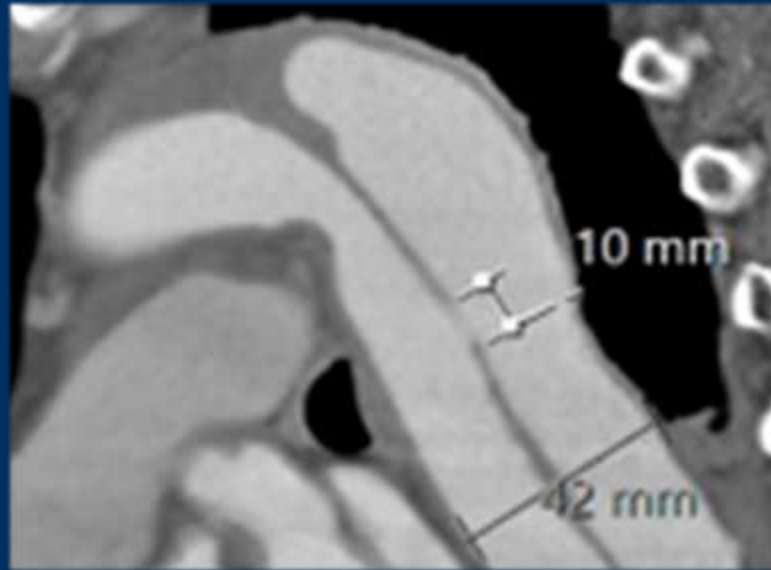
M, 69-yrs

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



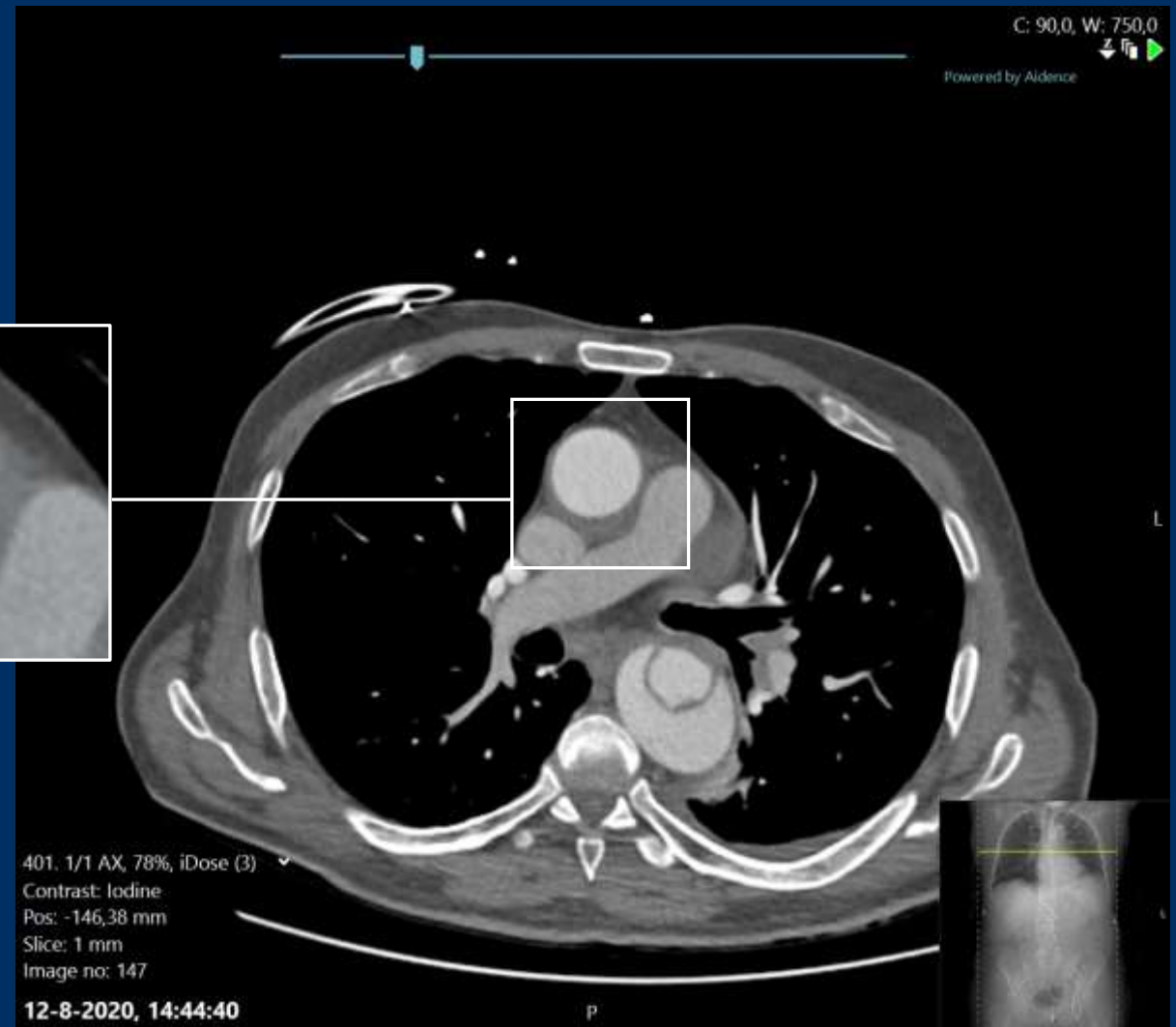
Retrograde IMH ('Type A')
No PE

M, 69-yr

Aug 5th, 2020

Aug 12th, 2020 :

Reduced thickness IMH



M, 69-yrs

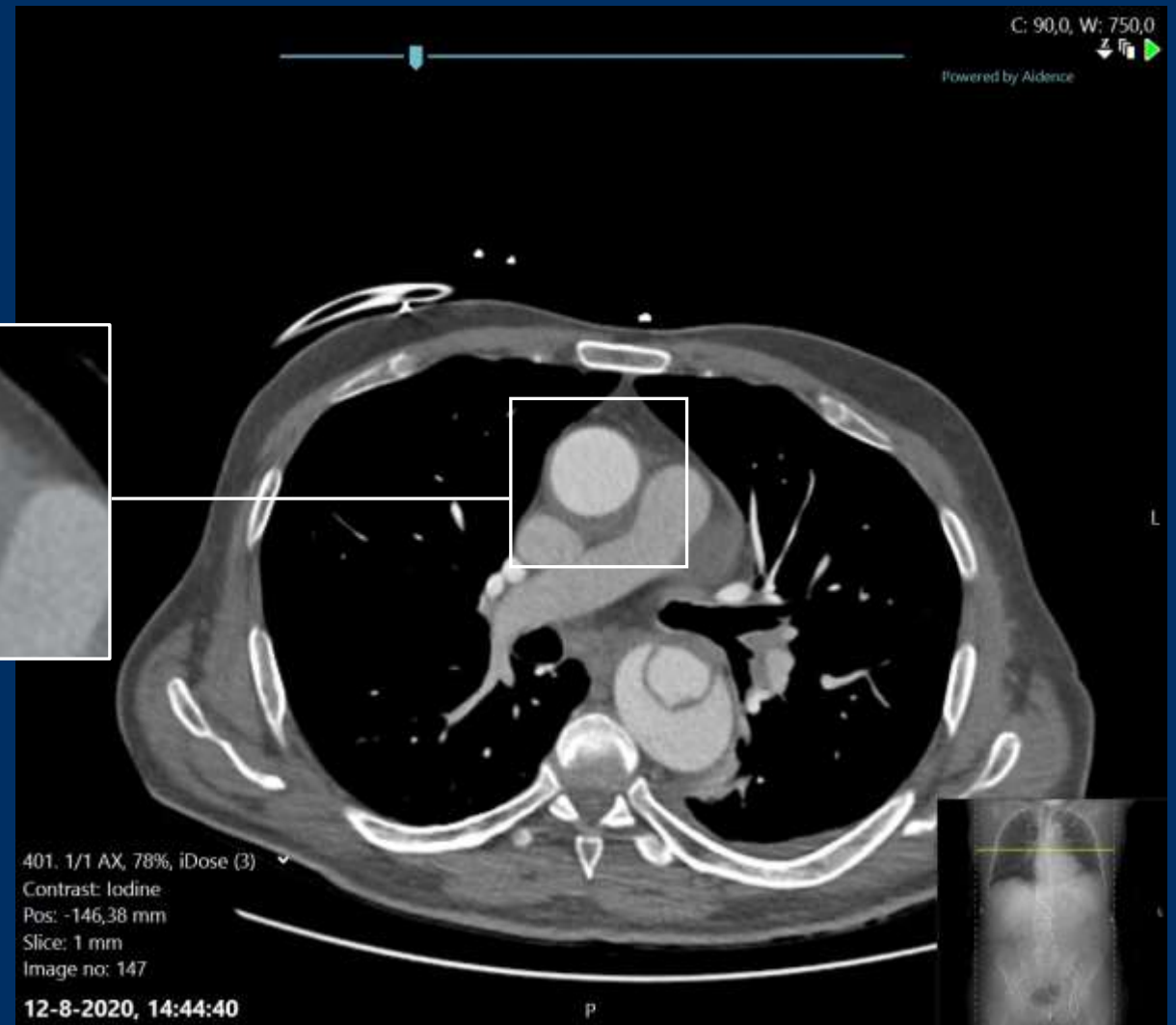
Aug 5th, 2020

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



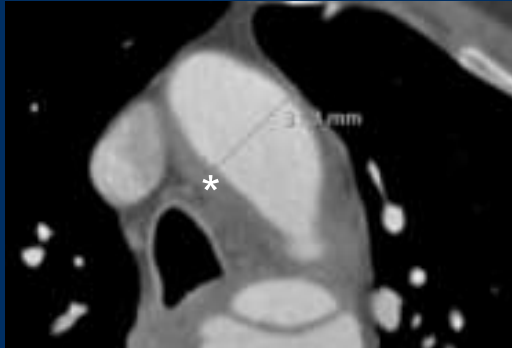
Valiant Navion™

	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Stent Graft Covered Length (mm)	Vessel Diameter: TAA, PAU (mm)	Vessel Diameter: Dissection (mm)	Vessel Diameter: BTAI (mm)	Catheter Outer Diameter (Fr)	
P :	VNMC 34	28	C 207	TU				
D :	VNMC 34	34	C 182	TU	28-31	31-33	28-32	20

M, 69-yrs

Aug 5th, 2020

Aug 12th, 2020 :



SIZING :

LZ proximal 31 mm (IMH*)

LZ distal 34 mm



	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Stent Graft Covered Length (mm)	Vessel Diameter: TAA, PAU (mm)	Vessel Diameter: Dissection (mm)	Vessel Diameter: BTAI (mm)	Catheter Outer Diameter (Fr)	
P :	VNMC 34	28	C 207	TU				
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whole descending thoracic aorta

M, 69-yrs

Aug 5th, 2020

Aug 12th, 2020

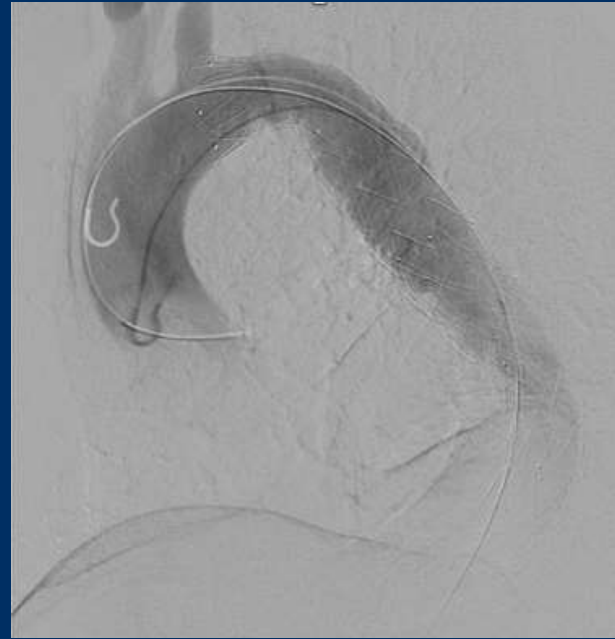
Aug 19th, 2020 :



TOE guided



Angiography



Proximal stentgraft.



Distal stentgraft

The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

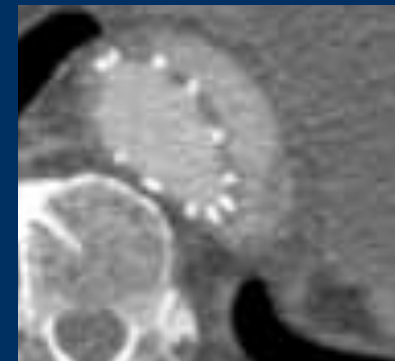
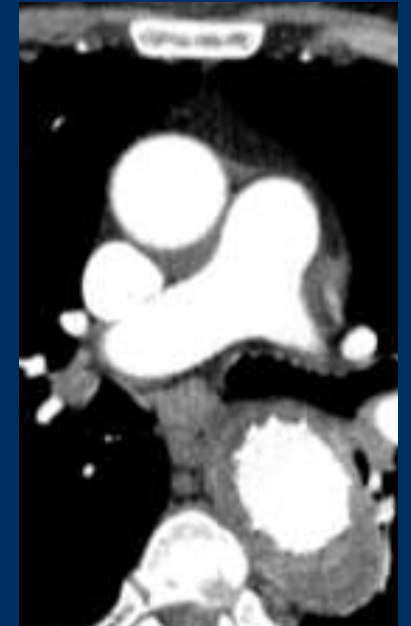
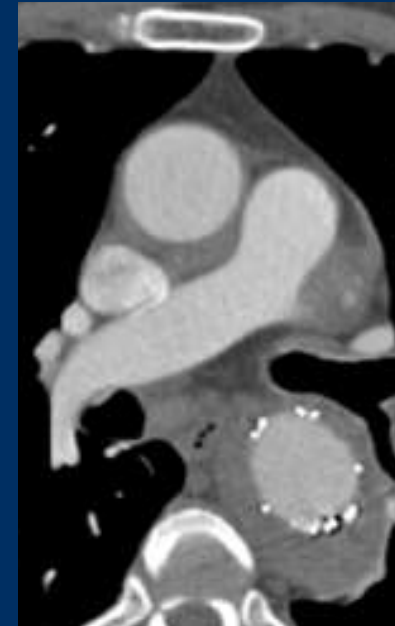
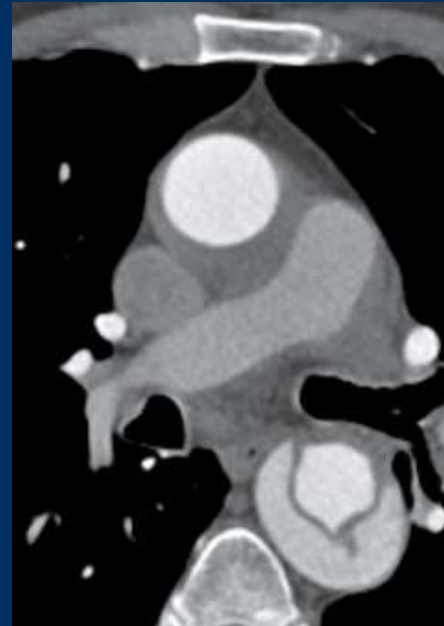
Lower descending Ao

Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month



The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

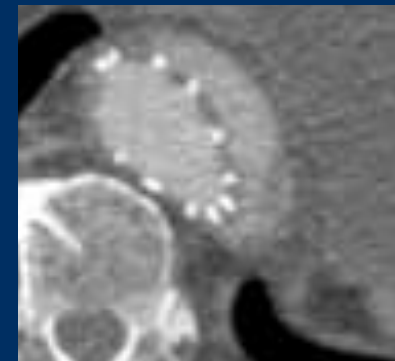
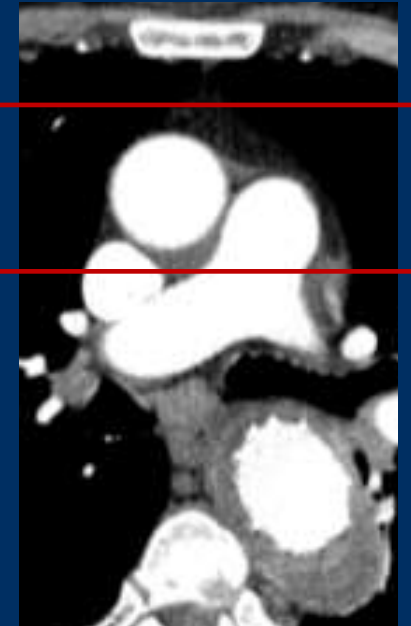
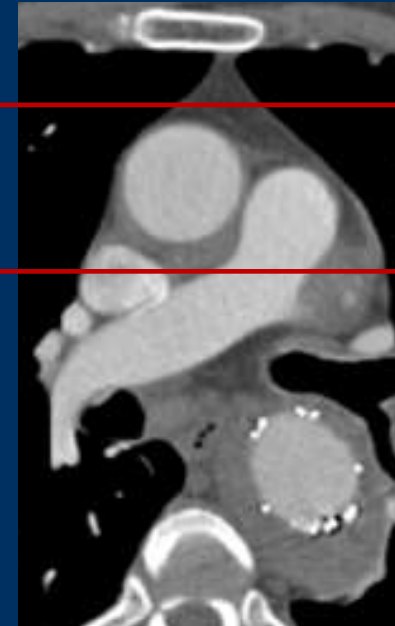
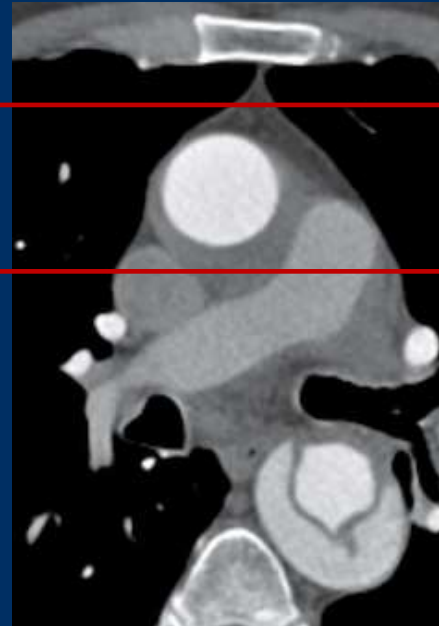
Lower descending Ao

Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month



The DISSECT-N Trial

PROGRESSIVE REMODELING

IMH

Upper descending Ao

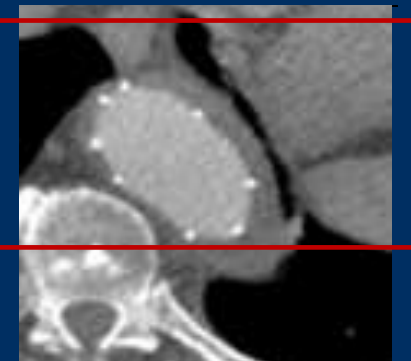
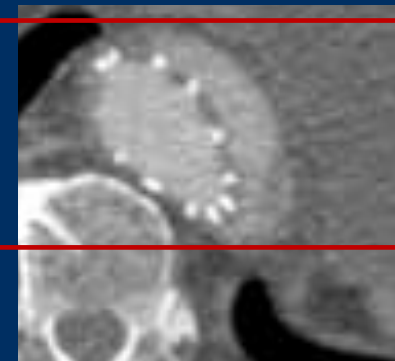
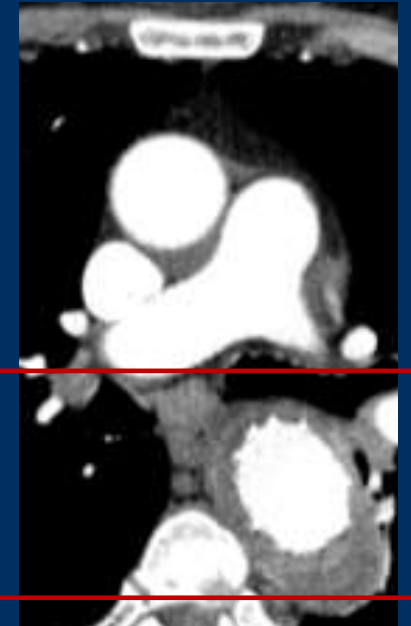
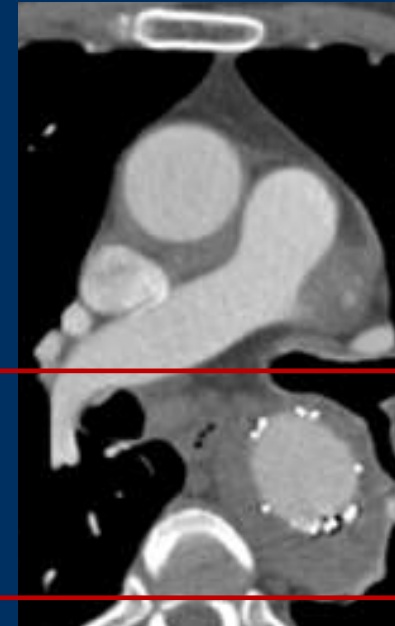
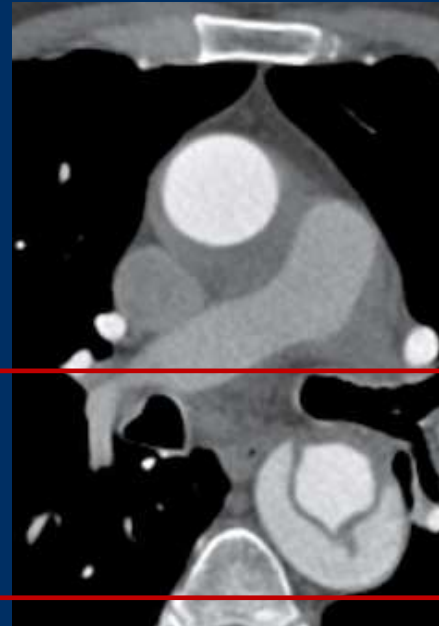
Lower descending Ao

Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month



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Valiant Navion™ in TBAD

preop

@ 1 week

@ 1 month

