


Progress In Endovascular Treatment Of Type A Aortic Dissections (TAADs) In 2024: What Is Here And What Is Coming: Experience With Ascending Aortic Endografting Including The Gore Device In The ARISE II Trial


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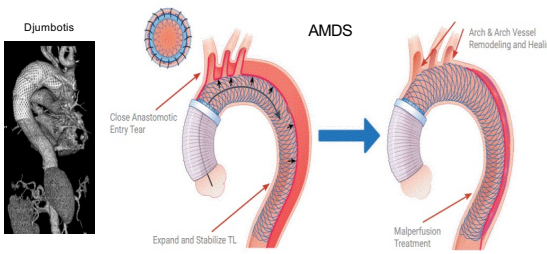
Disclosures


Artivion	Consultant, Investigator, Inventor
Cook	Speaker, Investigator
Corcym	Consultant, Investigator
Edwards Lifesciences	Consultant, Speaker
Medtronic	Speaker, Investigator
Terumo Aortic	Speaker, Investigator
WL Gore	Consultant, Investigator

Off-label and Investigational use of devices discussed

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Simplified Extended Procedures: Bare Stents



 Cleveland Clinic Investigational Devices

Hybrid Device for B-SAFER → Arcevo

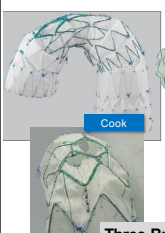


Pivotal Artizen Trial Planning Coming Soon (?early 2025)

 Cleveland Clinic Investigational Devices


Arch Branch Devices

Double Branches



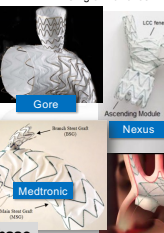
Cook

Single Branches



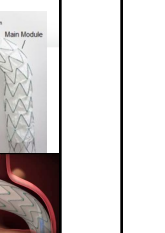
Terumo

Single Branches




Gore

Single Branches




Medtronic

Single Branches



Nexus

Three-Branch Devices In R and D Phase

 Cleveland Clinic Investigational Devices

GORE® Ascending Stent Graft Clinical Trials and Device Overview

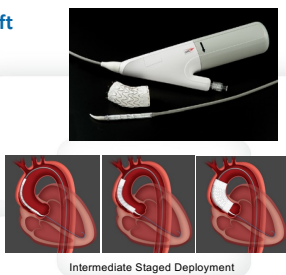


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GORE® Ascending Stent Graft

- Broad Diameters: 34mm - 53mm
- Two Lengths (7 or 8cm & 10cm)
- Precise, orthogonal positioning via staged deployment & angulation control
- Avoids coronary and aortic valve compromise



Intermediate Staged Deployment

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GORE® ASG Studies

ARISE

Early Feasibility Study (TBE 14-02)
Enrollment 2016 - 2021

- Type A Dissections (DeBakey I/II)
- Expanded access emergency and compassionate use
- National PI: Micheal Reardon, MD

NCT02380716

ARISE II

Pivotal Study (ASG 22-02)
Enrollment started end of 2023

- Isolated lesions: Pseudoaneurysm, Aneurysm, Penetrating Aortic Ulcer (PAU)
- Dissections: Residual Chronic Dissections, Chronic de novo Dissections - with or without involvement of the ascending aorta
- National PI: Eric Roselli, MD

NCT05800743

ARISE III

Pivotal Study (ASG 24-02)
Study currently in development

- De Novo Acute Type A Dissections (DeBakey Type I/II) all patients will be high-risk for open surgical repair
- National PI: Eric Roselli, MD

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ARISE II Pivotal Study Design

	Primary Arm: N=70	Secondary Arm: N=50 (min) N=150 (max)	Surgical Follow-up Cohort N=50 (min) N=150 (max)
Procedure / Devices	ASG Device Alone	ASG Device + TBE Device (CTAG as needed)	Open surgical repair
Patient Characteristics	High-risk Surgical Patient	High-risk Surgical Patient	High-risk Surgical Patient not meeting requirements for enrollment in primary or secondary arm
Disease States	Isolated aortic lesion of ascending aorta that can be treated with ASG device alone (aneurysms, pseudoaneurysms, PAU)	Isolated aortic lesion or chronic dissection (de novo or residual) that requires treatment with ASG device and distal extension with the TBE Device and/or the CTAG Device	Same as primary and secondary (Anatomic Screen Fail)

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Plans for Type A Dissection Study – ARISE III

- Second pivotal study trial (ARISE III) to study ASG device for primary treatment of de novo Type A dissections
- To provide an endovascular option for patients at high-risk for open surgical repair



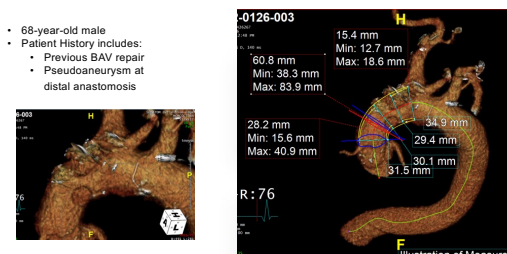
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Case Examples from ARISE II

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2First ARISE II Primary Arm Case

- 68-year-old male
- Patient History includes:
 - Previous BAV repair
 - Pseudoaneurysm at distal anastomosis



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