

AORTOSAVE

Next Generation Transcatheter Endo-Bentall System for Combined Aortic Valve and Ascending Aorta Replacement

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TCT[®]

TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS[®]

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Individual Stock(s)/Stock Options

Royalties/Patent Beneficiary

Executive Role/Ownership Interest

Other Financial Benefit

Ineligible Company

P&F

Medtronic, Abbott, Edwards, WL
Gore, P&F, Braile Biomedical

Company Name(s)

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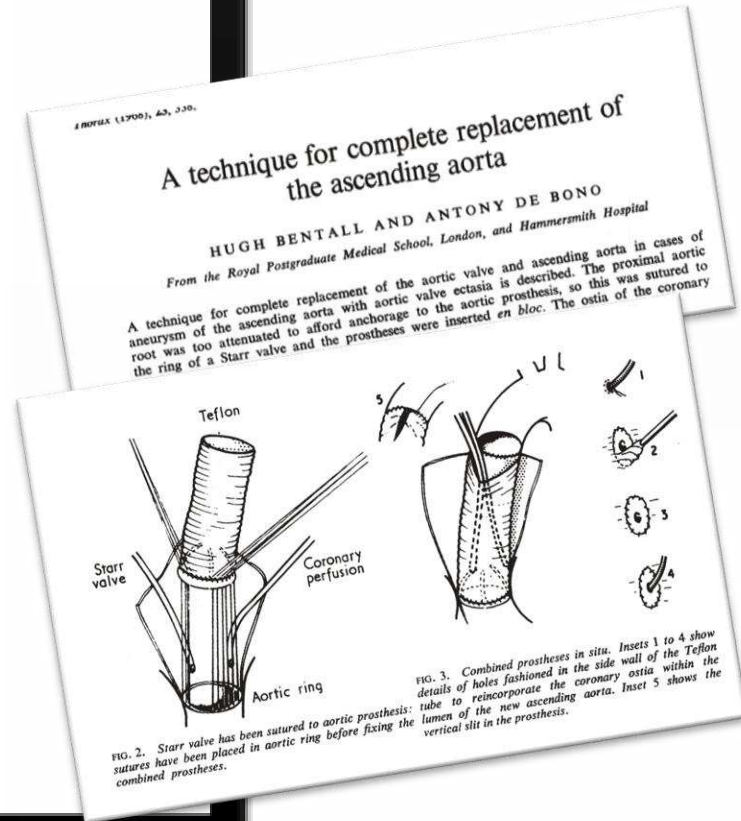
Company Name(s)

Unmet Clinical Need

- Bentall and composite root replacements represent about **15–20% of all aortic valve surgeries** in tertiary centers.
- Aortic root replacement **volumes are increasing** due to improved screening and aging populations.
- A **transcatheter solution - Endo-Bentall** can drastically improve patient outcomes and expand treatment to inoperable patients.

Estimates from surgical registries & literature suggest:

- USA: ~7,000–10,000 Bentall procedures per year
- Europe (EU): ~10,000–12,000 per year
- Global Total: ~ 30,000 per year (including Asia, LATAM, etc.)



UNMET CLINICAL NEED

ORIGINAL ARTICLE

European Journal of Cardio-Thoracic Surgery 46 (2014) 887–893
doi:10.1093/ejcts/ezu083 Advance Access publication 17 March 2014

Mortality characteristics of aortic root surgery in North America[†]

Manuel Caceres^{a,b}, Yicheng Ma^a, J. Scott Rankin^{a*}, Paramita Saha-Chaudhuri^a, Brian R. Englum^a,
James S. Gammie^a, Rakesh M. Suri^a, Vinod H. Thourani^a, Fardad Esmailian^a, Lawrence S. Czer^a,
John D. Puskas^a and Lars G. Svensson^a

relatively common



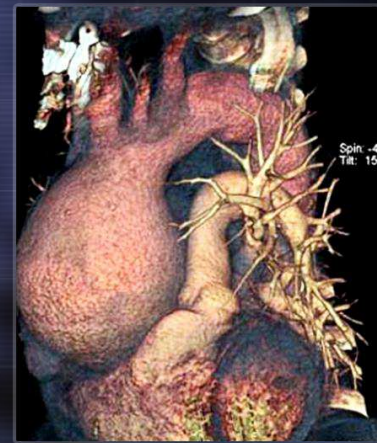
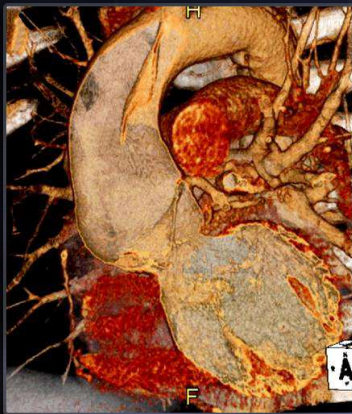
High-risk subgroups	Number	AVS (%)	Operative mortality (%)		
			AVS	CVR	P-value
Age > 75	4064	7.2	15.1	16.6	0.49
Endocarditis	3034	1.7	13.5	15.1	0.74
Aortic stenosis	7852	2.0	3.2	5.1	0.28
Dialysis	188	14.0	7.7	22.2	0.09
Concomitant valve procedure	926	19.0	5.2	11.1	0.02*
Previous valve surgery	1558	18.6	4.1	8.2	0.08
Emergency or salvage status	2727	13.9	14.6	22.5	0.0005*

(Bentall Procedure)

Type A Dissection Globally – 3.0/100.000
Estimated global cases – 200.000 cases/year ^{*1}

True Aneurysm Ascending – 10/100.000
Estimated global cases – 550.000 cases/year ^{*2}

TAVR patients with Ascending Aneurysm – 25%
Estimated global cases – 75.000 ^{*3}

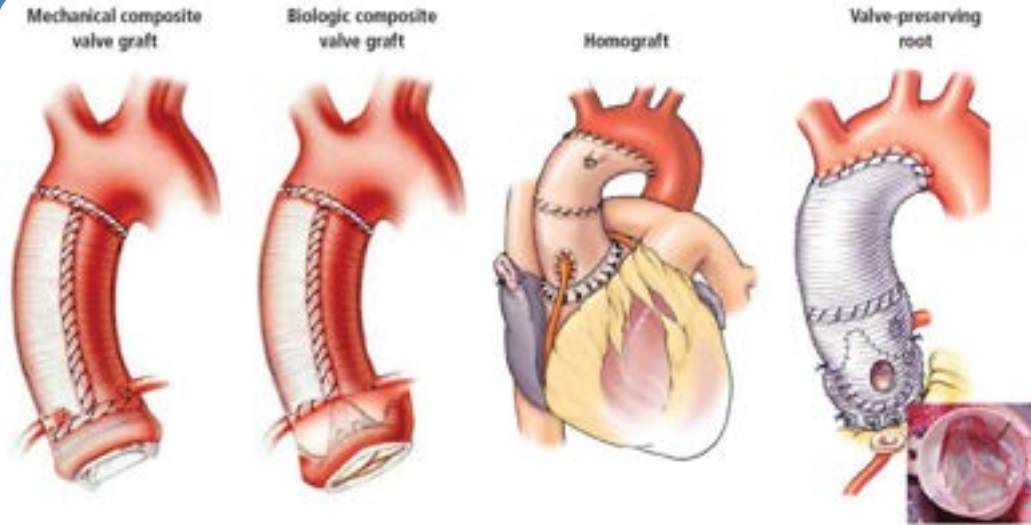


***Estimated Total Global Potential Cases
Approximately 1 Million Per Year***

1. Yin J. Cardiology Plus 2022
2. Nasab E. J Cardiothoracic Surg 2022
3. Rylski B. Eur J Cardio-Thoracic Surg 2014

Untreated Disease: A Critical Gap in Care

SURGICAL THERAPEUTIC OPTIONS



The **Bentall procedure** is among the most technically demanding cardiac surgeries, requiring **cardiopulmonary bypass**, **cardiac arrest**, & **reimplantation of the coronary arteries**.

Ascending TEVAR

Unique Anatomical Challenges

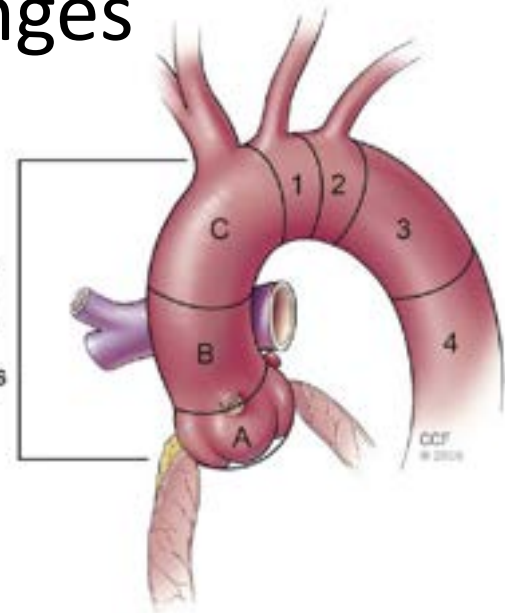
- Unique challenges
 - Curvature
 - Movement
 - Short length
 - Coronary arteries
 - AV commissures
 - Innominate artery
 - Shear stresses
 - Hemodynamics

Zone 0

0C: RtPA to Innominate

0B: Coronaries to RtPA

0A: Anulus to coronaries



Roselli. J Thorac Cardiovasc Surg 2018;155:1381-9





INTRODUCING AORTOSAVE

AORTOSAVE is a first-in-class transcatheter Endo-Bentall system that delivers a minimally invasive, modular solution for combined aortic valve and ascending aorta replacement.

No currently approved endovascular systems can fully replace the aortic root, ascending aorta, and valve in a single transcatheter procedure.



AORTOSAVE Technology Overview

- AORTOSAVE is a modular, transcatheter Endo-Bentall system.
- Combines a TAVR valve, branched stent graft for ascending aorta, and coronary stent grafts.
- Dry-tissue bovine pericardium enables ready-to-use delivery.
- AORTOSAVE integrates coronary access with branches.
- Design allows for: repositionable, retrievable and supra annular performance. Reducing procedural risks.

BRANCHES

Allow **access** to the **coronary arteries**

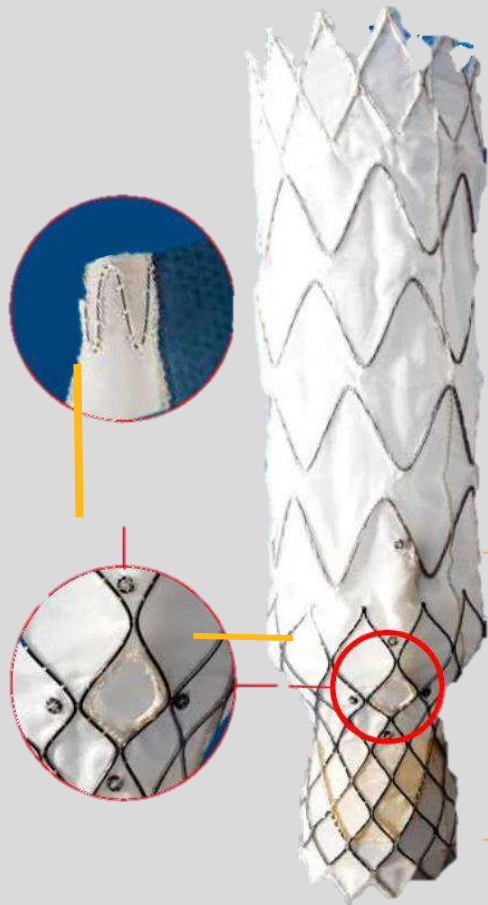
Greater **fixation area** for the branches

AORTIC GRAFT

Fixates into the ascending aorta

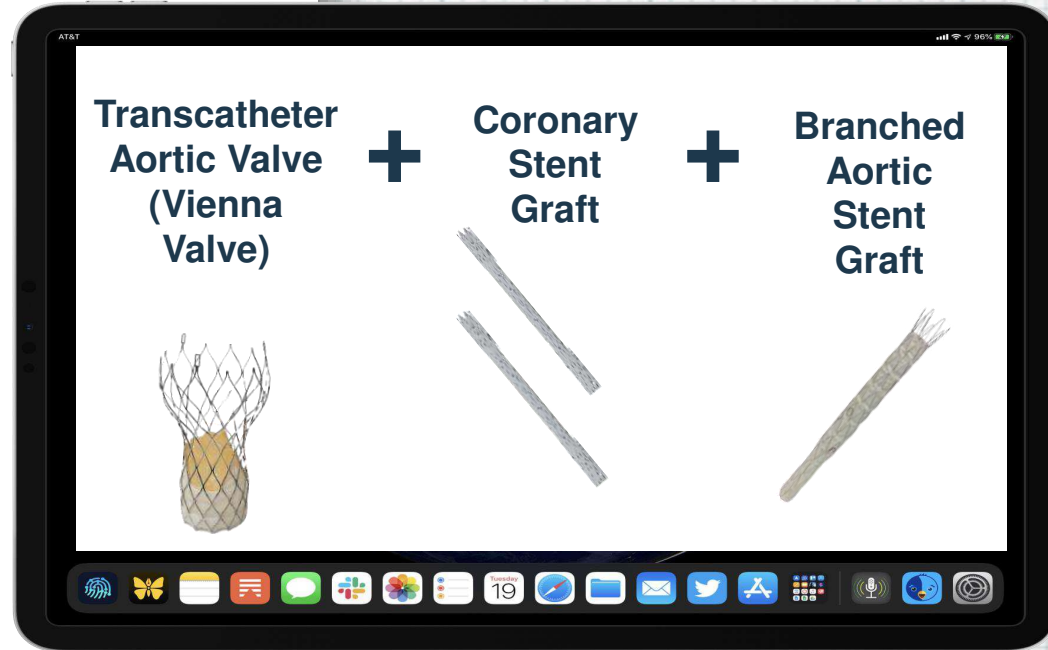
AORTIC VALVE

Replaces the patient's **native valve**; **Outer skirt** to improve **sealing**



The TAVR used in
Endo-Bentall is
**undergoing clinical
investigation for CE
Mark** (NCT04861805) and
has been **successfully
implanted in more
than 5y F.U.**

CE



AORTOSAVE Self-Expandable Transcatheter Endo-Bentall System

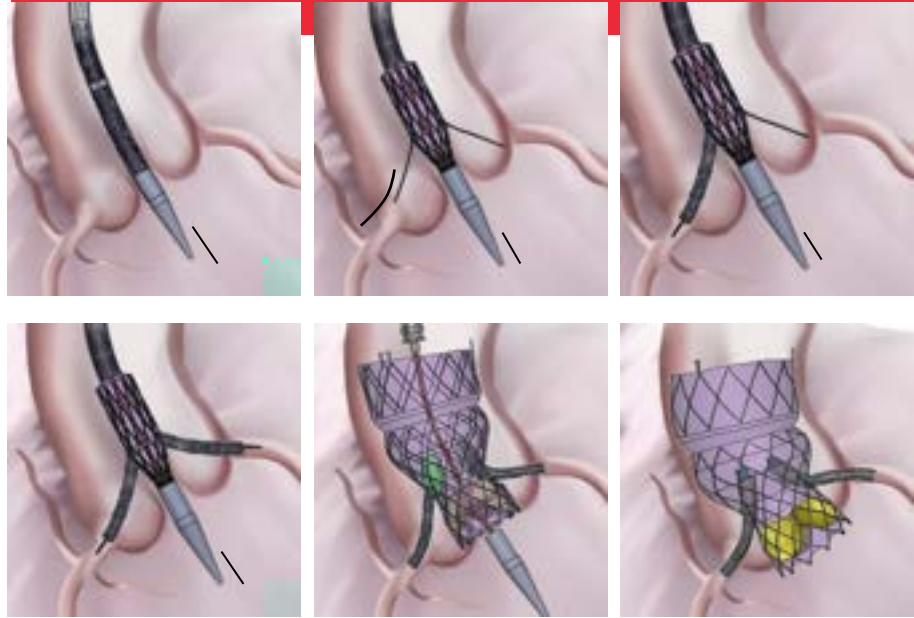
Delivery system

Pre-mounted
transcatheter system:

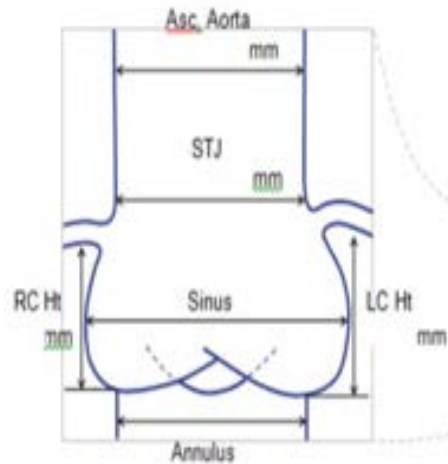
22-24Fr

Single access: subclavian,
BCT or femoral.

AORTOSAVE Endo-Bentall Procedure



AORTOSAVE Off the shelf !



42mm and 46mm



110mm
130mm

30mm

23mm, 26mm,
29mm, 31mm

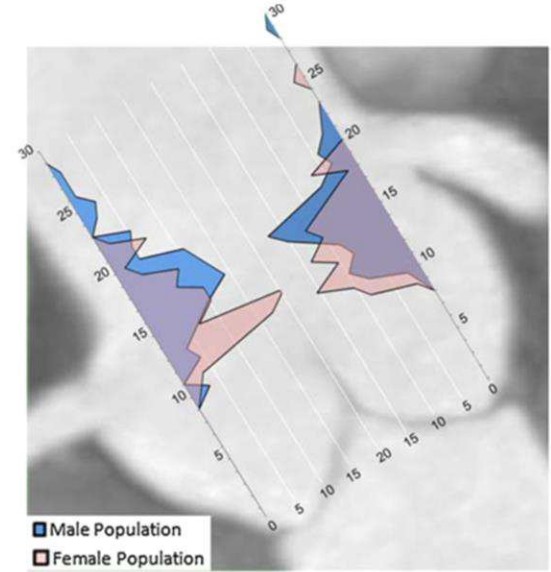


Fig. 3 Coronary ostial distribution—Visual representation of the distribution of the locations of the right and left coronary ostia overlaid onto a CT image showing the corresponding anatomy of the aortic root. Note the lower location of the right coronary artery (RCA) ostium and wider variation as compared to the ostium of the left main artery (LMA)

Knight J, Kurtcuoglu V, Muffly K, Marshall W Jr, Stolzmann P, Desbailles L, Seifert B, Poulikakos D, Alkadh H. Ex vivo and in vivo coronary ostial locations in humans. *Surg Radiol Anat.* 2009 Oct;31(8):597-604. doi: 10.1007/s00276-009-0488-9. Epub 2009 Mar 14. PMID: 19288041.

PRECLINICAL & CLINICAL ROADMAP

- 3D-printed human anatomical models
- Device conformability in the ascending aorta



Computational simulation



Bench test simulation



Beating Heart Simulation

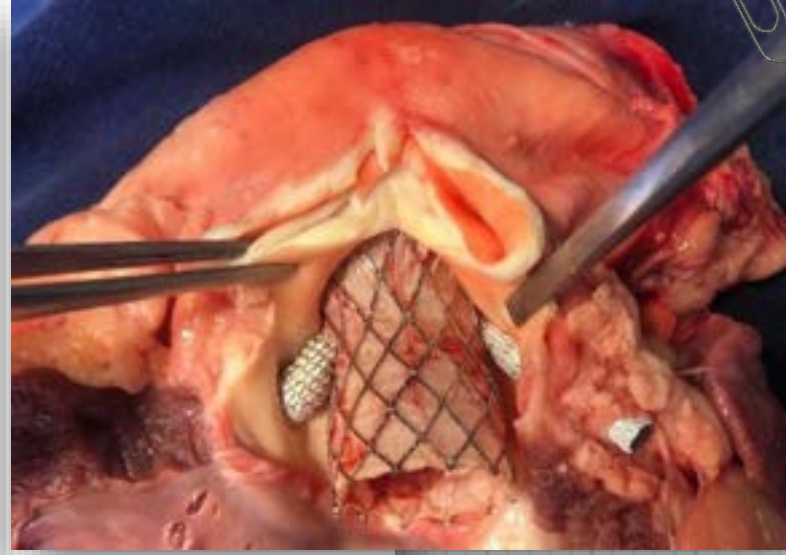
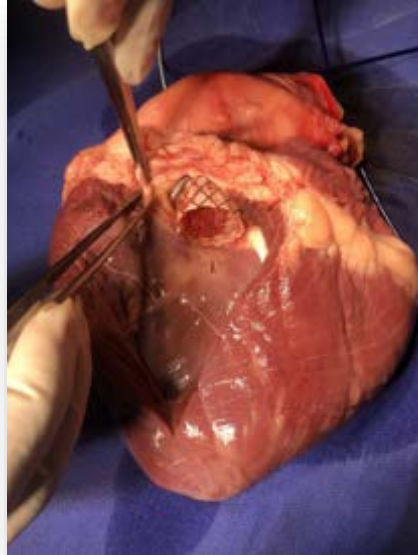
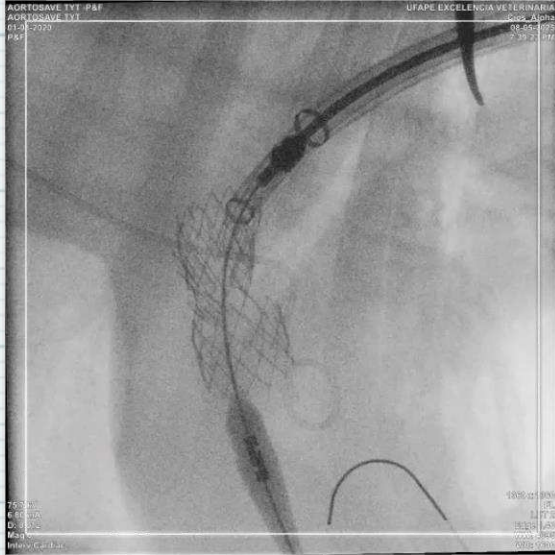


Procedure Simulation Confirming:

Coronary Artery Access | Successful Branch Implantation |
Preserved Coronary Flow

CRITICAL MILESTONES BEFORE ANIMAL TESTING

Animal Studies in Sheep & Calf



- Despite anatomical limitations, sheep studies demonstrated:
Trackability | Pushability | Accurate deployment
- Calf studies confirmed **safe connection of the main graft with coronary branches**

Human Proof-of-

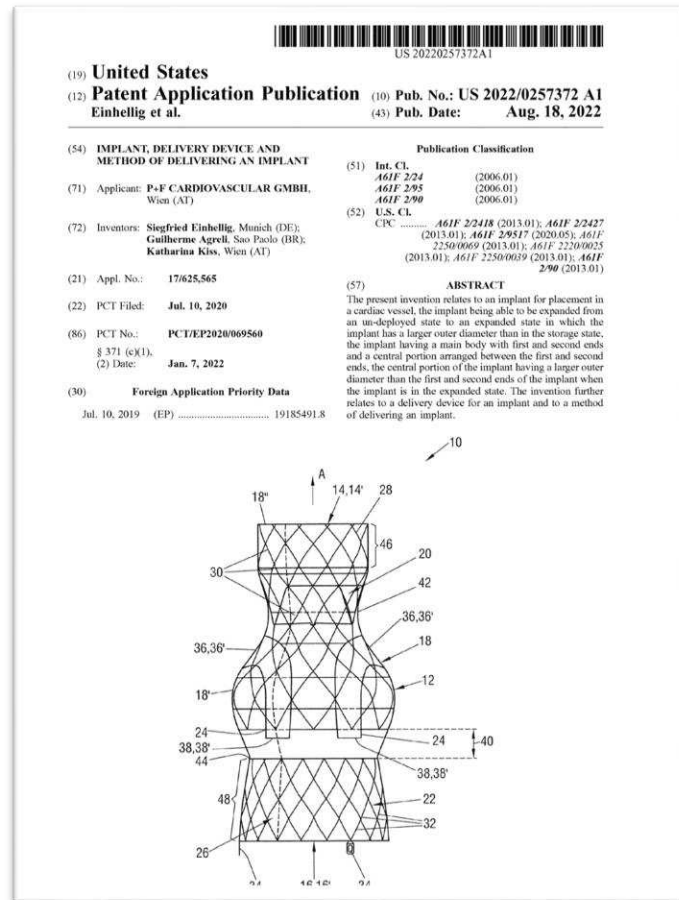


...approach.
(C) Right coronary stent connection with no endoleak & good distal flow. (D) Left coronary stent connection with no endoleak & good distal flow.

First-in-Human Endo-Bentall Procedure for Simultaneous Treatment of the Ascending Aorta and Aortic Valve

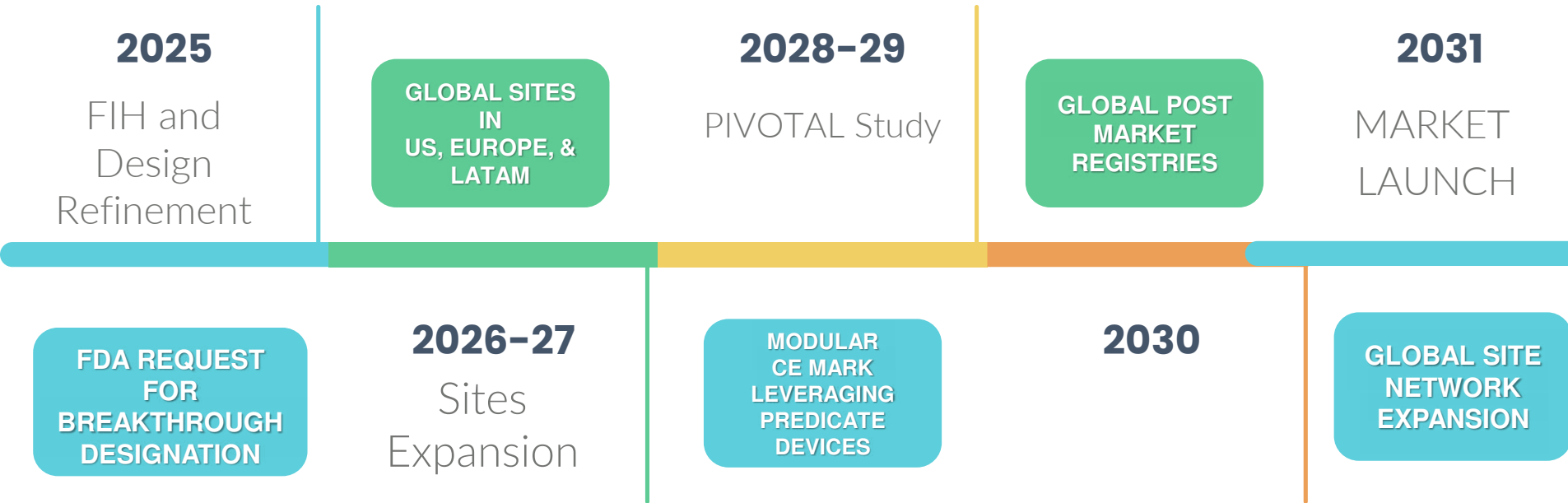
Diego Felipe Gaia, MD, PhD,¹ Oscar Bernal, MD,¹ Edilberto Castillo, MD,² Carolina Berta Neves Duarte Ferreira, MD,³ Danny Davis, MD,⁴ Mathew Simonato, MD,⁵ José Homero Palma, MD, PhD⁶

- Proprietary integration of modular TAVR + multibranched TEVAR architecture.
- Patient-specific customization approach and precannulated delivery method are novel.
- Patent applications pending in US, EU, and Brazil.



GO TO MARKET ROADMAP

AORTOSAVE



Endobentall market expected to be \$5 billion by 2031 (100.000 cases /y)

Conclusions

AORTOSAVE is the **first transcatheter Endo-Bentall system** designed to address the complex and underserved population with combined aortic valve and ascending aorta disease. By offering a **transcatheter solution**,

AORTOSAVE has the potential to:

- **Expand treatment** to high-risk and inoperable patients
- **Reduce surgical burden** and procedural complications
- **Preserve coronary access** for long-term management
- **Addresses** a significant unmet need for complex aortic interventions

That's not the future ! That's AortoSave, today !