New TAVR Systems and Accessory Devices

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CARDIOVASCULAR RESEARCH FOUNDATION

Disclosure Statement of Financial Interest
TCTAP2014: Seoul, Korea; April 22-25, 2014
Martin B. Leon, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation / Financial Relationship	Company
• Grant / Research Support	• Abbott, Boston Scientific, Edwards Lifescience, Medtronic
• Consulting Fees / Honoraria	• Angioscore, Meril Lifescience, Micell,
• Shareholder / Equity	• Apica, Angiometrix, Backbeat, Caliber, Cappella, Claret, Coherex, Elixir, GDS, Medinol, Mitralign, Valve Medical

New TAVR Systems and Accessory Devices

- New TAVR Systems
- Access and Closure Strategies
- Cerebral Embolic Protection Devices
- New Valvuloplasty Technologies
- Advanced Imaging Modalities

New TAVR Systems and Accessory Devices

New TAVR Systems

New TAVR Systems

Current limitations…

- System profiles still too large for "universal" trans-femoral access – entry sheath "OD" (esp. for large valves) generally >18 Fr
- Inaccurate and unpredictable positioning at optimal landing zone (ideally, without need for RV pacing)
- Increased permanent pacemaker requirements
- Increased para-valvular regurgitation
- Increased procedure-related strokes
- 4Rs – recapture, reposition, redeploy, and retrieve (if necessary)

New TAVR Systems

Current limitations…

- **Infrequent but important complications (e.g. coronary occlusion and annulus rupture)**
- **Structural issues - optimal frame geometry, opening force, hemodynamics, and valve durability**

PVT - The Foundation…

Percutaneous Valve Technologies
Aortic Heart Valve

Polyurethane

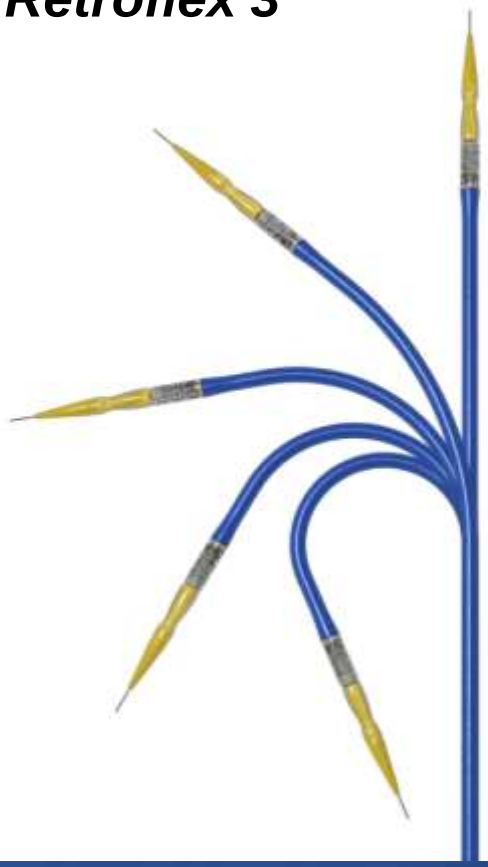
23mm max diameter

Bovine pericardium / Stainless steel stent

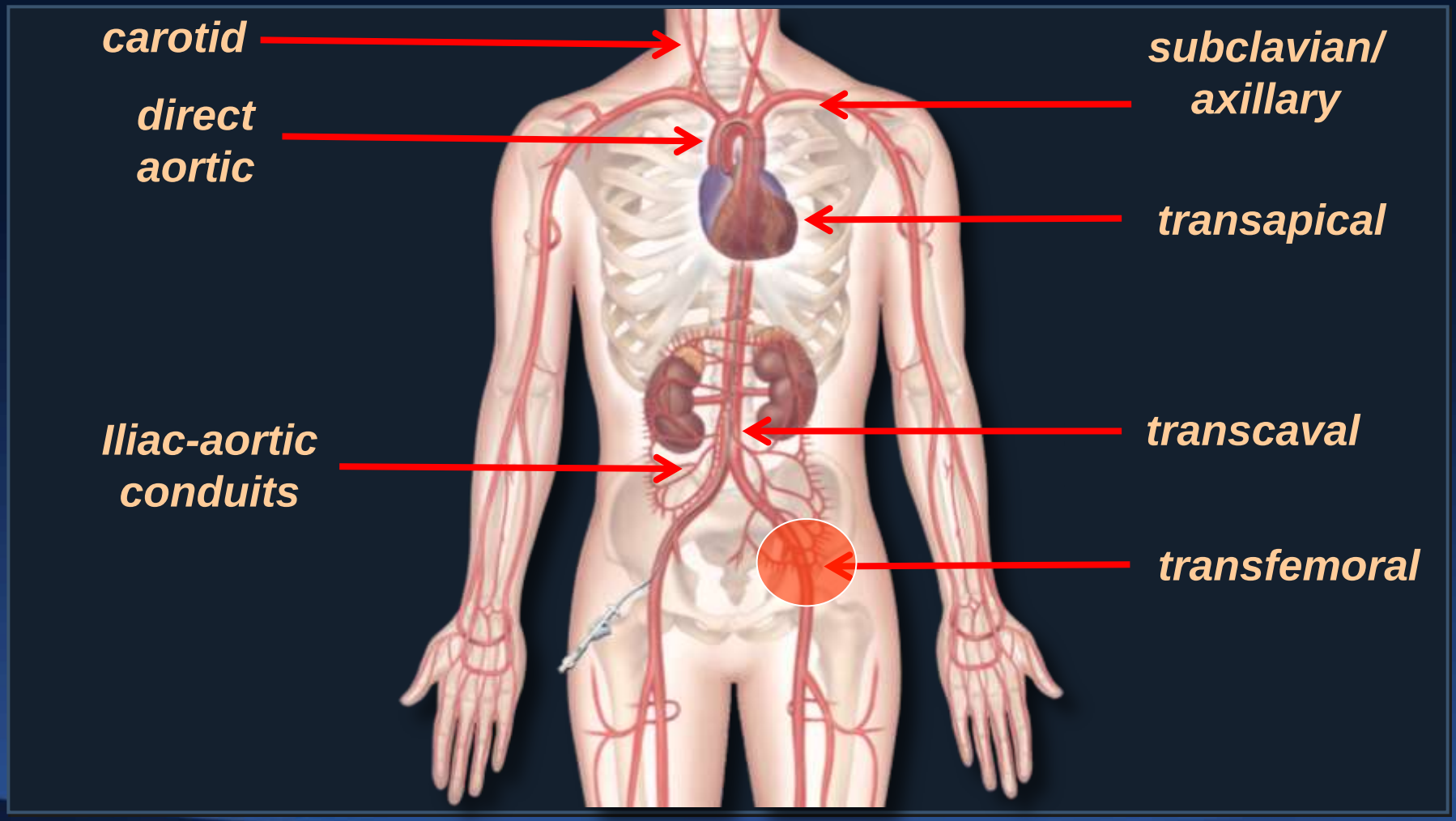
Edwards *Flex Cath* Delivery System Evolution

Retroflex Delivery Catheter

Retroflex 3



TAVR – 2014
Access Alternatives



New TAVR Systems

Edwards THV Evolution

- *Stainless Steel Frame*
- *Equine Pericardial Tissue*

2004

Cribier-Edwards™ THV 23mm

- *Stainless Steel Frame*
- *Bovine Pericardial Tissue*

2007

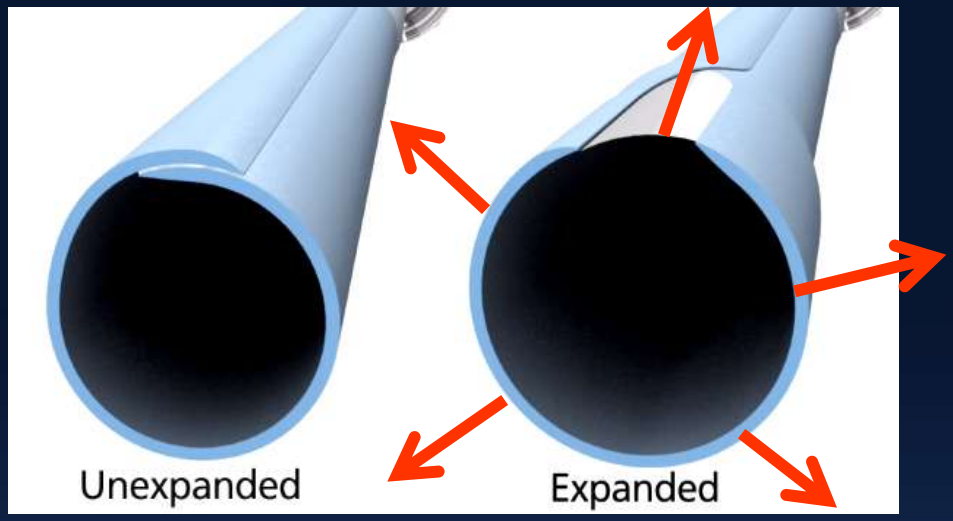
Edwards SAPIEN™ THV 23 mm and 26 mm

- *Cobalt-Chromium Frame*
- *Bovine Pericardial Tissue*
- *Semi-closed leaflets*
- *Reduced crimped profile*

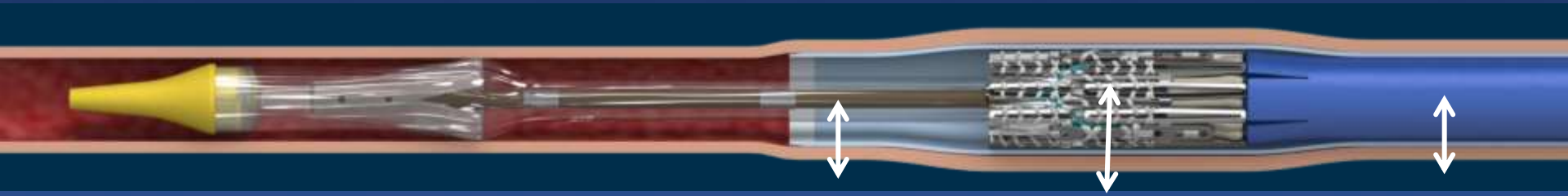
2010

Edwards SAPIEN XT ™ THV 23 mm, 26 mm, and 29mm

The New Edwards eSheath



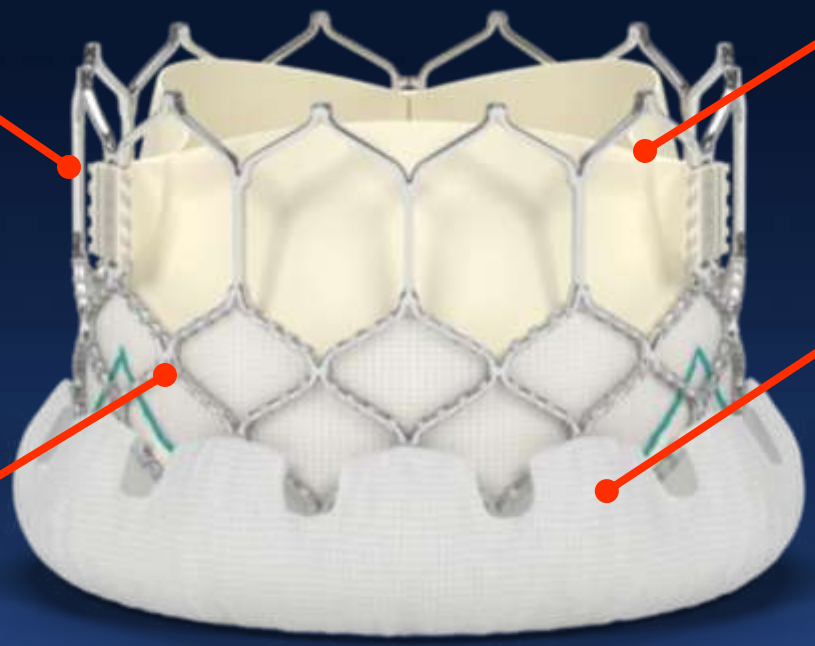
The eSheath expands from 14-16F to 18-20F which facilitates smooth delivery system passage, then returns to a reduced profile once the valve has passed through the sheath



SAPIEN 3 Transcatheter Heart Valve

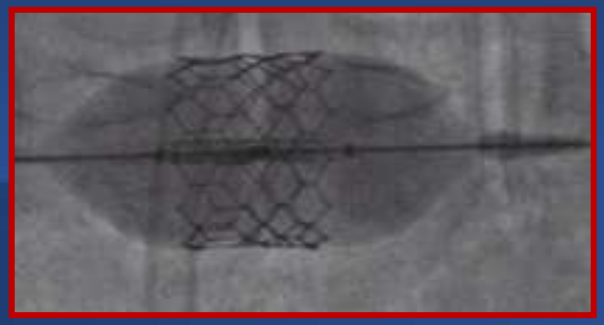
20, 23, 26, and 29 mm sizes

Bovine Thermafix Tissue Leaflets



External Sealing Ring

Balloon-expandable Cobalt Chromium Frame with larger landing zone



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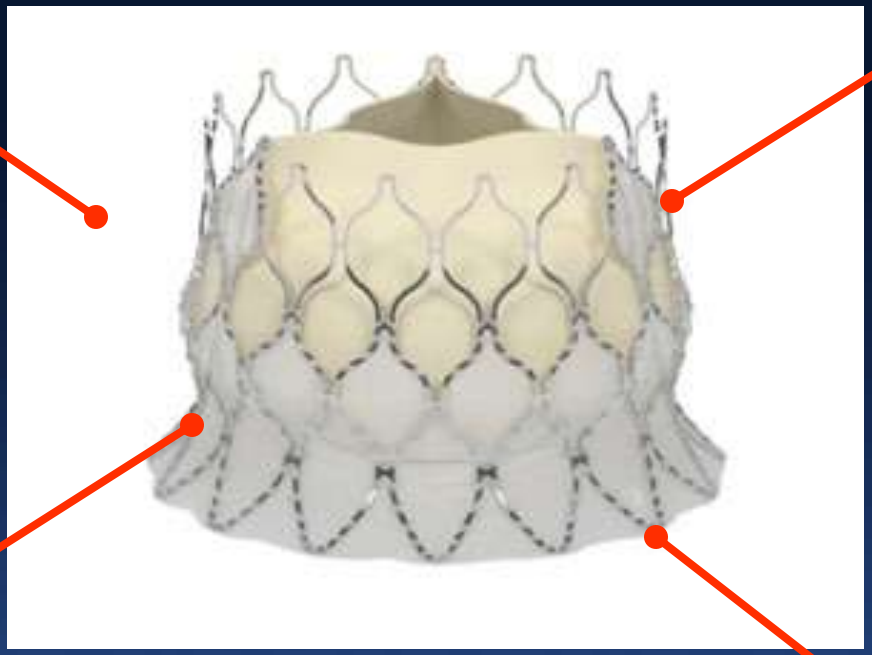
CENTERA Transcatheter Heart Valve

23, 26 and 29mm sizes

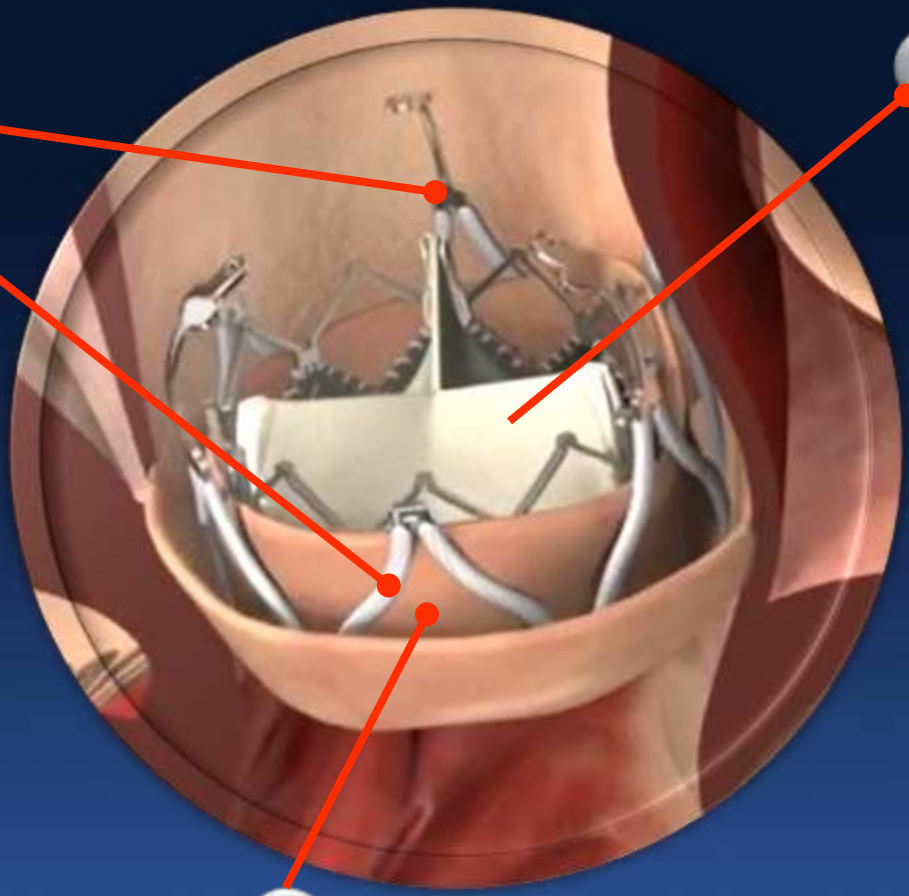
Bovine Pericardial Tissue Leaflets



Discrete Valve Designed to Anchor in the Annulus

Self expanding Nitinol Frame

Edwards HELIO AR Project Implant Technology



1 *Frame*

The Frame is positioned behind the aortic leaflets

2 *Native Leaflets*

3 *Sapien XT Valve*

The native leaflets are captured between the SAPIEN XT and the Frame

Edwards AR Device:
First-in-Human Procedure

TF Delivery of Frame

Orient the Frame behind the native leaflets and in the base of the aortic cusps

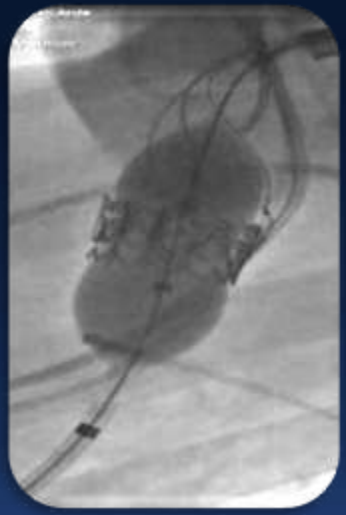
TA Delivery of SAPIEN XT valve

Guide SAPIEN XT valve through the native valve

Implant Alignment

Align SAPIEN XT valve and Frame

Balloon Inflation

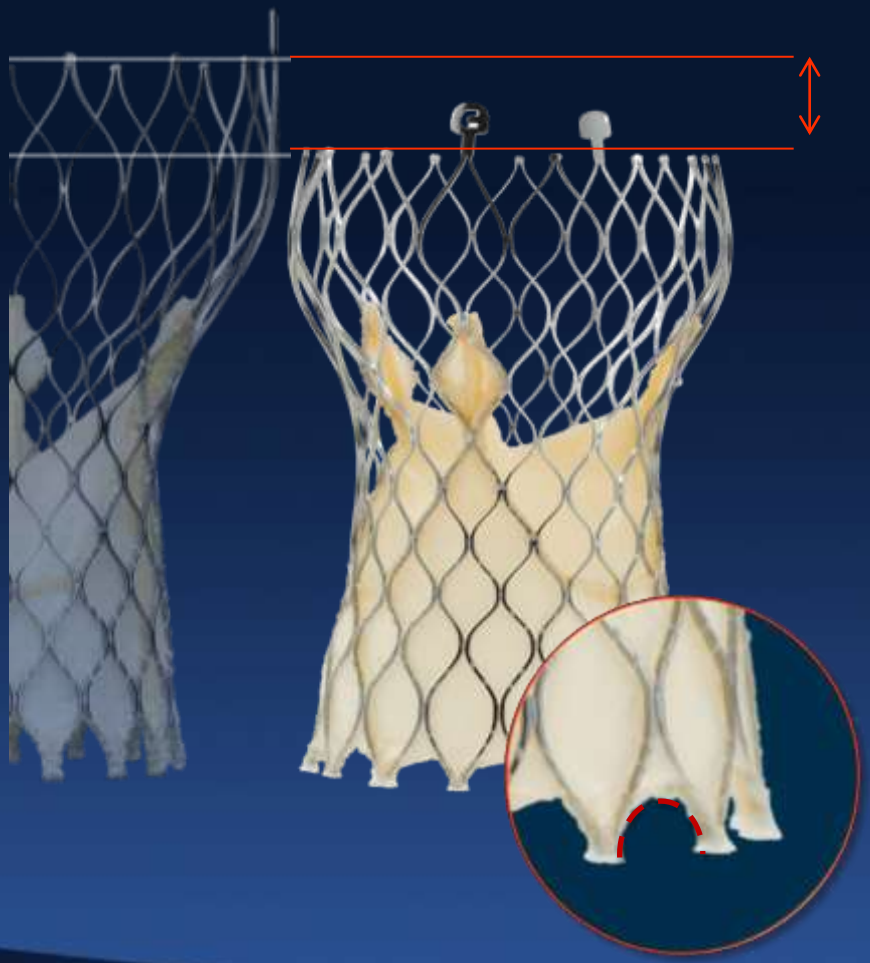


Deploy SAPIEN XT valve

Confirmatory Angio

Confirm placement

Medtronic CoreValve Evolut R



- *Outflow shortened and redesigned*
- *More consistent radial force*
- *Extended skirt at inflow*
- *Optimized cover index*
- *Optimal Implant Depth: ~3mm*
- *Porcine pericardium*
- *Supra-annular function*
- *Facilitates post-TAVI coronary access*

EnVeo R Delivery System

Recapturable, Retrievable, Repositionable

CoreValve w/ 18FR Cook Sheath

18FR

~22 FR (OD) 7.3mm

~4 FR Reduction

EnVeo R w/ InLine Sheath

18FR

Truly 18FR (OD) 6mm

Medtronic Engager Valve Design

- Control arms
- Self-expanding nitinol frame and polyester skirt
- Supra-annular valve function
- Bovine pericardial tissue
- True anatomic alignment

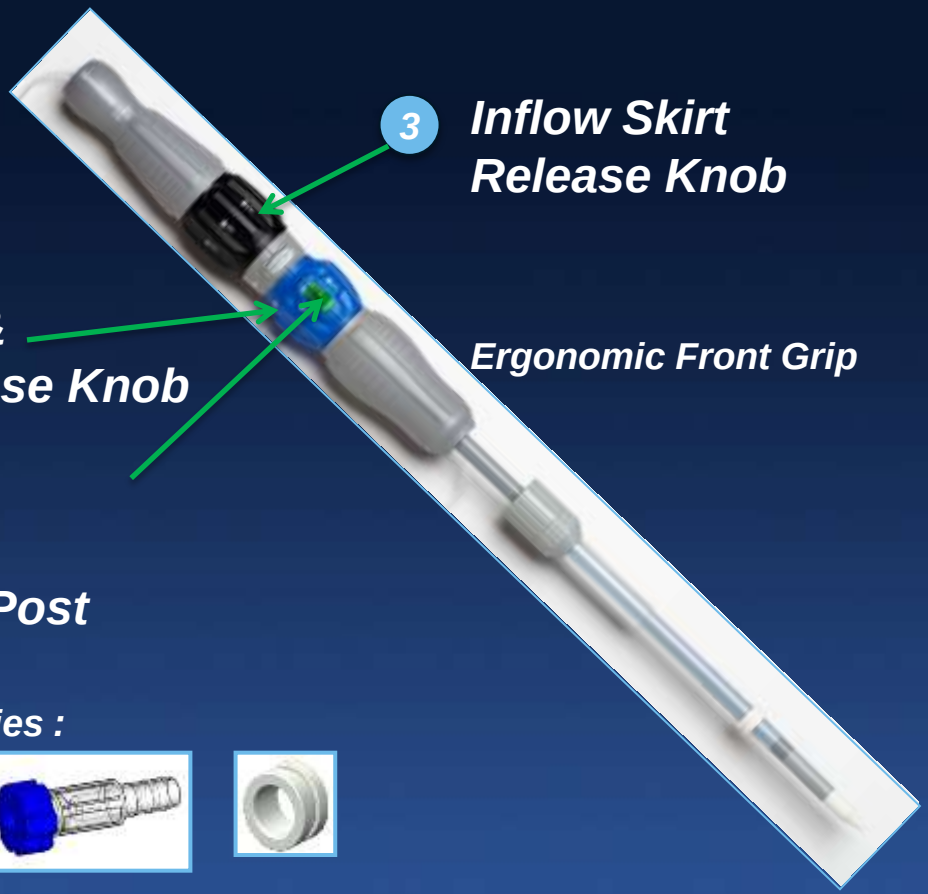
Engager TA Delivery System

- Tactile control during deployment
- 29 Fr equivalent TA delivery system
- Integrated introducer sheath
- Three step deployment

The outer diameter of the integrated sheath is 10.7 mm

Engager Direct Aortic Delivery System

The delivery system is designed for aortic access using a mini-sternotomy or mini-thoracotomy



3 ***Inflow Skirt Release Knob***

Ergonomic Front Grip

1 ***Control Arm & Outflow Release Knob***

2 ***Safety Stop - Allows for Commissure Post Release***

Optional Accessories :

Stability Sheath

Tuohy Borst

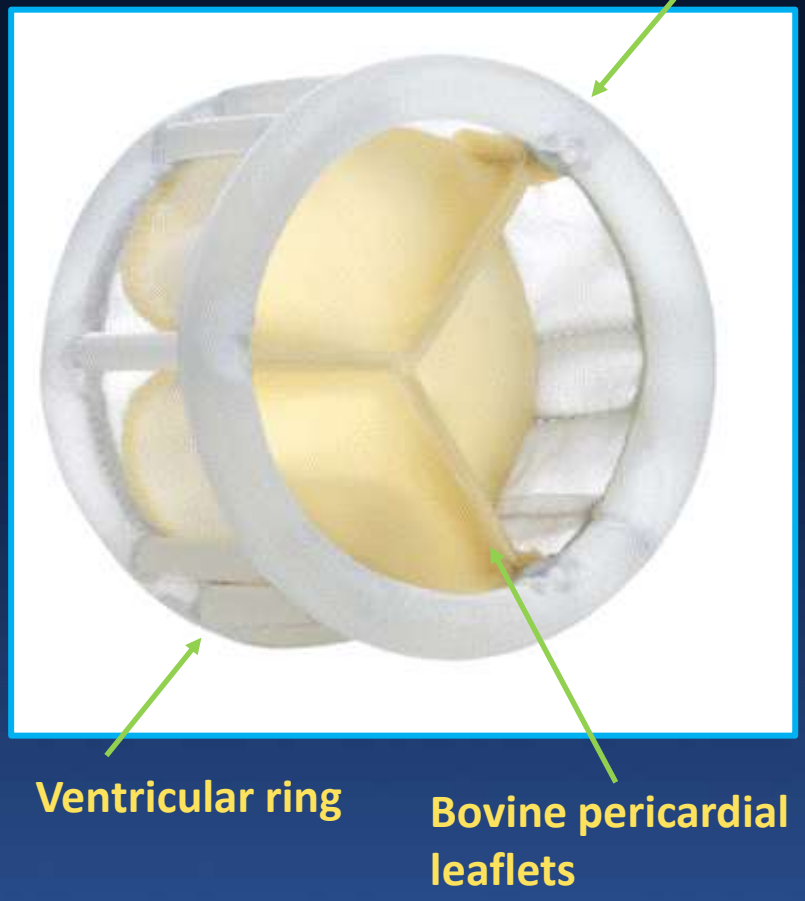
Suture Collar

New TAVR Systems

Direct Flow Valve – Design

Minimized Risk of Aortic Regurgitation

- Double-ring design for a secure and durable seal
- Complete hemodynamic assessment before final implantation
- Unlimited repositioning for optimized valve placement
- The valve is fully retrievable



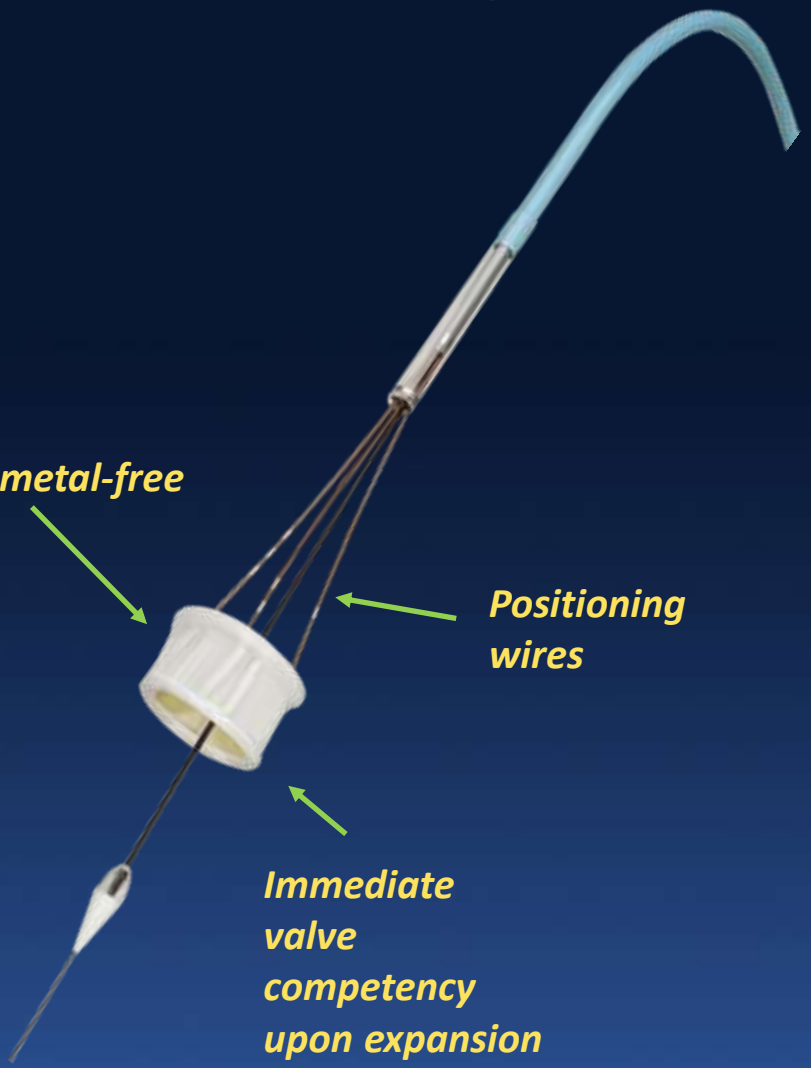
Direct Flow System – Design

Precise valve positioning and reduced hemodynamic instability

- Positioning wires allow for controlled adjustments of valve position
- Immediate valve competency upon expansion
- Minimum to no contrast necessary
- No rapid pacing required during positioning
- No post-dilatation used

Treatment range:

- 25mm valve treats 21-24mm annulus
- 27mm valve treats 24-26mm annulus



ACURATE TF™ Aortic Bioprosthesis

SELF-EXPANDING NITINOL

Conforms to native anatomy

3 sizes: 21mm to 27mm

STABILIZATION ARCHES

Flexible

Self-aligning

UPPER CROWN

Supra-annular anchoring

Stable positioning

Tactile feedback

LOWER CROWN

Minimal LV protrusion

Low risk of conduction defects

PERICARDIAL LEAFLETS

Porcine pericardium

Lower profile

PERICARDIAL SKIRT

Inner & outer skirt acts as seal to prevent PVL

ACURATE TF™ 3-Step Implantation

Initial Alignment

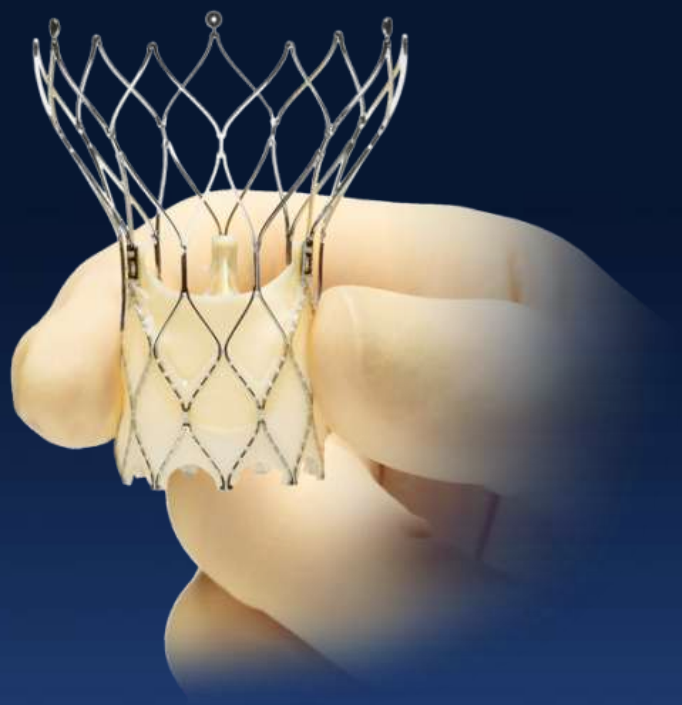
1. Open upper crown & gentle pressure forward

2. Open stabilization arches

3. Open lower crown for full deployment

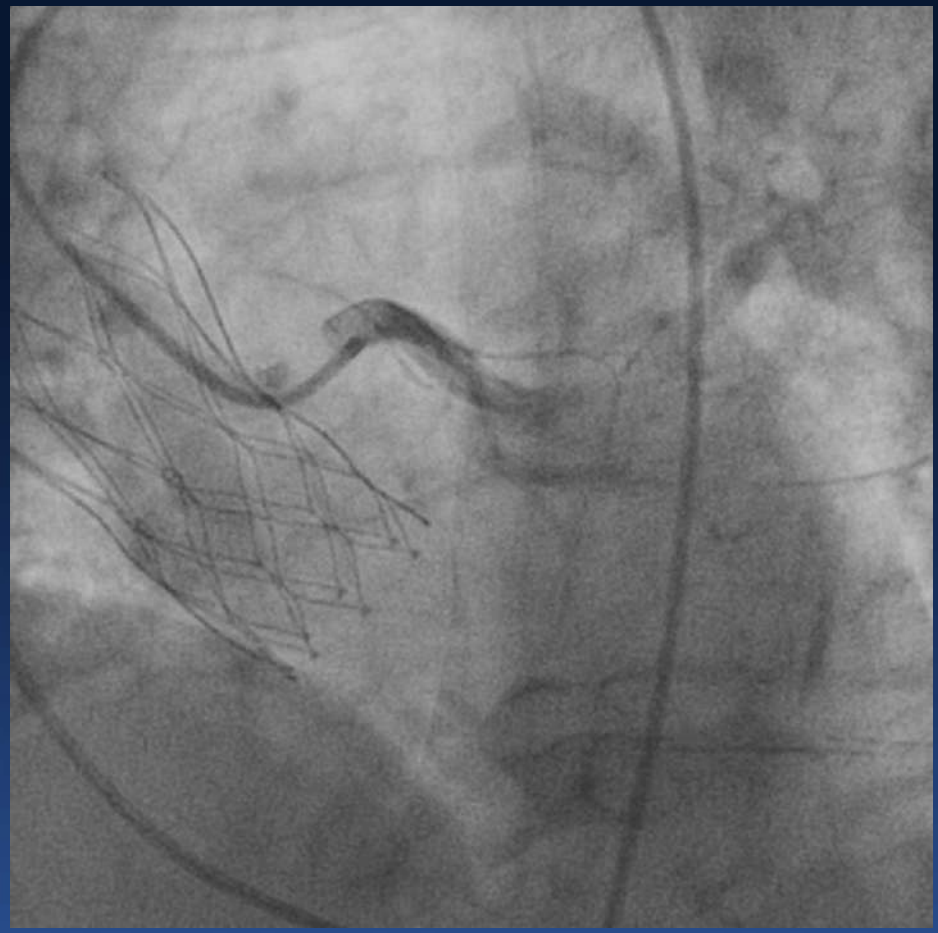
Portico Valve Design Features

- Self expanding stent design: fully repositionable and retrievable
- Bovine pericardium leaflets (intra-annular)
- Porcine pericardium sealing cuff
- Both leaflets and cuff are treated with Linx™ AC treatment*
  - Same anticalcification technology used on St. Jude Medical surgical aortic tissue valves
- 23, 25, 27 and 29mm valves



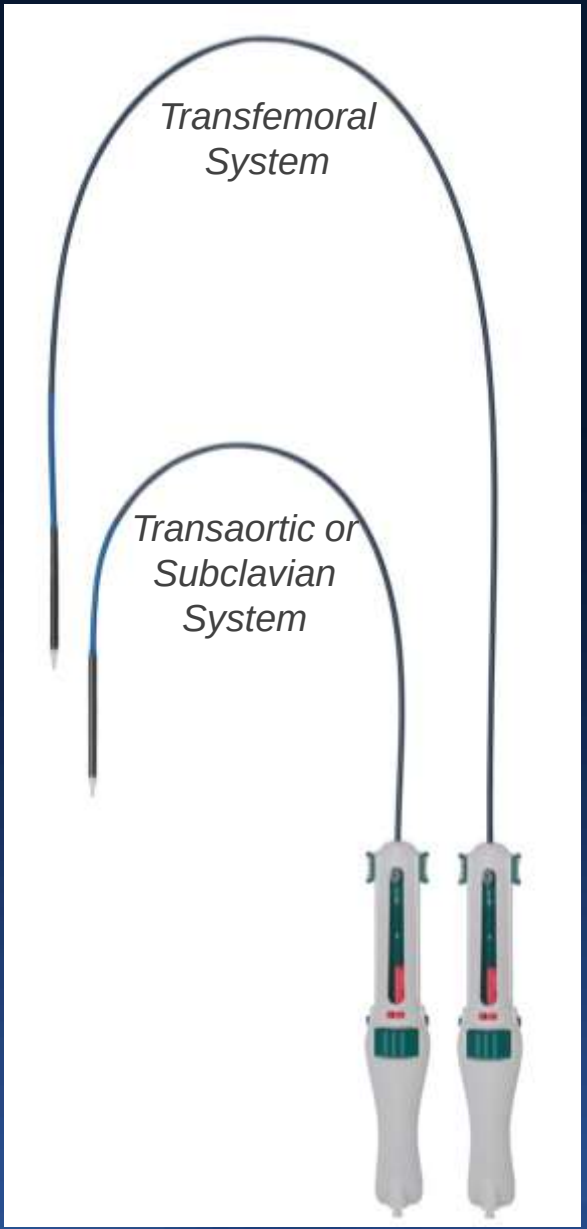
Portico Valve Design Features

- Large stent cells allows access to coronary ostia
- Annular placement minimizes conduction issues
- Improved seal zone to reduce PVL



Portico Trans-aortic or Subclavian Delivery Systems

- Compatible with 18 F introducer sheath
- Similar design to Transfemoral delivery system
  - 65cm working length



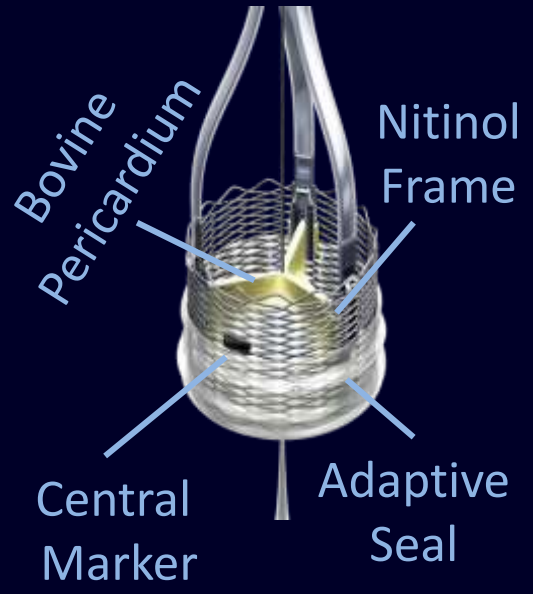
*Until fully deployed

Lotus Valve System

Design Goals

Preloaded delivery system

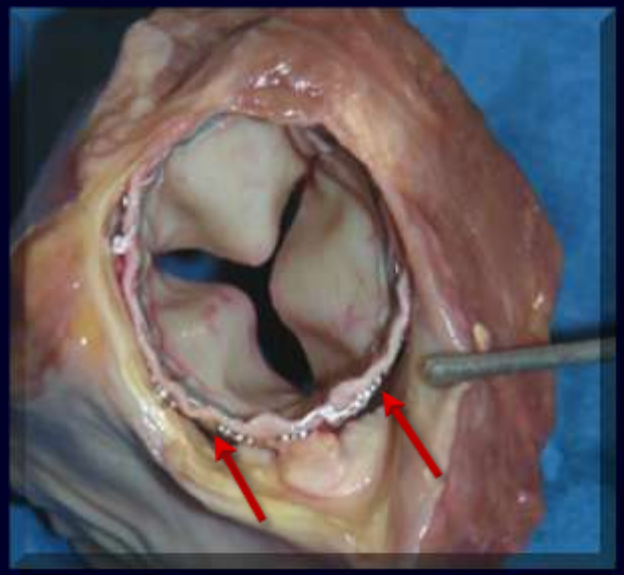
Intuitive handle design



- Deployed via controlled mechanical expansion
- No rapid pacing
- Functions early
- Central radiopaque marker to aid precise placement
- Fully repositionable and retrievable prior to release
- Adaptive seal to minimize paravalvular leak

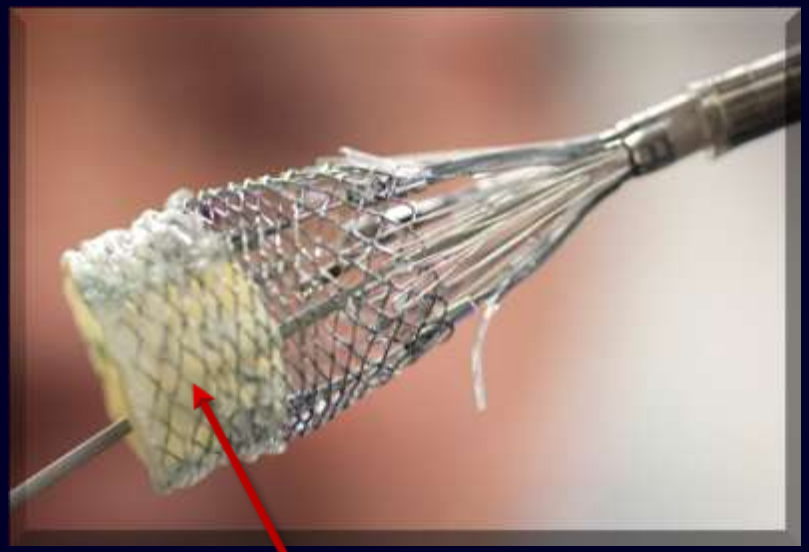
Lotus Valve System Design Goals

Minimize Paravalvular Leakage (PVL)



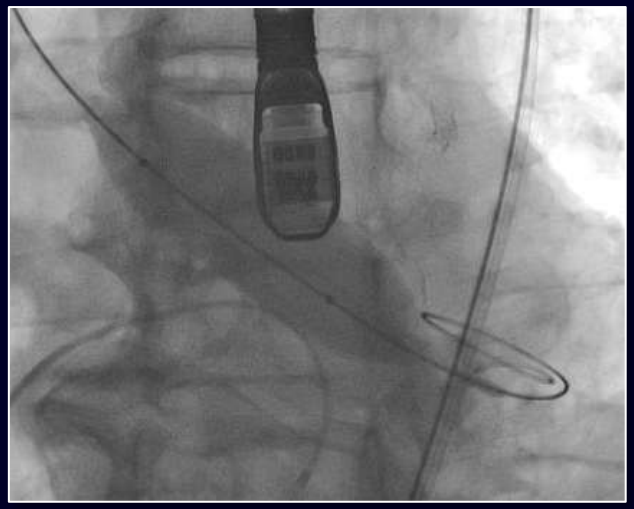
Non – Circular Annulus
+
Irregular calcification
=
PVL

Adaptive seal to mitigate PVL



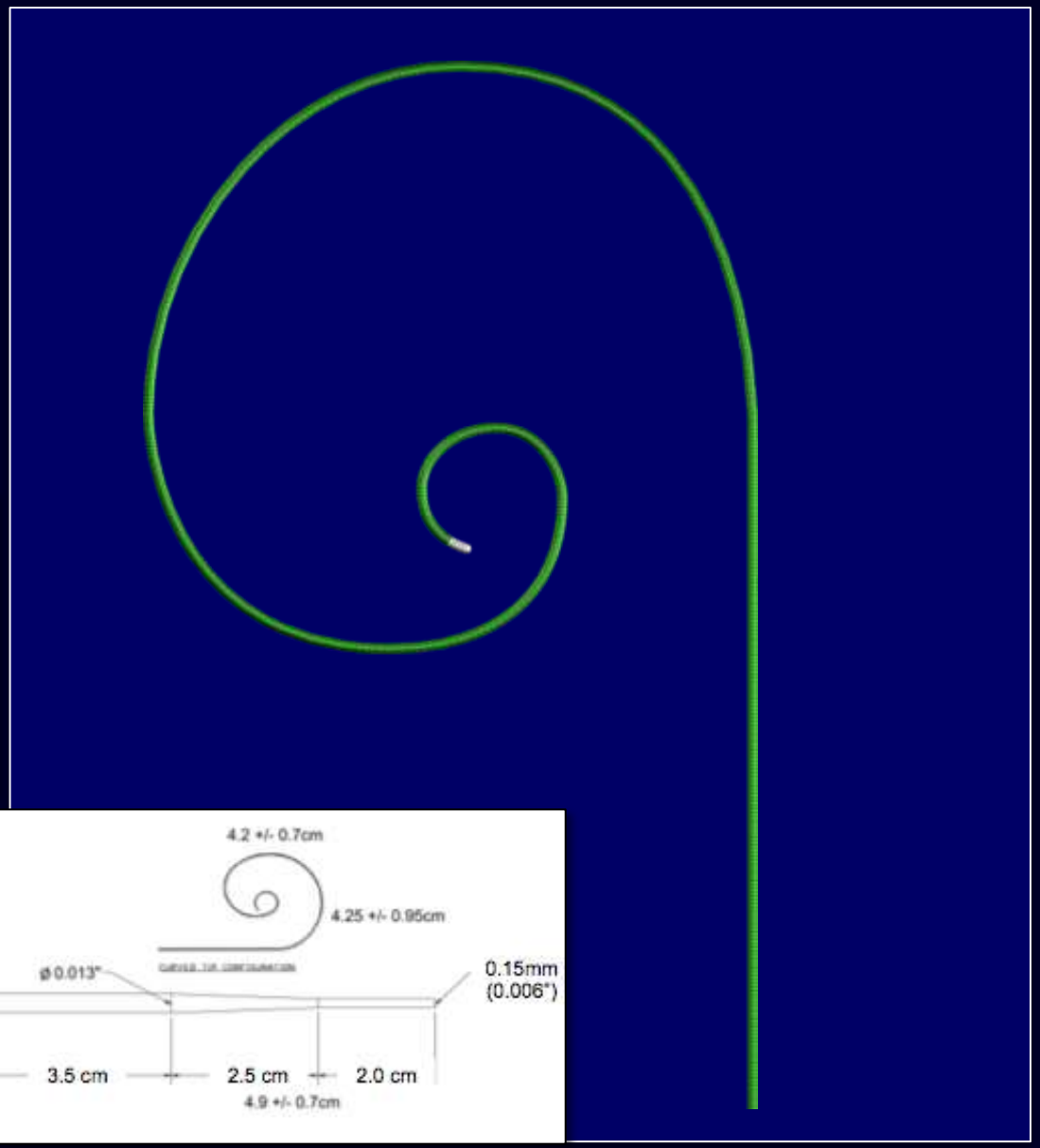
Adaptive
Seal

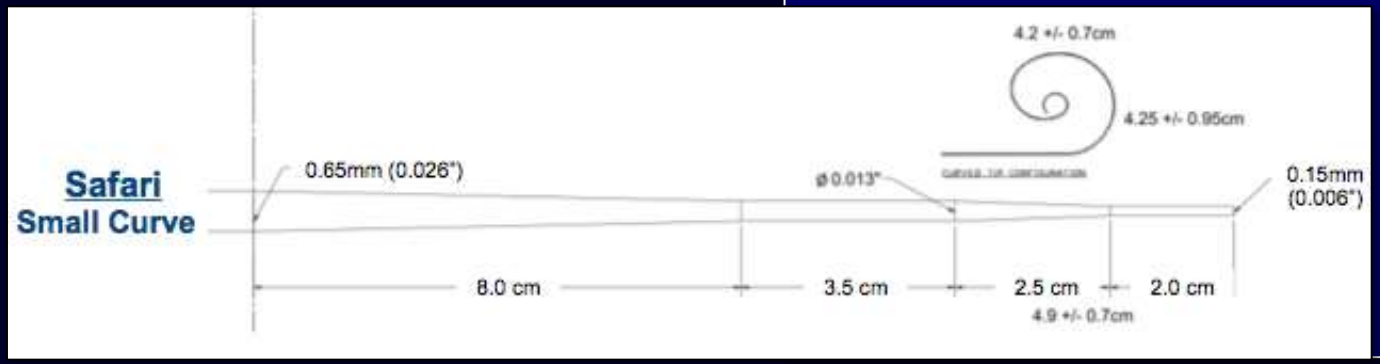
Safari Guidewire



LUBRIGREEN™ Pre-Coat PTFE

Leading Competitive Spray-Coat PTFE



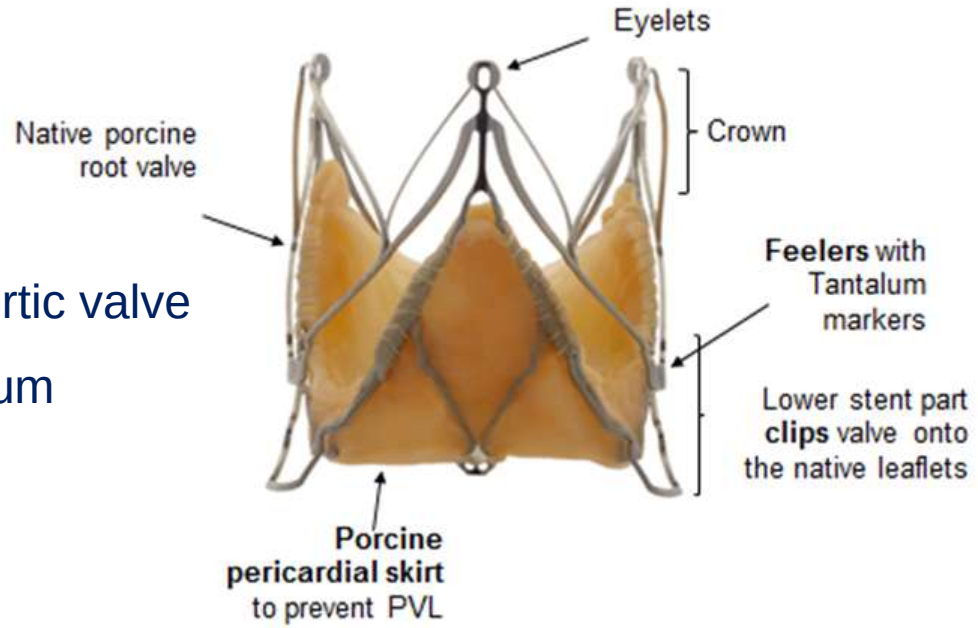


The Safari™ guidewire is manufactured by Lake Region Medical and distributed by Boston Scientific Corporation

Transapical JenaValve TAVI system

The JenaValve prosthesis

Deployment	Self expanding
Stent Material	Nitinol
Valve Material	Native porcine aortic valve
Skirt Material	Porcine pericardium
Valve Sizes	23, 25, 27 mm
Annulus Range	21-27 mm



Features

- Feeler guided, anatomically correct positioning
- JenaValve clipping mechanism embraces native AV cusps
- Enables valve deployment without rapid pacing
- Low risk of coronary obstruction

Transapical JenaValve TAVI System

Easy 3 step controlled implantation

Step 1
Release of positioning feelers

Step 2
Clipping of AV cusps

Step 3
Full deployment

JenaValve – the only TAVI system worldwide with CE mark for **Aortic Regurgitation**

Successful Treatment of Pure Aortic Insufficie
with Transapical Implantation of the JenaVal

Abstract
Keywords
- aortic valve
- transcatheter aortic valve implantation
- transapical

Introduction

Case Description

Transapical Implantation of a Second-Generation Transcatheter Heart Valve in Patients With Noncalcified Aortic Regurgitation

Moritz Seiffert, MD,* Patrick Diemert, MD,† Dietmar Koschyk, MD,†

replacement after evaluation by an interdisciplinary heart team (logistic EuroSCORE [European System for Cardiac Operative Risk Evaluation] range 3.1% to 38.9%). Procedural and acute clinical outcomes were analyzed.

Results Implantation was successful in all cases without relevant remaining aortic regurgitation or signs of stenosis in any of the patients. No major device- or procedure-related adverse events occurred and all 5 patients were alive with improved exercise tolerance at 3-month follow-up.

Conclusions Noncalcified aortic regurgitation continues to be a challenging pathology for transcatheter aortic valve implantation due to the risk for insufficient anchoring of the valve stent within the aortic annulus. This report provides first evidence that the JenaValve prosthesis may be a reasonable option in these specific patients due to its unique stent design, clipping the native aortic valve leaflets, and offering promising early results. (J Am Coll Cardiol Intv 2013;■:■–■) © 2013 by the American College of Cardiology Foundation

CASE REPORT

aortic valve (JenaValve) implantation for severe aortic
and aortic aneurysm

JENAVALVE
Designed with the patient at heart

September 16, 2013

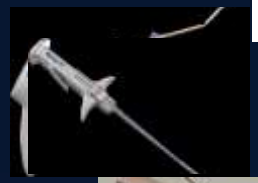
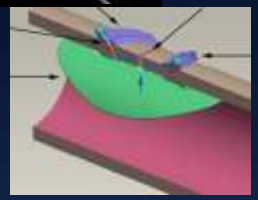
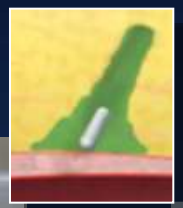
JENAVALVE TAVI SYSTEM RECEIVES EXTENDED CE MARK APPROVAL FOR TREATMENT OF AORTIC INSUFFICIENCY

Only TAVI System with Indications to treat Aortic Stenosis and Aortic Insufficiency

New TAVR Systems and Accessory Devices

Access and Closure Strategies

Large Vessel Closure Landscape

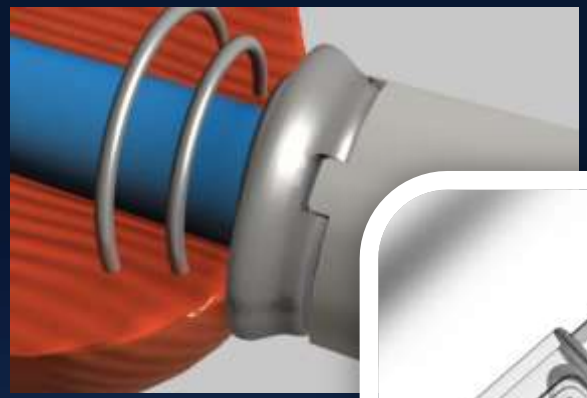
Category	Company	Technology
Emerging Suture Based Technologies	Sutura Superstich	
	MediGlobe	
	SpiRx	
	Vasostich	
Emerging Patch or Plug Technologies	Vivasure	
	Access Closure-GRIP	
	InSeal	
	Promed	

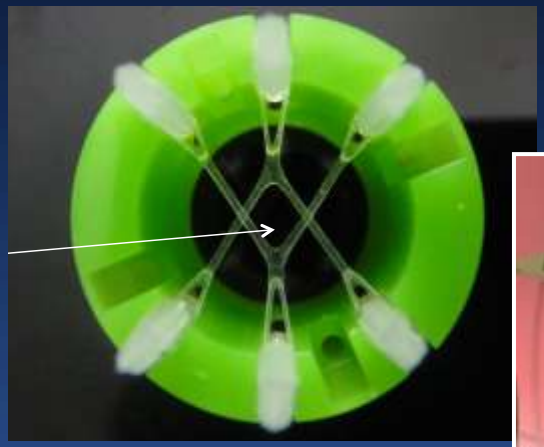
Strategic Players

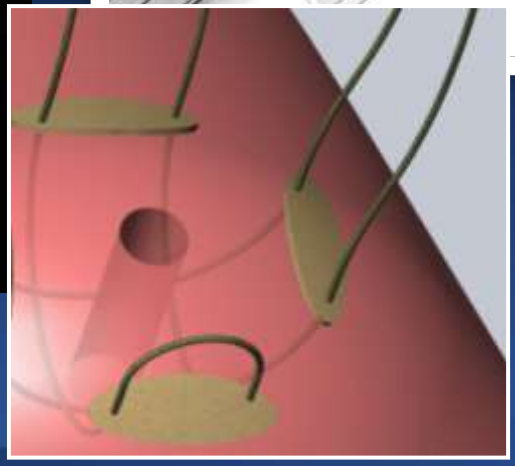
Medtronic, Inc.	*Abbott Vascular*	*St. Jude Medical*	*Cook/Cardica*
			COOK MEDICAL / cardica

Transcutaneous Ventricular Access and Closure (TVAC)

- *Apica*
- *Entourage CardioClose*
- *MID Permaseal*
- *Novogate*
- *SpiRx*
- *Cardiapex*







Apica ASC System

FIM Publication; April, 2013

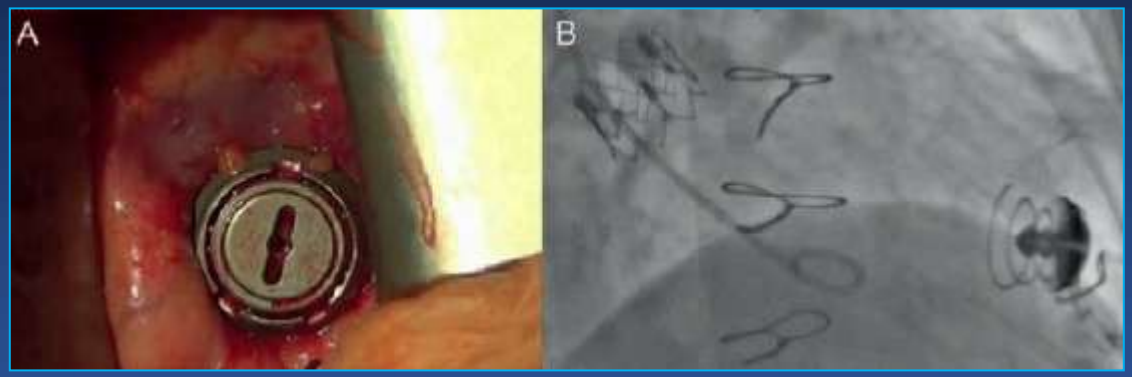
European Journal of Cardio-Thoracic Surgery Advance Access published April 5, 2013

European Journal of Cardio-Thoracic Surgery (2013) 1–6
doi:10.1093/ejcts/ezt198

ORIGINAL ARTICLE

First-in-man evaluation of the transapical APICA ASC™ access and closure device: the initial 10 patients†

Johannes Blumenstein[a,*], Joerg Kempfert[a], Arnaud Van Linden[a], Mani Arsalan[a], Sina K. Schmidt[a], Helge Mollmann[b], Won-Keun Kim[a,b], Vinod Thourani[c] and Thomas Walther[a]

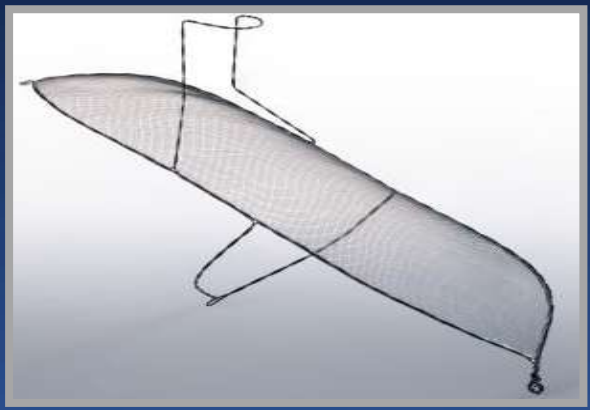


New TAVR Systems and Accessory Devices

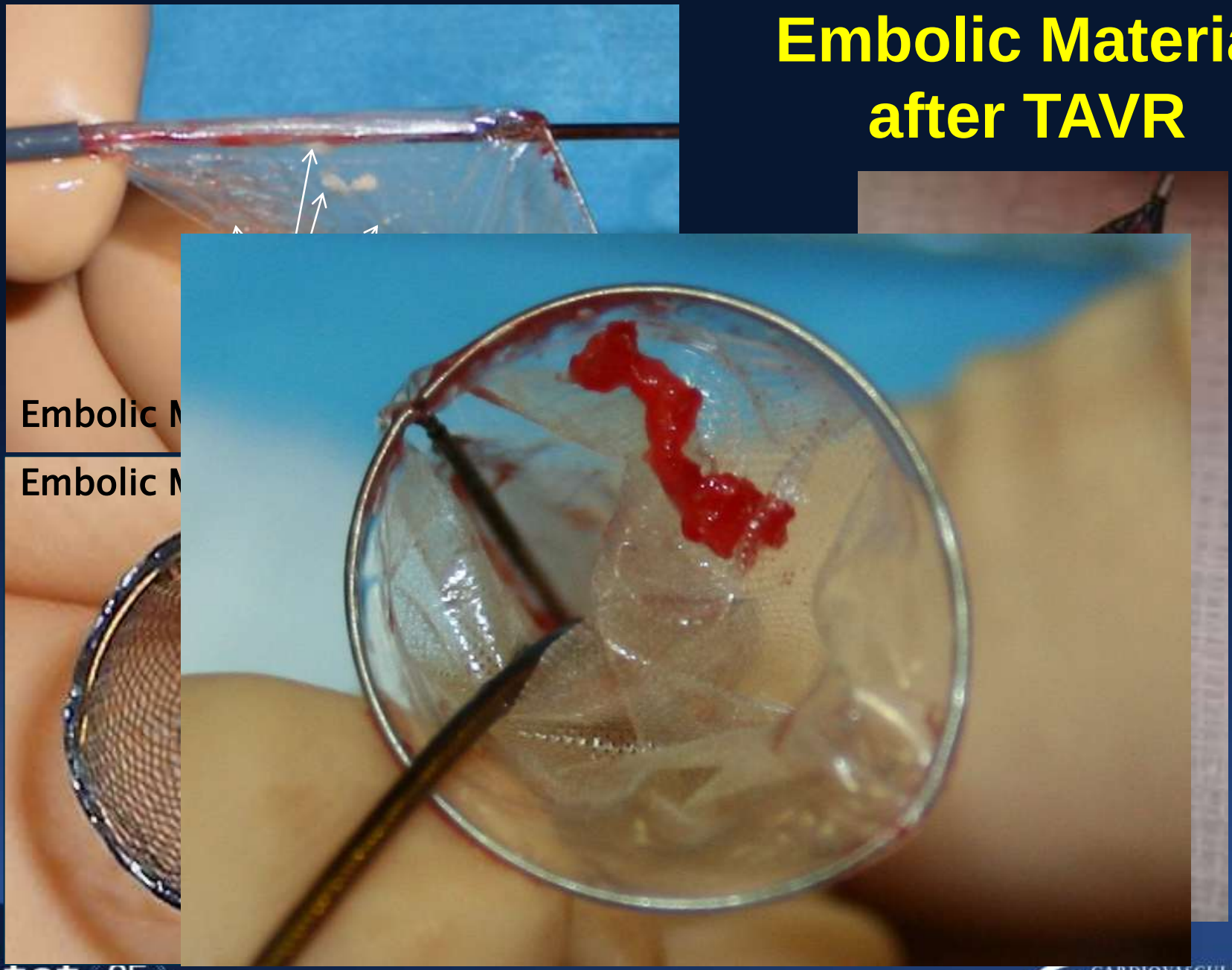
Cerebral Embolic Protection Devices

Cerebral Embolic Protection Devices

TriGuard™ Cerebral	Embrella™	Claret Sentinel™
Deflector	Deflector	Dual Filter
Femoral Access	Radial Access	Radial Access
9F Sheath (7F Delivery)	6F Shuttle Sheath	6F Radial Sheath



Embolic Material after TAVR



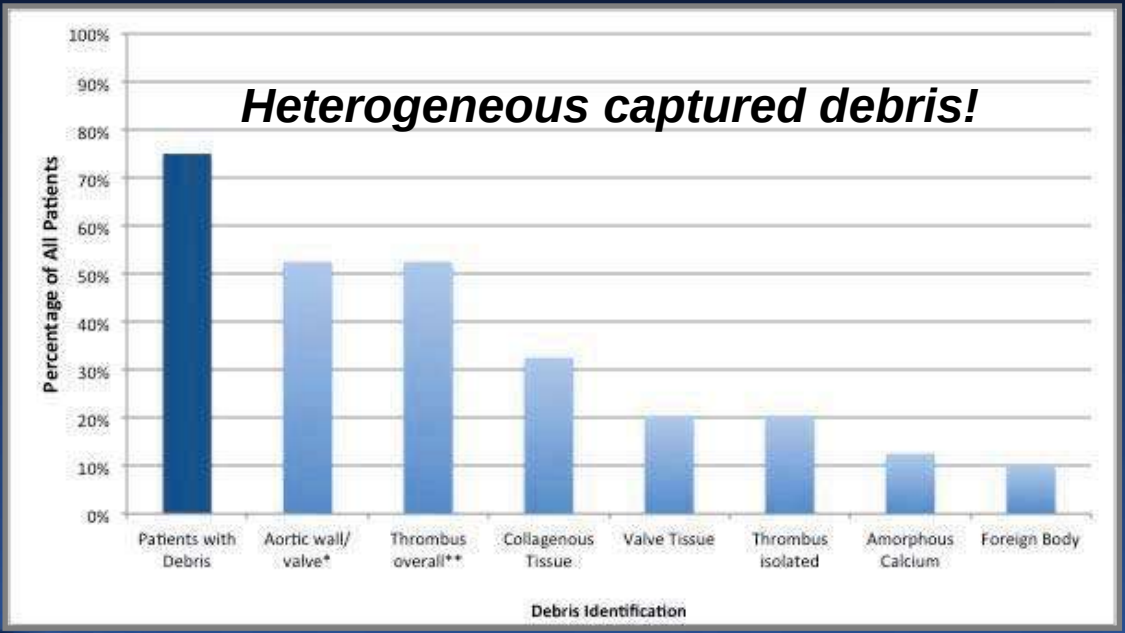
Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement

Nicolas M. Van Mieghem, Marguerite E. I. Schipper, Elena Ladich, Elham Faqiri, Robert van der Boon, Abas Randjgari, Carl Schultz, Adriaan Moelker, Robert-Jan van Geuns, Fumiyuki Otsuka, Patrick W. Serruys, Renu Virmani and Peter P. de Jaegere

40 TAVR pts treated with the dual filter system



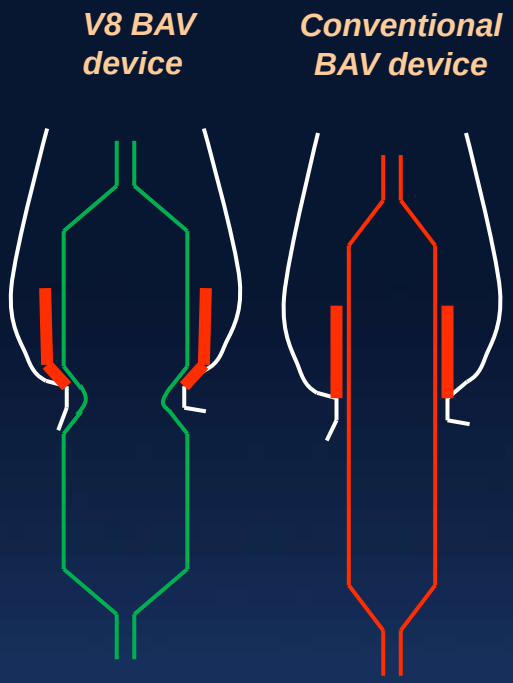
75% patients with macroscopic debris captured in one or both filters!

Van Mieghem NM et al. Circulation 2013

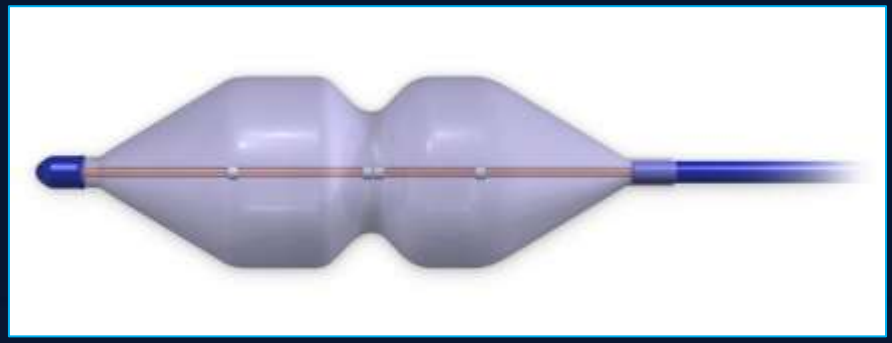
New TAVR Systems and Accessory Devices

New Valvuloplasty Technologies

V8 BAV Advantages



Post mortem BAV annular tear



1) Geometric shape locks into the valve anatomy

- *Limits balloon movement and avoids balloon trauma to collateral structures*

2) Figure-8 shape maintained throughout inflation

- *Proximal bulb hyperextends leaflets into sinuses to enhance valve opening*
- *Smaller waist reduces risk of annular dissection*
- *Improved evaluation of potential coronary occlusion with TAVR implant*

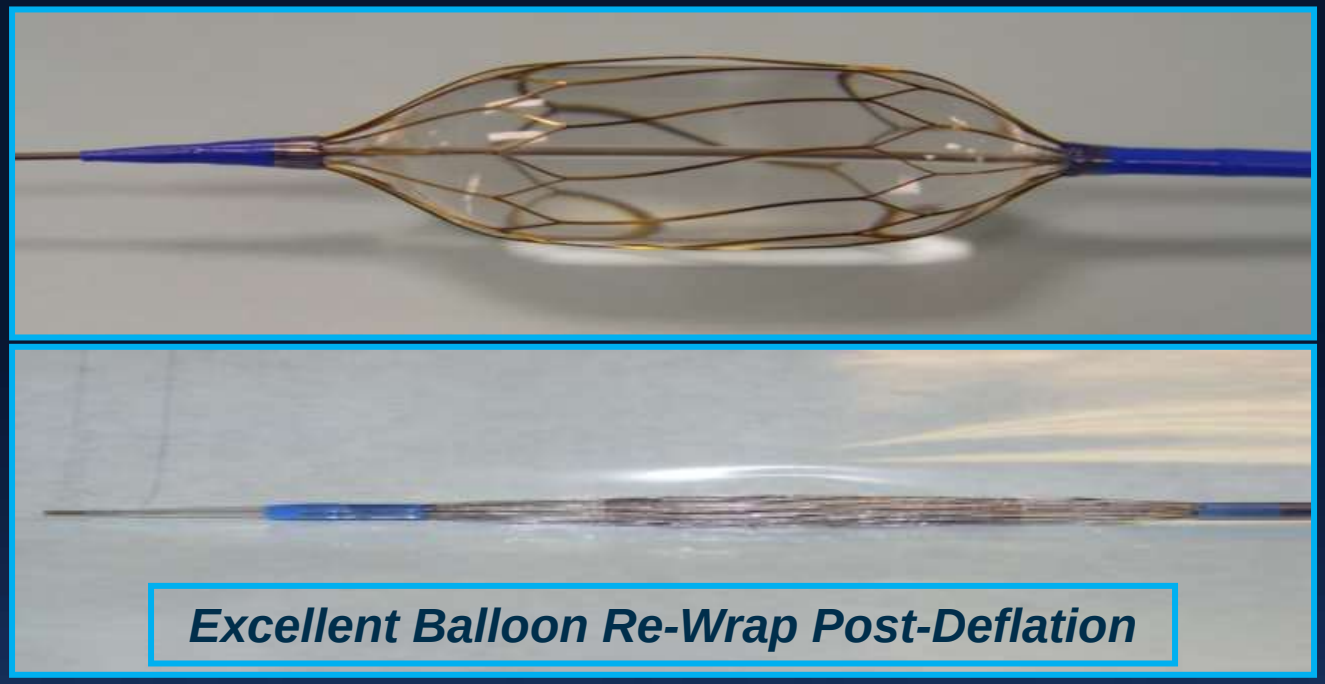
3) Rapid balloon inflate/deflate times

- *Minimizes ischemic time and hypotension*

Loma Vista TRUE Balloon

- *Kevlar composite balloon material*
- *Precise size and shape (<1% growth)*
- *Fast inflation and deflation (2-3X faster)*
- *Exceptional puncture resistance (no balloon ruptures in >1,500 cases)*
- *Excellent re-wrap*

CardioSculpt Design Elements



Excellent Balloon Re-Wrap Post-Deflation

- 18, 20, 22, and 24 mm diameter x 4.0 cm length balloons, atraumatic soft tip
- Laser cut nitinol scoring element with 4 rings and 12 rectangular wires/struts
- 12 French sheath compatible (0.035” guidewire)
- RBP 5-6 atm with scoring element force amplification ~20x
- Rapid deflation time ~5 seconds

Leaflex AVRT
(Aortic Valve RemodelingTherapy)

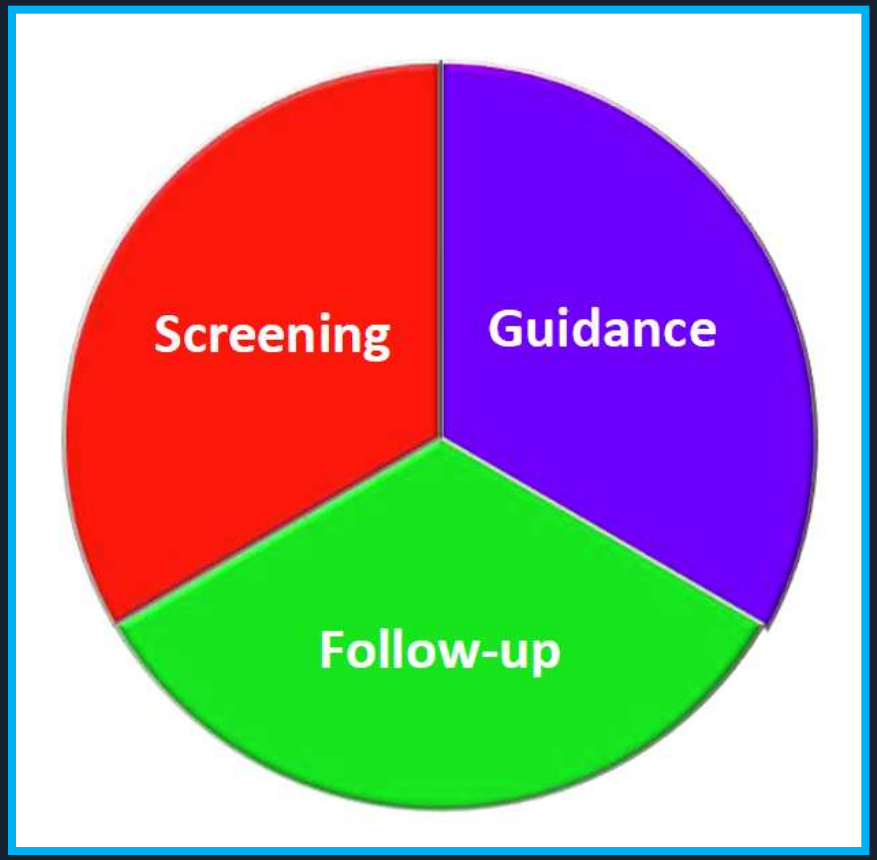
- Mechanical shock waves fracture calcium within valve
- Increased leaflet compliance: significant, true increase in AVA
- Trans-femoral 13Fr catheter
- Non-occlusive: no rapid pacing
- Device can be used as:
  - Stand-alone therapy
  - Bridge to TAVR or SAVR
  - Preparation for TAVR

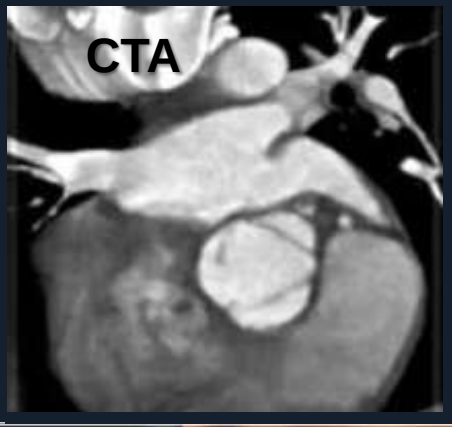
New TAVR Systems and Accessory Devices

Advanced Imaging Modalities

Adjunctive Imaging for TAVR

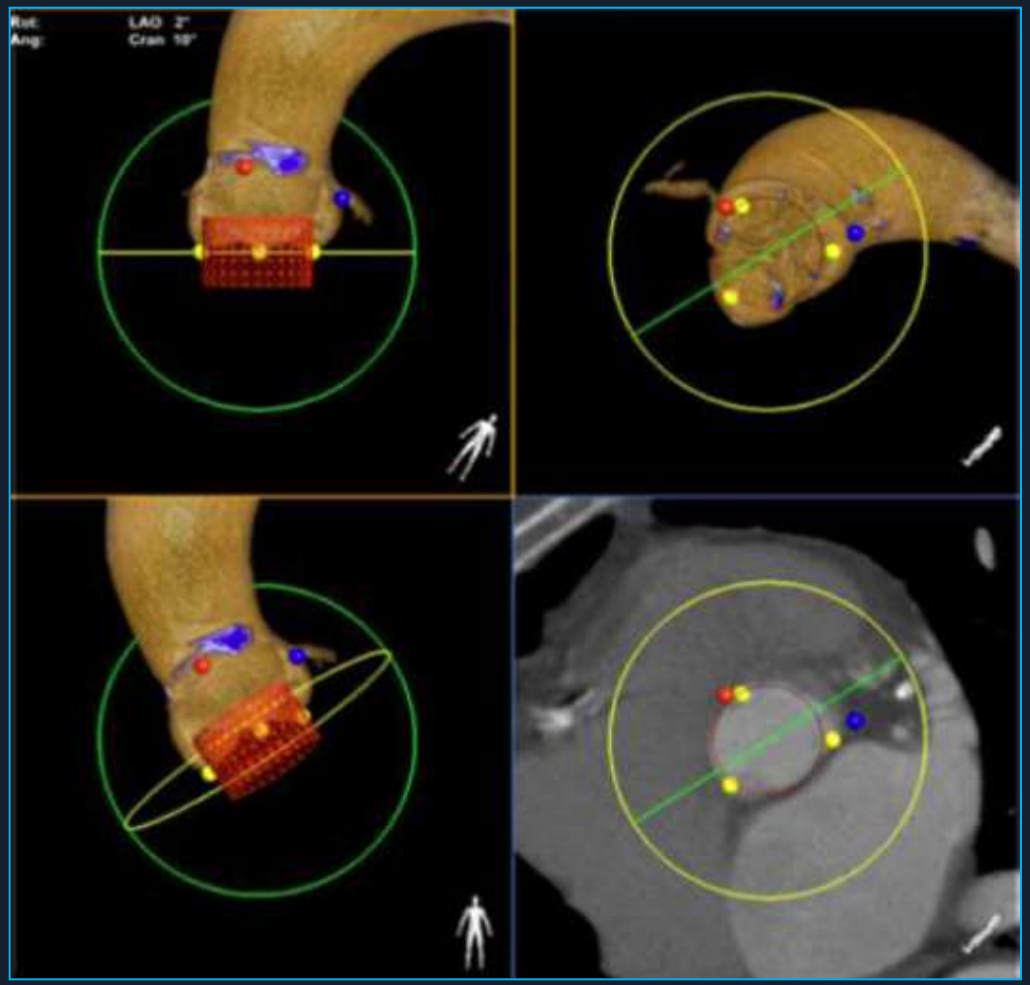
Multi-modality Imaging is the RULE





Adapted from: Lutz Buellesfeld

Advanced Imaging Modalities



CTA

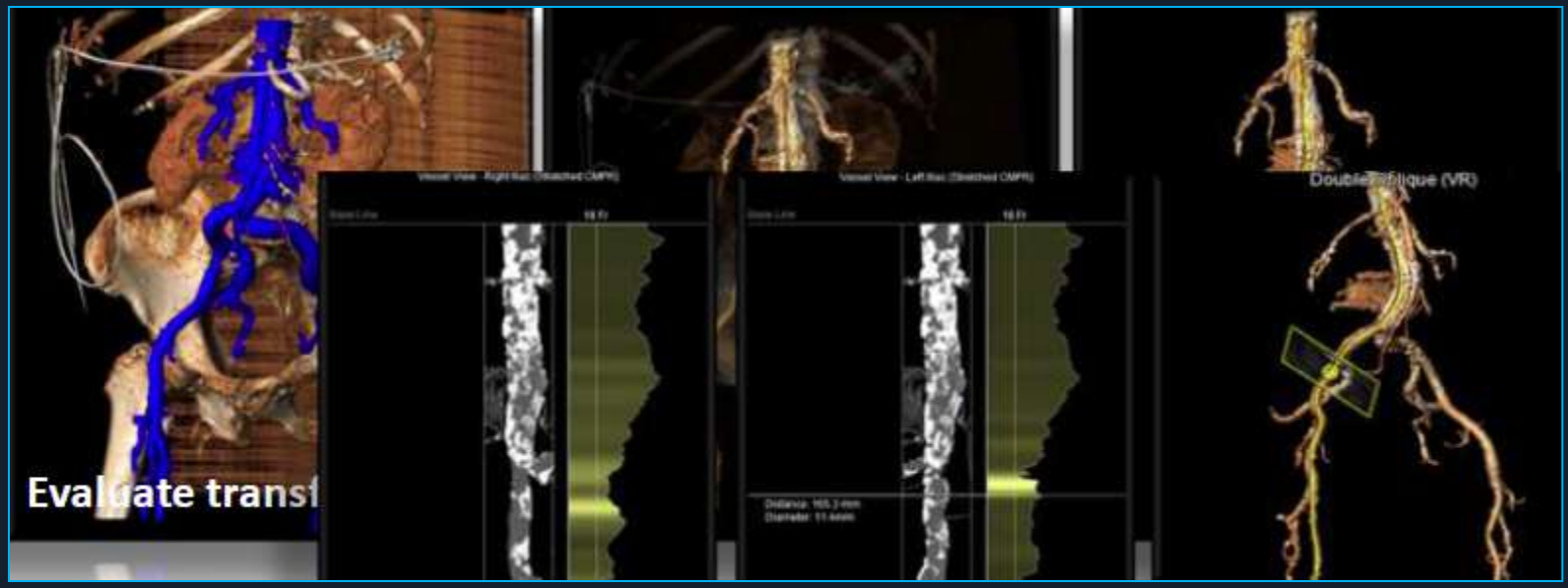
- ***Philips***
  3D Navigator
- ***Siemens***
  Dyna CT
- ***GE***
  Innova Vision

Advanced Imaging Modalities

CTA

3Mensio Valves

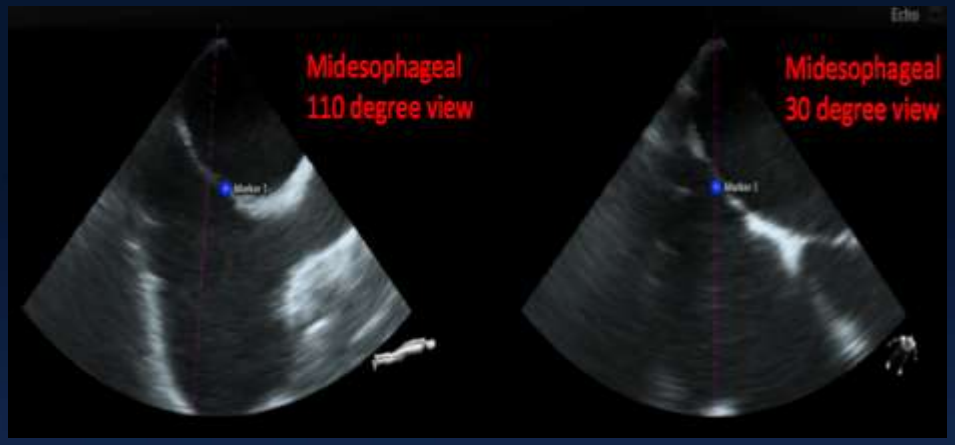
Advanced Imaging Modalities

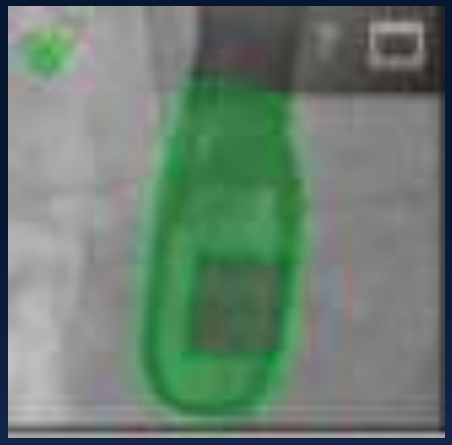


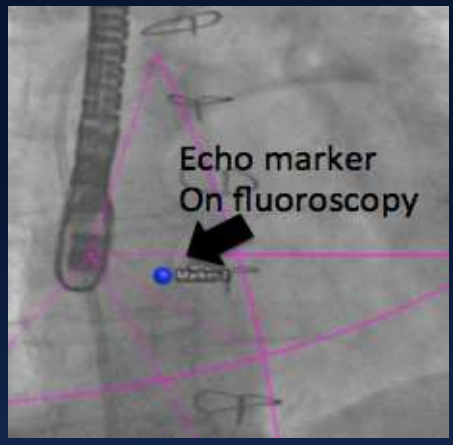
CTA

3Mensio Valves

EchoNavigator (Philips)
Co-registration of Echo and Fluoro







***Step 1**: mark structure in two echo views*

***Step 2**: register echo probe*

***Step 3**: see marker on fluoro*

- **Structure retains position despite change in C-arm → Real time echo overlay**
- ***All that is needed is registration of the echo probe position and angle for computer to change position of the markers***

New TAVR Systems and Accessory Devices

Final Thoughts

New TAVR Systems and Accessory Devices

- There is striking innovation and diversity in TAVR designs attempting to address the main current clinical and technical limitations.
- The current market leaders (Edwards and Medtronic) have developed impressive next generation pipeline technologies.
- There are 5 new TAVR systems already with sufficient clinical data to have achieved CE approval… and some have interesting differentiating features.

New TAVR Systems and Accessory Devices

- Other accessory technologies including dedicated access and closure strategies, cerebral embolic protection devices, new valvuloplasty systems, and advanced imaging modalities are in various stages of development – undoubtedly, many of these accessories will be used by practitioners to further improve clinical outcomes after TAVR.