

TCT-AP 2014
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New TAVI Devices

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Eberhard Grube, MD

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

Physician Name

Company/Relationship

Eberhard Grube, MD

Medtronic, CoreValve: C, SB, AB, OF
Direct Flow: C, SB, AB
Mitralign: AB, SB, E
Boston Scientific: C, SB, AB
Cordis: AB
Abbott Vascular: AB
Valtech: E, SB,
In Seal Medical: SB, E
Claret: SB
Keystone, SB

Key

G - Grant and or Research Support E - Equity Interests S - Salary, AB - Advisory Board
C - Consulting fees, Honoraria R - Royalty Income I - Intellectual Property Rights
SB - Speaker's Bureau O - Ownership OF - Other Financial Benefits



The Past

Dr. Alain Cribier First-in-Man PIONEER

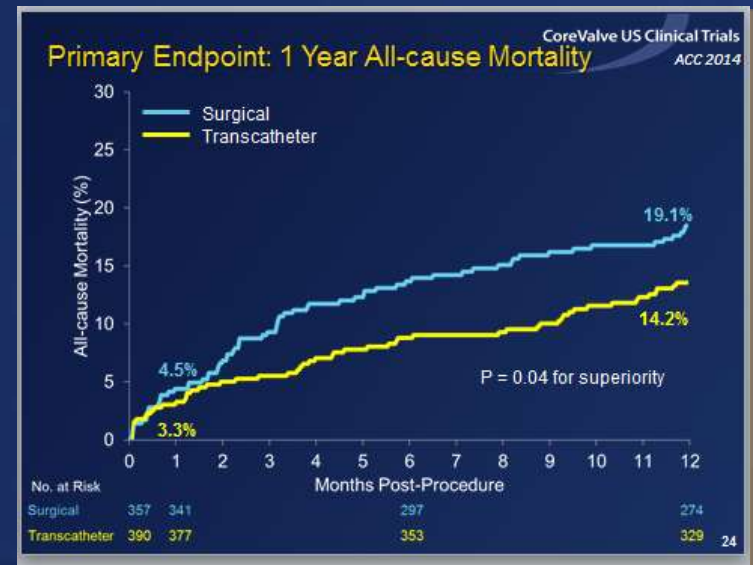
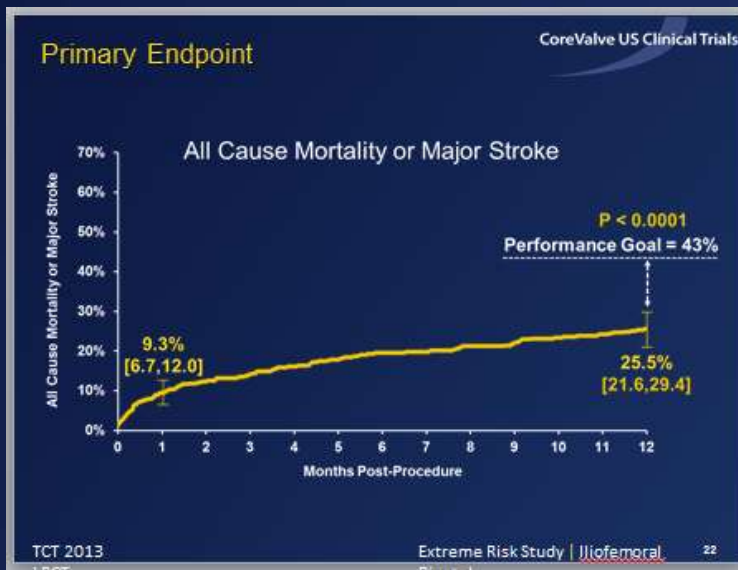
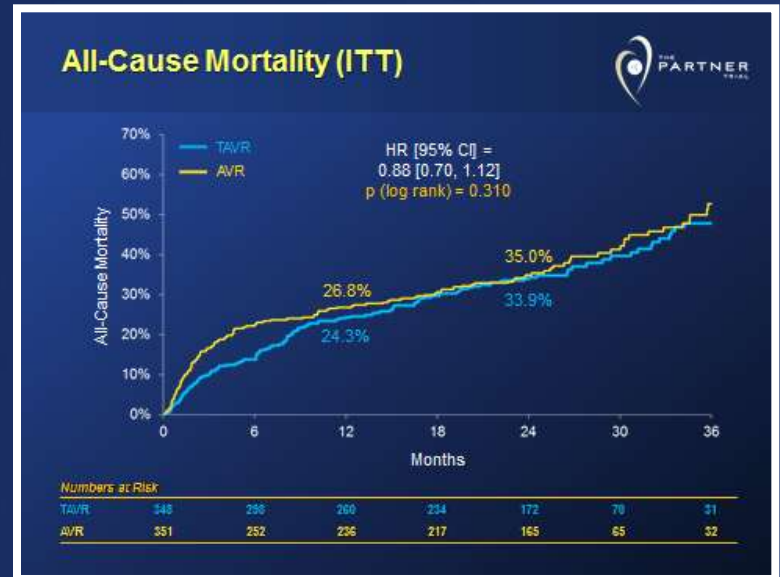
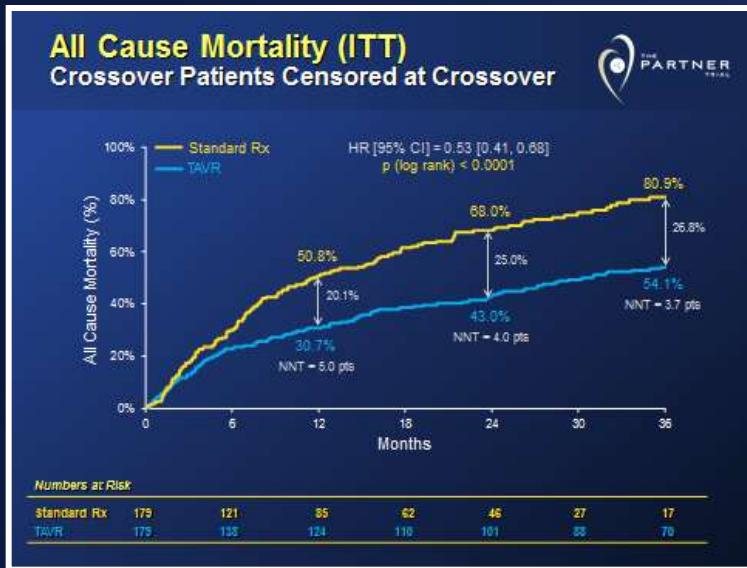


April 16, 2002

Anatomic “Footprint” of Edwards Sapien Valve vs. MDT CoreValve



Consistent positive Clinical Outcomes





The Present

Remaining TAVI Challenges

	<u>Procedure/Technique</u>	<u>Technology</u>
Stroke	Balloon strategies Anti-coagulation mgmt	Embolic Protection
AR and PVL	Sizing Post-implant intervention (dilation, snare) Depth of Implant	Frame design Advanced Sealing Positioning, Recapture
Vascular Complications	Alternative Access	Lower profile Access specific delivery Coatings
Conduction Disturbances	Depth of Implant Balloon strategies	Frame design Stable deployment with recapture

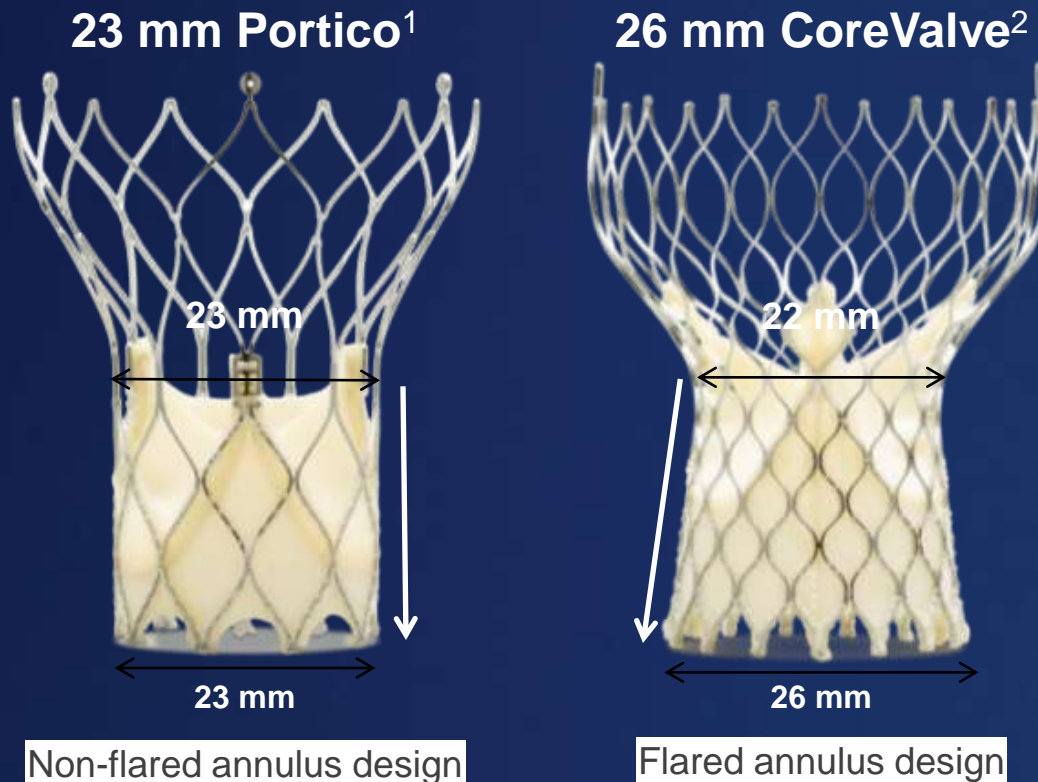


**Many New CE Mark
Valves in 6-12 months**

Several new TF and TA valves received CE Mark in last 6-12 months



Portico and CoreValve Design Comparison

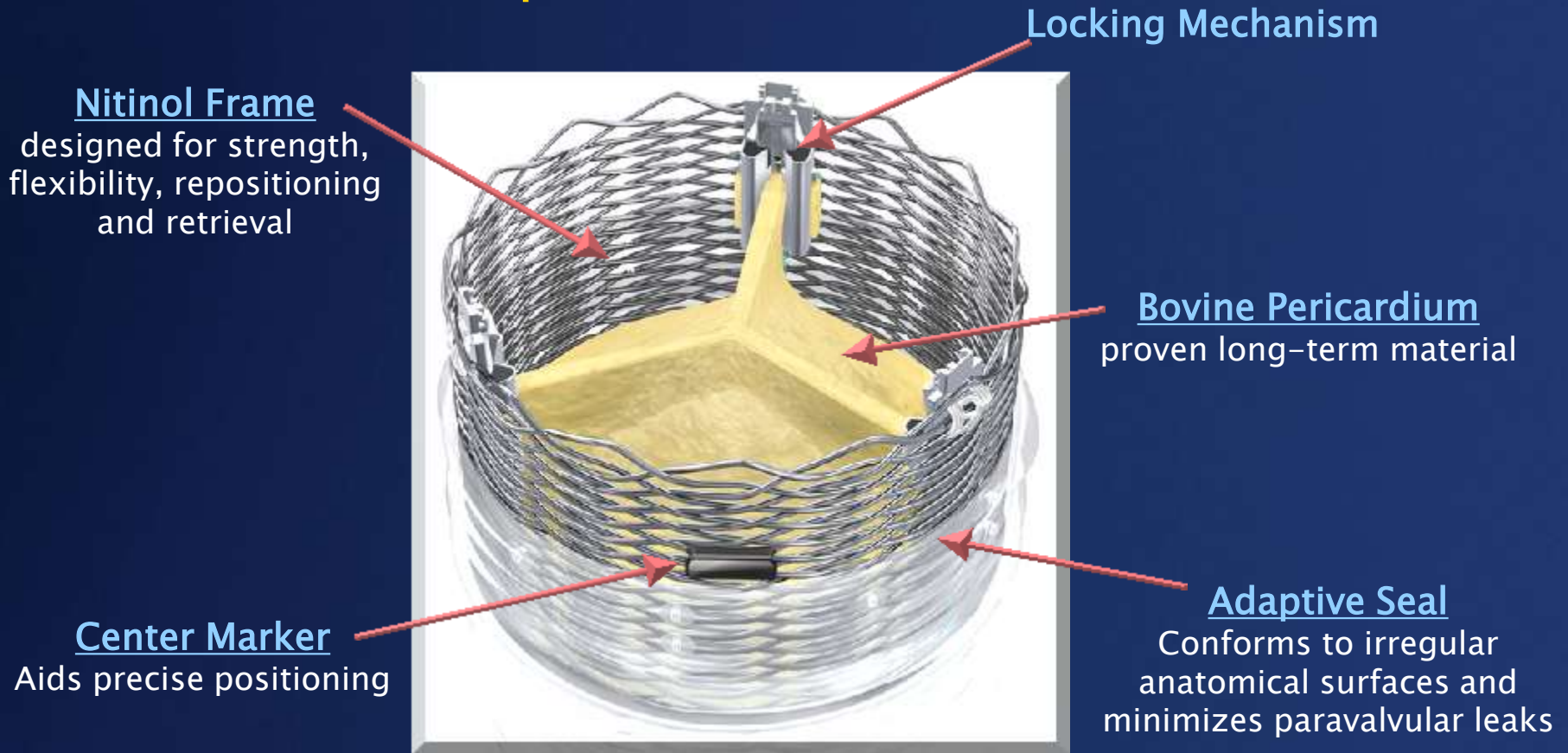


The annulus section of the Portico stent is not flared when compared to the flared annulus section of the CoreValve. Designed to minimize the risk of interfering with the conduction system and mitral valve apparatus.

1. St. Jude Medical Data on File.
2. Medtronic, CoreValve brochure, PN090401 V1 April 2007

Lotus™ Valve System

Components and Function



Lotus Valve System

Design Goals for Mechanism for Expansion

Manual mechanical expansion

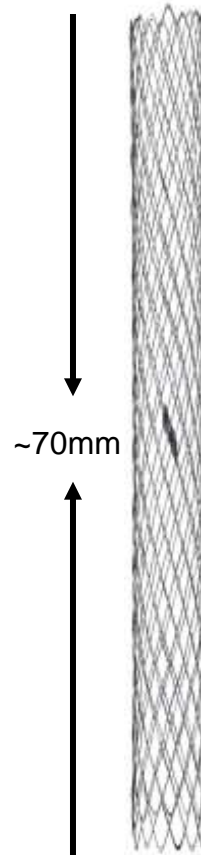


Controlled deployment



Valve expands radially as it shortens

1. Elongated Configuration (for Delivery)



2. Intermediate Configuration



3. Final Locked Configuration



Edwards – SAPIEN Evolution



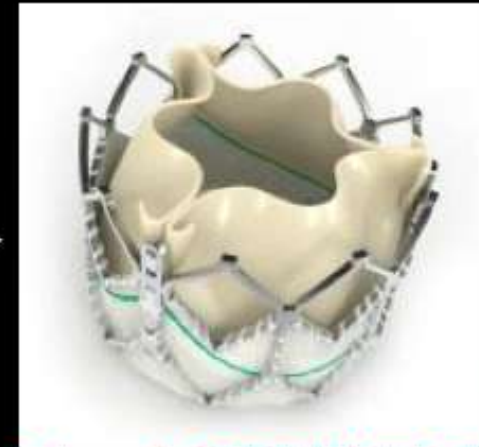
2002

Cribler-Edwards THV



2006

Edwards SAPIEN THV

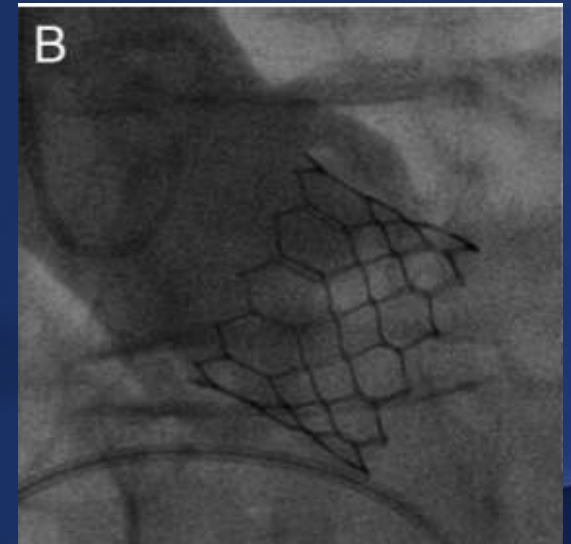
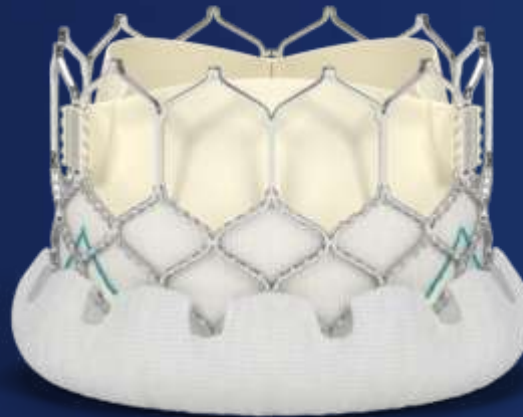


2010

Edwards SAPIEN XT* THV



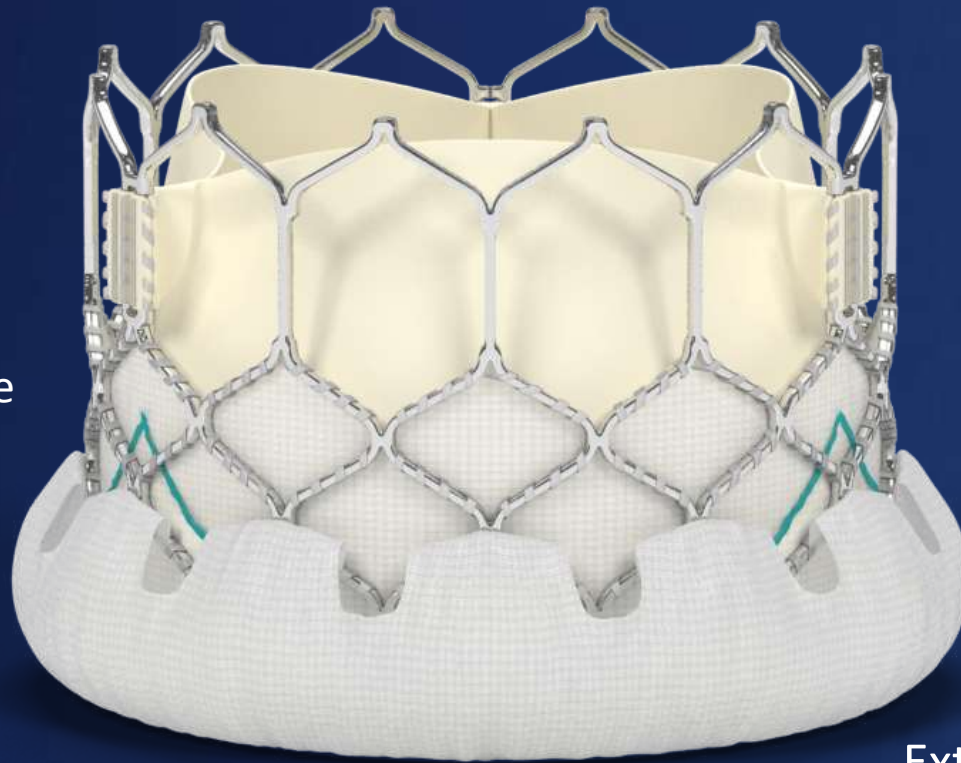
2014
SAPIEN 3



Edwards SAPIEN 3 (balloon-expandable THV)

20, 23, 26 and 29 mm sizes

Balloon-expandable
Cobalt Chromium Frame



Bovine Pericardial
Tissue Leaflets

External Sealing Ring

Direct Flow Medical

- **Non-metallic Frame**
 - Expandable Dacron polyester double-ring design containing non-compliant PCI technology
 - Tri-leaflet bovine pericardial tissue
- **18Fr delivery and retrieval for all sizes**
 - Compatible with 0.035" guidewire
 - 3 positioning wires used for expansion
- **Treatment range 19–26mm**
 - 25mm valve treats 21–24mm annulus
 - 27mm valve treats 24–26mm annulus



DFM Procedure Summary



Delivery - Valve delivered through flexible 18F sheath (all valve sizes)



Deployment - After initial expansion in the ventricle, the valve remains fully competent throughout the procedure



Positioning - To begin positioning, the valve is partially deflated and then placed into the native annulus



Assessment - Once the valve is positioned and fully deployed, a complete assessment of hemodynamic performance is done



Repositioning - Unlimited repositioning of the valve is possible by simply deflating either ring and manipulating the positioning wires



Implantation - After the valve placement is optimized, final implantation is done

ACURATE TF™ Aortic Bioprosthesis

SELF-EXPANDING NITINOL

Conforms to native anatomy
3 sizes: 21mm to 27mm

STABILIZATION ARCHES

PERICARDIAL LEAFLETS

Porcine pericardium
Lower profile

UPPER CROWN

Supra-annular anchoring
Stable positioning
Tactile feedback



LOWER CROWN

Minimal LV protrusion
Low risk of conduction
defects

PERICARDIAL SKIRT

Inner & outer skirt acts as
seal to prevent PVL



The Future

New Generation TAVI Devices

Non CE Marked:

- Edwards Centera
- Medtronic CoreValve Evolut R
- Foldax Heart Valve Technology
- Valve Medical

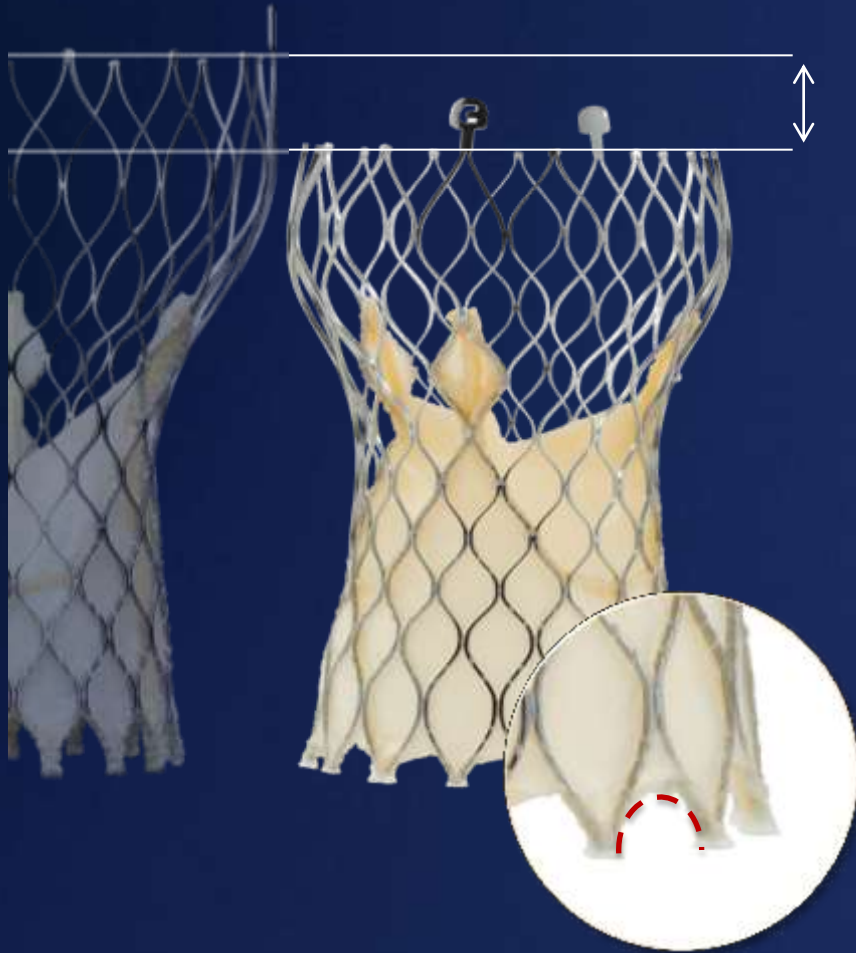
Edwards CENTERA Transcatheter Heart Valve

- Self-expanding Nitinol frame
- Treated bovine pericardium
- Contoured frame designed for optimal seating and sealing in the annulus
- Low frame height designed to minimize conduction disturbances
- Repositionable
- 23 mm, 26 mm, 29 mm sizes



CoreValve Evolut R

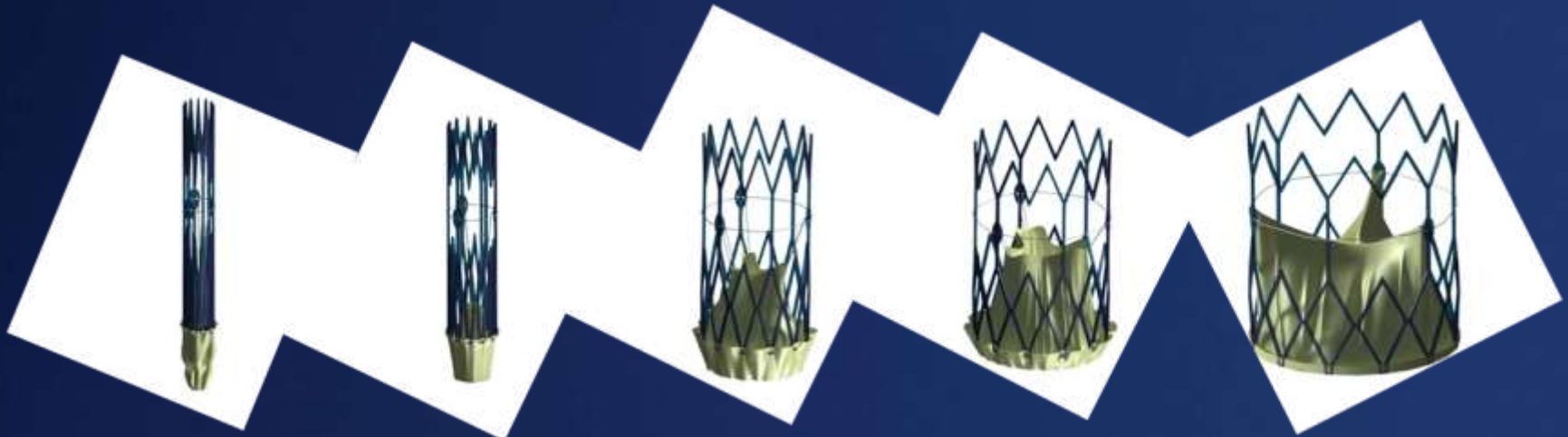
Goal: Enhanced Annular Seal and Reduced Conduction Disturbances



- Outflow shortened and redesigned
- Optimized cover index
- More consistent radial force across annulus range
- Extended skirt at inflow
- Less traumatic inflow edge

FOLDAX™

HEART VALVE TECHNOLOGY



14F delivery profile available

“Stressless” tissue loading

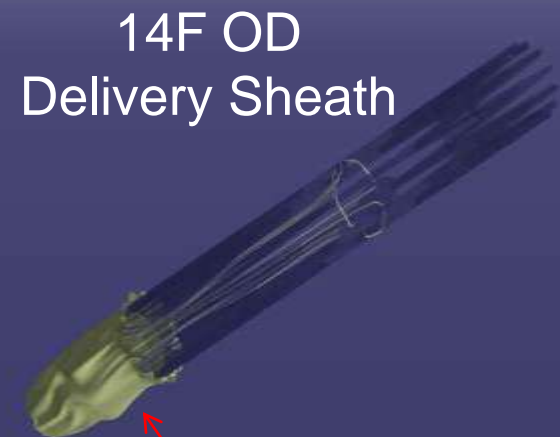
Allows use of bovine pericardium

Fully repositionable & retrievable

“Inside-Out” Leaflet Mounting

“Inside-out” Leaflet Mounting

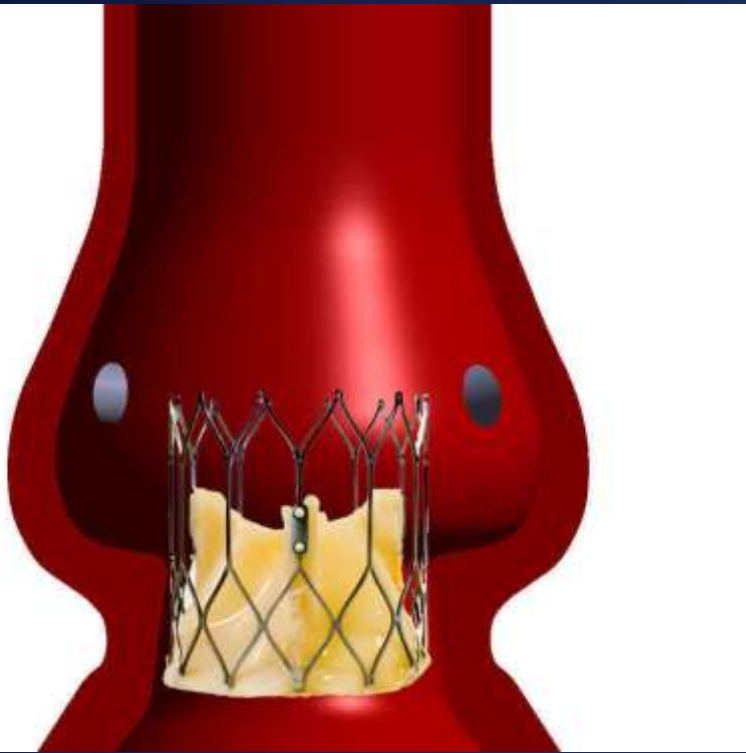
- 12Fr loaded valve profile w/ no tissue inside stent
 - Enables small/difficult vessel & acute aortic arch patients
- Eliminates compression of tissue in loaded stent
 - Enhances durability
 - Uses bovine pericardium



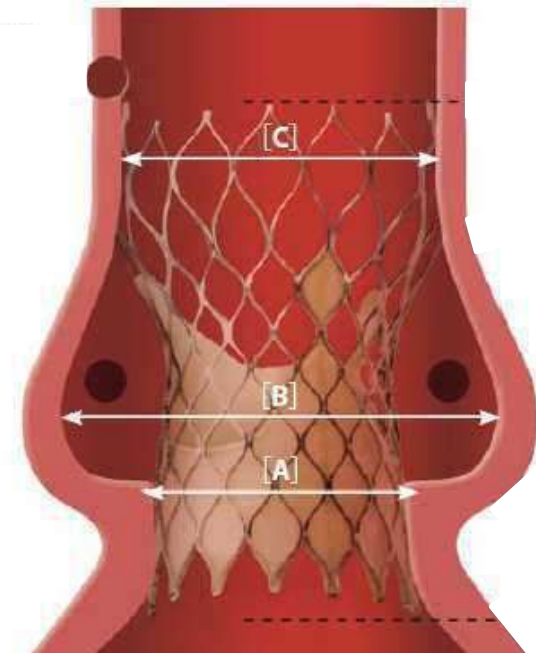
Leaflet tissue outside
crimped stent

FOLDAVALVE™ DEPLOYED

- Low profile design

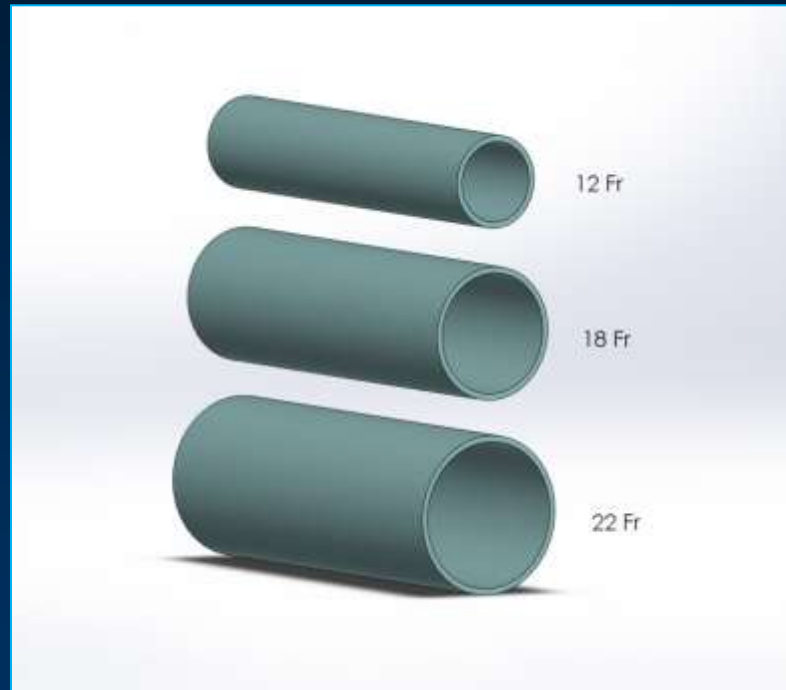


Note the
of any SV



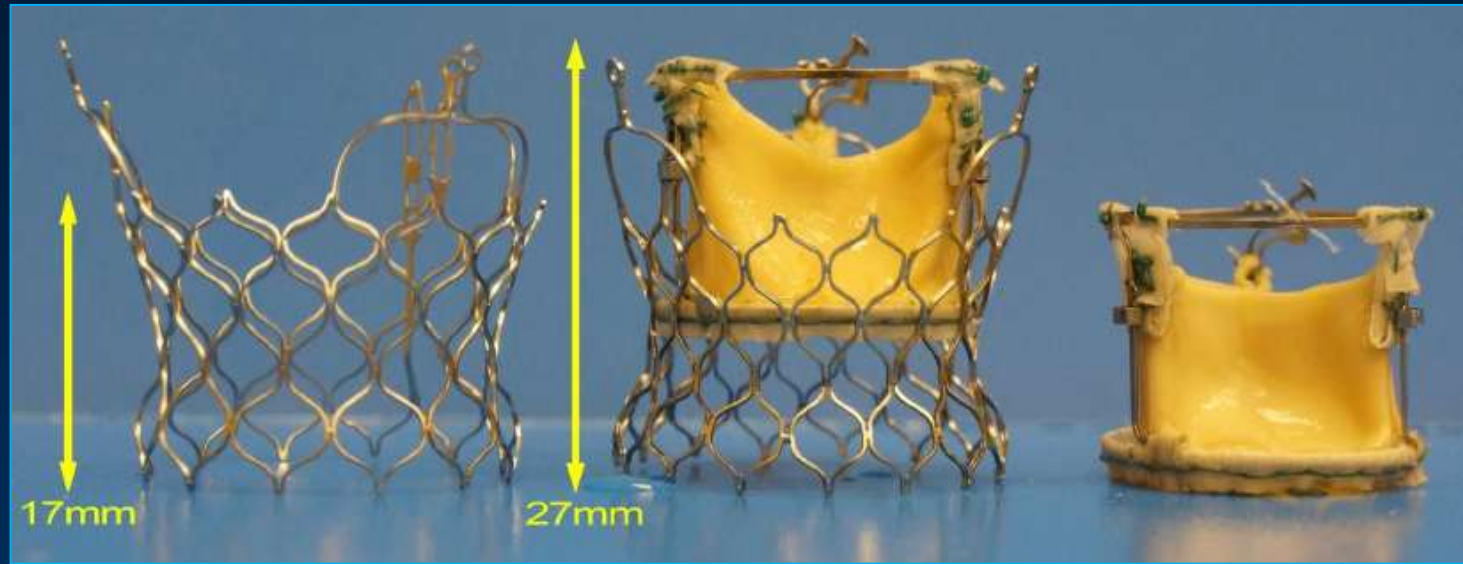
Valve Medical Inc

An Ultra-low Profile System



- *True 12Fr (catheter O.D.) profile (3.8 mm diameter) for all valve sizes (1st generation)*

Valve Medical Device Components



Frame Module



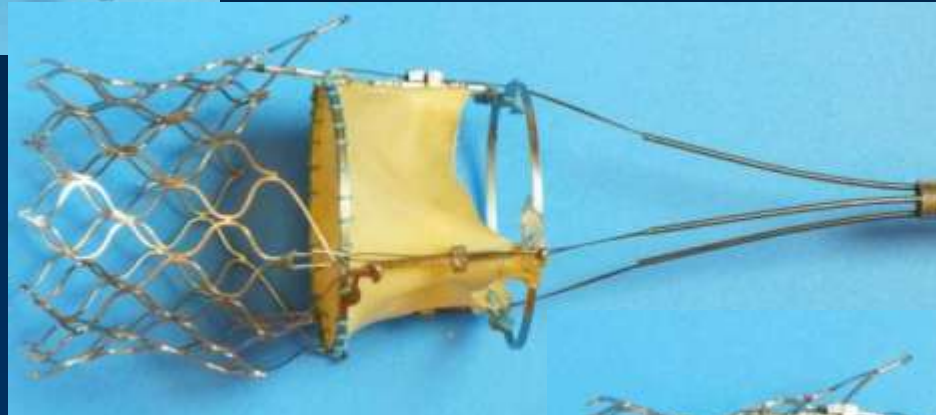
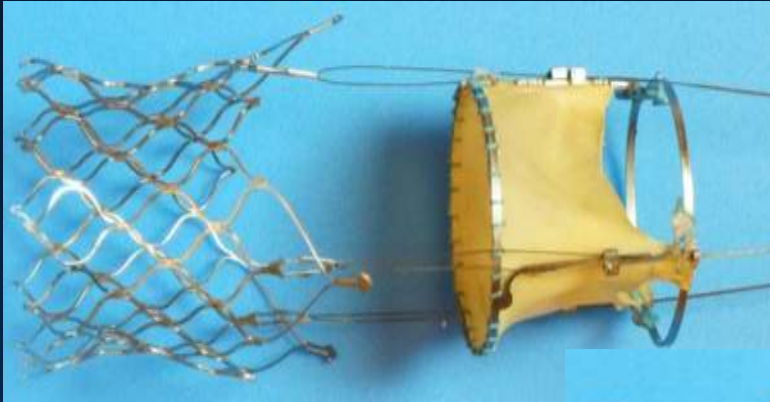
Assembled Device



Valve Module

1. Nitinol self-expanding frame module inserted in optimal annular location
2. Valve module is reconstituted in ascending Ao
3. Valve module is docked to frame

Valve Module Docking to Frame



Improving Clinical Outcomes: Competitive Landscape



CoreValve



Sapien XT



Direct Flow



Lotus



Portico



Symetis



Sapien 3



Centera



Evolut R



Valve Med

	CoreValve	Sapien XT	Direct Flow	Lotus	Portico	Symetis	Sapien 3	Centera	Evolut R	Valve Med
Survival	Green	Green	Green	Green	Green	Green	Green	Green	TBD	TBD
Major Vasc	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	TBD	TBD
PPM Rate	Orange	Green	Orange	Orange	Yellow	Yellow	Green	Orange	TBD	TBD
PVL	Yellow	Yellow	Green	Green	Yellow	Yellow	Green	Yellow	TBD	TBD
Durability	200M Valve 600M Frame								TBD	TBD
Stroke	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	TBD	TBD
Coronary Occlusions	Green	Yellow	Yellow	NR	NR	NR	NR	NR	TBD	TBD
Annulus Rupture	Green	Orange	Orange	NR	NR	NR	NR	NR	TBD	TBD
MI	Yellow	Yellow	Yellow	Yellow	Yellow	NR	NR	NR	TBD	TBD

- Near optimal performance
- Performance acceptable but not optimal yet
- Performance acceptable but not optimal, competitive disadvantage
- Performance not acceptable nor technically feasible

Final thoughts...

- TAVR in 2014 has been integrated as an important component of the optimal management of complex AS patients.
- Although clinical outcomes appear favorable, there are still areas to refine, including appropriate case selection, procedural complications (esp. strokes, vascular events, and PVL), and selection of specific THVs
- Future device development and clinical research are needed to resolve these issues!

Thank you very much for Your Attention!

