

TAVI

Valve Technology is Still Evolving

Alain Cribier, MD, FACC

Charles Nicolle Hospital, University of Rouen, France



Seoul, 18th Angioplasty Summit -TCT AP 2013

Disclosure

Consultant / Proctor for Edwards Lifesciences

Over 11 years, considerable technological advances on “first generation” valves and delivery systems

➤ Improved valves + platform

Positioning, expansion, hemodynamics, annulus coverage, durability

➤ Improved delivery systems and sheath size

Easiness of use

Less vascular complications



Improving the results
Decreasing the complications

Improved Prosthetic Heart Valves: Edwards

2002)

PVT Heart Valve



Bovine pericardium
Stainless steel frame

∅ 23mm

2003

Cribier Edwards



Equine pericardium
Stainless steel frame

23mm

2006

Edwards Sapien

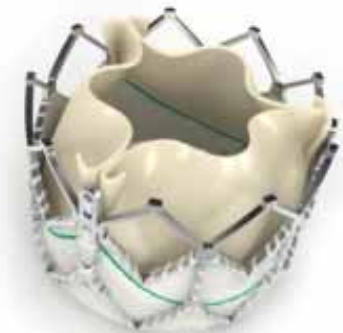


Treated anti Ca
bovine pericardium
Stainless steel frame

23, 26mm

2009

Sapien XT



Treated anti Ca
Bovine pericardium.
Cobalt Chromium frame

20, 23, 26, 29 mm


- Improved hemodynamics
- Higher resistance to compression
- Better annulus coverage
- Longer durability

Improved Prosthetic Heart Valves: Edwards



e-Sheath

THV 23mm
16F



THV 26mm
18F

THV 26mm
20F



TF: NovaFlex Delivery System
E-Sheath 16 to 20F
> 80% TF approach

2009

Sapien XT



Treated anti Ca
Bovine pericardium.
Cobalt Chromium frame

20, 23, 26, 29 mm



TA and TAo
Ascendra 2 and Ascendra + delivery system

Improved Valve and Delivery Systems: CoreValve

Generation 1
25F

Generation 2
21F

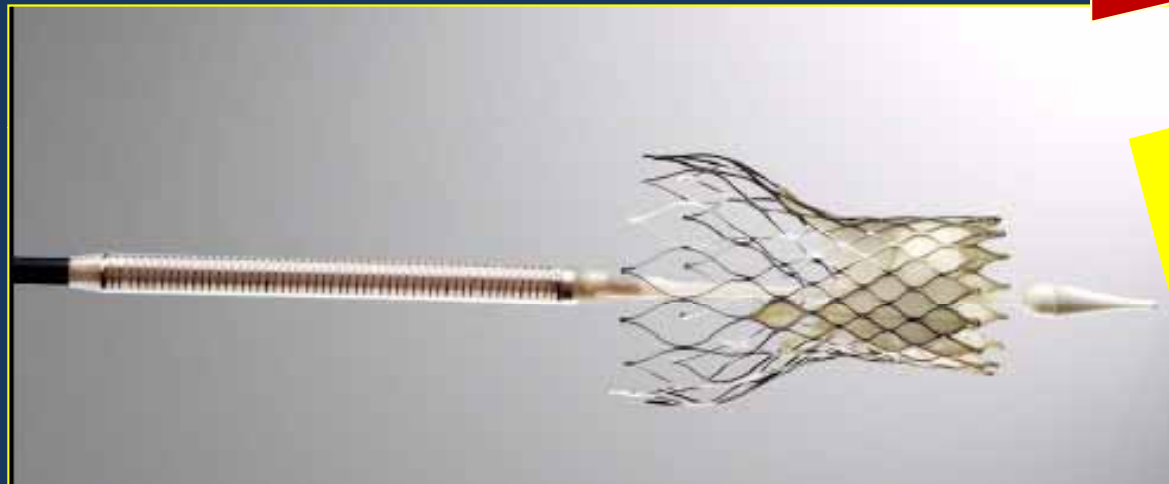
Generation 3
18F

Generation 4
18F

2004-2005

From 2006

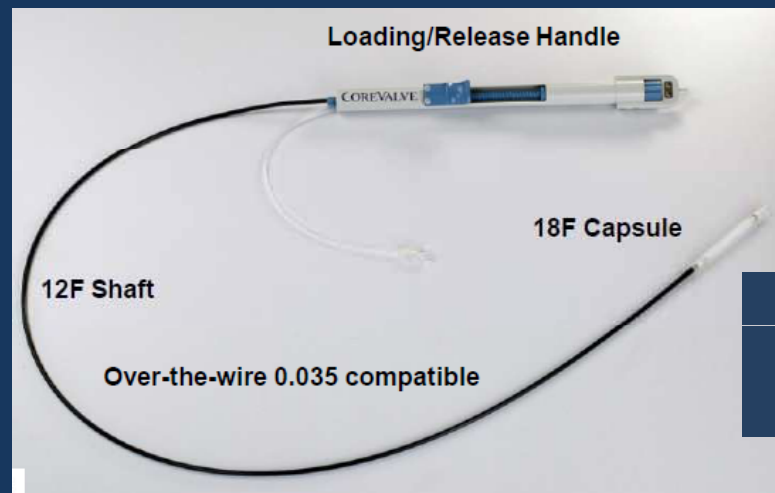
2010



SIZES
23, 26, 29, 31mm

AccuTrak
Delivery
System

Self Expanding
Nitinol frame
Porcine pericardium valve

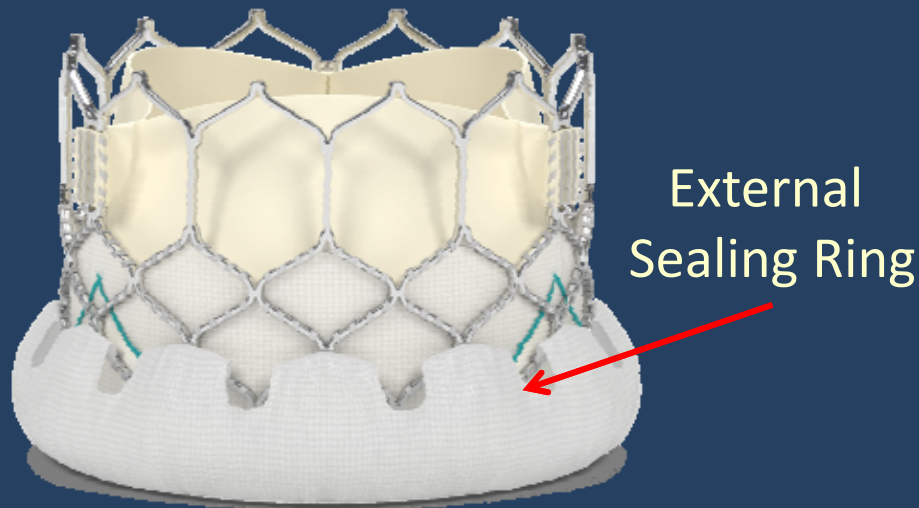


Percutaneous approach
18F Delivery system

The future: New valve / delivery designs

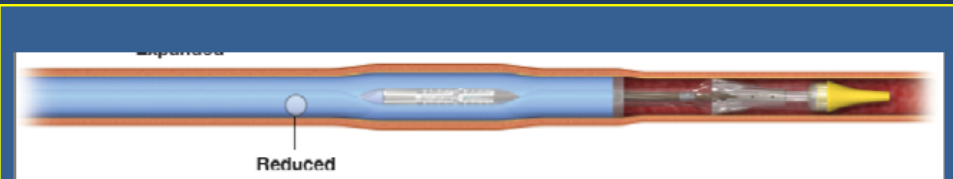
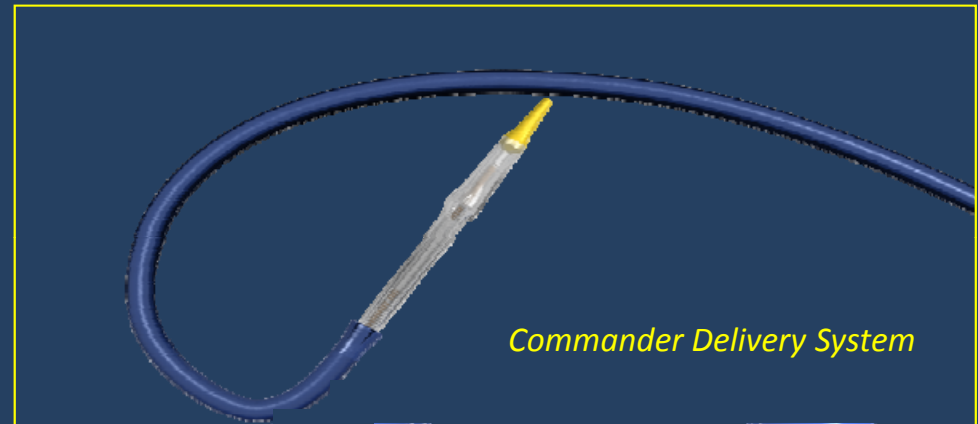
Edwards SAPIEN 3

- Balloon-expandable Cobalt Chromium Frame
- Treated Bovine Pericardial Tissue Leaflets



20, 23, 26 and 29 mm sizes

Delivery System: Improved distal flexing:
Challenging anatomies, positioning, coaxiality



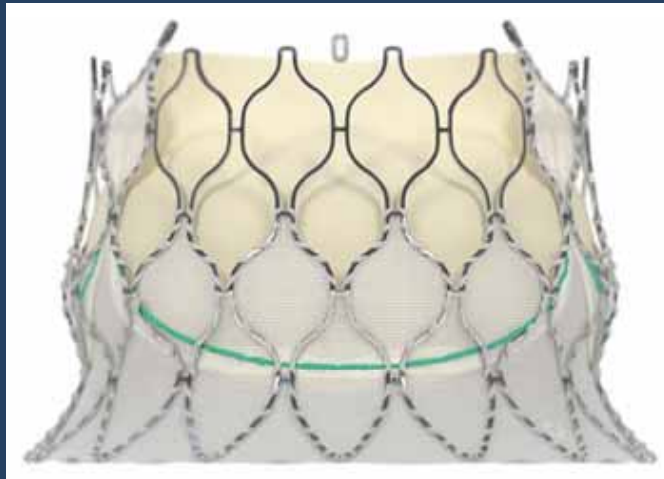
14F e-Sheath

To address the issues of annulus coverage, paravalvular AR and vascular complications

The future: New valve / delivery designs

Edwards CENTERA

- Self-expanding Nitinol Frame
- Treated Bovine Pericardial Tissue Leaflets



23, 26 and 29 mm sizes

Motorized Delivery System

Single operator use

Improved valve release, positioning, coaxiality



14F e-Sheath

An optimal new self-expanding Edwards technique, improving valve release mechanisms ergonomics

The future: New valve / delivery designs

Medtronic CoreValve[®] Evolut[™]

Adds TruFit[™] Technology



CoreValve

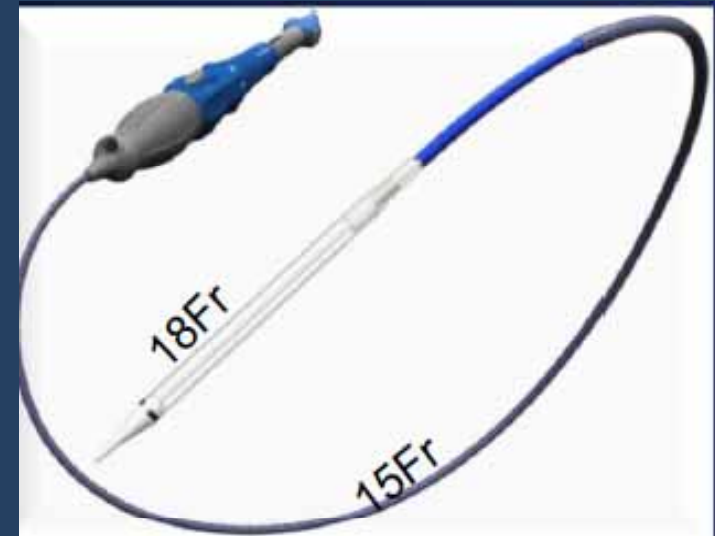


CoreValve
Evolut

23mm size

Improved anatomical fit:
New height and shape, promotes sealing
Supra-annular valve position

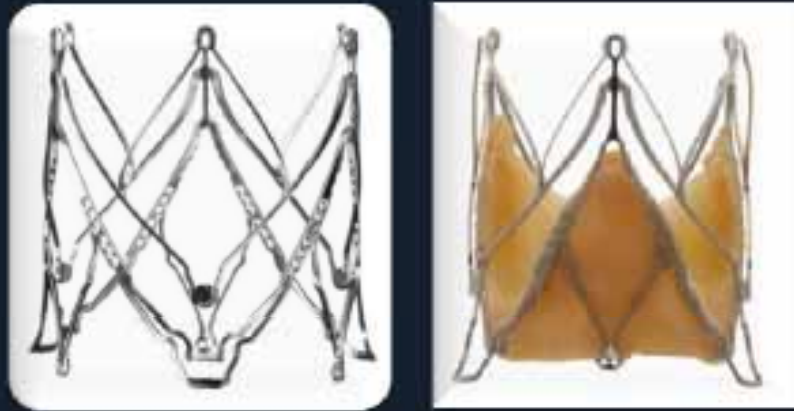
Next Generation Catheter
Delivery system



Ergonomic design
Hydrophylic coating
Shorter length (SC and TA)

The future: New models of valve and delivery systems

JenaValve TAVI System-TA

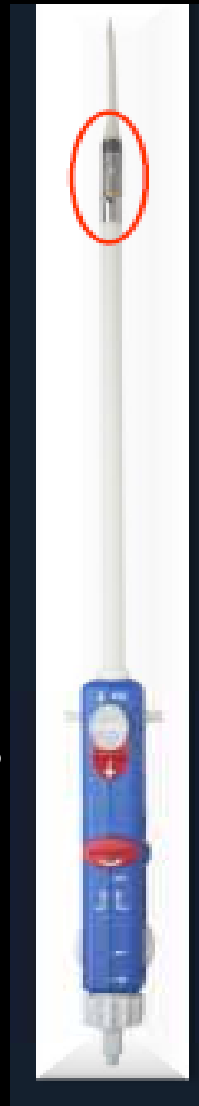


Porcine aortic root valve

Self-expanding Nitinol stent

Anatomical positioning feelers
with clipping mechanism

Sizes 23, 25, 27mm



*New generation « Cathlete »
Delivery System*



Sheathless delivery system

No rapid pacing needed

Easy 3 step delivery

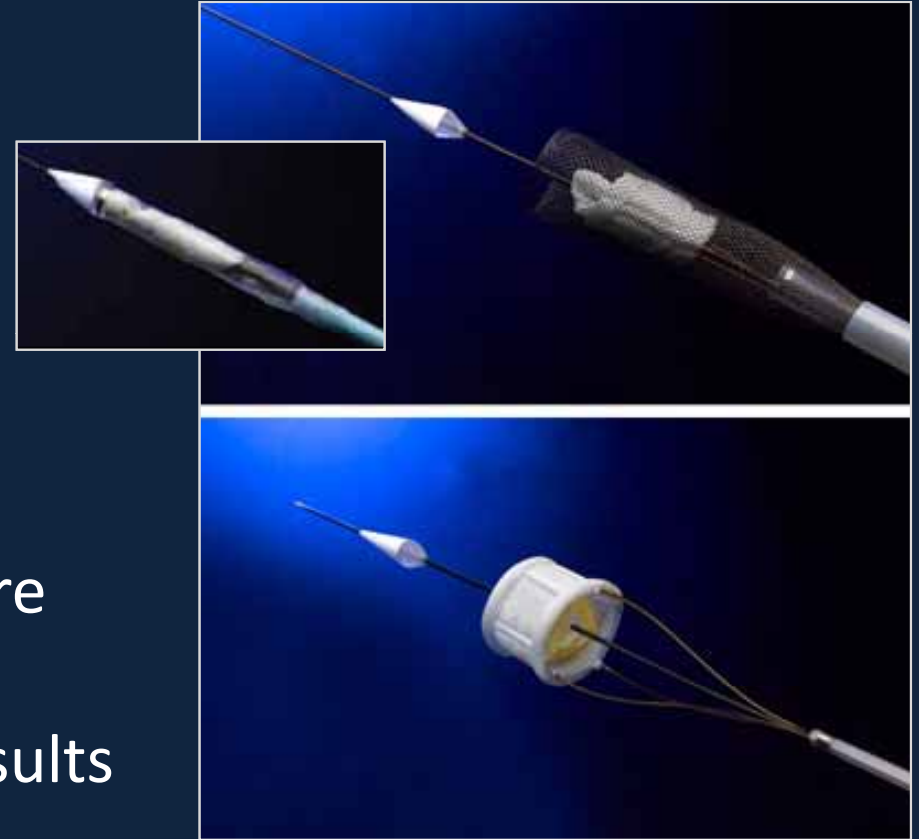
The future: New models of valve and delivery systems

Direct Flow Medical



- Non metallic frame,
- Tubular inflatable support structure
 - Treated bovine pericardial tissue
- Optimal control of hemodynamic results before detachment
 - Fully repositionable / retrievable

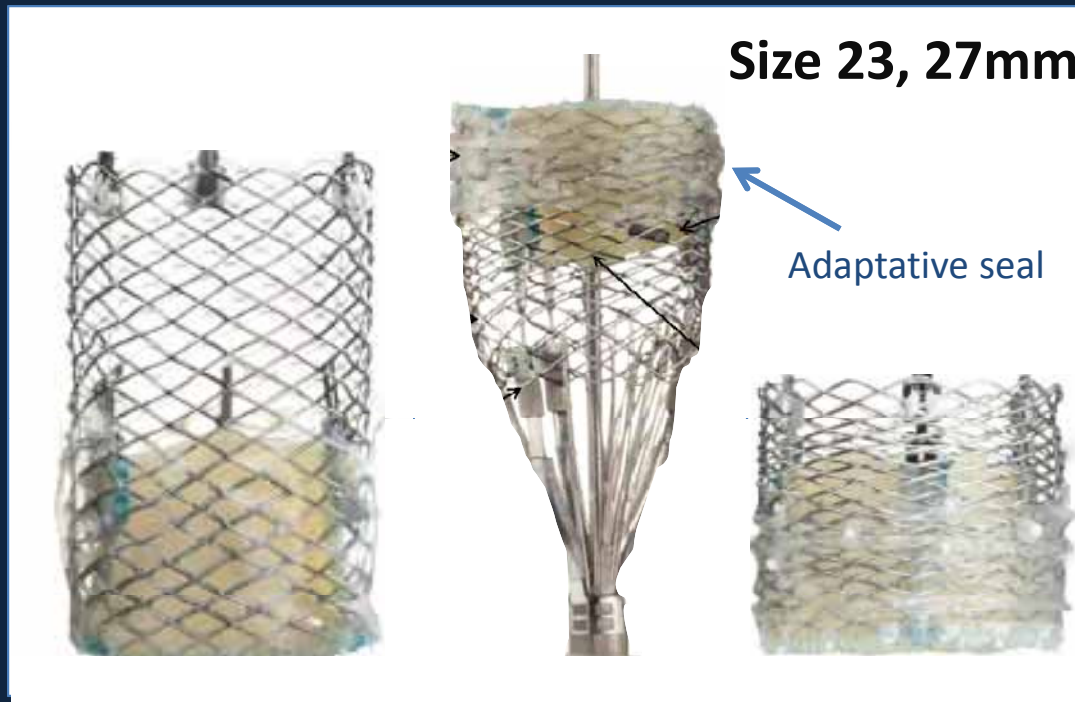
Sizes 25, 27mm



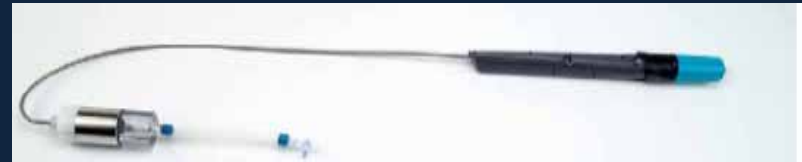
18F Delivery System

The future: New models of valve and delivery systems

BS Sadra Medical Lotus Valve System



System pre-packaged on delivery system



Valve delivery system



Proprietary Lotus 18F Introducer



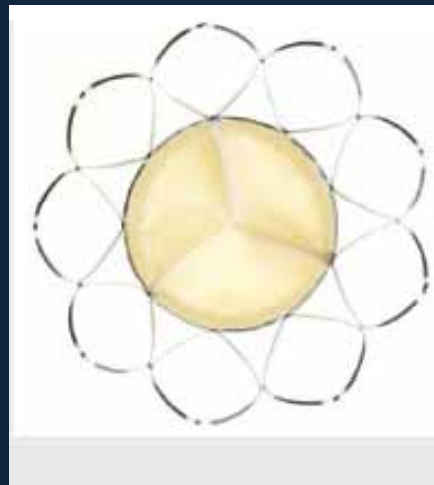
Bovine pericardial leaflets
Self Expanding Nitinol Stent

- Radial expansion as it shortens
- High radial strength
- Fully repositionable / retrievable
- Minimize aortic regurgitation

The future: New models of valve and delivery systems

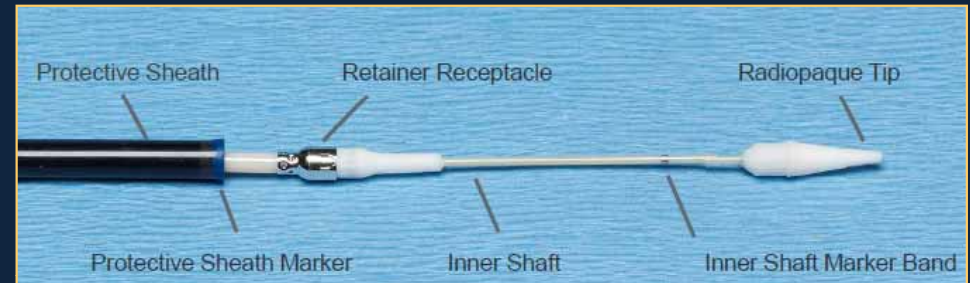
SJM Portico TAVI

Size 23, 25mm
(27,29mm)

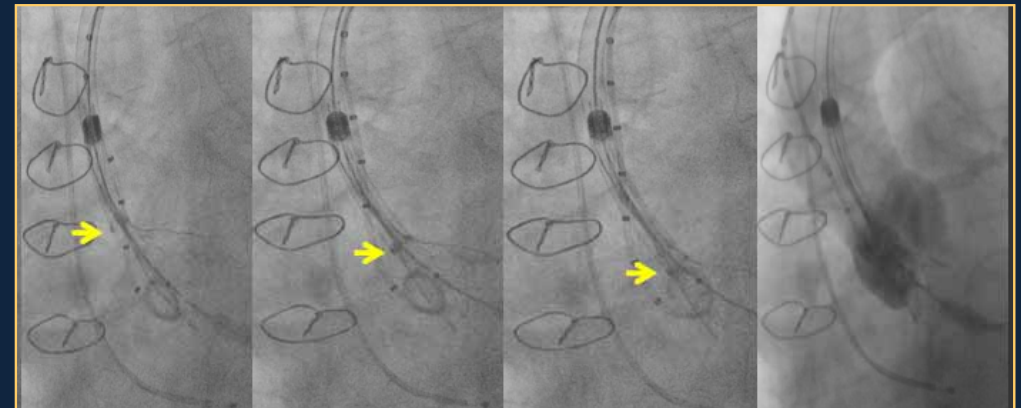


Treated bovine and porcine pericardial leaflets- Self Expanding Nitinol Stent

- Resheatable, repositionable, retrievable for placement accuracy
- Designed to minimize conduction system interference
- No need for RVP during expansion



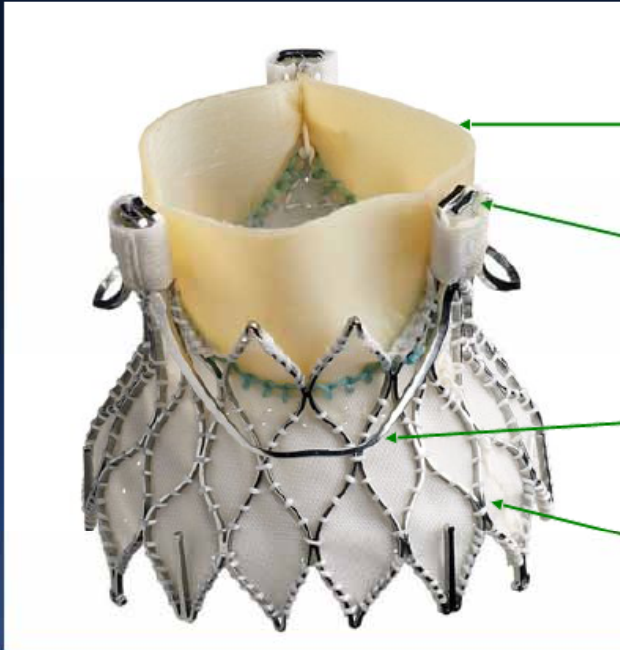
18F Delivery system



Resheathability is designed to enable optimised valve positioning during implantation

The future: New models of valve and delivery systems

Medtronic Engager Valve



Bovine tissue optimal for frame design and delivery profile

Flexible commissure posts reduce leaflet stress

Control Arms provide tactile feedback and stabilize bioprosthesis during deployment

Self-expanding nitinol frame and polyester skirt seal native annulus



Delivery system

Transapical

Direct Aortic



29F




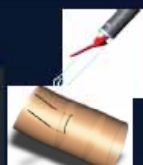
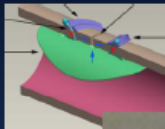
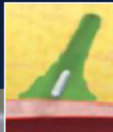






No separate introducer

The future: Adjunctive Technologies

The issue of vascular complications

New models of large vessel closure devices

Transfemoral

Category	Company	Technology
Emerging Suture Based Technologies	Interventional Therapies	
	MediGlobe	
	SpiRx	
	Vivasure	
Emerging Patch or Plug Technologies	ePacing	
	Sealing Solutions	
	Vascular Closure Systems	
	Apica Cardiovascular	
Strategic Players	Medtronic, Inc.	
	Abbott Vascular	
	St. Jude Medical	
	Cook/Cardica	

Transapical

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

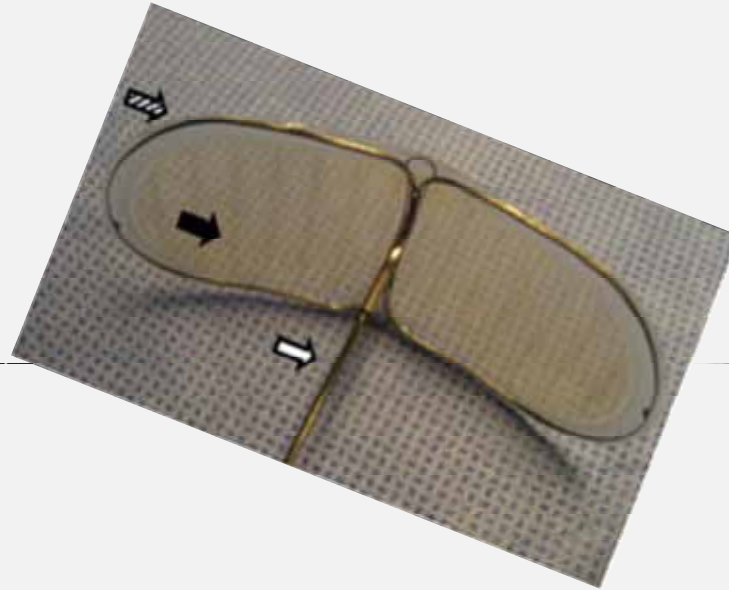


The future: Adjunctive technologies

The issue of stroke: a role for protection devices?



Feature
Access
Position
Coverage area
Mechanism
Size





Embrella Device

CE Mark

Randomized PRO-TAVI c

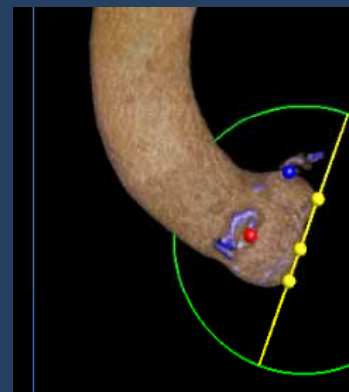
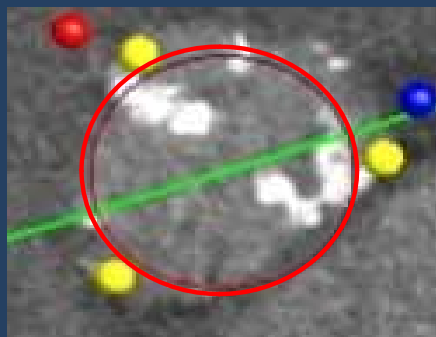
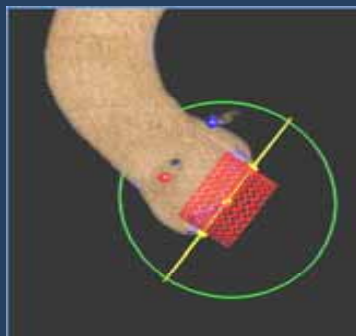
Study in Europe

	Claret Medical
	
	Radial
	Brachiocephalic Left common carotid
c &	Brachiocephalic & LCC
	Deflection
	6 Fr

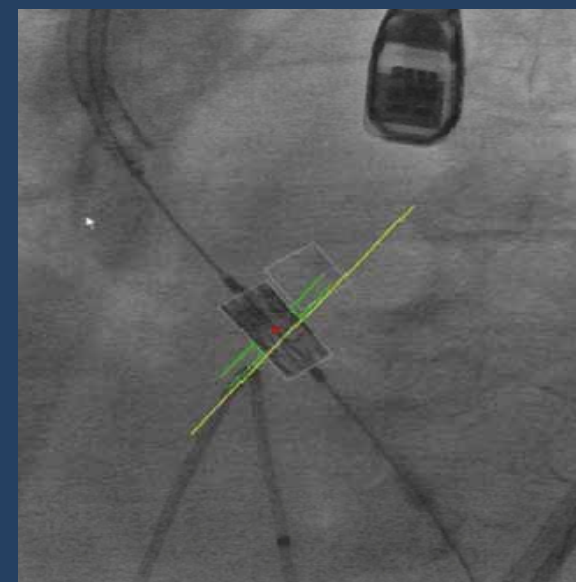
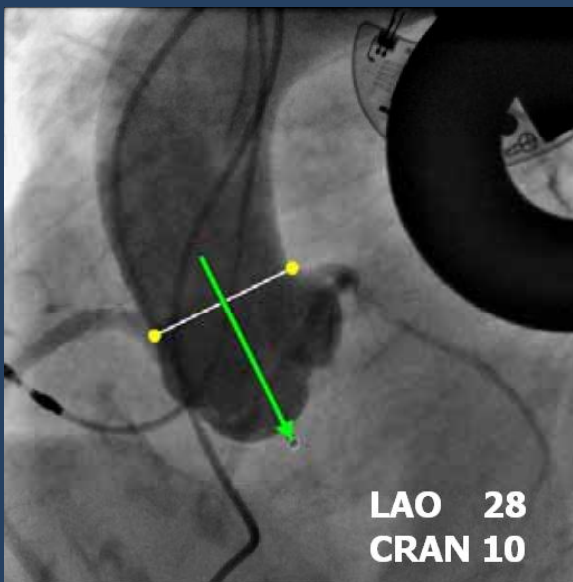
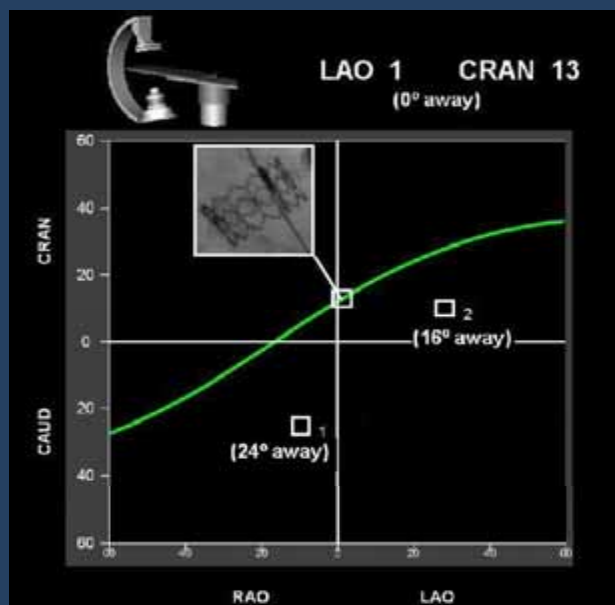
The future: Adjunctive Technologies

Valve sizing and positioning: New imaging technologies

Philips Heart Navigator (pre-procedure)



Paieon C-THV



Conclusions

Valve technology: a moving field

- In 2013, valve technology is still considerably evolving with marked differences among existing and new TAVI devices
- A number of new prosthesis and delivery systems should simplify the procedure and improve outcomes.
However, promising early results remain to be confirmed
- Simultaneously, new accessory devices and technologies should further decrease the complications in the near future (closure devices, embolic protection devices, imaging technologies...)
- These advances create an active and stimulating competition that should result in expanding TAVI in the future and transform therapy for most AS patients