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# Value of New Devices for Improving Outcomes

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# Background

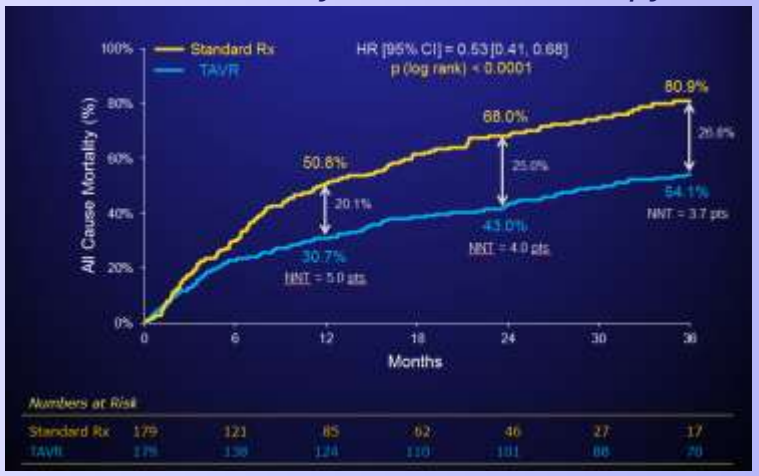
## Transcatheter Aortic Valve Implantation / Replacement (TAVI/R)

*Epidemiological data suggest*

- *~2-5% of adults >65 years old have severe aortic valve stenosis*
- *~30% - 40% of patients requiring aortic valve replacement do not undergo surgery:*

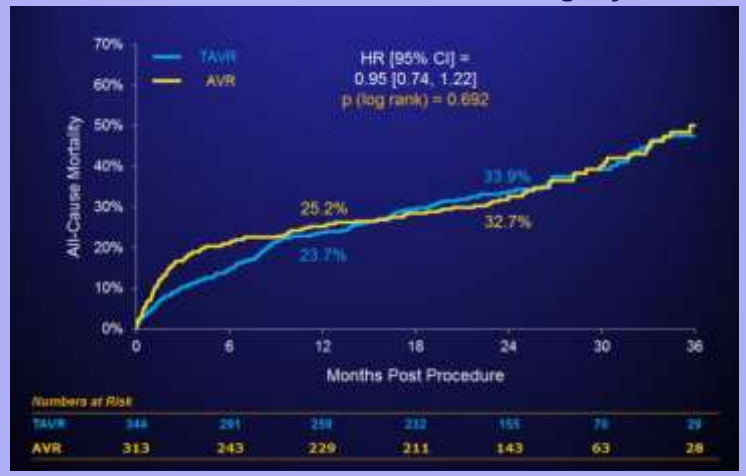
*TAVI/R provides an alternative treatment for patients with severe symptomatic aortic stenosis*

*Lower mortality vs. medical therapy*




*PARTNER Cohort B Presented by S Kapadia at TCT 2012*

*Similar survival rate vs. surgery*




*PARTNER Cohort A Presented by S Kodali at ACC 2012*

## ***Limitations with early TAVR devices***

*Stroke, bleeding & vascular complications*

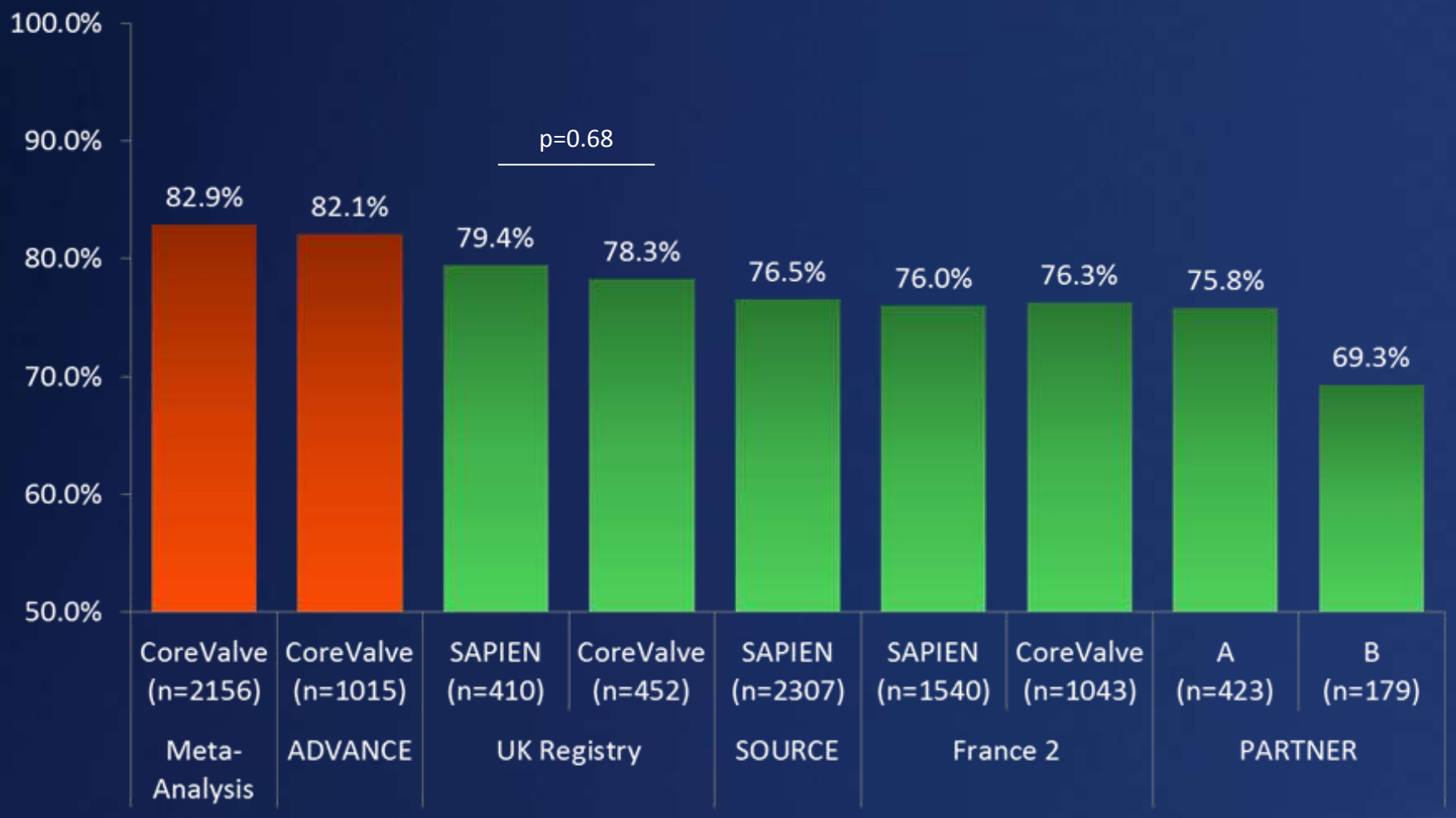
*Challenges with device positioning*

*Paravalvular leakage (associated with increased mortality*)*

**Kodali, etal. NEJM 2012;366:1685; Tamburino, et al. Circ 2011;123:299; Abdel-Wahab, et al. Heart 2011;97:899*

# Positive Survival is Being Consistently Achieved

## 1-Year Mortality



# Major Procedural Complications are Rare

CoreValve ADVANCE | Procedural Results

| Procedural Parameters N=996 | % |
|---|---|
| Successful vascular access, delivery & deployment of device & successful retrieval of the delivery system | 97.8 |
| Correct position of the device in the proper anatomical location | 98.7 |
| Mean aortic valve gradient < 20 mmHg | 96.2 |
| No severe AR requiring intervention | 97.9 |
| Only one valve implanted in the proper anatomical location | 96.0 |

| Major Complications; Valve Related N=996 | % |
|---|---|
| Annulus Rupture | 0.0 |
| Valve Embolization | 0.3 |
| Conversion to open AVR | 0.1 |
| Coronary Compromised | 0.1 |

# Remaining TAVI Challenges

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

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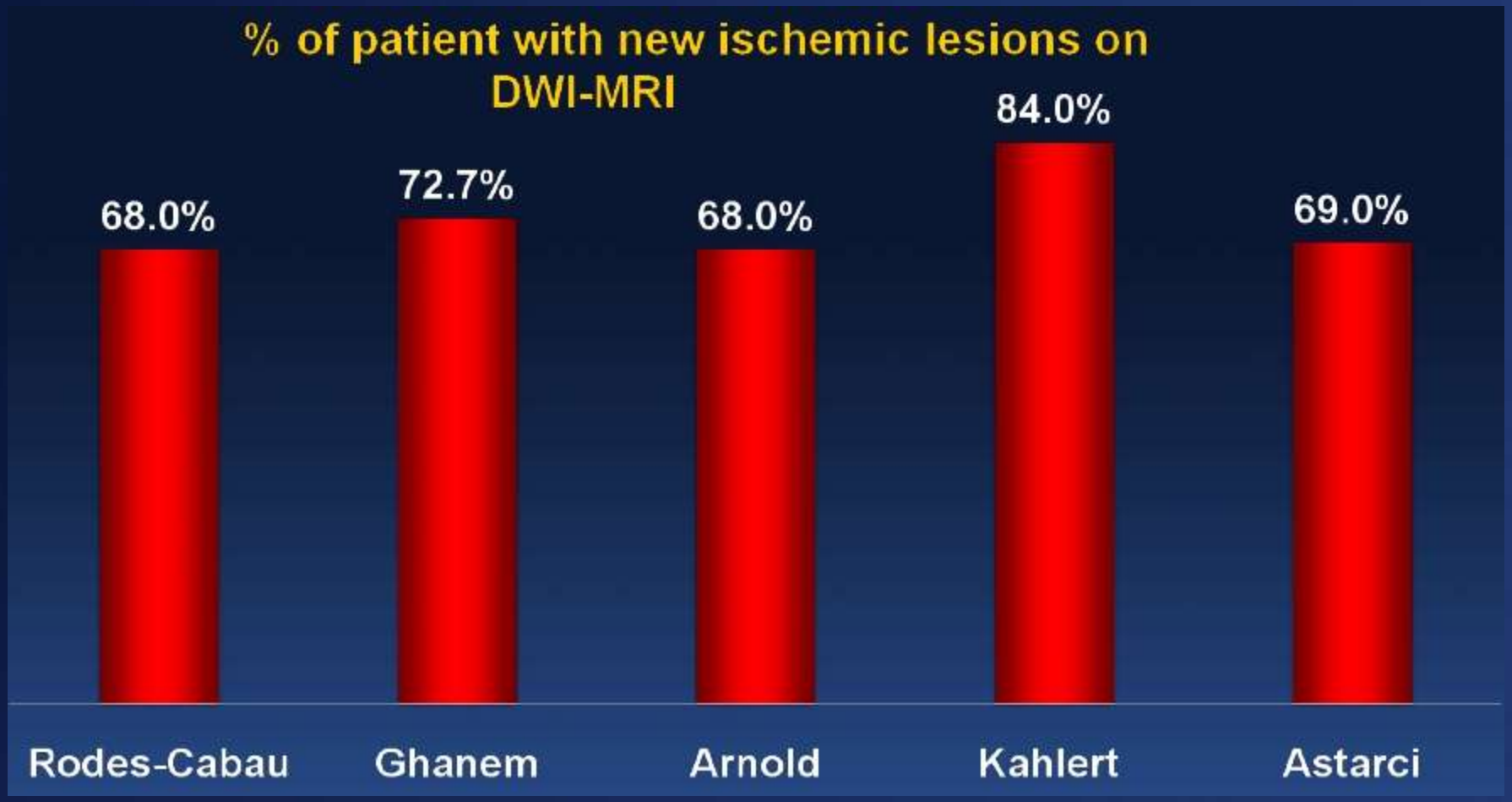
- Current State: Positive Overall Therapy Outcomes
- Opportunities to Advance Outcomes
  - Stroke
  - Aortic Regurgitation and Paravalvular leak
  - Vascular complications
  - Conduction disturbances

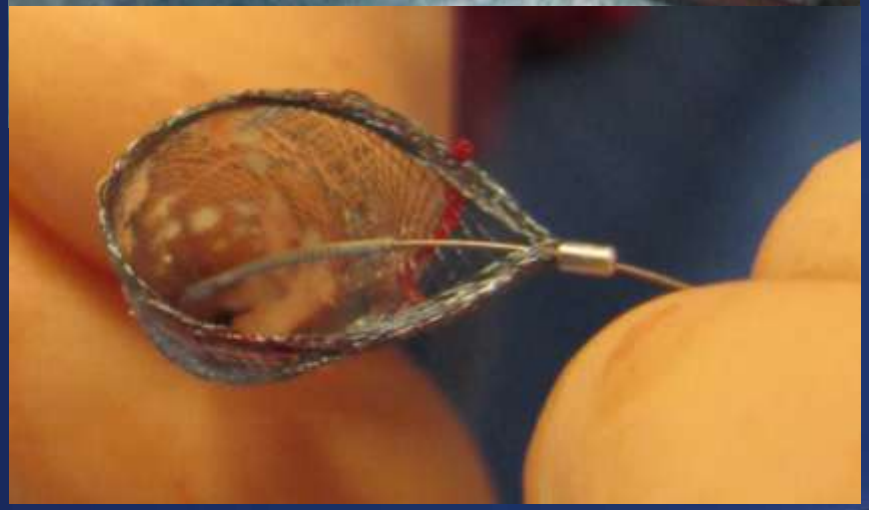
# Neuro-Imaging with TAVI




| *JACC* 2011 | *JACC* 2010 | *JACC Int* 2010 | *Circulation* 2010 | *EJCTS* 2011 |
|---|---|---|---|---|
| N=60 | N=30 | N=25 | N=32 | N=80 |

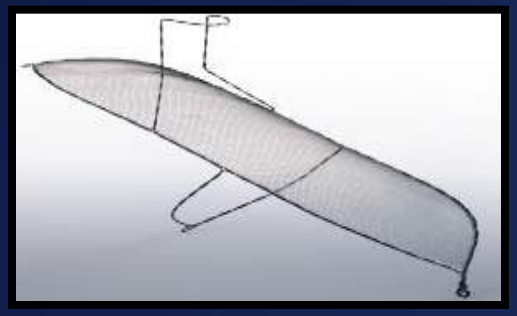
Daneault et al., JACC 2011;58: 2143-50

# Embolic Material after TAVI



# Competitive Analysis

| TriGuard™ Cerebral Deflector | Embrella™ Deflector | Claret Montage 2™ Filter |
|---|---|---|
| Deflector | Deflector | Filter |
| 3 Vessels Covered | 2 Vessel Coverage | 2 Vessel Coverage |
| Groin Access | Radial Access | Radial Access |
| Nitinol® Mesh | Polymer based Mesh | Polymer based Filter |
| EU Feasibility | CE approved | CE approved |
| 9F Sheath (7F Delivery) | 6F Shuttle Sheath | 6F Radial Sheath |



[1]*Embrella was acquired by Edwards Lifesciences in Mar 2011*

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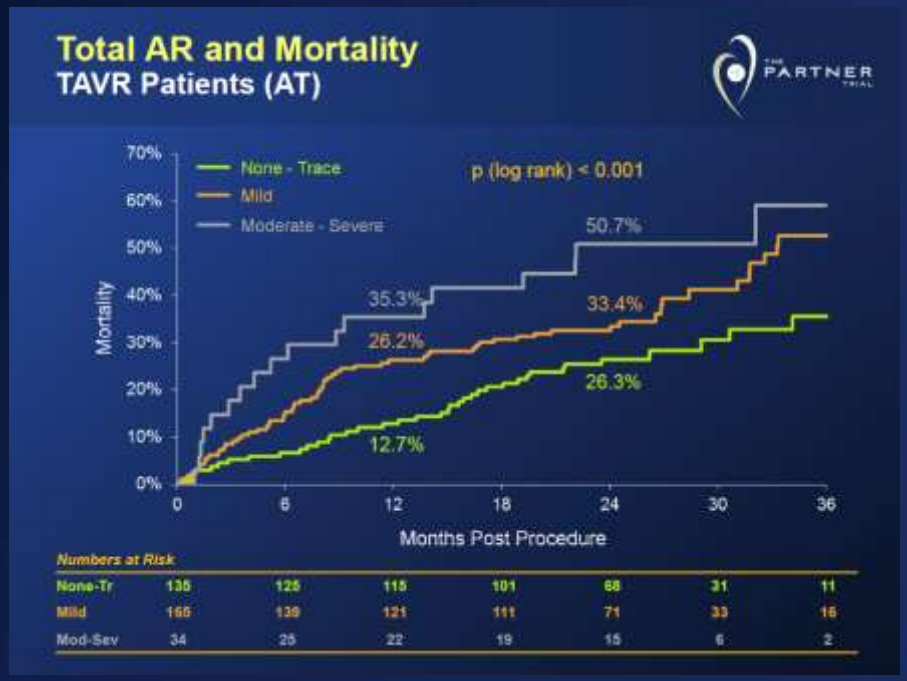
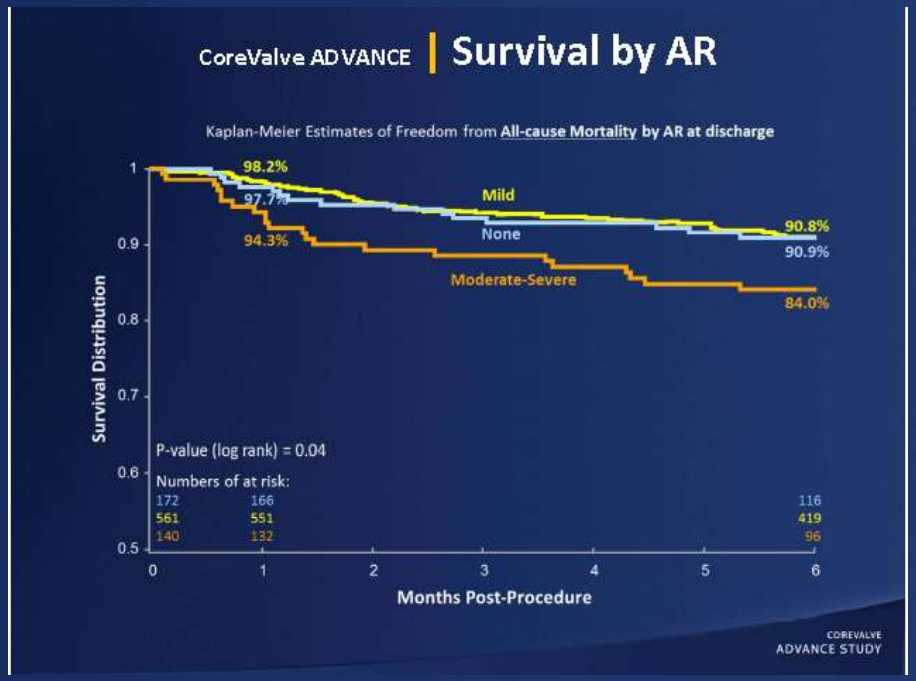
# Paravalvular Leak Associated with Mortality

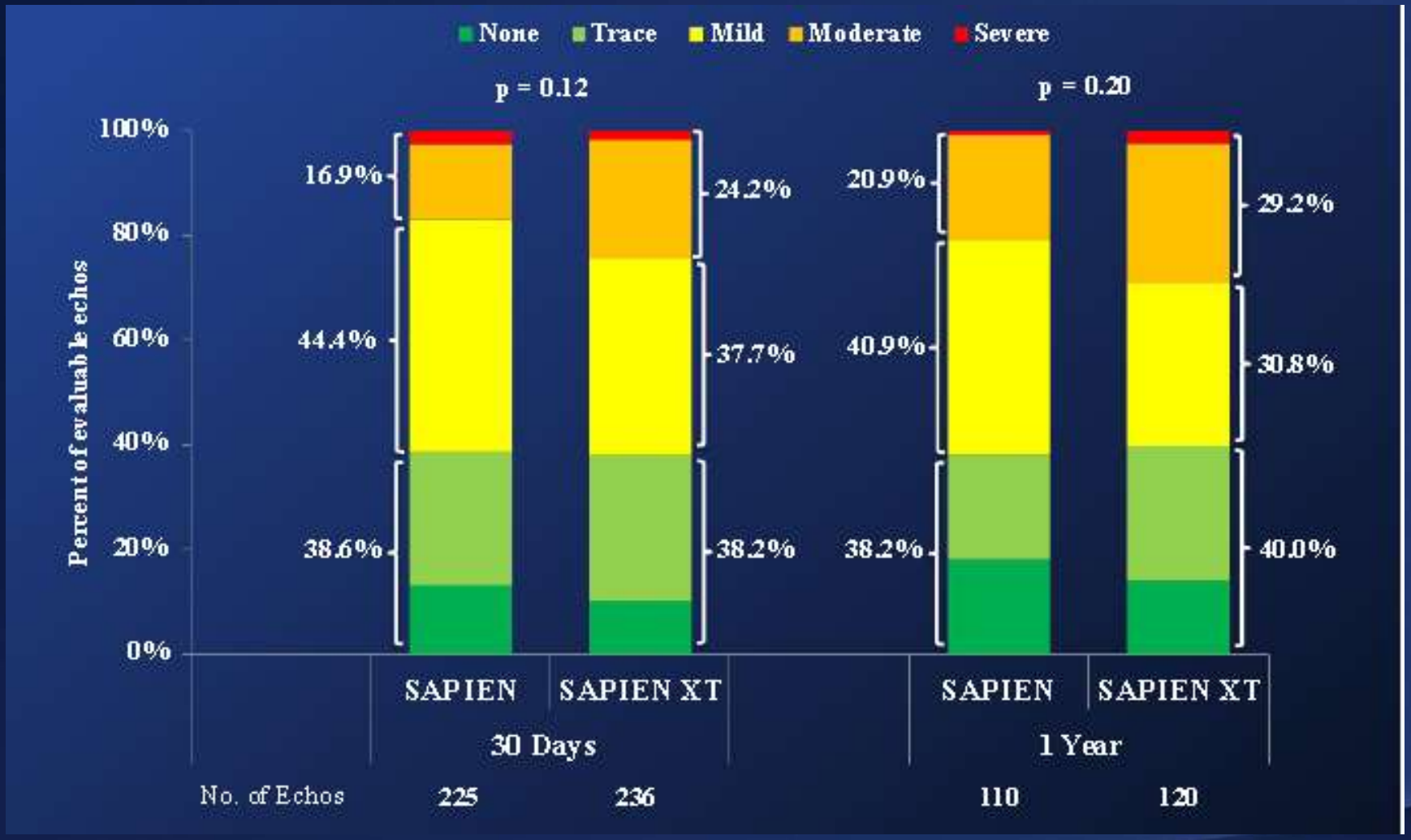
## PARTNER




## ADVANCE



# Challenges Remain



# New Generation TAVI Devices:

- Edwards Sapien/Centera Evolution
- Medtronic CoreValve Evolution
- Direct Flow Medical
- St. Jude Portico
- BSC Lotus Valve
- Symetis Acurate Valve

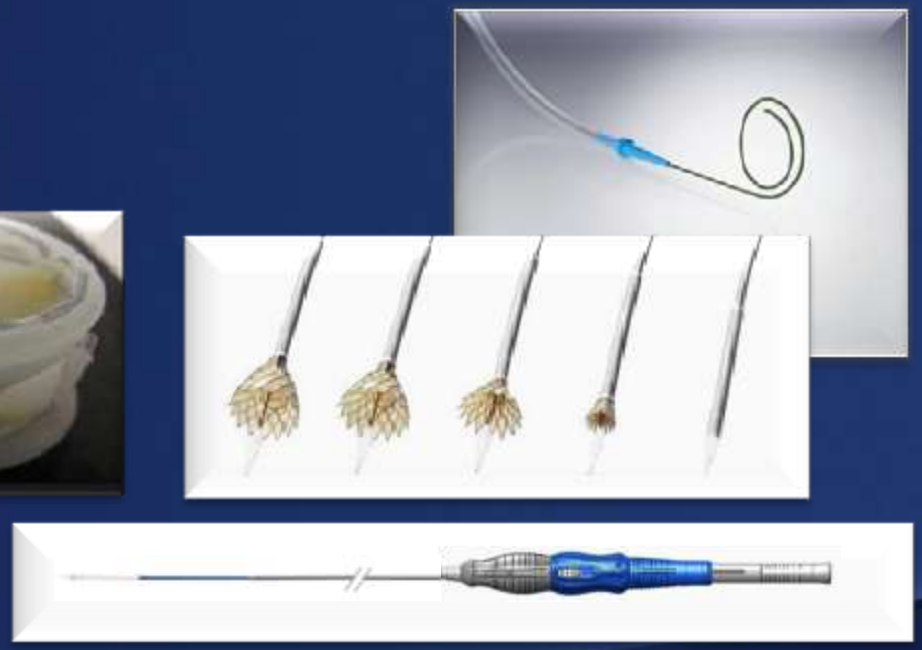
# New Technologies to Further Reduce PVL

## Annular Sealing

- Optimized radial force
- Positioning arms
- Skirt design

## Optimal Positioning

- Stable Deployment
- Recapture capability
- Accessories (e.g. guidewire)



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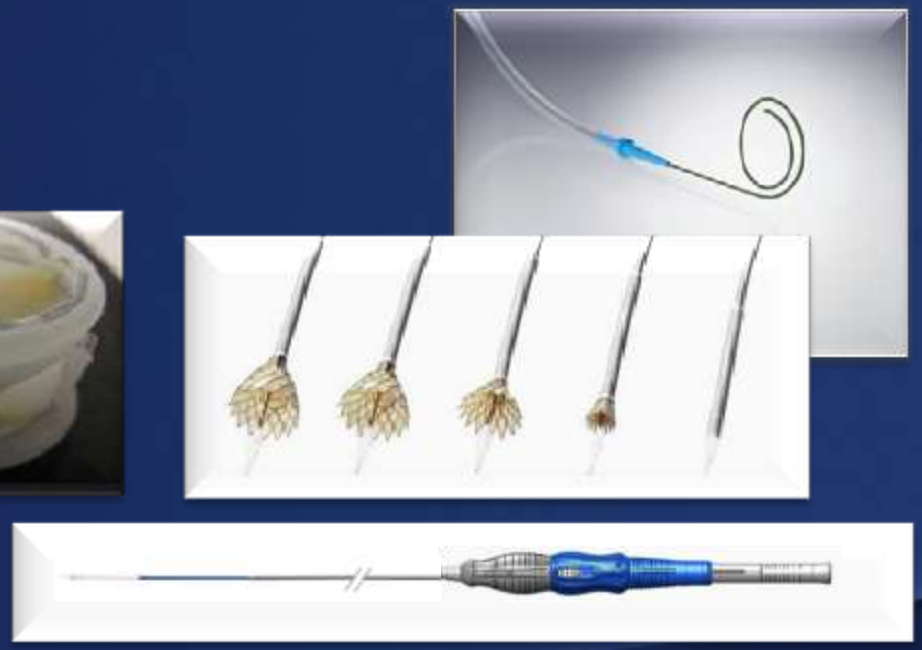


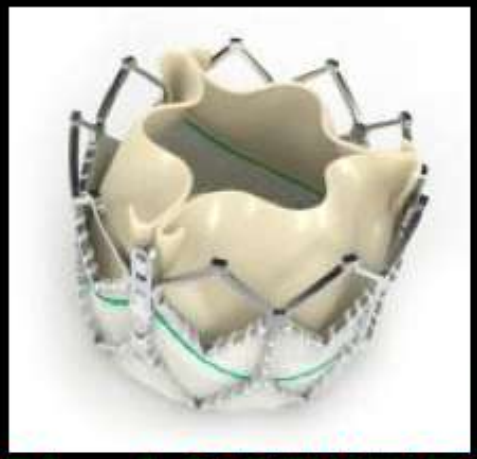
# Edwards – SAPIEN Evolution

2002

Cribier-Edwards THV

2006

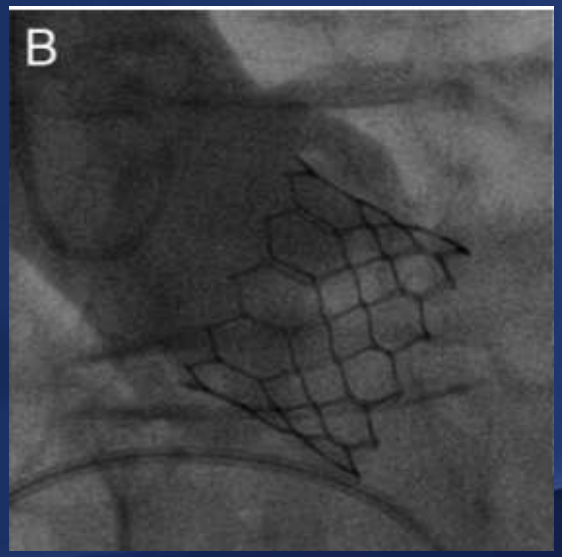
Edwards SAPIEN THV



2010

Edwards SAPIEN XT* THV

***2012***
***SAPIEN 3***

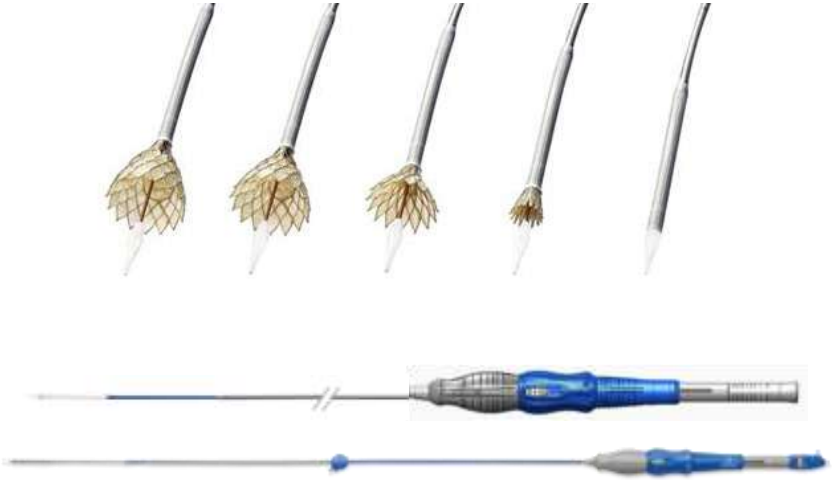


# CoreValve Evolut R System with EnVeo R DCS

*Fully resheathable, repositionable, recapturable*

**Evolut R Valve**

**EnVeo R Delivery System**



Ability to recapture across all valve sizes

InLine™ Sheath for 15F delivery profile

Full annulus range 18-29+ mm

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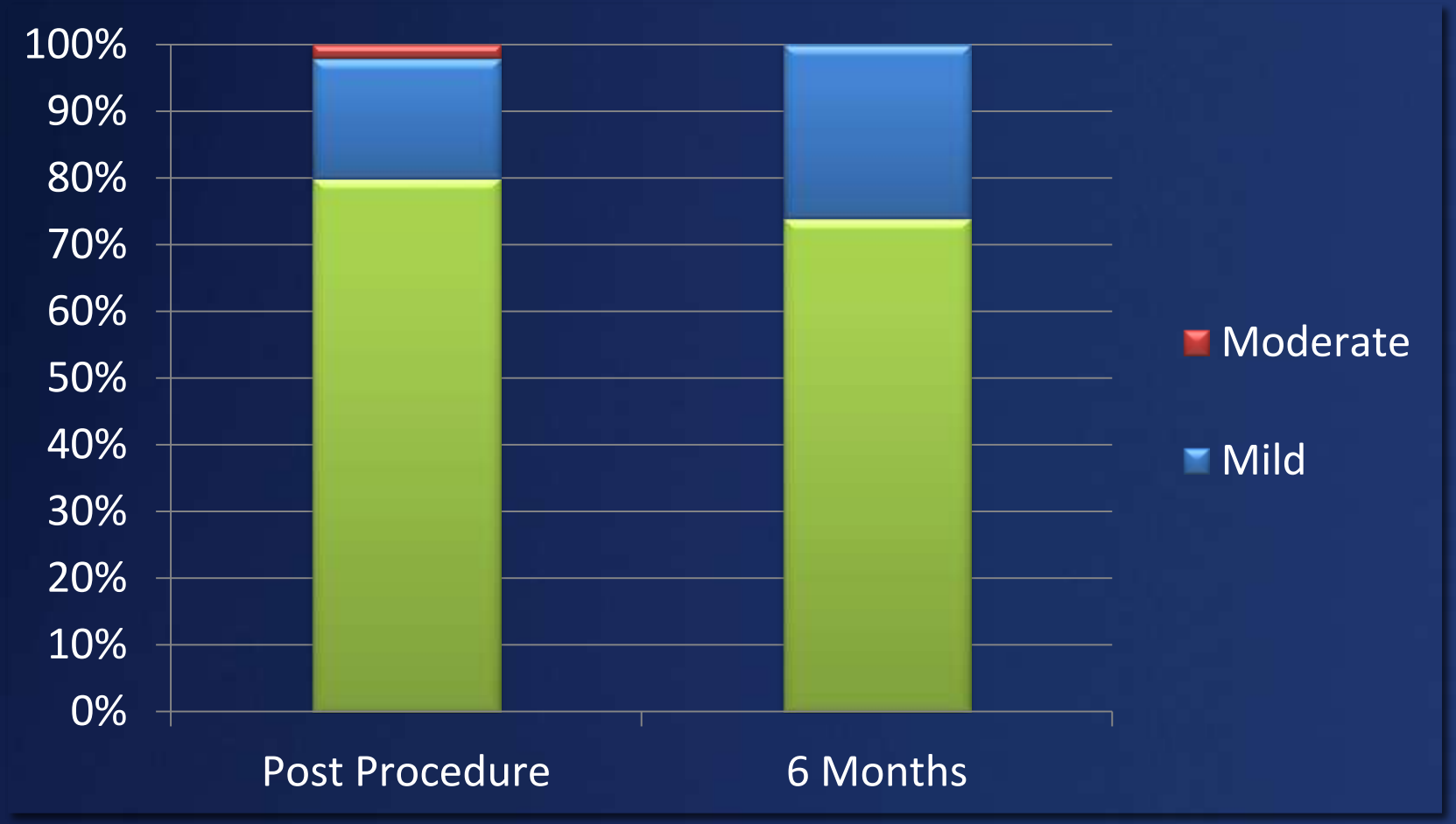
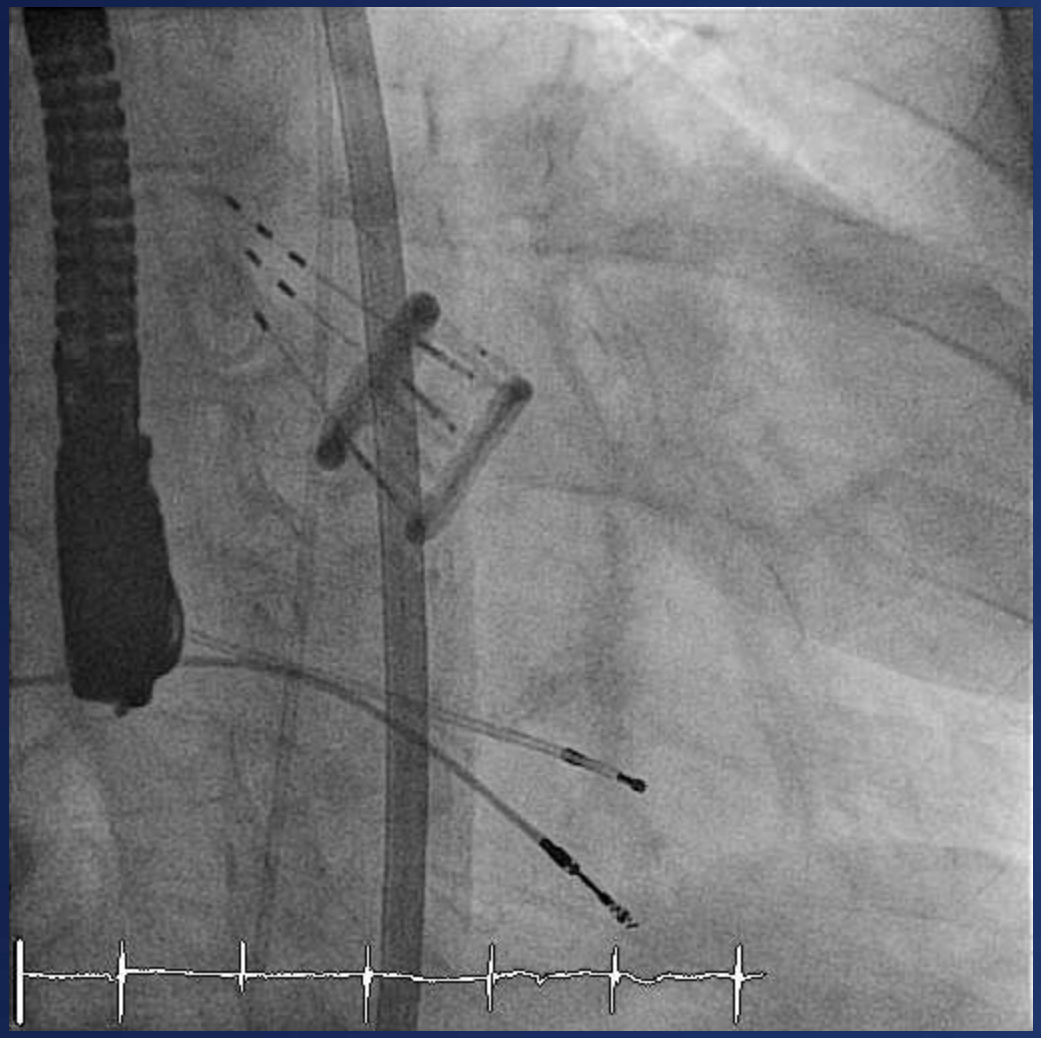
# DISCOVER Trial:

## Echocardiographic Aortic Regurgitation by Core Lab

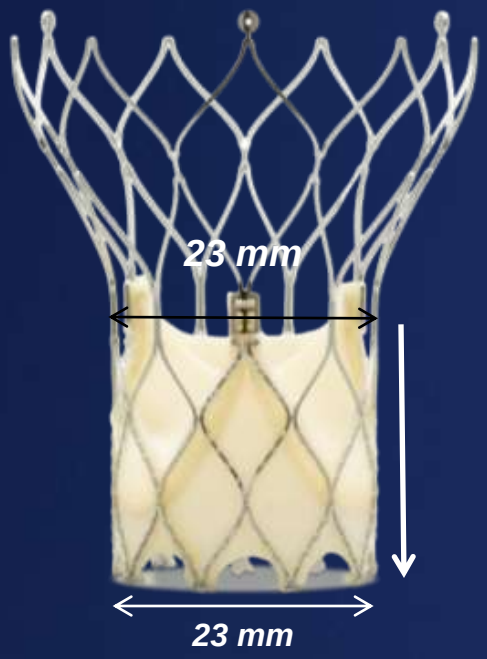


# Direct Flow – Positioning Annulus



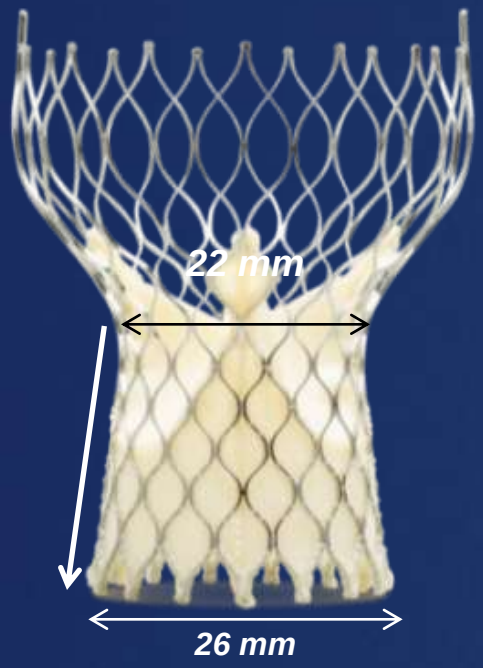
# Portico and CoreValve Design Comparison

***23 mm Portico[1]***




*Non-flared annulus design*

***26 mm CoreValve[2]***



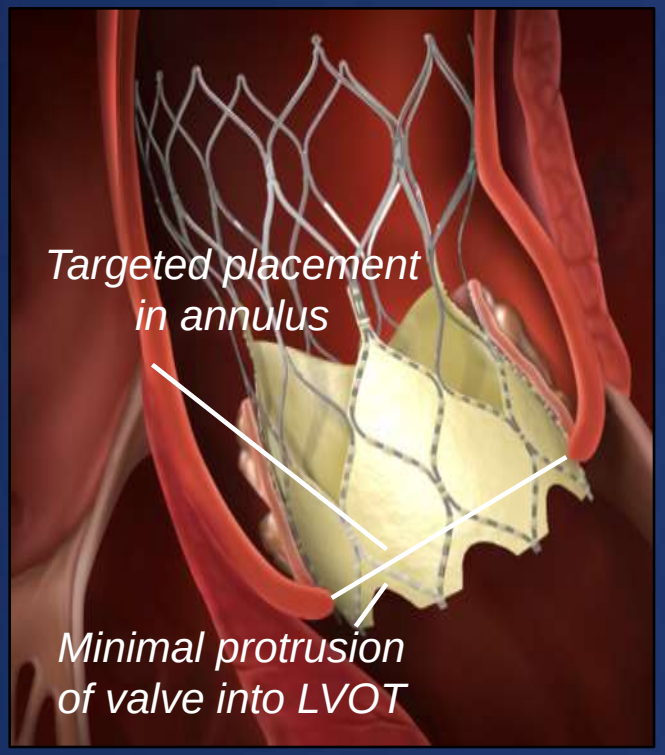

*Flared annulus design*

*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

# Mitigating Heart Block

- Ability to resheath* valve for improved placement accuracy
- Designed to minimize conduction system interference
  - Low valve placement within the stent allows for sealing without extending deep into the LVOT
  - Nonflared annulus section of the stent frame




*Targeted Valve Placement*

**Until fully deployed*

# *The Lotus™ Valve System*

## *Components and Function*

***Nitinol Frame***
*designed for repositioning and retrieval*

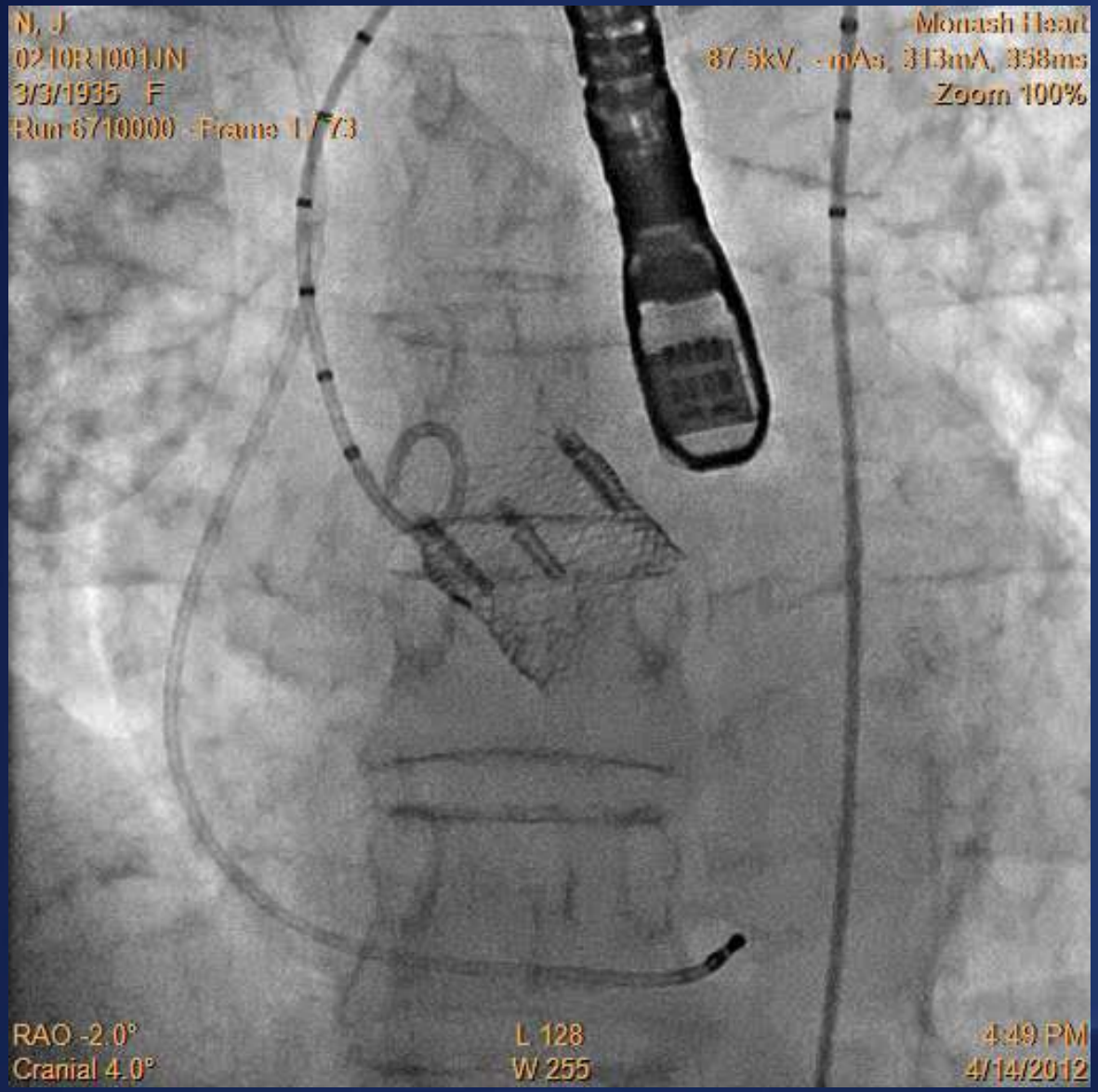
***Locking Mechanism***

***Bovine Pericardium***
*proven long-term material*

***Center Marker***
*marks the center of the implant during and after deployment*

***Adaptive Seal***
*designed to conform to irregular anatomical surfaces and to minimize paravalvular leaks*

# BSC Lotus Valve Final Angiogramm



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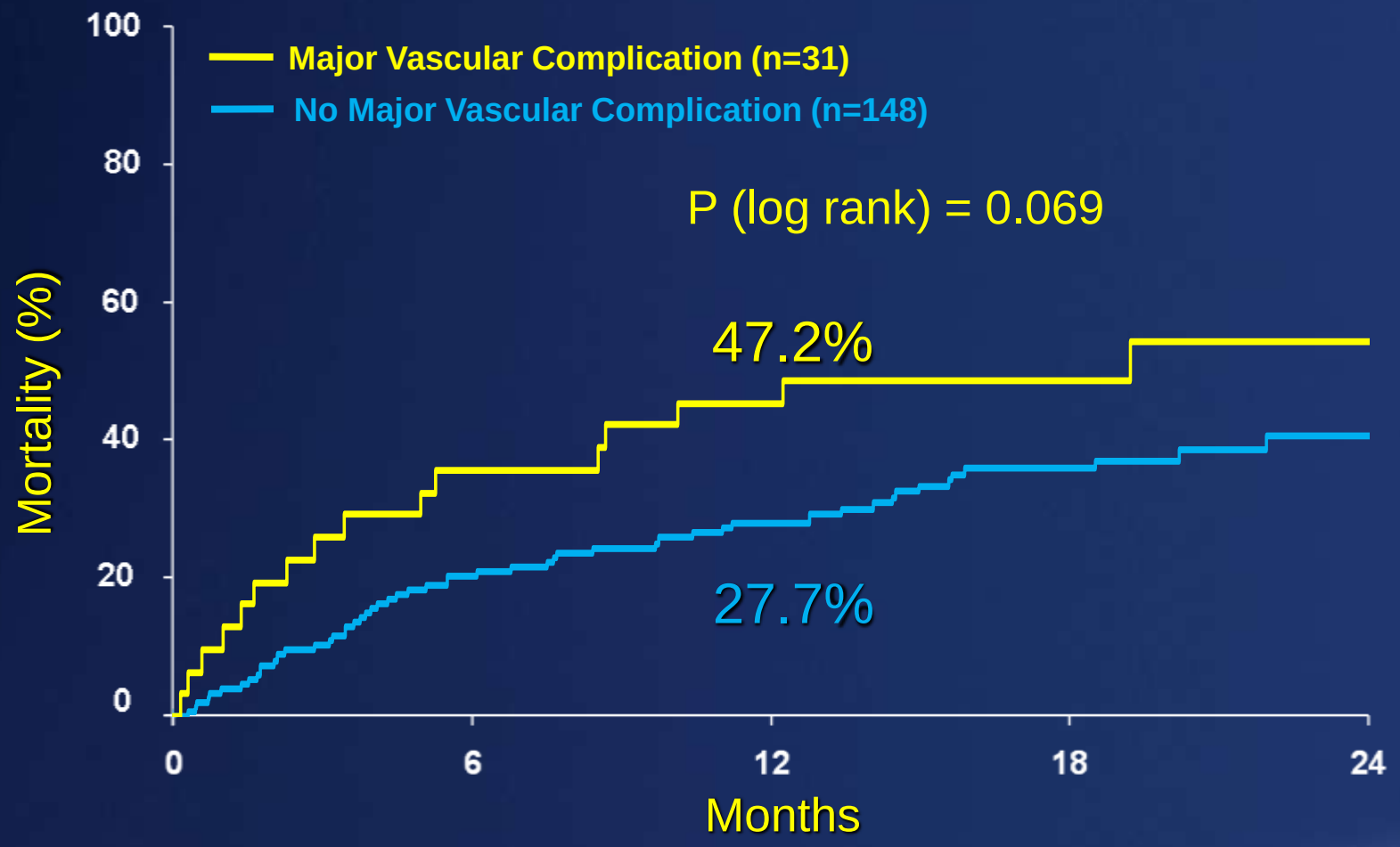
# Mortality and Major Vascular Complications

## PARTNER B—TAVI patients




Complications & Adverse Events: Frequency, Timing, Causes and Impact on Short- and Long-Term Outcome; Webb; TCT, 2010.

# Larger Sheath Size Can Contribute to Major Vascular Complications

A Sheath to Femoral Artery Ratio (SFAR) ≥ 1.05 is a Predictor of both VARC Major Vascular Complications and 30-Day Mortality

Sapien or Sapien XT (n = 102)
CoreValve (n = 28)

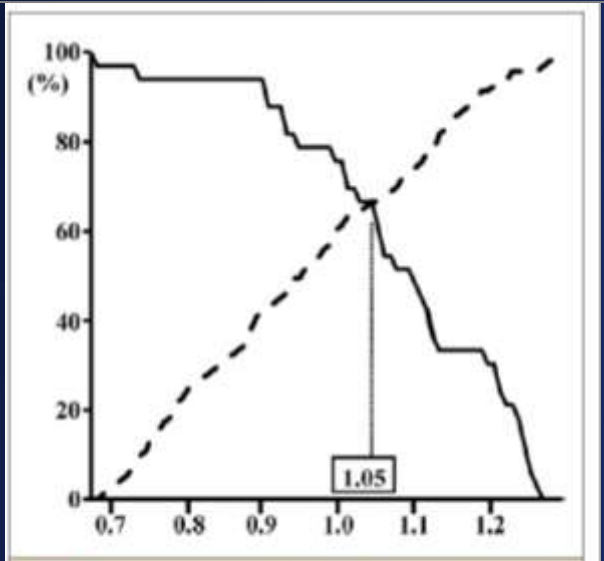
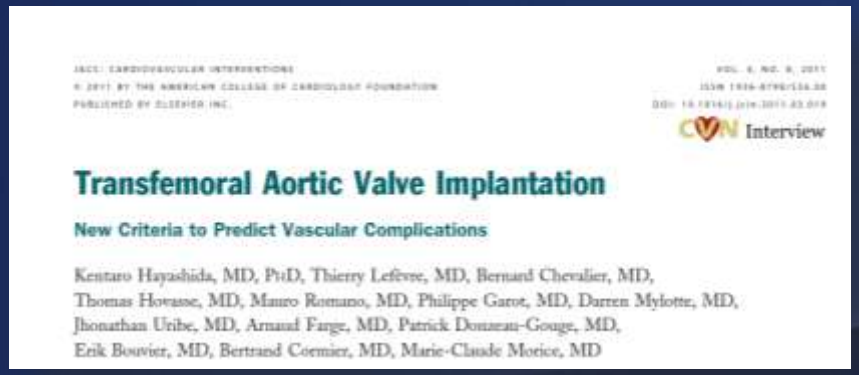



**Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications**

The sensitivity and specificity curve identified the threshold sheath femoral artery ratio (SFAR) of 1.05 as predictive of VARC major vascular complications. **Solid line** = sensitivity; **broken line** = specificity. VARC = Valve Academic Research Consortium.

**Table 6. Comparison of the Clinical Outcomes According to SFAR Threshold**

| Variables | SFAR ≥1.05 (n = 55) | SFAR <1.05 (n = 72) | p Value |
|---|---|---|---|
| Any vascular complication | 23 (41.8%) | 12 (16.7%) | **<0.001** |
| VARC Major | 17 (30.9%) | 5 (6.9%) | **0.001** |
| VARC Minor | 6 (10.9%) | 7 (9.7%) | 0.827 |
| Femoral artery complication | 15 (27.3%) | 9 (12.5%) | **0.035** |
| Iliac artery complication | 11 (20.0%) | 2 (2.8%) | **0.002** |
| In-hospital mortality | 11 (20.0%) | 5 (6.9%) | **0.033** |
| 30-day mortality | 10 (18.2%) | 3 (4.2%) | **0.016** |



CVN Interview

**Transfemoral Aortic Valve Implantation**

**New Criteria to Predict Vascular Complications**

Kentaro Hayashida, MD, PhD, Thierry Lefèvre, MD, Bernard Chevalier, MD, Thomas Hovasse, MD, Mauro Romano, MD, Philippe Garot, MD, Darren Mylotte, MD, Jhonathan Uribe, MD, Arnaud Farge, MD, Patrick Donzeau-Gouge, MD, Erik Bouvier, MD, Bertrand Cormier, MD, Marie-Claude Morice, MD

# Decreased Delivery System Profile to Reduce Major Vascular Complications

## InLine™ Sheath Eliminates Need for External Sheath

Sheath-to-femoral artery ratio (SFAR) with the **InLine™ Sheath** is less than 1.00 for all valve sizes (23, 26, 29, and 31mm) in vessels down to 6mm in diameter

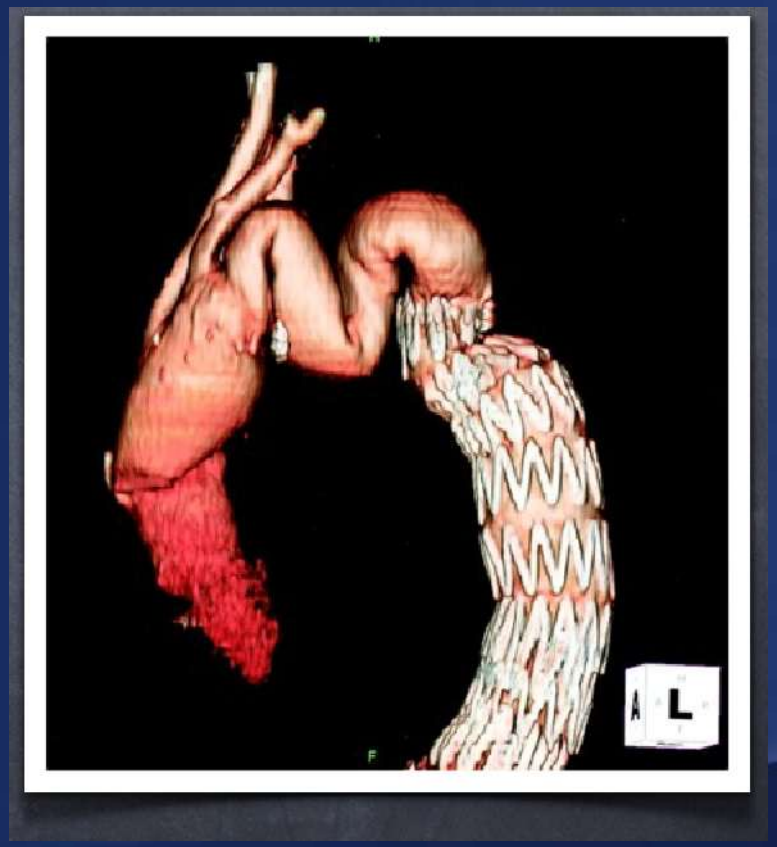
***Inner Diameter Becomes Effective Delivery Profile, resulting in 14FR equivalent delivery profile when using InLine™ Sheath***

| Current | | Future |
|---|---|---|
| 22 FR (OD) | 26.7-29.7FR (OD) | 18 FR (OD) |
| 18FR | 16FR | 18FR |
| *CoreValve w/ 18Fr Cook Sheath* | *Sapien XT w/ Edwards Sheath* | *CoreValve Evolut R w/ InLine Sheath* |

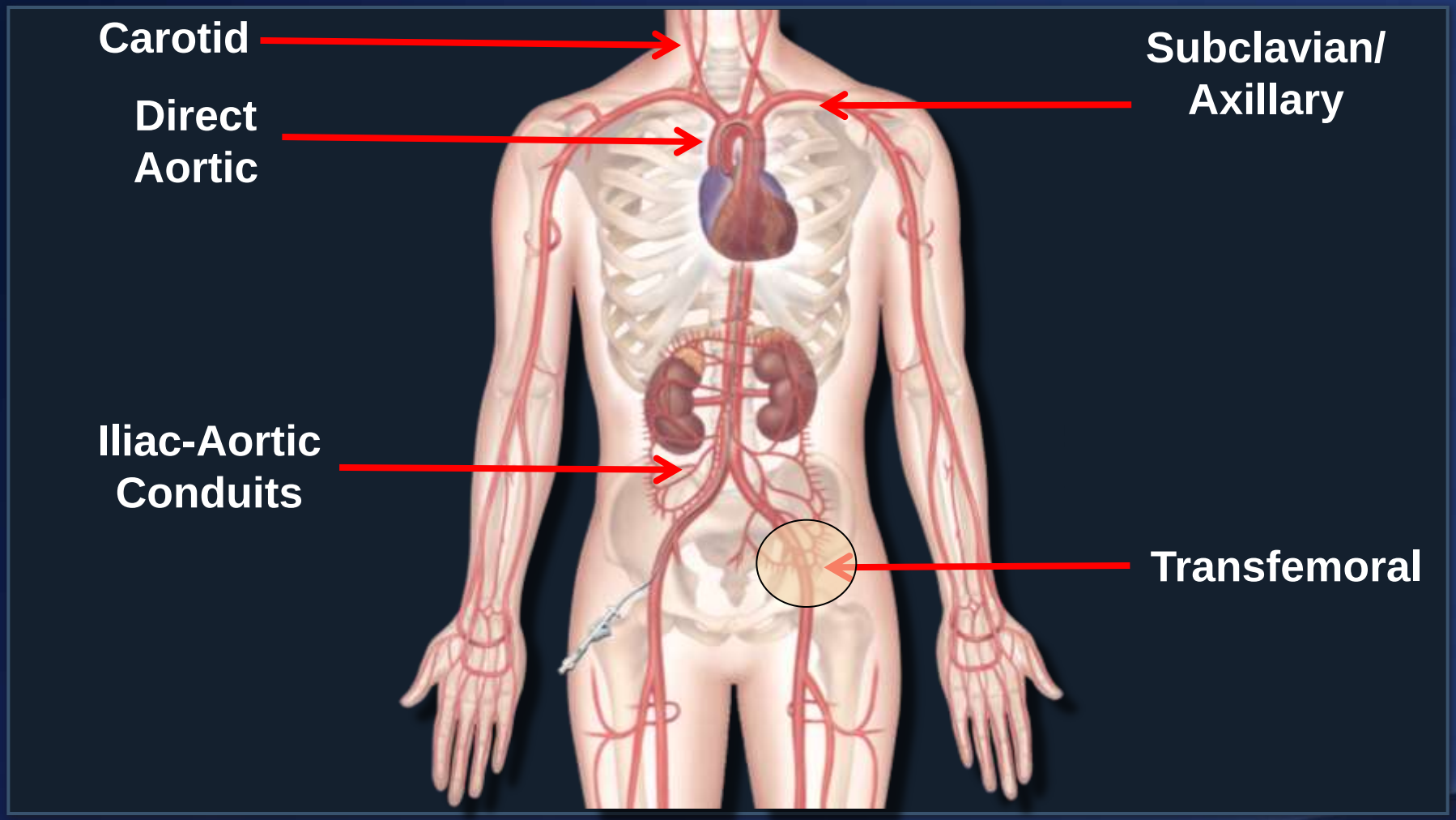
[1] Hayashida K., Lefevre T., Chevalier B.; et al. Transfemoral Aortic Valve Implantation; New Criteria to Predict Vascular Complications, J Am Coll Cardiol Intv 4 2011 851-858

# Alternative Access Options Are Important for Patients with Small Vasculature


Sometimes there just isn't enough room or excess tortuosity



# Growing TAVI Access Alternatives



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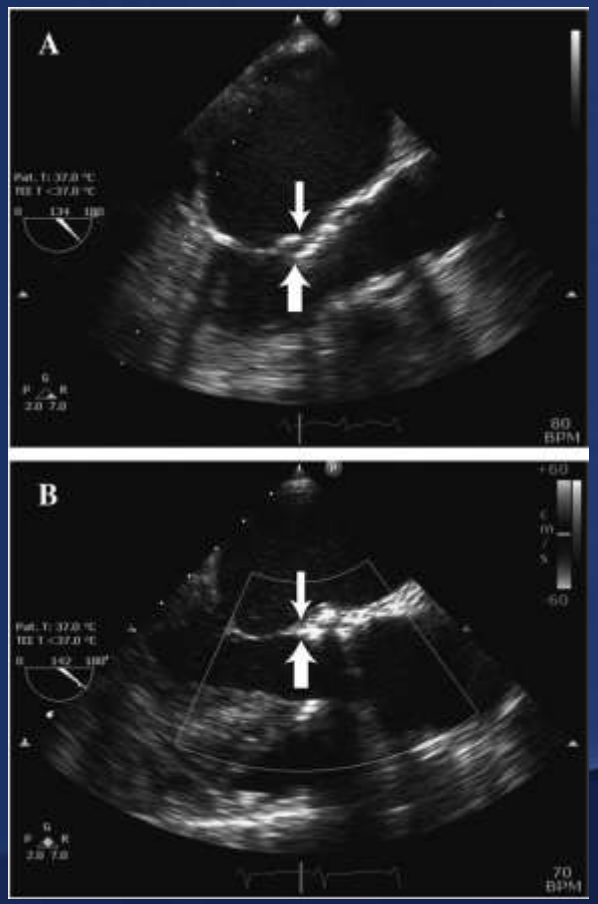
# Implant Depth Impacts Conduction Disturbances

- A lower (ventricular) position of the valve relative to the hinge point of the anterior mitral leaflet was associated with a higher incidence of new LBBB (35% vs. 0%, P = .029).

**Implanted Above** → 0% of patients developed LBBB

Hinge Point of the Anterior Mitral Valve

**Implanted Below** → 35% of patients developed LBBB



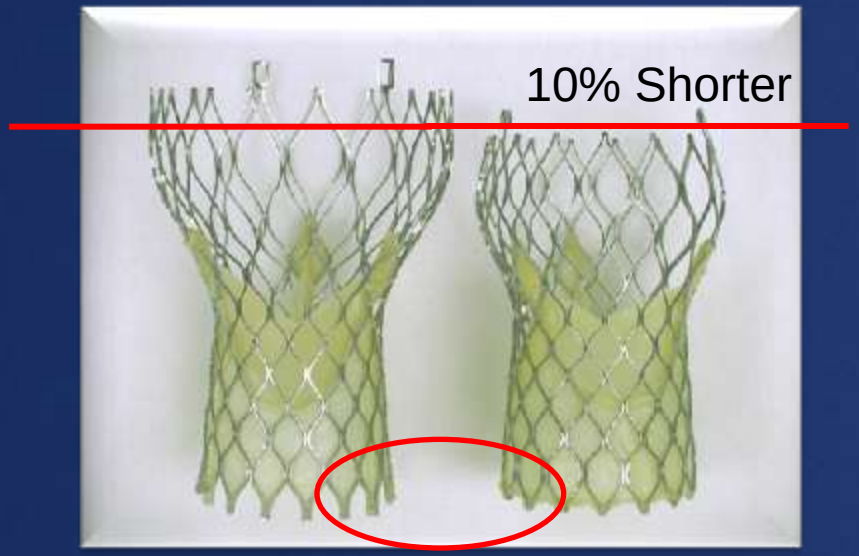

Gutierrez et al. Am Heart J 2009, (N=33)

# Reducing Post-TAVI Conduction Disturbance

## CoreValve Next Generation Systems optimize frame design and provide ability to recapture

CoreValve Evolut frame

- Shorter valve with reduced angulation
- Less traumatic Inflow Crowns




Evolut R with EnVeo R DCS

- Stable, controlled release
- Recapturability

# Thank you very much for Your Attention!