

TCT Asia-Pacific  
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# Which One is Better? CoreValve is Better!

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# Disclosure of Financial Interest

## Physician Name

Eberhard Grube, MD

## Company/Relationship

Medtronic, CoreValve: C, SB, AB, OF

Sadra Medical: E, C, SB, AB

Direct Flow: C, SB, AB

Mitralign: AB, SB, E

Symetis: AB

Boston Scientific: C, SB, AB

Biosensors: E, SB, C, AB

Cordis: AB

Abbott Vascular: AB

Capella: SB, C, AB

InSeal Medical: AB

Valtec: E, SB

Claret, SB

# CoreValve vs. Edwards – The Evidence I

	CoreValve	Edwards-SAPIEN
Annulus sizes	18-29 mm	18-27 mm
Pericardial tissue	Porcine	Bovine
Delivery Catheter	18 French	16/18 French
Repositionability	Yes	No („one shot“)
Deployment	Self-expanding	Ballon-expandable
Access strategy	Transfemoral Trans-subclavian Direct aortic Trans-carotid	Transfemoral Transapical (Trans-subclavian) (Direct aortic)

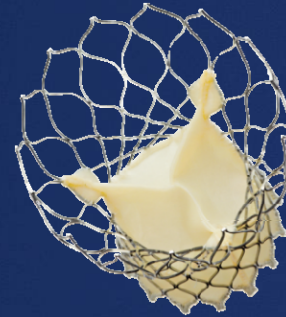
# CoreValve<sup>®</sup> System Components

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18Fr AccuTrak<sup>®</sup>  
catheter delivery  
system



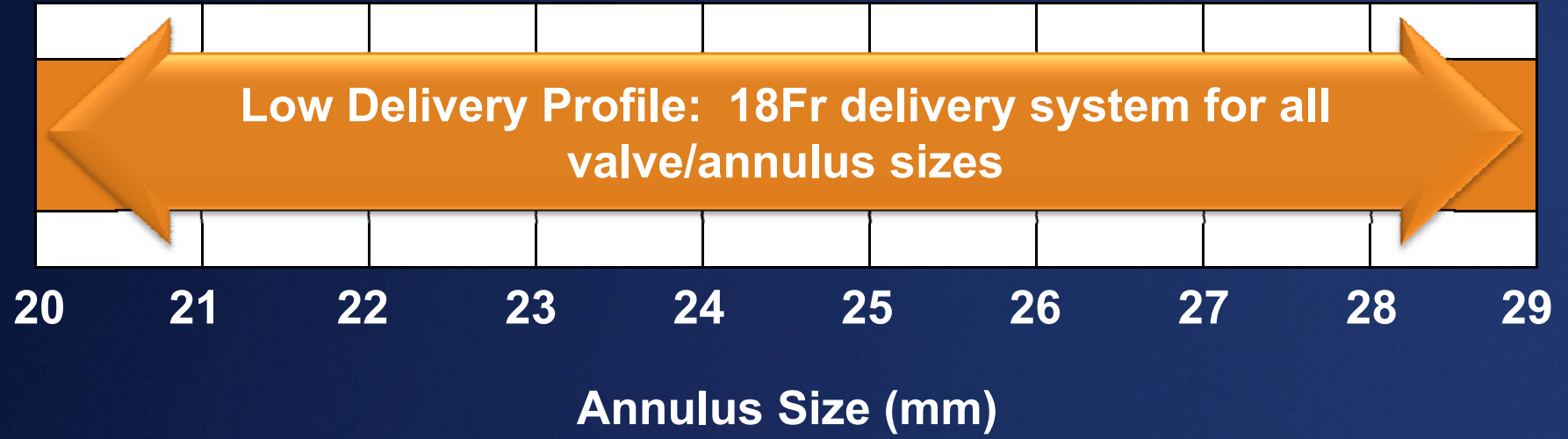
Self-expanding Nitinol  
frame with porcine  
pericardial valve



Disposable valve  
loading system

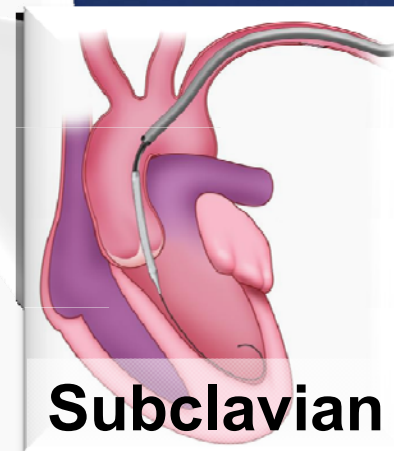
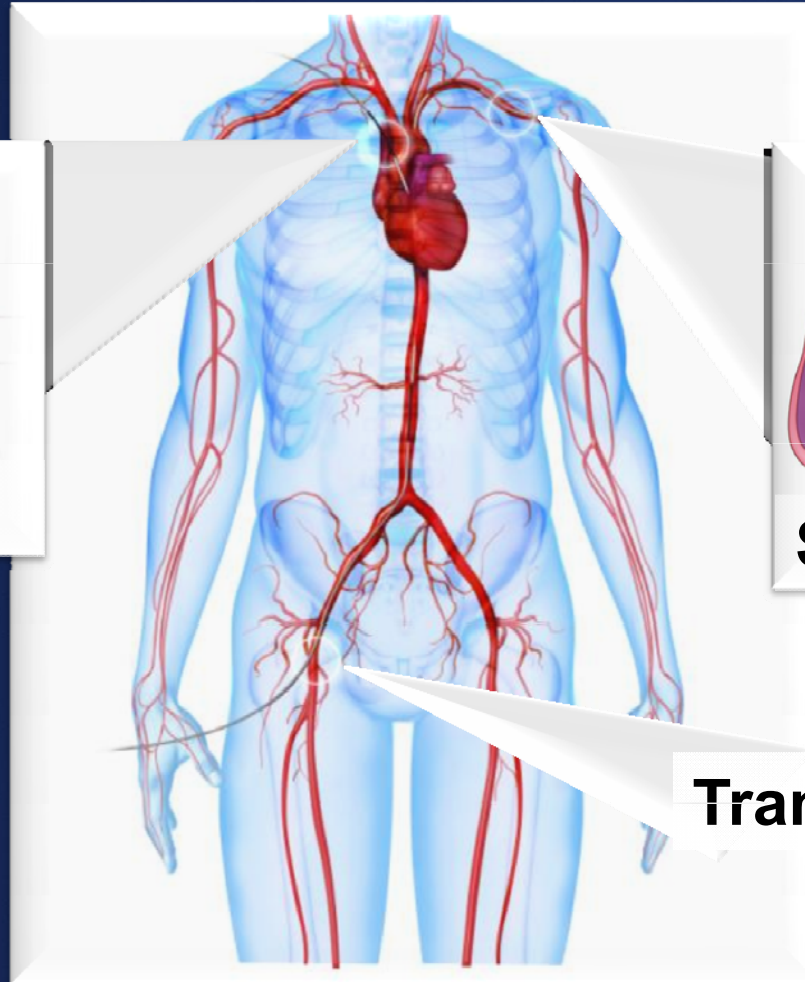
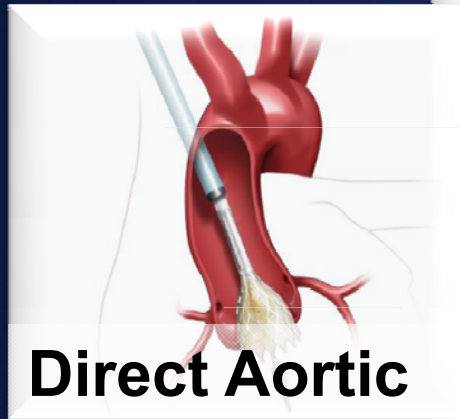


# 1 Access: Even in Patients with Small or Challenging Vasculature



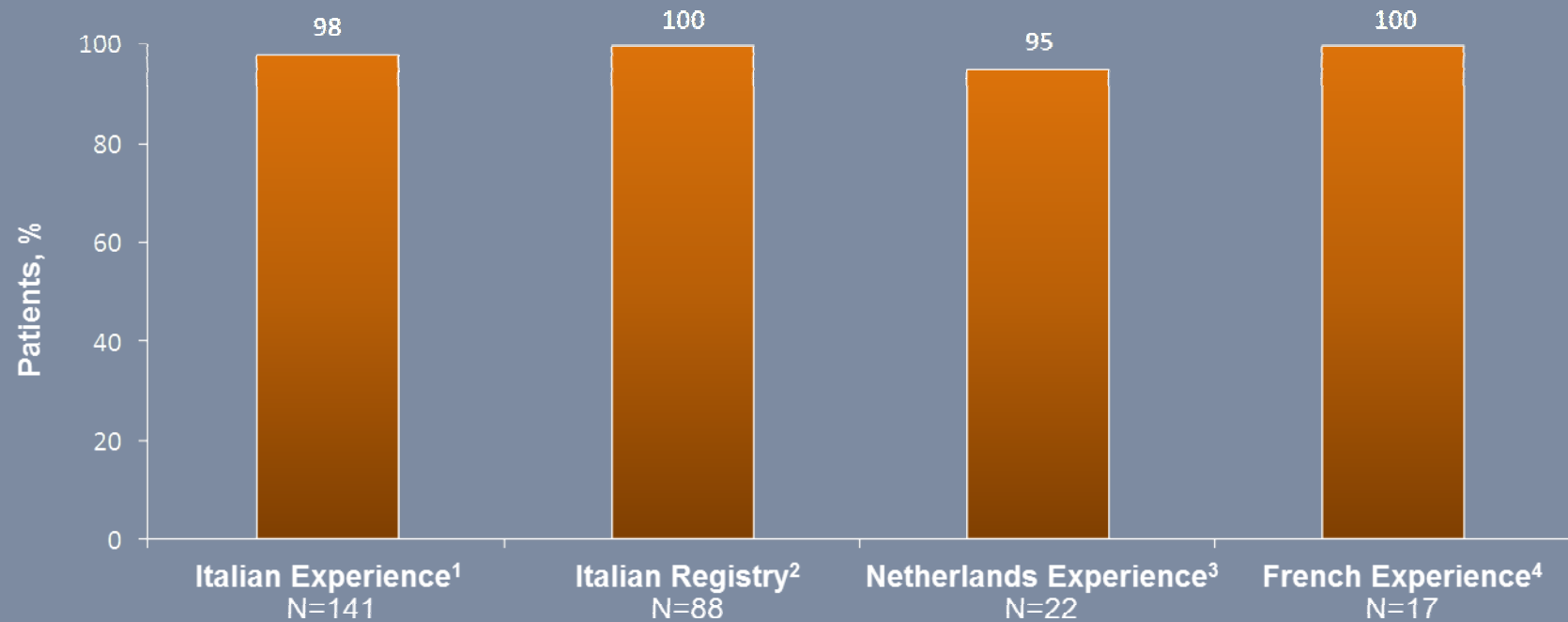
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## Access: Alternate Access Routes



Transfemoral

# CoreValve<sup>®</sup> System Procedure Success Subclavian



Note: Procedure success definition varies among publications

1. Petronio AS. Italian Experience Subclavian vs. Transfemoral. Presented at TCT 2011. 2. Laborde JC. TAVR Access Site Considerations. Presented at TVT 2011. 3. Verkroost MWA. TAVI Using Left Subclavian Route. Presented at TCT 2011. 4. Modine T. TAVI using Axillary/subclavian Access. *J Thorac Cardiovasc Surg.* 2011; 141(2).

# CoreValve<sup>®</sup> System Procedural Results Subclavian

	Italian Experience <sup>1</sup>	UK Registry <sup>2</sup>	Italian Registry <sup>3</sup>	Netherlands Experience <sup>4</sup>	French Experience <sup>5</sup>
<b>N</b>	<b>141</b>	<b>91</b>	<b>88</b>	<b>22</b>	<b>17</b>
Major Vascular Complication,%	5.7	5.4	NR	9	NR
Blood Transfusion / Major Bleeding,%	36.2	37.2	NR	NR	NR
Stroke,%	2.1	4.3	3.4	0	0
Myocardial Infarction,%	0	2.2	NR	5	0
Acute Renal Failure,%	5.3	4.3	NR	NR	0
New Pacemaker, %	24.1	22.1	NR	NR	NR

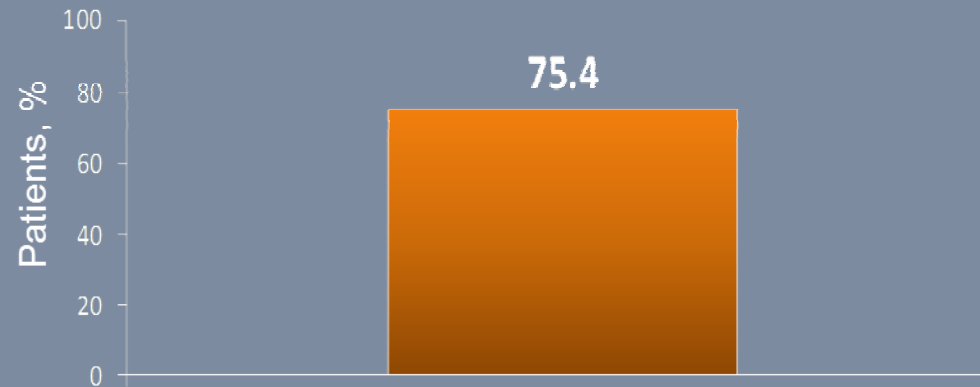
NR= Not Reported

1. Petronio AS. Italian Experience Subclavian vs. Transfemoral. Presented at TCT 2011. 2. Blackman D. UK Registry Comparison valve type and access approach. Presented at TCT 2011. 3. Laborde JC. TAVR Access Site Considerations. Presented at TVT 2011. 4. Verkroost MWA. TAVI Using Left Subclavian Route. Presented at TCT 2011. 5. Modine T. TAVI using Axillary/subclavian Access. *J Thorac Cardiovasc Surg.* 2011; 141(2).

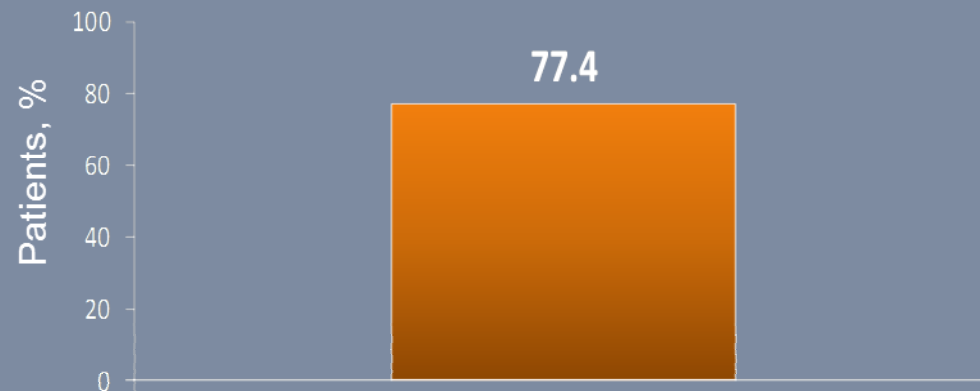


# Long-term Survival Subclavian

1 year Survival  
UK Registry<sup>1</sup>  
N=91



2 year Survival  
Italian Experience<sup>2</sup>  
N=141



1. Blackman D. UK Registry Comparison valve type and access approach. Presented at TCT 2011. 2. Petronio AS. Italian Experience Subclavian vs. Transfemoral. Presented at TCT 2011

# EUROPEAN EXPERIENCE OF DIRECT AORTIC TAVI WITH A SELF-EXPANDING PROTHESIS

*Neil Moat<sup>1</sup>, Hasan Bushnaq<sup>2</sup>, Marjan Jahangiri<sup>3</sup>, Domenico Mazitelli<sup>4</sup> Hafid Amrane<sup>5</sup>, Marian Branny<sup>6</sup>, Johan Bosmans<sup>7</sup>, Mo Bhabra<sup>8</sup>, Peter den Heijer<sup>9</sup>, Uday Trivedi<sup>10</sup>, Didier Tchetché<sup>11</sup>, Rudiger Lange<sup>4</sup>, Jean-Claude Laborde<sup>3</sup> and Giuseppe Bruschi<sup>12</sup>*

<sup>1</sup>Royal Brompton, London UK; <sup>2</sup>Martin-Luther-University, Halle an der Saale, Germany; <sup>3</sup>St Georges Hospital, London, UK; <sup>4</sup>German Heart Centre Munich, Munich Germany; <sup>5</sup>Medisch Centrum Leeuwarden; <sup>6</sup>Hospital Podlesi, Czech Republic; <sup>7</sup>Antwerp University Hospital, Antwerp Belgium; <sup>8</sup>University of Birmingham, London UK; <sup>9</sup>Amphia Hospital Breda, Breda, The Netherlands; <sup>10</sup>Brighton and Sussex University Hospitals, Brighton UK; <sup>11</sup>Clinique Pasteur, Toulouse, France, <sup>12</sup>Niguarda Ca' Granda Hospital, Milan, Italy

## Advantages

- Familiar access
- Familiar cannulation
- Excellent control of delivery
- Ability to be co-axial
- Potential for thoracoscopic approach (mini-thor)
- Enhanced potential for embolic protection
- Less painful than TA

## Disadvantages

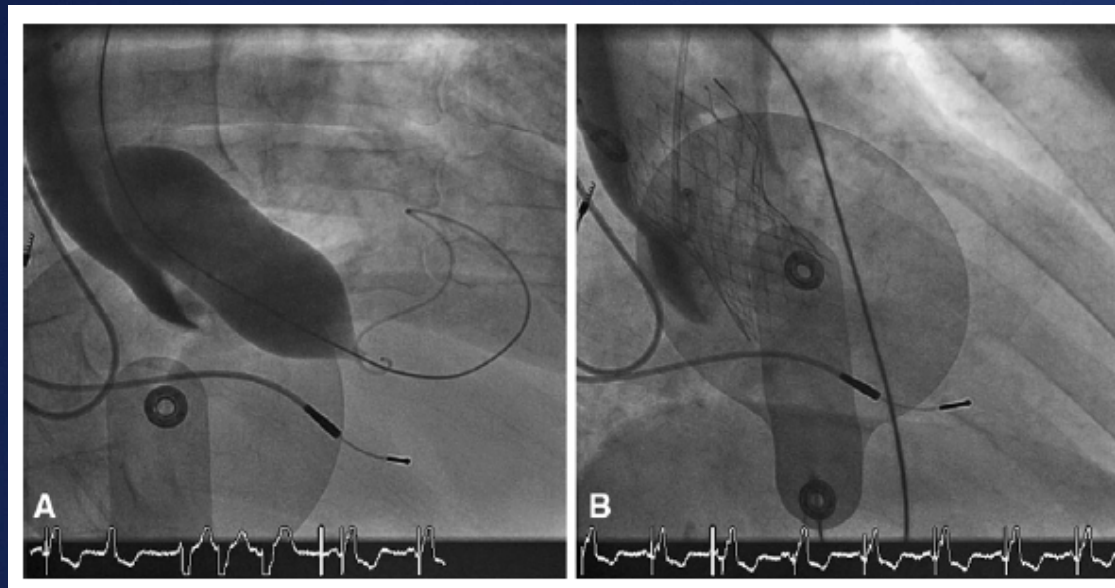
- More invasive than TF/SC
- More painful than TF/SC
- Increased radiation dose to the operators

2

## Access: Emerging Access Route?

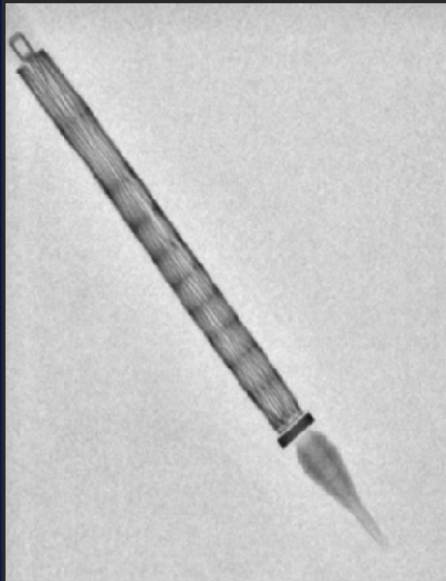
### Aortic valve implantation with the CoreValve ReValving System via left carotid artery access: First case report

Thomas Modine, MD,<sup>b</sup> Gilles Lemesle, MD,<sup>a</sup> Richard Azzaoui, MD,<sup>b</sup> and Arnaud Sudre, MD,<sup>a</sup> Lille, France

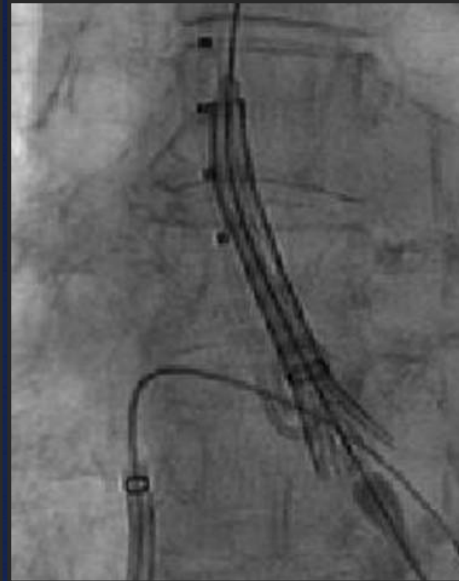


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## Positioning; Even in Challenging Anatomies



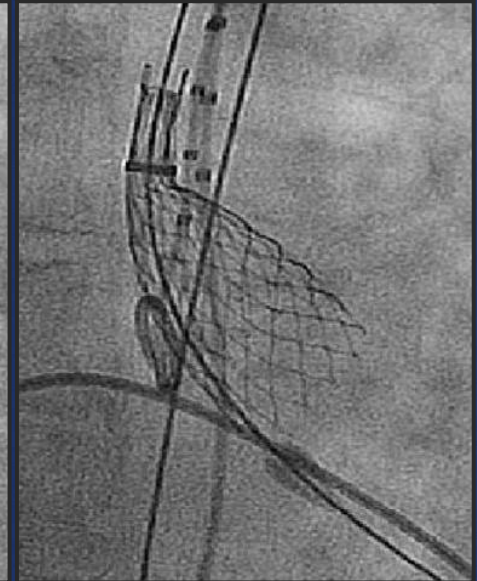
18Fr delivery



Repositionable  
prior to annular  
contact

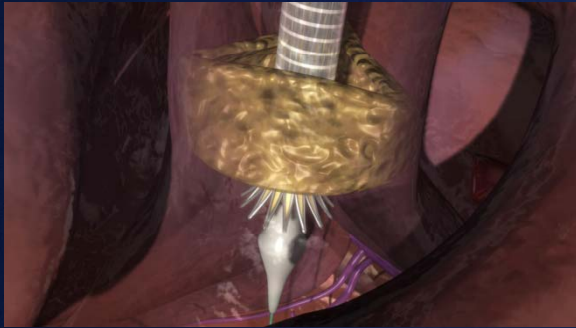


Gradual release

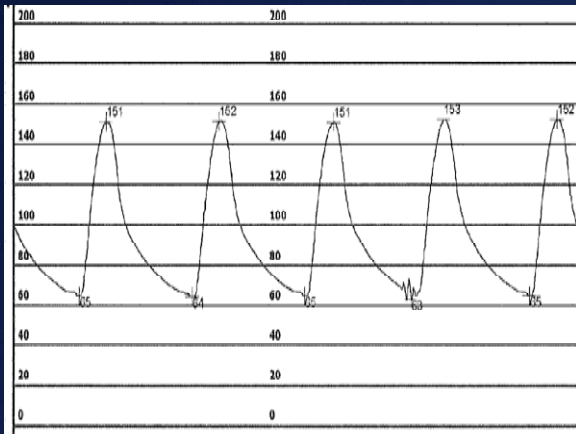


Conformable at  
annulus with  
supra-annular  
function

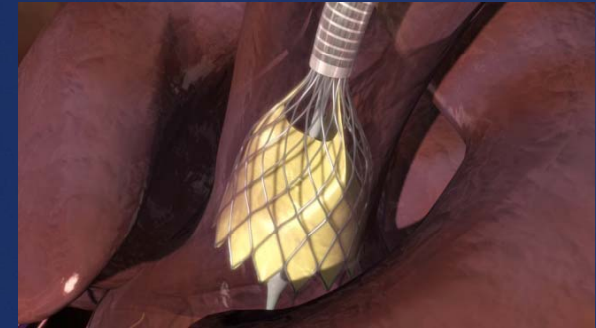
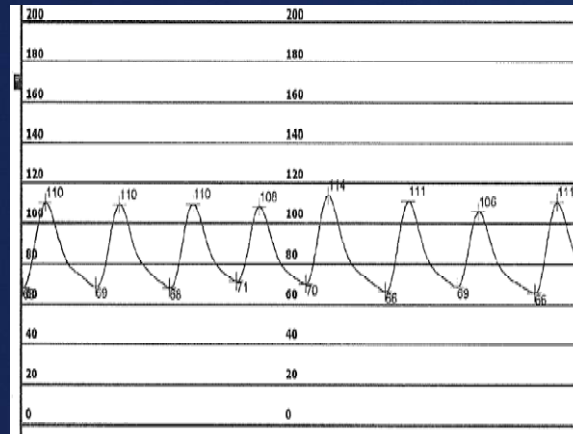
### 3 Positioning; Even in Challenging Anatomies



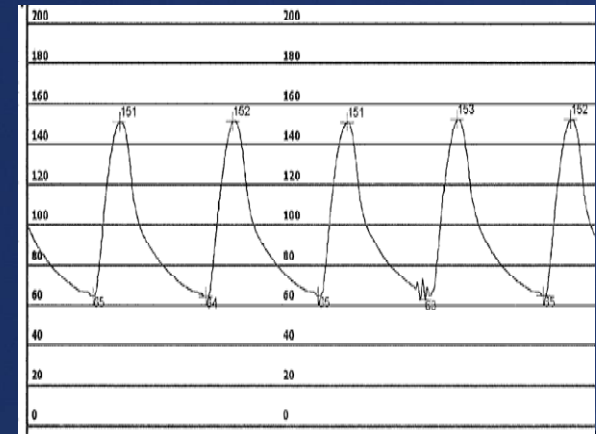
Normal blood pressure before annular contact



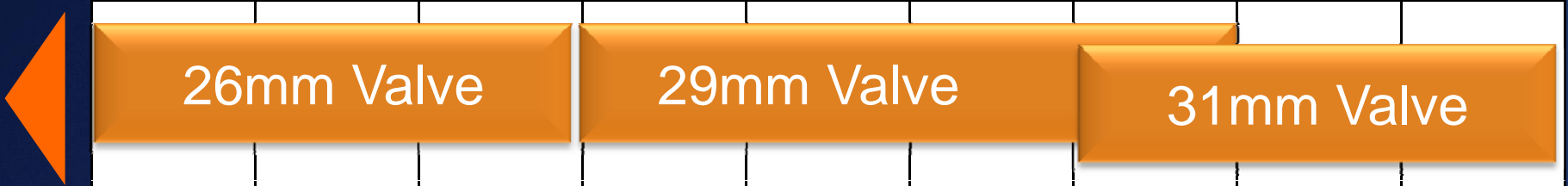
Reduced blood pressure only between 1/3 & 2/3 of the deployment



At 2/3 point, BP returns to normal and valve is still repositionable



**5 Wide Annulus Range Served (all on 18 Fr)**



20 21 22 23 24 25 26 27 28 29

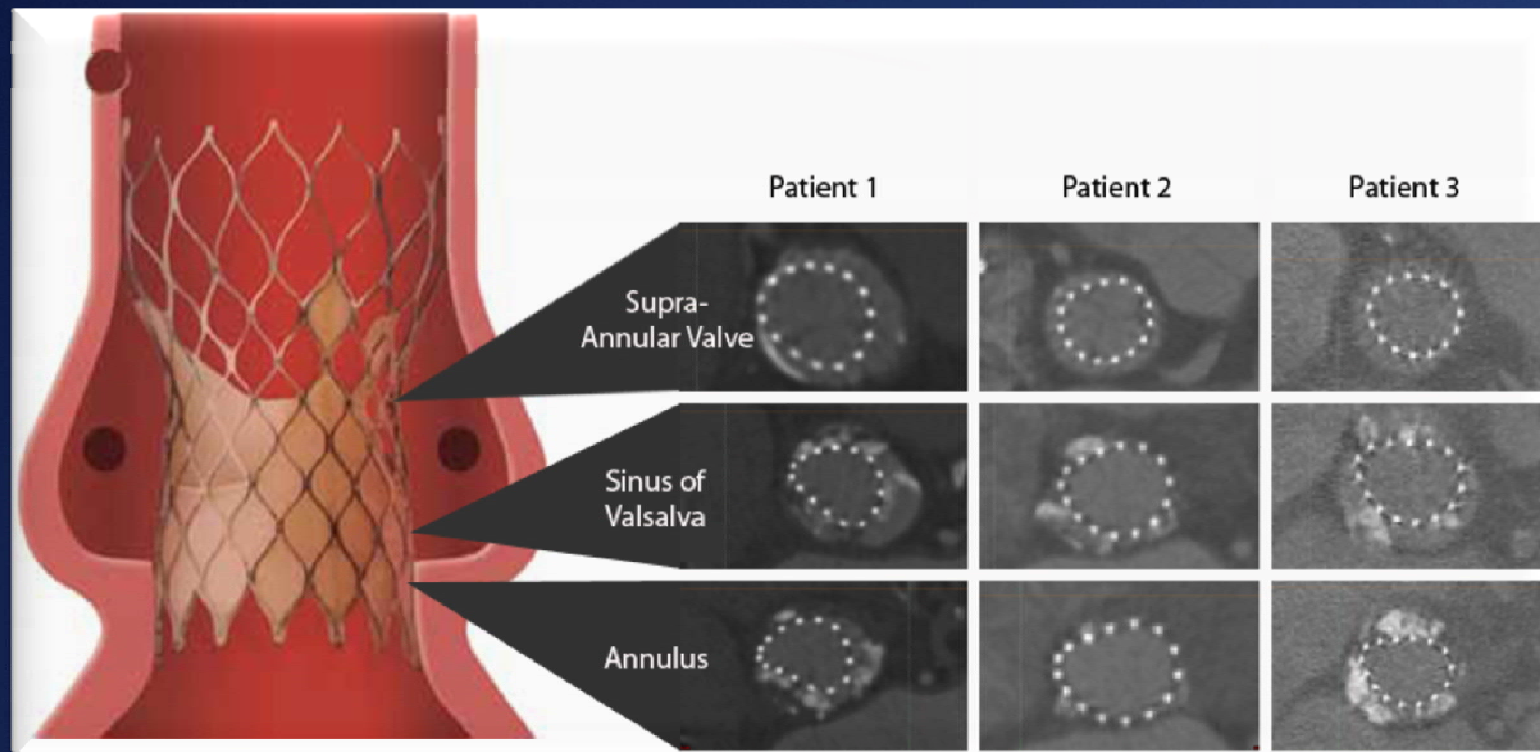
Future to 18

Annulus Size (mm)

7

## Supra Annular Valve Function

- Flexible frame conforms to native annulus shape while maintaining circularity of bioprosthesis in a higher position
  - This decoupling of the valve from native annulus shape minimizes the impact of ellipticity at the valve level post deployment<sup>1</sup>



1. Data on file at Medtronic

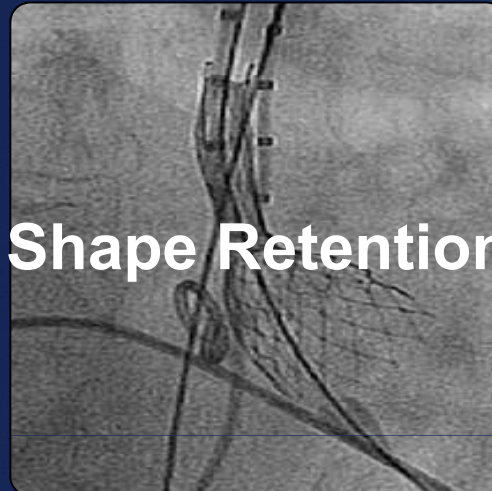


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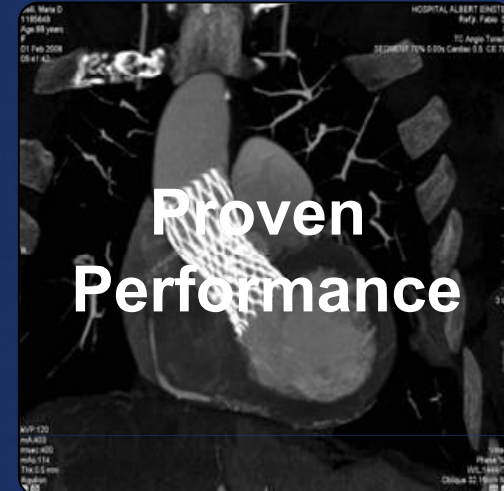
## Designed for Durability: Nitinol Frame



- Compact designs and small delivery systems



- Self-anchoring
- Controlled retraction for precise delivery and placement
- Maintain valve shape



- Resistant to corrosion
- Low thrombogenicity
- Conformable to patient anatomy
- Fatigue performance

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# Clinical Data is Expanding....

Medtronic Sponsored

Study	Study Size	30-Day	6-month	1-year	2-year	3-year	4-year
21 Fr EU Safety and Performance Study	52						
18 Fr EU Safety and Performance Study	126						
Australia-New Zealand Registry	900						
REDO Study	18						
ADVANCE Study	1015						
US Pivotal Trial	1497	enrollment underway					
Japan Pivotal	50	enrollment underway					
ADVANCE II Study	200	enrollment underway					
SURTAVI Trial	Up to 2000	2012 start					
ADVANCE DA Study	100	2012 start					
Belgian Registry	297						
Italian Registry	772						
UK Registry	460						
French Registry	785						
Spanish Registry	108						
German Registry	588						
Brazilian Registry	198	Procedural					

9,166 total patients

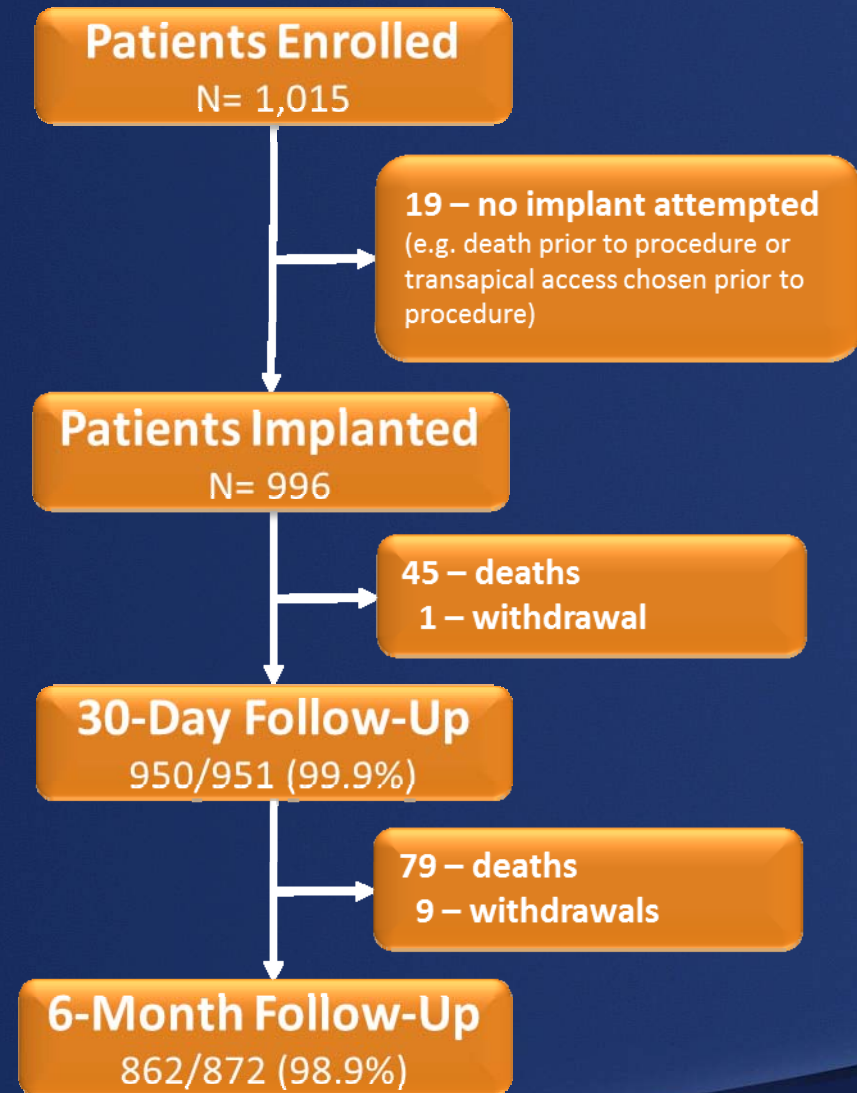
Independent

# In Perspective: TAVI with and without Predilatation

	Grube et al. <sup>10</sup> (n=60)	UKB Bonn (n=140) <u>With</u> Pre-dilatation	UKB Bonn (n=54) <u>Without</u> Pre-dilatation	P-Value*
Technical success, n (%)	58 (96.7)	137 (97.8)	53 (98.1)	0.97
Post-dilatation, n (%)	10 (16.7)	41 (29.3)	16 (29.6)	0.96
Mean gradient (mmHg)	4.4 ± 2.0	7.1 ± 6.4	9.2 ± 9.4	0.11
30-day mortality, n (%)	4 (6.7)	10 (7.1)	3 (5.6)	0.40
Pacemaker implantation, n (%)	7 (11.7)	35 (25.0)	7 (13.0)	0.011
Stroke, n (%)	3 (5.0)	8 (5.7)	0 (0)	0.073
Myocardial infarction, n (%)	0 (0)	4 (2.9)	0 (0)	0.21
Acute kidney injury, n (%)	n.a.	36 (26.3)	9 (16.7)	0.22
Moderate/severe periAR, n (%)	7 (11.7)	23 (16.4)	2 (3.7)	0.018

# CoreValve ADVANCE | Methods

- 1,015 patients enrolled from March 2010 to July 2011
  - 5 year follow-up
- 44 centers - 12 countries in Western Europe, Asia and South America
- All centers had conducted at least 40 TAVI procedures prior to the study and had Heart Team in place
- Clinical endpoints reported according to Valve Academic Research Consortium (VARC)



## CoreValve ADVANCE | 30-day Outcomes

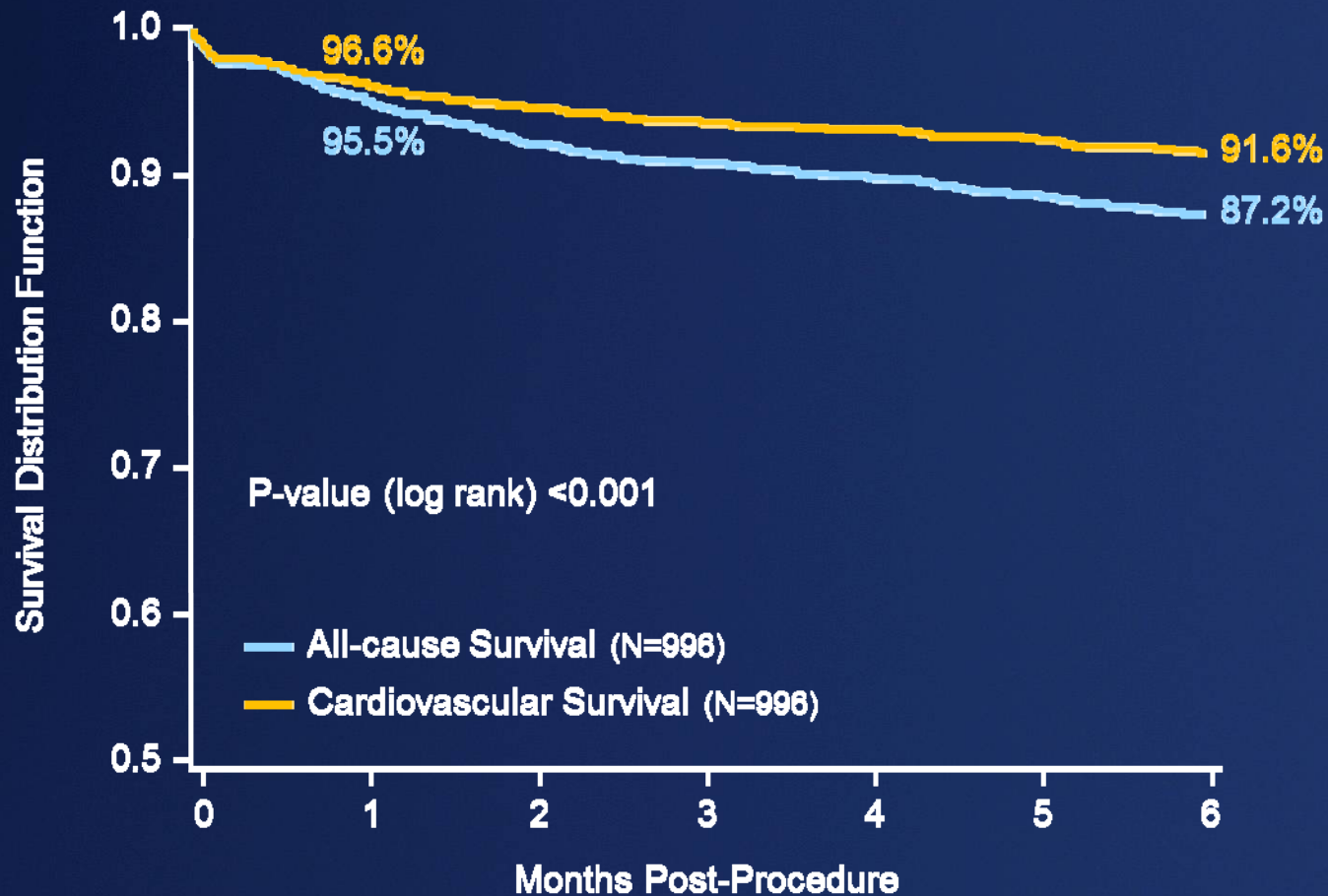
Primary Endpoint N=996	Kaplan-Meier Estimates, %
MACCE	8.3
All-cause Mortality	4.5
Myocardial Infarctions	0.2
Emergent cardiac surgery or percutaneous re-intervention	1.7
Stroke	2.9

Additional VARC Endpoints N=996	Kaplan-Meier Estimates, %
Cardiovascular Mortality	3.4
Major Bleeding	9.7
Life Threatening Bleeding	4.0
Major Vascular Complications	10.7
Acute Kidney Injury - Stage III	0.4

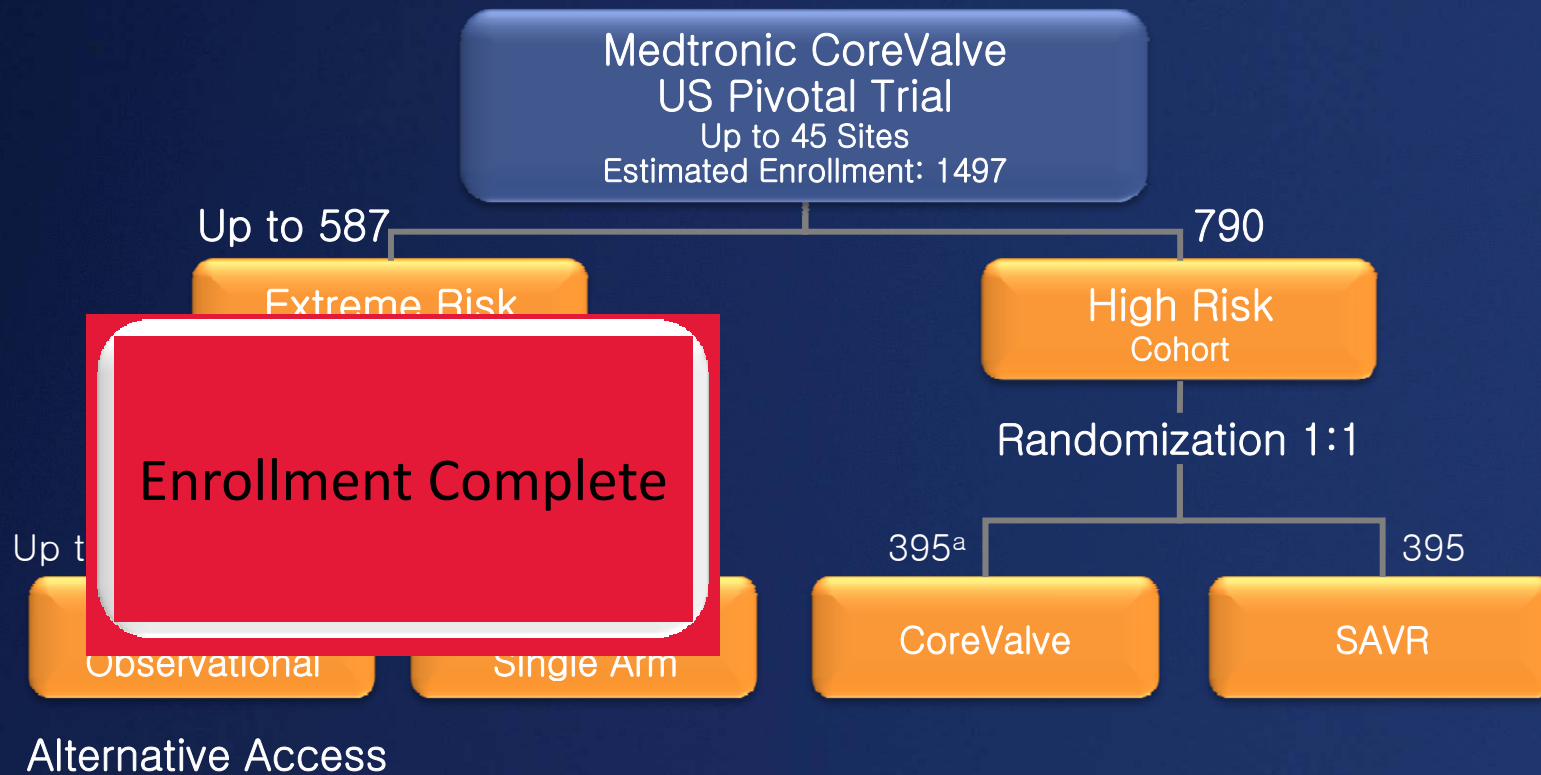
Additional Endpoint N=996	Kaplan-Meier Estimates, %
New Pacemaker Implantation	26.3

# CoreValve ADVANCE | 6-month Survival

Kaplan-Meier Estimates of Freedom from All-cause Mortality (VARC) and Cardiovascular Mortality (VARC)

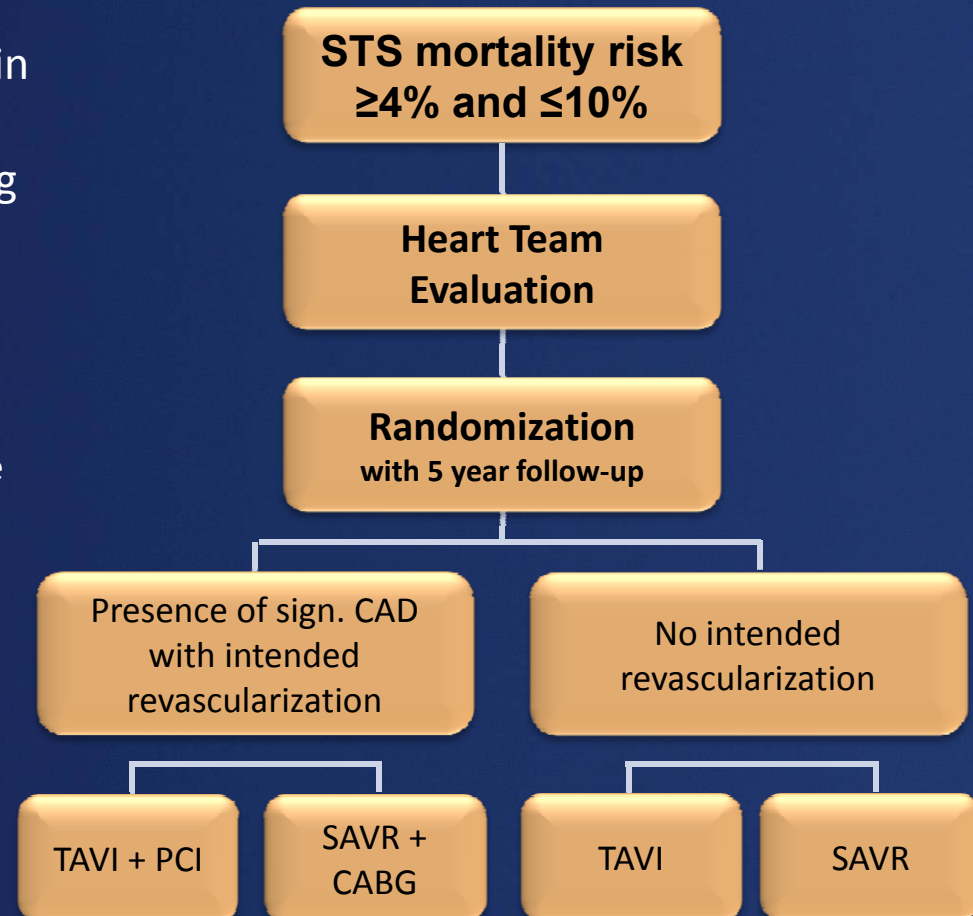


# CoreValve<sup>®</sup> US Pivotal



# CoreValve<sup>®</sup> SURTAVI Trial

- Evaluate the safety and efficacy of TAVI in patients with severe, symptomatic AS at intermediate surgical risk by randomizing patients to either SAVR or TAVI with the Medtronic CoreValve<sup>®</sup> System
- Primary Objective
  - Non-inferiority of combined endpoint of all-cause mortality and major stroke at 24 months.
- Study Design
  - Up to 2000 patients randomized 1:1 to TAVI and SAVR
  - 5-year follow-up



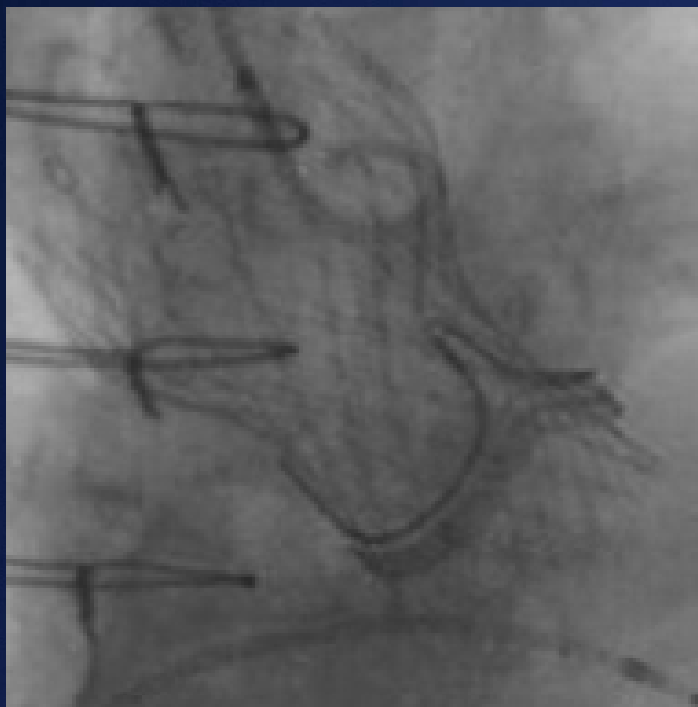
Medtronic Confidential Information.

These materials are provided to you strictly for your use in participating to and participating in the CoreValve<sup>®</sup> SURTAVI Trial.  
CAUTION – Investigational device. Limited by Federal Law (USA) to investigational use; Exclusively for Clinical Investigations.

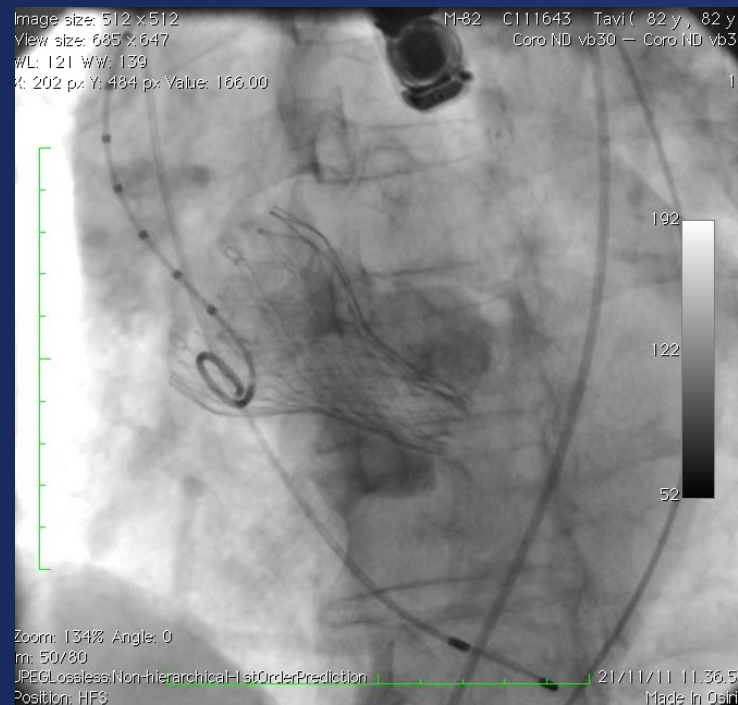


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## Self Expanding Potential for Future Indications



**CoreValve placed in a failed  
Edwards Perimount  
bioprosthesis<sup>2</sup>**



**CoreValve in Bicuspid**

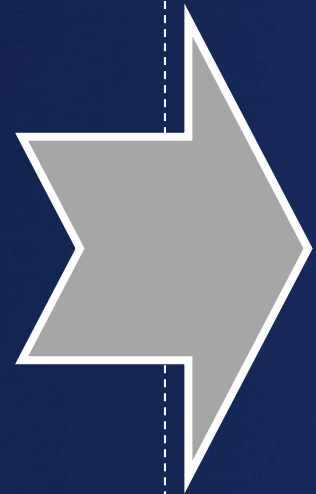
# 10 Self Expanding Will Be the Platform of the Future

## Self Expanding Today

## Self Expanding Tomorrow



Medtronic CoreValve



Next Gen. Medtronic CoreValve



Medtronic Engager



Boston Sci. Lotus™



Saint Jude Portico™



JenaValve



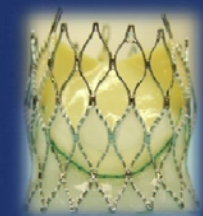
HLT



Direct Flow



Symetis ACCURATE



Edwards Centera

# CoreValve vs. Edwards – The Evidence II

	ADVANCE Registry (N=1,015)	PARTNER A TF (N=244)	PARTNER B (N=179)	SOURCE TF (N=920)
Logistic EuroSCORE, (%)	19.2 ± 12.4	29.3 ± 16.5	26.4 ± 17.2	23.9 ± 14.2
STS mortality score, (%)	n.a.	11.8 ± 3.4	11.2 ± 5.8	n.a.
30-day mortality, (%)	4.5	3.4	5.0	8.5
6-month mortality, (%)	12.8	(12.5)*	(22.0)*	(15.0)*
1-year mortality, (%)	n.a.	24.2	30.7	23.9
Moderate peri-prosthetic AR, (%)	n.a.	13.0	13.0	5.4
Stroke, (%)	2.9	4.7	6.7	2.5
Major vascular complications, (%)	10.7	11.0	16.2	12.8
Permanent pacemaker, (%)	26.3	3.8	3.4	7.0

\* extrapolated

# Summary: Why CoreValve is Better

1. Access: Small 18Fr OD Catheter Size Across Valve Size Range
2. Alternate Access Routes: Transfemoral, Subclavian and Direct Aortic
3. Valve positioning; even in difficult anatomies
4. Broad Annular Range Served (20-29; down to 18 in future)
5. Frame Design: Orientation, Function and Sealing
6. Supra Annular Valve Function
7. Designed for Durability
8. Promising Data
9. Future Potential Indications
10. Self Expanding is Platform of the Future

To date...served more than 26,000 CoreValve patients in more than 50 countries.

