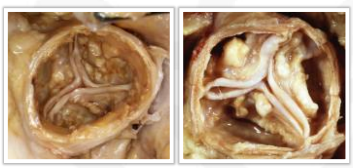
Red Fish On A Fly

Severe Aortic Stenosis

- Disease State and Overview of Etiology
- Symptoms and Prognosis

Aortic Stenosis



Gross specimen of minimally diseased aortic valve (left) and severely stenotic aortic valve (right)

Images courtesy of Renu Virmani MD at the CVPath Institute

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Major Risk Factors

Independent clinical factors associated with degenerative aortic valve disease include the following:[4]

- Increasing age
- Male gender
- Hypertension
- Smoking
- Elevated lipoprotein A
- Elevated LDL cholesterol

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Symptoms of Aortic Stenosis[5]

What are the symptoms of aortic stenosis?

- Angina - A sensation of aching, burning, discomfort, fullness, pain, or squeezing in the chest. It may also be felt in the arms, back, jaw, neck, shoulders and throat
- Fainting - A sudden and brief loss of consciousness
- Shortness of breath - Feeling winded and tired when walking or lying down
- Dizziness (after periods of inactivity)
- Rapid or irregular heartbeat
- Palpitations – An uncomfortable awareness of the heart beating rapidly or irregularly

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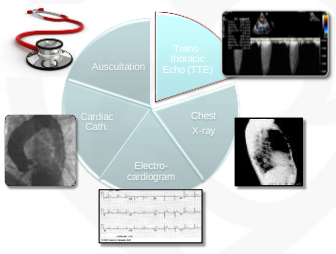
Multiple Modalities May Be Used to Diagnose Severe Aortic Stenosis[6]



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Echocardiographic Guidelines are the Gold Standard in Assessing Severe Aortic

Grading the Severity of Aortic Stenosis per the ACC/AHA Guidelines			
Indicator	Mild	Moderate	Severe
Jet velocity (m/s)	< 3.0	3.0 - 4.0	> 4.0
Mean gradient (mmHg)	< 25	25 - 40	> 40
Valve area (cm^2)	> 1.5	1.0 – 1.5	< 1.0
Valve area index (cm^2/m^2)	N/A	N/A	< 0.6

*Doppler-Echocardiographic measurements

- According to the 2008 ACC/AHA guidelines, severe aortic stenosis is defined as:
  - Aortic valve area (AVA) less than 1.0 cm^2
  - Mean gradient greater than 40 mmHg or jet velocity greater than 4.0 m/s

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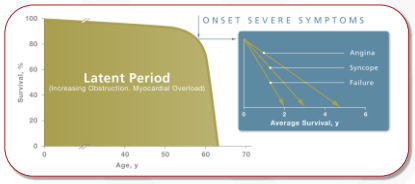
Aortic Stenosis Is Life Threatening and Progresses Rapidly[7]



- Survival after onset of symptoms is 50% at 2 years[1]
- Surgical intervention for severe aortic stenosis should be performed promptly once even minor symptoms occur[1]

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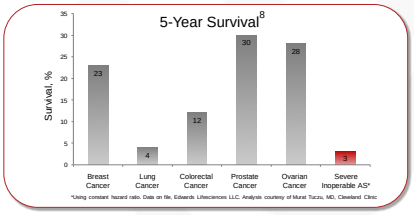
Sobering Perspective



5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

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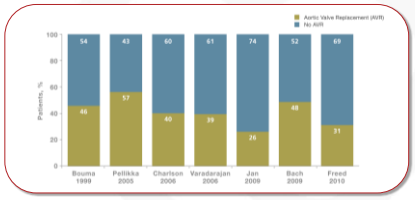
Addressing a Serious Unmet Need



- Studies show at least 40% of SAS patients are not treated with an AVR[9-15]

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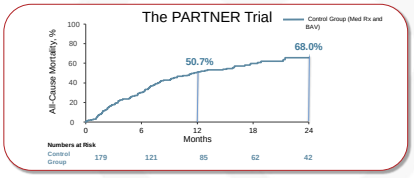
Standard Therapies are Inadequate Treatments for Severe Aortic Stenosis



- As seen previously, survival after onset of symptoms in patients with aortic stenosis is 50% at 2 years[1]
- The PARTNER Trial showed that in inoperable patients with severe aortic stenosis who did not receive a valve replacement, 50% died within *1 year*
- Despite the frequent utilization of BAV, standard therapy did not do much to alter the dismal course of disease for inoperable patients with severe aortic stenosis

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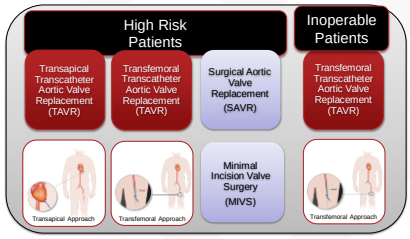
Options for Aortic Valve Replacement



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TAVR Procedure Overview

Edwards SAPIEN Transcatheter Heart Valve

The Edwards SAPIEN transcatheter heart valve is indicated for patients with ***severe symptomatic calcified native aortic valve stenosis*** who have been examined by a Heart Team including an experienced cardiac surgeon and cardiologist and found to be either ***inoperable, at high or intermediate risk for surgical aortic valve replacement***.

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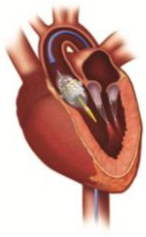
What is TAVR?

- For patients who are either at intermediate, high risk or too sick for open-heart surgery, TAVR may be an alternative
- This less invasive procedure allows the aortic valve to be replaced with a new valve while the heart is still beating



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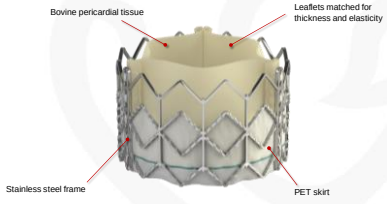
Edwards SAPIEN Transcatheter Heart Valve



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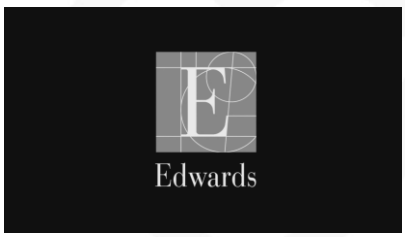
Transfemoral Procedural Animation



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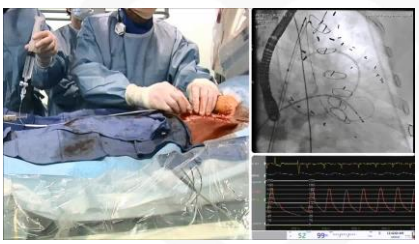
Balloon Aortic Valvuloplasty



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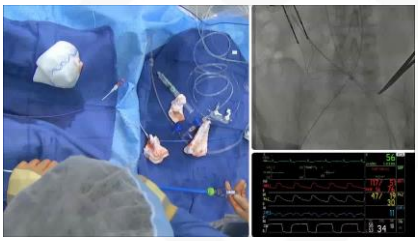
Sheath Insertion



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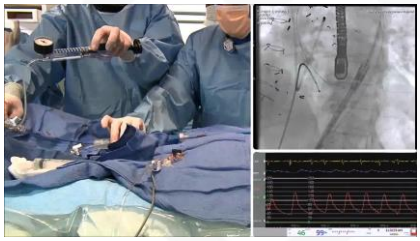
Tracking the Delivery System Over the Aortic Arch



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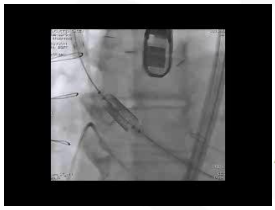
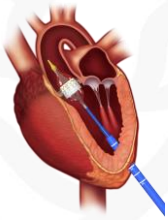
Edwards SAPIEN Transcatheter Heart Valve Deployment



An Alternative Option for Patients Without Vascular Access

- Some patients may not have adequate vascular access to accommodate the sheath used during transfemoral procedures
- For these patients, the transapical, supra-aortic, or subclavian or caval access procedure may be an option
- During the transapical approach, the Edwards SAPIEN transcatheter heart valve is delivered through the apex of the heart by making a small incision between the ribs



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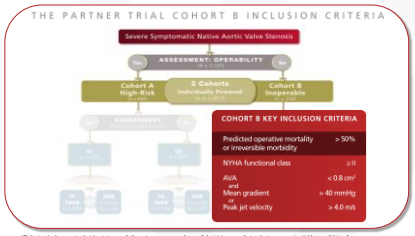
Transapical Procedural Animation

Edwards

The PARTNER Trial

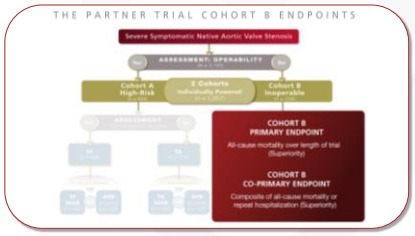
Edwards

Definitive Results Through Rigorous Design



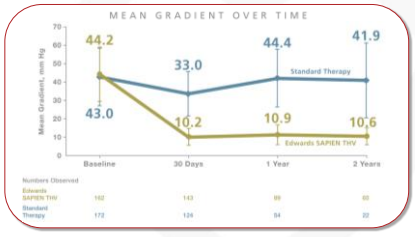
*Patient selection required at least two cardiothoracic surgeons and a cardiologist to agree that patients were not suitable candidates for surgery.
†This mean score reflects enrolled patient group; not required for inclusion.

Definitive Results Through Rigorous Design



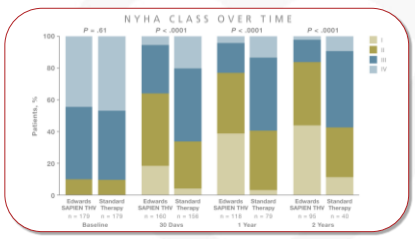
Edwards SAPIEN THV Improved Survival

Edwards SAPIEN THV Improved Cardiac Function



Error bars = ± 1 Std Dev

Edwards SAPIEN THV Reduced Symptoms



Complications

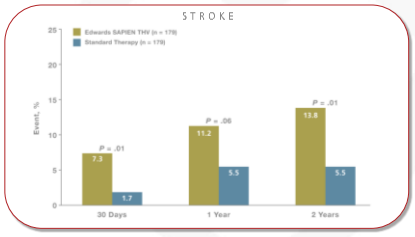
Complications						
	30 Days		1 Year		2 years	
Outcome	Edwards SAPIEN THV	Standard Therapy	Edwards SAPIEN THV	Standard Therapy	Edwards SAPIEN THV	Standard Therapy
All-cause mortality	5.00%	2.80%	30.70%	50.70%	43.30%	69.00%
Death or repeat hospitalization	11.70%	12.30%	44.10%	71.60%	56.70%	87.90%
Stroke	7.30%	1.70%	11.20%	5.50%	13.80%	5.50%
Major vascular complications	16.80%	1.10%	17.40%	2.80%	17.40%	2.80%
Bleeding events	16.20%	2.20%	17.30%	2.20%	17.30%	2.20%
New pacemaker implantation	3.40%	5.10%	4.70%	8.60%	6.40%	8.60%

Stroke was defined as follows: Neurological deficit lasting ≥ 24 hours or lasting less than 24 hours with a brain imaging study showing an infarction.

Major vascular complications were defined as any thoracic aortic dissection, access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, or hematoma) leading to either death, need for significant blood transfusion (> 3 units), or percutaneous or surgical intervention, and/or distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.

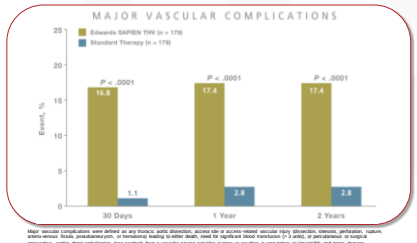
Bleeding event is defined as ≥ 2 units within the index procedure.

Edwards SAPIEN THV Had Higher Incidence of Stroke



Stroke was defined as follows: Neurological deficit lasting ≥ 24 hours or lasting less than 24 hours with a brain imaging study showing an infarction.

Edwards SAPIEN THV Had Higher Incidence of Major Vascular Complications



Major vascular complications were defined as any thoracic aortic dissection, access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudo-aneurysm, or hematoma) leading to either death, need for significant blood transfusion (> 5 units), or percutaneous or surgical intervention, and/or distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.

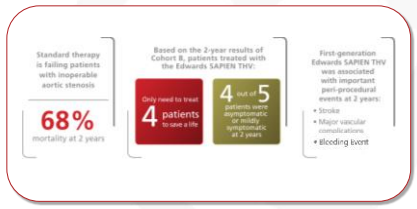
Edwards SAPIEN THV Had Higher Incidence of Bleeding Events

Bleeding Events

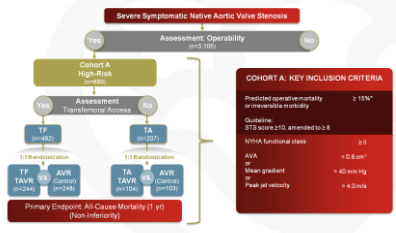
	30 Days		1 Year		2 years	
Outcome	Edwards SAPIEN THV	Standard Therapy	Edwards SAPIEN THV	Standard Therapy	Edwards SAPIEN THV	Standard Therapy
Bleeding Events	16.20%	2.20%	17.30%	2.20%	17.30%	2.20%

Bleeding event is defined as ≥ 2 units within the index procedure.

Critical Insights



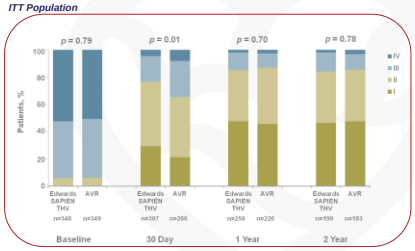
Study Design & Inclusion Criteria



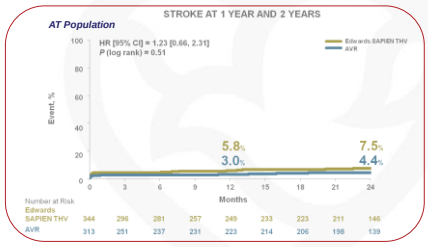
TA, transapical; TF, transfemoral.
* As determined by site surgeon and cardiologist.

NYHA Class

ITT Population

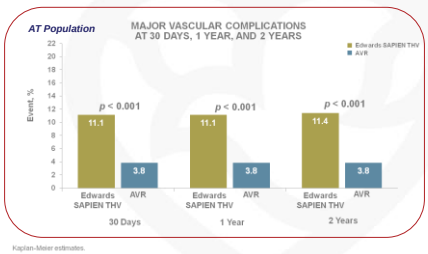


All Strokes



THE PARTNER TRIAL COHORT A

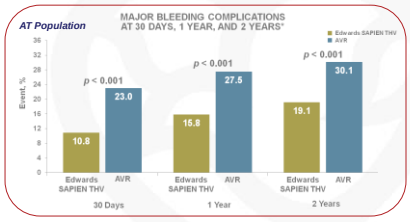
Major Vascular Complications



Kaplan-Meier estimates.

THE PARTNER TRIAL COHORT A

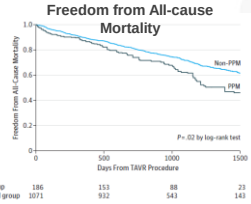
Major Bleeding



Kaplan-Meier estimates. *Major bleeding is defined as any episode of: major internal or external bleeding that caused death, hospitalization or permanent injury (e.g., vision loss) or necessitated transfusion of greater than 3 units PRBCs within a 24-hour period, pericardiocentesis, open and/or endovascular procedure for repair or hemostasis.

THE PARTNER TRIAL COHORT A

Retrospective Analysis: PPMI Resulted in Increased Long-term Mortality & Readmission[1]



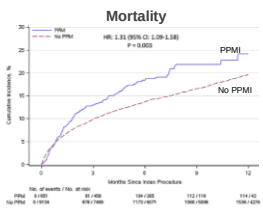
1

Retrospective analysis of 1,263 TAVR patients, **PPMI resulted in**:

- **Increased mortality** (HR: 1.40; P=.04)
- **Greater readmission** (HR: 1.28, P<.001)
- **Longer hospital stay** (P=.001)

1. Ajibbey, Talal, et al. Association of clinical and economic outcomes with permanent pacemaker implantation after transcatheter aortic valve replacement. JAMA 2018;1(1):e180[illegible]

TVT Registry Analysis: PPMI is an Independent Predictor of 1-year Mortality[1]



1

TVT registry analysis of 9,785 TAVR patients:

- **PPMI independent predictor of 1-year mortality** (HR: 1.31)
- Use of self-expandable valves independent predictor of PPMI

1. Fadahunsi, Oyeyemi O, Olowoyeye, Abiola, et al. Incidence, predictors, and outcomes of permanent pacemaker implantation following transcatheter aortic valve replacement – Analysis from the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. JACC: Cardio Inter 9.(5) (2016) 2189-2199.

Key Takeaways - Cohort B

At 2 years, in patients with severe symptomatic native aortic valve stenosis who were not suitable candidates for surgery:

- Treatment with the Edwards SAPIEN THV remained superior to standard therapy with incremental benefit from 1 to 2 years, reducing the rates of mortality and repeat hospitalization
- Treatment with the Edwards SAPIEN THV improved NYHA functional status and decreased class III/IV symptoms compared to standard therapy
- There were significantly more strokes in patients treated with the Edwards SAPIEN THV than in patients who received standard therapy
- Patients treated with the Edwards SAPIEN THV also had a higher incidence of major vascular complications and major bleeding than standard therapy patients

Key Takeaways – Cohort A

At 2 years, in patients with symptomatic severe aortic stenosis who were high-risk candidates for surgical AVR:

- Edwards SAPIEN THV was non-inferior to surgical AVR with similar rates of all-cause and cardiovascular mortality
- Resulted in symptom improvement that was similar in both groups and maintained through two years
- Hemodynamic performance of the Edwards SAPIEN THV was maintained with similar valve gradients and effective orifice areas compared with surgical AVR
- Both TAVR and AVR had adverse procedural events which impacted subsequent mortality, such as stroke and major bleeding for both procedures, and major vascular complications for TAVR
  - There was no statistically significant difference in stroke rate between Edwards SAPIEN THV and AVR patients despite increased peri-procedural events after TAVR; there was no late (after 30 days) stroke hazard in TAVR patients
- Two-year results from the high-risk operable PARTNER cohort support the use of Edwards SAPIEN THV as an alternative to surgery with similar mortality and clinical benefits

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Characteristics of a TAVR Patient[17]

TAVR patients may present with some of the following:

Severe, symptomatic native aortic valve stenosis

History of stroke/CVA
Reduced EF
Prior CABG
History of AFib
Prior open chest surgery
Fatigue, slow gait
Peripheral vascular disease

Old age
Heavily calcified aorta
Prior chest radiation
History of COPD
Frailty
History of renal insufficiency

History of syncope
History of CAD
Diabetes and hypertension

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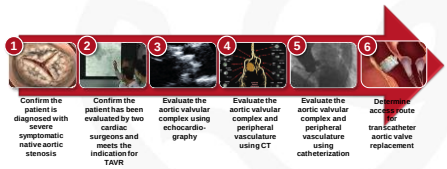
THERE ARE OPTIONS ON HOW A VALVE CLINIC CAN BE ORGANIZED

Key Strategic Considerations

Range of Options

Scope	TAVR Only	Comprehensive Aortic Stenosis or Structural Heart Clinic
Infrastructure	Virtual Clinic	Dedicated space, time, and staff
Medical Staff	Independent	Employed
Patient Identification	Individual: HCP Identification	Systematic: chart and database reviews; echo alert systems

Following Patient Referral, the TAVR Team will Perform Further Evaluation



Note: The above is a suggested flow for the patient screening process, however, the order in which screening tests are conducted varies depending on the patient's profile and should be at the discretion of the Heart Team.

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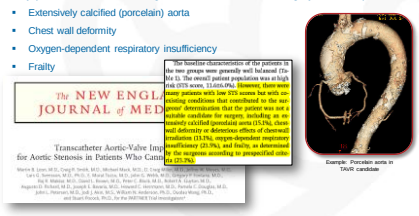
Identifying the Inoperable Patient[17]

While some patients may have low STS scores, certain co-existing conditions may preclude them from being suitable candidates for surgery, for example:

- Extensively calcified (porcelain) aorta
- Chest wall deformity
- Oxygen-dependent respiratory insufficiency
- Frailty



Example: Porcelain aorta in TAVR candidate

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Identifying the High Risk Patient[18]

- Patients may be considered at high risk for surgical valve replacement if they have an STS operative risk score of ≥ 8% or are judged by the Heart Team to be at a ≥15% risk of mortality for surgical aortic valve replacement

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Intermediate Risk SURTAVI COR Valve

- STS 4.4%+/-1.6% Any cause death or disabling stroke
- No embolic protection allowed
- 12.6% primary endpoint TAVR/14% in surgical group
- Stoke similar in both groups/better in transfemoral TAVR
- More bleeding in surgical group/less PPM in TAVR group
- More vascular access complications in TAVR group (4%)
- More AFIB in surgical group
- More pacers in TAVR constant despite EvoluteR in 27% of pt.
- Shorter LOS in TAVR (not an endpoint)
- More AR in TAVR but better orifice area in TAVR

PARTNER 2 Intermediate risk

- SAPIEN XT second generation device
- Better Areas with TAVR
- More AR 3.7% severe and 21% mild/moderate
- Transfemoral had lower death/stroke Apical access similar to surgery
- SAPIEN XT already replaced by SAPIEN 3
- Similar Pacer rates 8.5/6.9 TAVR/SURG

LOW RISK TRIALS

- ENROLLMENT BEGAN 2016/COMPLETE 2021Medtronic
- Low Risk defined as surgical mortality at 30 days <3%
- These patients have the longest expected lifespan

LOW RISK

- WAKSMAN et al multicenter investigator initiated trial
- 11 centers
- No mortality first 125 patients at 30 days/no strokes
- 4% major vascular access complications
- 4.8% AFIB
- 4.8% new pacer
- HALT Hypo-attenuating leaflet thickening 12.5%
- 14.4% on antiplatetlet RX (n=97) none on warfarin or direct anticoagulant (n=21)
- Subclinical thrombosis may result in diminished durabilty

LOW RISK TRIALS

- MEDTRONIC 1200 patients with EVOLUTE R
- PARTNER 3 EDWARDS 1300 patients with SAPIEN 3
- NOTION 2 European trial
- STS score <2%

Echocardiographic Guidelines are the Gold Standard in Assessing Severe Aortic Stenosis[6]

According to the 2008 ACC/AHA guidelines, severe aortic stenosis is defined as:

- Aortic valve area (AVA) less than 1.0 cm^2
- Mean gradient greater than 40 mmHg or jet velocity greater than 4.0 m/s

Grading the Severity of Aortic Stenosis per the ACC/AHA Guidelines *

Indicator	Mild	Moderate	Severe
Jet velocity (m/s)	< 3.0	3.0 - 4.0	> 4.0
Mean gradient (mmHg)	< 25	25 - 40	> 40
Valve area (cm^2)	> 1.5	1.0 – 1.5	< 1.0
Valve area index (cm^2/m^2)	N/A	N/A	< 0.6

*Doppler-Echocardiographic measurements

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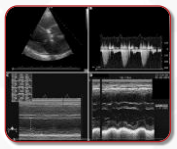
Paradoxical Low Flow and/or Low Gradient Severe Aortic Stenosis[19]

- Dobutamine stress echocardiography can be used to differentiate between true and pseudo severe aortic stenosis
  - Better define the severity of the aortic stenosis
  - Accurately assess contractile/pump reserve
- Some patients with severe aortic stenosis based on valve area have a lower than expected gradient (e.g. mean gradient < 30 mmHg) despite preserved LV ejection fraction (e.g. EF > 50%)
  - Up to 35% of patients with severe aortic stenosis present with low flow, low gradient
  - These low gradients often lead to an underestimation of the severity of the disease, so many of these patients do not undergo surgical aortic valve replacement



Dobutamine stress in low gradient, low ejection fraction AS Chambers, Heart. 2006 April; 92(4): 554–558

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Frailty: An Important Parameter

- Frailty is an important parameter in assessing operative risk
- Transcatheter aortic valve replacement is a new therapy for high risk inoperable patients with severe aortic stenosis
- Prevalence of frailty increases with aging; old does not necessarily equal frail
- Elderly patients achieve measurable benefit from cardiac surgery, particularly in terms of:
  - Quality of life
  - Increased survival
  - Prevention of adverse cardiovascular events

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Multiple Modalities for Assessing Frailty[20]

- Various tests may be used as objective measures of frailty, and markers of frailty may include a decline in lean body mass, strength, endurance, weight loss, grip strength, etc.
- Examples of frailty measures may be found in published literature, including the 7-point Clinical Frailty Scale developed by the Canadian Study of Health and Aging

CSHA Frailty Scale

Very fit — robust, active, energetic, well motivated and fit; these people commonly exercise regularly and are in the most fit group for their age

Well — without active disease, but less fit than people in category 1

Well, with treated comorbid disease — disease symptoms are well controlled compared with those in category 4

Apparently vulnerable — although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms

Mildly frail — with limited dependence on others for instrumental activities of daily living

Moderately frail — help is needed with both instrumental and non-instrumental activities of daily living

Severely frail — completely dependent on others for the activities of daily living, or terminally ill

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Multiple Modalities for Assessing Frailty[21]

- **Columbia Frailty Index**
  - Gait speed
  - Grip strength
  - Exhaustion implied in symptomatic AS
  - Serum albumin
  - Katz ADLs - (Independence in dressing, bathing, toileting, transferring, feeding, continence)

Columbia Frailty Index, adapted from Fried, J Gerontol Med Sci 2001

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Frailty Toolkit

- Katz Activities of Daily Living (ADL) survey
  - Measures continence, feeding, dressing, bathing, transferring, toileting
- Tape measure
  - Ideally 15 foot course in clinic hallway
- Stop watch
- Dynamometer
- Serum albumin

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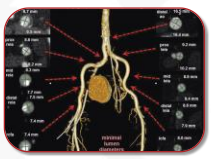
Assessing Appropriate Vascular Access



Vessel diameters must be a minimum of 5.5mm

- Newer Medtronic devices require 5mm access vessels

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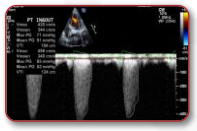
Patients with Severe Aortic Stenosis who are Inoperable or at High Risk for Surgery Should be Referred to a TAVR Heart

Aortic stenosis is considered severe when:

- Valve area is < 1.0 cm^2
- Pressure gradient > 40 mmHg
- Jet velocity is > 4.0 m/s



Due to the complexity of patient screening for TAVR, refer patients with severe aortic stenosis who are inoperable or at high/intermediate risk for surgery to a TAVR Heart Team for further evaluation

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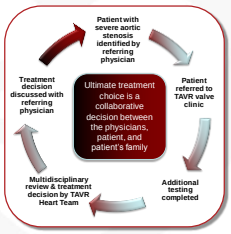
Devising a Treatment Plan – A Collaborative Process

Multiple treatment pathways are now available to treat severe aortic stenosis

- TAVR
  - For inoperable, high or intermediate risk patients
- Surgical or MIS AVR
  - For patients who are suitable for open-chest aortic valve replacement
- Medical Management and BAV
  - For patients not suitable for invasive procedures
  - Currently direct TAVR would be a consideration



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Conduction Disturbances & PPMI Have a Negative Impact on Patient Outcomes & Cost

Increased length of stay[1] and index hospitalization costs[2]

Impaired LV function and rehospitalization for heart failure.[3]

Increased long-term mortality among TAVR[1,4] and surgical AVR patients[5-6]

1. Ajjabbary, Talal, et al. Association of clinical and economic outcomes with permanent pacemaker implantation after transcatheter aortic valve replacement. JAMA. 2018;121(14):1808
2. FY 2016 MedPAR claims.
3. Chamandi, Chekrallah; Barbanti, Marco; et al. Long-term outcomes in patients with new permanent pacemaker implantation following transcatheter aortic valve replacement. JACC: Cardiovasc Interv. 2018; 301–10.
4. Nazif, Tamim M.; Dizon, Jose M.; et al. Predictors and clinical outcomes of permanent pacemaker implantation following transcatheter aortic valve replacement – Analysis from the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. JACC: Cardio Inter. 8,21 (2016): 2506-2506.
5. Greason, Kevin L.; Lahr, Brian D.; et al. Long-term mortality effect of early pacemaker implantation after surgical aortic valve replacement. Ann Ann Thorac Surg. 2017 Oct;104(4):1259-1264
6. Mehaffey, J. Hunter; Haywood, Nathan S.; et al. Need for Permanent Pacemaker after Surgical Aortic Valve Replacement Reduces Long-Term Survival, Ann Thorac Surg. 2018 Mar 2. pii: S0003-4975(18)30372-2

70

Proven platform performance
EVOLUT FAMILY TAV DESIGN

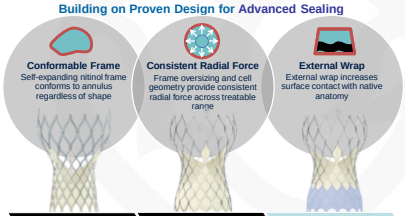
SUPRA ANNULAR VALVE DESIGN
- Preserves valve area and circularity for unsurpassed hemodynamics
- Keeps working portion above native annulus

PORCINE PERICARDIAL TISSUE
- Thin for low profile delivery
- Strength and pliability for long-term durability

SELF-EXPANDING FRAME
- Conforms and seals to the annulus
- The foundation for recapturability

Evolut PRO Transcatheter Valve
ADVANCED SEALING

Building on Proven Design for Advanced Sealing

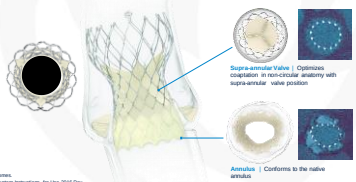


Unsurpassed
HEMODYNAMICS

Supra-annular valve design maximizes leaflet coaptation and promotes single digit gradients and large EOA's.

7.5 mm Hg
single digit gradients

2.0 cm^2
Large EOA

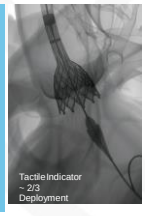


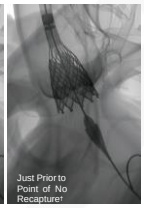
Evolut™ R 30 Day Outcomes.
CoreValve™ Evolut™ R System Instructions for Use 2016 Rev. 1F.

control
DURING DEPLOYMENT

RECAPTURE AND REPOSITION

EnVeo™ R provides an option to recapture and reposition for accurate placement.

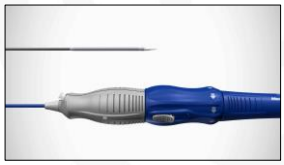




†Up to 80% deployment.

Proven Platform Performance
CONTROLLED, ACCURATE DELIVERY WITH ABILITY TO RECAPTURE

EnVeo™ R 16Fr Equivalent DCS enables controlled 1:1 Response with ability to Recapture

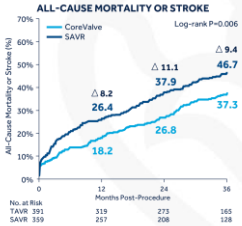


Clinical Trials have Demonstrated
SIGNIFICANT BENEFITS OF A SELF-EXPANDING PLATFORM

- The only platform to show Superiority in a RCT and show a sustained result to 3 years
- Unsurpassed Hemodynamics

Superior Long-term
CLINICAL OUTCOMES

ALL-CAUSE MORTALITY OR STROKE



LOWER RATE OF MORTALITY OR STROKE

The CoreValve™ Platform shows superior outcomes vs. surgery.[1]

1. CoreValve™ US Pivotal High Risk Trial 3-year Outcomes Presented at ACC 2016.

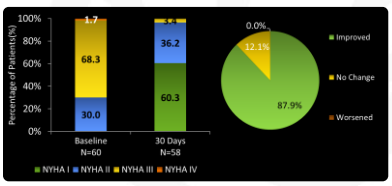
Evolut PRO system Clinical Trial
PATIENT CHARACTERISTICS

Characteristic, mean ± SD or %	N=60
Age, years	83.3 ± 7.2
Female	65.0
BSA, m²	1.8 ± 0.2
STS – PROM, %	6.4 ± 3.9
NYHA Class III or IV	70.0
Peripheral vascular disease	43.3
Atrial fibrillation / atrial flutter	18.6
Diabetes mellitus	43.3
Severe aortic calcification	20.5
LV ejection fraction, %	58.9 ± 12.4
Pre-existing pacemaker	15.0

Forrest, et al., ACC, 2017

Evolut PRO Clinical Trial
SYMPTOMATIC IMPROVEMENT

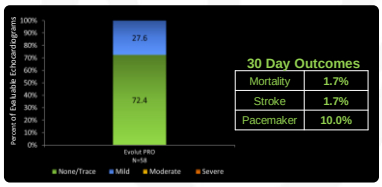
87.9% of survivors improved NYHA class at 30 days



Forrest, et al., ACC, 2017

Evolut PRO System Clinical Trial
ADVANCED SEALING

Low rates of PVL while maintaining
low rates of mortality, stroke, and need for pacemaker



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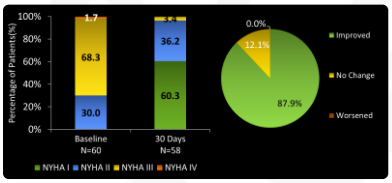

Forrest, et al., ACC, 2017

Argentina Brown Trout

LONG TERM DURABILITY OF TAVR PROSTHESIS

- BLACKMANN et al JACC 2/2/2019 UK REGISTRY
- 241 PATIENTS MEAN FU 5.8 YRS (5-10)
- 64% SE VALVE 35.7BE VALVES
- Lower gradients at 5yrs vs implantation 17vs19 mm
- None/trivial AR 47.5/33% SE vs BE
- Mild AR 42.5/57% SE vs BE
- 8.7% severe prosthetic dysfunction 57% AR 43% restenosis
- 91% of patients were free of SVD 5-10 years post TAVR

Durability of Transcatheter and Surgical Bioprosthetic Aortic valves in low risk patients

- Sondergaard et al JACC 2/2/2019
- NOTION (Nordic Aortic Valve intervention trial)SAVR/TAVR
- Moderate/severe SVD defined as >20mm Hg mean gradient or >10mm increase > 3 mos post procedure.
- Nonstructural valve deterioration defined as moderate/severe PPM, or moderate/severe paravalvular leak
- Bioprosthetic valve failure defined as valve related death/valve reintervention or severe hemodynamic SVD
- SVD in SAVR 24% SVD in TAVR4.8%
- NSVD SAVR=TAVR **BPV Savr 6.7 vs Tavr7.5%**
- **Structural valve failure Bioprosthetic valve failure Nonstructural valve deterioration**

Durability TAVR vs SAVR Sondergaard

- Conclusion that thru 6 years SVD (structural valve deterioration) was significantly greater in SAVR vs TAVR.
- BVF (bioprosthetic valve failure) was low in both groups