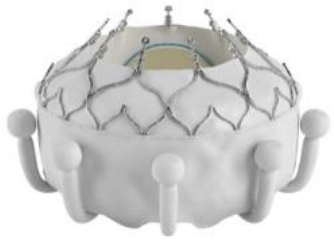
TRISCEND study one-year outcomes: Transfemoral transcatheter tricuspid valve replacement

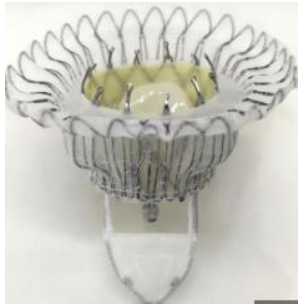
Severe Tricuspid Regurgitation Therapies

Annular Dilatation

- Edwards LifeSciences
  Evoque



- Jenscare
  LUx Valve

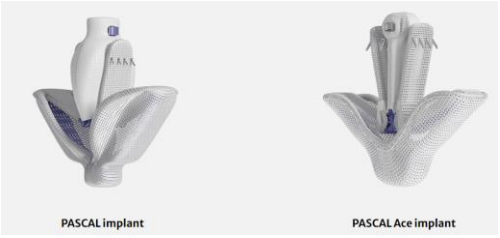


Coaptation Devices

- Abbott

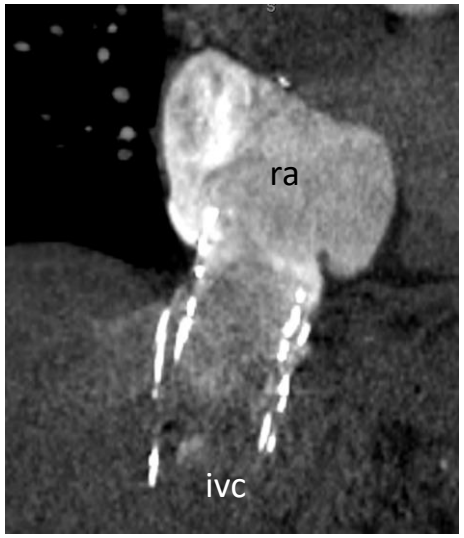
TriClip TTVr device

- Edwards LifeSciences
  PASCAL



Advanced disease, Pacer interference

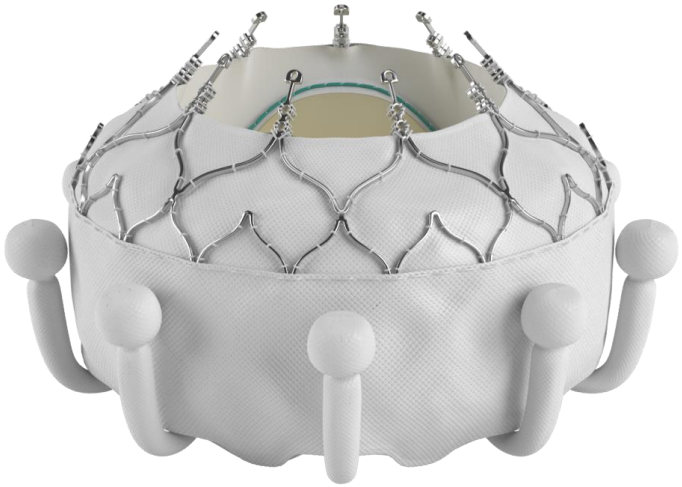
- Caval valve implant

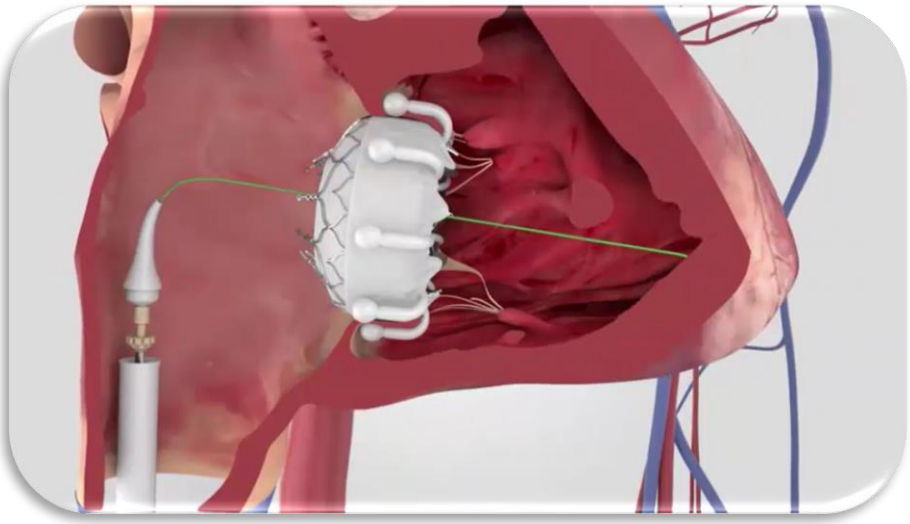


MIAMI 2023 VALVES
MiamiValves.org

*EVOQUE Tricuspid Valve Replacement System

Unique valve design engages leaflets, chords, and annulus to achieve secure placement





Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (44, 48, 52 mm)

28F transfemoral delivery system compatible with all valve sizes

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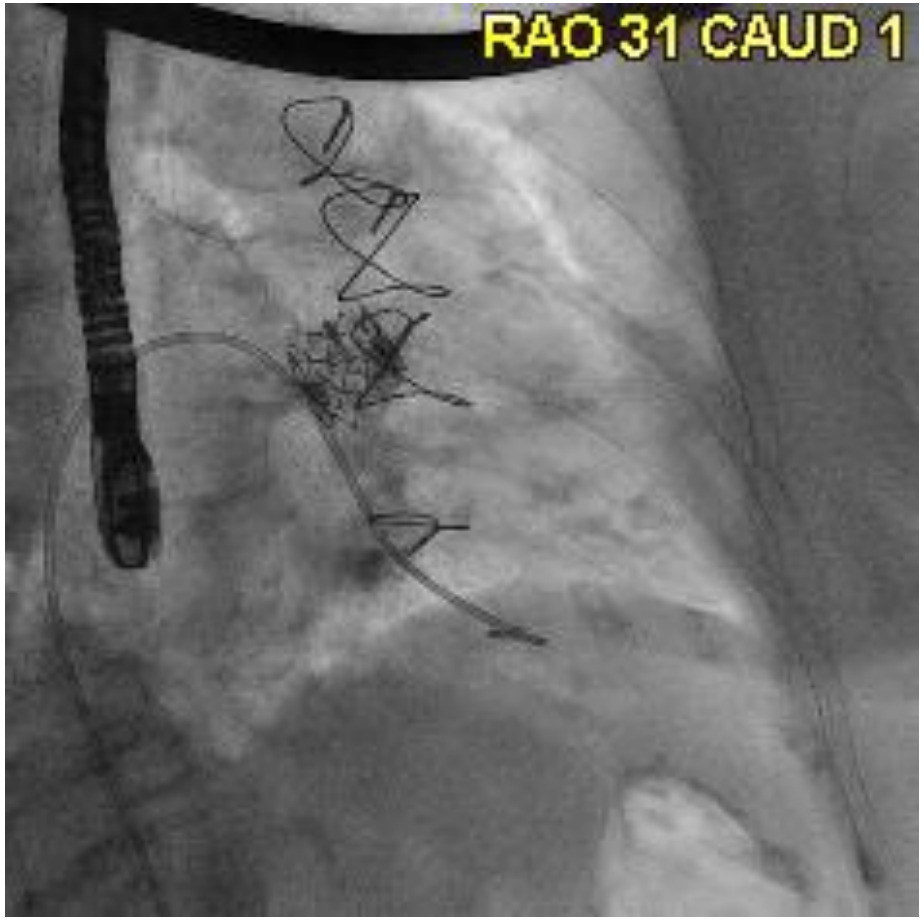
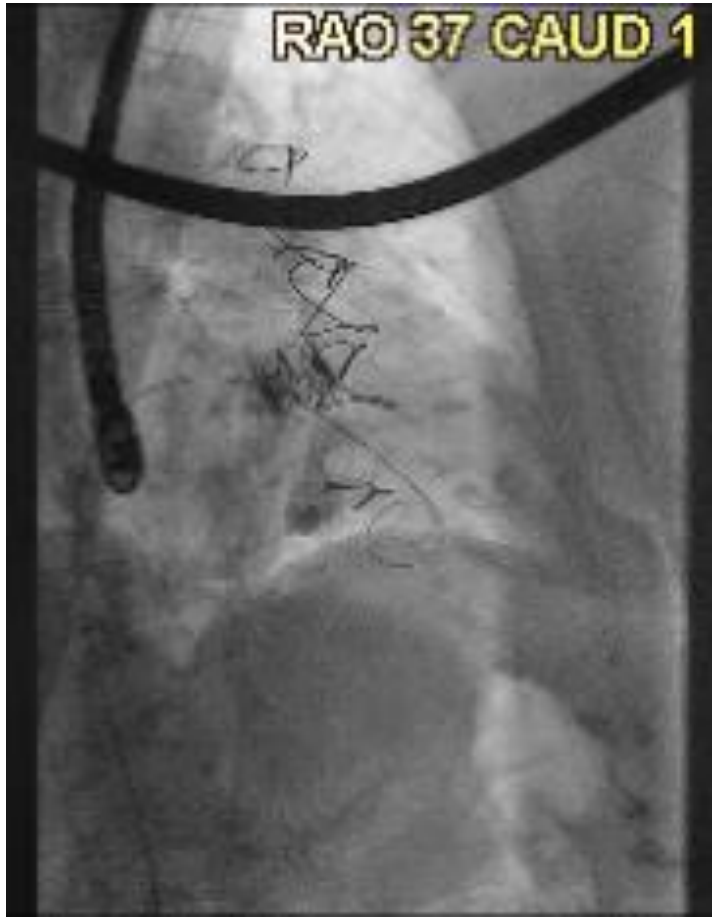
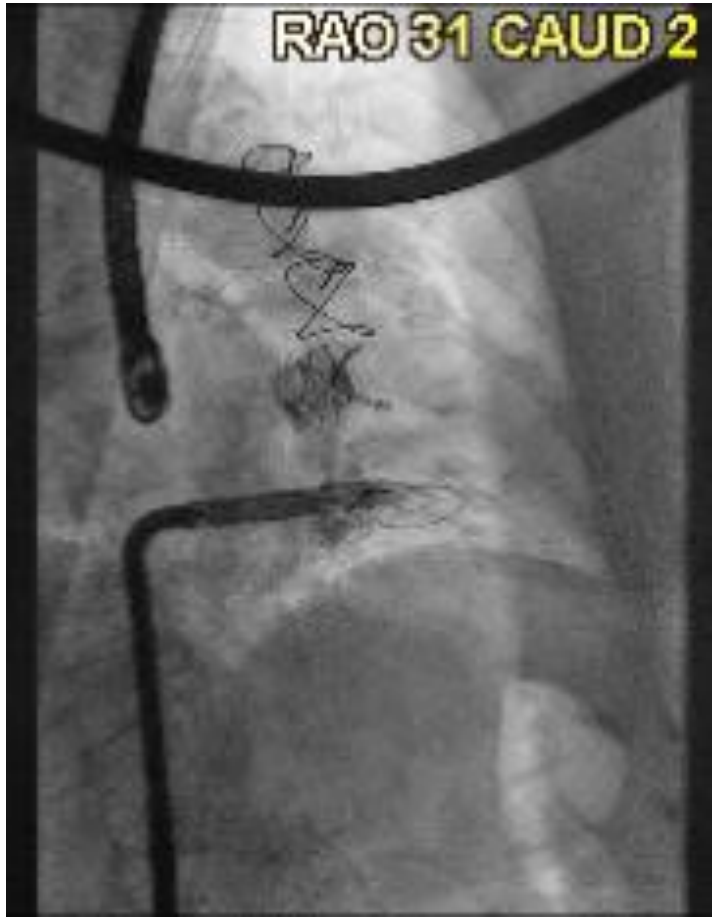
RV Angio Baseline



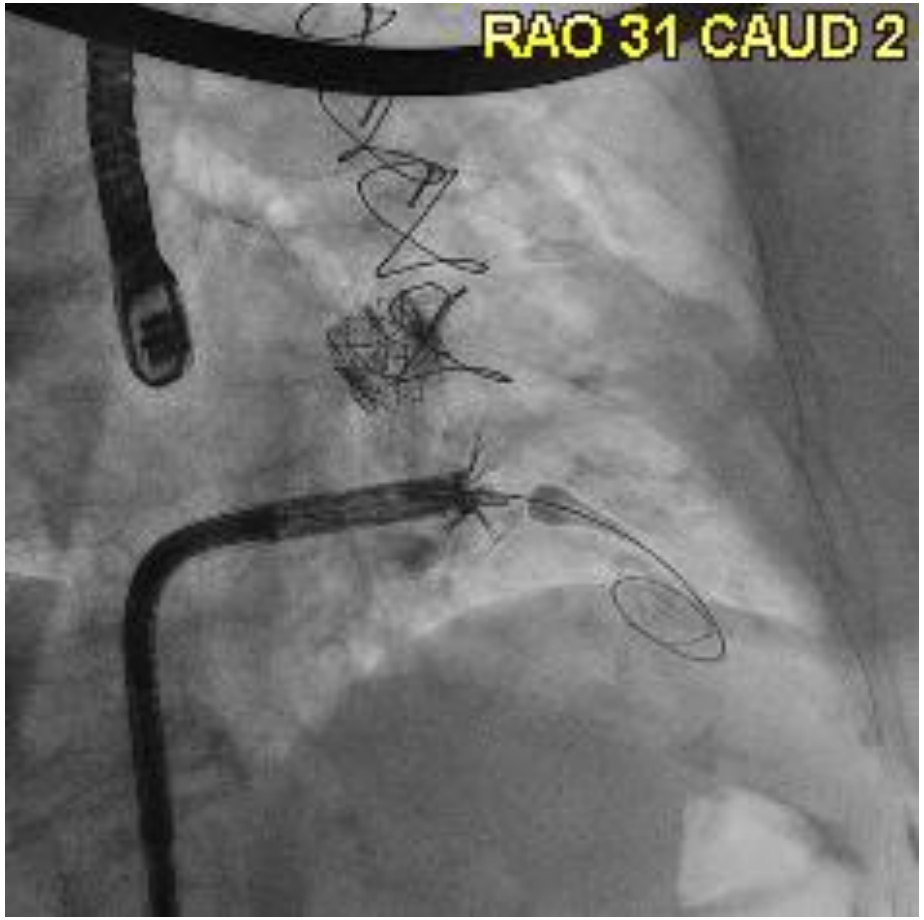
Confida Wire in RV



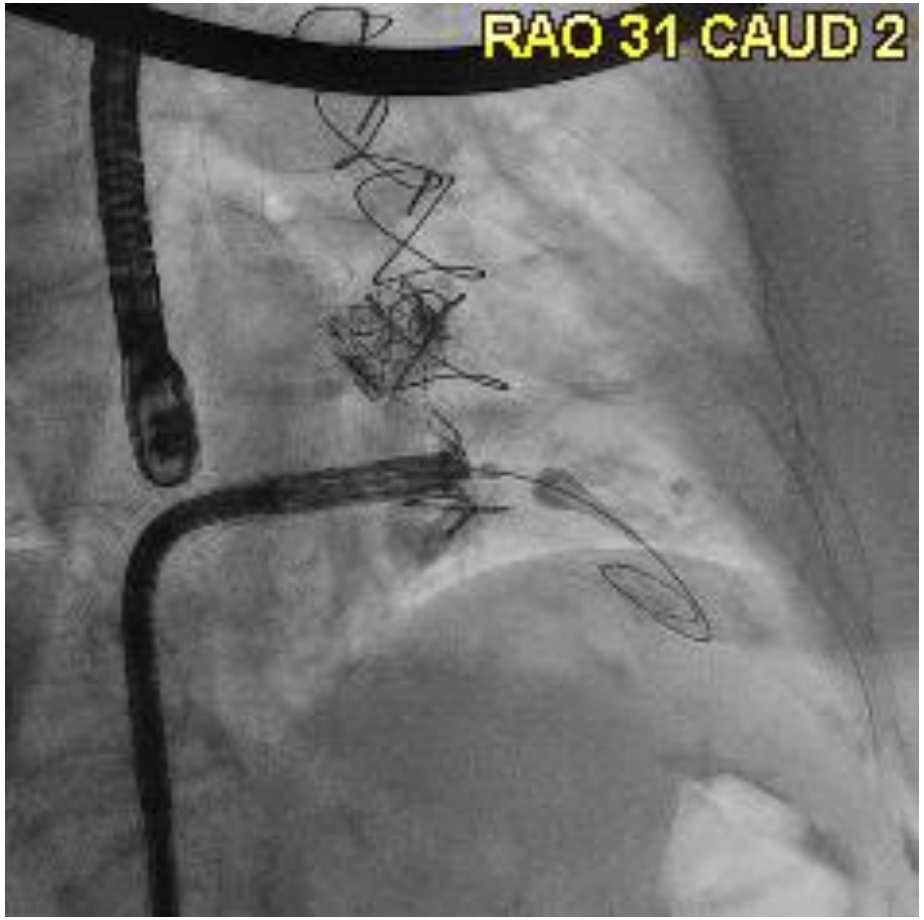
Valve Undeployed



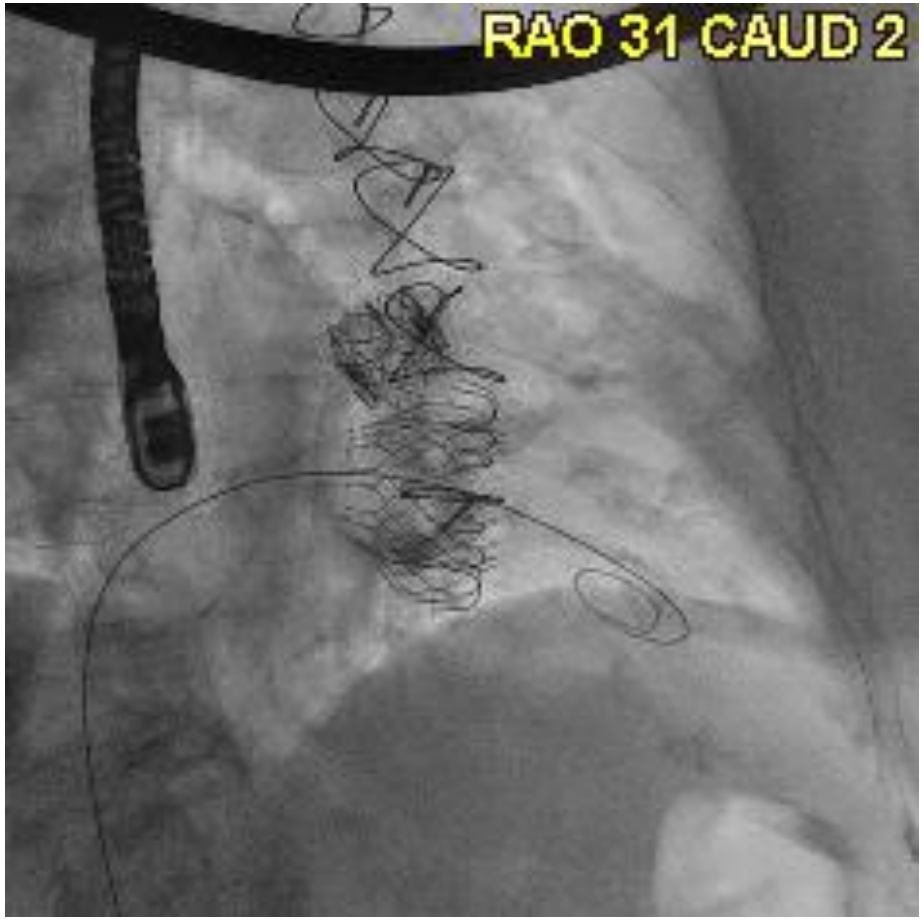
Tynes Opened Partial

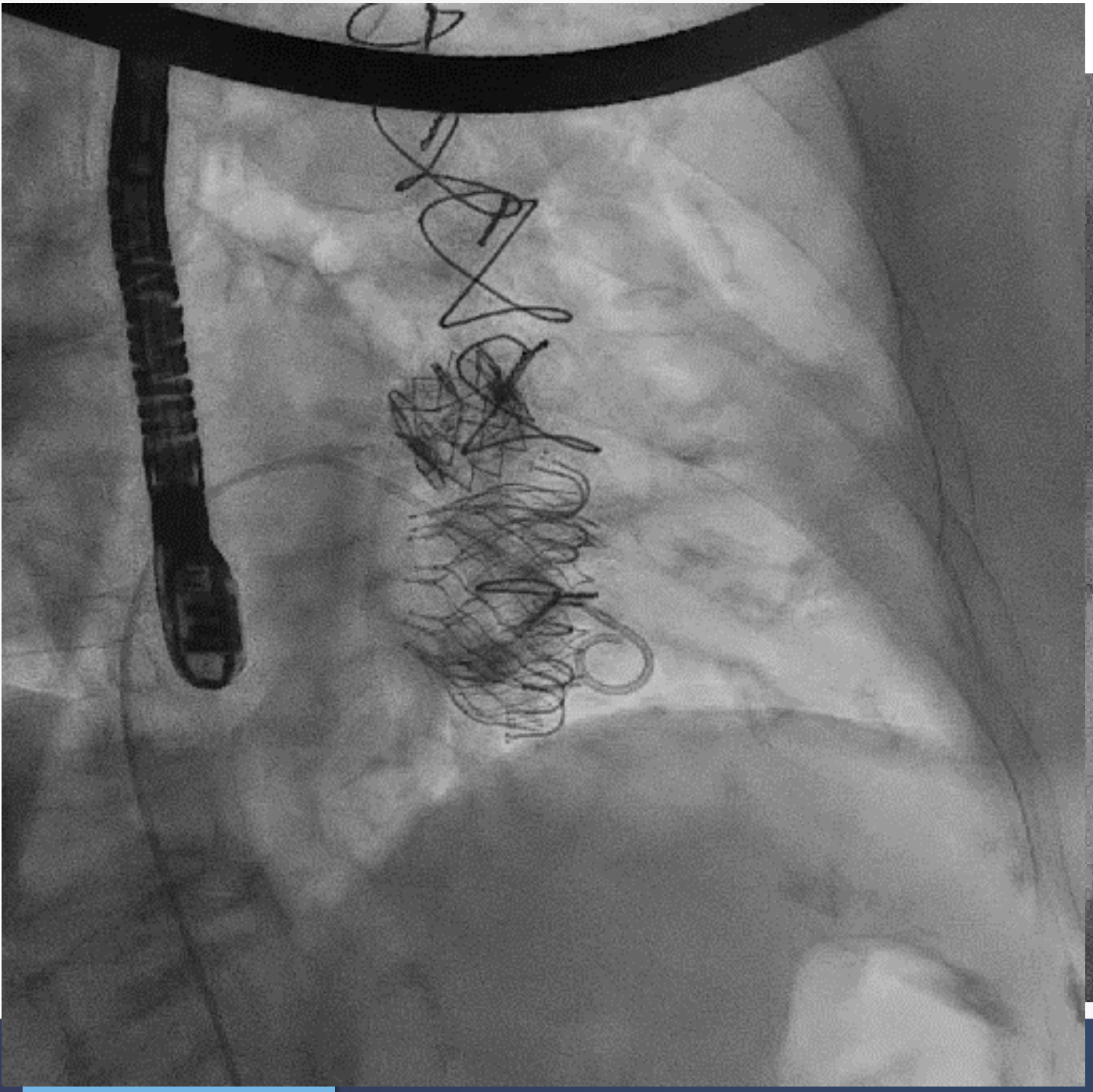


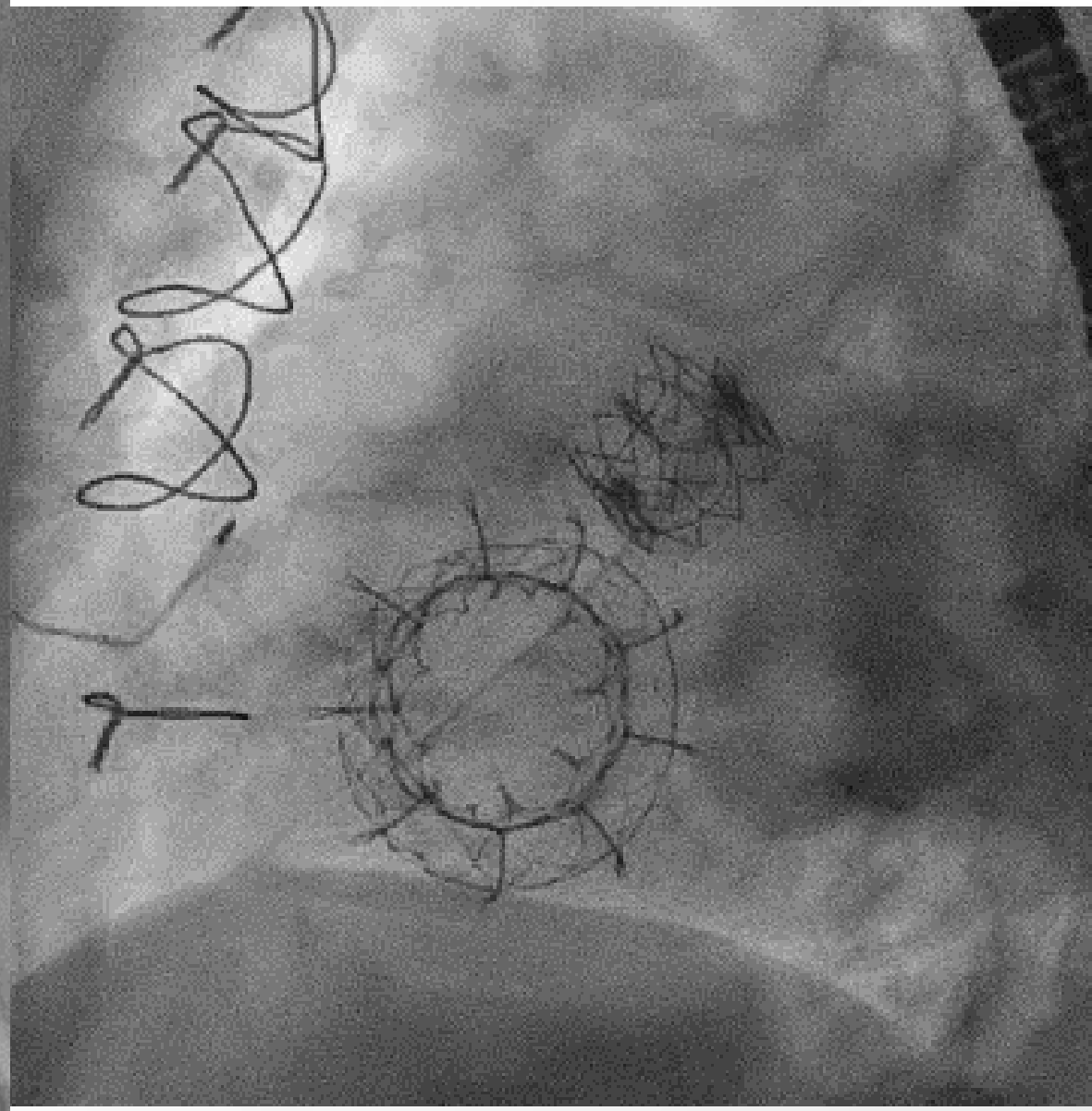
Tynes Opened Fully



Valve Fully Deployed







THE TRISCEND STUDY

EVOQUE Tricuspid Valve Replacement (TRISCEND)

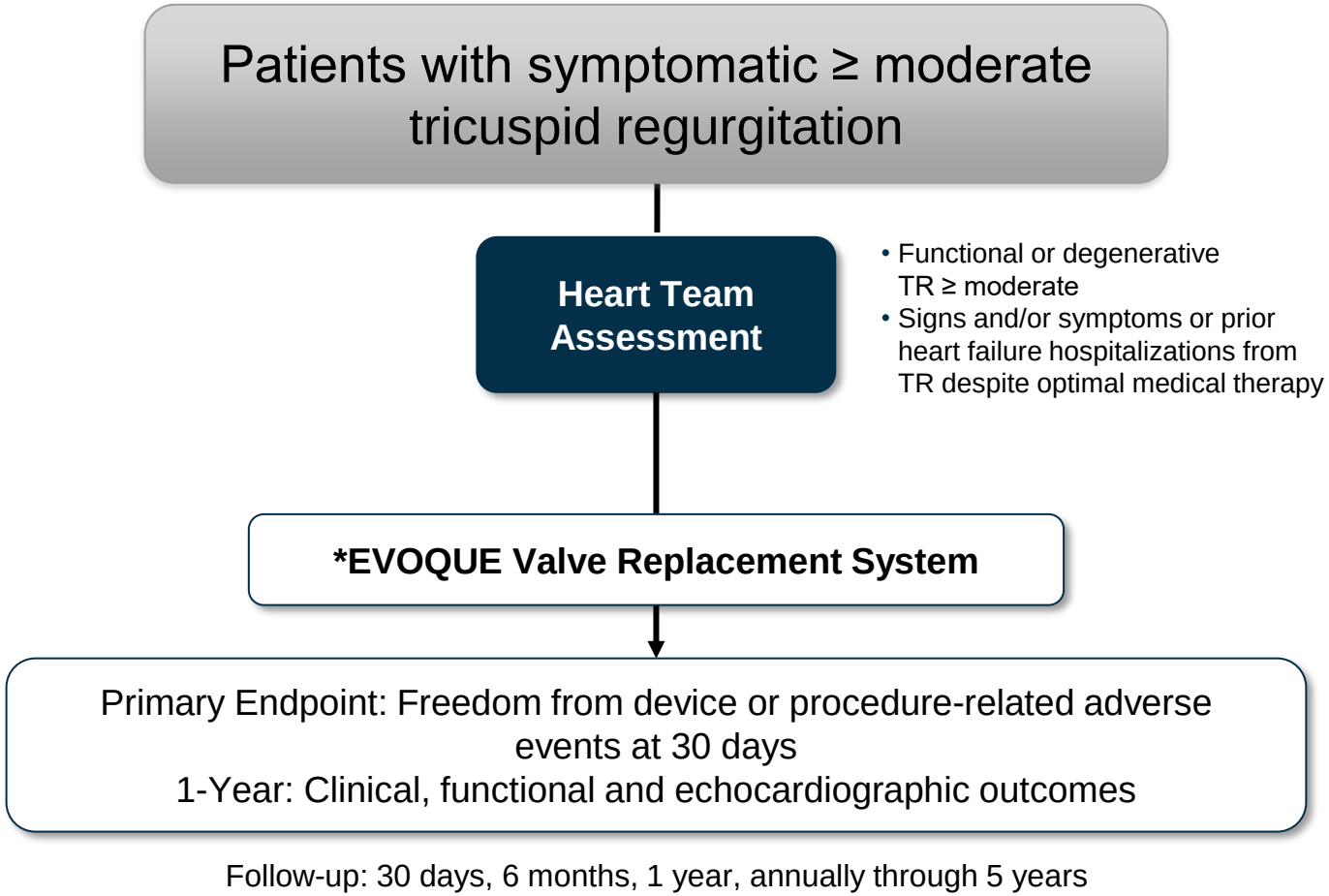
Prospective, multicenter, single-arm study

Purpose:
Evaluate the safety and performance of the EVOQUE Transcatheter Tricuspid Valve Replacement System

Principal Investigator:
- Susheel K. Kodali, MD

Trial Oversight:
- Echocardiographic core laboratory
- Clinical events committee
- Data safety monitoring board

ClinicalTrials.gov:
NCT04221490



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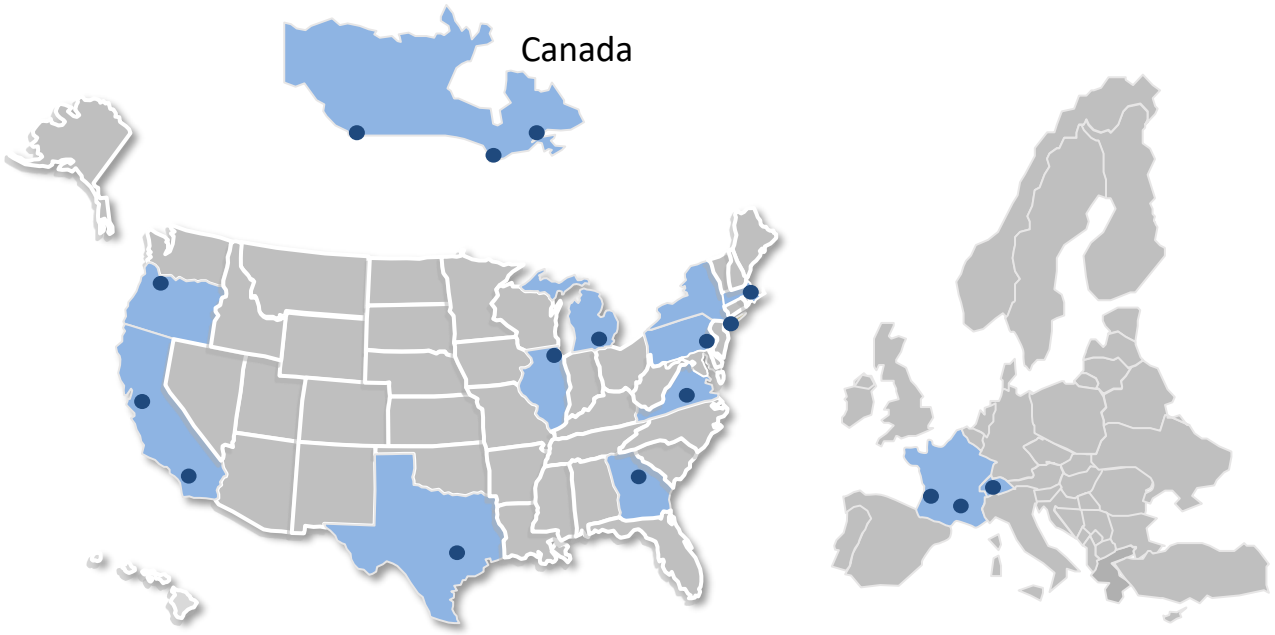
Enrolling sites in the TRISCEND study



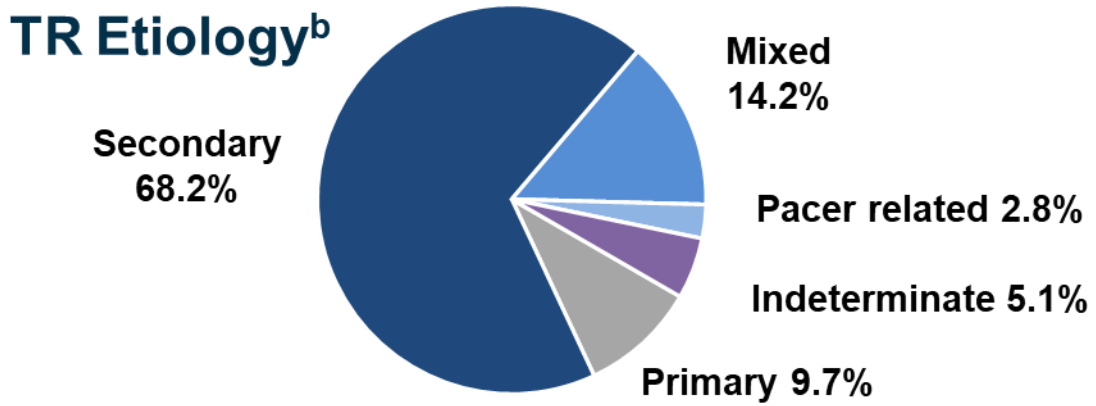
	Sites
CA	•Cedars Sinai Medical Center
IL	•Northwestern Medical Center
OR	•Oregon Health & Science University
NY	•Columbia University Medical Center/NYPH
ONT	•St. Michael's Hospital
GA	•Piedmont Heart Institute
MI	•Henry Ford Hospital
FR	•Clinique Pasteur, Toulouse
GA	•Emory University Hospital
CA	•Stanford University
TX	•Baylor Scott & White The Heart Hospital Plano
CH	•InselSpital University Hospital Bern
MA	•Massachusetts General Hospital
PA	•Hospital of the University of Pennsylvania
VA	•University of Virginia Health System
BC	•St. Paul's Hospital Vancouver
FR	•CHU Bordeaux, Hôpital Cardiologique Haut Lévêque
NY	•Montefiore Medical Center
QC	•Institut universitaire de cardiologie et de pneumologie de Québec - Université Laval (IUCPQ-ULaval)
MA	•Brigham and Women's Hospital

Reflects patient enrollment in the current data set.

Baseline Characteristics and Device Success

	N=176 % or mean ± SD
Age	78.7 ± 7.3
Female	71.0%
STS score (MV replacement), %	10.0 ± 5.3*
EuroSCORE II, %	5.1 ± 4.0
NYHA class III-IV	75.4%¶
TR grade ≥ severe	88.0%¶
Atrial fibrillation	92.0%
Pulmonary hypertension	75.0%
Renal disease	58.5%
Ascites	22.2%
Stroke	13.6%
CABG	16.5%
Prior valve surgery/intervention	37.5%
Pacemaker/ICD	32.4%

Index procedure	%, mean ± SD, or median (IQR)
Device success[a]	94.4%§
Time for implant delivery system insertion to removal, mins	71.6 ± 31.4^
Length of hospital stay, days	3 (2,7)‡
Discharge to home	91.1%†



[a]Device deployed and delivery system retrieved as intended by patient's exit from catheterisation laboratory. [b]Aetiology based on site-reported data. *CABG*, coronary artery bypass graft; *ICD*, implantable cardiac defibrillator; *NYHA*, New York Heart Association; *MV*, mitral valve; *STS*, Society of Thoracic Surgeons. *n=127, ¶n=175, §n=177 (one patient had two devices attempted), ^n=167, ‡n=168, †n=169

Clinical Outcomes to 1 Year

CEC-adjudicated MAEs	30 days N=172[a] % (n)	1 year N=149[a] % (n)
Cardiovascular mortality	1.7% (3)	9.4% (14)
Myocardial infarction	0% (0)	0% (0)
Stroke	0.6% (1)	1.3% (2)
Non-elective tricuspid valve reintervention	2.3% (4)	4.0% (6)
Severe bleeding[b] Major Extensive Life threatening Fatal	16.9% (29) 8.1% (14) 7.0% (12) 1.7% (3) 0.6% (1)	25.5% (38) 10.7% (16) 10.7% (16) 4.7% (7) 0.7% (1)
Major access site and vascular complications	2.3% (4)	2.7% (4)
Major cardiac structural complications	0% (0)	0% (0)
Device-related pulmonary embolism	0% (0)	0% (0)
Unplanned dialysis or renal replacement therapy	1.7% (3)	3.4% (5)
Composite MAE rate	**18.6% (32)**	**30.2% (45)**

Other events:

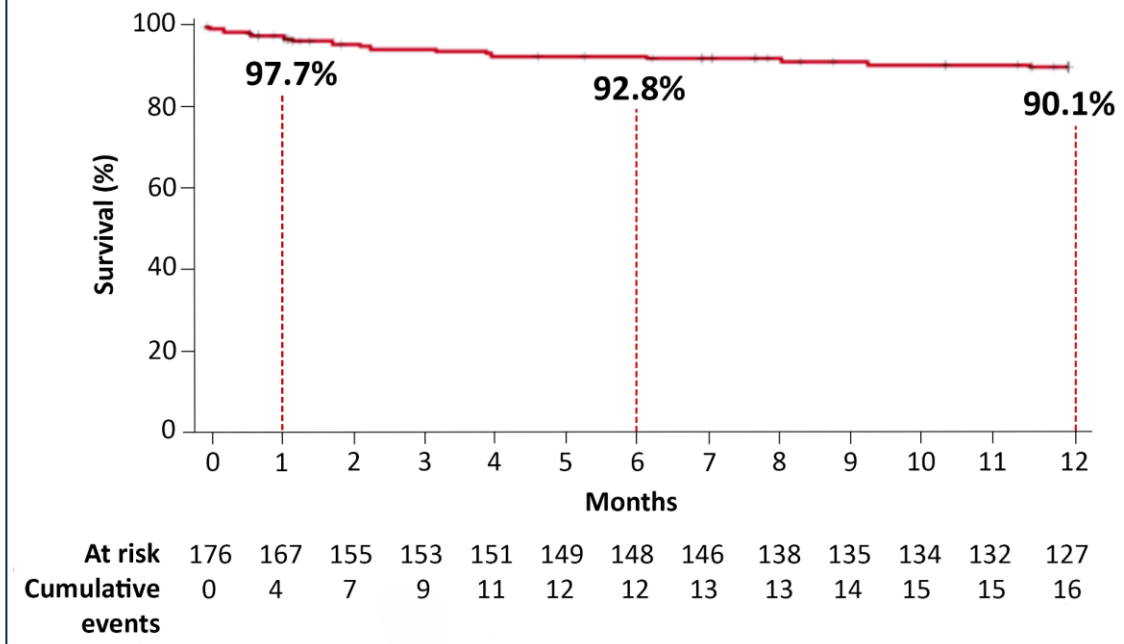
13.3% (15/113)[c] patients had new pacemaker at 30 days

No new pacemakers after 30 days

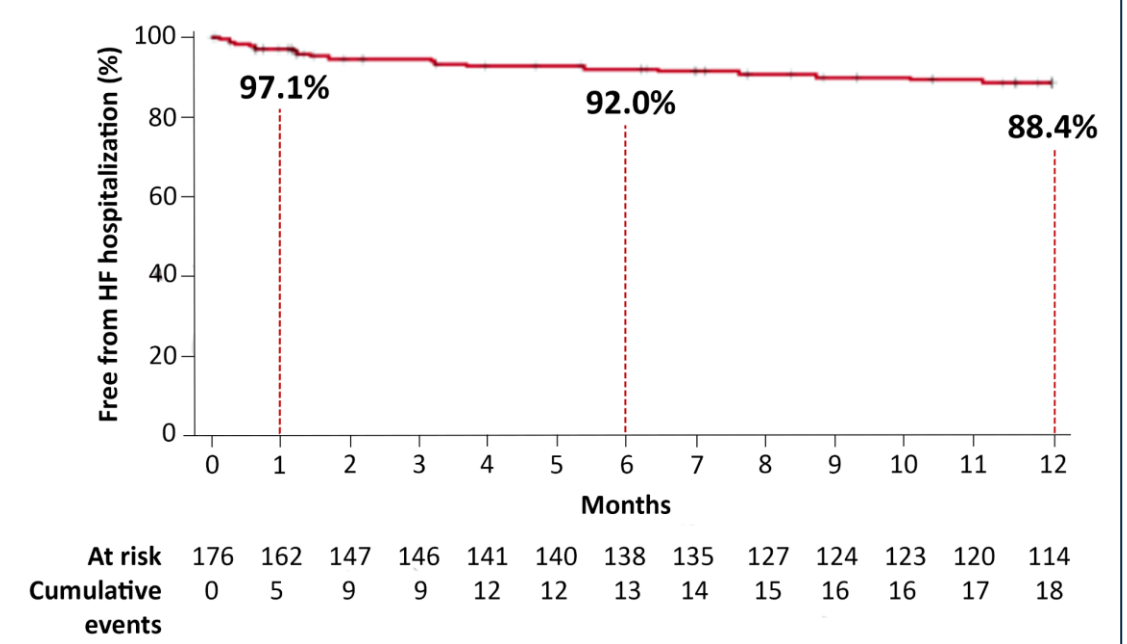
[a]Denominator includes all patients who reached the follow-up timepoint and any patients who experienced an event prior to follow-up. [b]Severe bleeding defined by Mitral Valve Academic Research Consortium. Patients may have had more than one event. [c]Pacemaker denominator excludes patients with baseline pacemaker. *CEC*, clinical events committee; *HF*, heart failure; *MAE*, major adverse events

Survival and Heart Failure Hospitalization at 1 Year

Survival



Freedom from HF Hospitalization

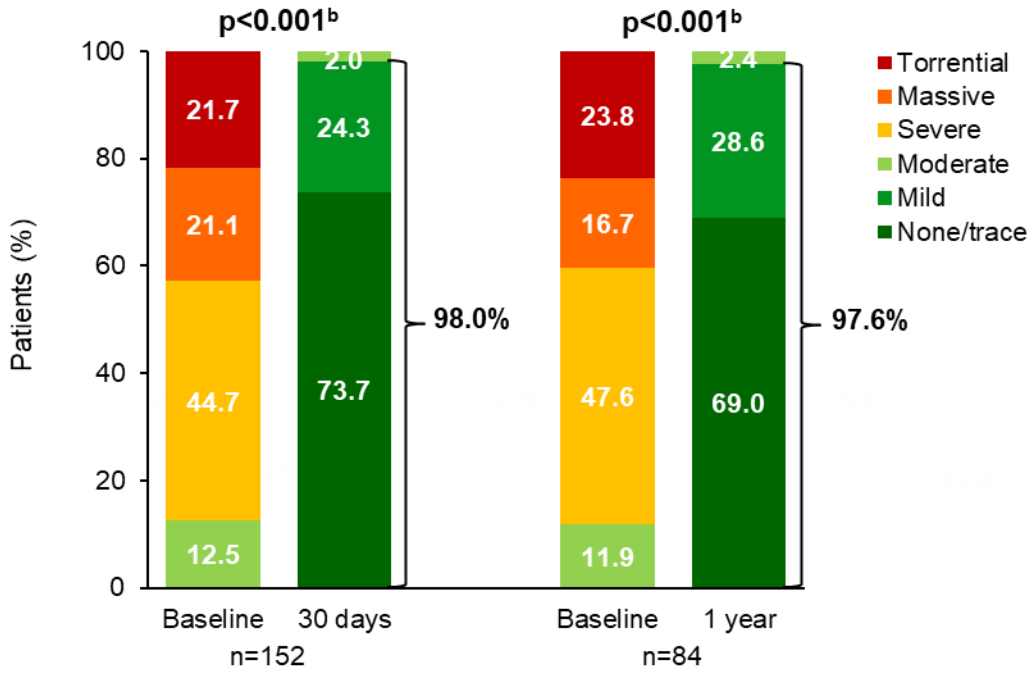


KM estimates of 90% survival and 88% freedom from HF hospitalization at 1 year

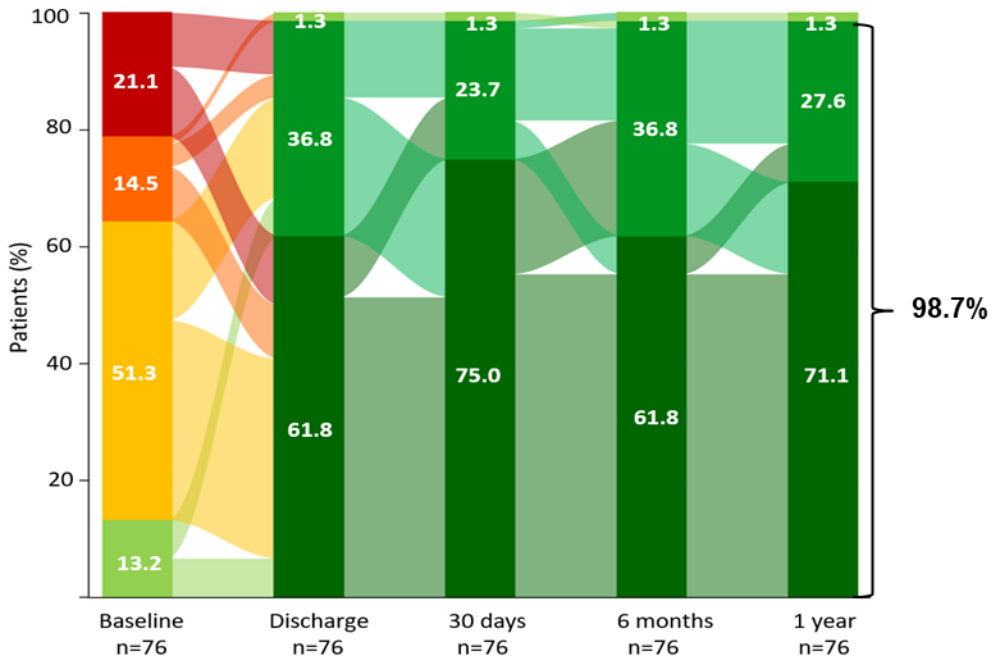
HF, heart failure; *KM*, Kaplan-Meier

Serial Core Lab[a] Assessment of TR to 1 Year

TR reduction at 30 days and 1 year vs baseline



TR reduction over time, same patients



At 1 year, 98% had ≤ mild TR, and 69% had no or trace TR

Graphs show paired analysis. [a]Cardiovascular Research Foundation. [b]Wilcoxon signed-rank test. *TR*, tricuspid regurgitation

Echocardiographic results by core lab[a] at one year

	n	Baseline	One year	Δ One year – baseline	P-value[b]
RV end-diastolic mid diameter, mm	69	41.4 ± 8.8	35.0 ± 7.4	-6.3 ± 9.5	**p<0.001**
RV fractional area change, %	59	38.7 ± 10.1	30.3 ± 10.6	-8.4 ± 13.8	**p<0.001**
TAPSE, mm	46	15.3 ± 5.2	12.5 ± 4.2	-2.8 ± 6.5	**p=0.006**
IVC diameter (expiration), mm	76	27.6 ± 7.7	20.4 ± 5.1	-7.2 ± 5.9	**p<0.001**
Stroke volume (LVOT), mL	81	54.8 ± 15.8	65.3 ± 17.6	10.5 ± 16.8	**p<0.001**
Cardiac output (LVOT), L/min	81	4.0 ± 1.1	4.5 ± 1.1	0.6 ± 1.2	**p<0.001**
PASP, mmHg	40	39.3 ± 12.8	32.5 ± 11.0	-6.8 ± 13.6	**p=0.003**
TV mean gradient, mmHg	82	1.7 ± 1.0	3.4 ± 1.4	1.7 ± 1.6	**p<0.001**

Evidence of RV remodeling after *EVOQUE implant

Table shows paired data as mean ± standard deviation. [a]Cardiovascular Research Foundation. [b]P-values calculated by paired t-test. *IVC*, inferior vena cava; *LVOT*, left ventricular outflow tract; *PASP*, pulmonary artery systolic pressure; *RA*, right atrium; *RV*, right ventricle; *TAPSE*, tricuspid annular plane systolic excursion; *TV*, tricuspid valve

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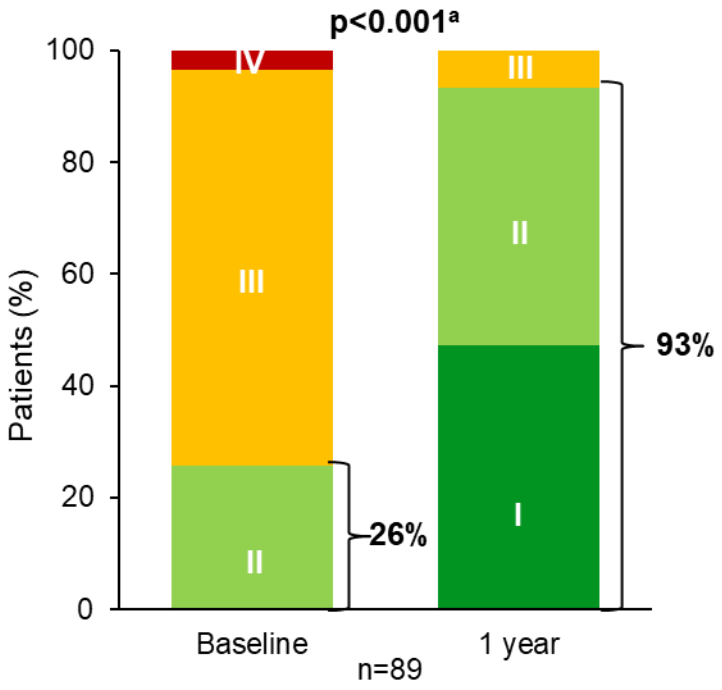
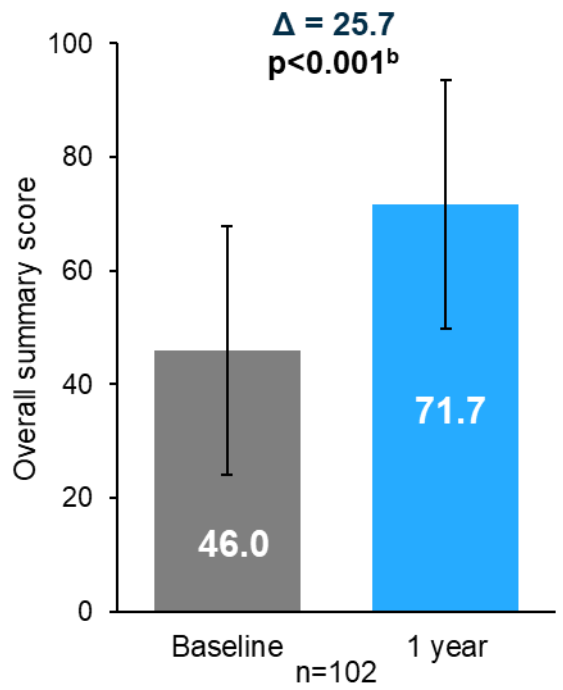
Clinical, Functional and Quality-of-Life Changes from Baseline to 1 Year

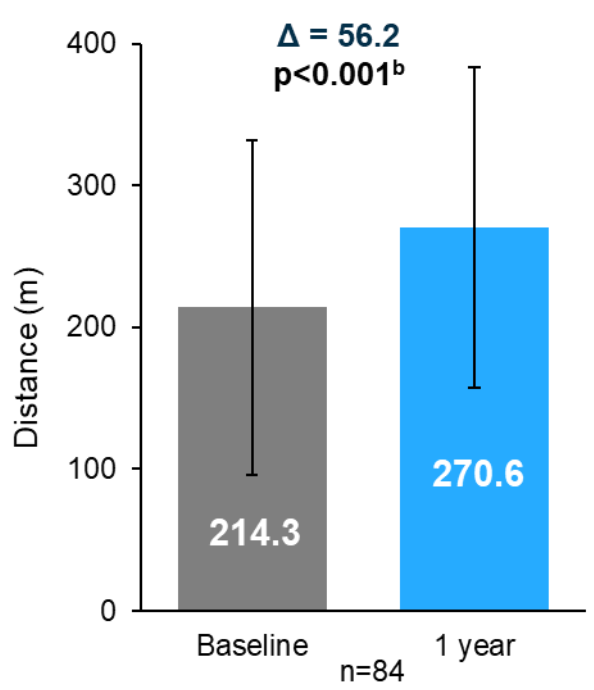
NYHA Class



KCCQ Score



6MWD



At 1 year, 55% had ≥ 20 point KCCQ improvement, 22% had 10-19 point improvement

Graphs show paired analysis. [a]Wilcoxon signed-rank test for NYHA class. [b]Paired t-test for KCCQ and 6MWD. Error bars represent standard deviation. *6MWD*, 6-minute walk distance; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *NYHA*, New York Heart Association

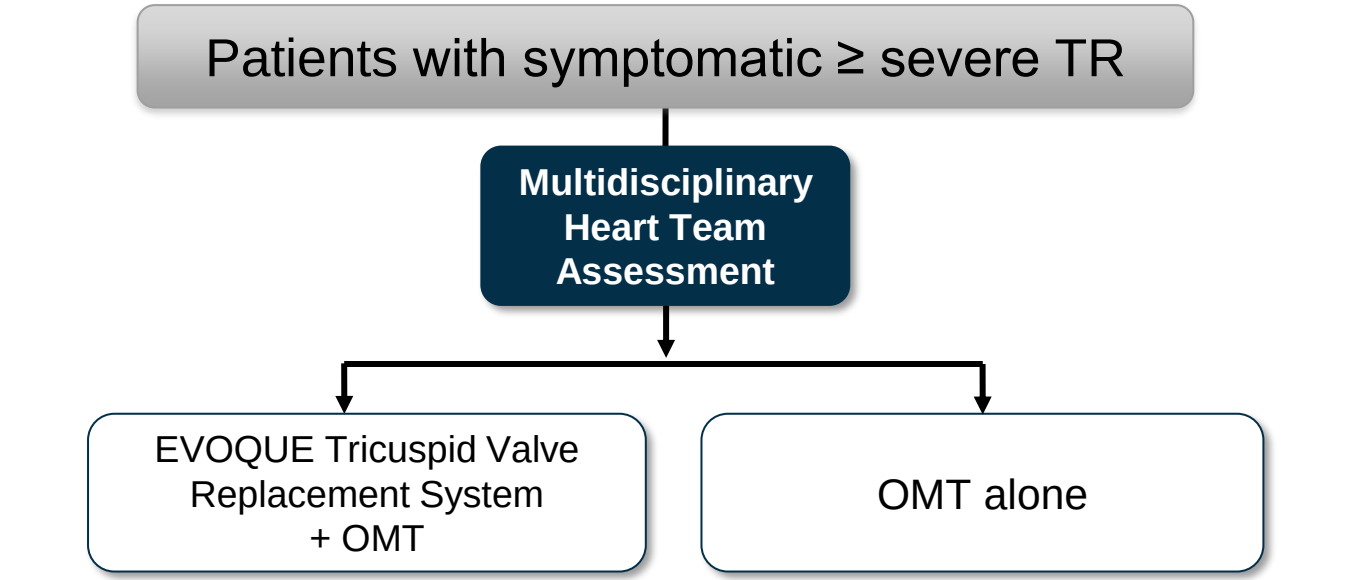
THE TRISCEND II PIVOTAL TRIAL

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy Using a Novel Device

Prospective, multicenter, randomized, controlled pivotal trial

Purpose:
Evaluate the safety and effectiveness of the EVOQUE Tricuspid Valve Replacement System with optimal medical therapy (OMT) compared to OMT alone in the treatment of patients with at least severe TR

Principal Investigators:
- Vinod Thourani, MD
- Rebecca Hahn, MD
- Susheel K. Kodali, MD
- Philipp Lurz, MD



Follow-up: discharge, 30 days, 3 months, 6 months, 1 year, and annually through 5 years

Primary Endpoints:
- TR grade reduction and composite endpoint including: KCCQ, NYHA, and 6MWD improvement at 6 months
- MAE rate at 30 days
- Composite endpoint including all-cause mortality, RVAD implantation or heart transplant, tricuspid valve intervention, heart failure hospitalizations, and improvements in KCCQ, NYHA, and 6MWD at 1 year

NCT04482062

Conclusions

- Tricuspid regurgitation (TR) is prevalent and undertreated, with limited treatment options
- Safety and performance of the transcatheter, transfemoral *EVOQUE Tricuspid Valve Replacement System in a wide range of TR patients, including those with primary, functional, and pacer-related TR
- Global, multicenter, prospective, single-arm study of patients with ≥ moderate, symptomatic TR
- Outcomes at 1 year:
  - Favorable survival and heart failure hospitalization rates
  - Core lab adjudicated significant and sustained TR reduction, with 98% ≤ mild TR
  - Echocardiographic evidence of right-heart remodeling
  - Significant improvements in NYHA class (93% in class I/II), overall KCCQ score (+26 points), and 6MWD (+56m)

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Conclusions

- In the ongoing TRISCEND study at 1 year, transfemoral tricuspid valve replacement with the *EVOQUE system demonstrated favourable clinical outcomes
- Despite a high burden of comorbidities, patients had favourable survival and freedom from heart failure hospitalization
- Results demonstrated significant and sustained TR reduction and improvements in clinical, functional, and quality-of-life outcomes
- The randomized pivotal trial (TRISCEND II, NCT04482062) is underway