Global Insights from the TRICUS Registry

Real-World Outcomes with TricValve Bi-Caval Valve Therapy for Tricuspid Regurgitation

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CRF®
TCT® TRANSCATHETER CARDIOVASCULAR THERAPEUTICS®

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Consultant	Abbott, Bristol-Myers Squibb, Edwards Lifesciences, P&F Products & Features GmbH, Philips
Research Contract	Abbott

Unmet Clinical Need

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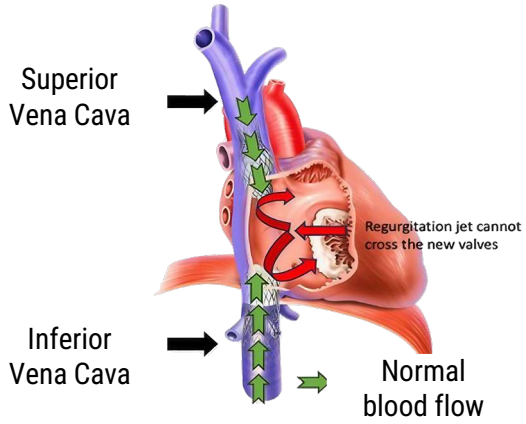
Intended Use
The TricValve® Transcatheter Bicaval Valve System is indicated for patients with symptomatic severe tricuspid regurgitation (hemodynamically relevant) and caval reflux, at high risk for open surgical therapy.

CE Marked since 2021 and commercially available outside the US

Breakthrough device designation

As the device enters pivotal U.S. trials, long-term clinical data are critical to guide its future role in treatment algorithms



TricValve Model	Valve size (mm)
SVC 25	25
SVC 29	29
IVC 31	31
IVC 35	35

☑	Prior tricuspid interventions or surgery
☑	Existing pacemakers or defibrillator leads
☑	TTE guidance for IVC (Fluoro for SVC deployment)
☑	100% agnostic to tricuspid anatomy
☑	TricValve can be done under conscious sedation
☑	Easier imaging requirements
☑	Minimal to zero HALT in global experience, under standard OAC conditions) Low rate of thrombosis

TRICUS Registry: European post market study

Objective

The objective of this study is to monitor the mid- and long-term safety of the TricValve® in a real-world setting

Patients and sites

Target # of patients: 450 patients
Target # of sites: 100 sites

Data shown: **107 patients at 36 sites** in Europe

Endpoints

Primary endpoint

- First unplanned heart failure hospitalization (HFH) at 12 months

Secondary endpoints

- All-cause mortality,
- Serious adverse events (SAEs),
- NYHA class, functional capacity
- Device-related complications up to 5 years

	Procedure N =107	30 days N=102	3M N=96	6M N=89	1Y N=80	2Y N=58	3Y N=41	4Y N=33	5Y N=12
N. of pts with completed visit	107 (100%)	76 (75%)	71 (74%)	64 (72%)	72 (90%)	34 (59%)	16 (39%)	10 (30%)	3 (25%)
N. of pts with missed visit	26 (25%)	25 (26%)	25 (28%)	8 (10%)	24 (75%)	25 (41%)	61 (75%)	23 (70%)	9 (75%)

Medical History

Baseline Medical History	N. Patients	% Patients
Medical Condition		
Tricuspid regurgitation	107	100.0%
Tricuspid regurgitation (primary/organic)	16	15.0%
Tricuspid regurgitation (secondary/functional)	91	85.0%
Comorbidities		
Atrial Fibrillation	96	89.7%
Arterial Hypertension	77	72.0%
Chronic Renal Failure	39	36.4%
Diabetes Mellitus	18	16.8%
Significant coronary heart disease (>75% stenosis)	14	13.1%
Chronic Obstructive Lung Disease	13	12.1%
Prior Stroke	10	9.3%
Prior Myocardial Infarction	7	6.5%
Peripheral Vascular Disease	4	3.7%
Other	67	62.6%
Surgeries / Medical Procedures		
Pacemaker implantation	23	21.5%

TRICUS Registry - Baseline Characteristics

Parameter (N = 107 patients)	Mean ± SD or n (%)
Age	77.9 ± 6.0
Female	72%
Male	28%
Height (cm)	162.1 ± 8.9
Weight (kg)	68.6 ± 14.4
BMI (kg/m2)	26.1 ± 5.2
EuroScore II	5.4 ± 4.1
NYHA Class I	0 (0%)
NYHA Class II	20 (20%)
NYHA Class III	69 (70%)
NYHA Class IV	9 (9%)
KCCQ-12	40.5 ±21.1
6MWT (m)	230.9 ± 95.5

Major Adverse Events (MAE)

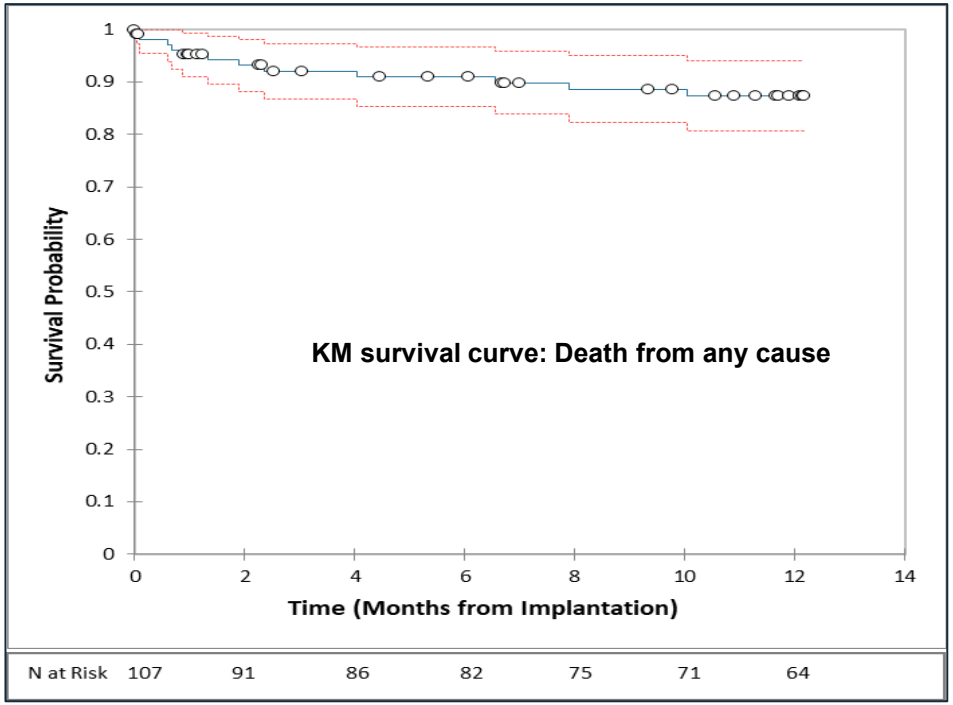
MAEs in TRICUS registry, cumulative over time (N=107)

MAE	Causality	N (%)							
		30 D	3 M	6 M	1 Y	2 Y	3 Y	4 Y	5 Y
Death	Related	2 (2%)	3 (3%)	3 (3%)	3 (3%)**	4 (4%)	4 (4%)	4 (4%)	4 (4%)
	Unrelated	3 (3%)	5 (5%)	6 (6%)	9 (8%)*	12 (11%)	13 (12%)	15 (14%)	16 (15%)
	All-cause	5 (5%)	8 (7%)	9 (8%)	12 (11%)	16 (15%)	20*** (19%)	22***(21%)	25*** (23%)
Stroke	Related	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)
	Unrelated	0 (0%)	1 (1%)	2 (2%)	3 (3%)	3 (3%)	3 (3%)	3 (3%)	3 (3%)
	All-cause	1 (1%)	2 (2%)	3 (3%)	4 (4%)	4 (4%)	4 (4%)	4 (4%)	4 (4%)
Major Bleeding	Related	3 (3%)	3 (3%)	3 (3%)	3 (3%)**	3 (3%)	3 (3%)	3 (3%)	3 (3%)
	Unrelated	0 (0%)	1 (1%)	3 (3%)	3 (3%)*	4 (4%)	5 (5%)	5 (5%)	5 (5%)
	All-cause	3 (3%)	4 (4%)	6 (6%)	6 (6%)	7 (7%)	8 (7%)	8 (7%)	8 (7%)
Cardiac Surgery	Related	0	0	0	0	0	0	0	0
Cardiac Tamponade	All-cause	0	0	0	0	0	0	0	0
Myocardial Infarction	All-cause	0	0	0	0	0	0	0	0
Total (related)		6 (6%)	7 (7%)	7 (7%)	7 (7%)**	8 (7%)	8 (7%)	8 (7%)	8 (7%)
Total (unrelated)		3 (3%)	7 (7%)	11 (10%)	15 (14%)*	19 (18%)	21 (20%)	23 (21%)	24 (22%)
Total (All-cause)		9 (8%)	14 (13%)	18 (17%)	22 (21%)	27 (25%)	32* (30%)	34*(32%)	37* (35%)

MAE profile of TricValve® supports the clinical acceptability of the safety risk in this surgically inoperable population.

Extremely low (< 1%) onset of new pacemaker due to TricValve® Implantation

All-Cause Mortality



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All cause mortality at 1 year, N = 107

11.2%

1-year survival rate is particularly notable when considering the high baseline mortality risk typically associated with this patient population

Heart Failure Hospitalizations

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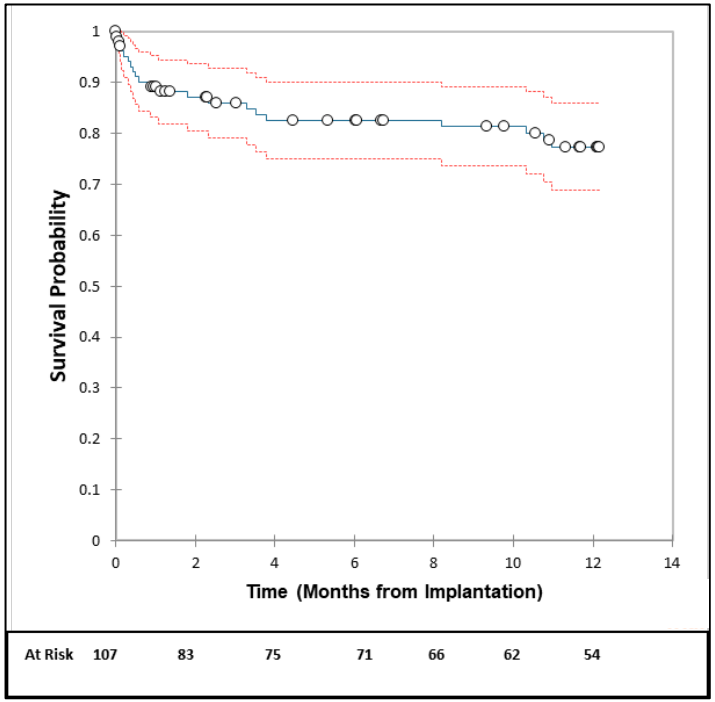
Kaplan–Meier survival curve – First Heart Failure Hospitalization



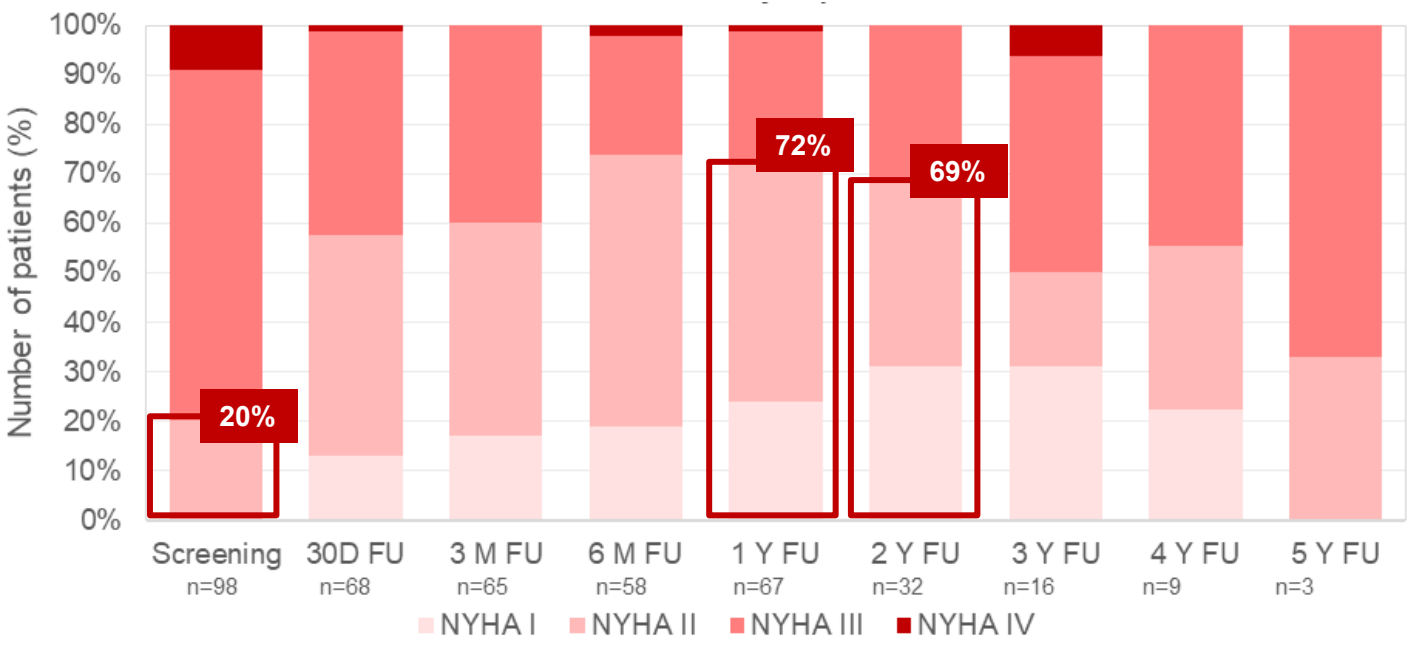
Freedom from HFH at 1 year

80%

First Heart Failure Hospitalization during follow up

	30 days N (%)	3 months N (%)	6 months N (%)	1 year N (%)	2 years N (%)	3 years N (%)	4 years N (%)	5 years N (%)
N. of patients	102	96	89	80	58	41	33	12
N. of first HFH	11 (11%)	3 (3%)	3 (3%)	4 (5%)	2 (3.5%)	1 (2%)	0	1 (8%)
Related	1 (1%)	0	0	0	0	0	0	0
Unrelated	10 (10%)	3 (3%)	3 (3%)	4 (5%)	2 (3.5%)	1 (2%)	0	1 (8%)

NYHA Class



72%
NYHA Class I or II at 12 Months

69%
NYHA Class I or II at 24 Months

Quality of life improvements

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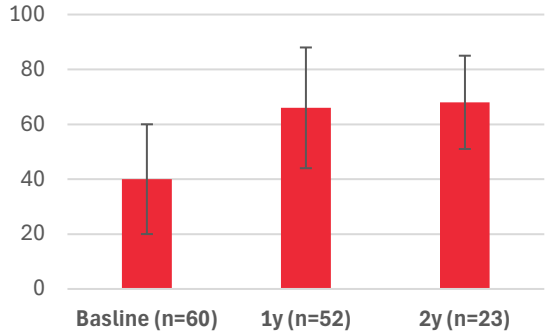
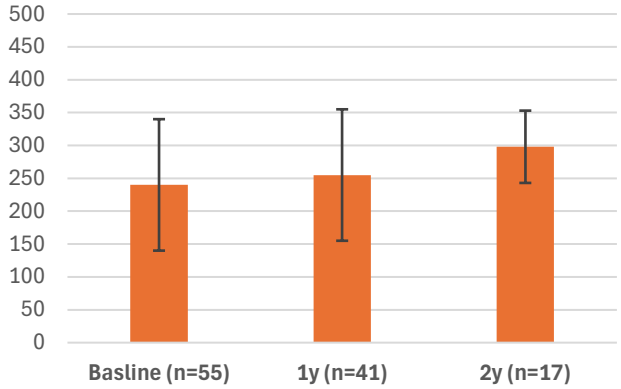
KCCQ Score



54%
KCCQ Score increase at 12 Months

6MW Distance



15%
6MW Distance increase at 12 Months

Conclusions

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- TRICUS Registry represents the **post market dataset** to date for the TricValve® system
- The interim results confirm the **safety and durable clinical benefit** in a high-risk, comorbid patient population
- This global, real-world experience offers essential insights into patient selection and long-term performance, especially for US pivotal trials