DUO™ Tricuspid Coaptation Valve System: Long-Term Follow Up from the TANDEM I Study

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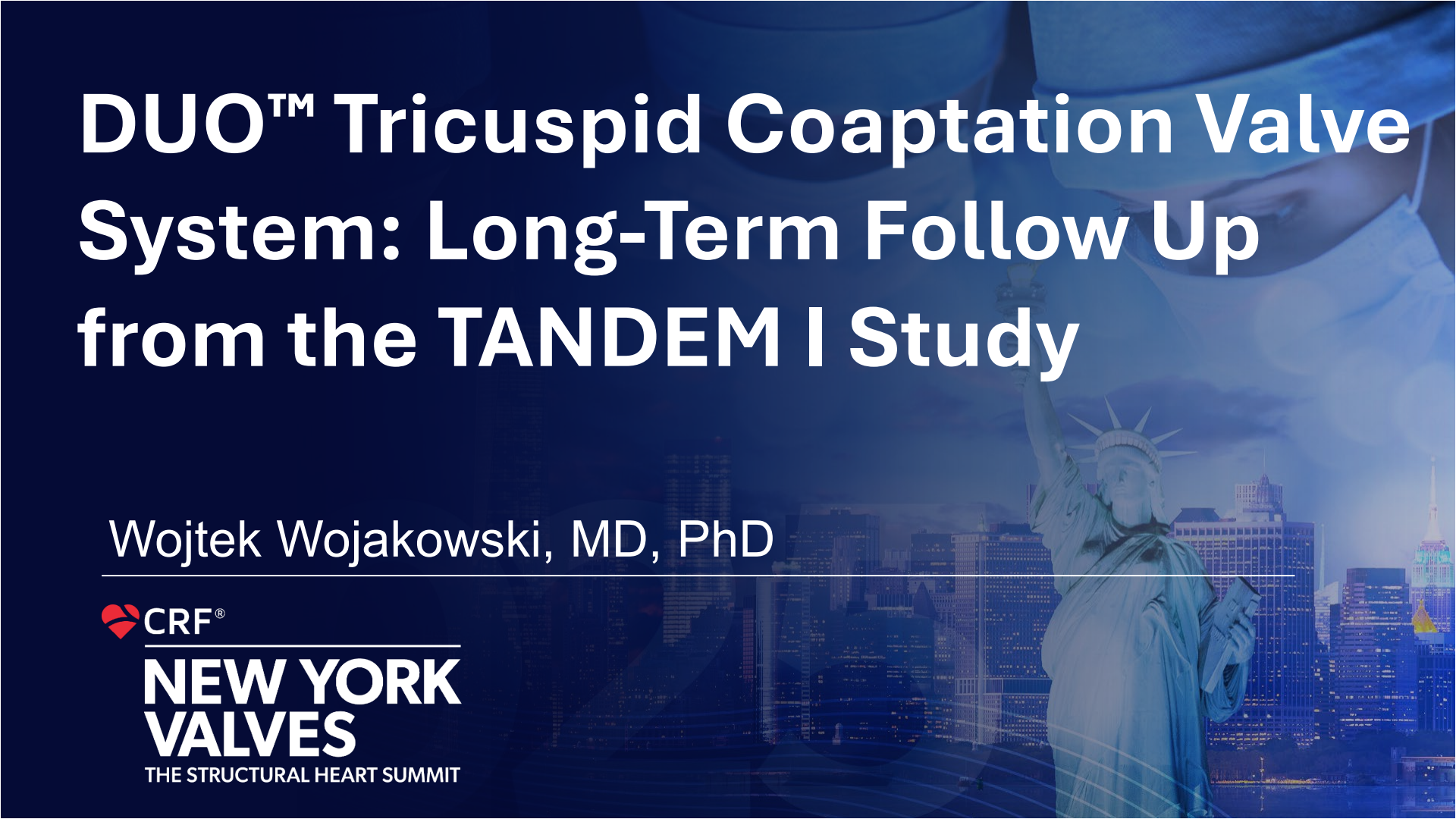

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Disclosure of Relevant Financial Relationships

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
Proctor	Abbott Inc.

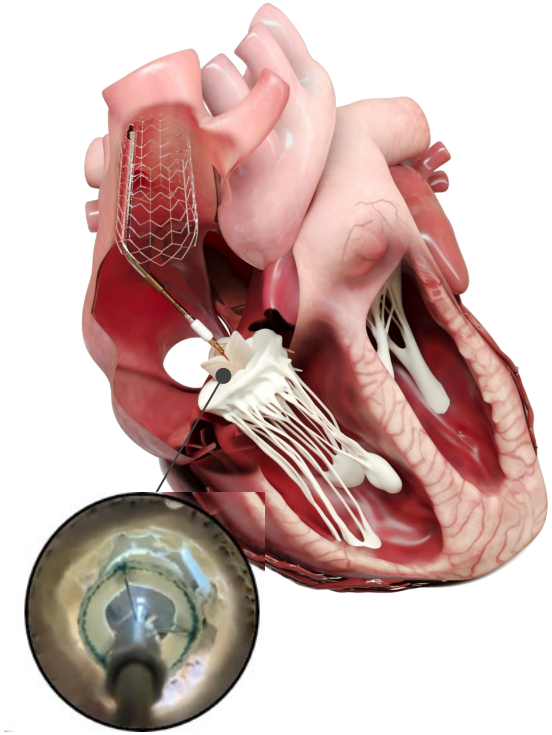
All Relevant Financial Relationships have been mitigated.
Faculty disclosure information can be found on the app

Unmet Clinical Need

- TR is a challenging disease to treat due to the heterogeneity of patient anatomies, multiple etiologies and advanced comorbidities resulting in right heart failure

- The DUO™ System is a novel transcatheter tricuspid coaptation valve designed to address the complexity of treating TR
  - Preserves the native anatomy
  - Treats a broad patient population
  - Enables a scaleable procedure

DUO™ Coaptation Valve System



Coaptation Valve

- Porcine pericardial tissue valve
- Fills the regurgitant orifice, with native leaflets sealing against outer pericardial skirt to prevent TR
- Works in tandem with native valve to supports diastolic flow

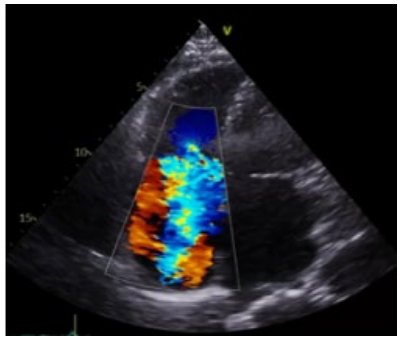
Anchor System

- Adjustable catheter suspends coaptation valve between native leaflets
- Stent in the SVC anchors catheter while leaving the right heart untouched

TANDEM I Patients

Complex Anatomies and Advanced Comorbidities

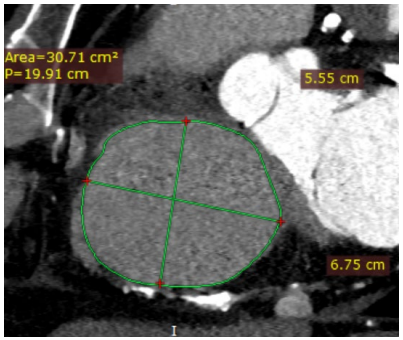
Large Coaptation Gaps



EROA: 2.54 cm^2

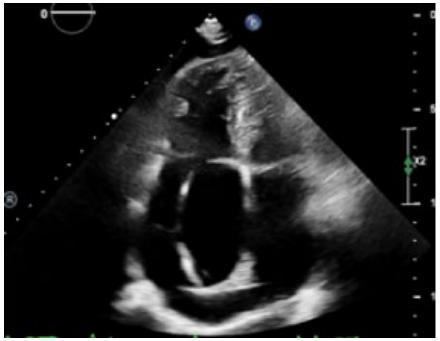
Coaptation gap:
17 mm (AP); 23.5 mm (SL)

Large Annulus Size



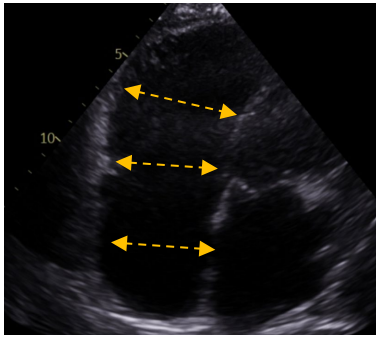
Annulus diameter 67.5 mm

CIED Leads



Baseline TR: Massive

Advanced Disease



55% with Torrential TR

57% with moderate to severe RV function

TANDEM I First in Human Study

Sites

- Warsaw: Prof. Witkowski
- Katowice: Prof. Wojakowski
- Gdańsk: Prof. Jagielak
- Warsaw: Prof Huczek

Objective

- Demonstrate safety and effectiveness of the DUO Coaptation Valve System

Enrollment

- 11 patients
- Patients being followed to 2 years

Study Outcome Measures

Safety: Freedom from device or procedure related SAEs at 30 days
Efficacy: Improvement in NYHA Classification, 6MWT, & KCCQ, Reduction in TR

TANDEM I Study: Patient Demographics

Patient Demographics	N=11
Age *(years)*	78 (71-84)
Female	91%
NYHA Class III or IV	91%
HFH in prior 12 months	45%
Massive/Torrential TR	82%
LVEF *(%)*	49 (43-56)
Annular Diameter *(mm)*	52 (43-69)
Atrial Fibrillation	100%
Previous Left-Sided Valve Intervention	27%
Renal Insufficiency	64%

Characteristics of Patient Population:

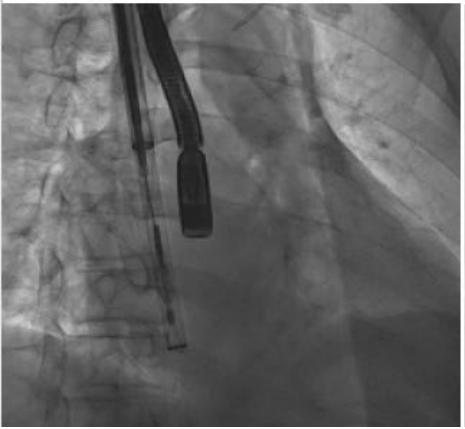
- Wide range of annular diameters
- Wide range of coaptation gaps

DUO™ System Procedure

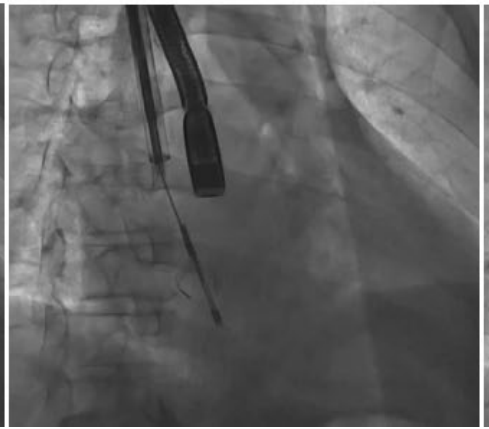
Predictable, scalable procedure

- Short learning curve
- Standard echo imaging
- Scalable procedure

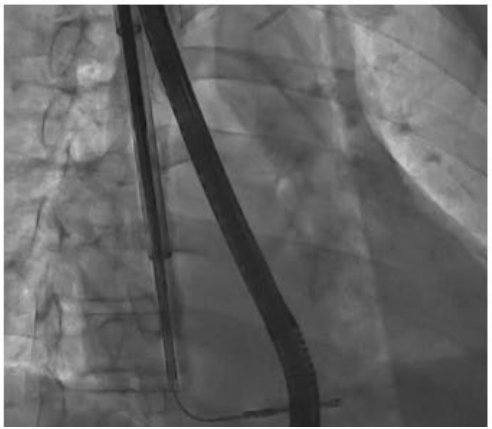
	% or Mean (Range)
Device Time (mins)	43 (34 – 58)
Sites/Operators	4



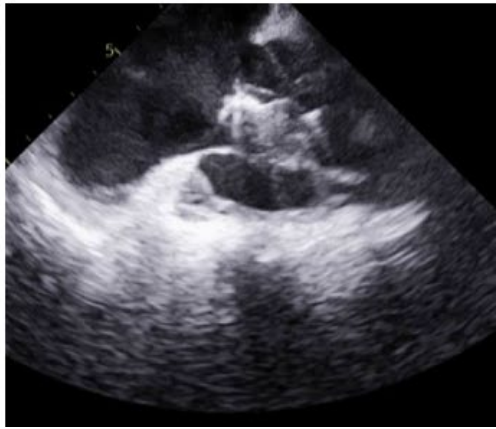
1. Coaptation Valve deployed



2. Coaptation Valve positioned across TV



3. Stent deployed to planned position in SVC



4. Valve position optimized for efficacy

TANDEM I Study: 30 Day Safety

MAEs (n=11)	30D
Reintervention	2
Death	0
Disabling stroke	0
Myocardial infarction	0
Major access site and vascular complications	0
Severe bleeding	0
Renal failure requiring dialysis	0
Major cardiac structural complications	0
New PPM	0

- 2 reinterventions due to initial learnings of fitment, addressed through sizing, procedure and device updates
- No interference with right heart function: disruption of leaflets, annulus, RV or conduction system

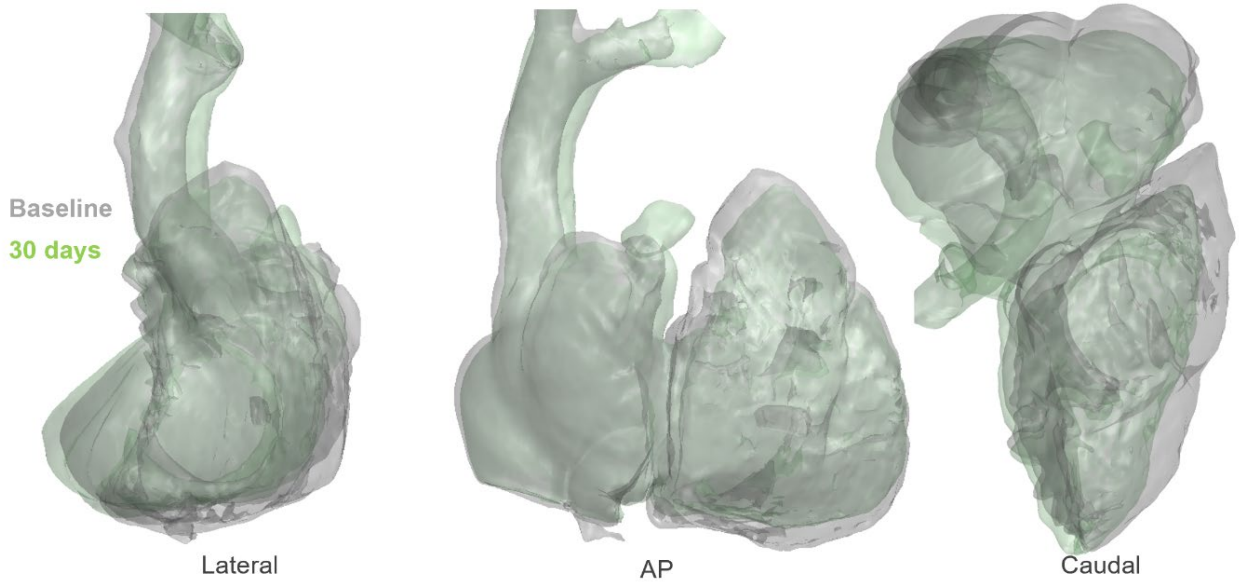
Right Heart Remodeling

Supports Natural Reverse Remodeling

- No structural interference
- No impact on device function/position

CT Measurements at 30 Days

Parameter	Baseline	30-Days	Change
RVEDV (ml)	238 ± 55	200 ± 47	-37 ± 44
RV Stroke Volume (ml)	125 ± 33	103 ± 26	-22 ± 36



TANDEM I Study: Long-Term Outcomes

- 7 patients beyond 1 year follow up, 4 beyond 2 years, average follow up duration 16 months
- Durable TR reduction out to **2 years**
- Sustained Quality of life improvement demonstrated by KCCQ and 6MWD
- No late safety events

2 Year Outcomes

Patient #	Baseline TR	Residual TR	TRISCORE	KCCQ Improvement (points)
1	Severe	Moderate	7	+15
2	Torrential	Moderate	3	+37
3	Torrential	Moderate	3	+25
4	Massive	Moderate	6	+8*

*Patient is wheel-chair bound

Conclusion

- Designed to treat a broad patient population
  - Independent of annular diameter and coaptation gap size
  - Preserves native leaflets, no leaflet capture
- Excellent clinical outcomes
  - Sustained TR reduction (4 TANDEM I patients out to 2-year follow up)
  - Significant QoL improvements
  - Avoids contact with critical structures: conduction system, RCA
  - Supports natural reverse remodeling, without structural interference or impact on device function
- Predictable and scalable procedures
  - Short learning curve
  - Standard echo imaging, not limited by leaflet visibility

TANDEM II EFS currently enrolling