



# 6 Month Follow Up with the CroíValve DUO™ System for the Percutaneous Treatment of Tricuspid Regurgitation



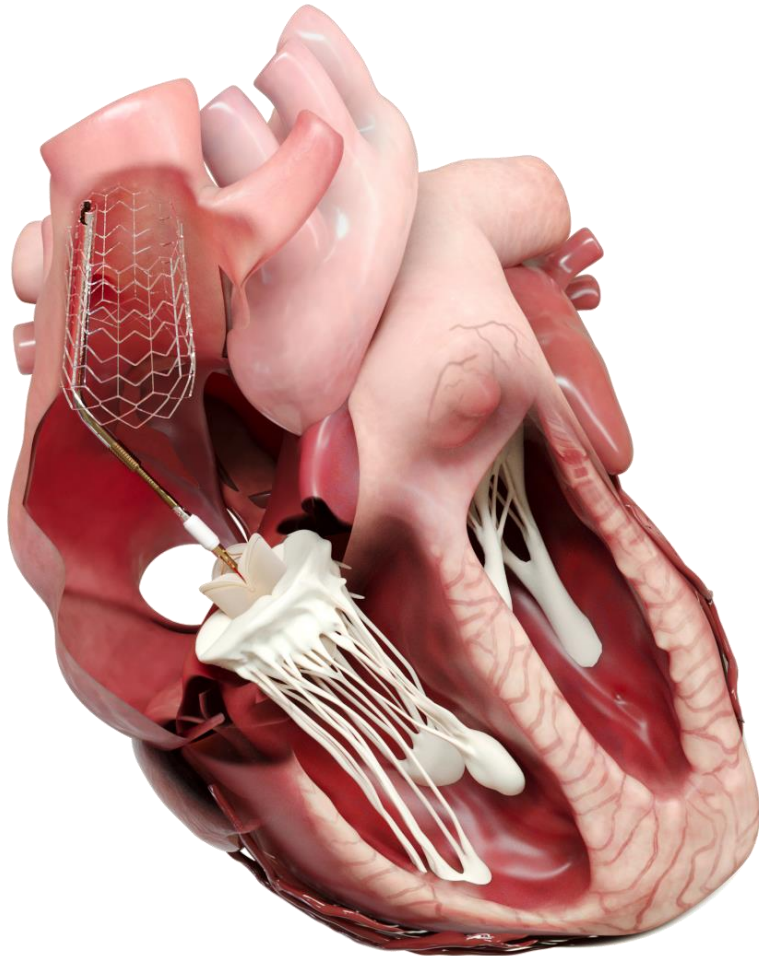
# Potential conflicts of interest

- ☐ I do not have any potential conflict of interest to report
- ☐ I have the following potential conflicts of interest to report:

# A New Approach

- Solutions have finally arrived for treating TR, setting the stage for differentiated innovation
- Complexity in treating TR needs a versatile toolbox approach
- DUO provides a dual-purpose approach with a Coaptation Valve to:
  - Fill regurgitant orifice, allowing the native leaflets to naturally seal and prevent TR
  - Support normal diastolic flow with central prosthetic valve

# DUO Tricuspid Coaptation Valve System



## Coaptation Valve

- Fills regurgitant orifice, native leaflets naturally seal to prevent TR
- Supports normal diastolic flow with central prosthetic valve

## Anchor System

- No disruption to native leaflets, annulus, RV function or conduction pathways
- Adjustable catheter system suspends coaptation valve between native leaflets

## Procedure

- Quick, predictable learning curve and procedure, with users consistently achieving optimized result
- Standard echo imaging

# TANDEM I FIH Trial

- **Design:** Prospective, non-randomized, multicentre study
- **Objective:** Demonstrate safety and effectiveness of the DUO Coaptation Valve System in patients with severe symptomatic TR
- **Investigators:** Professors Adam Witkowski, Wojciech Wojakowski, Dariusz Jagielak, Zenon Huczek
- **Trial Oversight:** Echo core lab, Clinical events committee, NCT05296148

Patients with severe+ symptomatic TR



DUO Coaptation Valve System



Primary Outcome Measures:

Safety: Freedom from device or procedure related SAEs at 30 days

Secondary Outcome Measures at 30 days, 3, 6, 12 & 24 Months

- Reduction in TR Grade as assessed by echocardiography
- Improvement in NYHA Functional Class
- Improvement in 6MWT
- Improvement in KCCQ

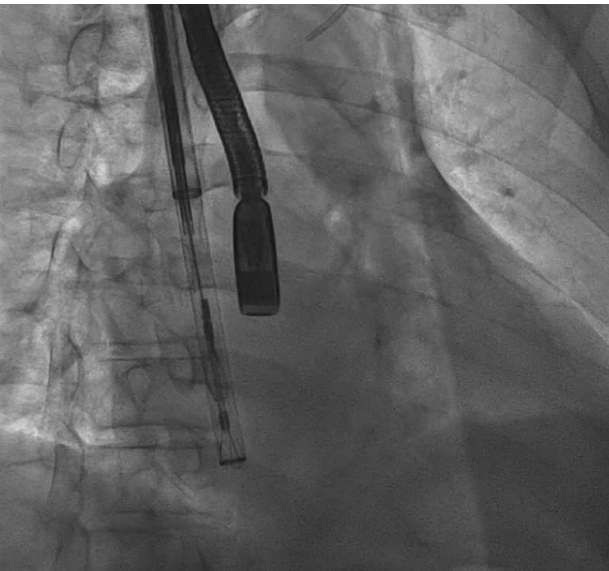
| Patient Demographics                   | N = 10     |
|----------------------------------------|------------|
| Age (years)                            | 77 (71-84) |
| Female                                 | 90%        |
| NYHA Class III or IV                   | 100%       |
| HFH in prior 12 months                 | 50%        |
| Massive/ Torrential TR                 | 70%        |
| LVEF (%)                               | 49 (43-56) |
| Annular Diameter (mm)                  | 52 (43-69) |
| Atrial Fibrillation                    | 100%       |
| Previous Left-Sided Valve Intervention | 40%        |
| Renal Insufficiency                    | 60%        |

# Procedure Characteristics

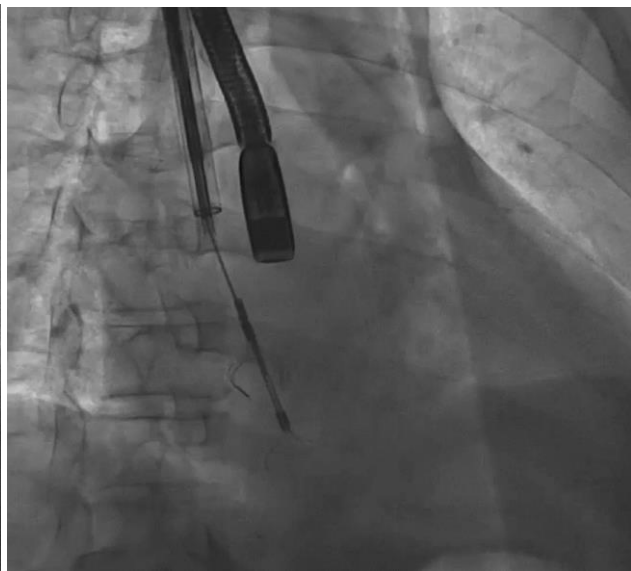
## Easy to Use

- Quick, predictable learning curve & procedure
- Users achieve consistent outcomes
- Standard echo imaging

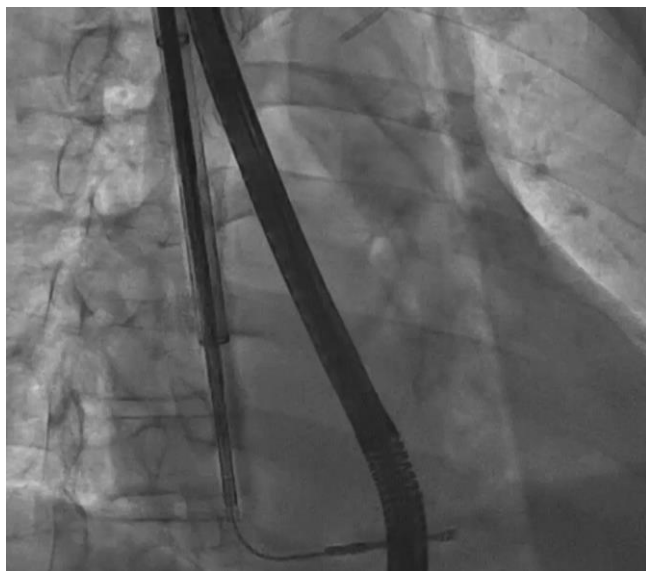
|                    | % or Mean (Range) |
|--------------------|-------------------|
| Device Time (mins) | 43 (34 – 58)      |
| Sites/Operators    | 4                 |



1. Coaptation Valve deployed



2. Coaptation Valve positioned across TV



3. Stent deployed to planned position in SVC



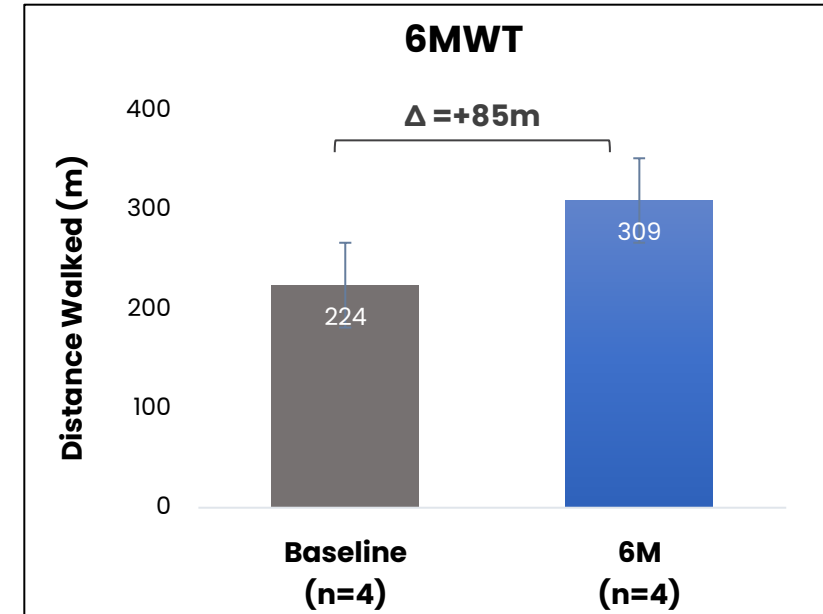
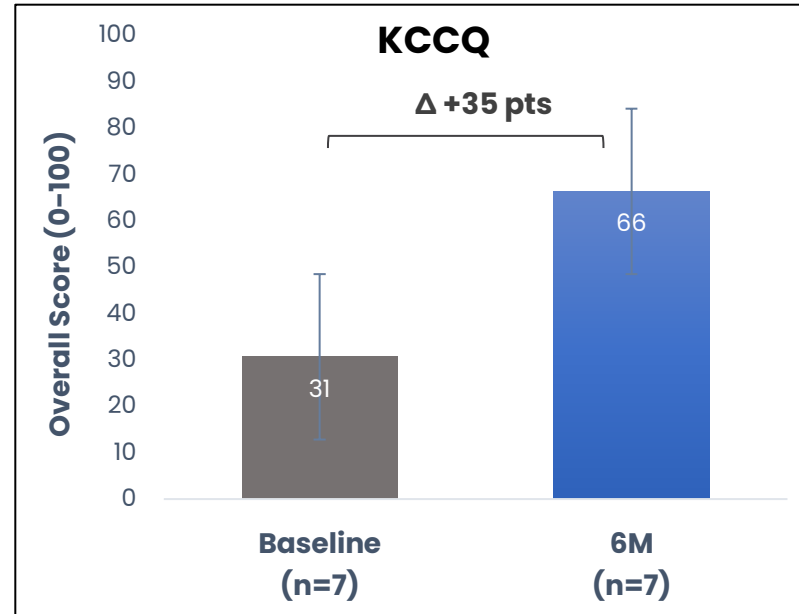
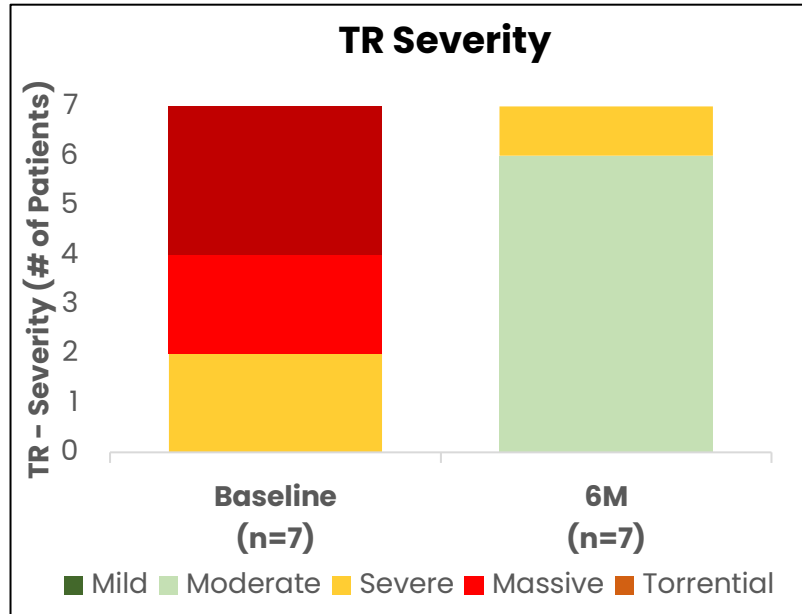
4. Valve position optimized for efficacy

# Safety

- No incidences of major bleeding
- No incidences of PPM demonstrating advantage of avoiding right heart contact
- 2 reinterventions: one off events due to initial learnings of fitment with human anatomy addressed through pre procedural planning and sizing updates

| Major Adverse Events at 30D                  | N |
|----------------------------------------------|---|
| Death                                        | 0 |
| Reintervention                               | 2 |
| 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 |

# Efficacy at 6 Months





# Reverse Remodelling

## Supports Natural Reverse Remodelling

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

|          | RV ED Vol (ml)  | RV ES Vol (ml)  | RV Stroke Vol (ml) |
|----------|-----------------|-----------------|--------------------|
| Baseline | 234 ± 55        | 106 ± 33        | 128 ± 33           |
| 30 days  | 197 ± 49        | 93 ± 27         | 104 ± 26           |
| Change   | <b>-37 ± 44</b> | <b>-14 ± 22</b> | <b>-24 ± 36</b>    |

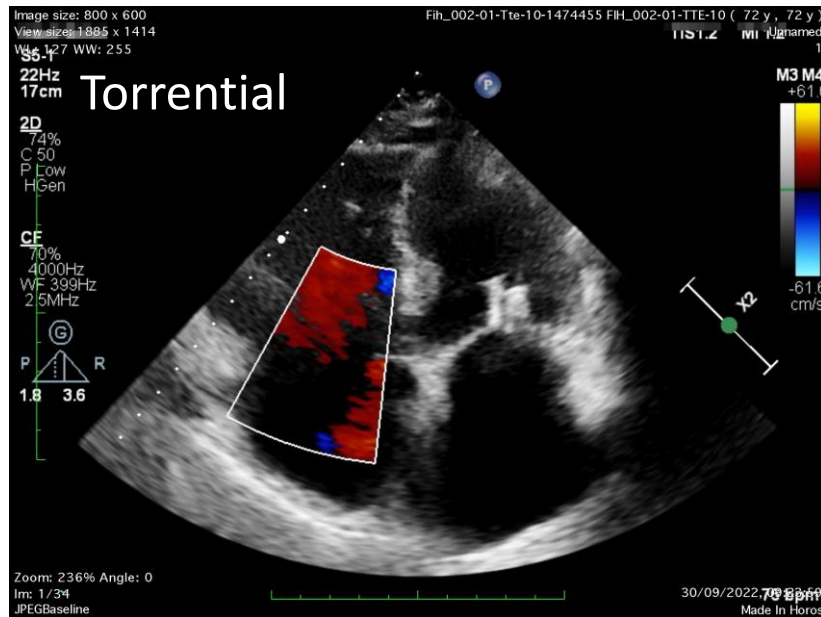


Systole (Pre-Implant)  
Systole (30D FU)

# Sustained Outcomes Through 1-Year Follow Up

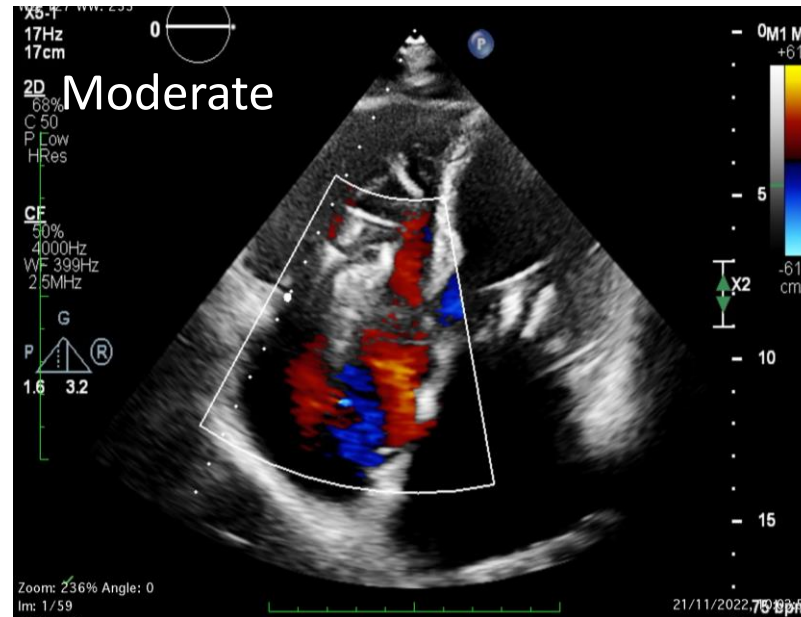
## 75-year-old Female with Torrential TR

Baseline



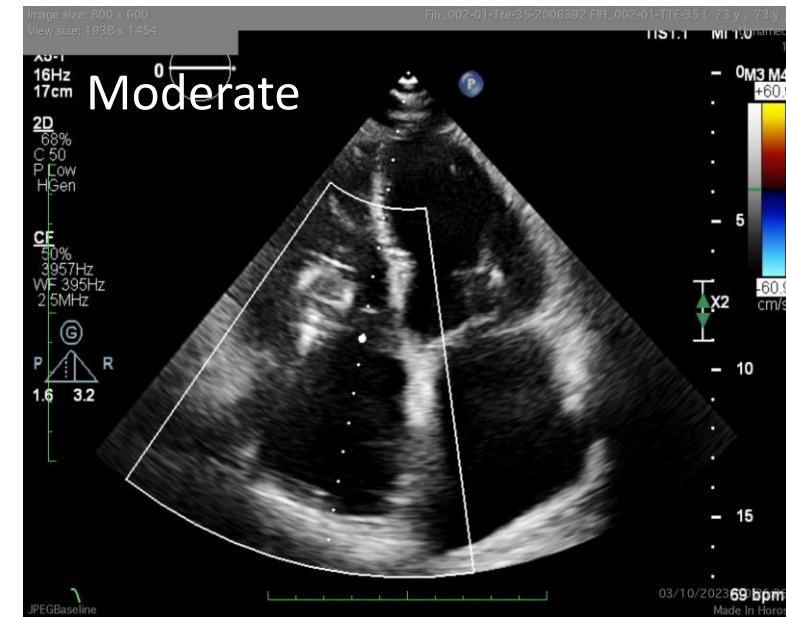
- NYHA Class III
- 6MWT: 201 m
- KCCQ: 19

30D



- NYHA Class II
- 6MWT: 360 m
- KCCQ: 62

1 Year



- NYHA Class II
- 6MWT: 425 m
- KCCQ: 74

# Conclusion

## Positive Clinical Outcomes

- Significant QoL improvements
- No interference with right heart function: disruption of leaflets, annulus, RV or conduction system
- Stable long-term position and device function
- Supports natural reverse remodeling, without structural interference or impact on device function

## Universally Applicable

- Independent of annular diameter, coaptation gap, leaflet morphology and visibility
- Offering a simplified procedural & imaging experience that is intuitive and predictable
- Users consistently achieve predictable results

PCR

PCRonline.com