Cephea TMVR Program
Technology and Clinical Update

Juan F. Granada, MD
Cardiovascular Research Foundation
New York

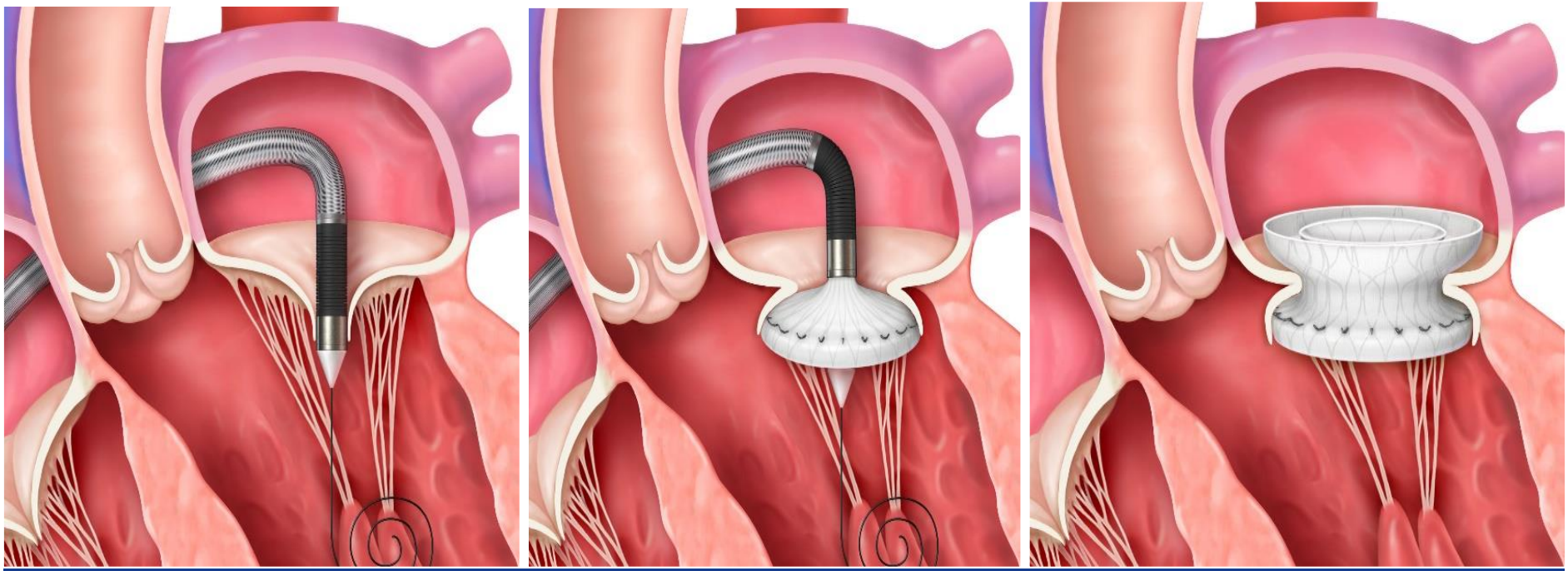
CRF®
NEW YORK VALVES
THE STRUCTURAL HEART SUMMIT

Disclosure Statement of Financial Interest

Within the past 12 months, I, or my spouse/partner, have had a financial interest, arrangement, or affiliation with the organization(s) listed below.

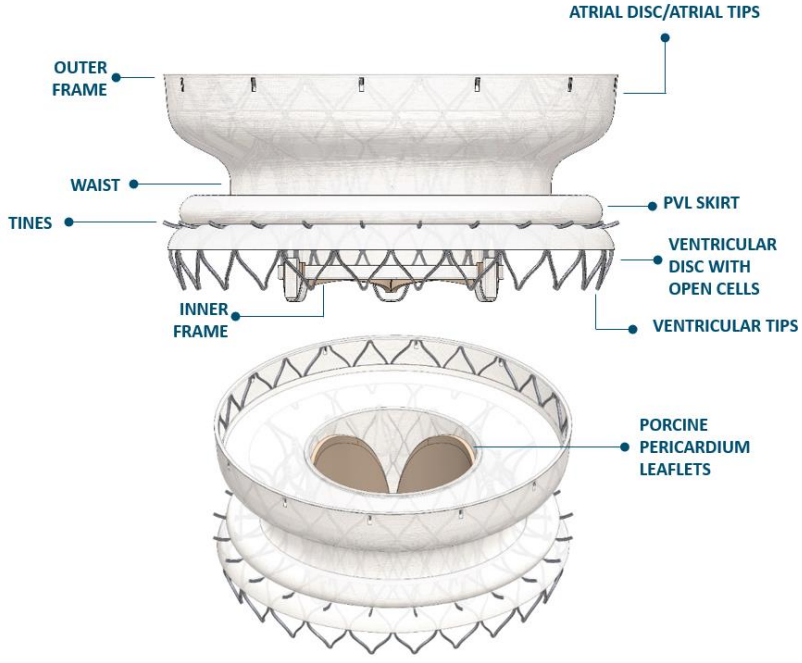
Affiliation/Financial Relationship	Company
Institutional Grant/Research Support	Abbott, BSCI, Medtronic, Edwards
Co-Founder	Cephea Valve Technologies (Abbott)

Cephea™ TMVR: Single-Step Procedure



Percutaneous, Trans-Septal Procedure, No Rapid Pacing Needed

Gen 2 Cephea™ Mitral Valve



SELF-EXPANDING RADIALLY SYMMETRIC NITINOL DUAL FRAME

- Outer frame for anchoring
- Inner frame to support leaflets
- **28,32,36 and 40-mm**

TRI-LEAFLET PORCINE PERICARDIUM BIOPROSTHESIS

- Valve stored dry
- No glutaraldehyde storage

SHAPE SET PET SKIRT

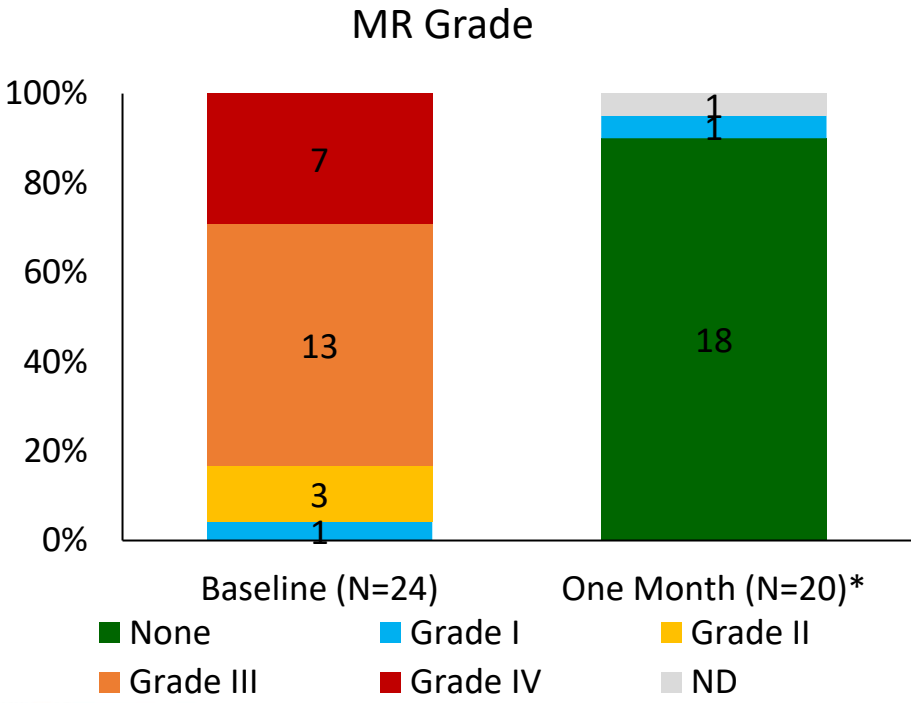
- PVL reduction skirt
- Open ventricular cells

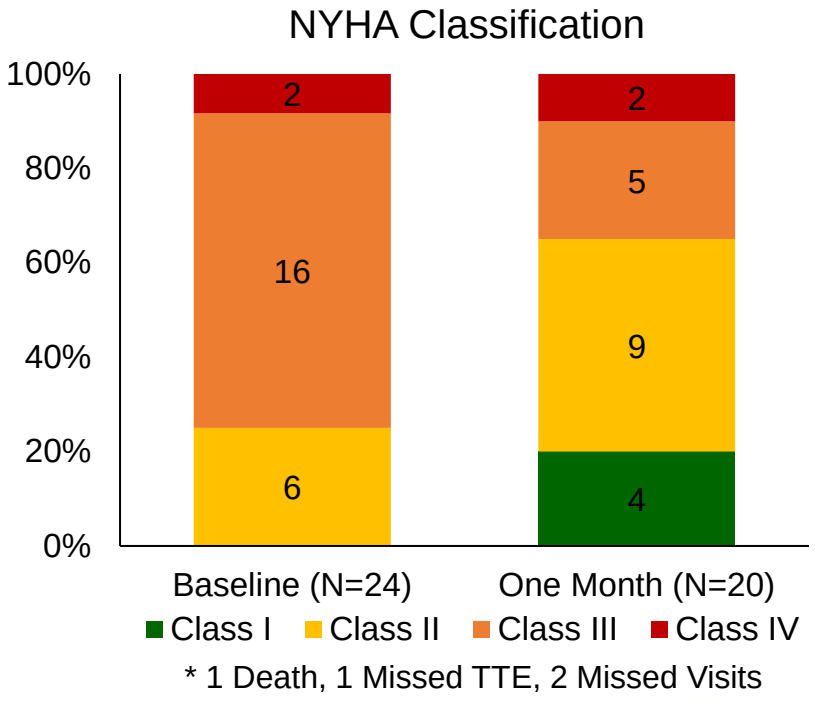
Gen 2 Cephea™ Valve: EFS Experience
Demographic Characteristics

Subject Characteristics (N=24)	n (%)
Age (yrs)	75.0 ± 7.5
Female – no. (%)	15 (62.5)
NYHA Functional Class III/IV	18 (75.0)
ESRD (eGFR < 30 or dialysis)	3 (12.5)
Mean MVG	5.5 ± 3.7
LV Ejection Fraction (%)	53.7 ± 11.6
EFT Score ≥ 2	8 (33.3)
STS-PROM (%)	5.9 ±2.7

Mitral Valve Dysfunction (N=24)	n (%)
Mitral Regurgitation (Grade 3+/4+)	22 (91.7)
▪ Primary	11 (45.8)
▪ Secondary	9 (37.5)
▪ Mixed	2 (8.3)
Isolated Mitral Stenosis (MVA <1.5 cm^2)	1 (4.2)
Mixed Valve Disease (MR + MS)	1 (4.2)
Concomitant MAC	6 (25.0)

Gen 2 Cephea™ Valve: EFS Experience
MR Resolution and Functional Status (30 Days)





Gen 2 Cephea™ Valve: EFS Experience
Procedural and 30-Day Events

Procedural Events (N=24)	n (%)
Valve implanted	23 (95.8%)
Conversion to Surgery	1 (4.2%)
Procedural Stroke	0 (0.0%)
LVOT Obstruction*	2 (8.3%)
Procedural PVL	1 (4.2%)
Procedural Mortality	0 (0.0%)
iASD Closures	3 (12.5%)

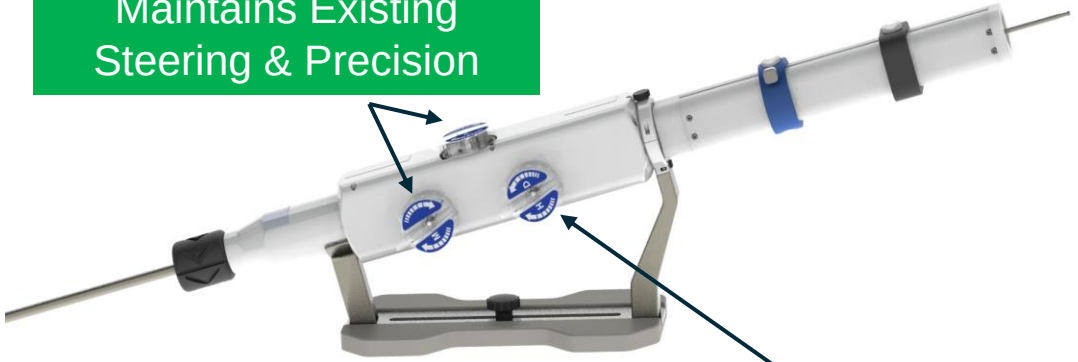
*Post-procedural increase in LVOT gradient successfully treated with ETOH ablation (MS and MAC).

30-Day Adverse Events (N=24)	n (%)
Any Mortality	1 (4.2%)
Cardiovascular Mortality	1 (4.2%)
Disabling Stroke	0 (0.0%)
Reintervention for MV	0 (0.0%)
Myocardial Infarction	0 (0.0%)
Atrial Fibrillation (new or worsening)	2 (8.3%)
Cardiac Injury*	2 (8.3%)
Endocarditis	0 (0.0%)
Hematoma (Non-Surgical)	2 (8.3%)

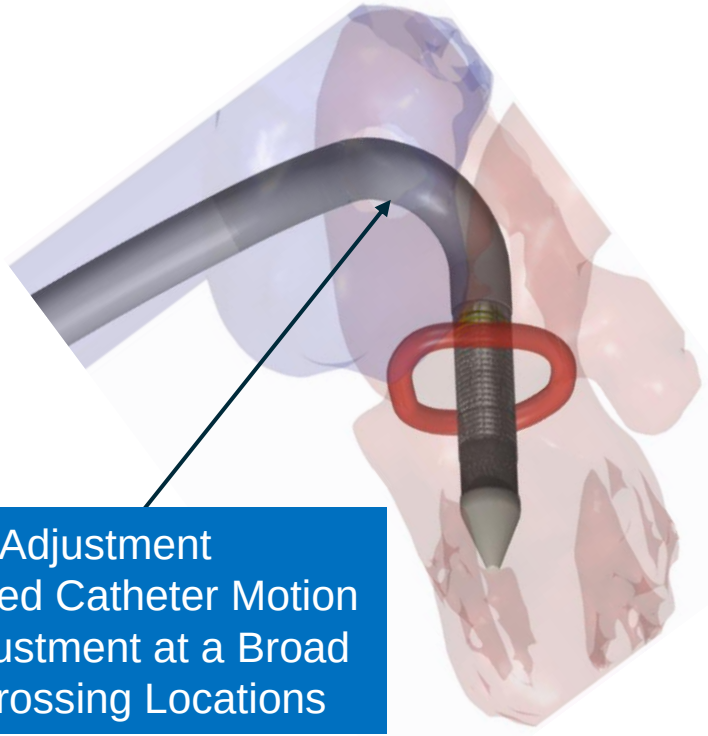
*Incidental partial chordal disruption seen in follow-up echo.

Gen 3 Cephea™ Delivery System

Maintains Existing Steering & Precision



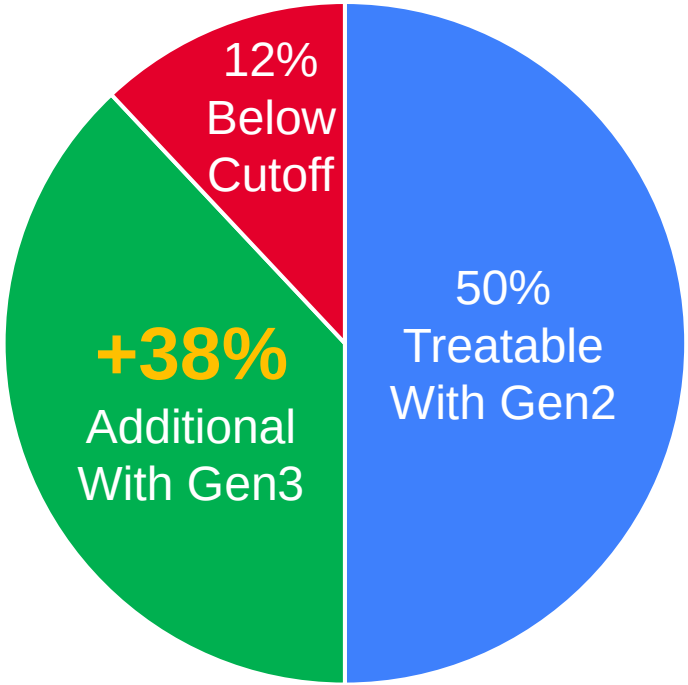
Enhanced Stabilizer
75% Weight Reduction



Height-Depth Adjustment
New Axis of Controlled Catheter Motion
Allows Position Adjustment at a Broad Range of Septal Crossing Locations

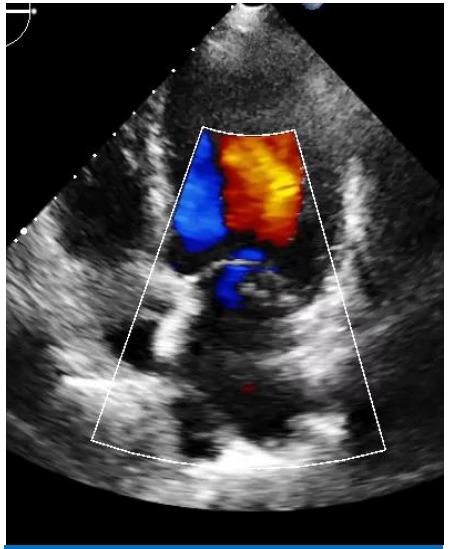
Gen 3 Cephea™ Delivery System
Projected Impact on Patient Screening

- Low septal height was one of the leading causes of screen failure
- Half of the submitted cases were excluded due to inadequate septal height
- The Gen 3 catheter enables treatment of nearly all patients with respect to septal height

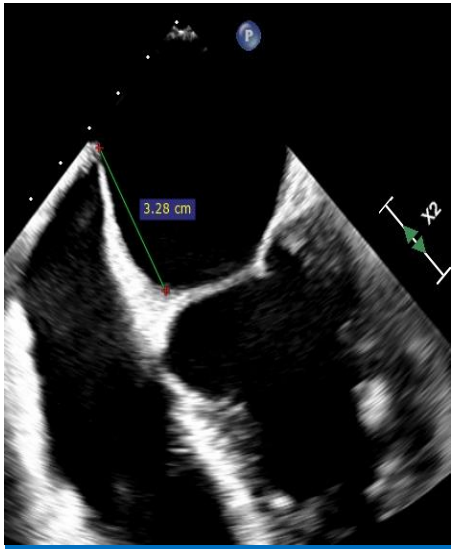


Early Cephea™ Gen 3 Clinical Experience
South America Feasibility Study

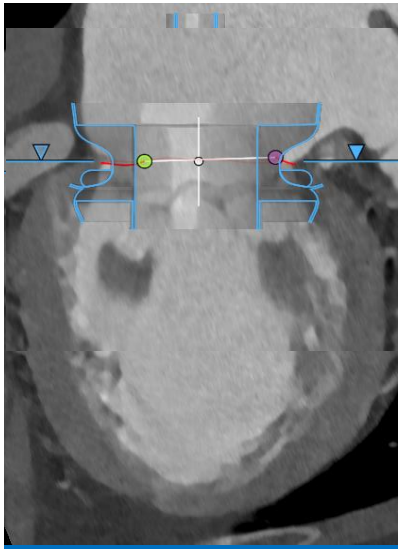
Age	80
Gender	F
MV Disease	4+ SMR
LVEF	32%
LVEDD	5.7 cm
MVA	2.5 cm^2
NYHA	II
STS-PROM	3.3



LOW EF
Hemodynamic Stability



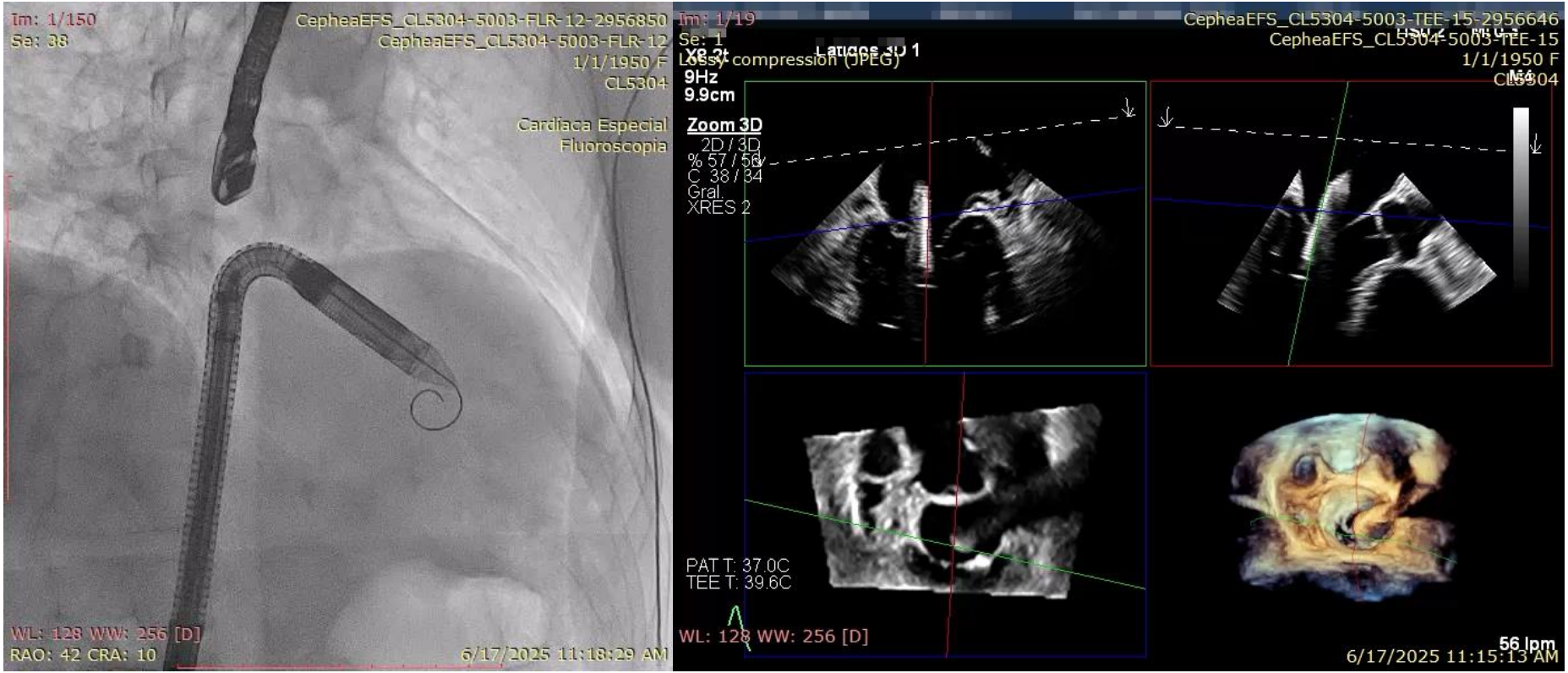
LOW SEPTAL HEIGHT
Depth Control



HIGH PAPILLARY
Precise Delivery

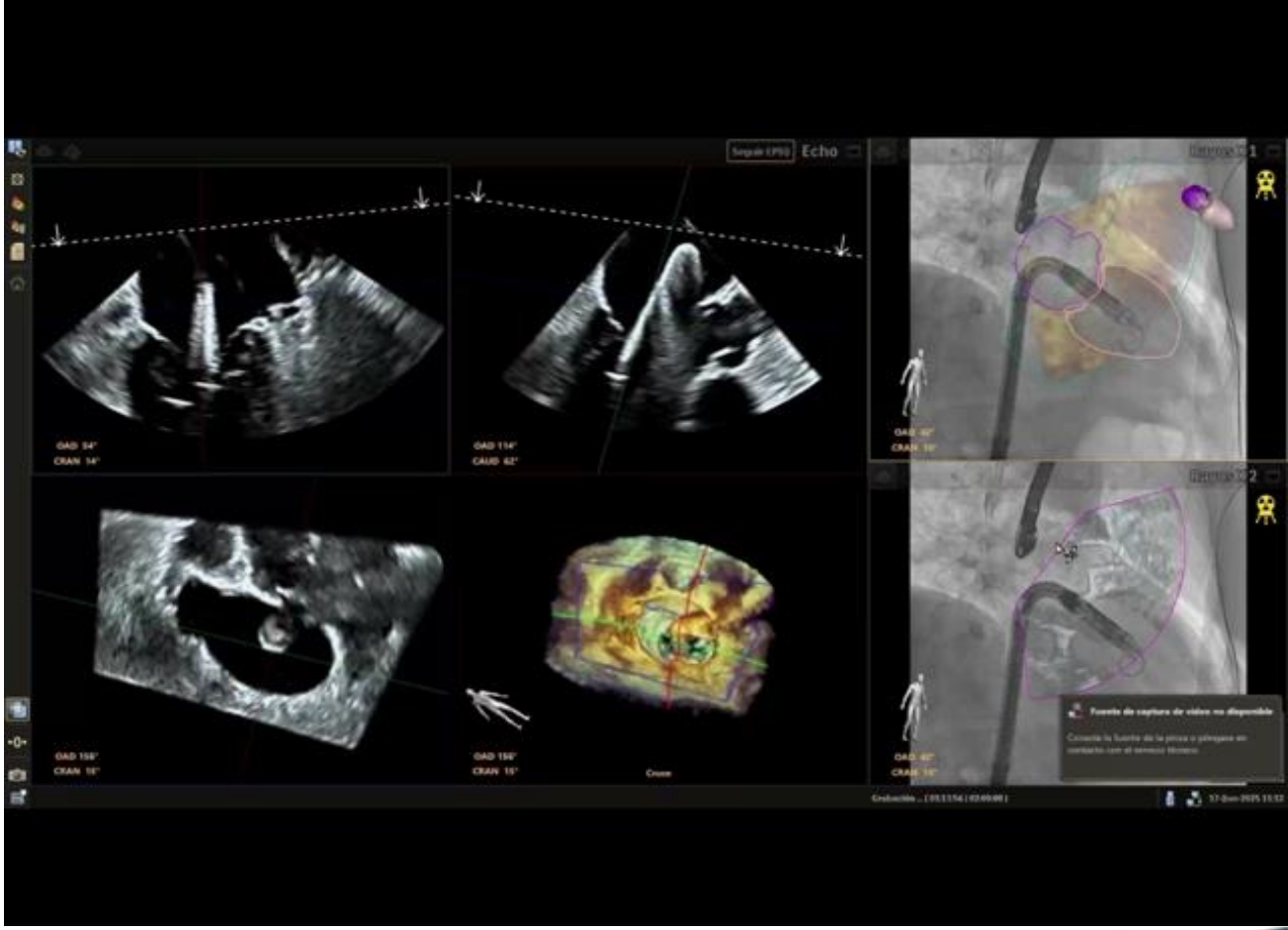
c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

Cephea™ Gen 3: Capsule Separation



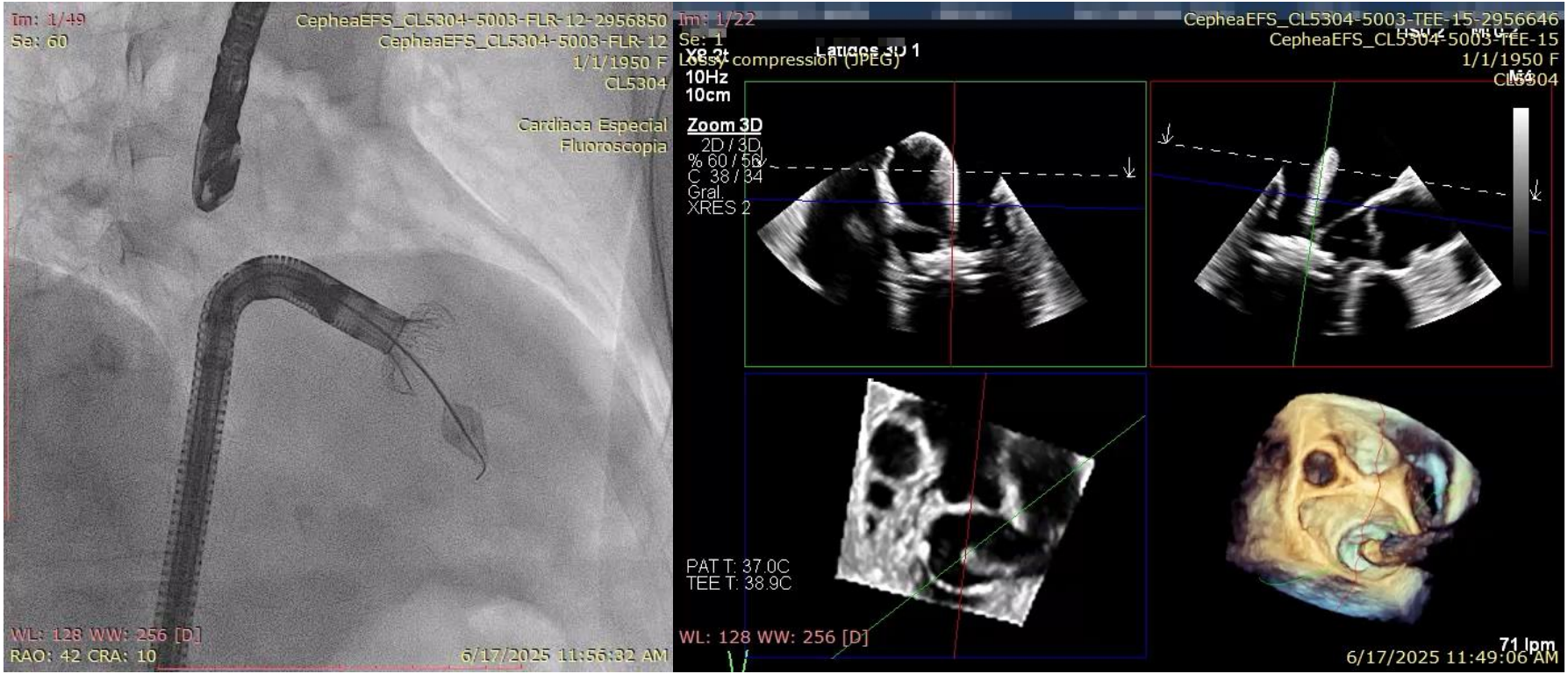
c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

Cephea™ Gen 3: Trajectory and Depth Correction



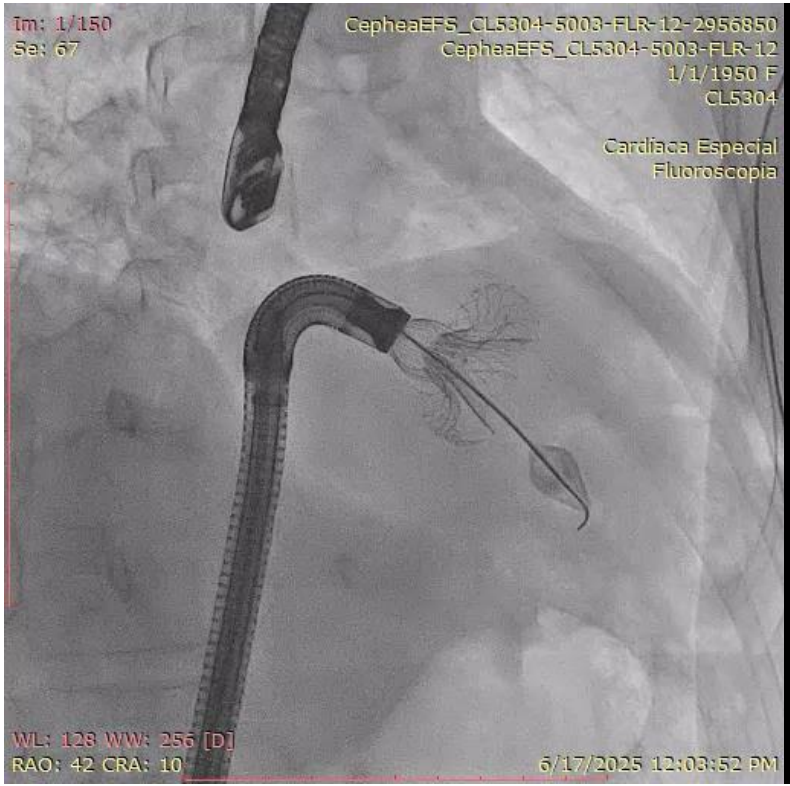
c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

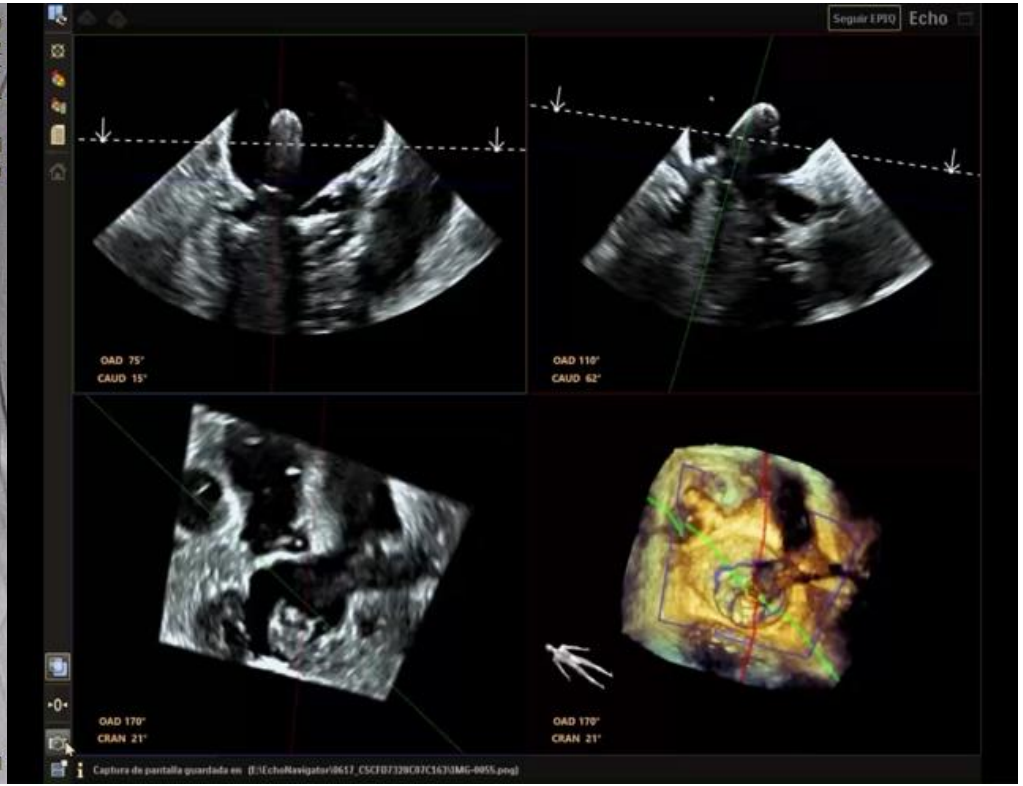
Cephea™ Gen 3: Second Position



c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

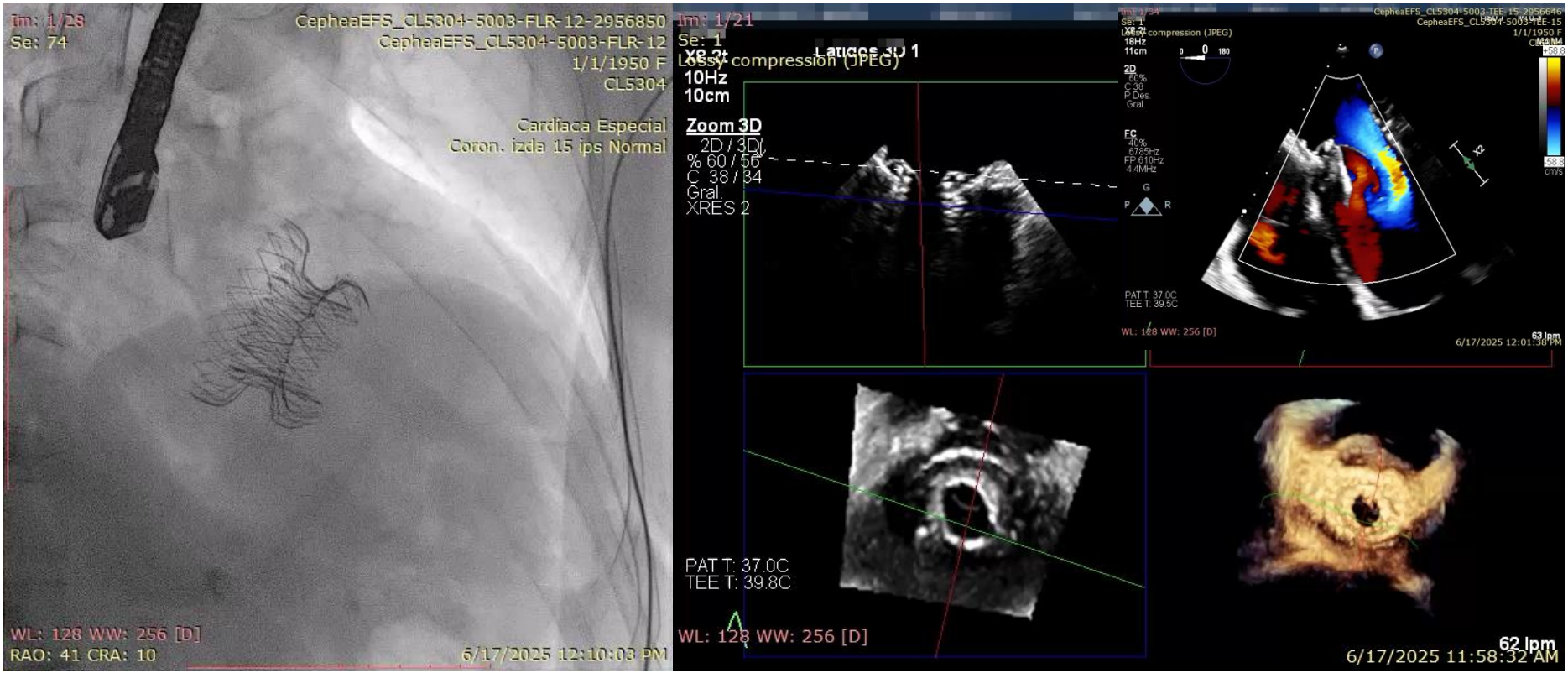
Cephea™ Gen 3: Valve Deployment





c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

Cephea™ Gen 3: Final Result



c/o Sandoval J. Instituto Nacional del Torax (Santiago, Chile)

Cephea TMVR: Program Update

- EFS experience using the second-generation Cephea TMVR system demonstrated:
  - The ability to treat a broad range of complex anatomies
  - High technical success rate (97%) and no major vascular complications or procedural mortality
- Third-generation delivery system and expanded valve sizes are designed to improve patient eligibility and treat more challenging anatomies
- Global EFS to transition into the U.S. pivotal study in 2026