Early Human Experience with the Trans-Septal Saturn TMVR System

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on behalf of the CASSINI investigators

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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:

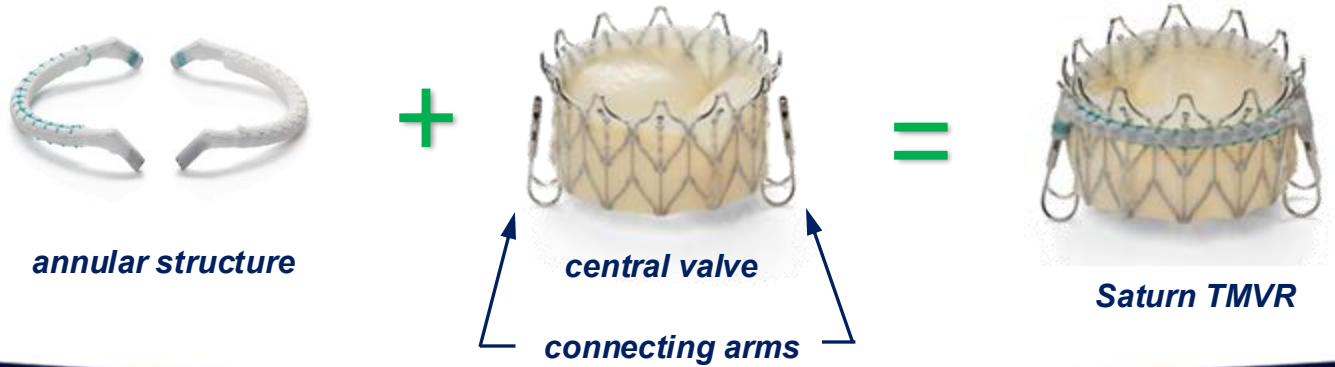
Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Edwards Lifesciences, Boston Scientific, Medtronic, JenaValve
Consultant Fees/Honoraria	4C Medical, Abbott, Innovheart, Philips
Individual Stock(s)/Stock Options	NA
Royalties/Patent Beneficiary	NA
Executive Role/Ownership Interest	NA
Other Financial Benefit	NA

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

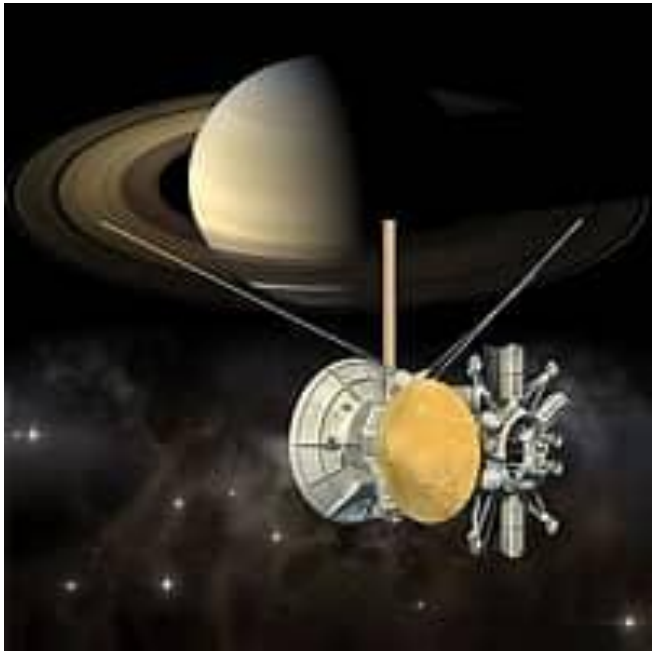
SATURN TMVR

The Saturn TMVR is a two component system with an ***interlocked*** design which includes:

- an **annular structure**, intended to be positioned behind the native mitral leaflets, to reshape and stabilize the MV annulus
- a **central valve**, intended to be expanded inside the mitral orifice
- a **set of connecting arms**, to provide mechanical ***bond*** between the valve and the annular structure



InnovHeart's SATURN TMVR CASSINI Studies



- After completing the SATURN TA study of 5 subjects with 2-year follow-up, InnovHeart initiated the TS CASSINI-EU study (N=30)
- The CASSINI-US study (N=15) is expected to start by end of 2025



CASSINI-EU Study


Study Overview	
Purpose	To evaluate feasibility, safety, and performance of the SATURN TS TMVR System for the treatment of moderate-to-severe or severe, symptomatic mitral regurgitation through a transcatheter, trans-septal approach
Trial Design	A prospective, multi-center, single-arm, non-blinded feasibility study.
Scope	Up to 30 subjects treated at 10 sites in Europe (Lithuania, Poland, Georgia, Italy and UK)
Primary Endpoints	1. Technical Endpoint: Technical implant success at exit from procedure room 2. Safety Endpoint: Freedom from device-related, major adverse events at 30D 3. Performance Endpoint: Reduction of MR Grade to ≤ 1+ at 30D
Secondary Endpoints	Reduction of MR grade compared to baseline, and freedom from associated hemolysis at 30D, 1Y and annually to 5Yrs.
Governance	• Subject Screening Committee • Echo Core Laboratory • CT Core Laboratory • Clinical Events Committee • Data Safety Monitoring Board

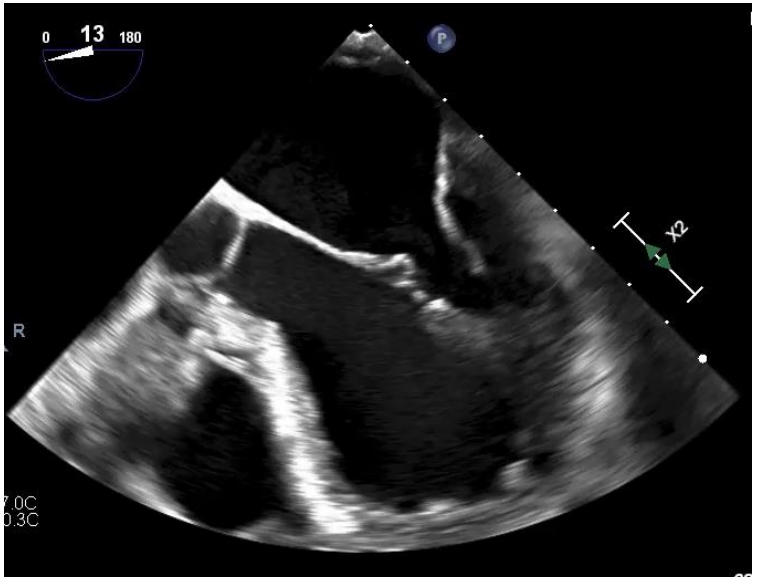
CASSINI-EU STUDY - *Key Inclusion and Exclusion Criteria*

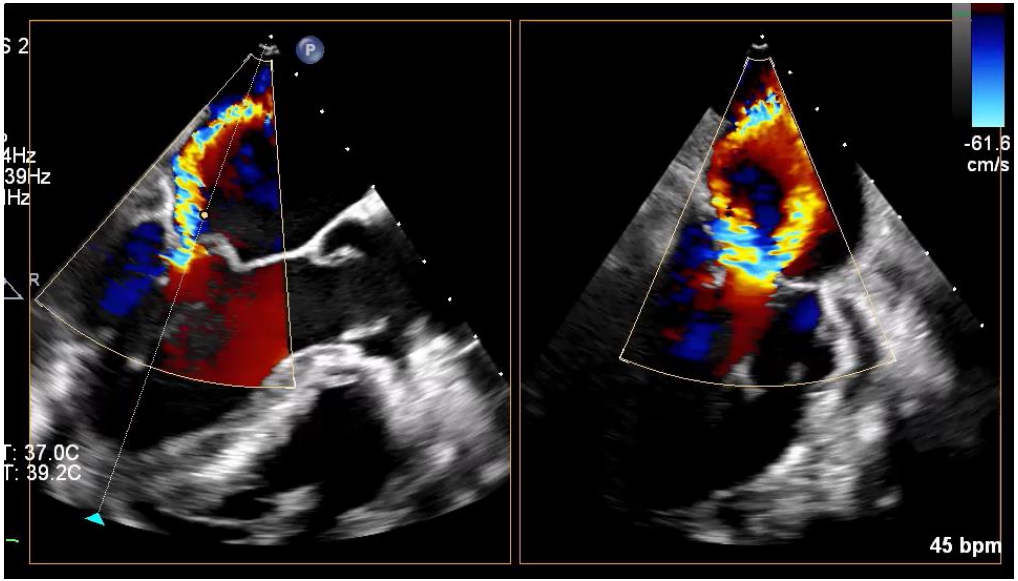
Inclusion Criteria	• 18 Years of age or older • Symptomatic, moderate-severe or severe functional or mixed mitral regurgitation (≥ Grade 3+) • NYHA functional Class ≥ II • High risk for open-heart mitral valve surgery, as determined by the Heart Team • Willing and able to provide informed consent
Exclusion Criteria	• Exclusively primary/degenerative mitral regurgitation • eGFR <30mL/min/m^2 • LVEF <30% • Severe MAC, severe stenosis, vegetation or mass • Prior mitral valve repair or replacement • Severe aortic regurgitation or stenosis • Prior surgical, mechanical or transcatheter aortic valve implant • Severe tricuspid regurgitation • Severe RV dysfunction • Inadequately treated for cardiac condition (e.g. CAD, LVD, MR, or HF) • Contraindications for TEE imaging • Active systemic infection or endocarditis within 3M of procedure • Life expectancy <1 year due to non-cardiac conditions

CASSINI-EU STUDY

Sites
Vilnius, Lithuania
Warsaw, Poland
Tbilisi, Georgia
Katowice, Poland
Milan, Italy
Brighton, UK

CAS 001-001 – *Preoperative echocardiography*

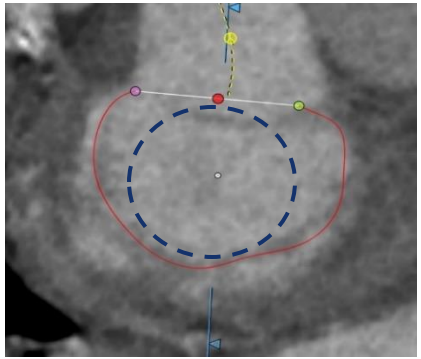


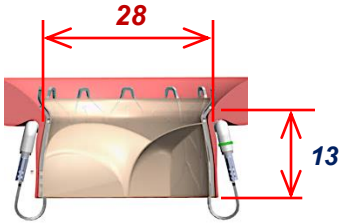


Severe MR – Mixed type II (predominant) and type IIIb, with A2-A1 prolapse and flail

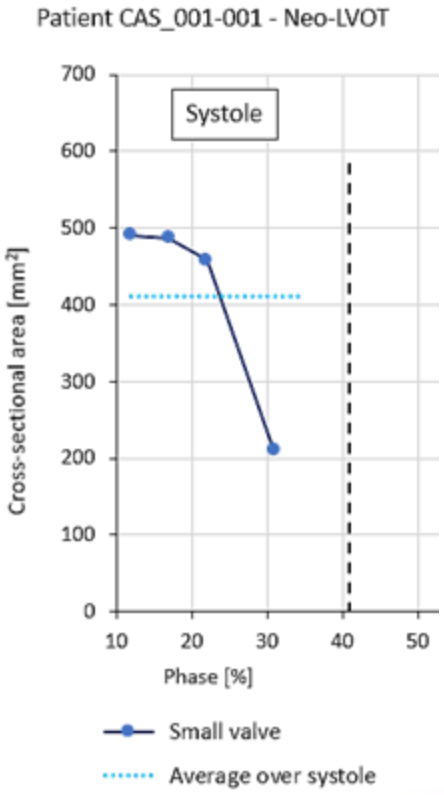
CAS 001-001 – *Preoperative planning*

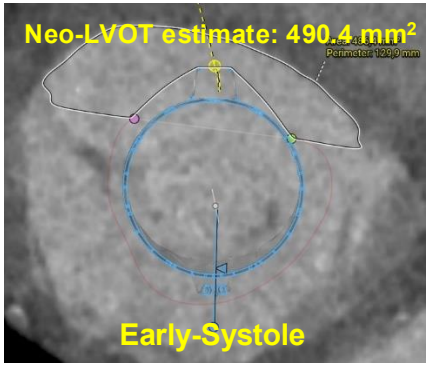
		ES	ED
D perimeter	mm	116.7	117.8
P Diameter	mm	37.1	37.5
A-P	mm	31.4	29.2
C-C	mm	37.5	40.3

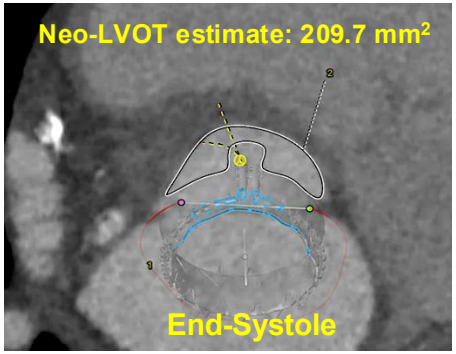




Annulus dimensions compatible with Saturn Small Size (28mm)

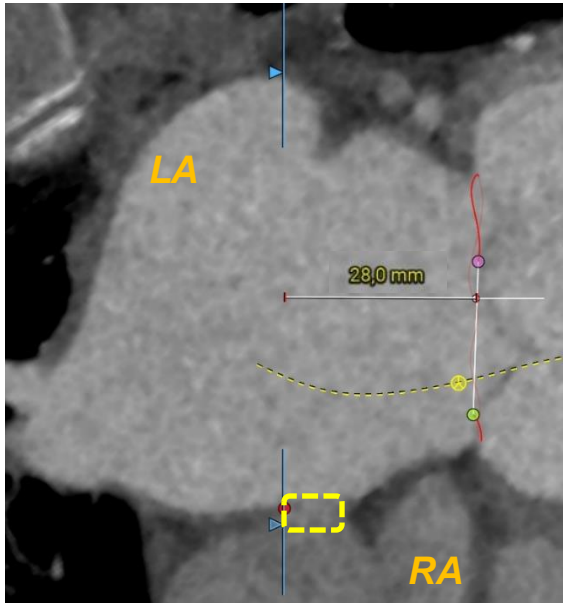


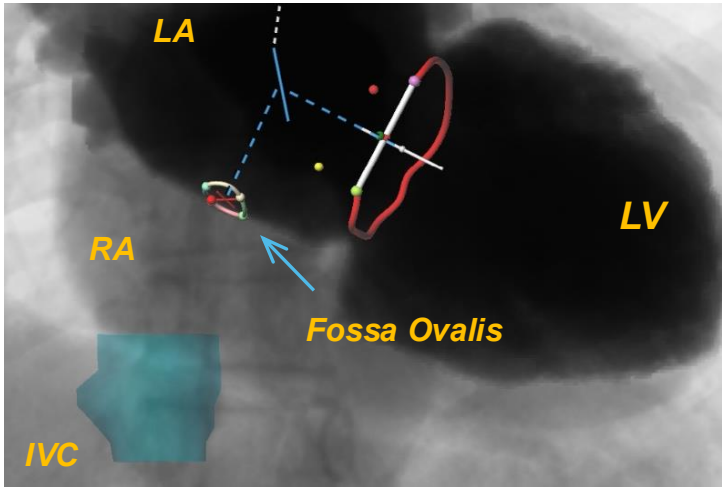


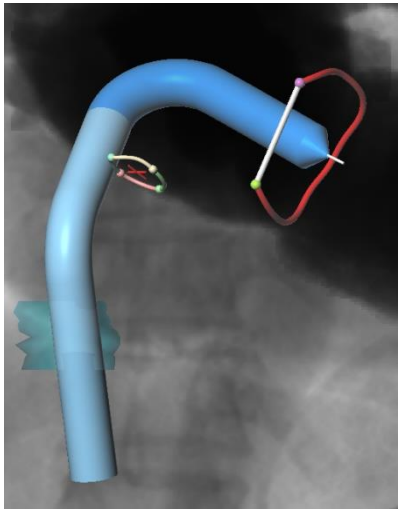


No risk of LVOTO

CAS 001-001 – *Preoperative planning*



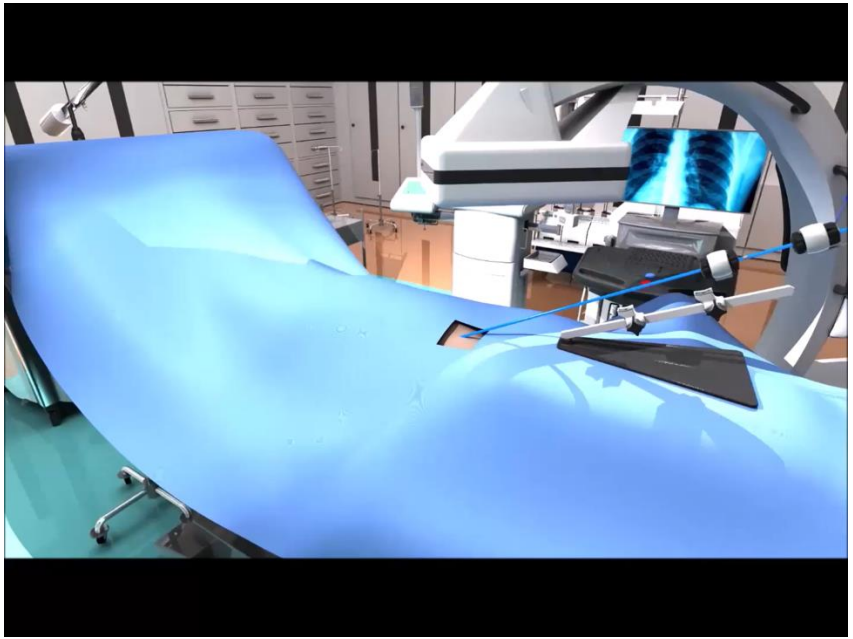




Fossa Ovalis Upper Rim		Height
End Systole	cm	2.8
End Diastole	cm	2.9

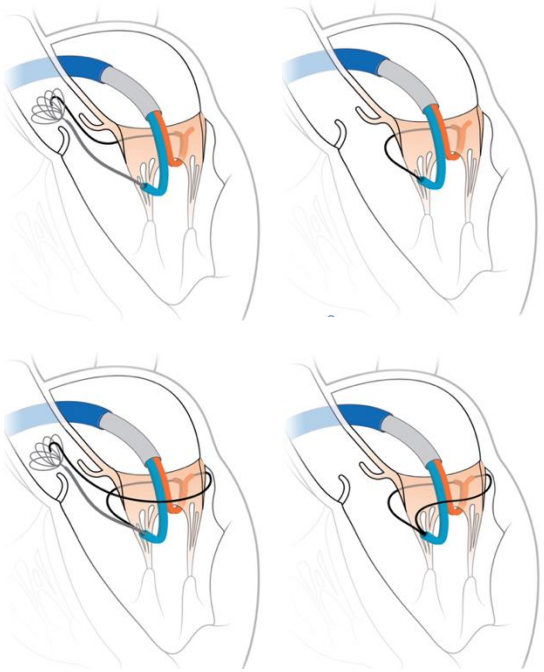
Small LA (height = 55mm) – Expected TSP height < 3 cm

CAS 001-001 – *Procedure*

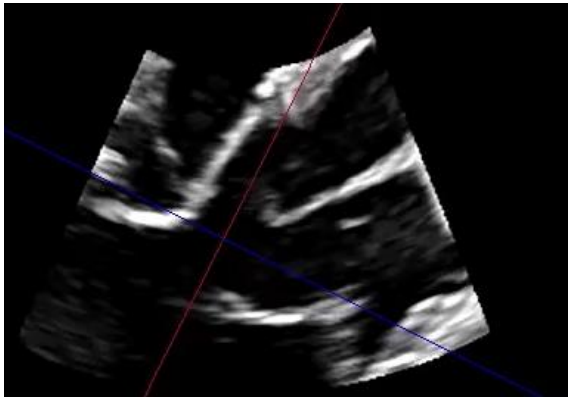


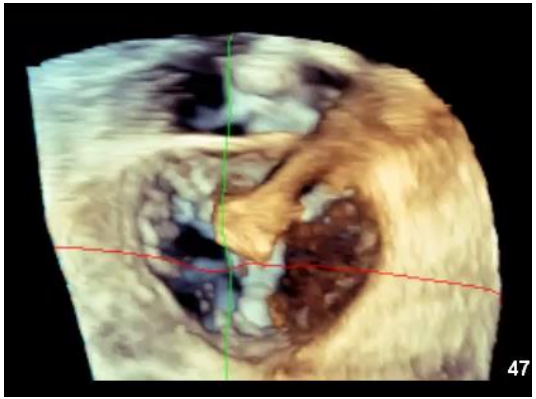
1. *Insert Delivery System and position GWDS in MV*
2. *Create Medial and Lateral Cable Loops*
3. *Introduce Annular Segments*
4. *Exchange GWDS for VDS and position VDS in MV*
5. *Connect Valve to Annular Segments*
6. *Withdraw Cables from System*
7. *Position & deploy Implant and withdraw DS*

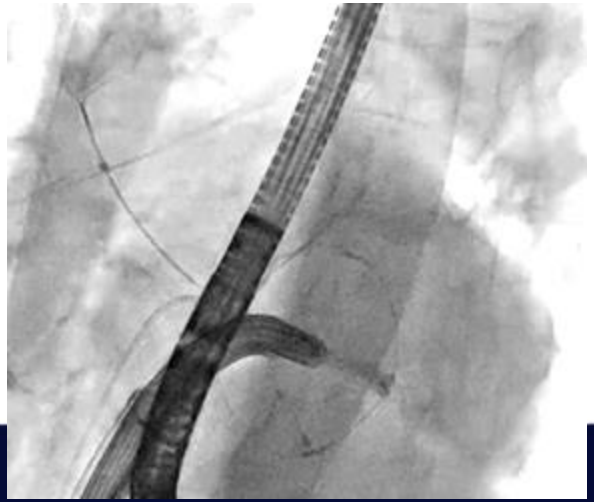
CAS 001-001 – *Procedure*

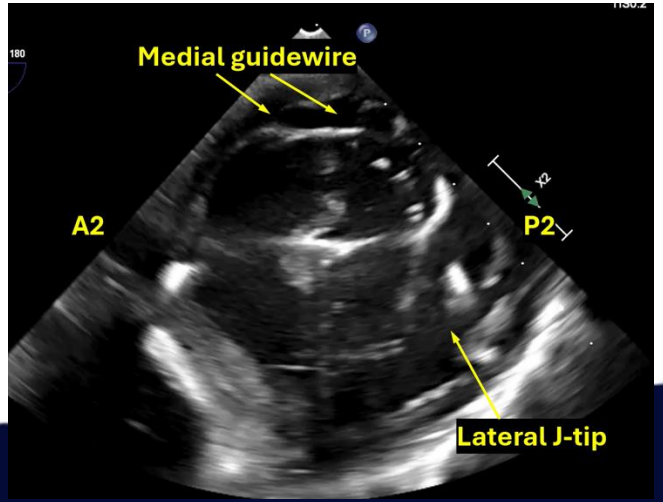


Two standard guidewires are inserted behind leaflets to embrace the native mitral valve

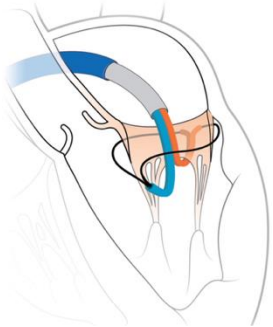


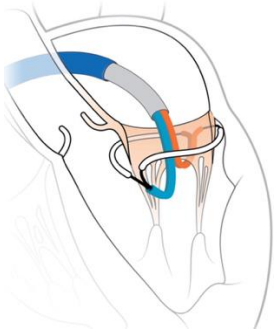




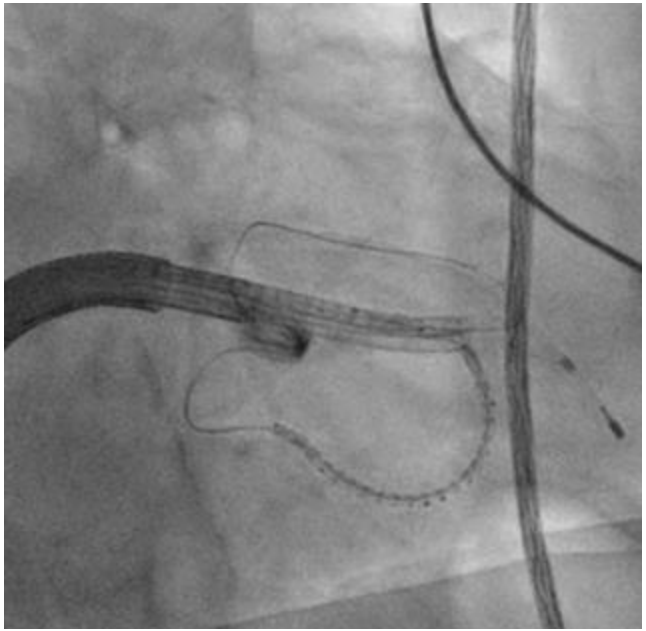


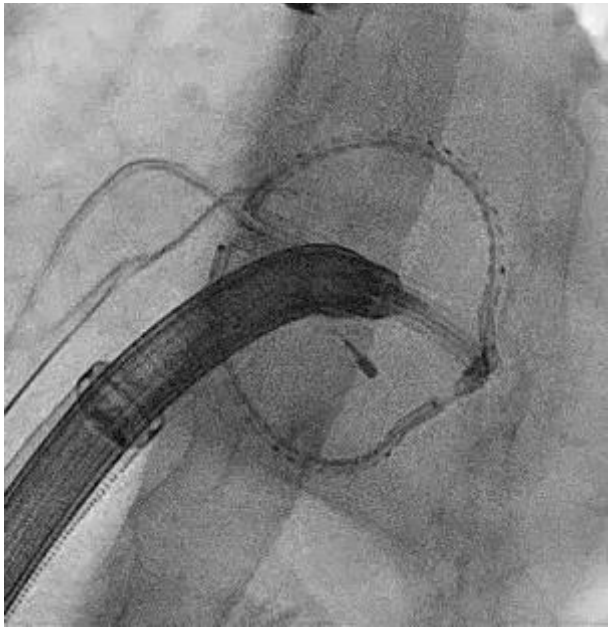
CAS 001-001 – *Procedure*



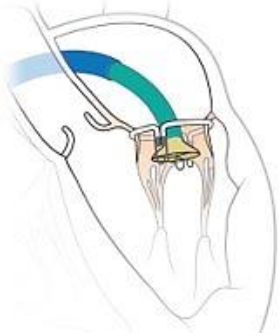


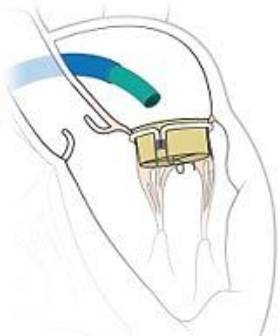
Annular segments are introduced over each wire and positioned behind the leaflets



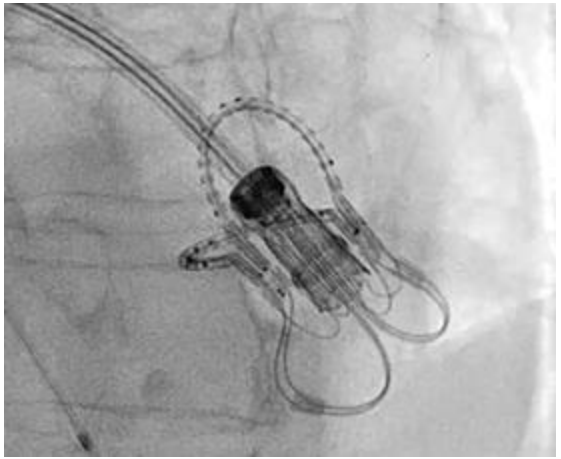


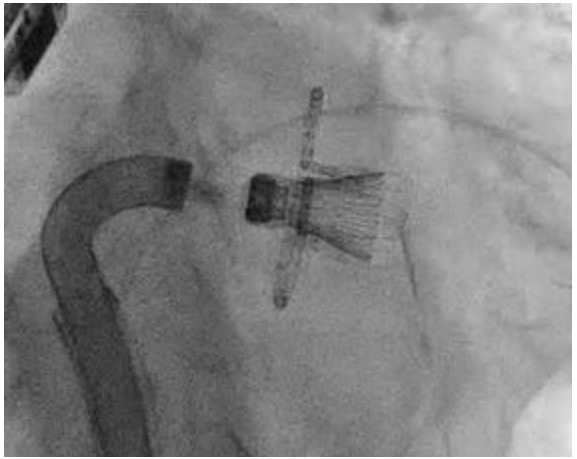
CAS 001-001 – *Procedure*

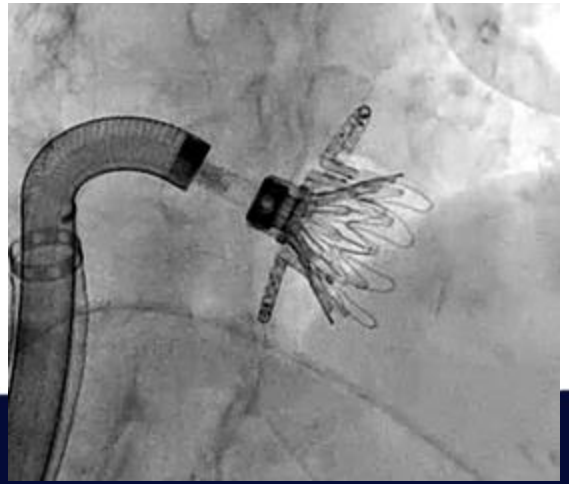


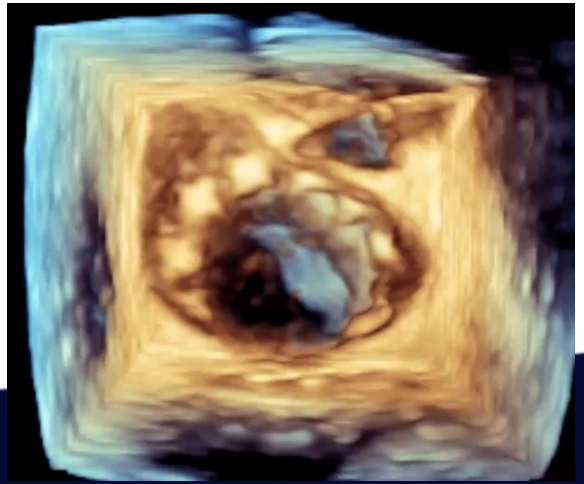


The central valve is connected to the annular segments and deployed, capturing the native leaflets between components

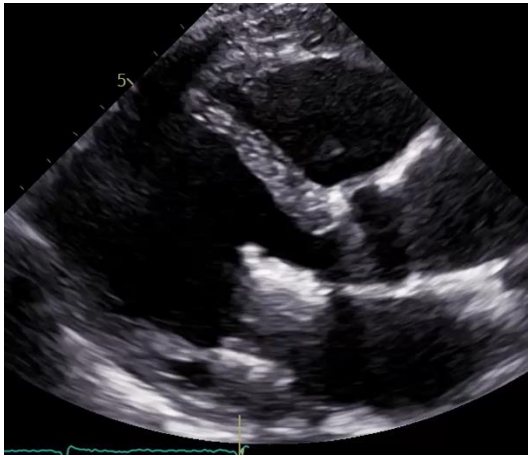


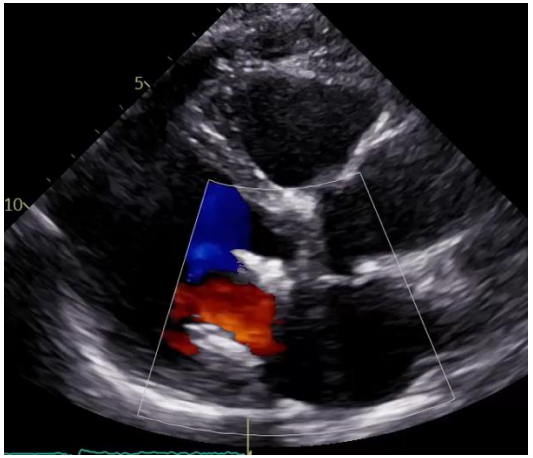


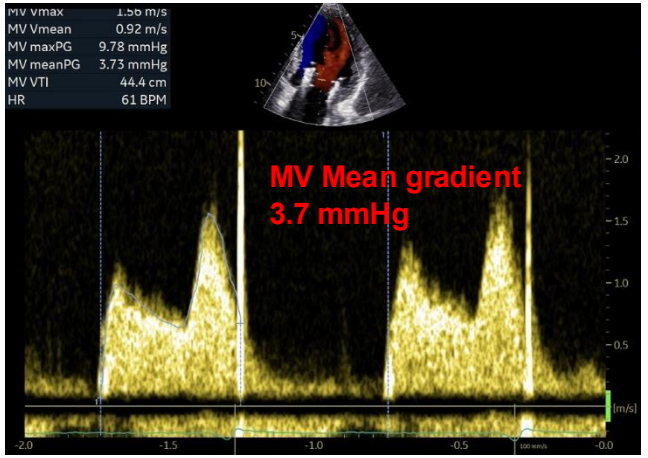


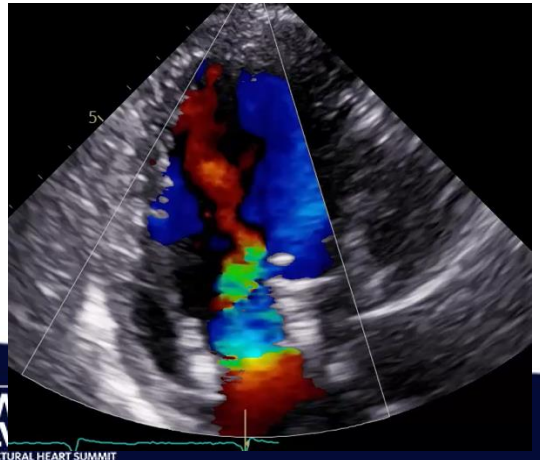


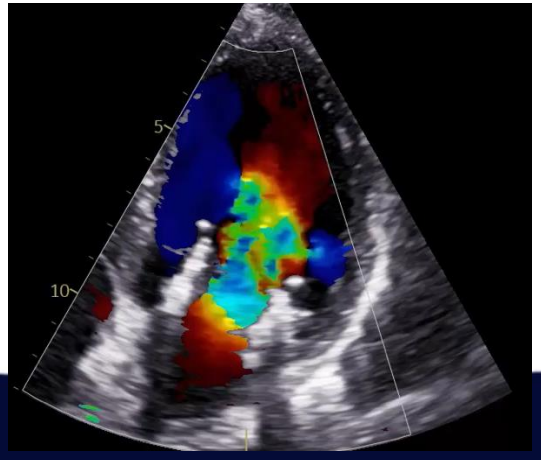
CAS 001-001 – *1 Year follow-up*

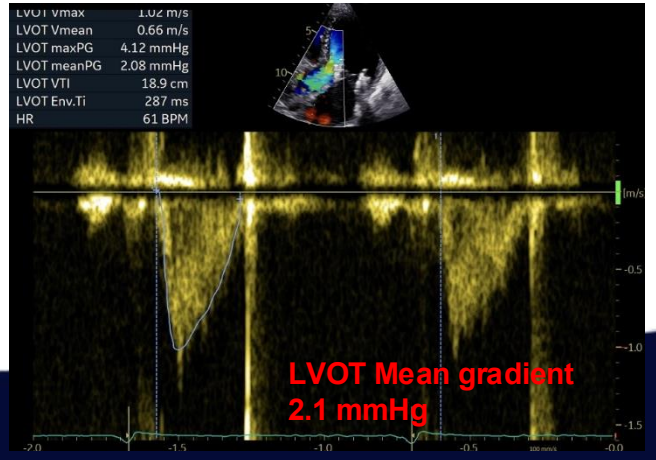








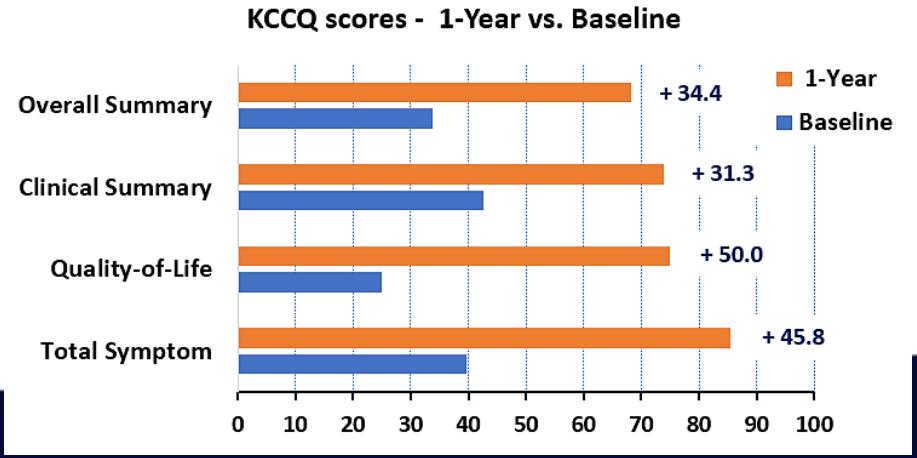




CAS 001-001 – *1 Year follow-up*

- No MR at any follow-up (1M, 3M, 6M, 1Y)
- No LVOT gradient
- No ASD closure

- Improved 6MWT (Baseline = 150m → 1 Year = 290m)
- Improved KCCQ Scores



Conclusions

- The transseptal SATURN system offers a novel solution for MR reduction and annular stabilization.
- The SATURN TMVR bioprosthesis has several unique advantages including:
  - Ability to resize the mitral annulus
  - Low profile (13 mm) in the LV, reducing the risk of LVOT obstruction
  - Anterior connecting arm immobilizes the anterior leaflet preventing SAM
- The safety and efficacy of the transseptal SATURN TMVR is now being evaluated in the CASSINI-EU EFS study
- 1-Year follow-up has been achieved for the first patient, confirming safety and performance in the mid term