

Fully Percutaneous Transseptal Delivery of the SATURN Transcatheter Mitral Valve Replacement Bioprosthesis in a Porcine Model

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Ineligible Company

Boston Scientific

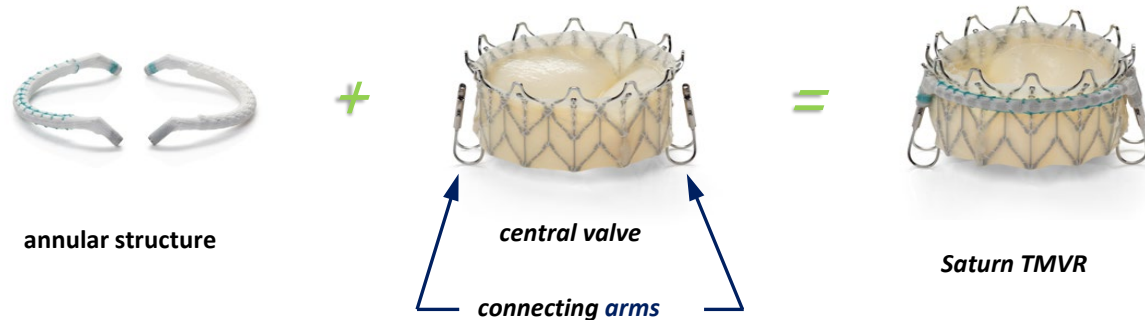
4C Medical, InnovHeart, Philips

All relevant financial relationships have been mitigated.

Faculty disclosure information can be found on the app

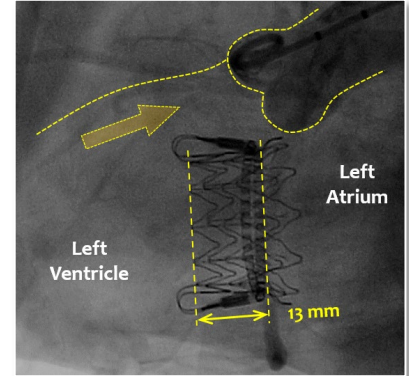
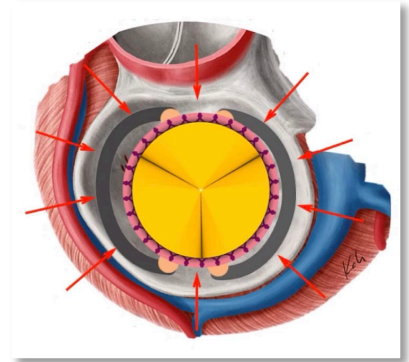
SATURN TMVR

- Transseptal TMVR is currently under investigation for high-risk patients with severe MR. Common reasons for screen failure include valve sizing and risk for LVOT obstruction.
- The SATURN valve is a TMVR system developed for transseptal and transapical delivery.
- The multicomponent design includes: (1) an annular structure positioned behind the native MV annulus, (2) a central valve that is expanded within the mitral valve orifice and (3) a set of connecting arms that provide mechanical continuity between the central valve and annular structure



SATURN Valve Unique Device Features

- Designed to **resize the mitral annulus** to more physiological dimensions.
- Provides long-term stabilization and minimizes risk of late paravalvular leak or migration.
- 28 mm and 31 mm valve sizes accommodate a broad range of annulus sizes.
- **Low-profile (13 mm) in the LV** to reduce the risk of LVOT obstruction.
- Anterior connecting arm immobilizes anterior leaflet preventing SAM.
- No atrial structure therefore avoiding flow turbulences.
- Same valve accommodates both TA and TS implantation.



SATURN TS Delivery System Components



33Fr (OD) Steerable Access Sheath

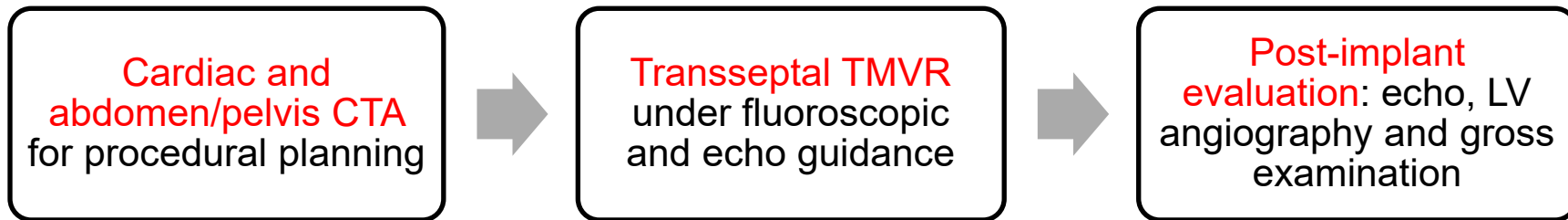
26Fr Steerable Guidewire Delivery System (GWDS)

29Fr Steerable Valve Delivery System (VDS)

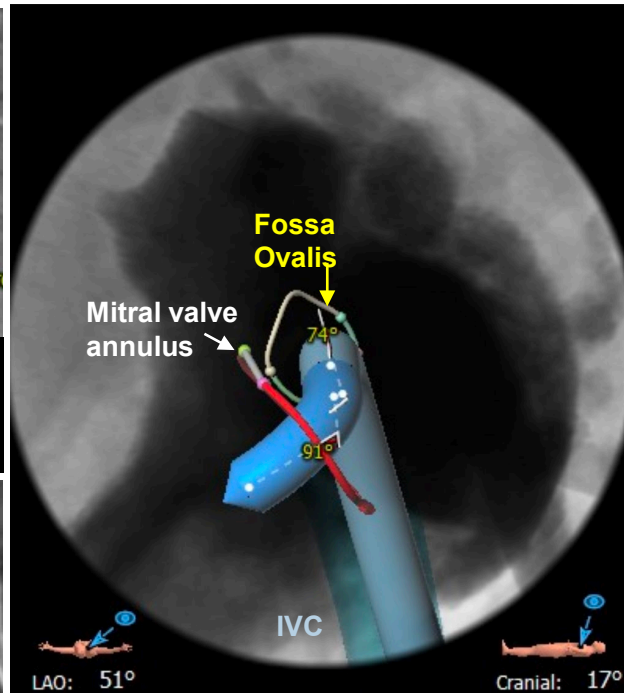
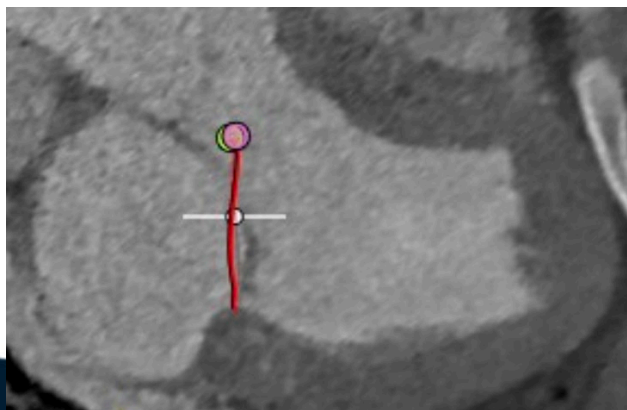
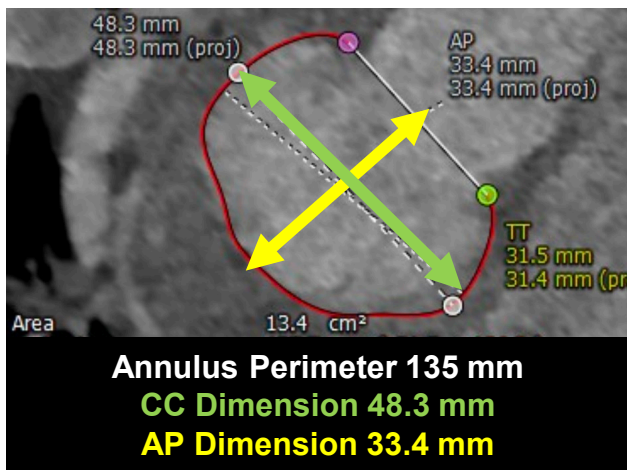
Methods

- **Study Aim:** to evaluate the feasibility of fully percutaneous transfemoral transseptal delivery of the SATURN valve in an acute porcine model.

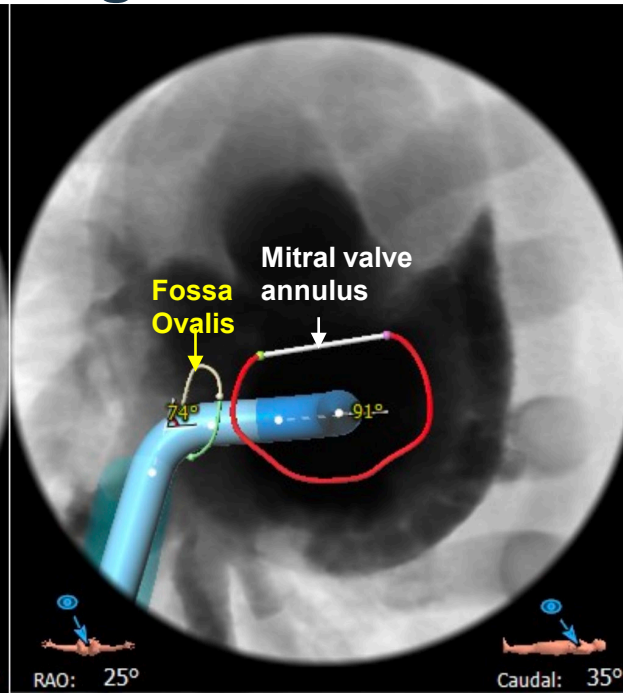
- **Study Flow:**



Pre-Procedural CT Planning



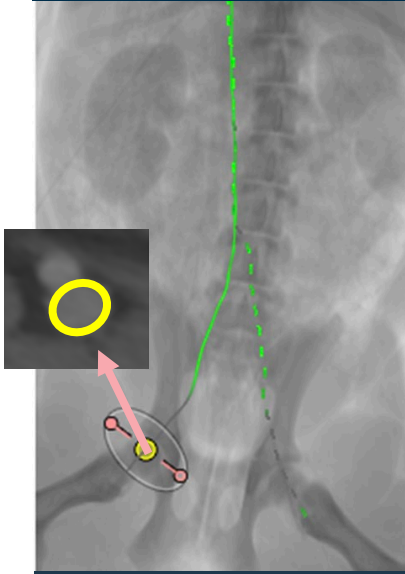
**3-Chamber
Deployment View**



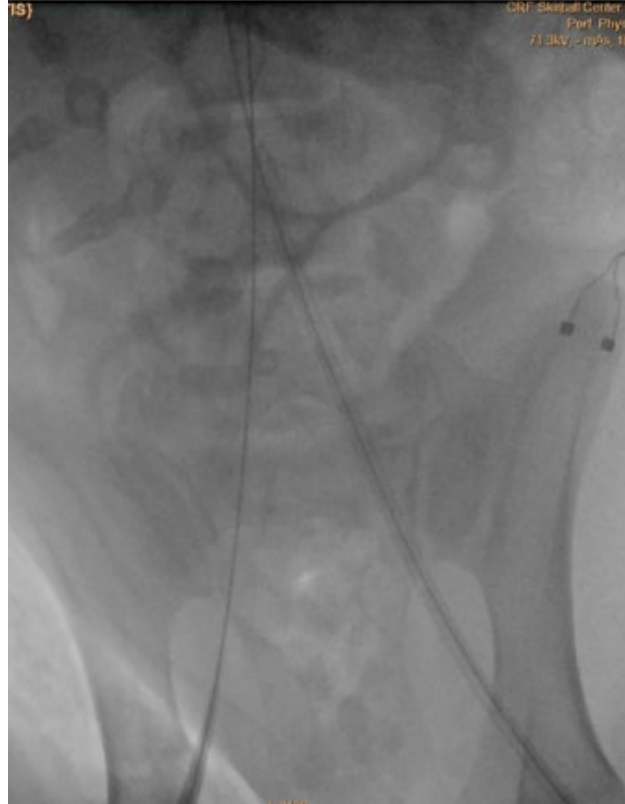
Short Axis View

Transfemoral Access

CT Planning



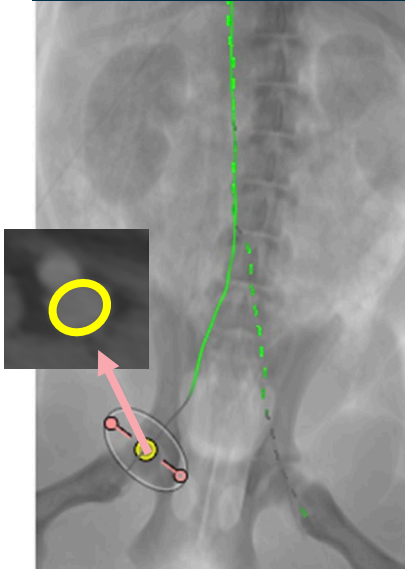
Right Common Femoral Vein
9.7 x 10.6 mm
Average 10.1 mm



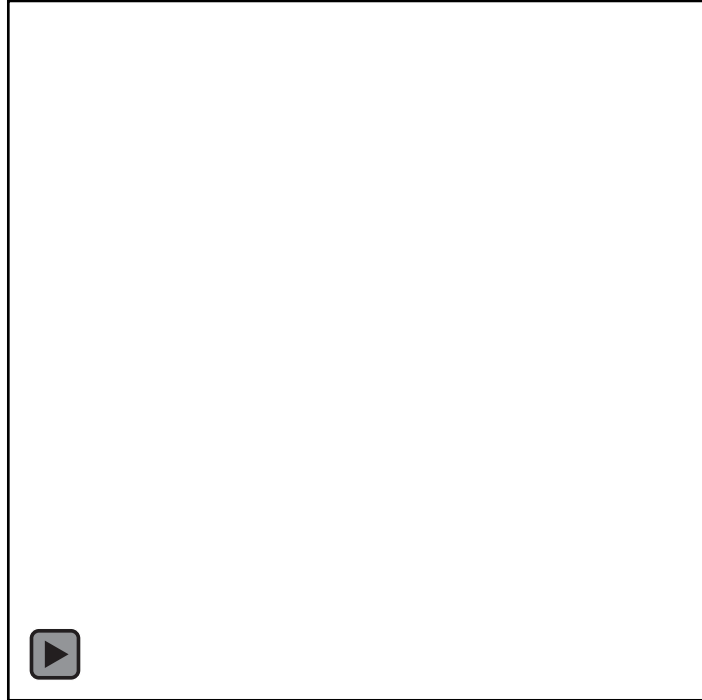
- Femoral access obtained under US guidance
- Transseptal puncture performed
- Safari XS placed in the LA
- 34 – French dilator used for pre-dilation of the femoral vein

Transfemoral Access

CT Planning



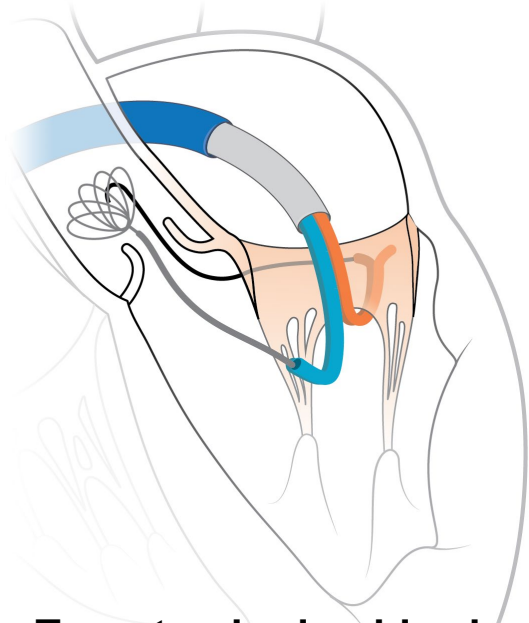
Right Common Femoral Vein
9.7 x 10.6 mm
Average 10.1 mm



- Introducer sheath advanced over Safari XS wire

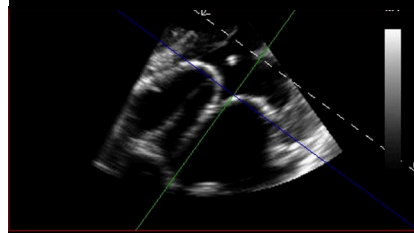


SATURN TS Procedural Steps

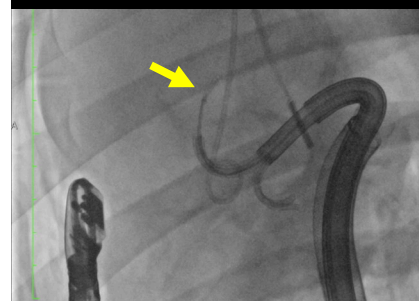


Two standard guidewires are inserted behind leaflets to embrace the native mitral valve

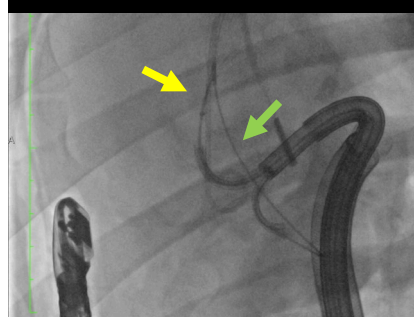
A. GWDS at A2 and P2 for placement of medial and lateral loops



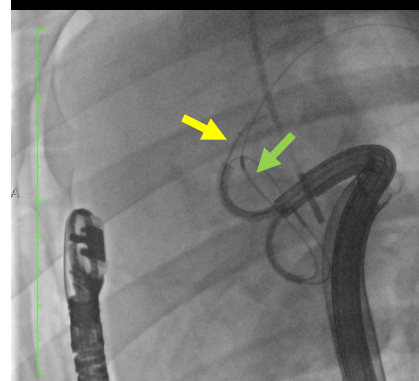
B. Snare (yellow) in LVOT



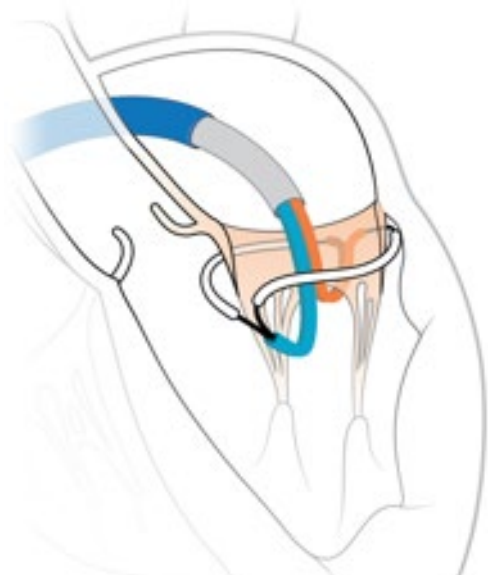
C. First guidewire (green) around MV and loop closure



D. Second loop closure

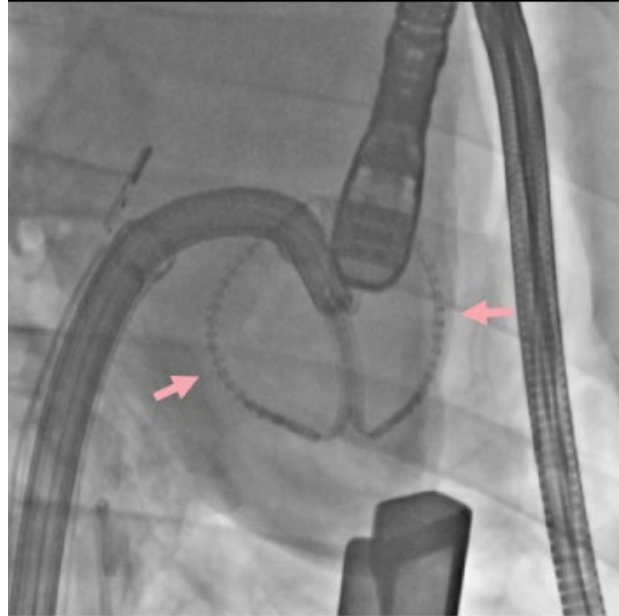


SATURN TS Procedural Steps

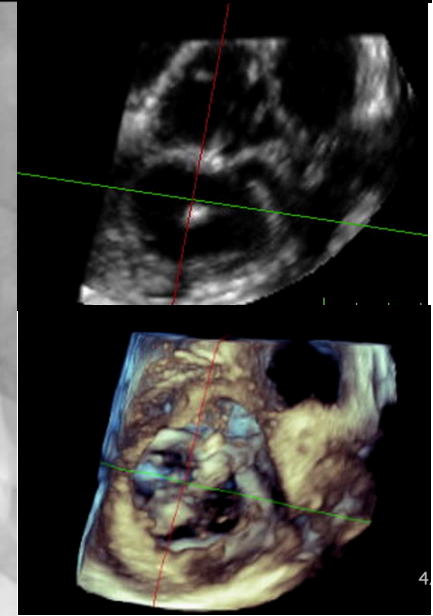


Annular segments are introduced over the wires and positioned behind the leaflets

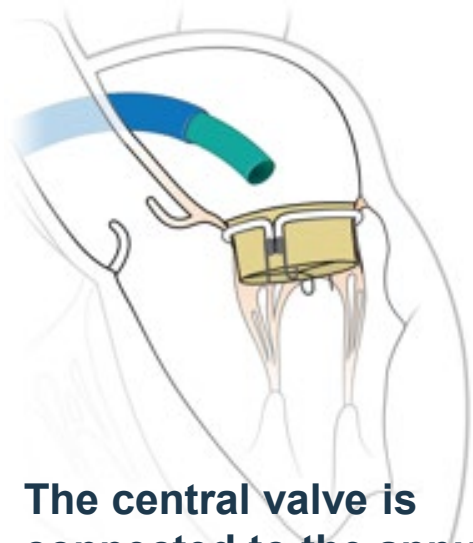
Annular segments (pink) embracing the native mitral annulus



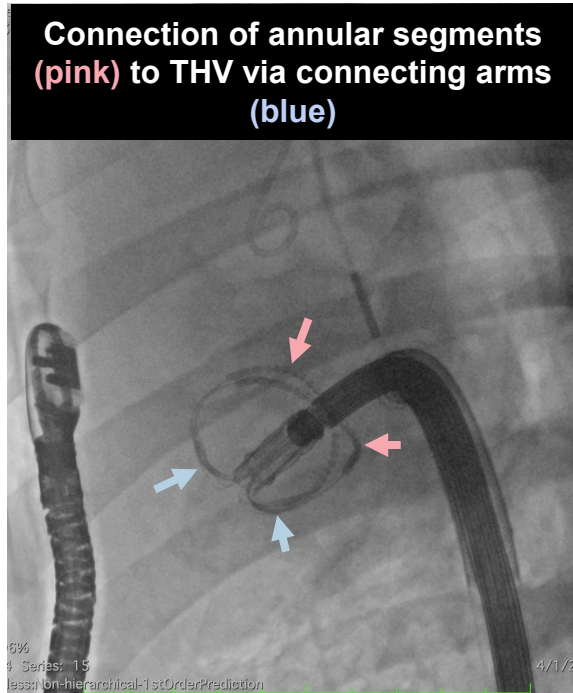
Visualization of Annular segments by TEE



SATURN TS Procedural Steps



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

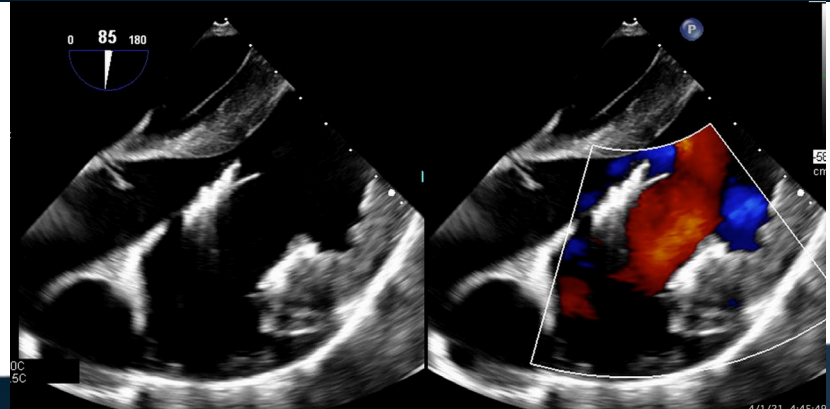


Results/Procedural Success (N = 12)

- Twelve consecutive successful implants between November 2022 and March 2023 in Yorkshire pigs (99.6 ± 7.9 kgs)
- Mean femoral vein size was 9.3 ± 0.6 mm
- Acute performance of the bioprosthetic valve was excellent with good hemodynamics, and absence of PVL

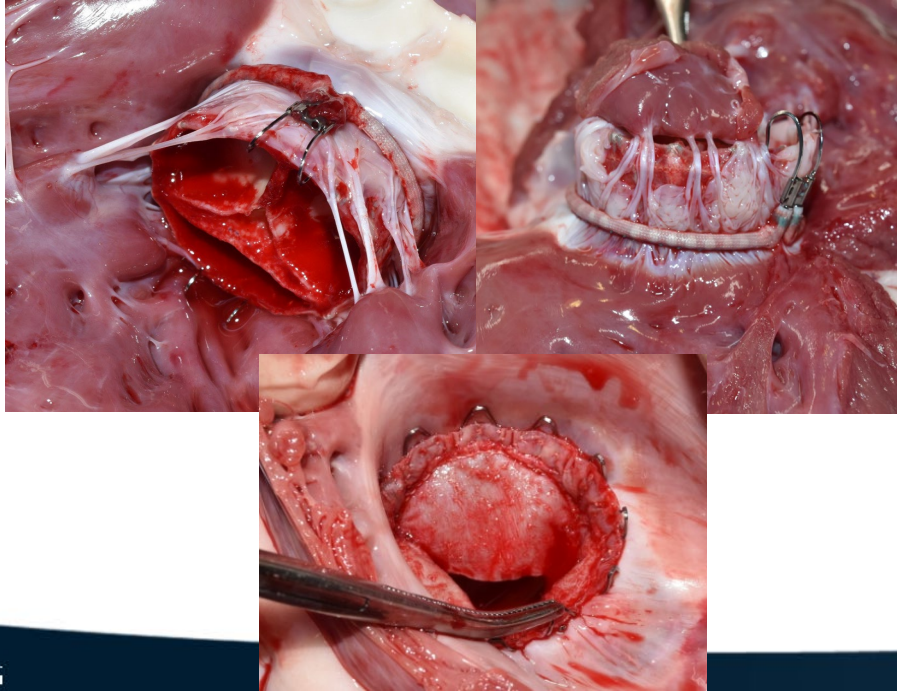
Post-implant characteristics

Peak MV gradient, mmHg	9.6 ± 2.5
Mean MV gradient, mmHg	3.8 ± 1.4
Central MR > Trace	1 (8.3%), mild
Paravalvular leak > Trace	none



Results/Procedural Success (N = 12)

- Mitral leaflets successfully captured by the annular segments in all animals
- Mitral bioprosthesis in the intended position



Summary

- The transseptal SATURN system may offer a robust 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
- Transfemoral transseptal deployment of the SATURN TMVR in the porcine model was achieved with a high technical success rate, and resultant excellent valve hemodynamics.
- Initiation of the transseptal SATURN TMVR early feasibility study in humans is anticipated for 2H 2023.