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10<sup>th</sup> AP VALVES & VIRTUAL  
STRUCTURAL HEART  
AUGUST 5-6, 2021

# Intrepid™ Tricuspid Program

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**DIRECTOR: UNITÉ MEDICOCHIRURGICALE DE  
VALVULOPATHIE**



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# POTENTIAL CONFLICT OF INTEREST

Speaker's name : T. Modine

Consultant, proctor and advisory board for Medtronic

# The Ignored valve!!!



**ESC**

European Society  
of Cardiology

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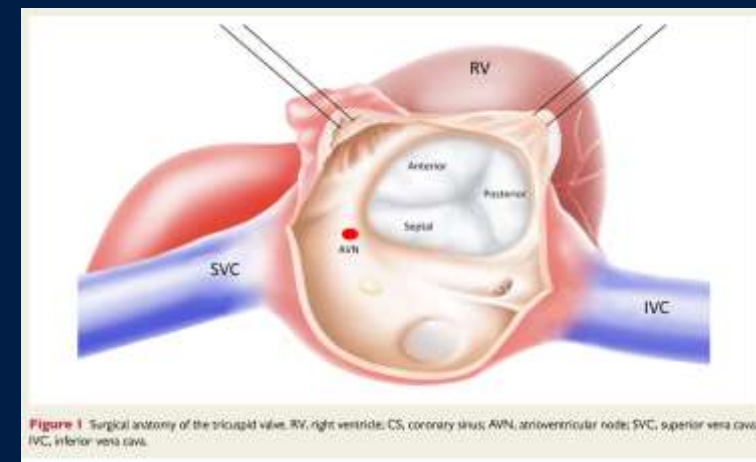
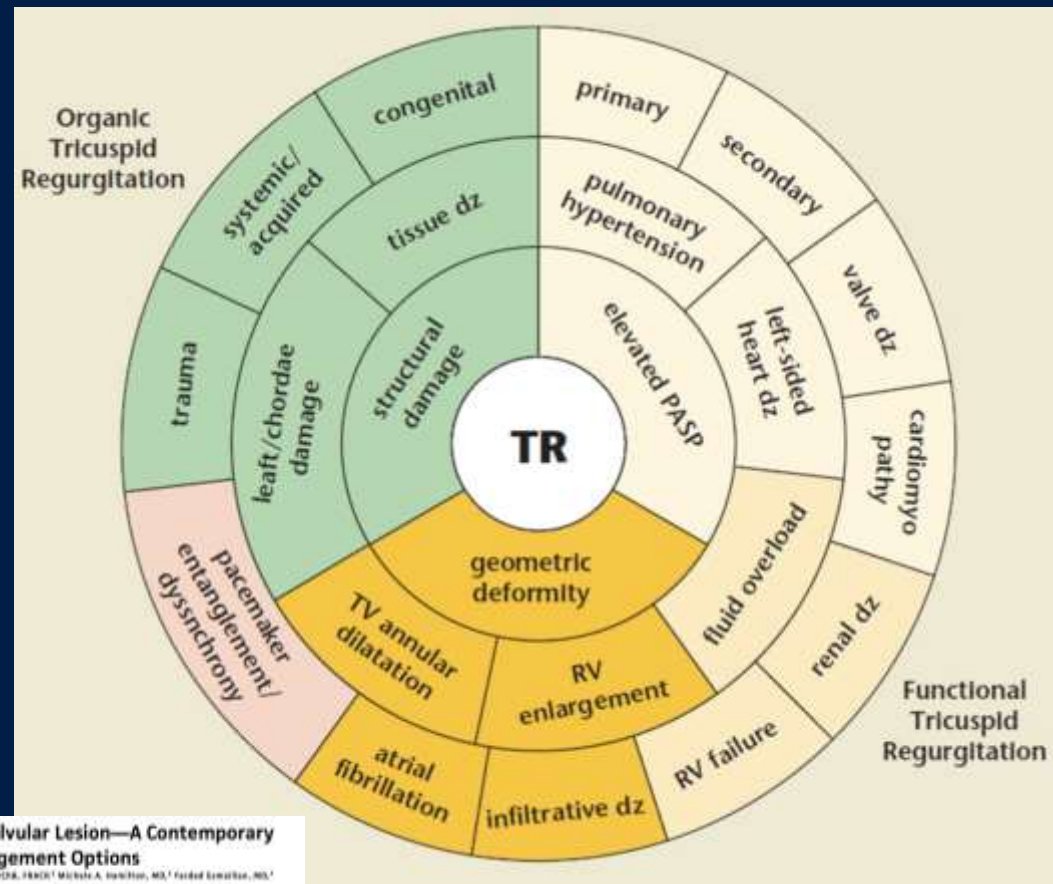
**CLINICAL REVIEW**

*Controversies in cardiovascular medicine*

## Uncertainties and challenges in surgical and transcatheter tricuspid valve therapy: a state-of-the-art expert review

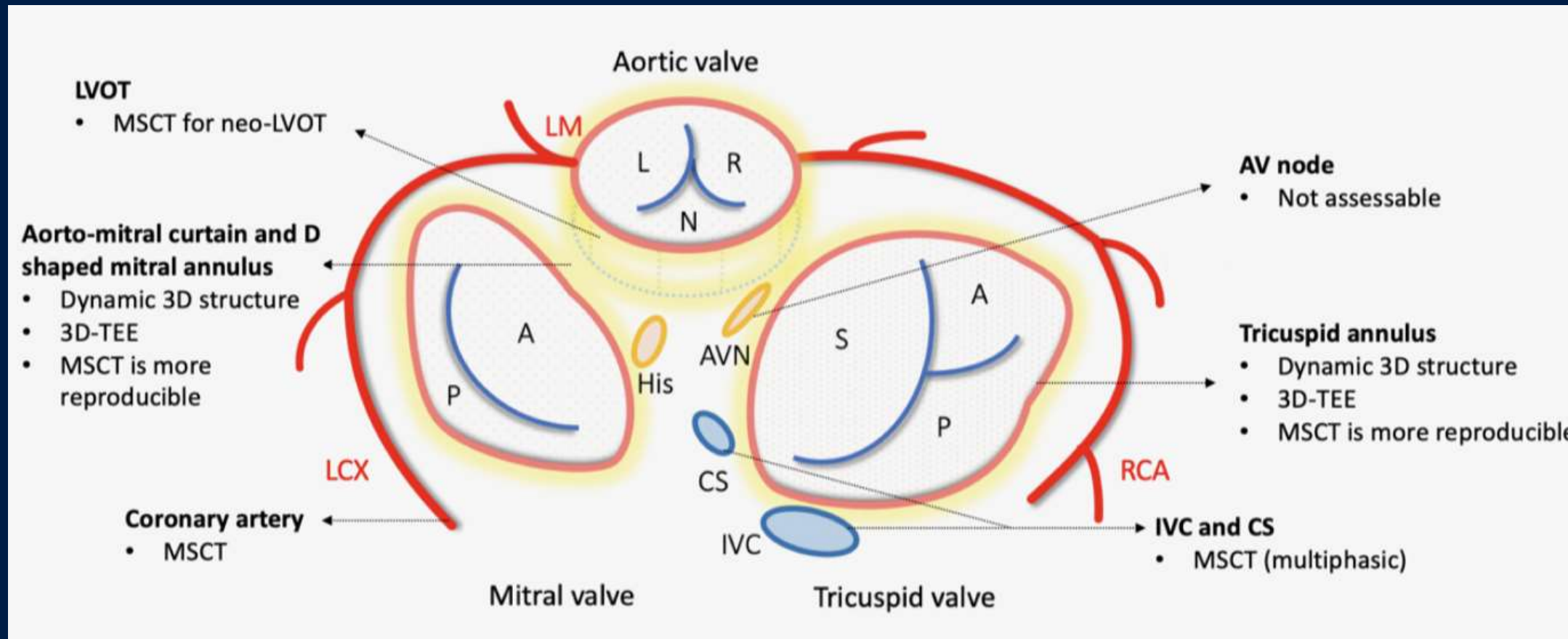
**Chun Chin Chang<sup>1†</sup>, Kevin M. Veen<sup>2†</sup>, Rebecca T. Hahn <sup>3</sup>, Ad J.J.C. Bogers<sup>2</sup>, Azeem Latib <sup>4</sup>, Frans B.S. Oei<sup>2</sup>, Mohammad Abdelghani<sup>5,6</sup>, Rodrigo Modolo <sup>6,7</sup>, Siew Yen Ho<sup>8</sup>, Mohamed Abdel-Wahab<sup>9</sup>, Khalil Fattouch<sup>10,11</sup>, Johan Bosmans<sup>12</sup>, Kadir Caliskan <sup>1</sup>, Maurizio Taramasso <sup>13</sup>, Patrick W. Serruys <sup>14</sup>, Jeroen J. Bax <sup>15</sup>, Nicolas M.D.A. van Mieghem<sup>1</sup>, Johanna J.M. Takkenberg <sup>2</sup>, Philip Lurz<sup>9</sup>, Thomas Modine<sup>16</sup>, and Osama Soliman <sup>1\*</sup>**

# Tricuspid regurgitation



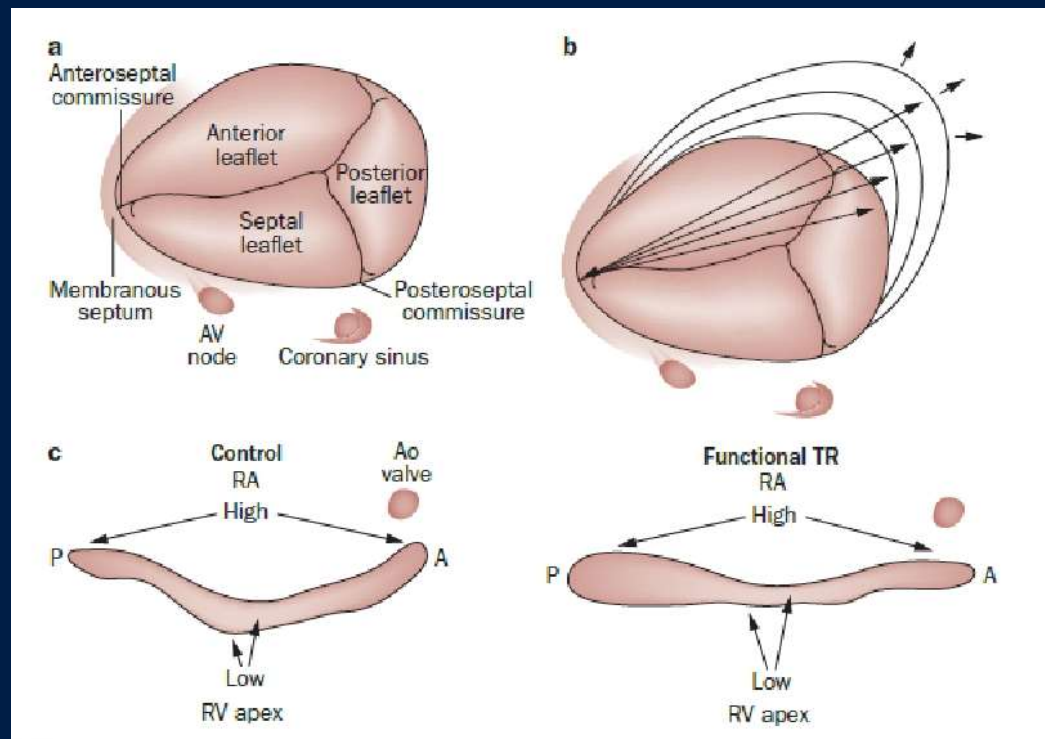
**Tricuspid Regurgitation, the Forgotten Valvular Lesion—A Contemporary Review of Etiology, Prevalence, and Management Options**  
 Richard Cheng, MD,<sup>1</sup> Amir Asif, MD,<sup>2</sup> Jose Carrion, MD,<sup>3</sup> James E. J. Thomson, MD, PhD, FRCPC,<sup>4</sup> Michael A. Danforth, MD,<sup>5</sup> Farid Samir, MD,<sup>6</sup> Robert Azzabi, MD,<sup>7</sup> ...  
<sup>1</sup>UCLA Medical Center, Los Angeles, CA; <sup>2</sup>Department of Medicine, University of Hawaii Medical Center, Honolulu, HI; <sup>3</sup>Division of Cardiology, University of California, Los Angeles; <sup>4</sup>Department of Medicine, University of Toronto, Toronto, Ontario, Canada; <sup>5</sup>Department of Cardiology, University of California, Los Angeles; <sup>6</sup>Department of Cardiology, University of California, Los Angeles; <sup>7</sup>Department of Cardiology, University of California, Los Angeles.

# TRICUSPID ENVIRONMENT

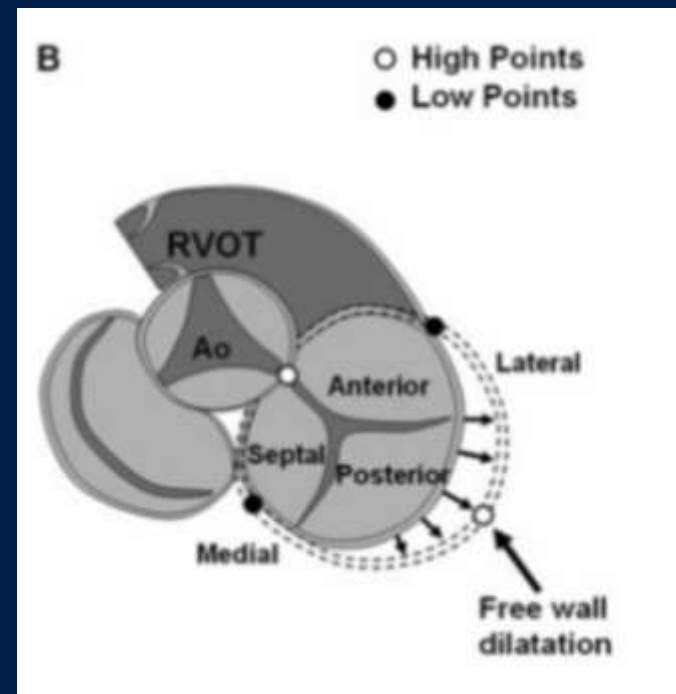




# PHASE 1: ANNULAR DILATATION



Valve more circular  
Same perimeter gives bigger area



Not always associated with  
regurgitation

# Phase 2: Failure of leaflet coaptation

- **OFTEN ASSOCIATED WITH TR, MODERATE TO SEVERE**
- **IF ANNULUS DIAMETER IS >40MM ON ECHO, AN ANNULOPLASTY IS RECOMMENDED WITH OR WITHOUT TR**
- **VOLUME OVERLOAD**
- **PULMONARY HYPERTENSION (MAYBE THE CAUSE OF TR)**

# PHASE 3: THETHERING OF LEAFLETS

- SEVERE TR
- ANNULOPLASTY ALONE IS UNLIKELY TO BE DURABLE
- RISK OF RECURRENENCY

Too late for intervention???







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# Uncertainties and challenges in surgical and transcatheter tricuspid valve therapy: a state-of-the-art expert review

**Chun Chin Chang<sup>1†</sup>, Kevin M. Veen<sup>2†</sup>, Rebecca T. Hahn <sup>3</sup>, Ad J.J.C. Bogers<sup>2</sup>, Azeem Latib <sup>4</sup>, Frans B.S. Oei<sup>2</sup>, Mohammad Abdelghani<sup>5,6</sup>, Rodrigo Modolo <sup>6,7</sup>, Siew Yen Ho<sup>8</sup>, Mohamed Abdel-Wahab<sup>9</sup>, Khalil Fattouch<sup>10,11</sup>, Johan Bosmans<sup>12</sup>, Kadir Caliskan <sup>1</sup>, Maurizio Taramasso <sup>13</sup>, Patrick W. Serruys <sup>14</sup>, Jeroen J. Bax <sup>15</sup>, Nicolas M.D.A. van Mieghem<sup>1</sup>, Johanna J.M. Takkenberg <sup>2</sup>, Philip Lurz<sup>9</sup>, Thomas Modine<sup>16</sup>, and Osama Soliman <sup>1\*</sup>**

## Surgical tricuspid landscape

## Transcatheter tricuspid landscape

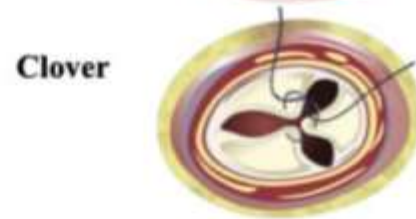
Suture annuloplasty



Ring annuloplasty



Coaptation enhancement



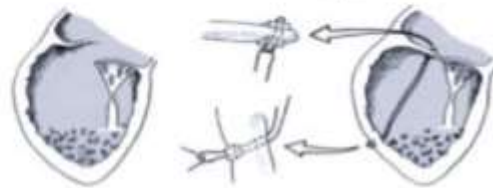
Replacement



Leaflet augmentation



Neochordae repair



Trialign



TriCinch



MIA



PASTA



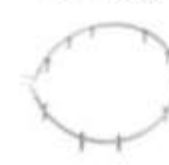
Cardioband



Millipede



DaVinci



MitraClip



FORMA



PASCAL



NaviGate



Lux



TriSol



TRiCares



TricValve



Tricento

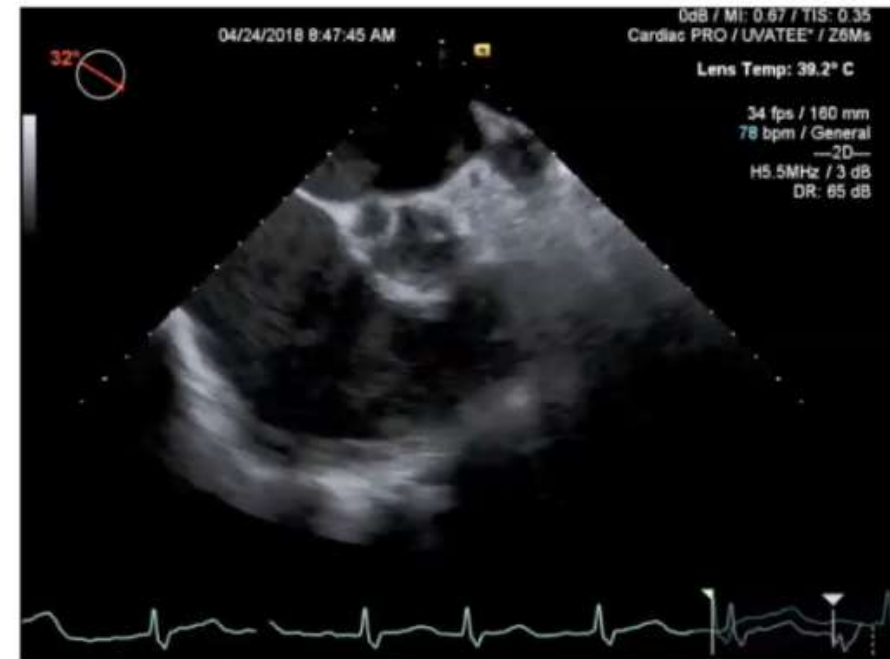


# CHALLENGE: ECHOGUIDANCE IS ESSENTIAL

How do we guide tricuspid interventions?

## TEE

- Off axis imaging
- Inconsistent imaging
- Shadowing of septal leaflet by the aortic root
- Difficulty imaging the lateral annulus



Courtesy S. Lim

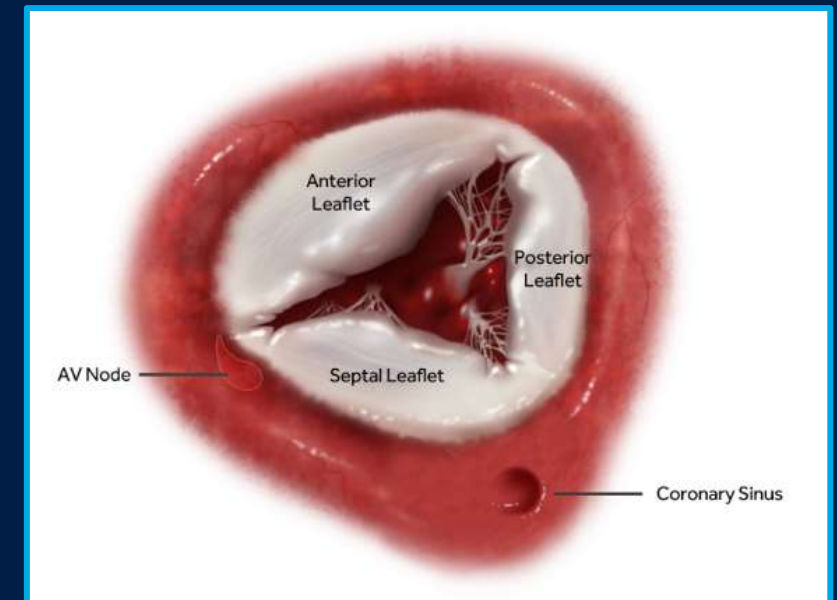
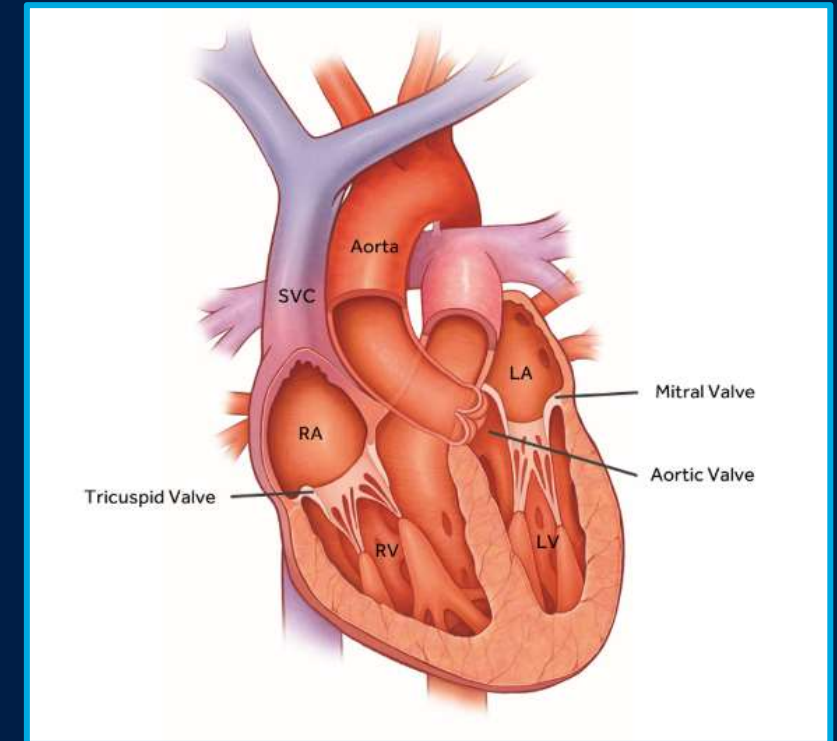
# RATIONALE FOR TRICUSPID TRANSCATHETER REPLACEMENT (TTVR)

## TR Challenges

1. Delicate valve structure
2. Poorly defined annulus
3. Challenging imaging
4. Large coaptation gaps

## Opportunity for TTVR

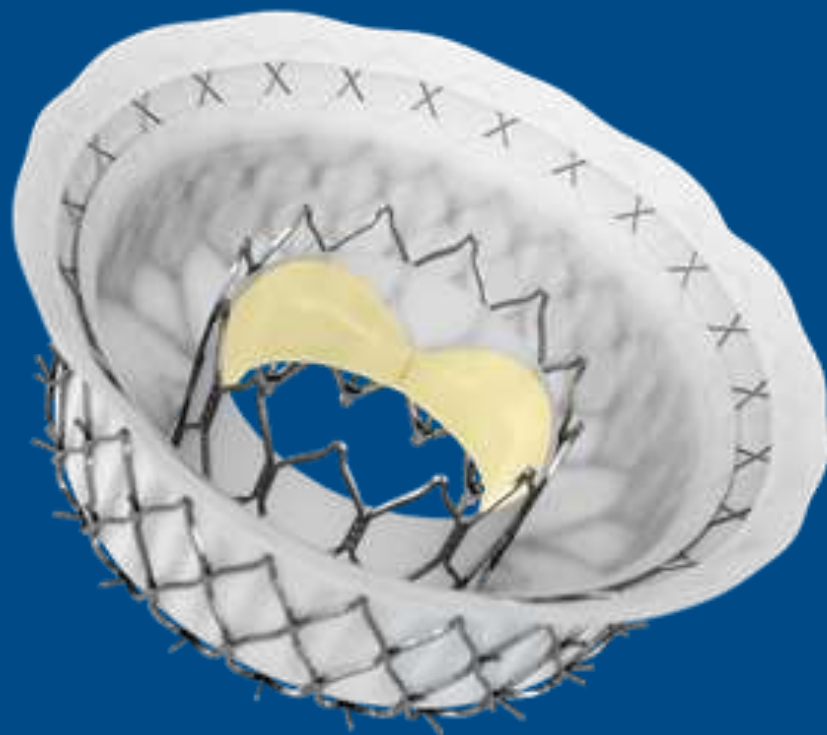
1. Designed to eliminate TR
2. No risk of RVOT
3. Applicable to most valve morphologies





# INTREPID\* VALVE DESIGN

*DESIGNED FOR MITRAL AND TRICUSPID VALVE REPLACEMENT*



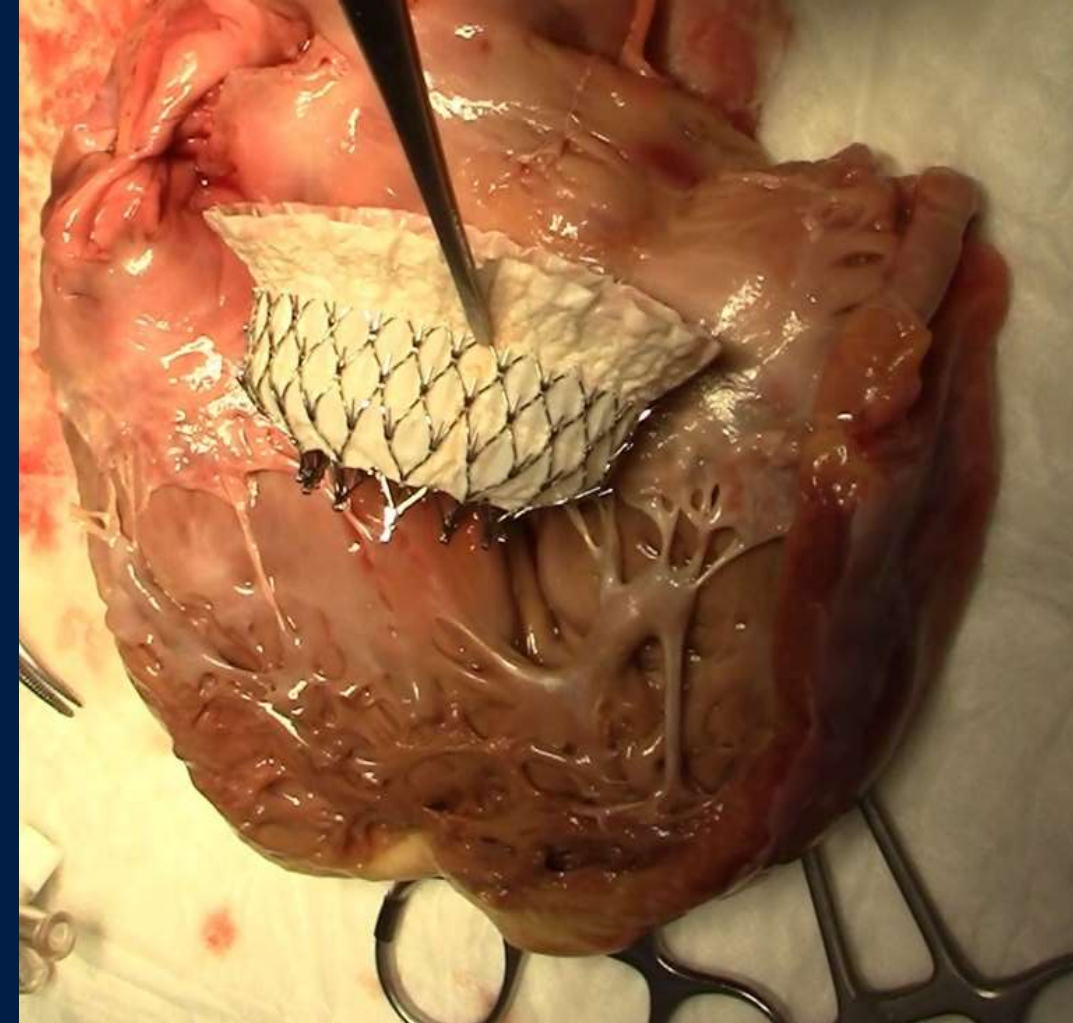
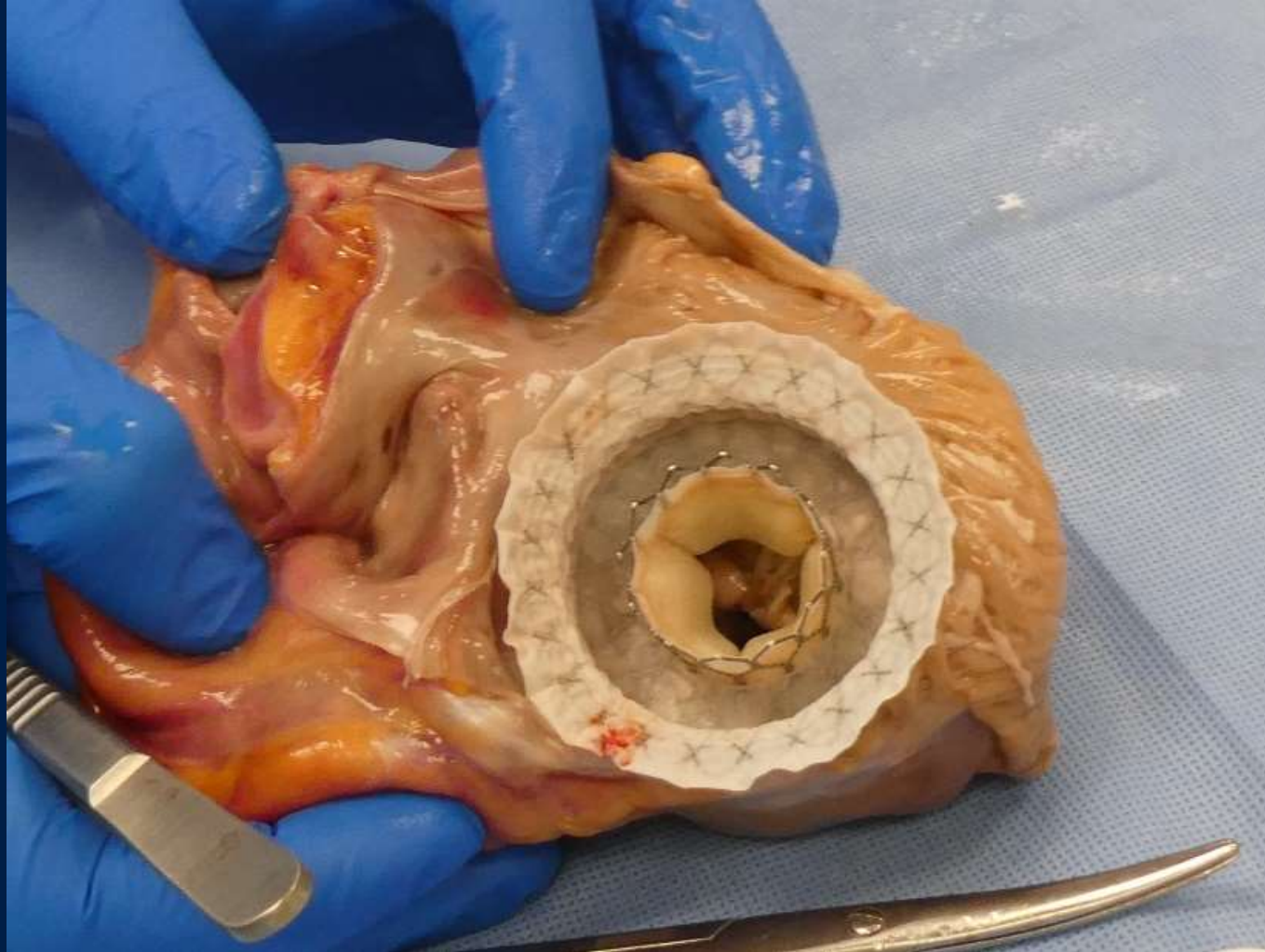
## INTREPID VALVE DESIGN

- ✓ Conformable outer stent anchors without leaflet capture or need for rotational alignment
- ✓ Circular inner stent houses a 27 mm tri-leaflet bovine pericardial valve
- ✓ No atrial protrusion or profile
- ✓ 42 & 48 mm valves in clinical evaluation; XL valve in development

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# THE INTREPID\* VALVE DESIGN

## TRICUSPID POSITION

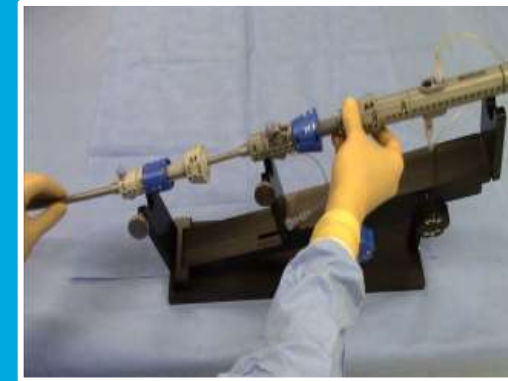
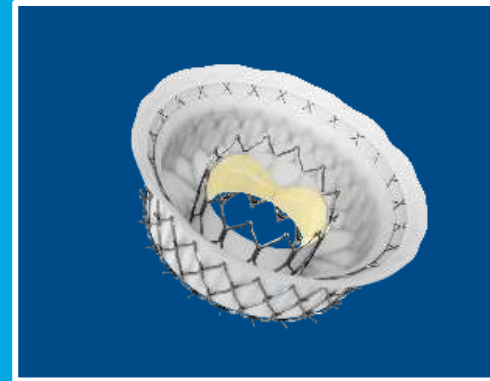
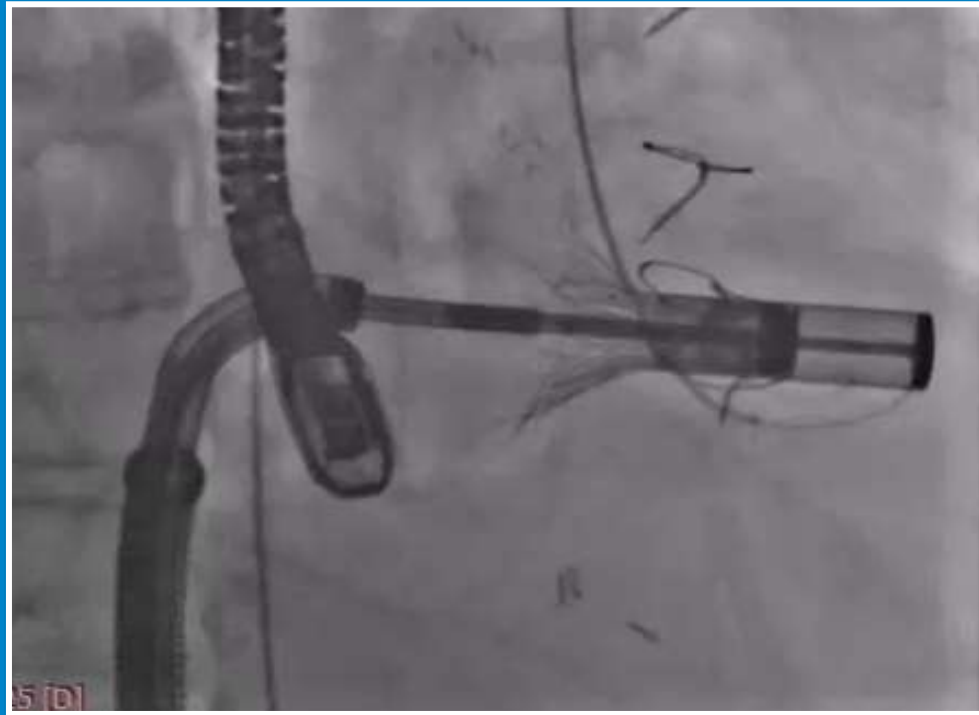


These cadaver studies may not be indicative of clinical performance and are for illustrative purposes only.



# INTREPID\* TRICUSPID PROGRAM

## EARLY EVALUATION OF APPLICATION FOR TRICUSPID REGURGITATION



- Multidirectional steering
- Clear tricuspid visualization under fluoroscopy
- Current generation profile (35 Fr) for venous access in patients with severe TR
- FIM procedures performed

# INTREPID™ TRICUSPID TRANSFEMORAL PROGRAM

EFS APPROVED & BREAKTHROUGH DEVICE DESIGNATION GRANTED

## TF TTVR

Study will examine the safety and performance of the Intrepid™ TTVR system with the transfemoral (TF) 35 Fr delivery system

**15** pts

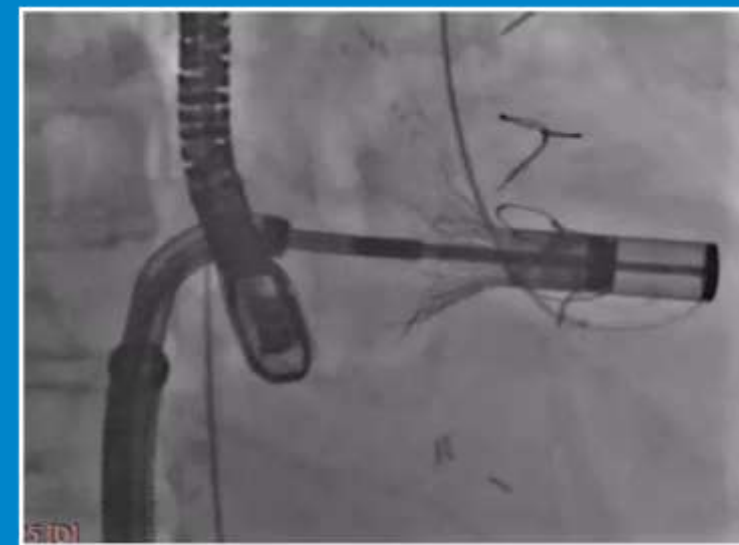
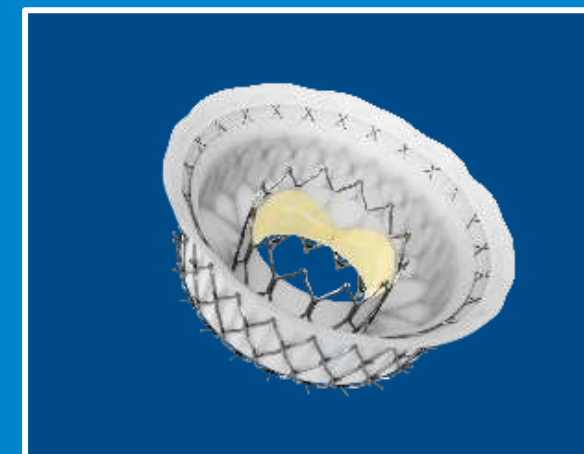
Study will include up to 15 patients with severe, symptomatic TR who are not eligible for surgery

**11** sites

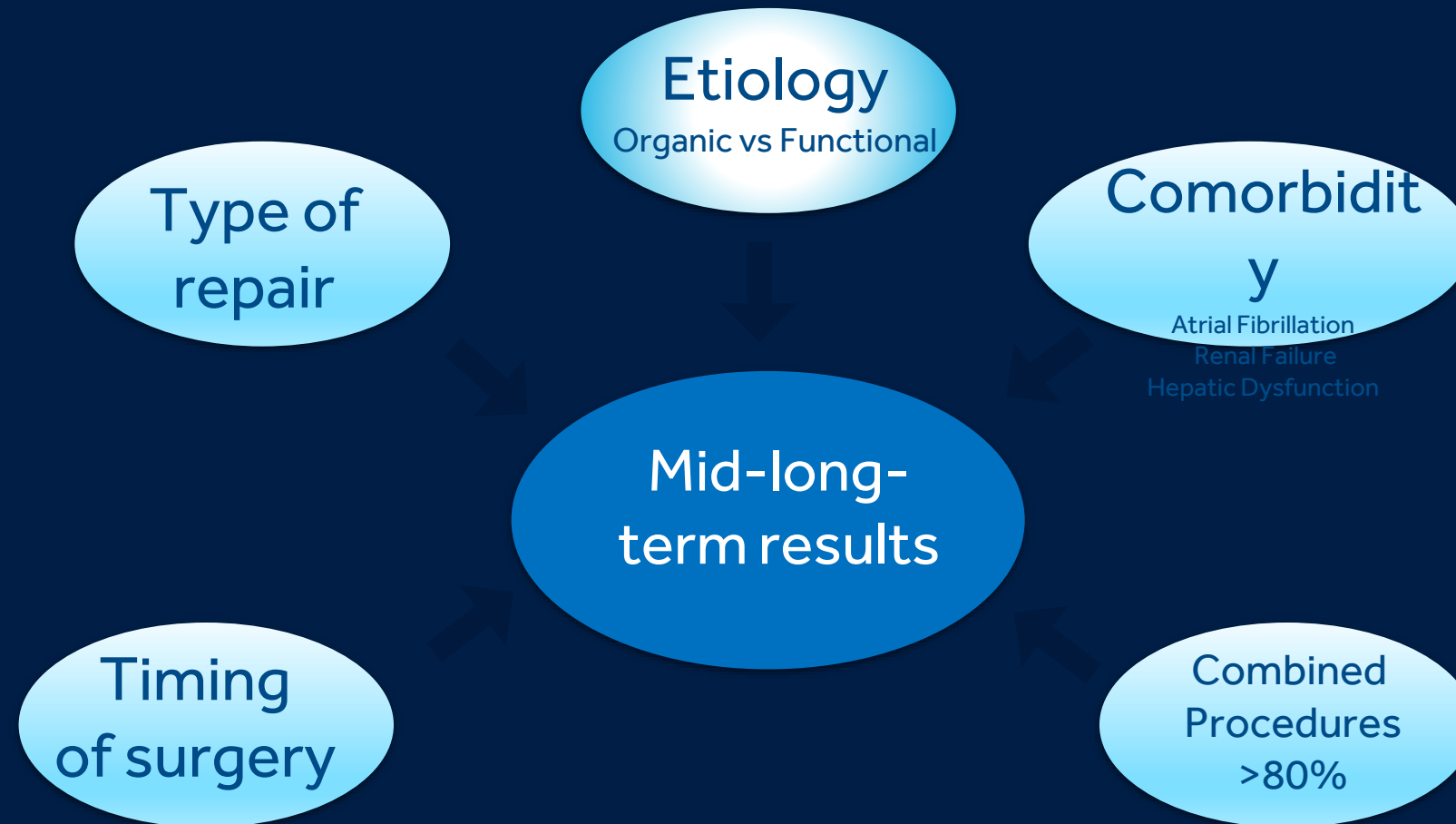
Up to 11 U.S. sites will be included in the early feasibility study

## CONTINUOUS INNOVATION

Data will inform technical development of the next-gen TF delivery system and future clinical research

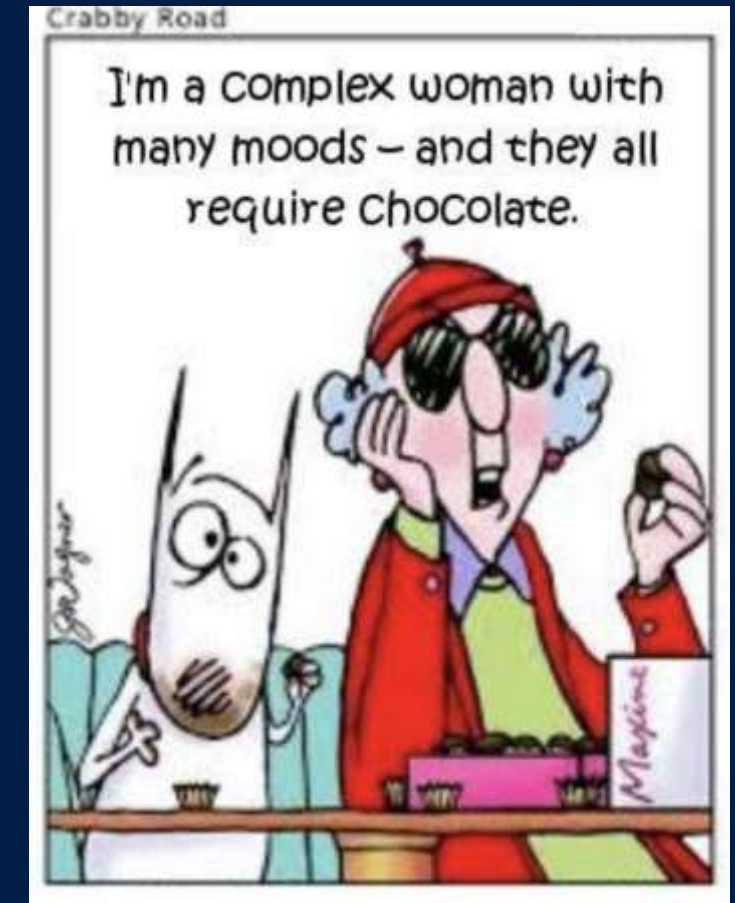


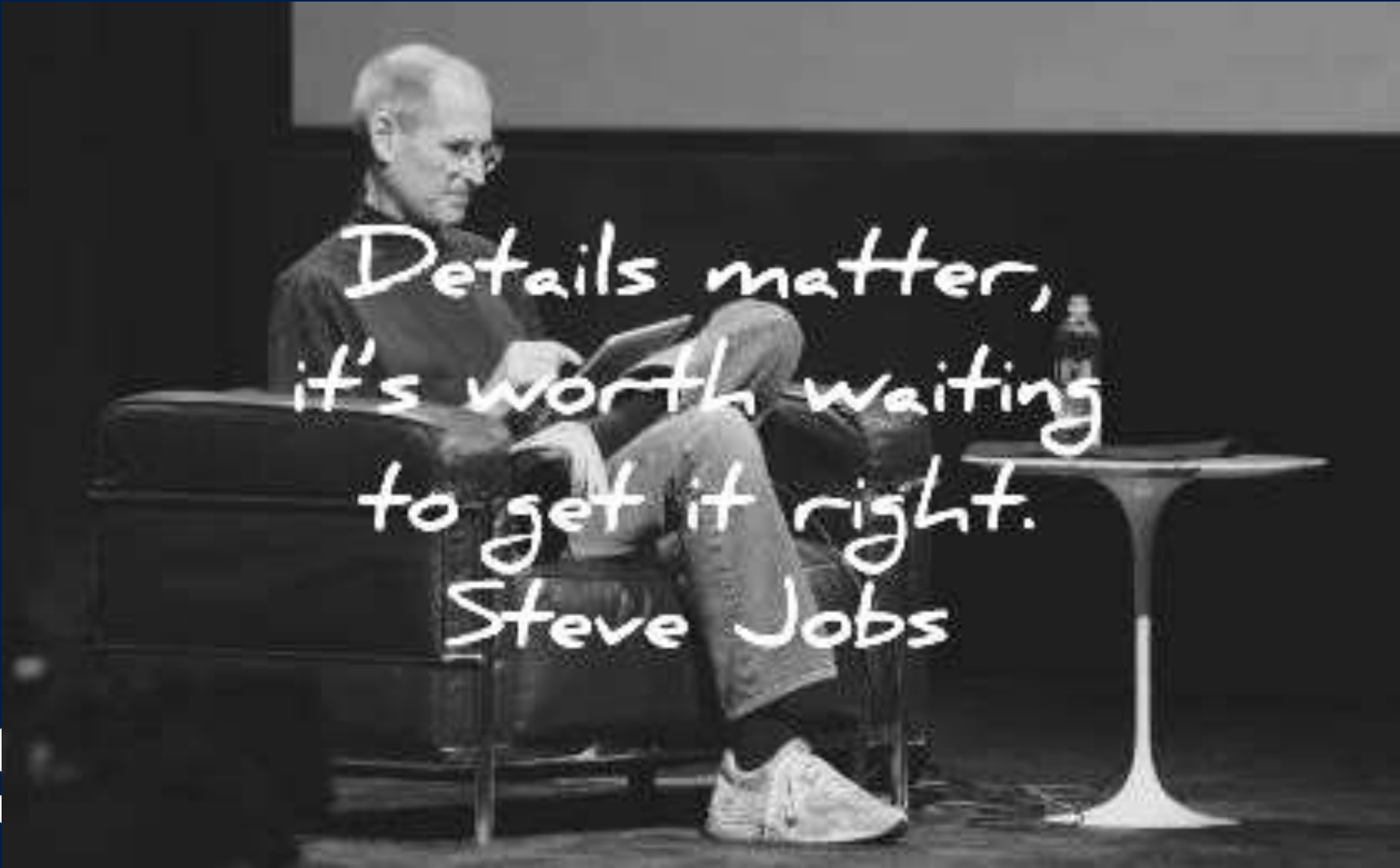
# FACTORS INFLUENCING MID-LONG-TERM RESULTS



# CONCLUSIONS

- Right ventricular failure may not be treated only by eliminating the TR
- Timing of intervention is crucial
- Catheter treatment may be an option, especially in redo situations
- No specific device is better than the other
  
- The solution is to be more aggressive in treating TR in earlier stage and in the first procedure



A black and white photograph of Steve Jobs sitting on a dark leather chair, reading a book. He is wearing his signature dark turtleneck, light-colored jeans, and white sneakers. To his right is a small, modern white table with a water bottle on it. The background is a dark stage setting.

Details matter,  
it's worth waiting  
to get it right.  
Steve Jobs

Quest