

# Edwards CENTERA Self-Expanding THV System - Initial Experience

## Professor Darren Walters

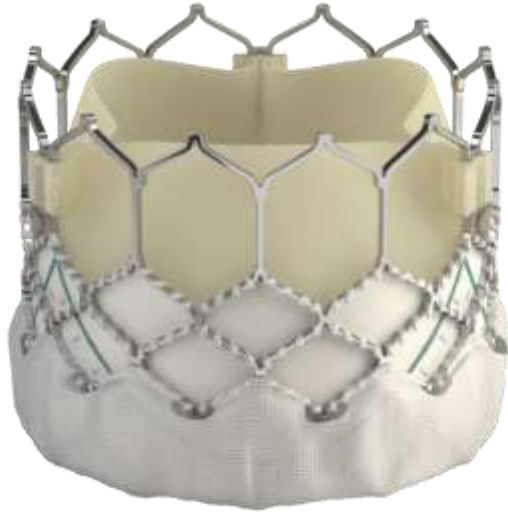
University of Queensland  
Heart Lung Institute  
The Prince Charles Hospital



# Disclosure

Consultant and proctor to Edwards Lifesciences

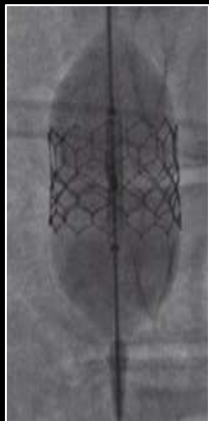
# Edwards Platforms



- Complementary
- Similar design features
- Designed to deployed similar position

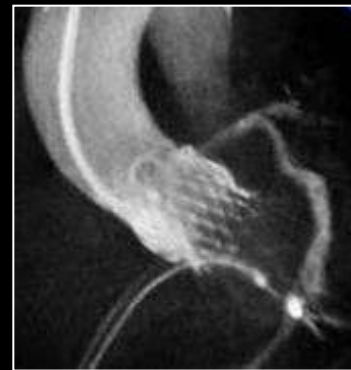


## Edwards **SAPIEN 3** Valve



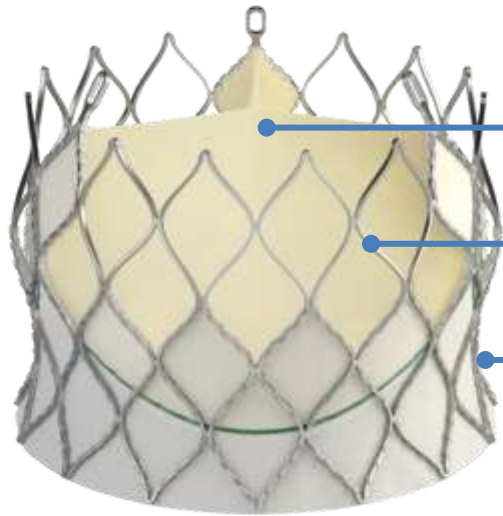
*Balloon Expandable*

## Edwards **CENTERA** Valve



*Self Expanding*

# Edwards CENTERA Transcatheter Heart Valve



**Treated bovine pericardium**

**Self-expanding Nitinol frame**

**Contoured frame design**

## Low Frame Height



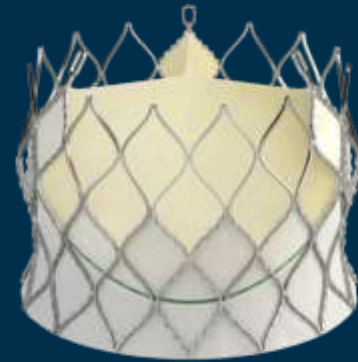
18 mm

23 mm



21 mm

26 mm



23 mm

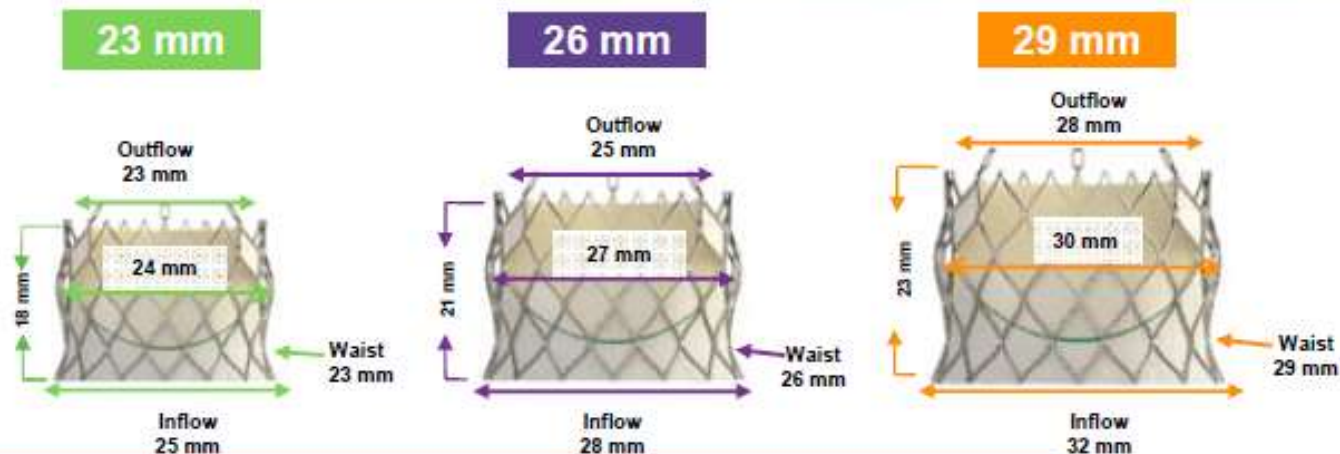
29 mm

# Edwards CENTERA THV



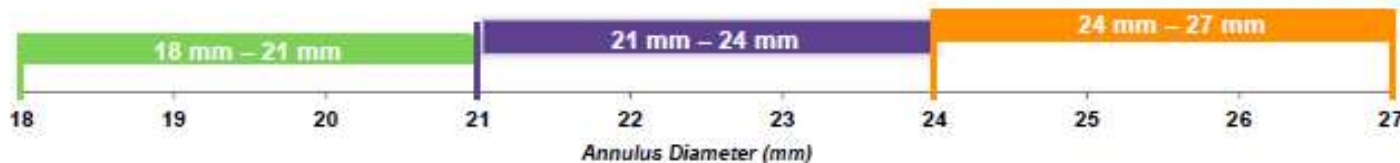
## NOTE:

Approximately half of the height of the THV is covered by PET Skirt

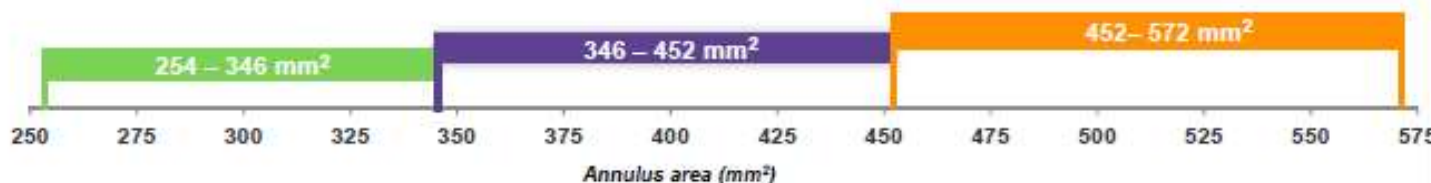


**Nominal diameter measured at the level of the waist**

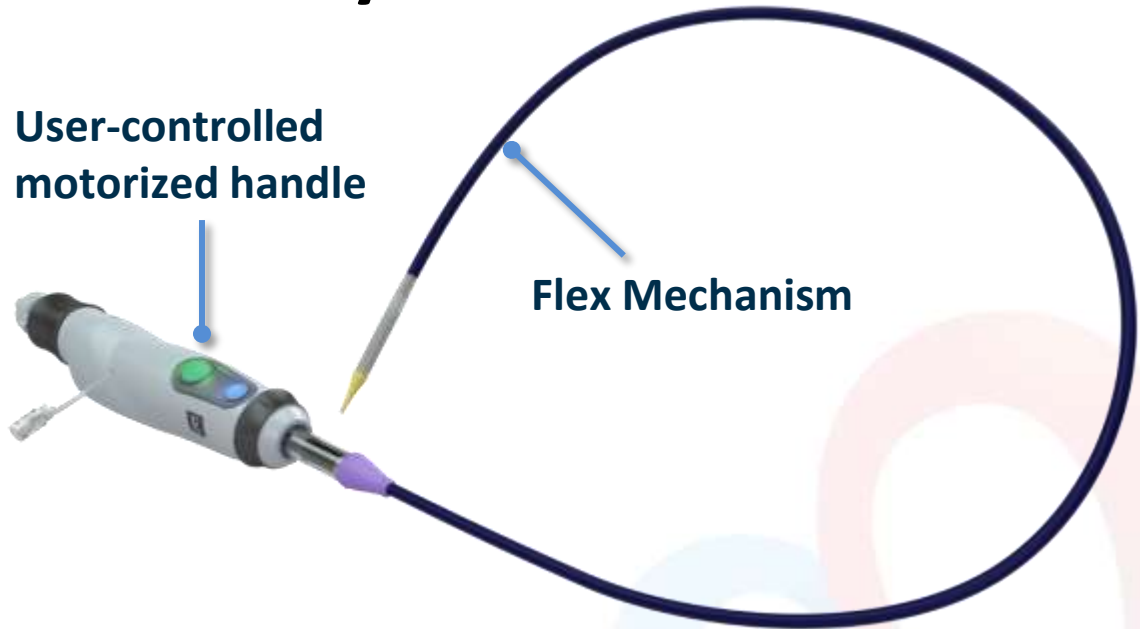
The THV is intended to be implanted in the following native annulus diameter range, as measured by CT:



The above diameters correspond to the following annulus area range:



# Edwards CENTERA Transcatheter Heart Valve System



- Compatible with ultra-low profile 14F eSheath
- THV deployment achieved via user-controlled motorized handle
- Quick preparation system
- Flex mechanism for trackability and coaxial alignment



# Edwards CENTERA Transcatheter Heart Valve System



# CENTERA EU Study

## Investigational Sites

23 active centers across 9 countries

The CENTERA EU Trial	
<b>Objective:</b>	To assess the safety and efficacy of the Edwards CENTERA Self-Expanding Transcatheter Heart Valve in high-risk/inoperable patients who are eligible for surgical aortic valve replacement
<b>Primary Endpoint:</b>	All-cause mortality at 30 days post-index procedure
<b>Secondary Endpoints:</b>	Technical success, safety and efficacy endpoints, echocardiographic endpoints
<b>Organization:</b>	Steering Committee, Clinical Events Committee (VARC 2), Echo Core Lab and CT Core Lab
<b>Scope:</b>	N = 200 pts / Location = EU & ANZ / sizes = 23, 26, 29mm / Access = TF Population: HR; inoperable (risk scores & Heart Team Assessment)
<b>Follow-Up:</b>	30 days, 6 months, 1 year, and annually for 5 years



innovation and collaboration



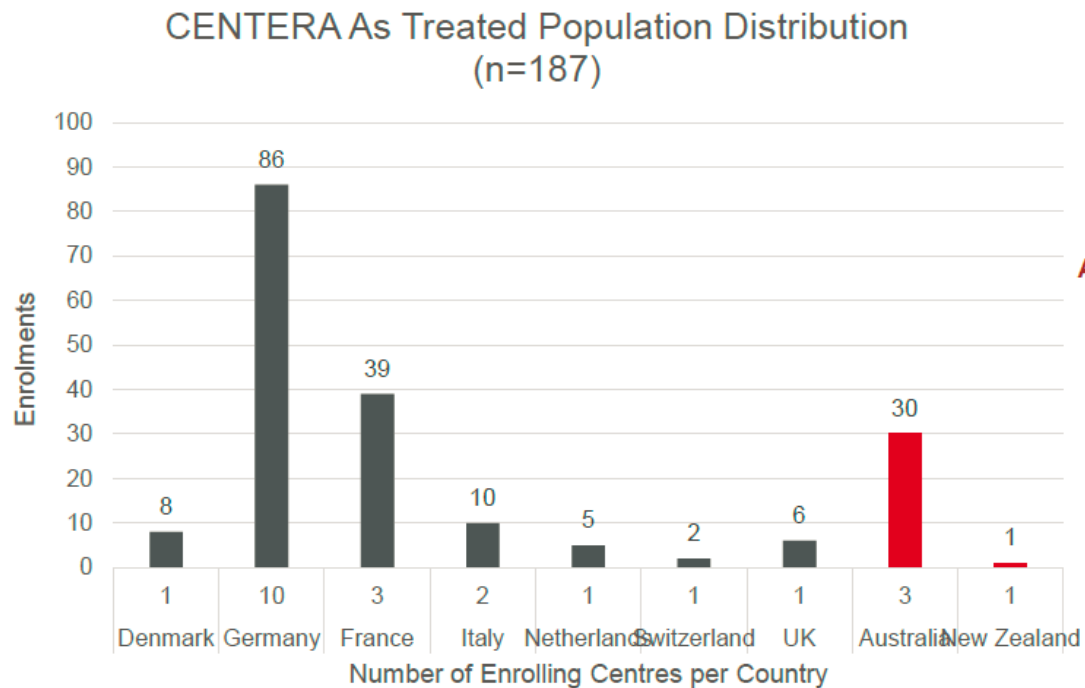
# CENTERA EU Study - Investigational Sites

**23** Active Centers  
across **9** Countries

Enrollment of  
**200 patients**  
completed  
June-2016



# CENTERA EU Study - Investigational Sites



# TPCH 12 patients

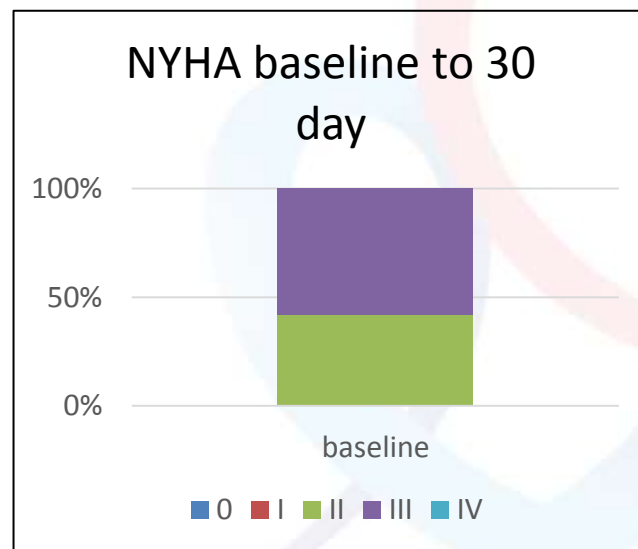
## Patient Baseline Profile

Mean  $\pm$  SD

Age (yr)	85.17 $\pm$ 7.1
Female	8/12 (66.7%)

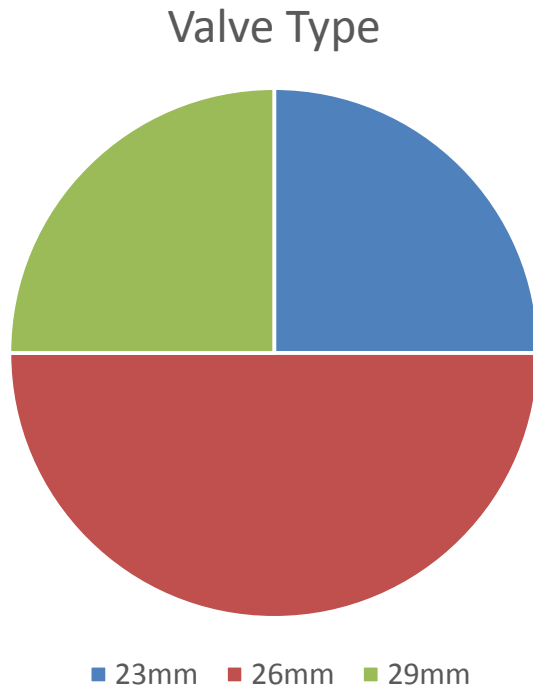
Risk Scores	
STS Score	5.3 $\pm$ 2.4
Logistic EuroSCORE	24.9 $\pm$ 14.4
Euroscore II	8.5 $\pm$ 6.1

Medical History	
Coronary Artery Disease	58.3%
CABG	33.3%



# Methods

## Procedural Information



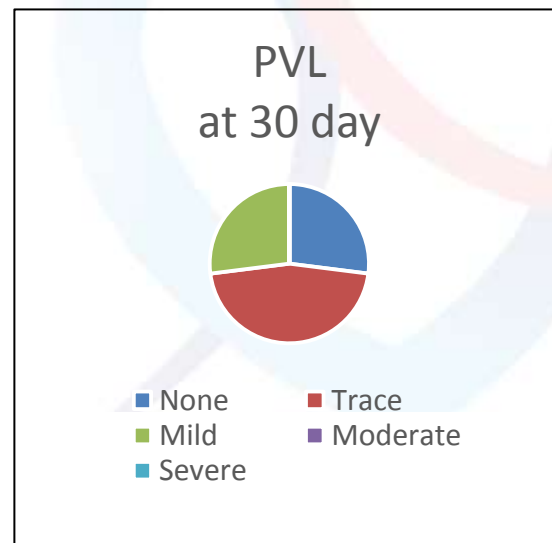
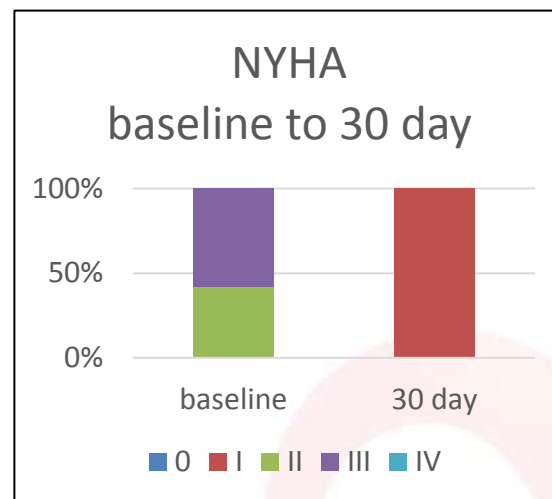
Valve Deployment Position	
Acceptable – Correct at intended site	100%
Too ventricular	0.0%
Too aortic	0.0%
Conversion to AVR	0.0%

In Hospital mortality 0.0%

# 30 Day Safety Endpoints

Event	# of Events	% of patients
All-Cause Mortality	1	8.3
All Stroke	0	0
Life-Threatening or Disabling Bleeding	0	0
Acute Kidney Injury - Stage 3	1	8.3
Peri-procedural Myocardial Infarction	0	0
Major Vascular Complication	1	8.3
Pacemaker	1	8.3

One late death related to sepsis and heart failure late after discharge in rural pt



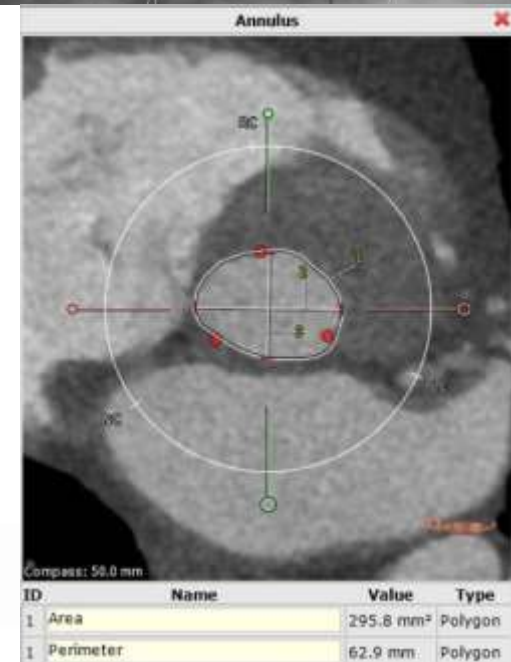
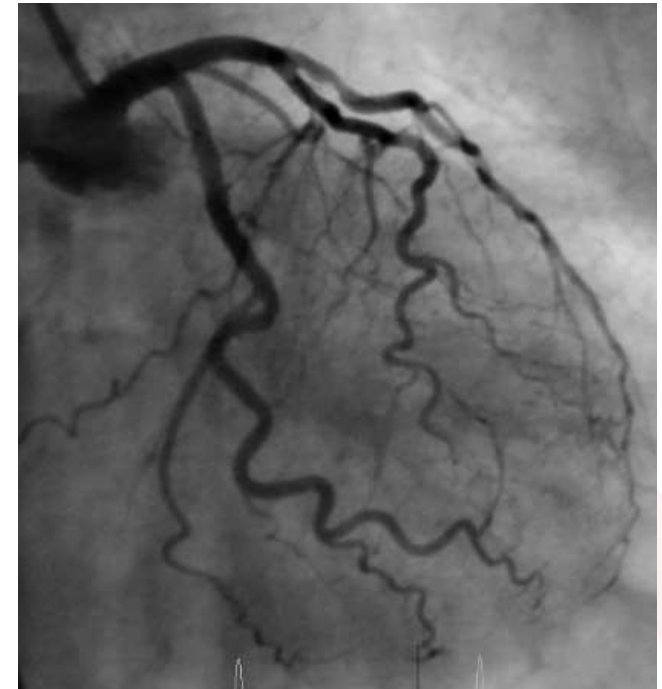
# Case Example

## Patient Information

Age	88
Gender	F
NYHA Class	2
Height	160
Weight	60
BMI	23.4

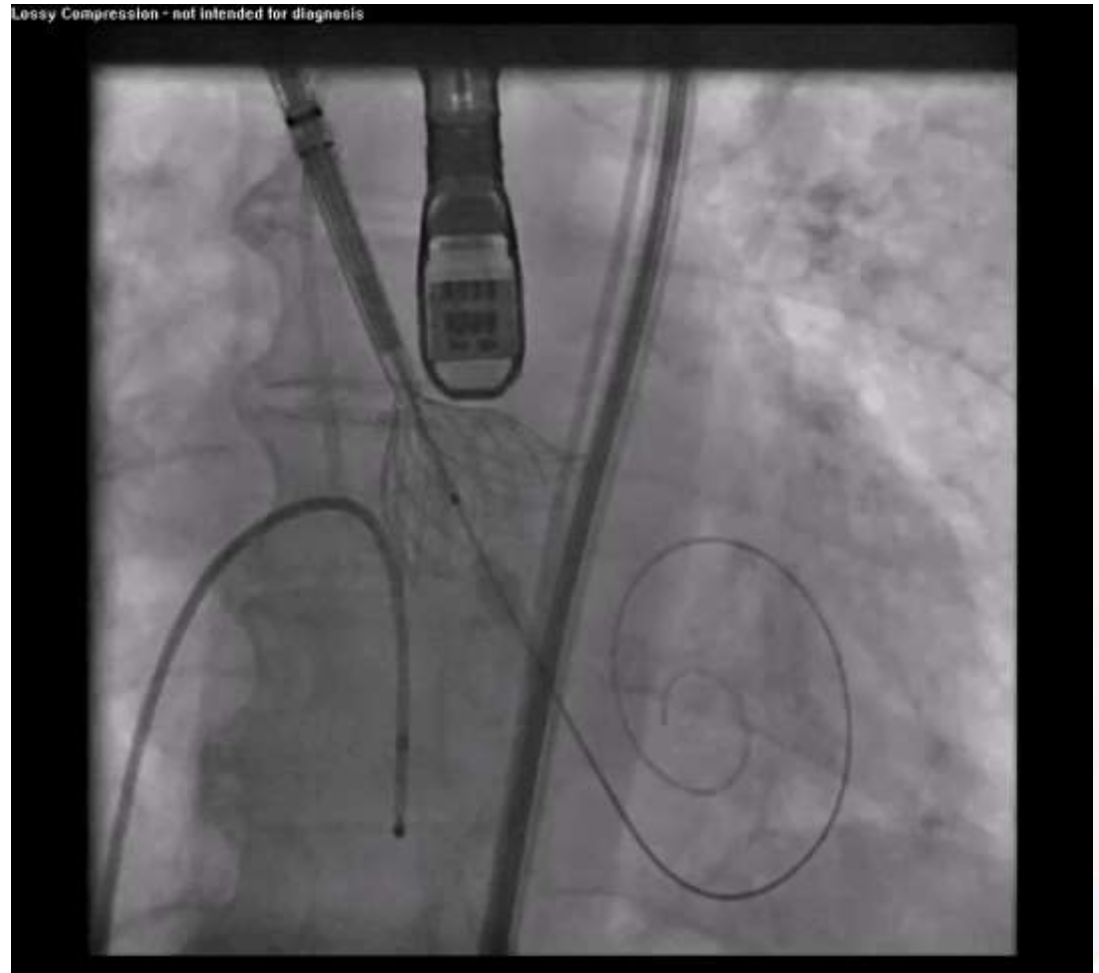
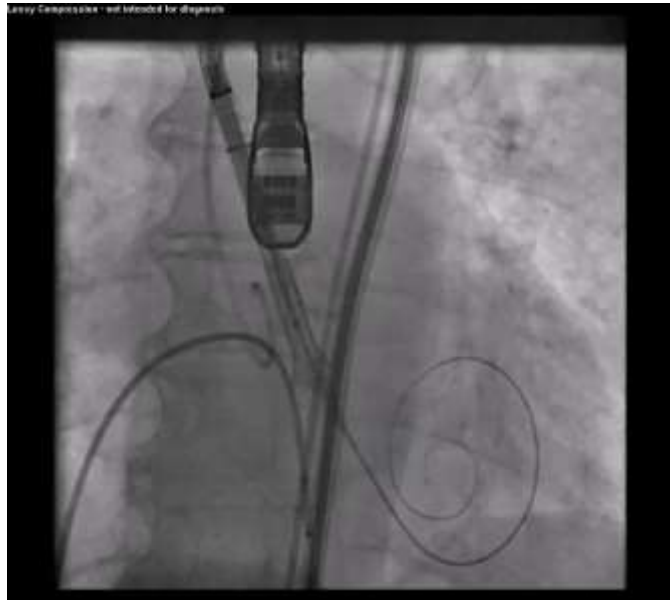
## High Risk Justification:

Method	Risk Score
<b>STS</b> $8 \leq \text{STS Score} \leq 15$ France Only: $10 \leq \text{STS Score} \leq 15$	9.1
<b>OR</b>	
<b>EuroSCORE I</b> $15 \leq \text{EuroSCORE I} \leq 40$ France Only: $20 \leq \text{EuroSCORE I} \leq 40$	7.87

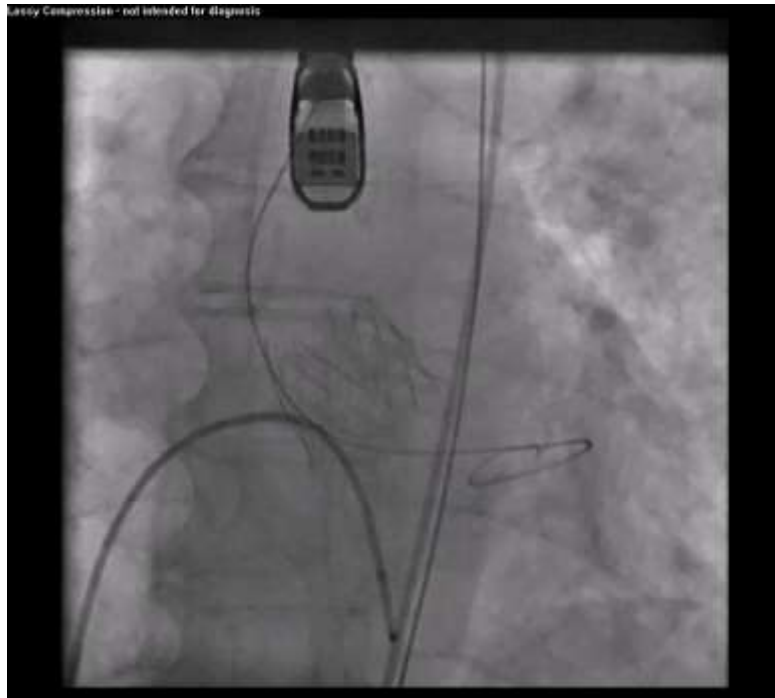




# Case example



# Case example



# Next Generation CENTERA System



User-controlled  
Motorized Handle



Flex Mechanism  
for Trackability  
and Coaxial Alignment

- **Enhanced delivery system articulation**
- **100% repositionability**

- Low 14F profile
- Quick device preparation
- Stable and predictable deployment
- ?Single Operator

innovation and collaboration