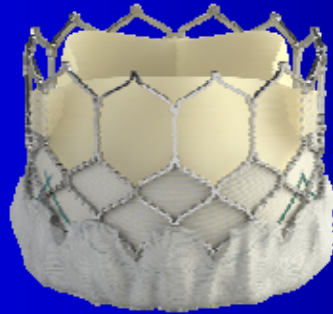


Edwards SAPIEN 3 and CENTERA System



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TAVI Summit Korea, 2013



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Heart Valve Innovation
St. Paul's Hospital, Vancouver



HEART CENTRE
AT ST. PAUL'S HOSPITAL

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.

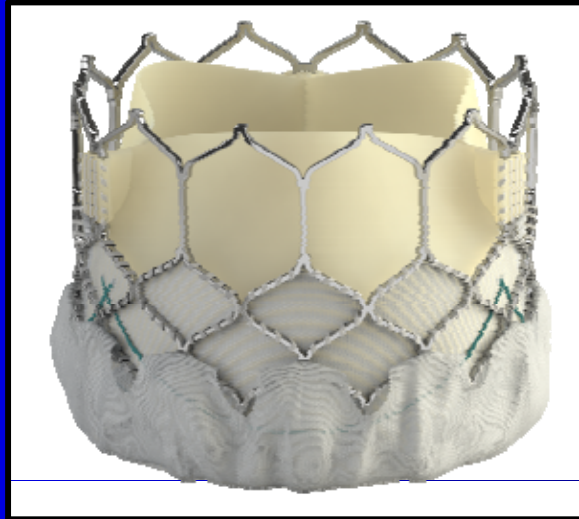
Affiliation/Financial Relationship

- Consulting Fees/Honoraria

Company

- Edwards Lifesciences

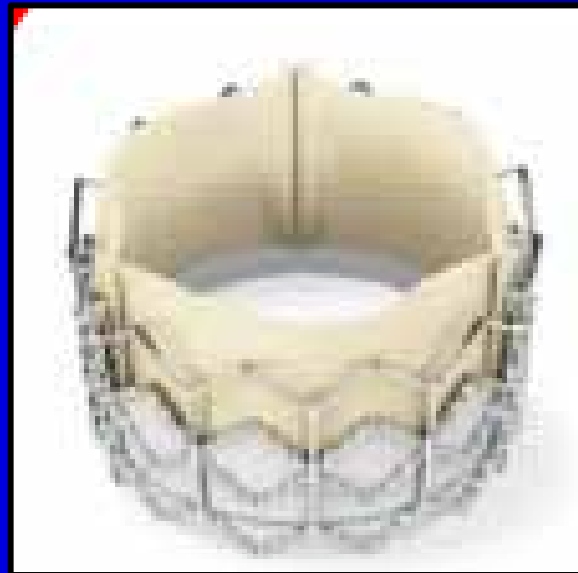
Evolution of Edwards Valves



SAPIEN 3



Cribier-Edwards



SAPIEN



SAPIEN XT

The 4 principles of aortic valve design have not changed since 1962¹



Principles

Surgical aortic valve

Predictable procedure

- Implantability

Optimal hemodynamics

- Circular frame design
- Optimal leaflet opening

Low rate of complications

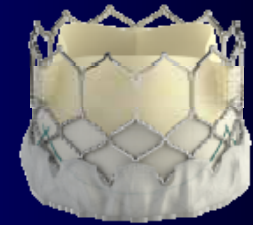
- Low thrombogenicity
- Low paravalvular (PV) leak
- Low conduction disturbances
- Low bleeding

Durability

- Circular geometry for low leaflet stress
- Tissue choice
- Anti-calcification tissue treatment

1. Harken DF, et al. Aortic valve replacement with a caged ball valve. *Am J Cardiol.* 1962;9:292-299.

The 4 principles of aortic valve design apply to future transcatheter heart valves



Principles

SAPIEN 3 Valve

Predictable procedure

- Balloon-expandable design
- Fine control of valve positioning and deployment

Optimal hemodynamics

- Circular expansion at the annulus

Low rate of complications

- Outer skirt and high radial strength frame minimize PV leak
- Low frame height

Durability

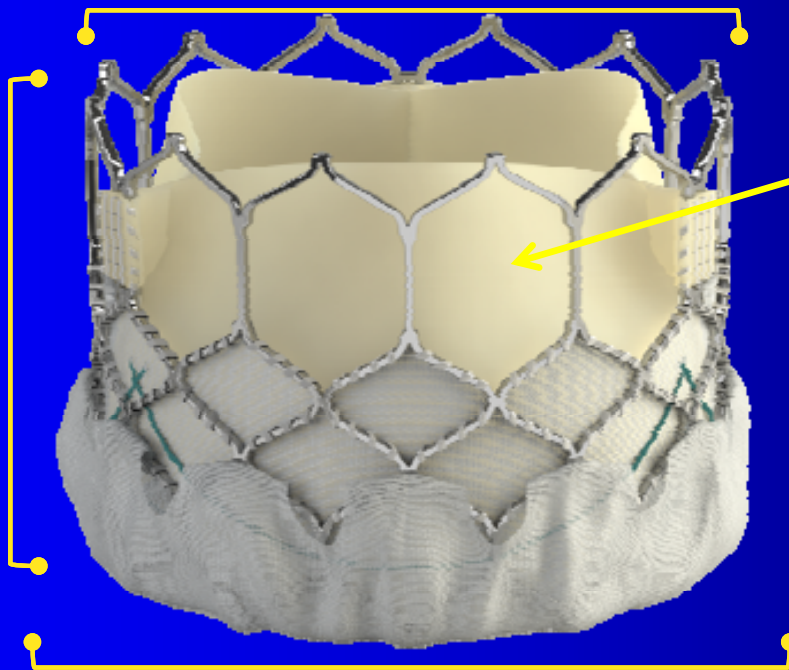
- Circular expansion
- Bovine pericardial tissue
- Anti-calcification treatment and leaflet matching

Edwards SAPIEN 3 Transcatheter Heart Valve

Enhanced frame design

- New frame geometry
- High radial strength for circularity and optimal hemodynamics

Low
frame
height



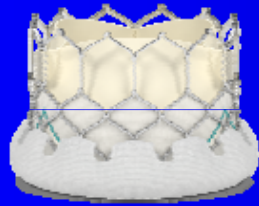
New outer skirt

Bovine pericardial tissue

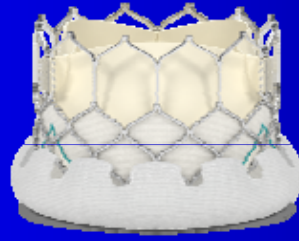
- Optimized leaflet shape
- Tissue treatment

The Edwards SAPIEN 3 valve, Edwards Commander and Certitude systems are investigational devices only and not for commercial sale

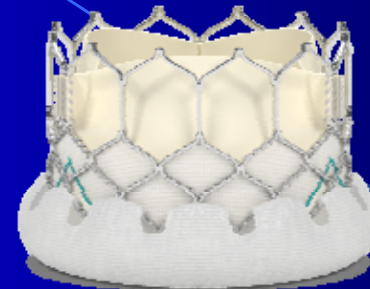
Edwards SAPIEN 3 Valve Sizes and Delivery System Profiles



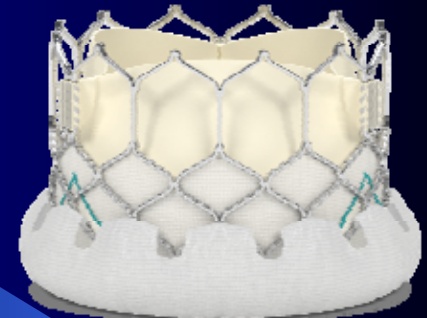
20 mm



23 mm



26 mm



29 mm

eSheath for
Commander
(TF)

14F

14F

14F

16F

Sheath for
Certitude
(TA, TAo)

18F

18F

18F

21F

Annulus
size by TEE

16-19
mm

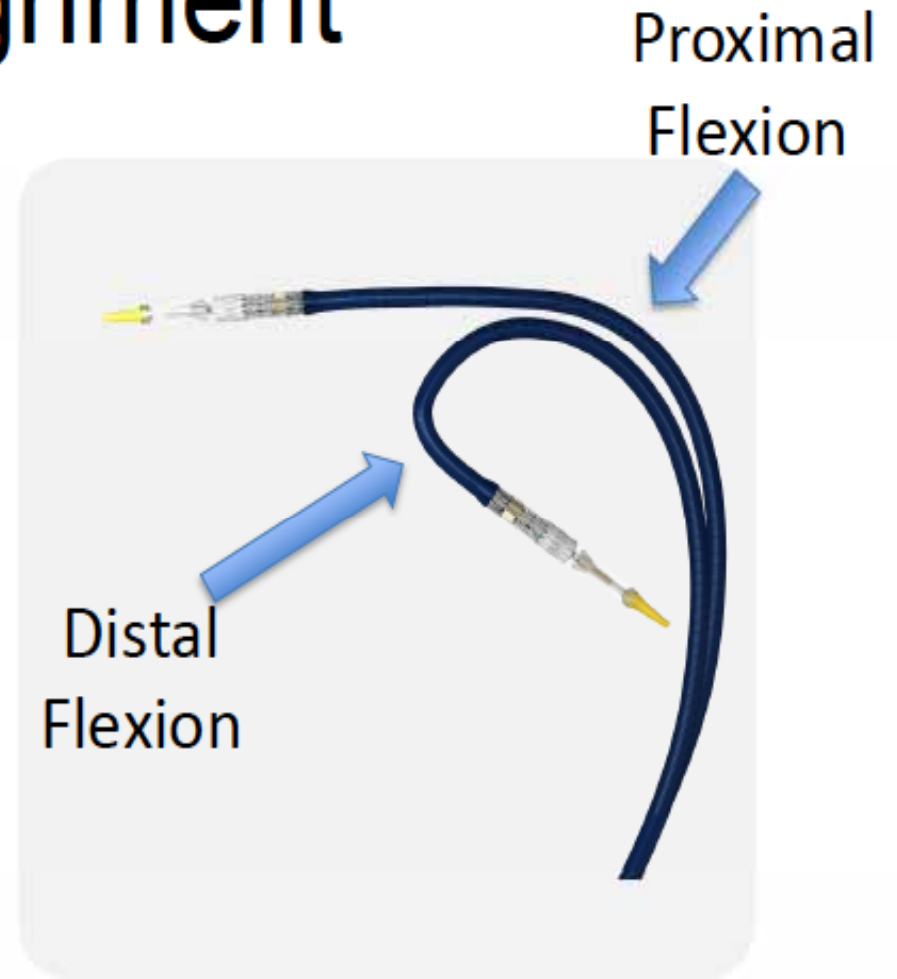
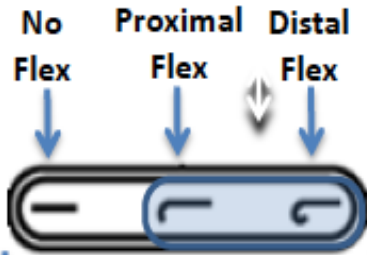
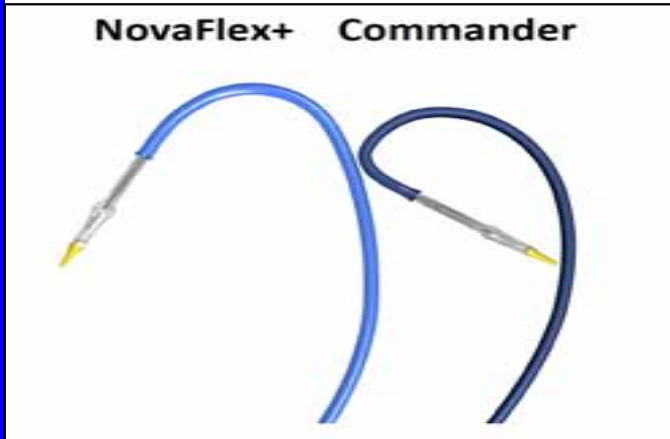
18-22
mm

21-25
mm

24-28
mm

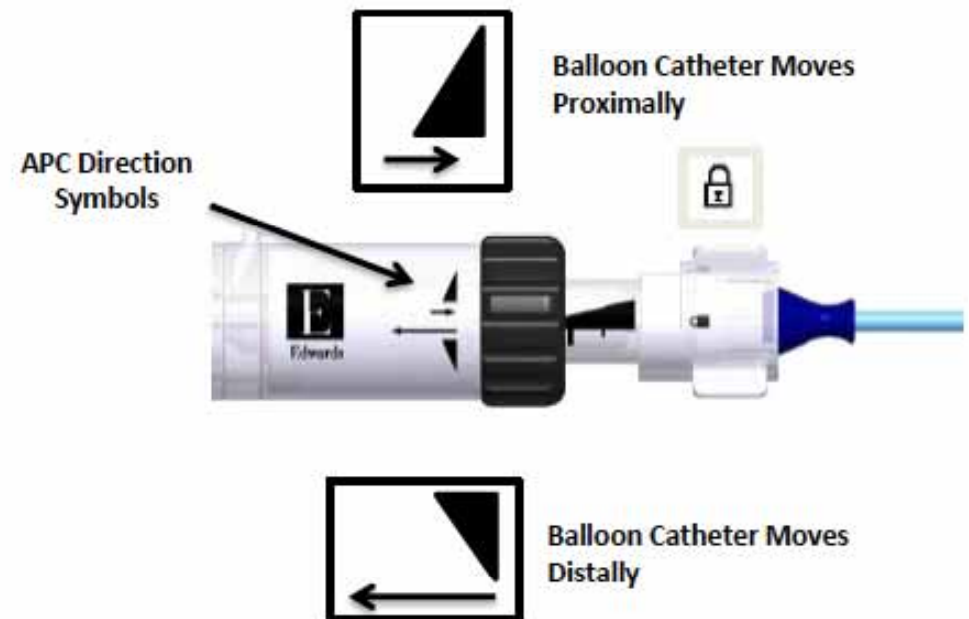
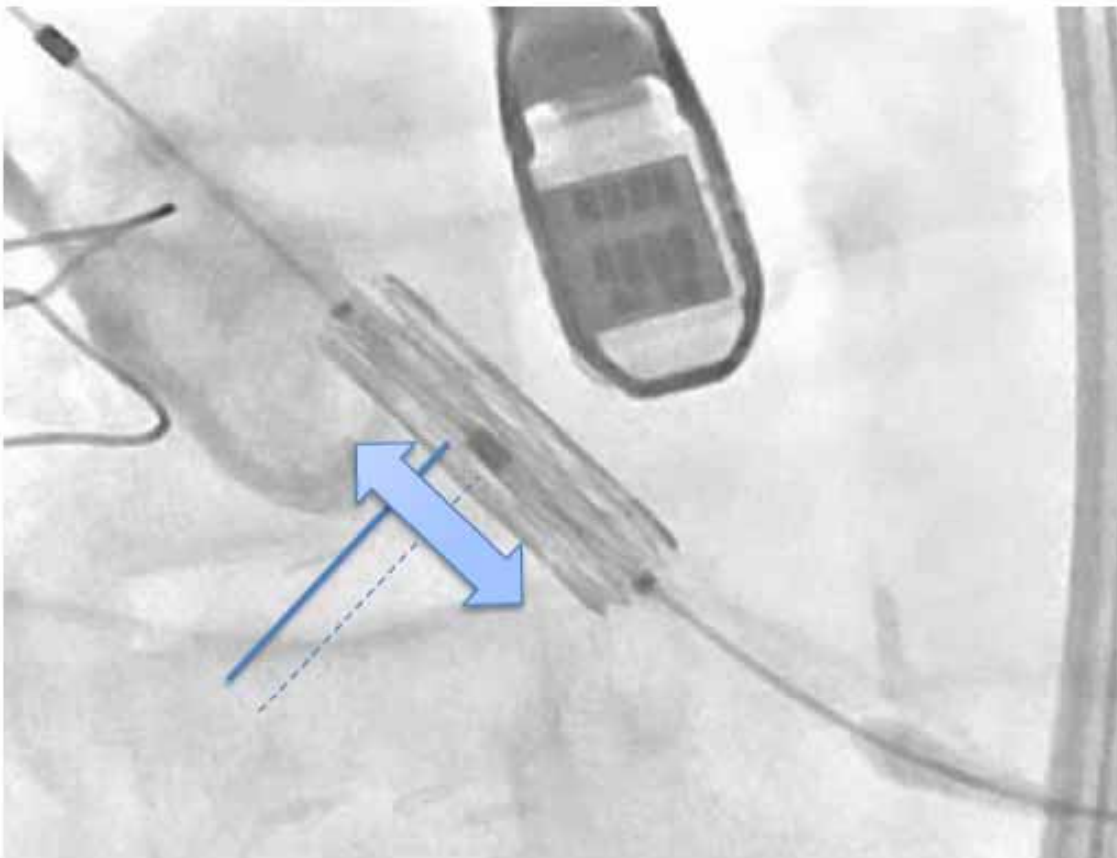
Edwards Commander Delivery System For TF Approach

Coaxial alignment

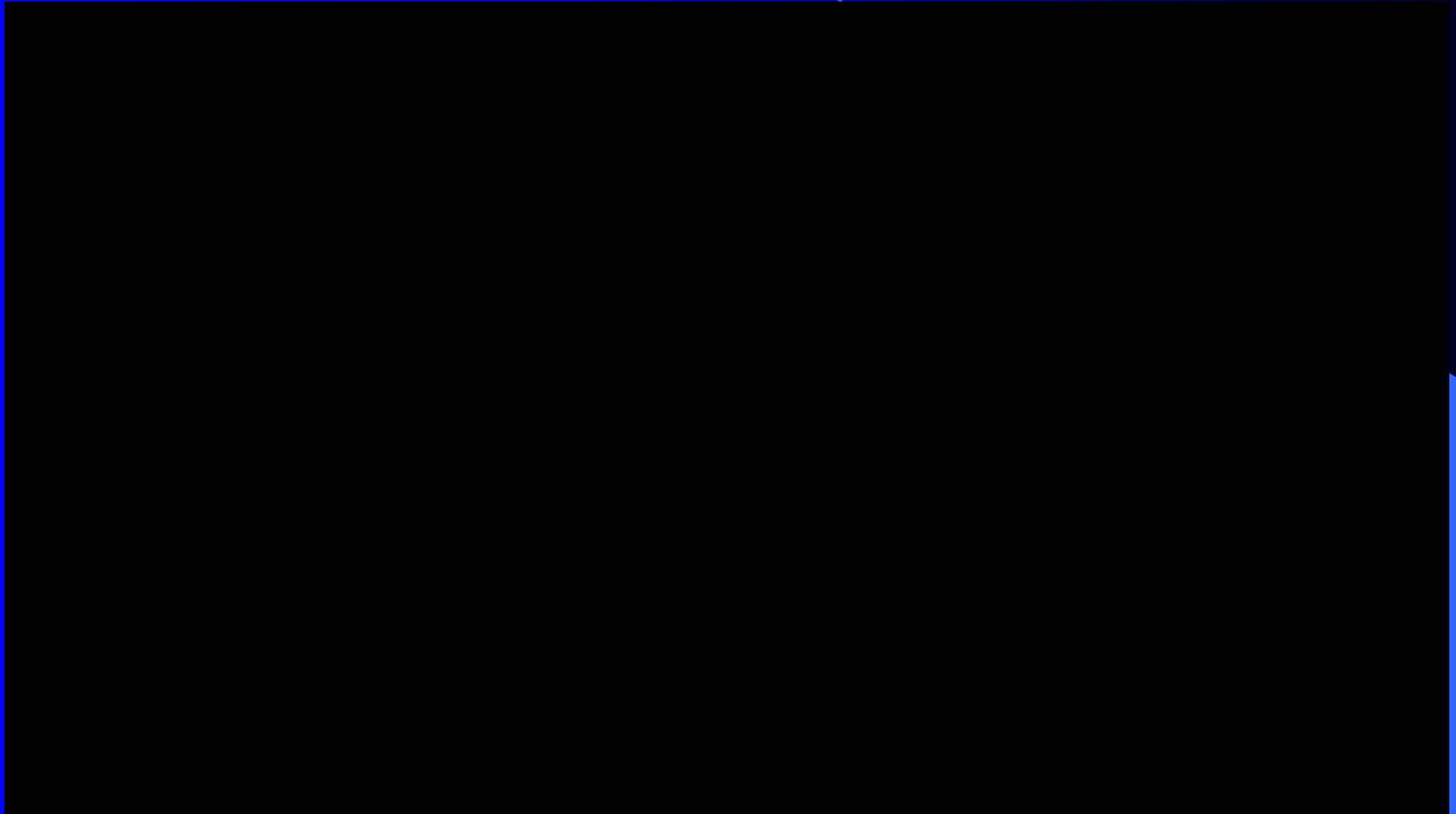


Edwards Commander Delivery System For TF Approach

Up & Down THV Positioning “Accurate Positioning Control”



SAPIEN 3 and Commander System for TF



Edwards Certitude Delivery System for TA and TAo Approaches



**Integrated
pusher**



**Articulation
feature**

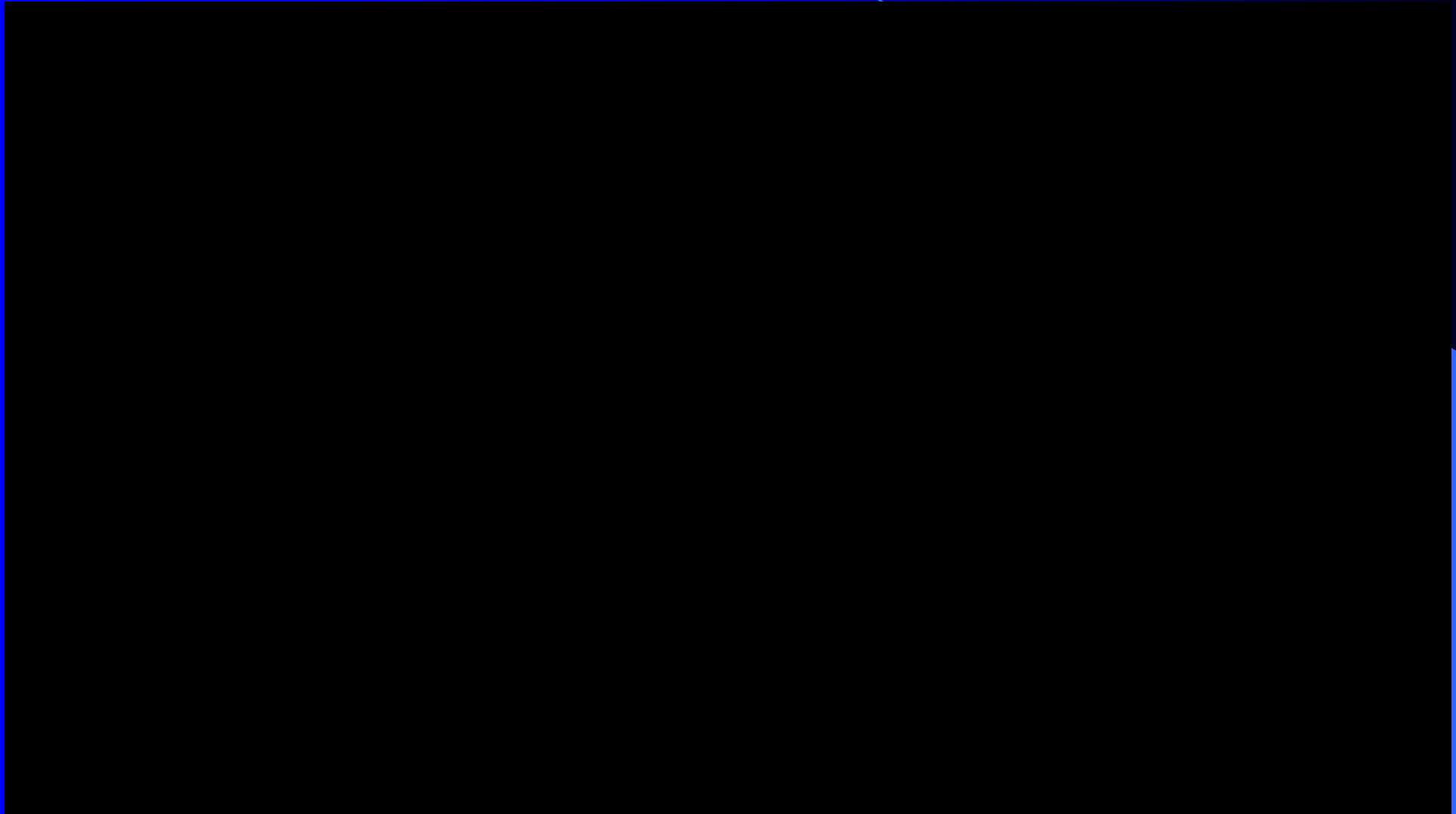


**Redesigned
handle**



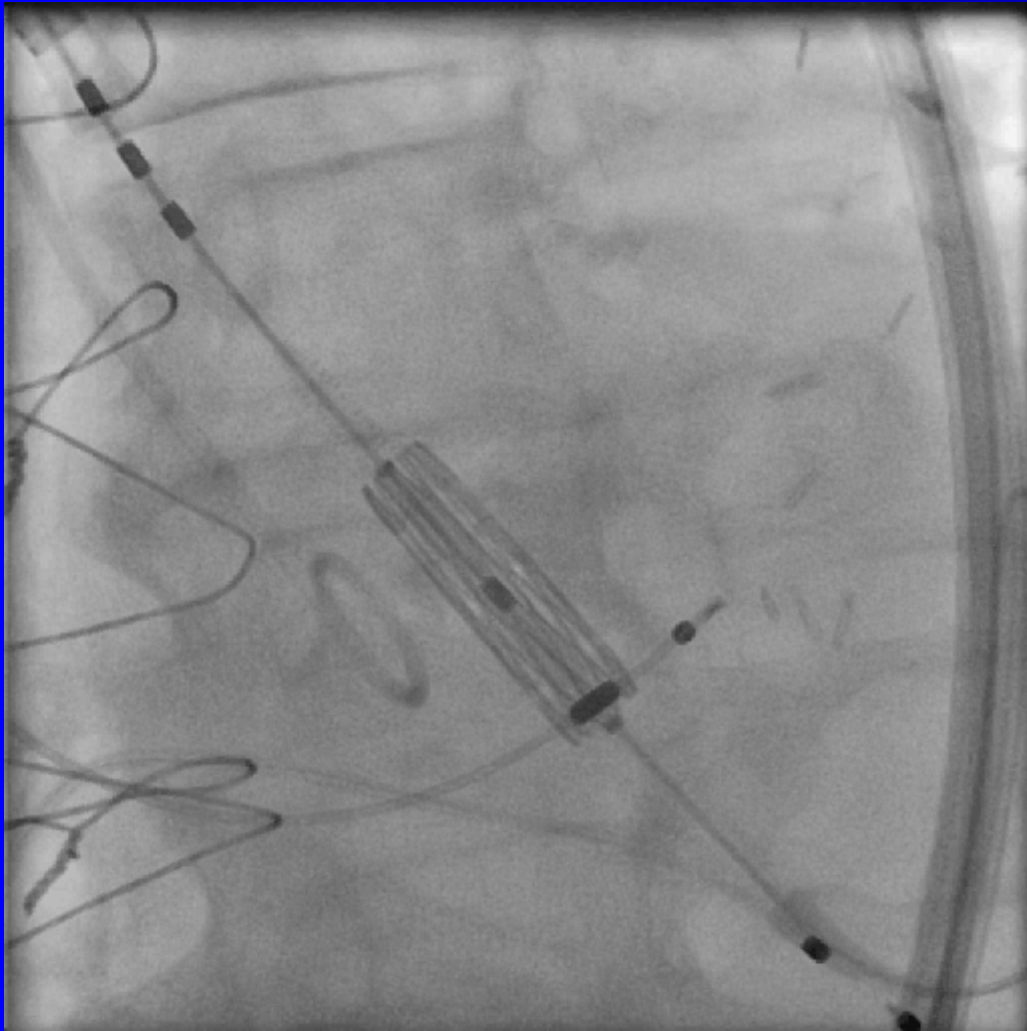
**Ultra-low profile system (18/21F sheath
compatible)**

SAPIEN 3 and Certitude Delivery System for TA or TAo

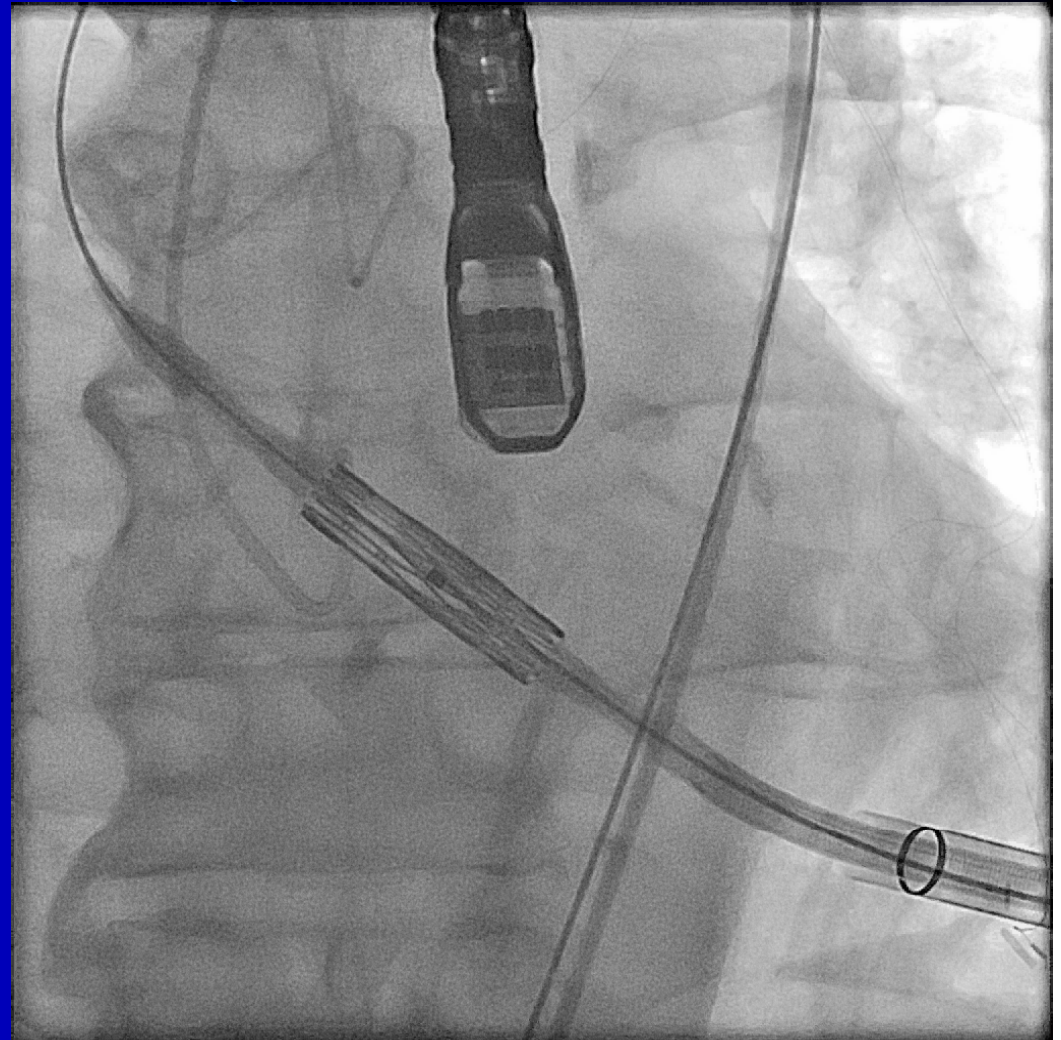


Accurate Positioning and Predictable Deployment

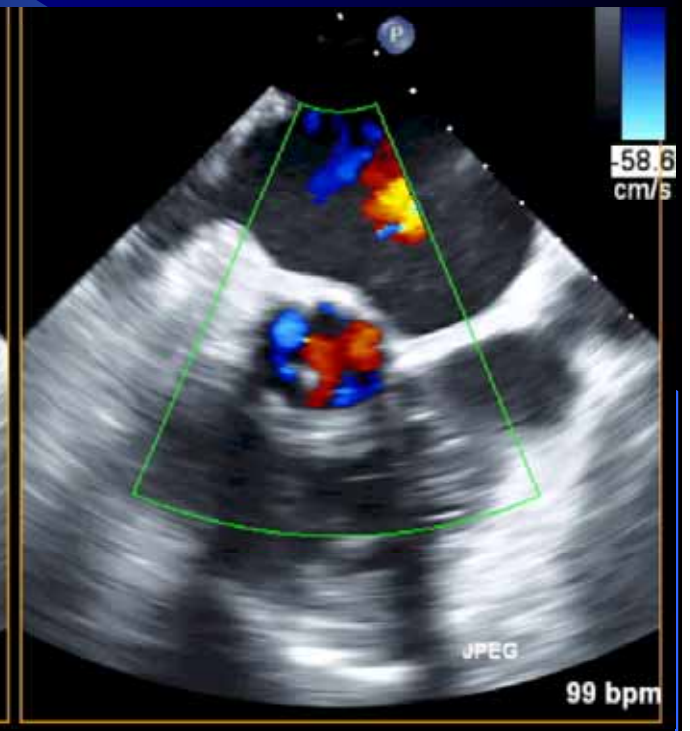
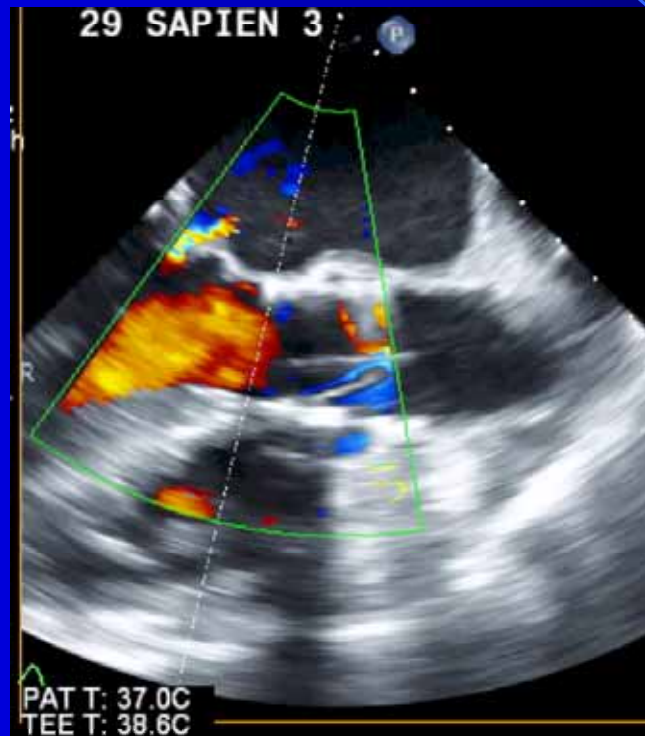
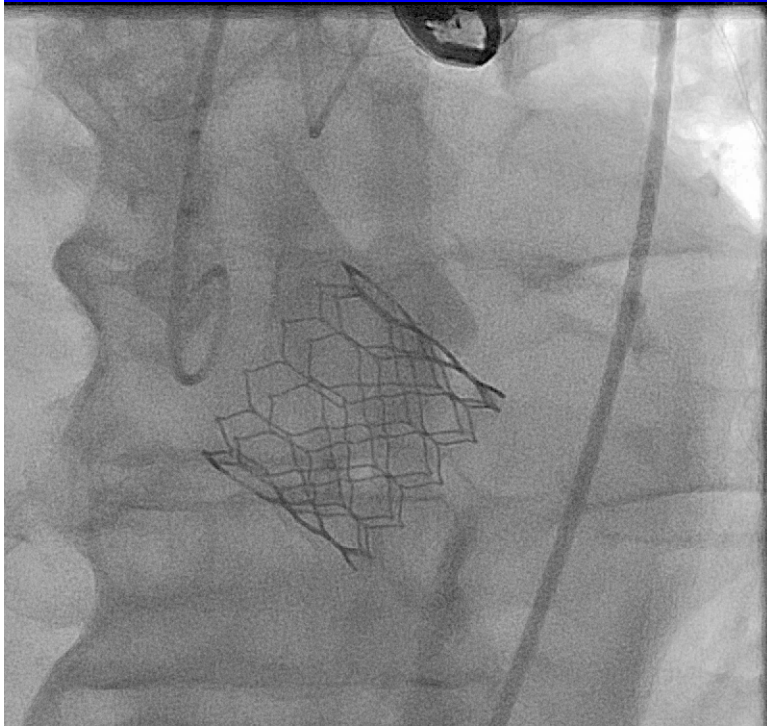
TF



TA

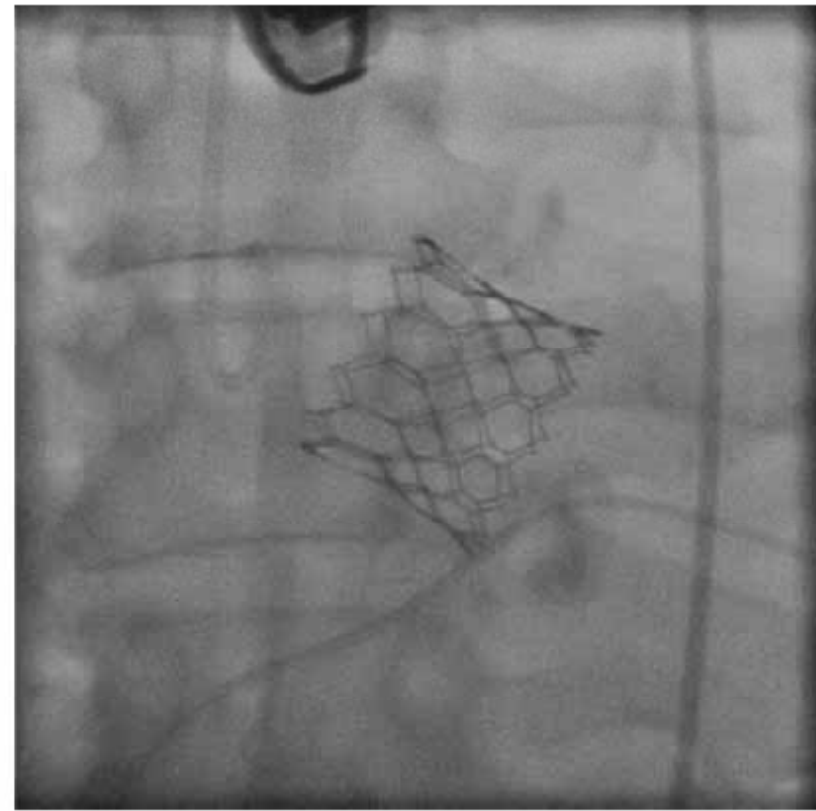
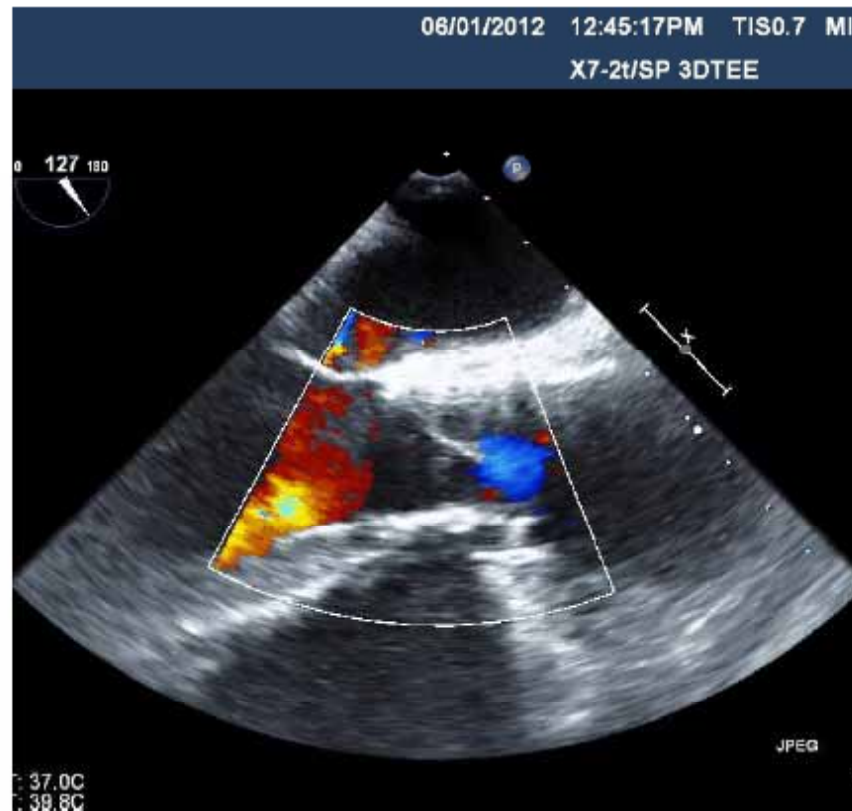


Predictable Sealing



Predictable Sealing

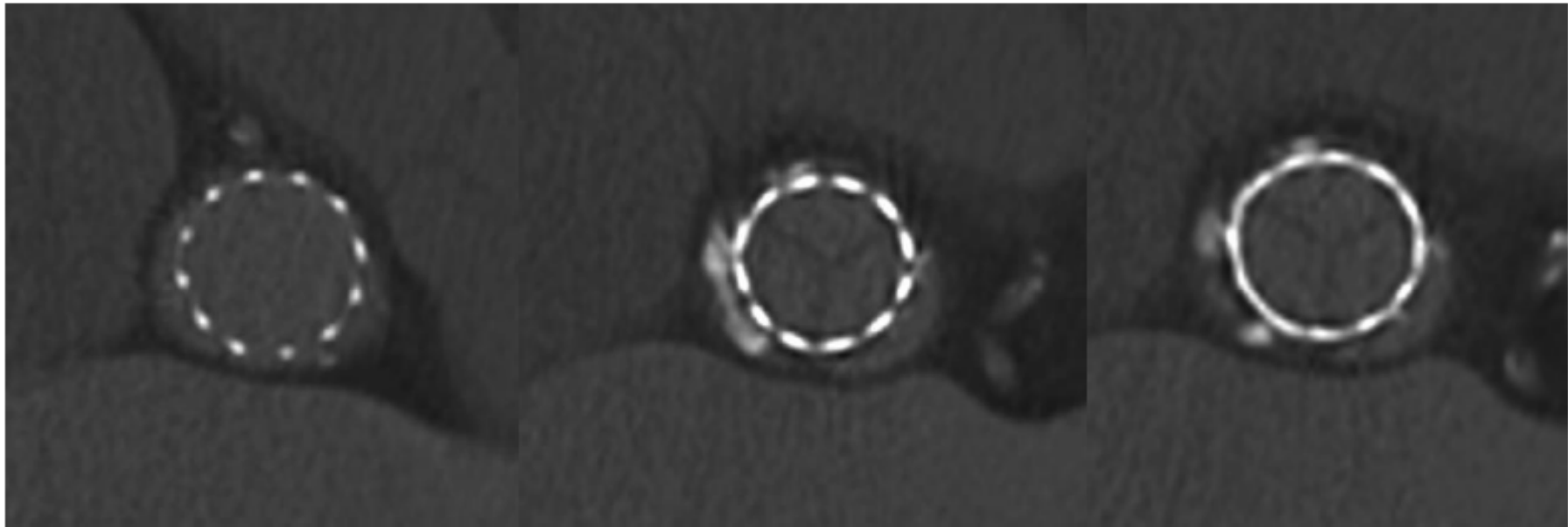
0% over sizing, no leak



CT annulus area = implant area = 5.3cm² = 0% oversizing

Adapted from John Webb, TVT 2013

Symmetric Expansion



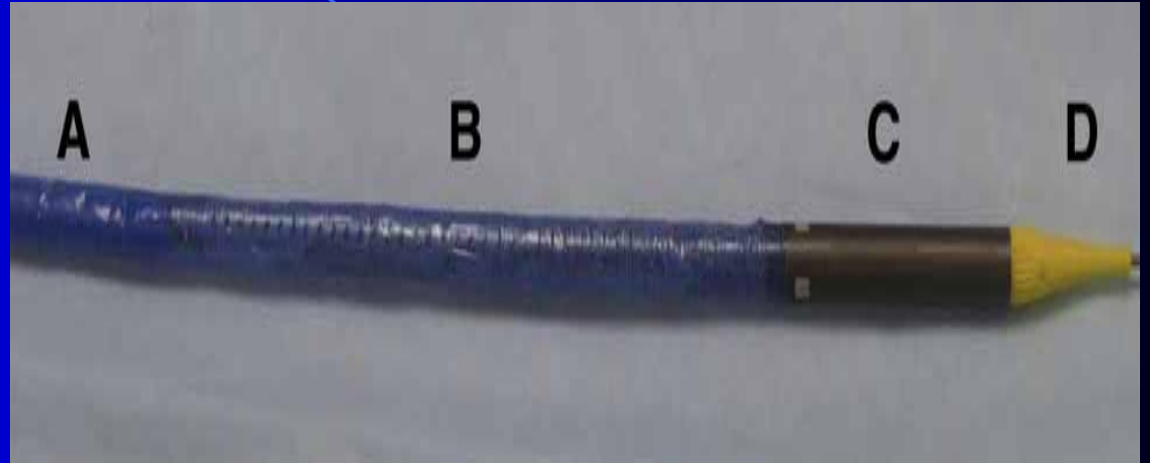
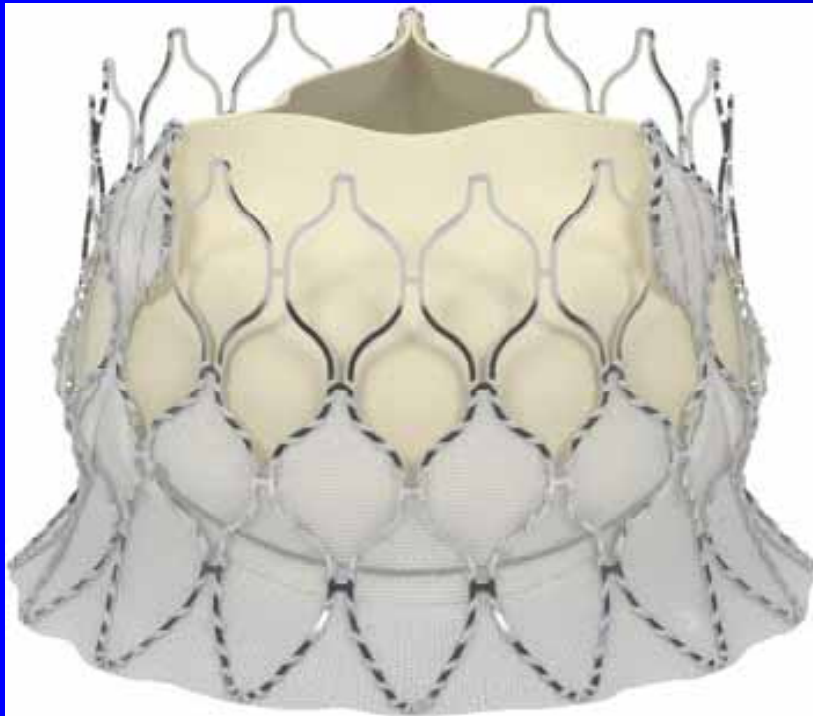
Adapted from John Webb, TVT 2013

SAPIEN 3 experience

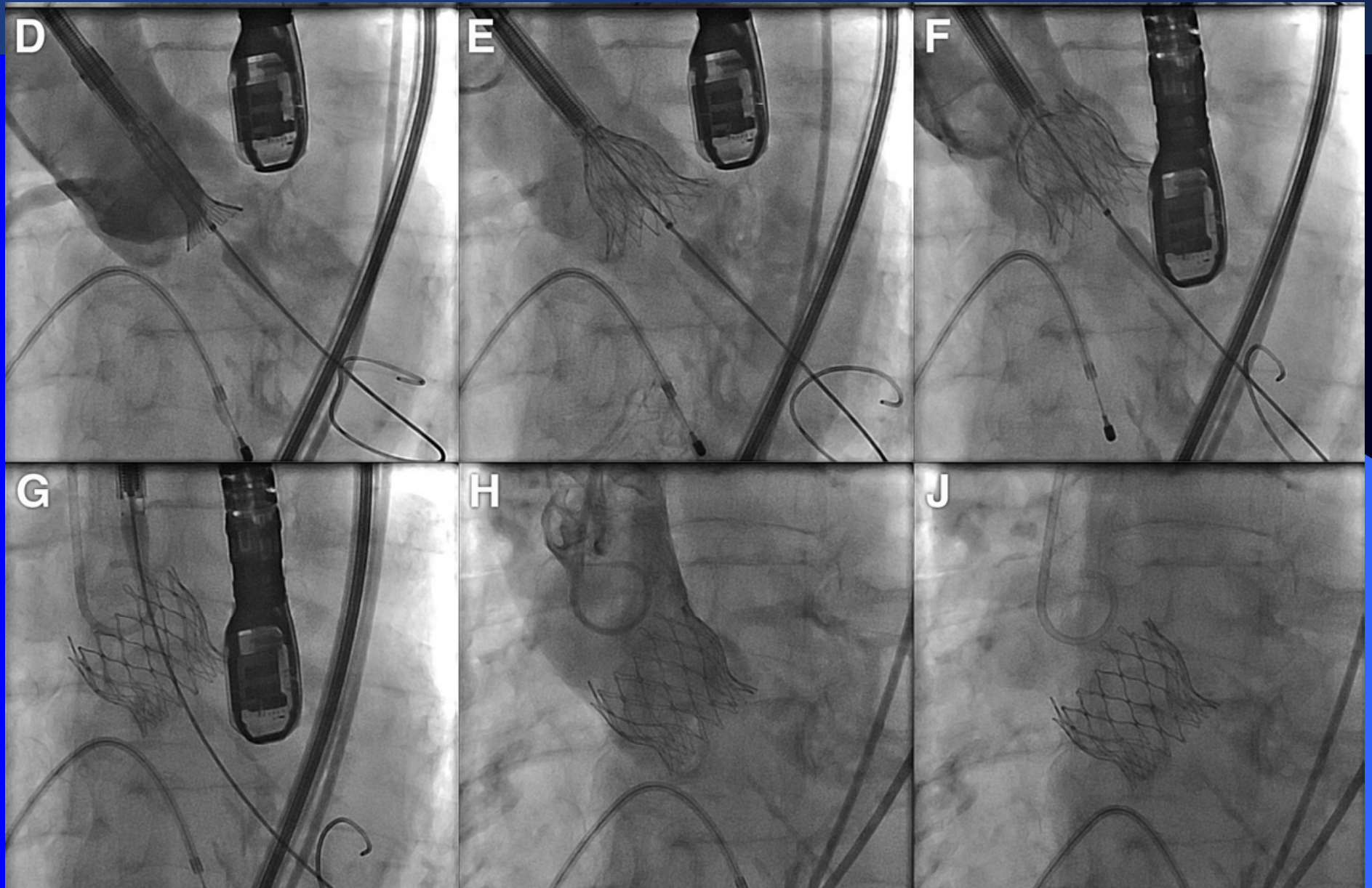
Vancouver and Quebec city

	30-day (n = 29)
Death	1 (3.4%)
Stroke	0
Major vascular complication	3.4%
Repeat procedure	0
Pacemaker implantation	1
Readmission	0
AR > mild	0
Hospital discharge	Median 3 days

CENTERA Self-expanding Valve and Motorized Delivery System



Clinical Experience



Binder, et al. J Am Coll Cardiol Interv 2013;6:301-7

Table 2. Cumulative In-Hospital, 30-Day, and 1-Year Outcomes

	In-Hospital Outcomes	30-Day Outcomes	1-Year Outcomes
Death	2	2	3
Myocardial infarction	0	0	0
Major stroke	0	0	0
Minor stroke	0	0	0
Transient ischemic attack	0	0	0
Major vascular complication	0	0	0
Minor vascular complication*	2	2	2
Major or life-threatening bleeding	1	1	1
Minor bleeding	1	1	1
Blood transfusions	2	2	2
Acute kidney injury (VARC)	1	1	1
Kidney failure (RIFLE)	3	3	3
Repeat procedure for valve-related dysfunction	0	1	1
Permanent pacemaker implantation	4	4	4
Readmissions to hospital			
Valve-related	—	1	1
Cardiac	—	1	2
Noncardiac	—	1	5