TCT AP 2011

Seoul, April 27th – 29th

TAVI Perspectives from the European Theater New Indications and Multiple Devices

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Financial Disclosure

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Physician Name	Company/Relationship
Eberhard Grube, MD	Medtronic, CoreValve: C, SB, AB, OF Sadra Medical: E, C, SB, AB Direct Flow: C, SB, AB Mitralign: AB, SB, E Boston Scientific: C, SB, AB Biosensors: E, SB, C, AB Cordis: AB Abbott Vascular: AB Capella: SB, C, AB Devax: SB, AB, Embrella: SB Claret: SB

Key
G – Grant and or Research Support E – Equity Interests S – Salary, AB – Advisory Board
C – Consulting fees, Honoraria R – Royalty Income I – Intellectual Property Rights
SB – Speaker's Bureau O – Ownership OF – Other Financial Benefits'

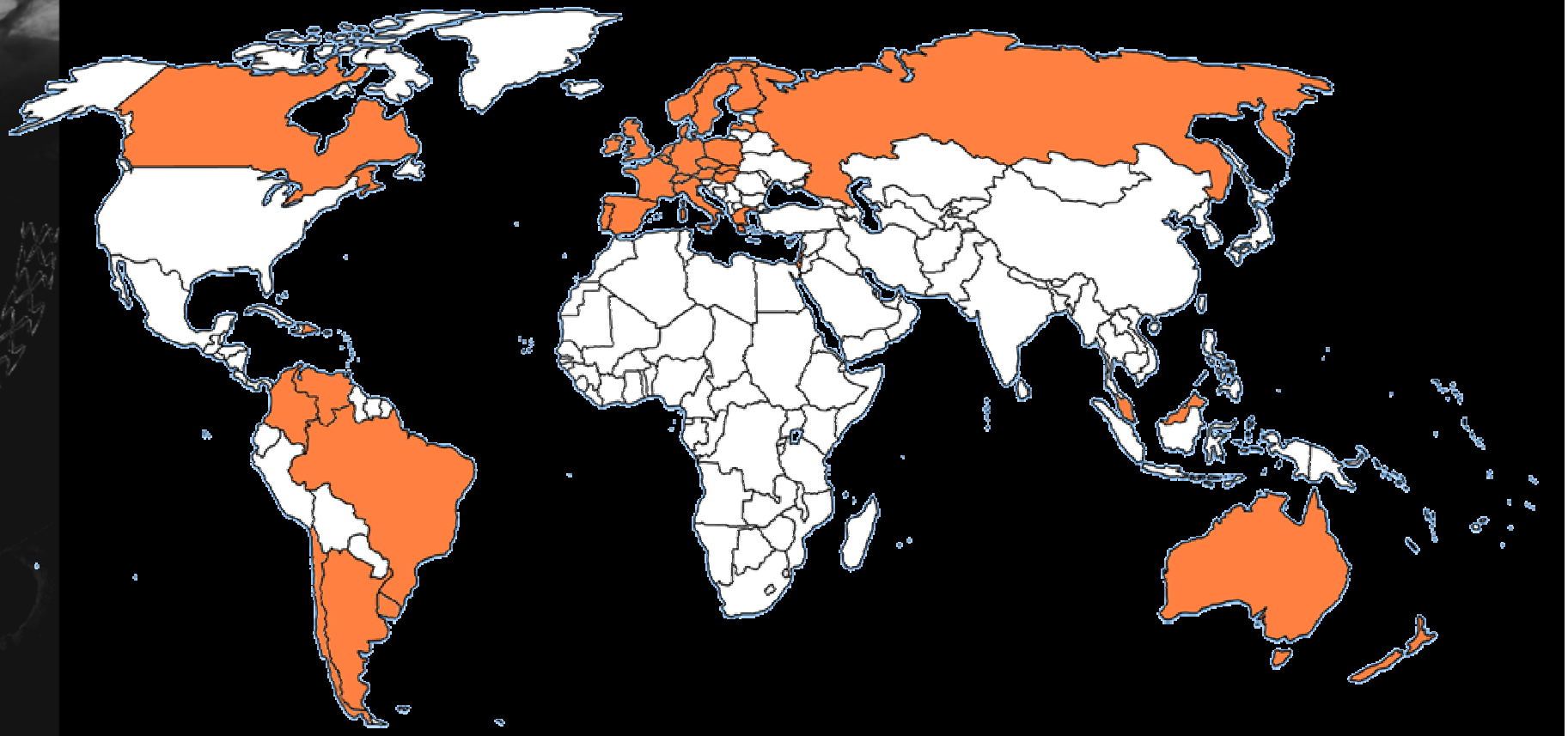
Transcatheter AVI

Current Generation Devices

Edwards
>15,000 patients

CoreValve
>15,000 patients

TAVI has spread through the World



More than 35,000 implants in 34 countries as of June 2011

TAVI – Current Issues

- Device related
  - Inaccuracies in Positioning / Lack of Repositionability ('One shot' procedure)
  - Paravalvular leackage
  - Profile size
  - Durability
- Non-Device related
  - Which specialty?
  - Logistics (Hybrid-OR)
  - Reimbursement
- Complications
  - Stroke,
  - Vascular Complications
  - Pacemaker need

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Issue of Durability

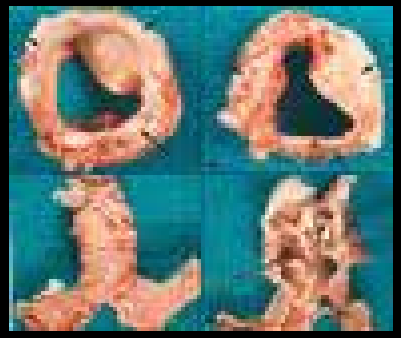
- How behaves the valve in the long-term ? Longest experience so far 6.5 (ES), 5.5 (CV) years
- What are the consequences on valve *durability* of...
  - Valve squeezing – balloon dilatation?
  - Less than perfect deployment?
  - Asymetric – Oblique implantation?

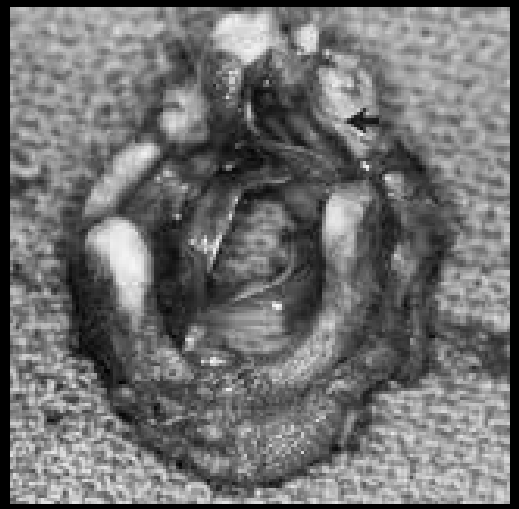
But:

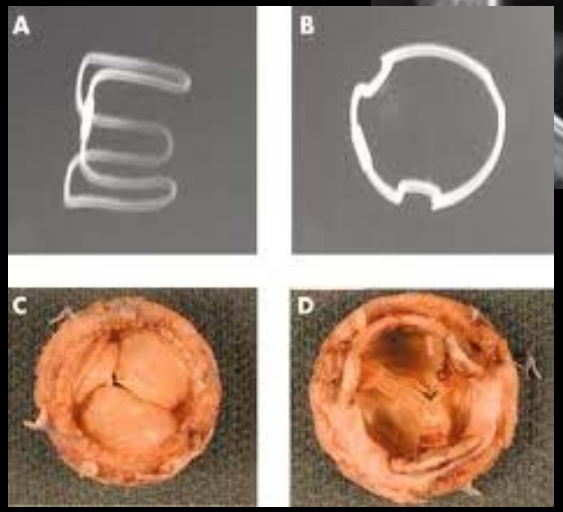
Surgical experience for several decades does not mean the use of one particular prosthesis for decades!

New prosthesis with lack of long-term experience will be implanted even today, too!

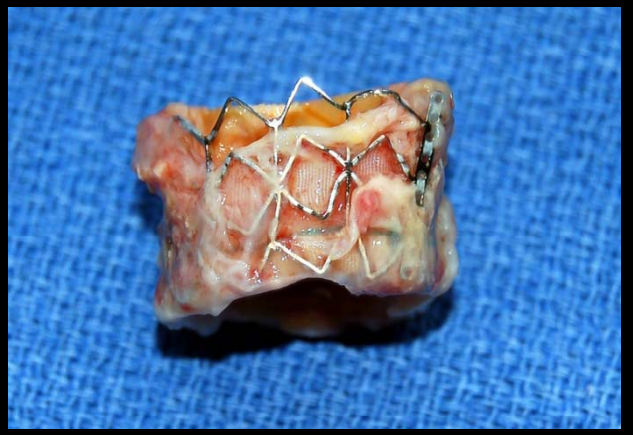
Degenerated Surgical Valves



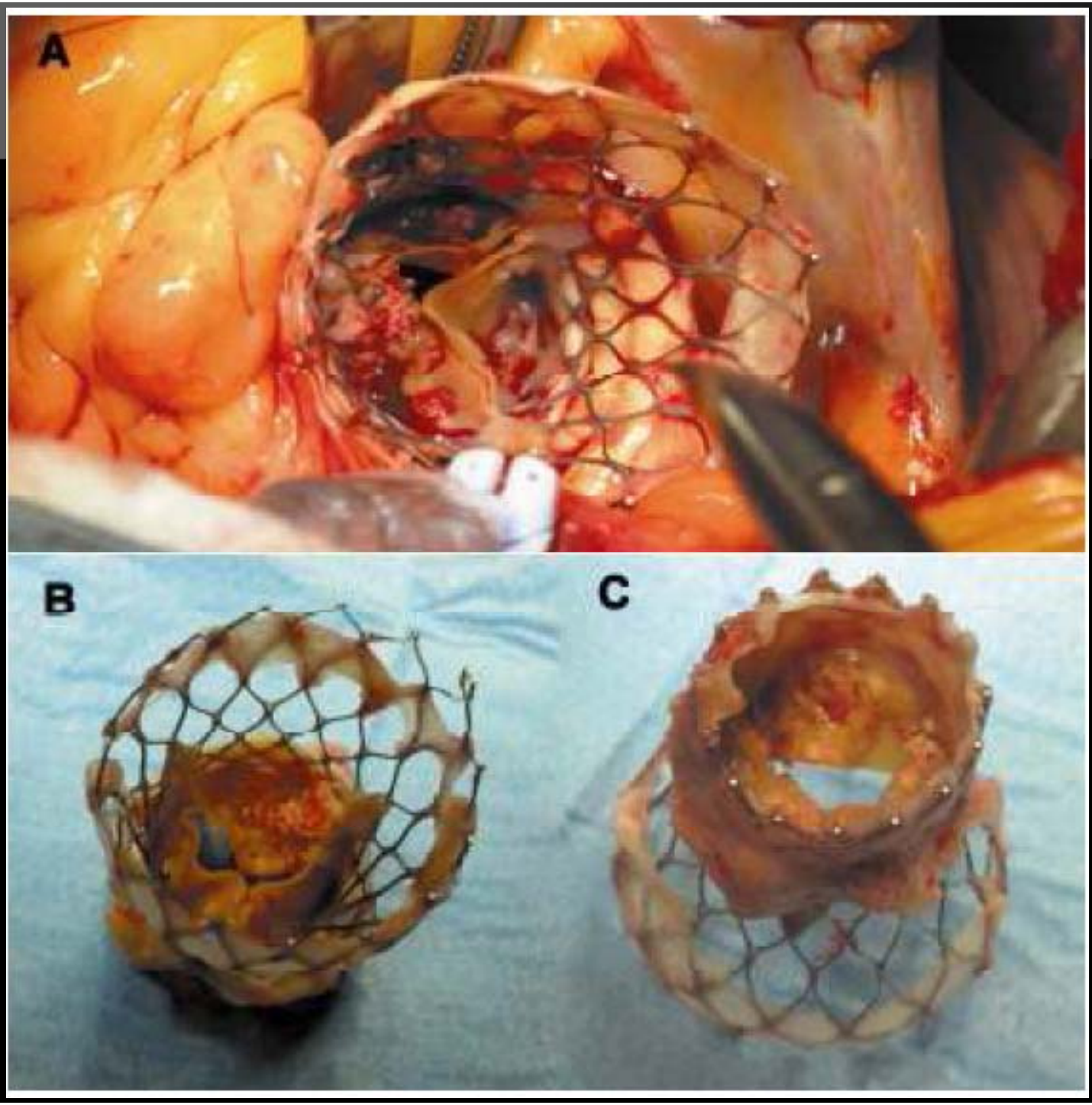




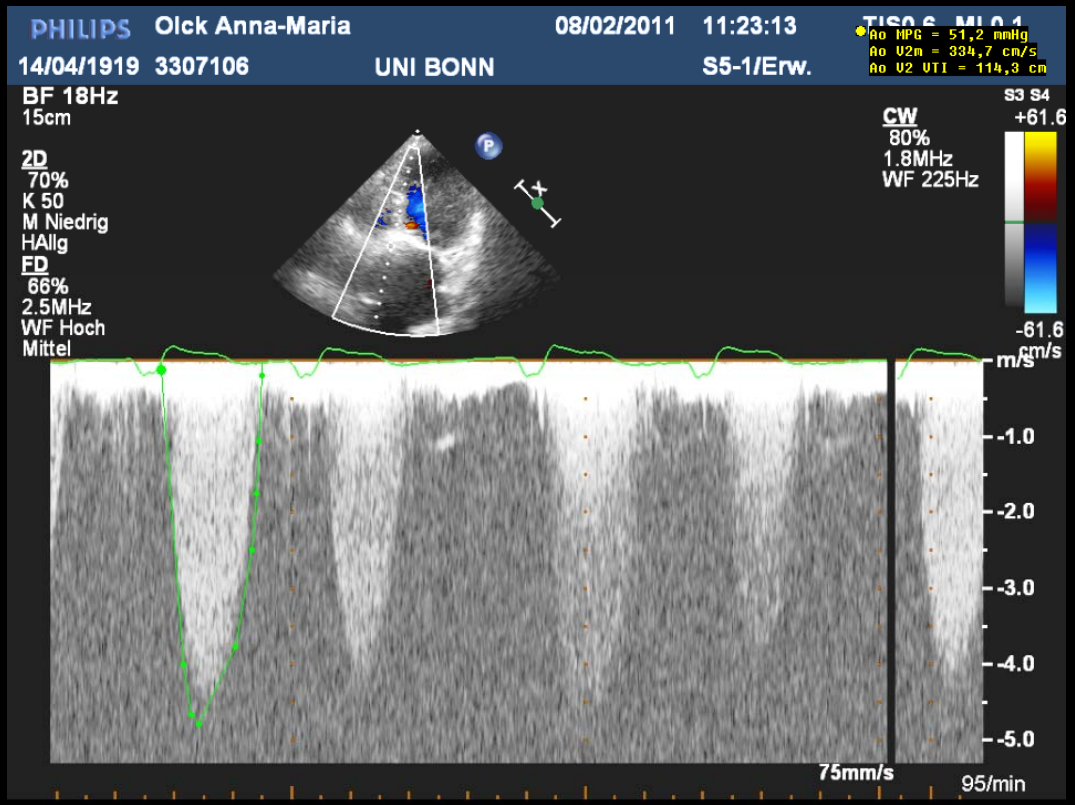
Restenosed Sapien Valve



Courtesy Gus Pichard


A
B
C

Restenosed Core Valve



26mm 2nd generation porcine valve implanted in August 2005

Treatment Valve in Valve

TAVI – Current Issues

- Device related
  - Inaccuracies in Positioning / Lack of Repositionability
  - Paravalvular leackage
  - Profile size
  - Durability
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  - Which specialty?
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  - Stroke,
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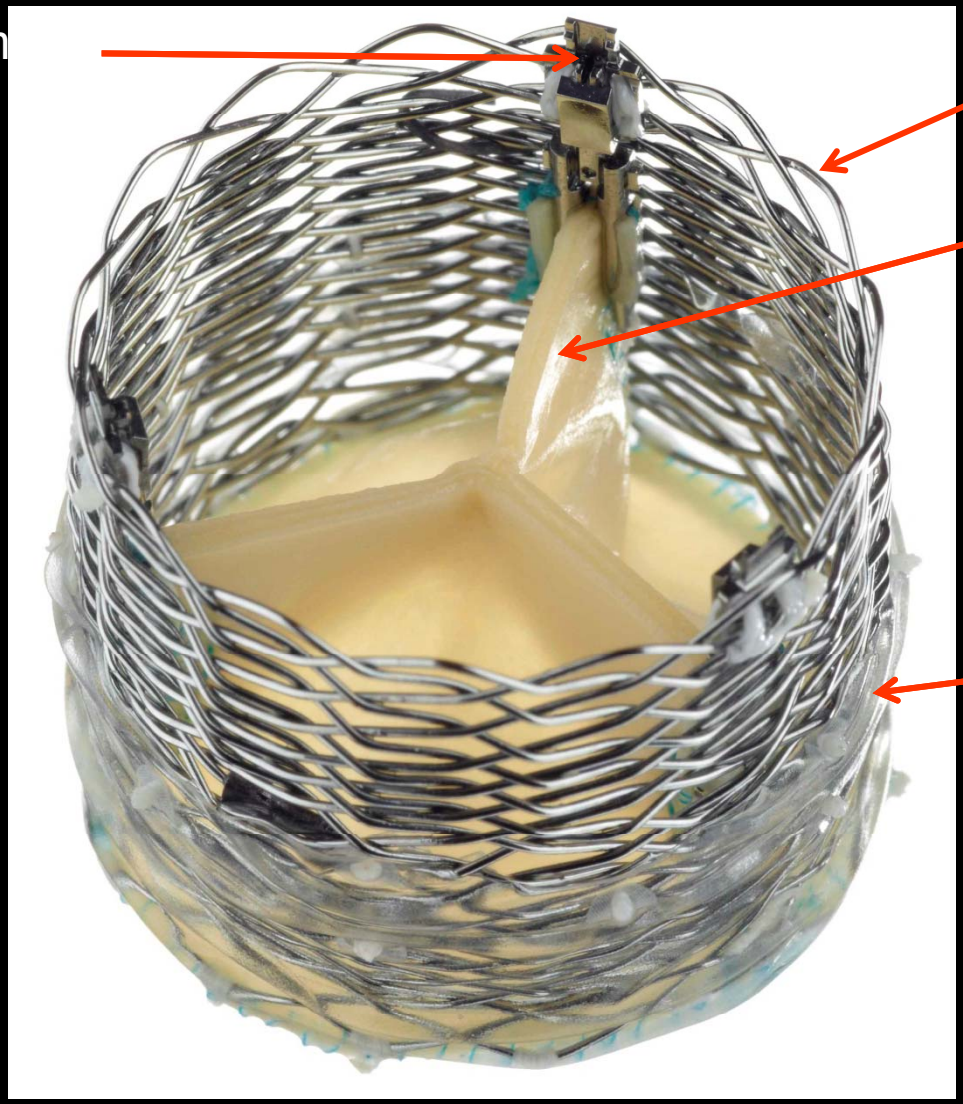
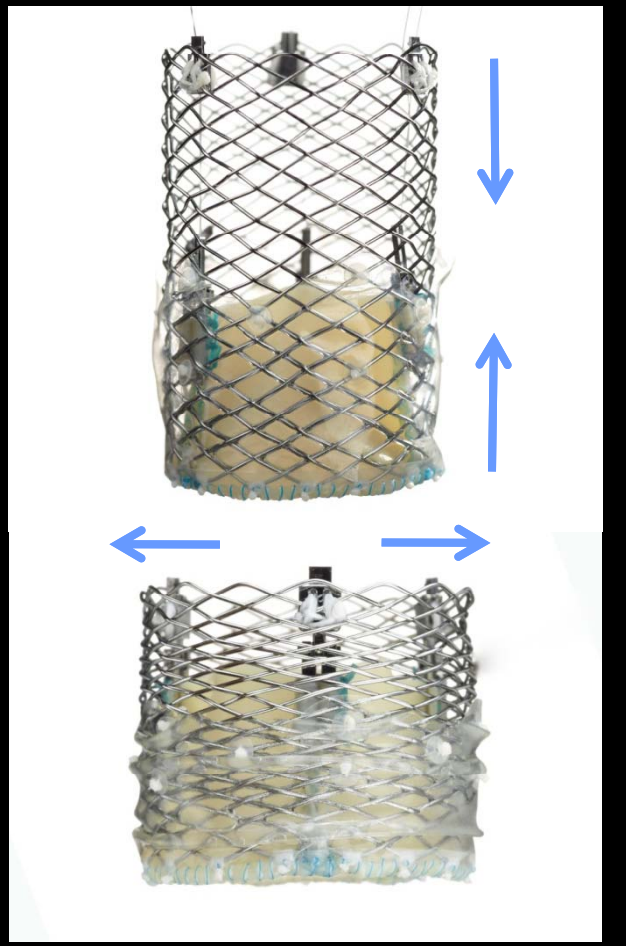
Next Generation
Transcatheter aortic valves

Sadra Lotus™ Valve



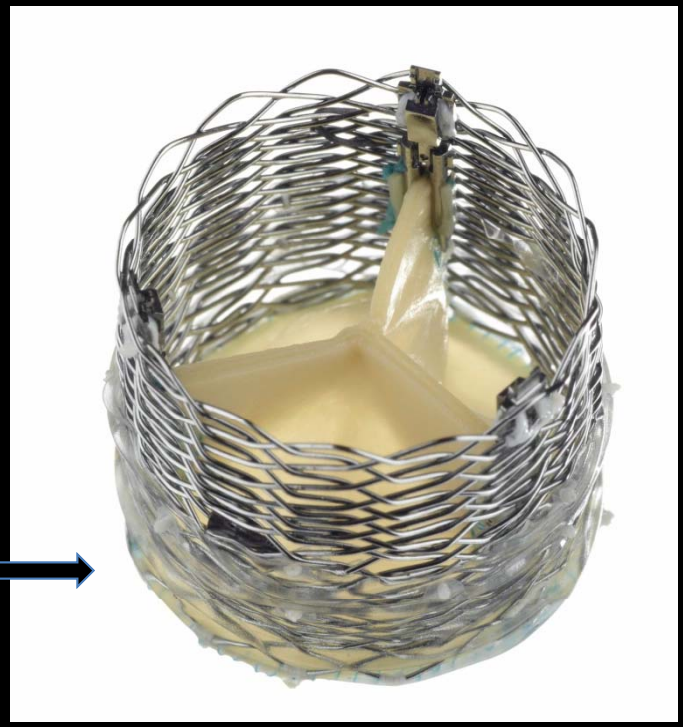
Sadra Lotus™ Valve Concept

- **Braided nitinol stent structure**
- Radial expansion as it shortens
  - § Enables a more flexible delivery system
  - § Enables device repositioning or retrieval
  - § Provides significant radial strength



Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
- Minimal perivalvular leakage
  - Adaptive™ Seal fills gaps between native valve and implant

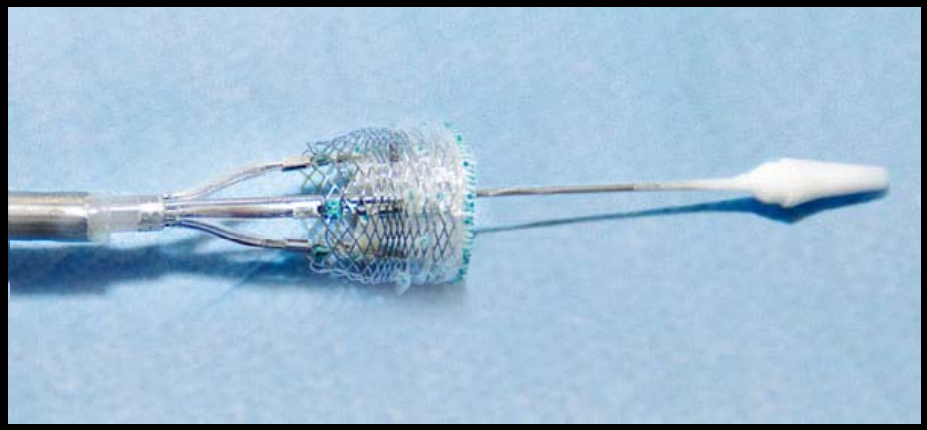


Advantages of the Lotus Valve System

- **Ease of Use**
  - **System is pre-packaged on delivery system**
  - **Two handle controls**
    - **1 - deploy / retrieve and 2**

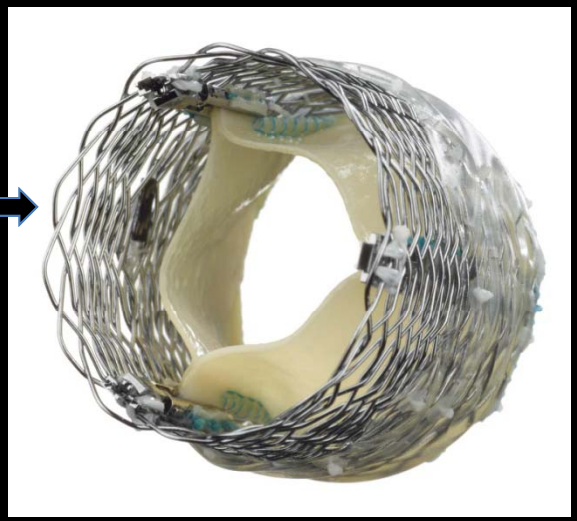
Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
  - Predictable, reversible deployment
  - Fully repositionable, both distally and proximally as needed
  - Retrievable at any point prior to release



Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
  - Center marker facilitates alignment with native valve
  - Valve leaflet function begins early during deployment
    - Hemodynamic stability
    - Enhances precision positioning



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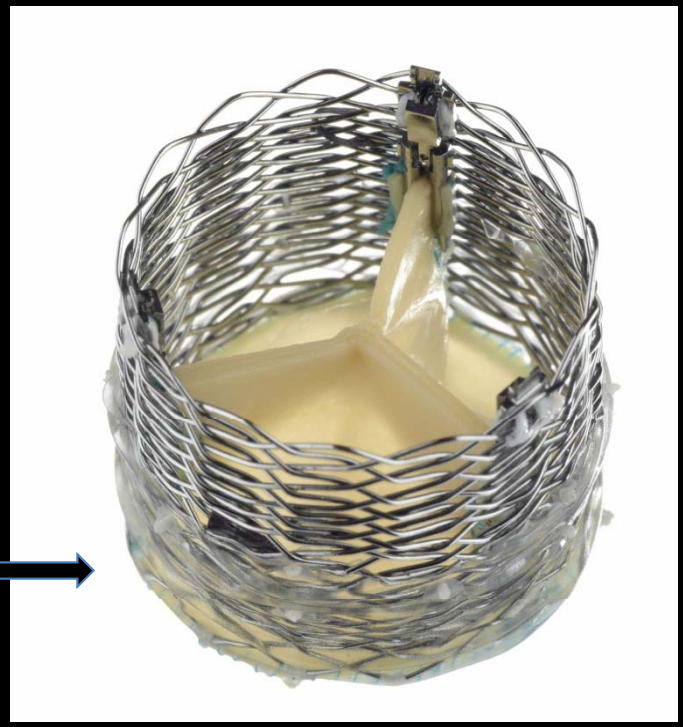
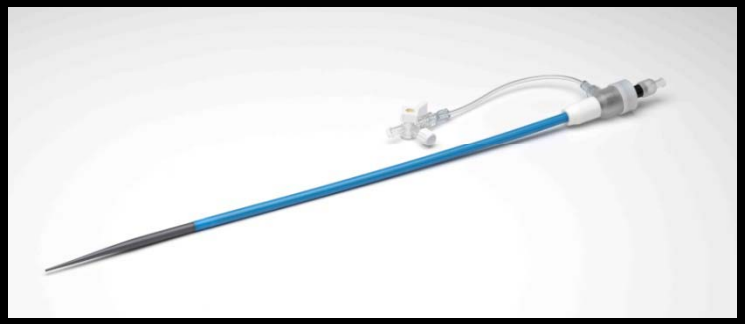


Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
- Minimal perivalvular leakage
- Percutaneous delivery
  - Proprietary Lotus Introducer Sheath provides access to ≥ 6.0mm femoral vessels - equivalent to Cook 18F introducer

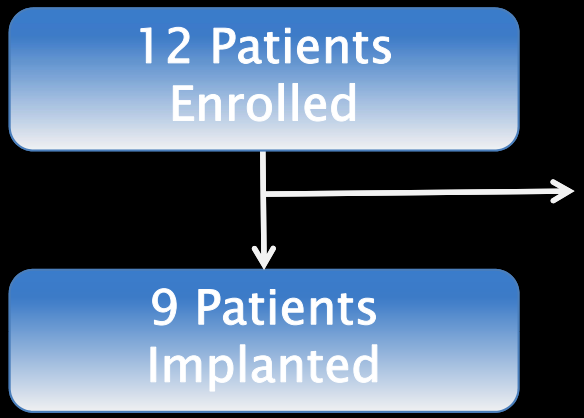


Study Enrollment

- 12 patients have been enrolled at 3 sites, with 9 patients implanted with the Lotus™ Valve System
- First patient enrolled: April 13, 2010 at Essen Elisabeth by Prof. Grube

Site #	PI	Pts Enrolled	Pts Implanted
01 – Siegburg	Dr. R. Mueller	4	4
02 – Essen Elisabeth	Prof. E. Grube	4	2
03 – Essen University	Prof. R. Erbel	4	3
	Total	12	9

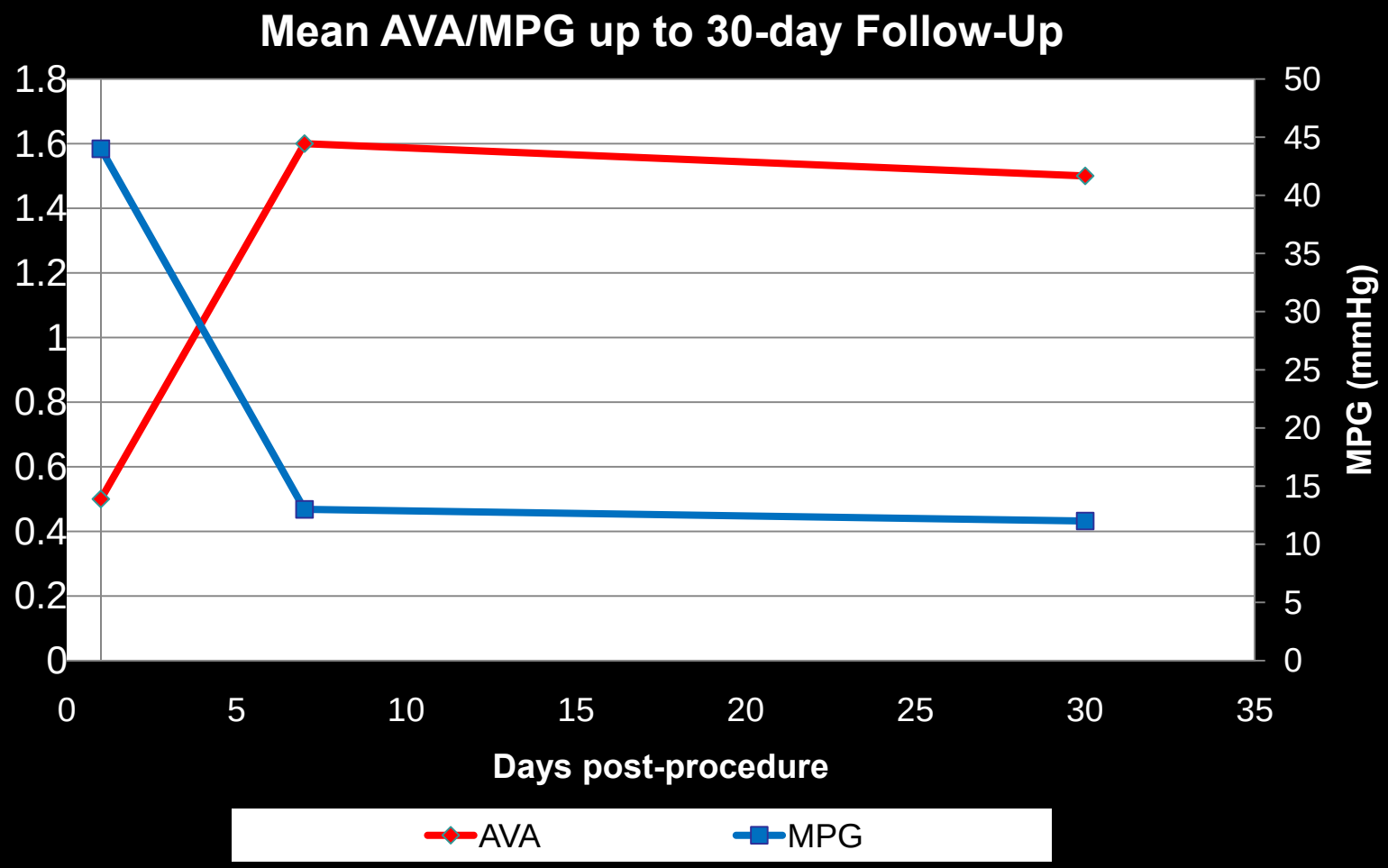
Clinical Results at 30 Day Follow-up



Primary Endpoint Events	Implanted (n=9)
All Deaths	**1**
MI *(ARC definition)*	**1**
Stroke with permanent deficit	**1**
Re-intervention for Valve-related complications	**0**
Procedure Success	**9**

To be used exclusively for clinical investigations. Not for Sale or Use in the United States

Echo Data – Pre, Post & 30-Day Follow-up



* Site

Larger Valve Project Progress

- **Design targets**
  - 27 mm diameter to treat 23-26 mm AS
  - Valve height: 18-19 mm
  - Delivery introducer profile: < 20 Fr
- **Status**
  - First prototypes complete
  - 3 valves @ 200mm cycles
  - Modified delivery handle underway

Next Steps

- Preparing for multi-center OUS CE trial submission.
- 27mm valve achieved 200MM cycles in testing.
- Initiating CE trial with both 23 and 27mm valves in 2011.

DIRECT FLOW MEDICAL, INC.

"it's all about flow..."

Direct Flow Medical

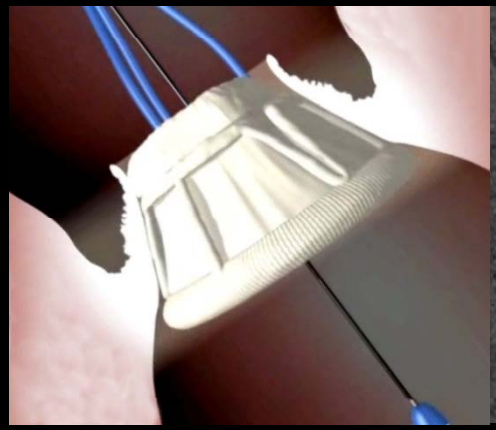
3 sizes matching
valvuloplasty balloons

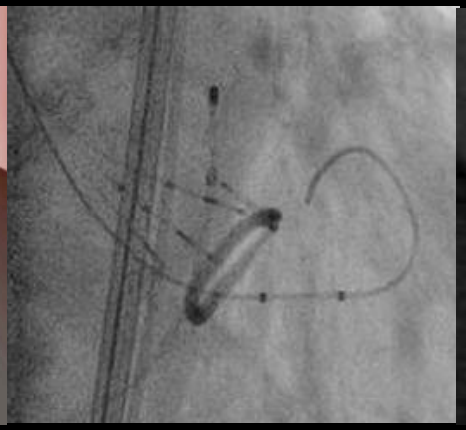
22F Design

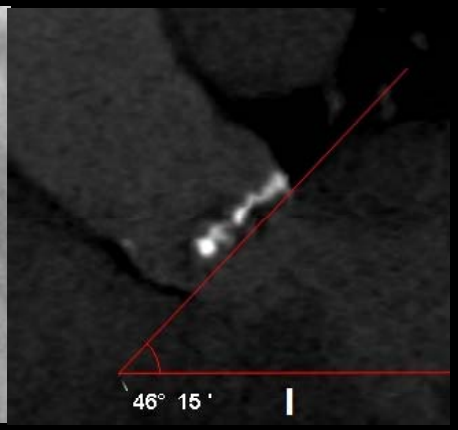
18F Design

Positioning Securement & Sealing

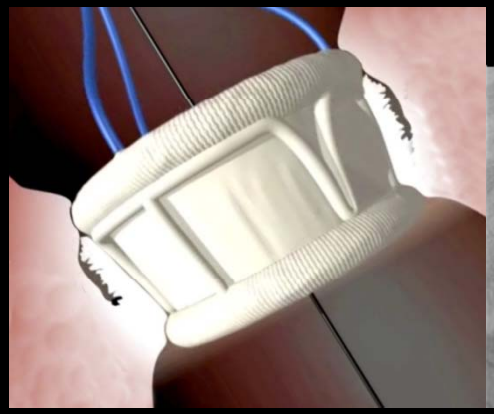
Positioning

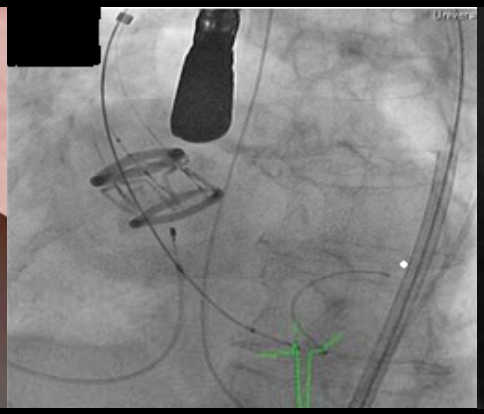


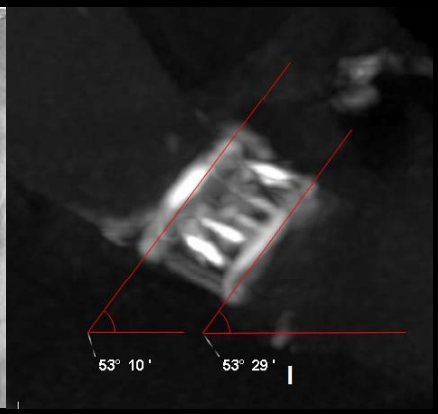




Sealing
&
Securement



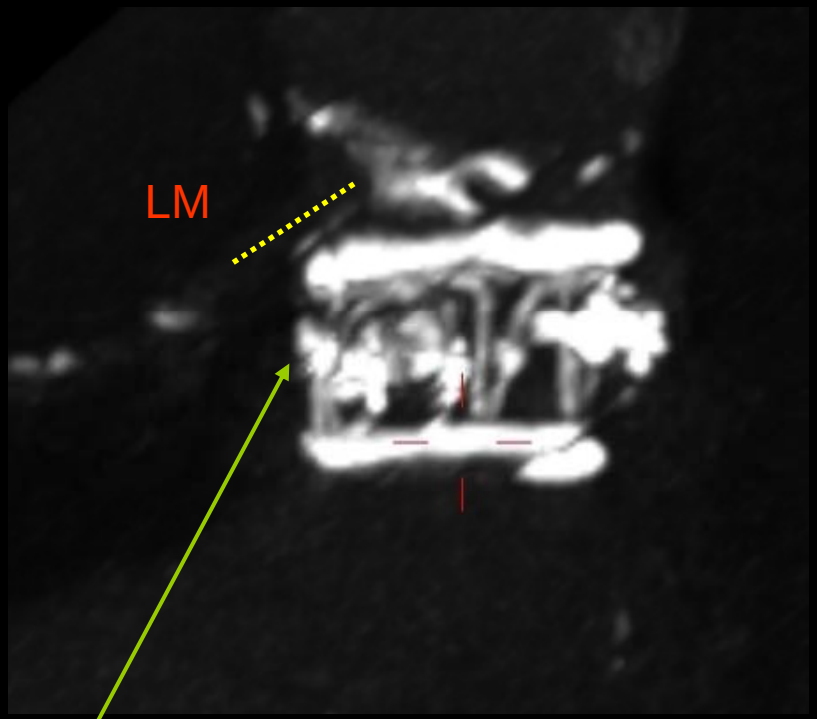


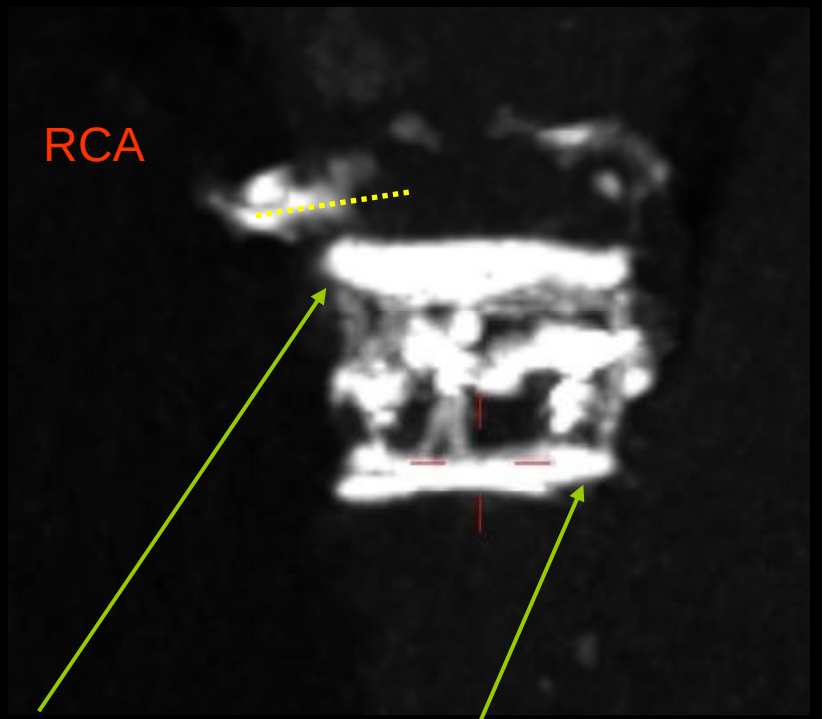


Direct Flow Medical
Aortic Valve

The valve is designed to seat in the intra-annular space capturing the native leaflets

The LVOT cuff is designed to seal inferior to AV in the LVOT



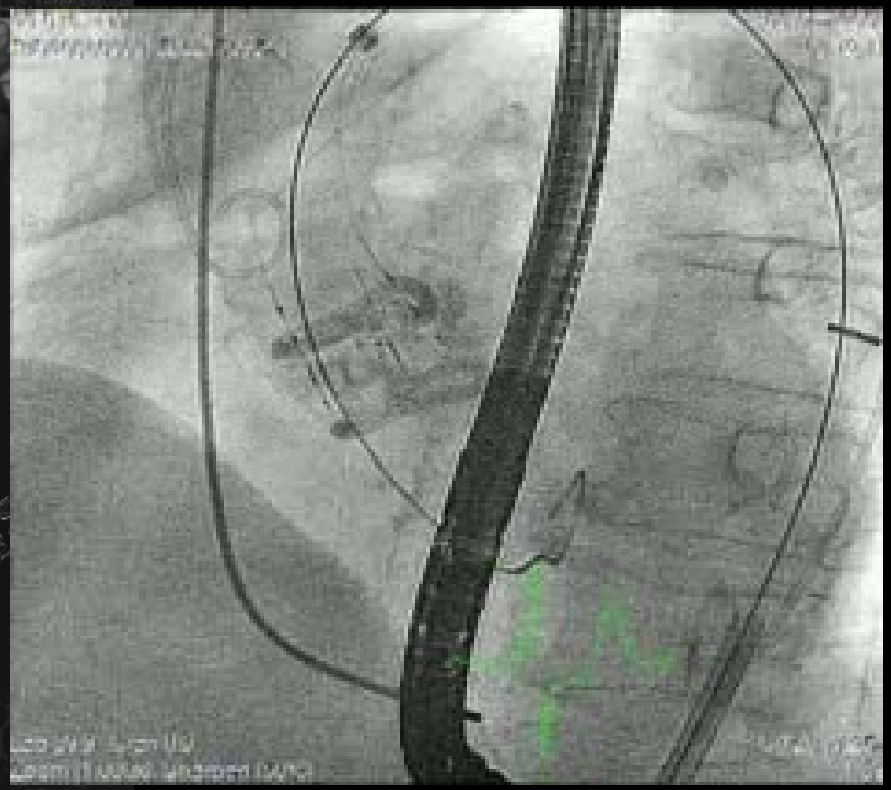


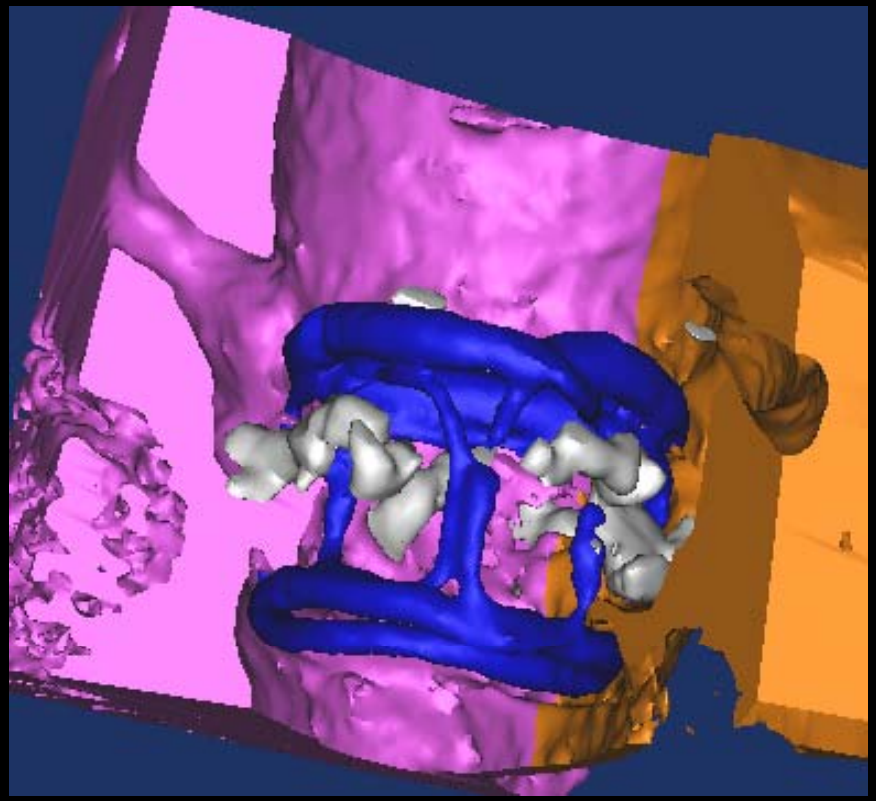
Native Valve Leaflets

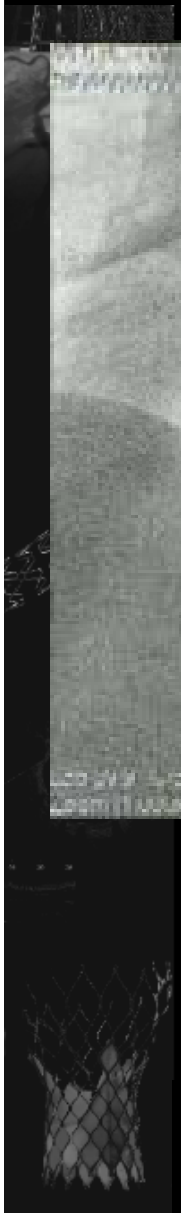
Aortic Implant Cuff

LVOT Implant Cuff

DFM Aortic Valve
Aortic Insufficiency - PV Leaks







Conformable cuff design maximizes sealing
to prevent PV leaks

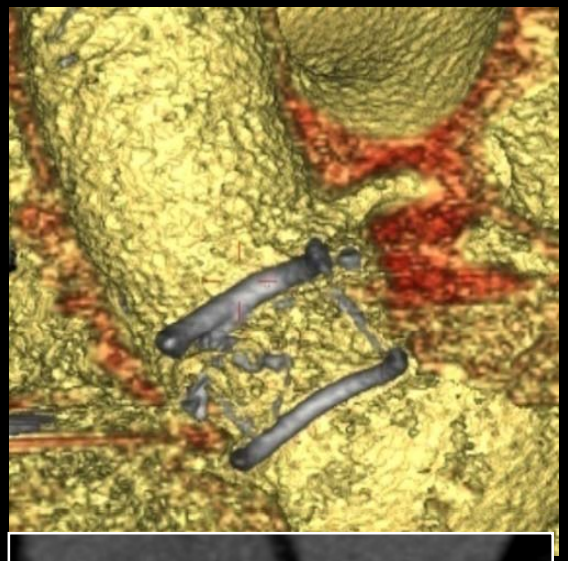
European Feasibility Study: 22F System

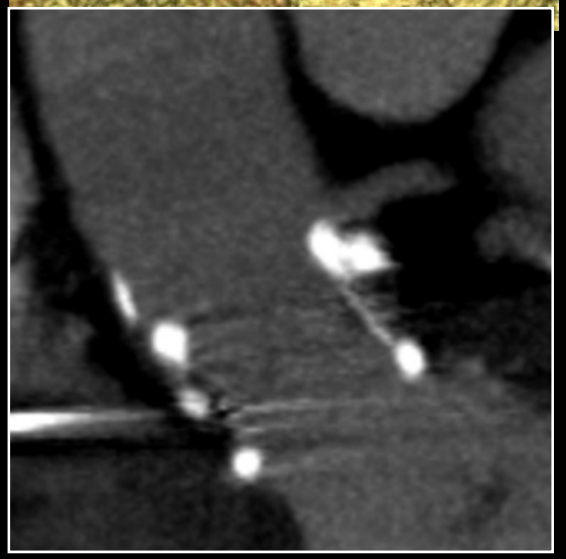
Design

- Prospective, non-randomized, multi center clinical study
- German Centers
  - Hamburg University Cardiovascular Center
  - Helios Heart Center, Siegburg

Purpose

- Inclusion Criteria
  - High risk surgical patients
  - EuroSCORE ≥ 20%
  - Age ≥ 70 years
  - Severe aortic stenosis ≤ 0.8cm^2





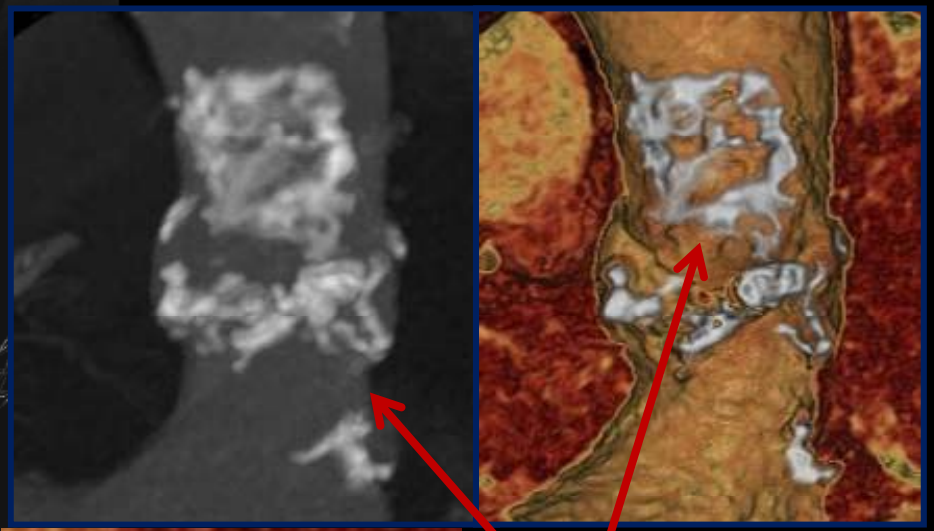
Investigational device not for sale in or outside the United States

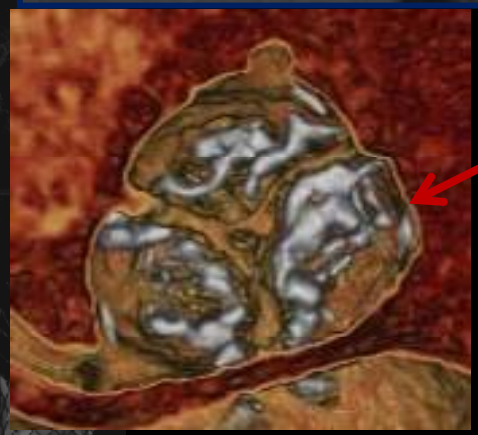
European Feasibility Study: 22F System

- **Patients Enrollment @ Baseline (n=31)**
  - Age — 82 ± 4 years
  - Female/Male — Female 52%, Male 48%
  - NYHA III – IV — 71%
  - Logistic EuroSCORE — 29 ± 7%
  - Mean pressure gradient (MPG) — 49 ± 14 mmHg
  - Effective Orifice Area (EOA) — 0.54 ± 0.13 cm^2

Clinical Case Example
Severe Aortic Valvular Disease

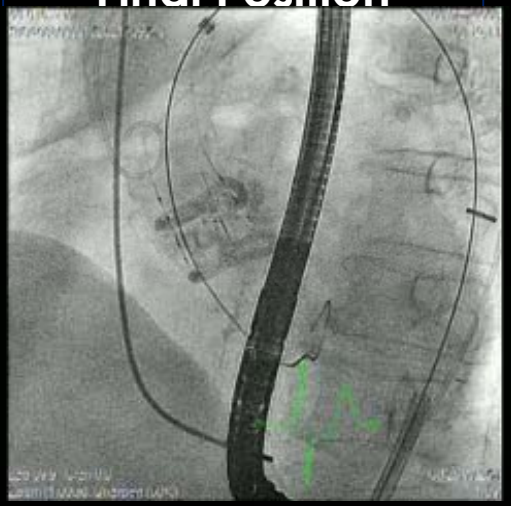
- **Patient Profile**
  - 79 year old female
  - EuroSCORE = 20.3

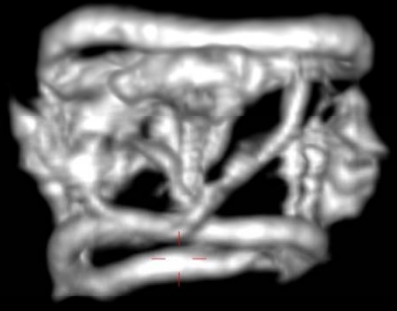


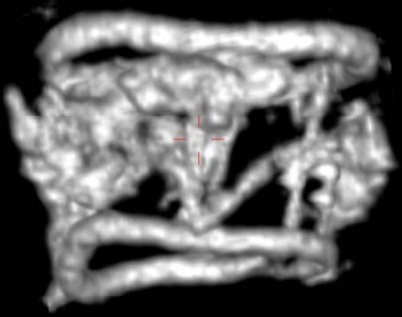


High Calcification

Final Position







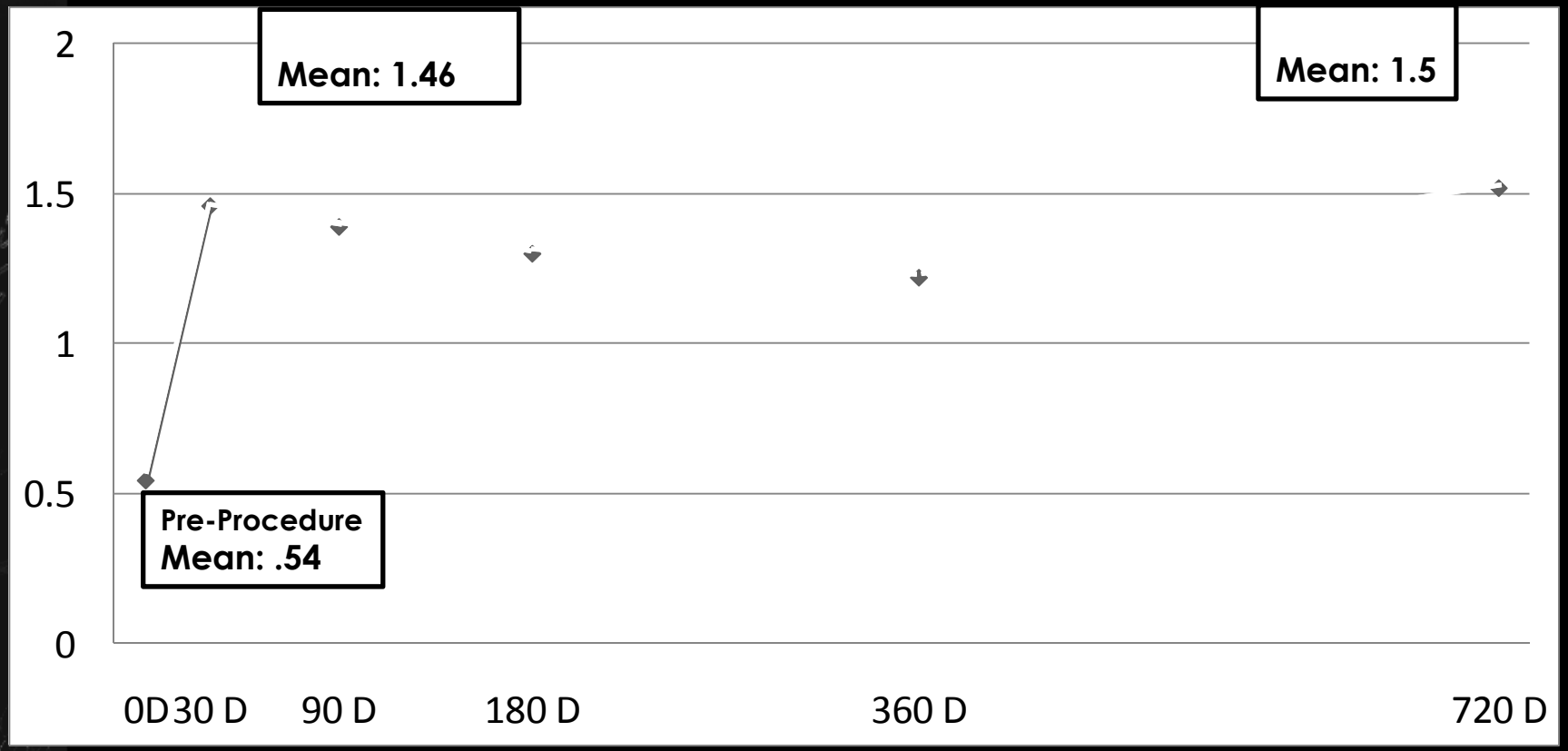
6 Month CT

15 Month CT

- **Current Status**
  - 31 months post-procedure

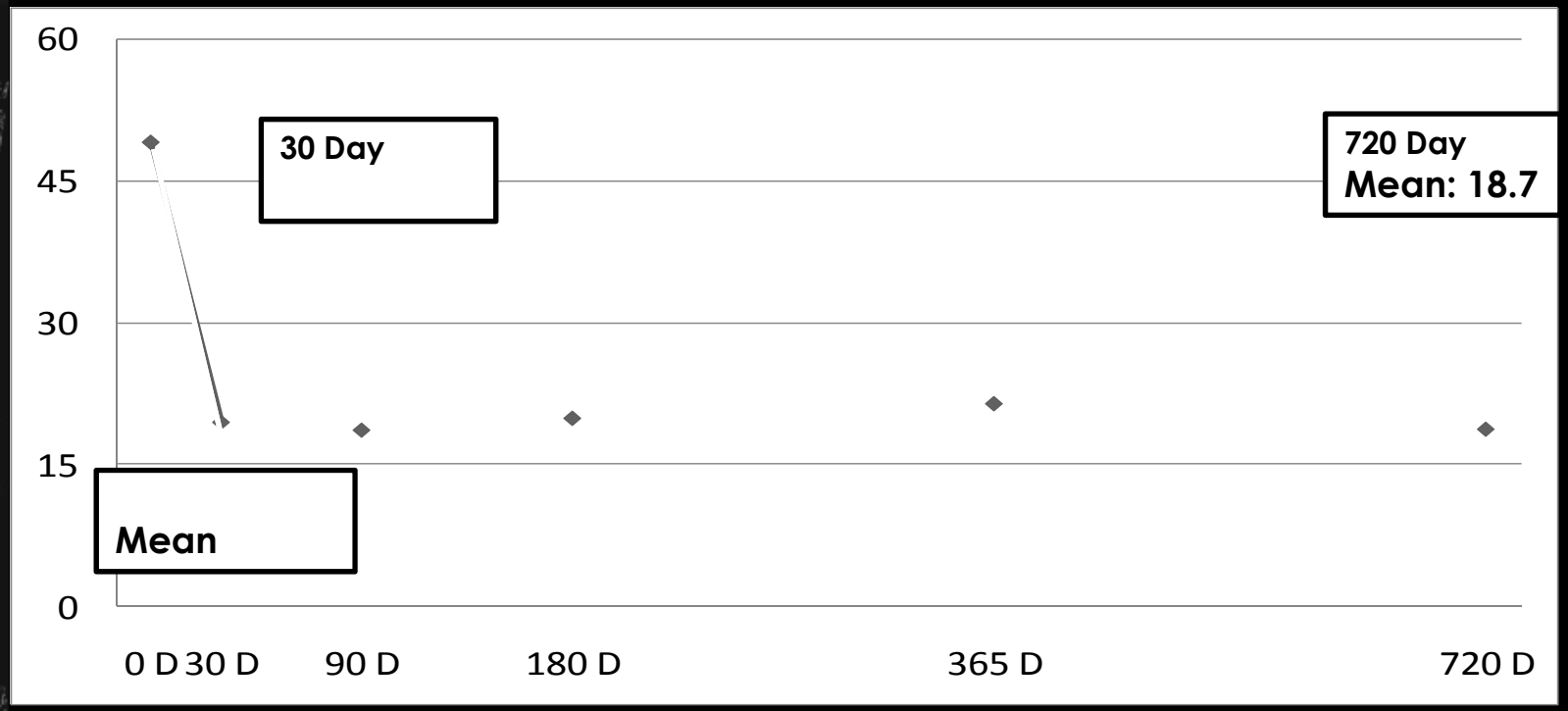
2 Year Data (22 French)

Effective Orifice Area (cm2)



2 Year Data (22 French)

Mean Gradient (mm Hg)



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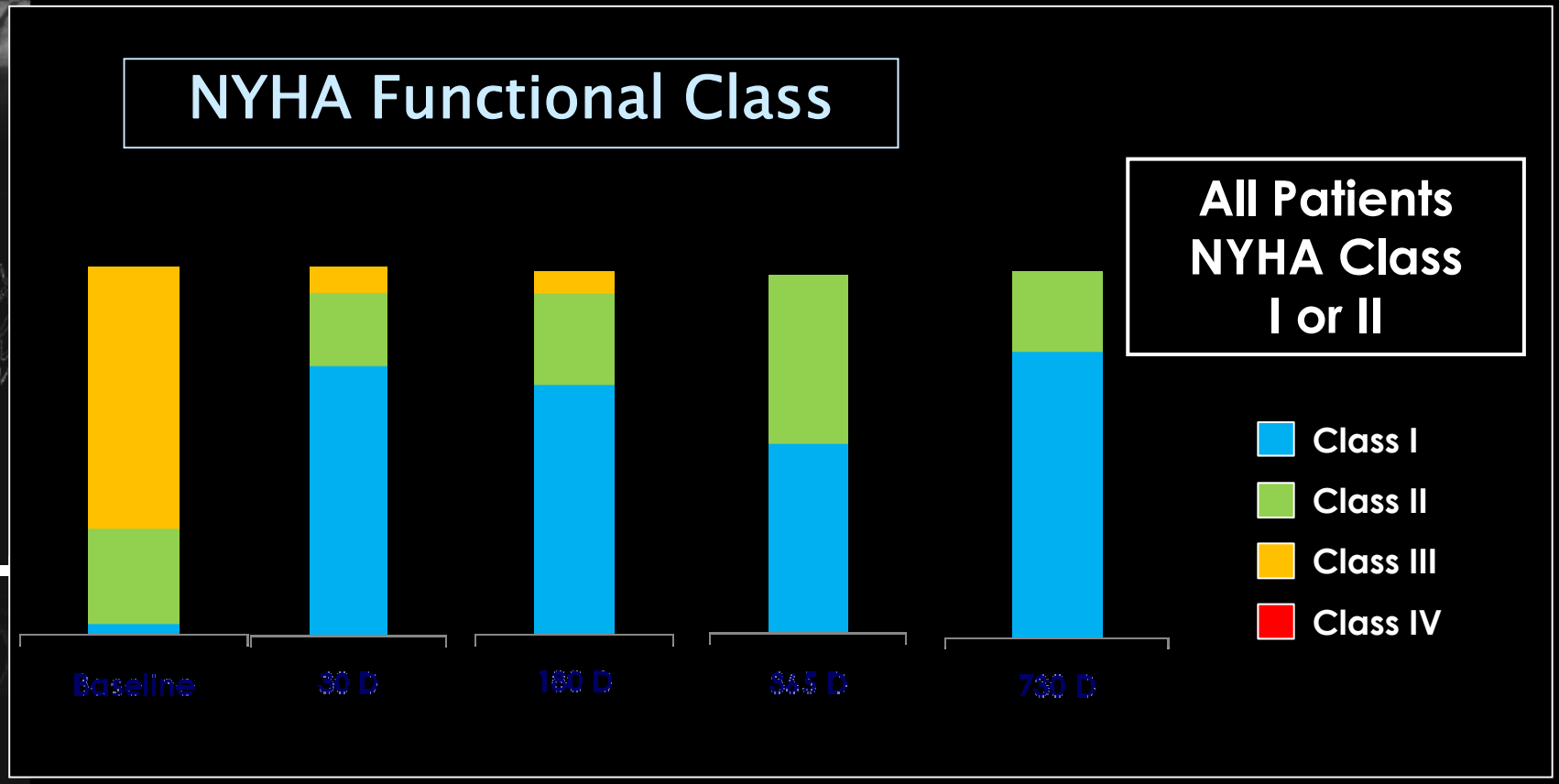

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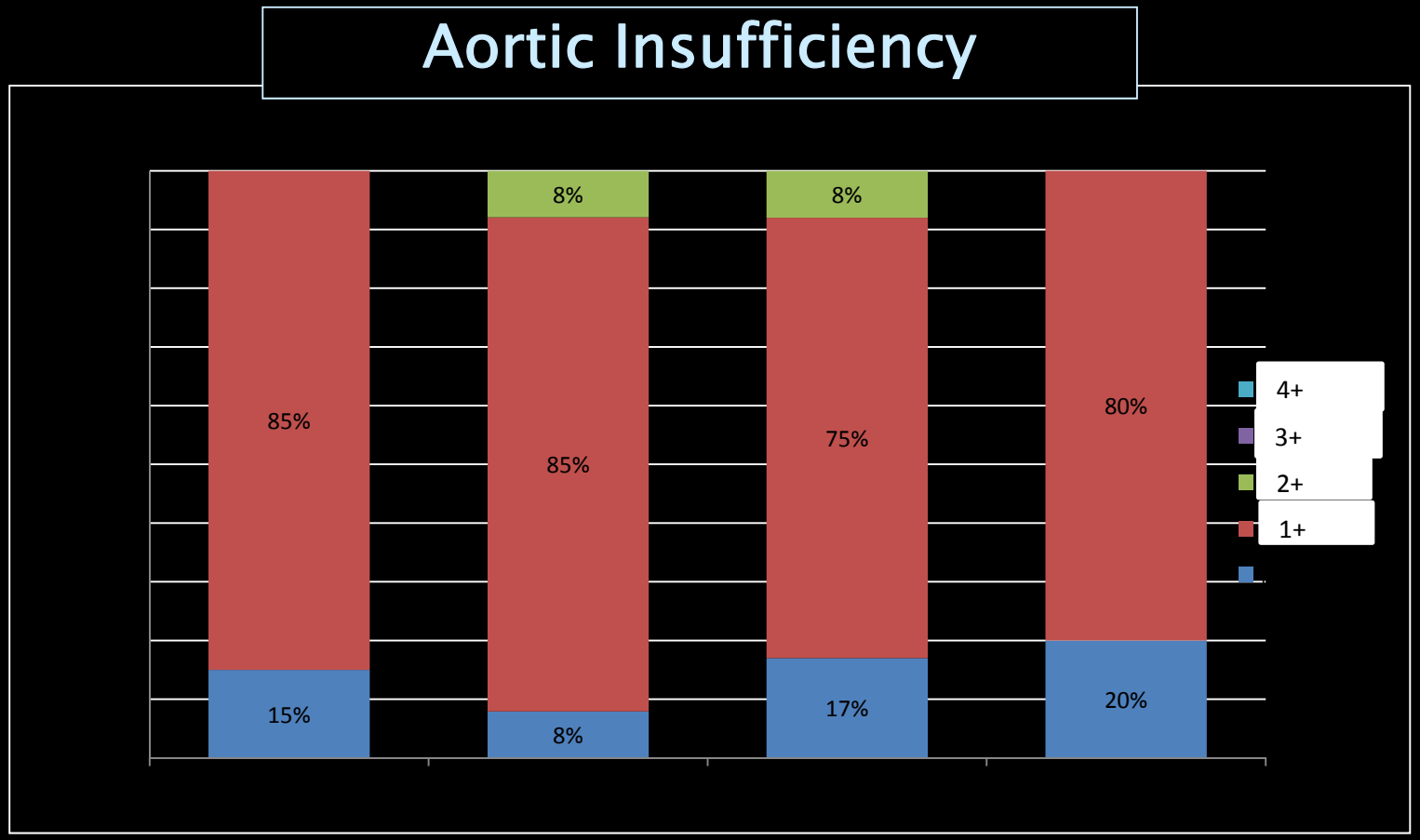

*** As measured by TTE**

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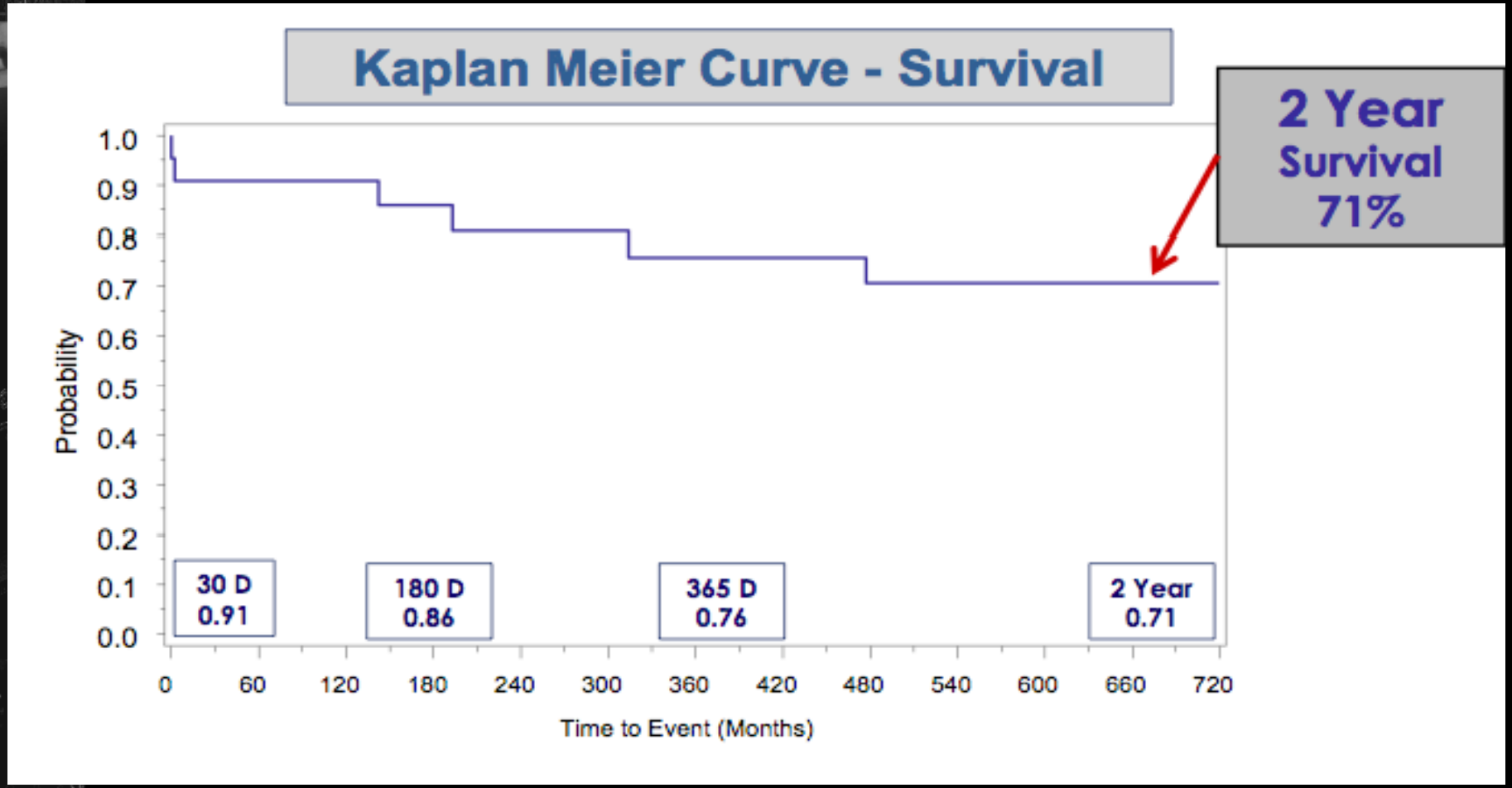
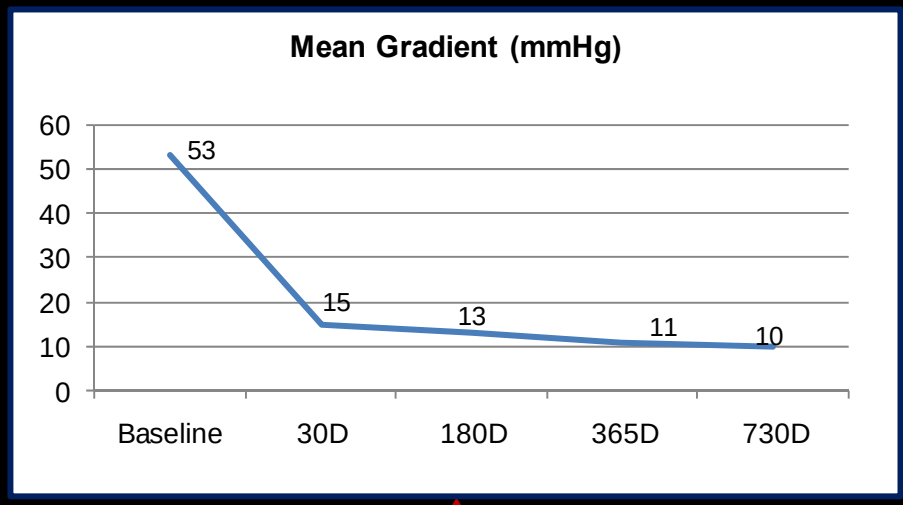
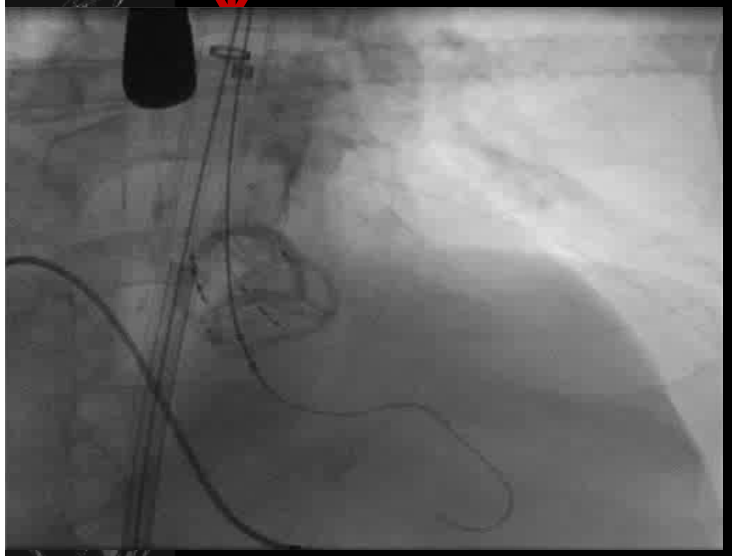


First Patient Enrolled (Oct 2008): European Feasibility and Safety Study

Screening

- **Patient Profile**
  - 81year old male
  - EuroSCORE = 25.8
- **Current Status**
  - Alive > 3.5 years
  - NYHA Class I
  - MPG = 10 mmHg
  - EOA = 1.98 cm²



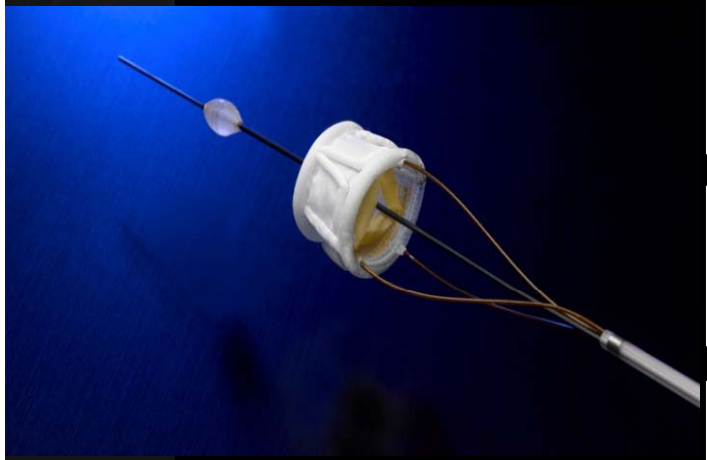


Final Positioning

Post Op CT

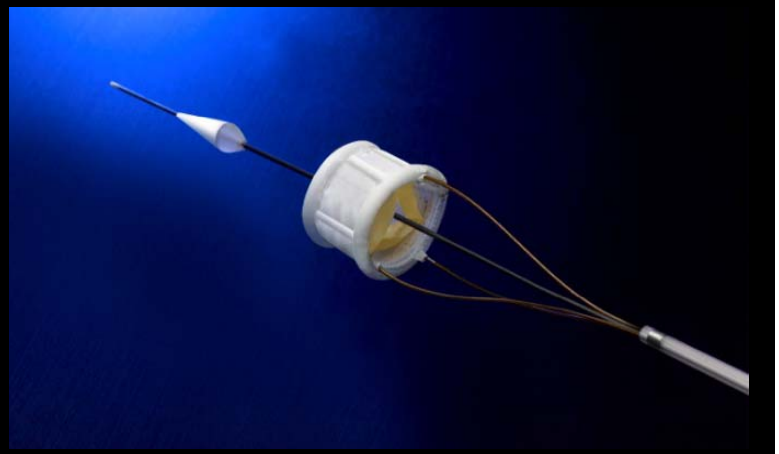
DFM Aortic Valve System Next Generation

22F



- **Profile Reduction**
- **Increased Radial Force**
- **Improved Positioning**
- **Simplified Valve Retrieval**
- **Improved Valve Loading**
- **Improved System Safety**

18F



Commercial Design Completed

Investigational device not for sale in or outside the United States

Thank you very much!