ISET 2012

Mimai, December, 17, 2012

# Next Generation TAVI Systems

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ISET 2012

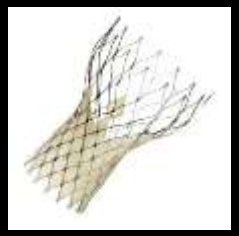
# *Disclosure*
# *Eberhard Grube, M.D.*

I disclose the following financial relationship(s):

- Speaker/Honoraria: Direct Flow, Biosensors, Boston Scientific, Cordi J&J, Abbott Vascular, Medtronic, Mitralign
- Consultant/Advisory Board: Direct Flow, Claret, InSeal Medical, Biosensors, Boston Scientific, Cordi J&J, Abbott Vascular, Medtronic, Mitralign
- Equity: Direct Flow, Claret, Biosensors, Medtronic, Mitralign

# New TAVI valves are coming to the market in a few year's time

## Today

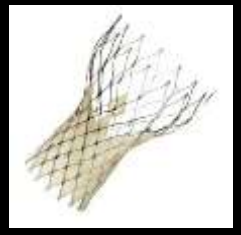


Medtronic CoreValve

Edwards Sapien XT

Edwards Sapien

## Tomorrow



Next Gen. Medtronic CoreValve

Boston Sci. Lotus™

HLT

Medtronic Engager

Saint Jude Portico™

Direct Flow

Edwards Sapien XT

JenaValve

Symetis ACCURATE

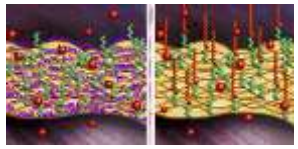
# CoreValve Innovation

Focused Efforts on:

- Expansion of patient access
- Further improvement of ease of use
- Continue to advance patient and procedural outcome

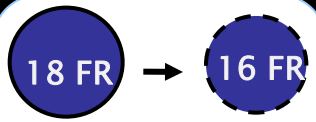
*Delivery System Improvements

Alternative Access Technology



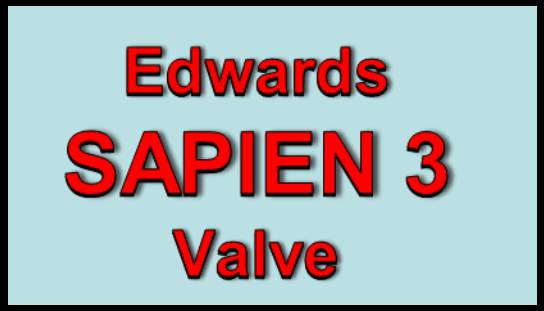
Anti-Mineralization Tissue Treatment

*Greater Annulus Coverage

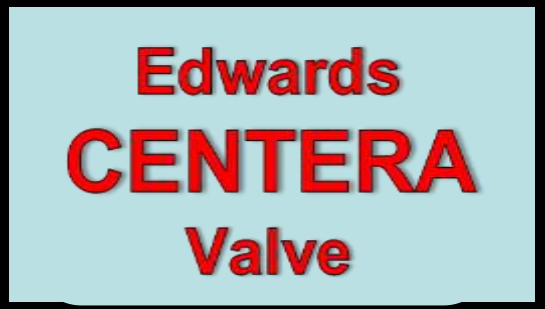



Profile Reduction

# Edward's new Valve Platforms




*Balloon Expandable*




*Self Expanding*

# SAPIEN 3 Advances

*Low-Profile Balloon Expandable Platform*

- Further **reduces PV leaks**
- Lower profile valve delivered through a **14 Fr eSheath**
- Treated bovine pericardial tissue leaflets
- Reduced profile for the transapical approach

# CENTERA
# Self- Expanding Transcatheter Valve

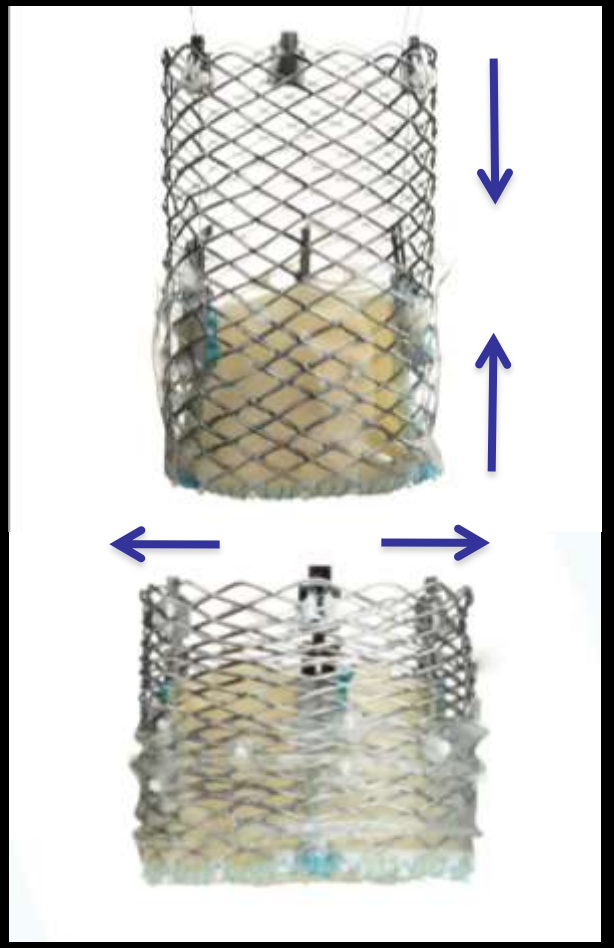
*Low-Profile Self Expanding Platform*

- **Motorized delivery system** for stable deployment and single operator use
- **Repositionable**
- Delivered through a **14 Fr eSheath**
- Treated bovine pericardial tissue leaflets
- Transfemoral and subclavian approach

***First-in-Man Experience Completed***

# Sadra Lotus™ Valve Concept (BSC)

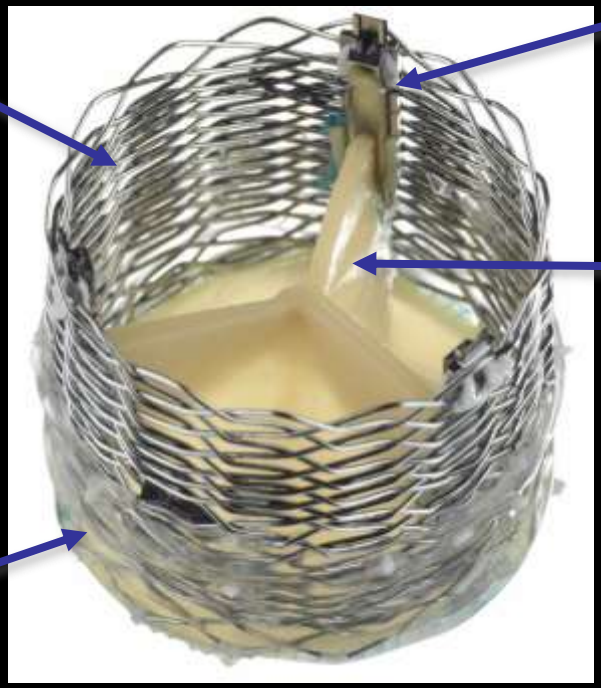
- Braided nitinol stent structure
- Radial expansion as it shortens
  - Enables a more flexible delivery system
  - Enables device repositioning or retrieval
  - Provides significant radial strength



# The Lotus™ Valve System

## *Components and Function*

**Nitinol Frame**
designed for retrieval and repositioning



**Locking Mechanism**

**Bovine Pericardium**
Long-Term Proven material

**Adaptive Seal**
Designed to conform to irregular anatomical surfaces, and to minimize perivalvular leaks

# REPRISE Clinical Program

**REPRISE I Feasibility**

| | |
|---|---|
| Objectives | To assess the acute safety and performance of the Lotus™ Valve System for transcatheter aortic valve replacement (TAVR) in symptomatic patients with calcified stenotic aortic valves who are considered high risk for surgical valve replacement. |
| Primary Endpoint | Clinical procedural success: Device Success without in-hospital MACCE thru discharge or 7d post-procedure |
| Valve size | 23 mm |
| N | 10 patients in Australia |


Principal Investigator: Prof. Ian Meredith

- Prof. Ian Meredith, Monash Heart Center
- Prof. Rob Whitbourn, St. Vincent Hospital
- Prof. Stephen Worthley, Royal Adelaide Hospital

# REPRISE Clinical Program

**REPRISE II**
**CE Mark**

| | |
|---|---|
| Objectives | To evaluate the safety and performance of the Lotus™ Valve System for transcatheter aortic valve replacement (TAVR) in symptomatic subjects with severe calcific aortic stenosis who are considered high risk for surgical valve replacement. |
| Primary Endpoint | Device Performance Endpoint: Mean aortic valve pressure gradient at 30d<br>Safety Endpoint: All-cause mortality at 30d |
| Valve size | 23 and 27 mm |
| N | 120 patients in Australia, France, Germany, UK |

Principal Investigator: Prof. Ian Meredith

- Prof. Ian Meredith, Monash Heart Center
- Prof. Rob Whitbourn, St. Vincent Hospital
- Prof. Stephen Worthley, Royal Adelaide Hospital

- Prof. Thierry Lefevre, Institut Jacques Cartier
- Dr. Didier Tchetche, Clinique Pasteur
- Prof. Gilles Rioufol, Univ. De Lyon
- Prof. Didier Carrie, CHU de Rangeuil

- Dr. Simon Redwood, St. Thomas Hospital
- Dr. Ganesh Manoharan, Royal Victoria, Belfast
- Dr. Daniel Blackman, Spire Leeds Hospital
- Dr. David Hildick-Smith, Royal Sussex

- Prof. Peter Boekstegers, Helios Klinikum, Siegburg
- Prof. Rudiger Lange, German Heart Center, Munich
- Prof. Friedrich Mohr, Herzzentrum, Leipzig

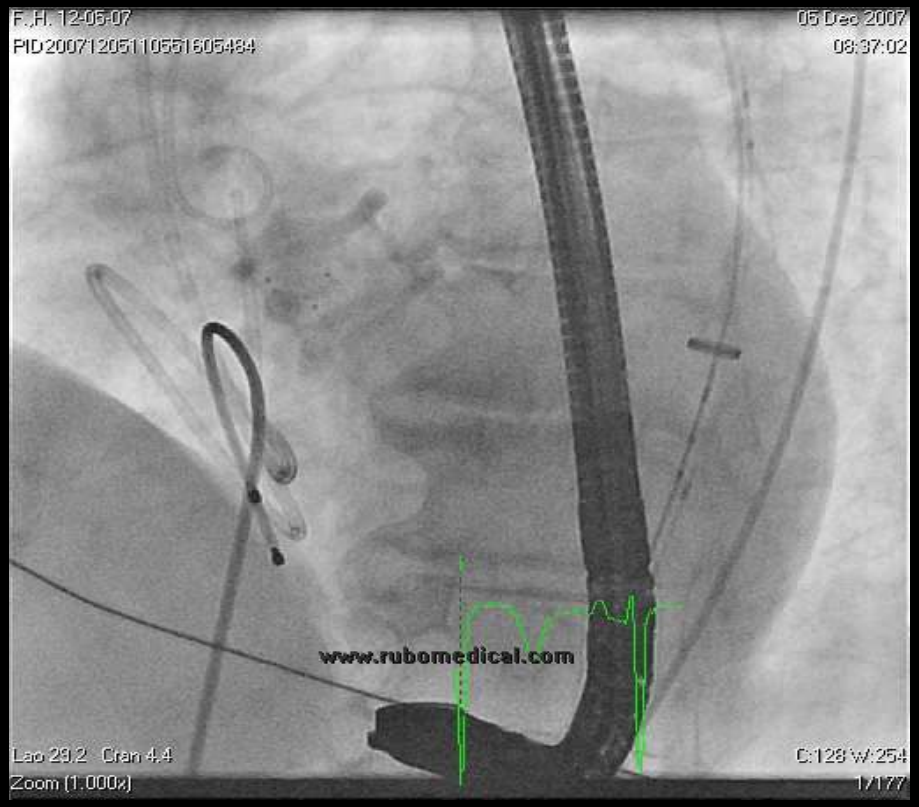
# Direct Flow Medical

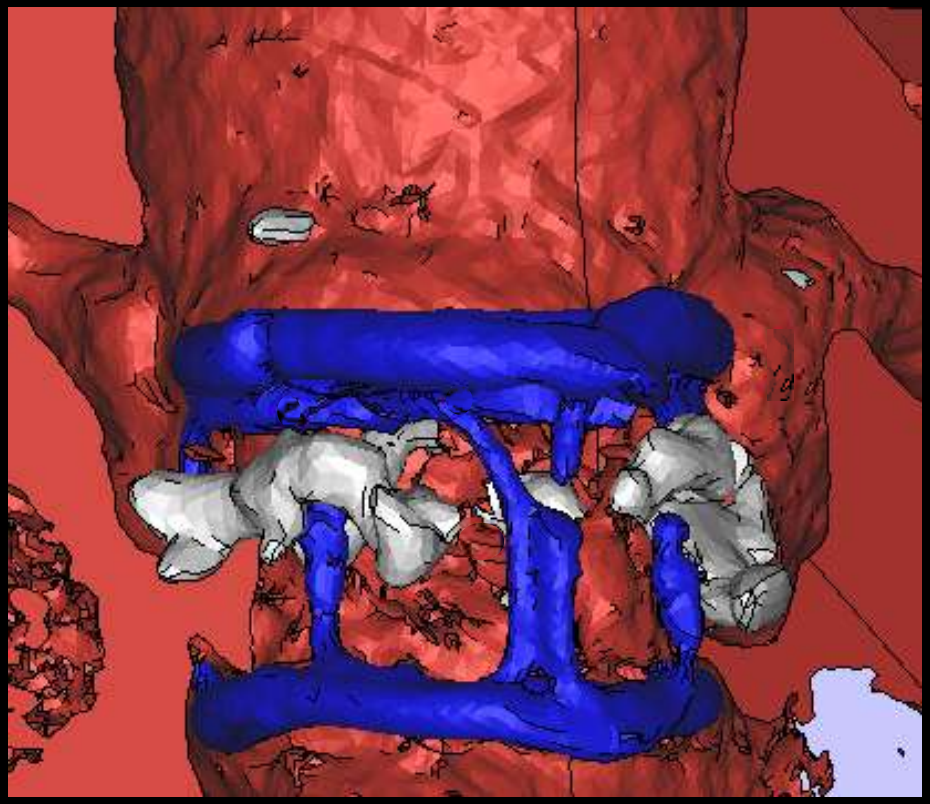
2 sizes matching
valvuloplasty balloons

22F Design

18F Design

# DFM Aortic Valve

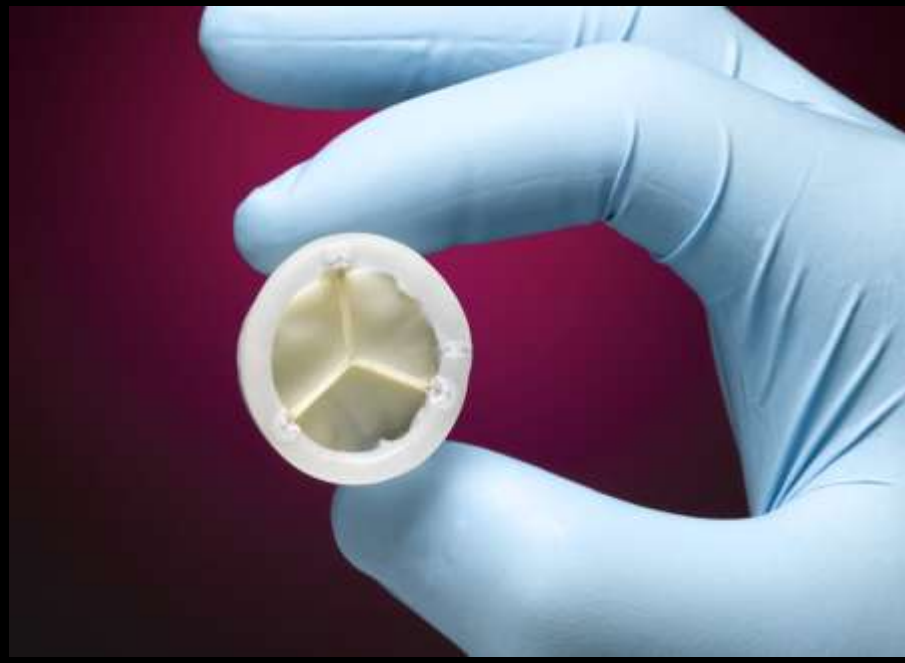


Conformable cuff design and precise positioning maximizes sealing to prevent PV leaks

# Direct Flow Valve – Potential Advantages

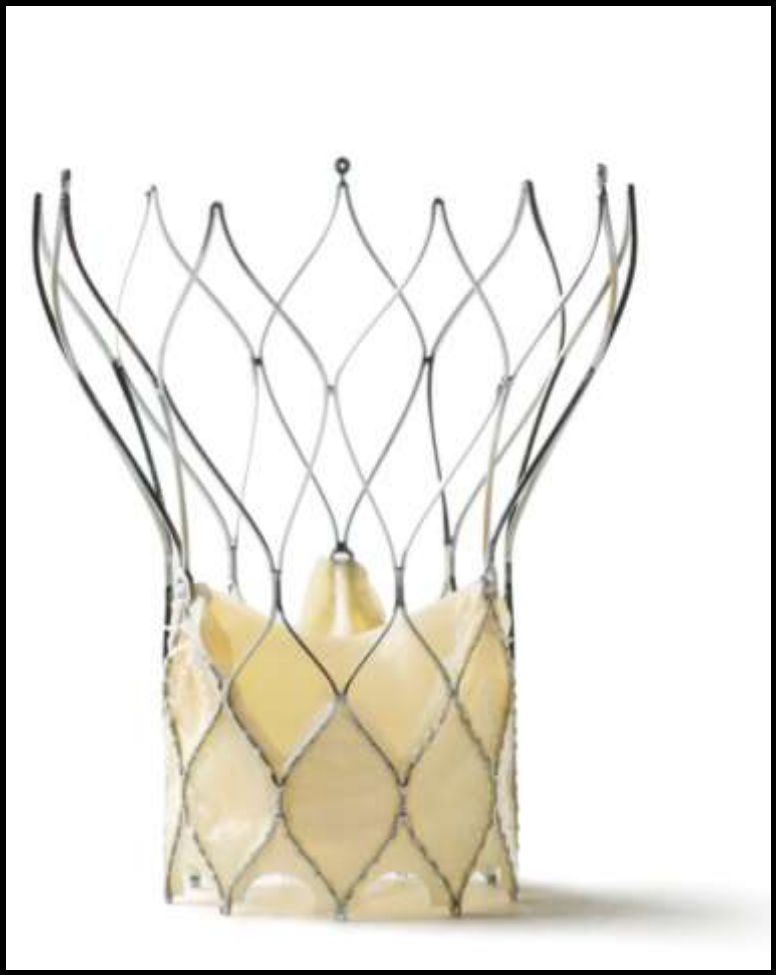
- "Surgical" valve design
- Repositionable & Removable
- Reduces PV Leaks and AI
- Immediately competent



Valve design allows hemodynamic assessment prior to final device deployment

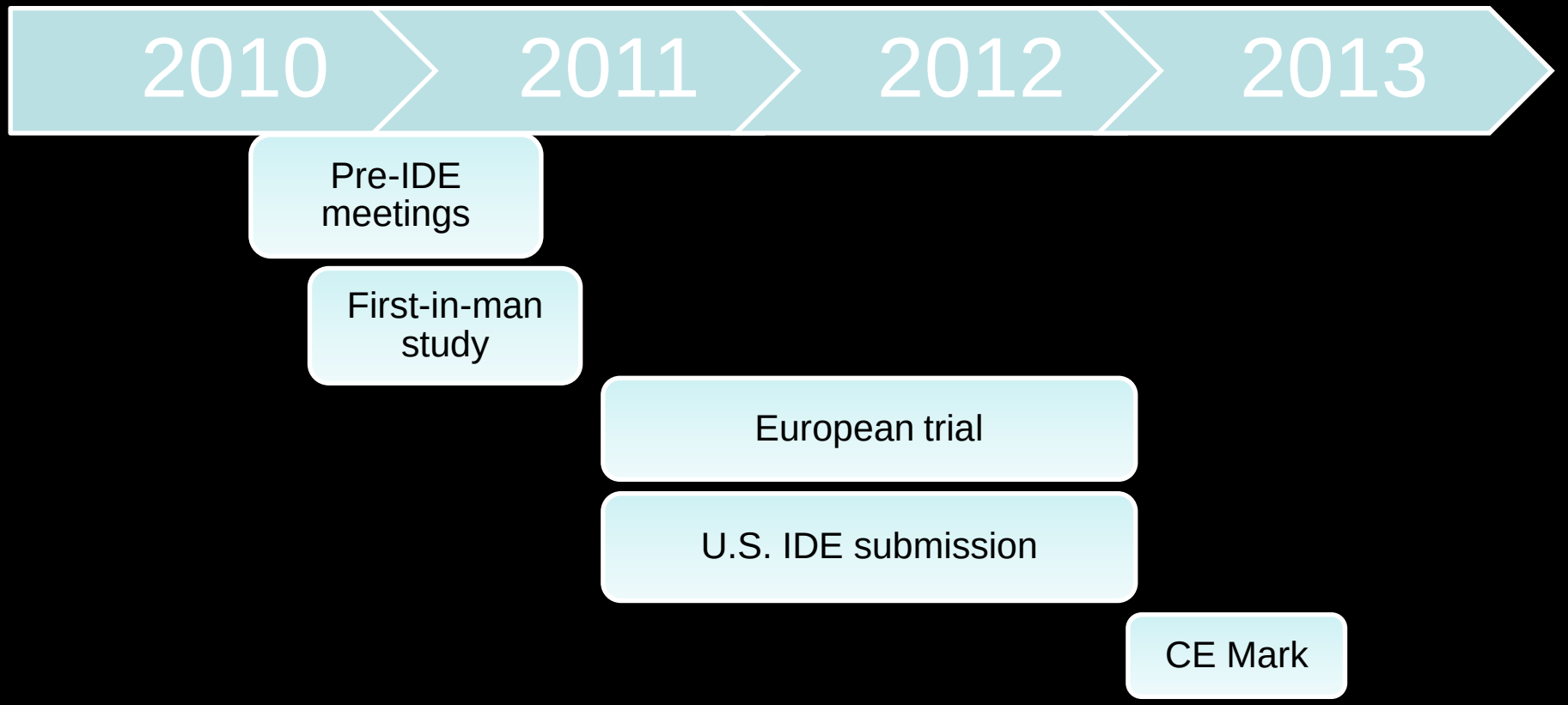
# Portico TAVI System (St. Jude Medical):

- Nitinol self expanding stent
- Open stent cell allows access to coronaries and low crimp profile
- Bovine and porcine pericardial valve (Linx™ anticalcification technology*)
- Low placement of leaflets/cuff within stent frame allows for minimal protrusion into the LVOT
- Repositionable and Retrievable



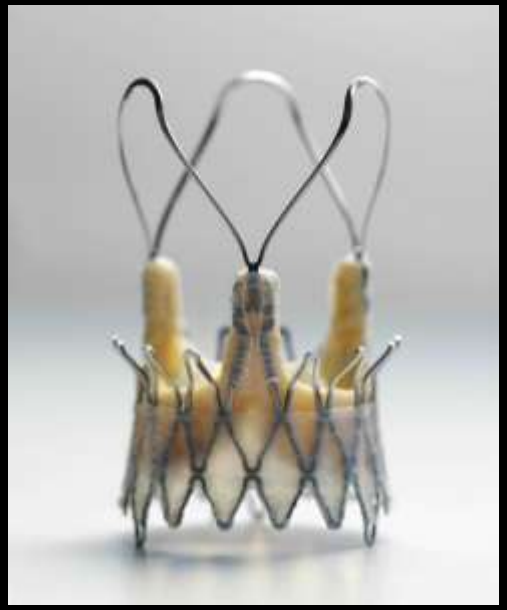
First Human Implant June 7th, 2011

# St Jude Medical TAVI System
## *Program Status*



# Symetis ACURATE TF™ and TA™ Bioprosthesis

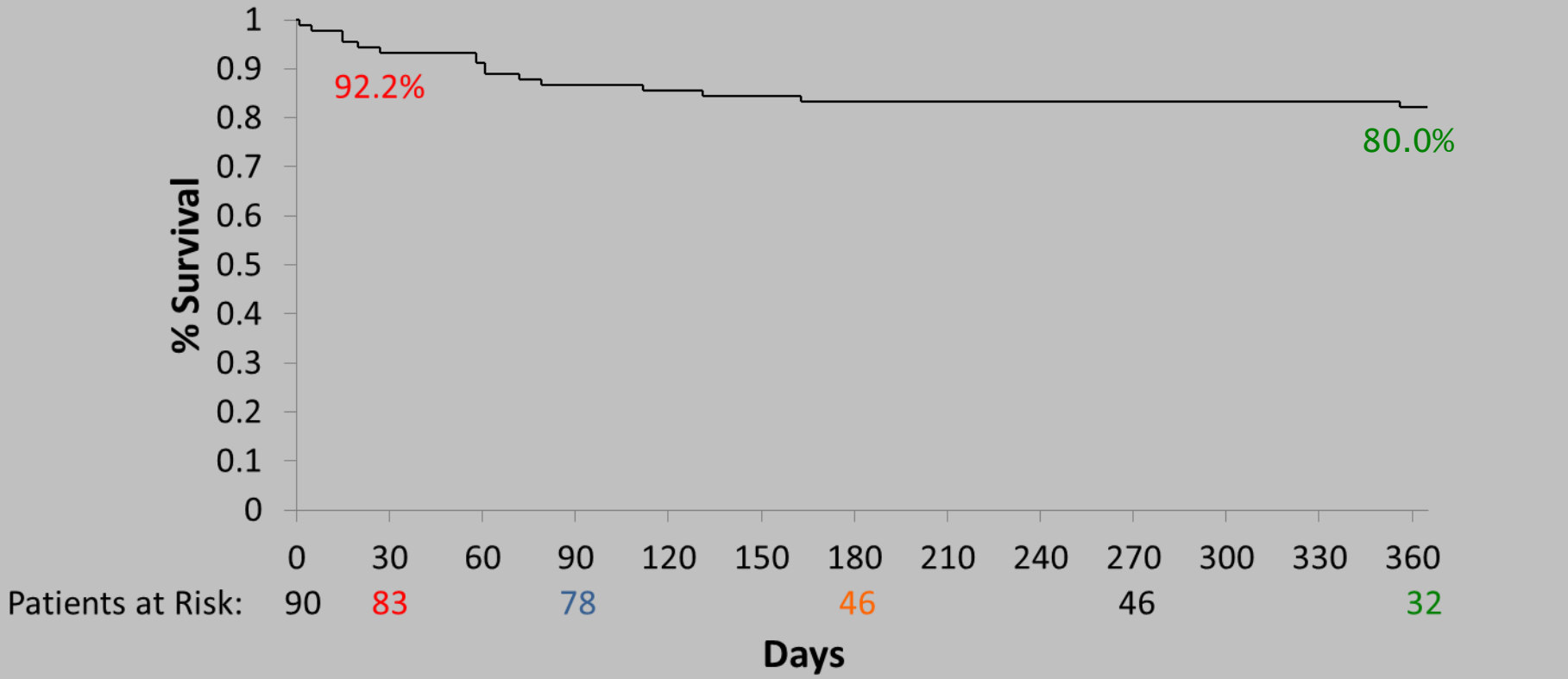
- Porcine pericardium
- Self-expanding nitinol stent
- Stent covered inside and out with double porcine pericardium skirt



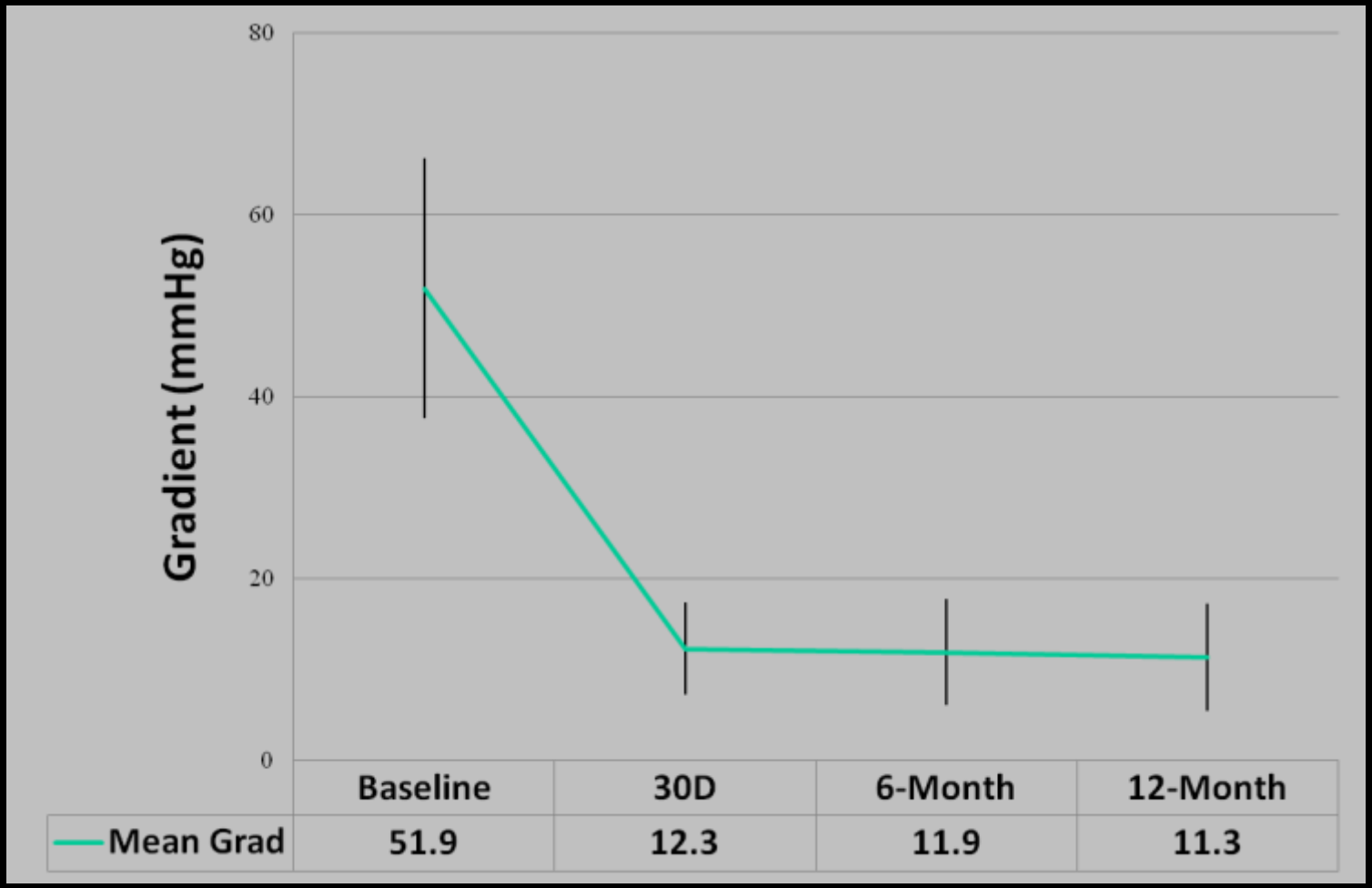
# ACURATE™ Highlights

- Trans Apical:
  - FIM (n=40) 6M results @ EACTS 2011
  - Pilot (n=50) 30D results @ TCT 2011
  - FIM (n=40) 1Y results @ AHA 2011
  - Pivotal (n=150) enrollment start Q4 2011
  - SAVI post-market registry (n=250) with commercial implants
  - Received CE Certification in November 2011 for commercial use
- Trans Femoral:
  - FIM (n=20) enrollment start Q1 2012 (Brazil/Germany/France)
  - Pilot (n=50) enrollment start Q3 2012

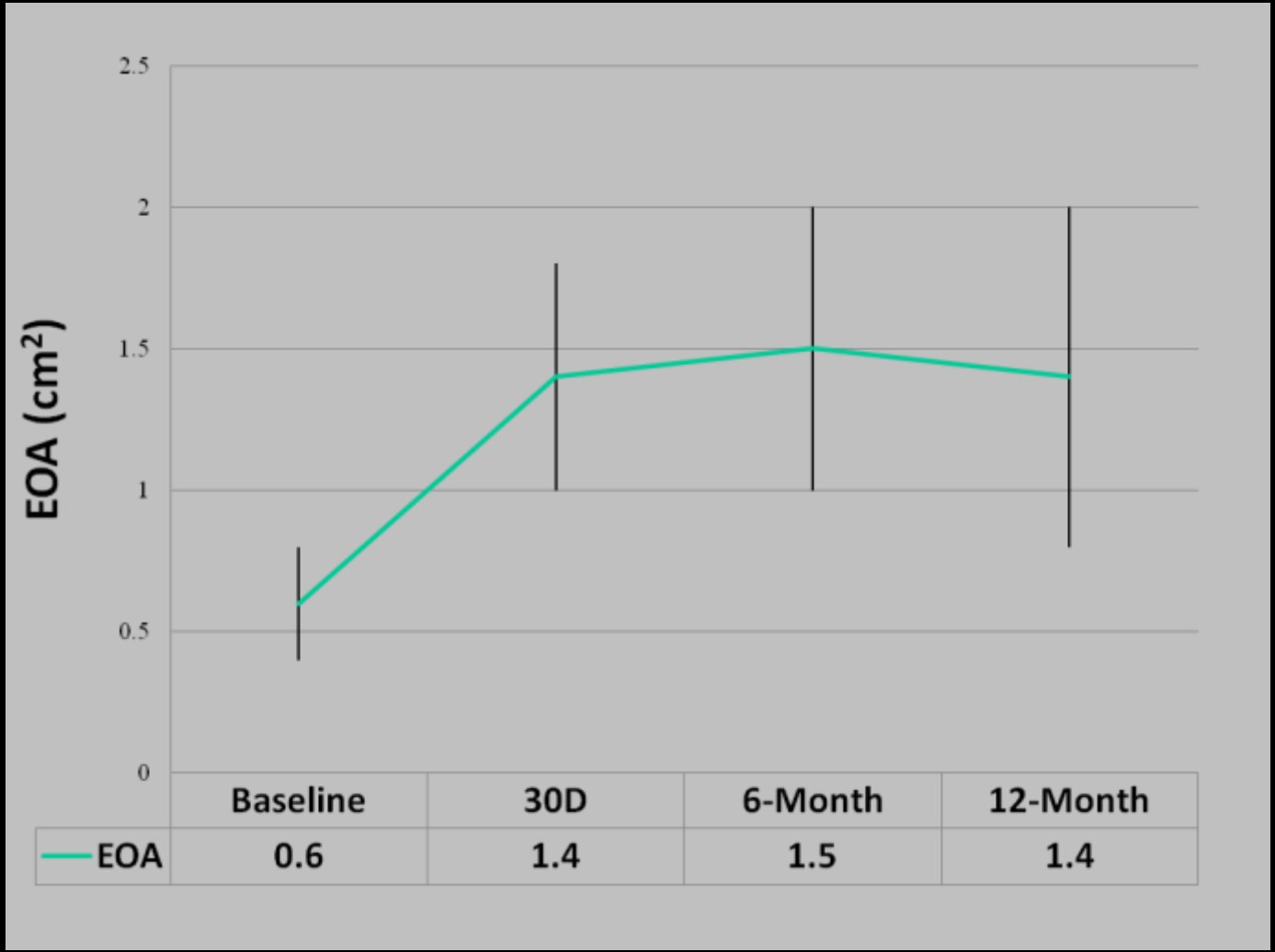
# ACURATE TA™: survival



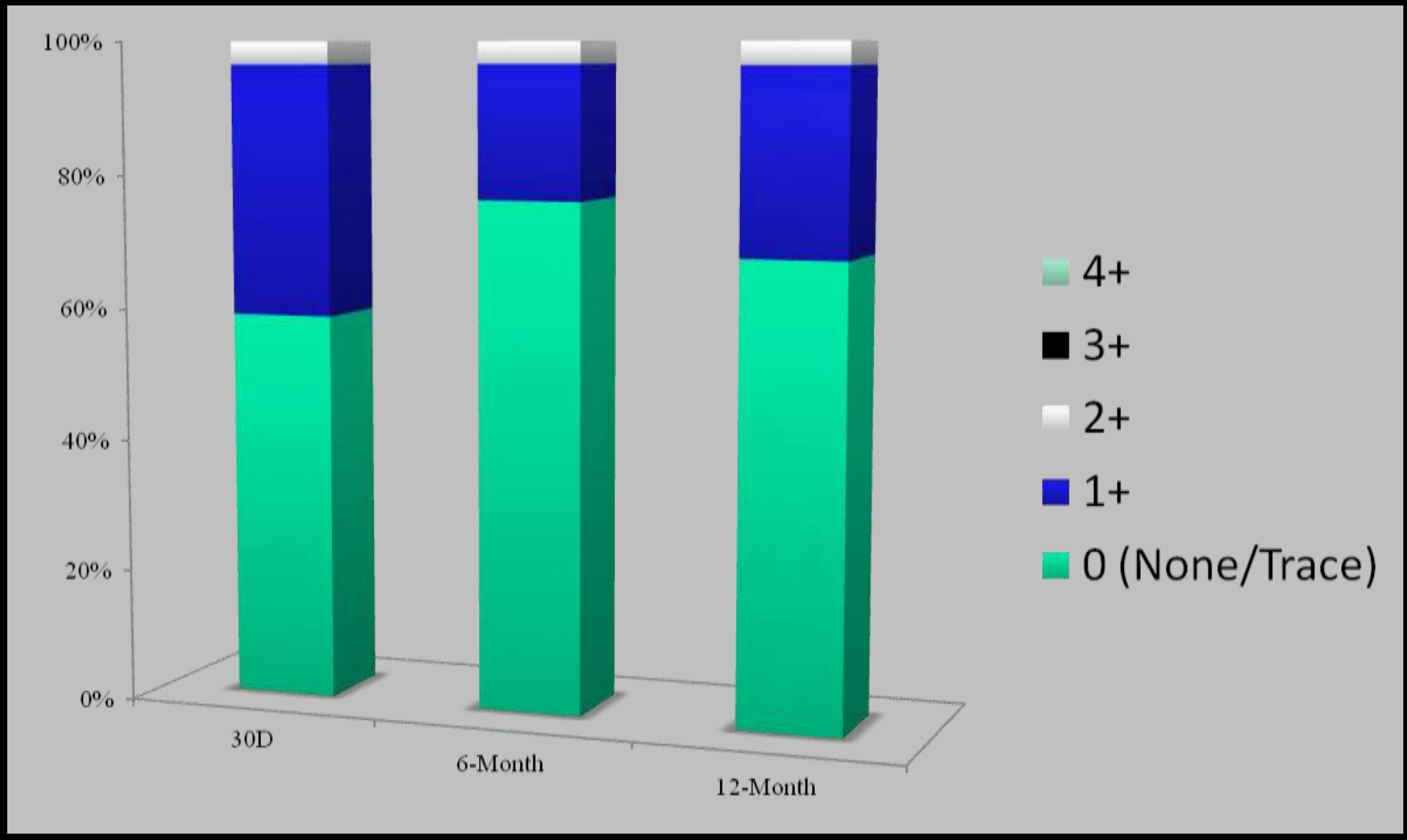
# FIM Gradient



# FIM EOA

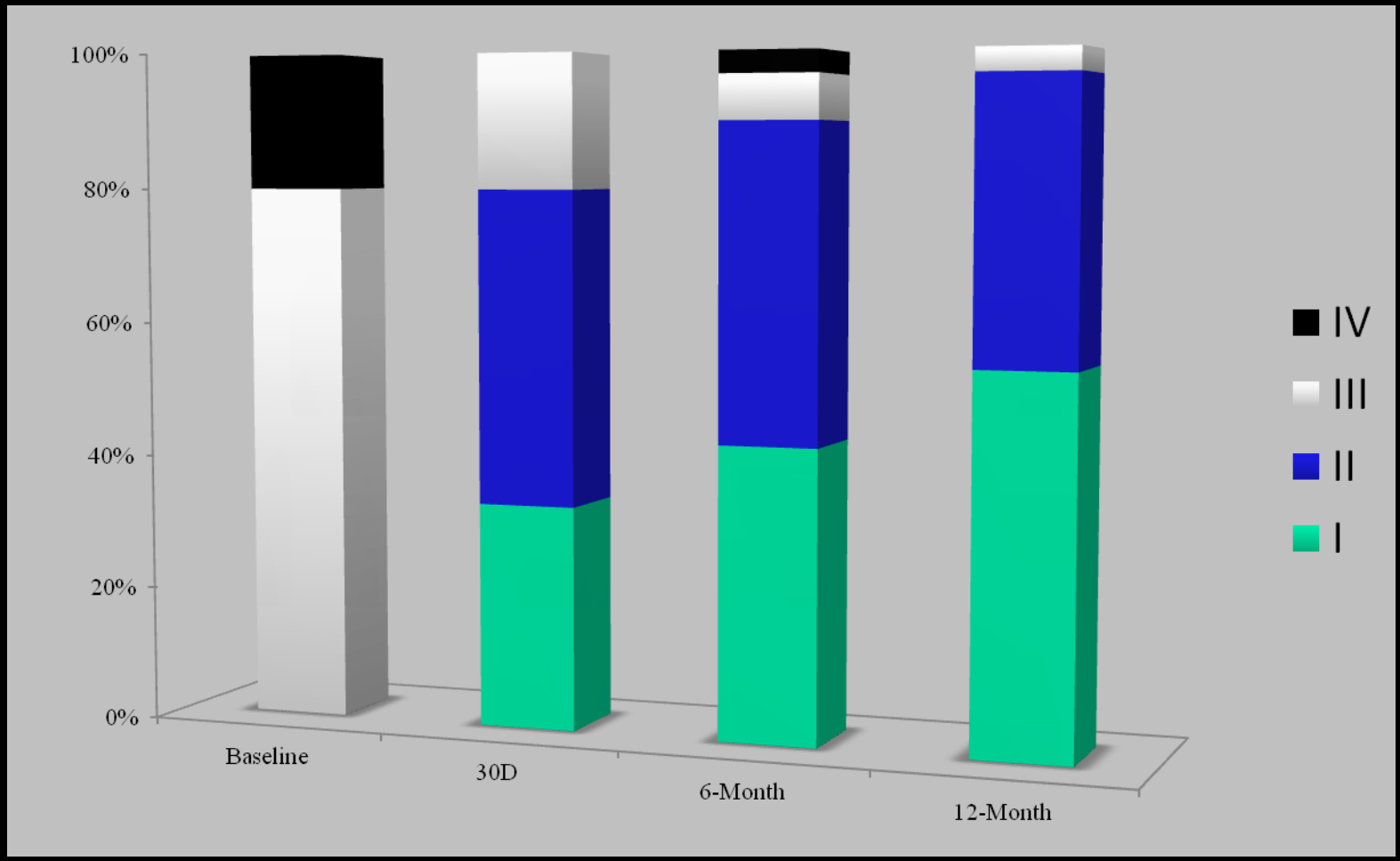

EOA (cm²)
2.5
2
1.5
1
0.5
0
Baseline
30D
6-Month
12-Month
EOA
0.6
1.4
1.5
1.4

# FIM PV Leak

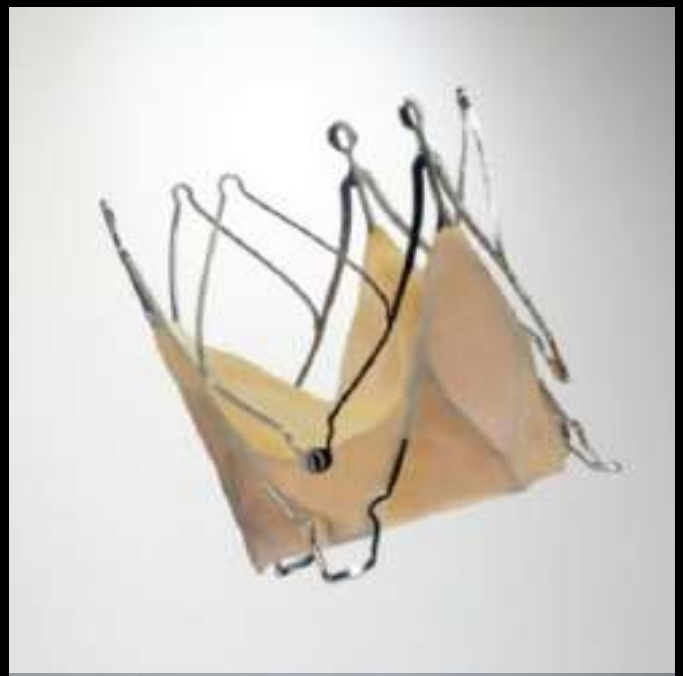



12M FU: 96.7% of patients = ≤ +1 PVL
Only 1 patient ≥ +2 PVL

# FIM NYHA



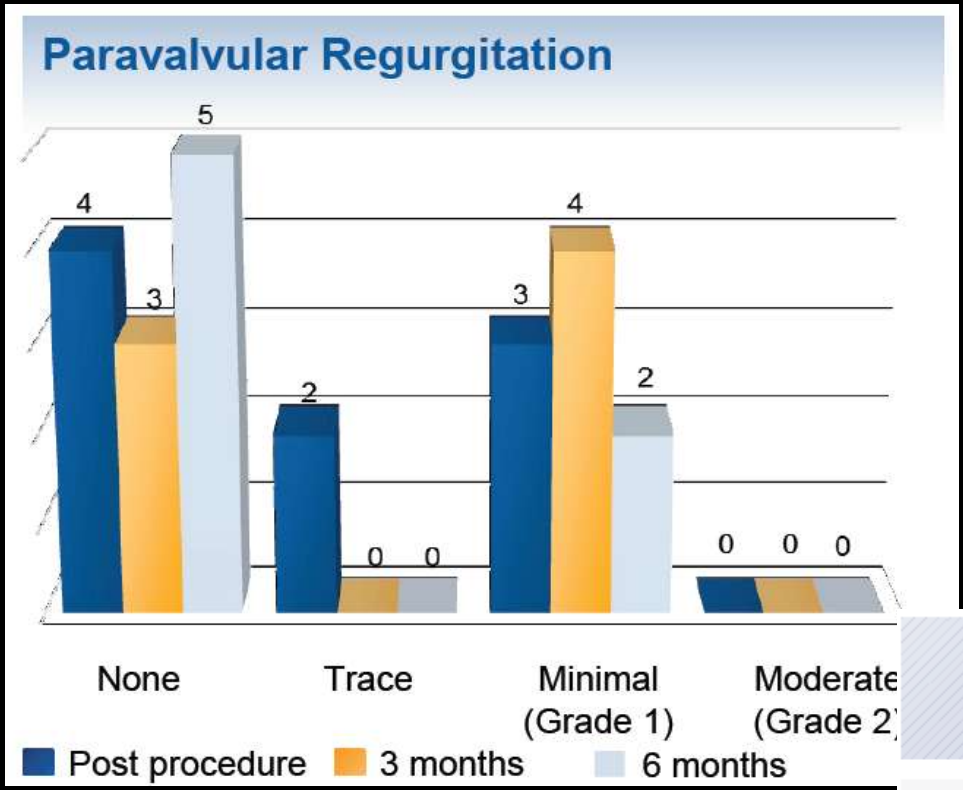

12M FU: 90% of patients with improvement from baseline



# Jena Valve

- Self-expanding nitinol stent with flexible s tent posts
- Porcine root valve
- Sizes 23,25,27
- 32F introducer sheath for transapical access

# Jena Valve FIM Trial




**CE certified for transapical use!**

| 30 d safety outcomes | FIM pts (N=10) |
|---|---|
| All cause death (30 d)<br>cardiac death | 0<br>0 |
| Stroke | 0 |
| Myocardial infarction | 0 |
| Emergent cardiac surgery | 1 |
| Onset of AV block | 0 |

Thank you very much!