

# Transcatheter Aortic Valve Therapies

*Evolution and glimpse into the future*

2<sup>nd</sup> TAVI Summit 2012, Seoul Korea



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# Disclosure Statement of Financial Interest

## **Affiliation/Financial Relationship**

- Consulting Fees/Honoraria

## **Company**

- Edwards Lifesciences

The background of the slide is a photograph of a sunset or sunrise. The sun is a bright, glowing orb in the center-right, casting a warm orange and yellow light across the sky. Silhouettes of trees are visible against the bright sky, particularly on the left and right sides. The overall mood is serene and hopeful.

# T ranscatheter A ortic V alve I mplantation

10 YEARS



Rouen,  
May 13th  
Celebration



## Rouen, May 13th, 2012, 10th year FIM-TAVI Celebration





# Rouen, May 13th, 2012, 10th year FIM-TAVI Celebration

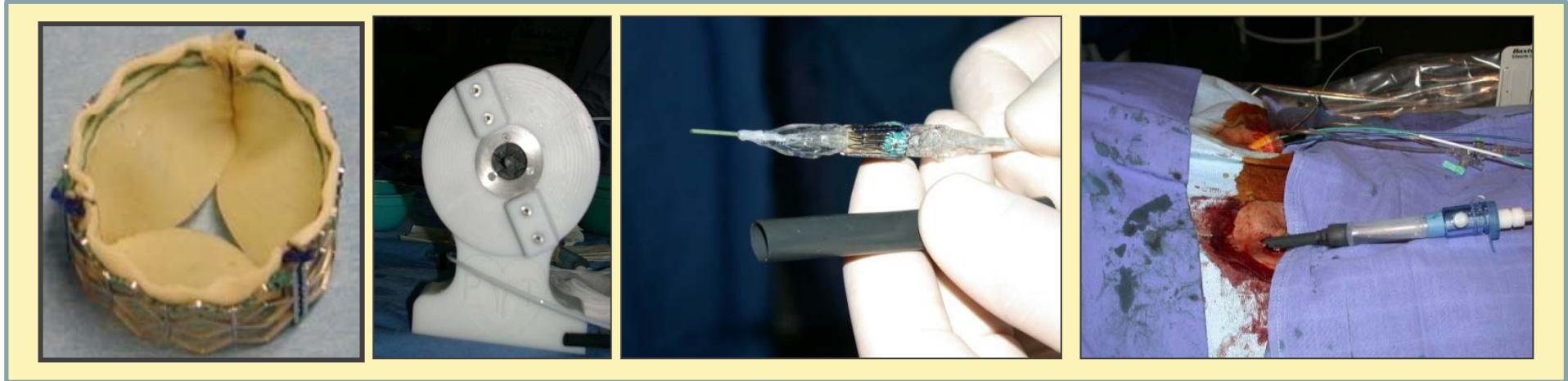


Rouen, May 13th, 2012, 10th year FIM-TAVI Celebration



# ***2002-2004: The old “heroic period”: TS Approach***

*First-in-Man and I-REVIVE & RECAST trials, 40 Pts (85% success)*



The D-Day  
Rouen, April 16th, 2002



30 min post-TAVI



8 days post-TAVI





CoreValve

Ongoing US Pivotal

Registries

CE Mark

FIM

Oct 2011: FDA Approval (Non Surgical)

2008-09

Ew PARTNER US Pivotal

Since 2007

Post market registries

2007

CE mark  
commercialization

2005-07

International TF and TA

2004

In 2012

> 50 000 valves implanted worldwide  
> 500 centers in Europe  
400 centers up to open in USA  
(> 100 centers to date)

intra-valvular stenting

F.I.M. Balloon Aortic Valvuloplasty

# *TAVI Clinical Indications*

## *NEW EUROPEAN GUIDELINES (ESC 2012)*

Severe aortic stenosis

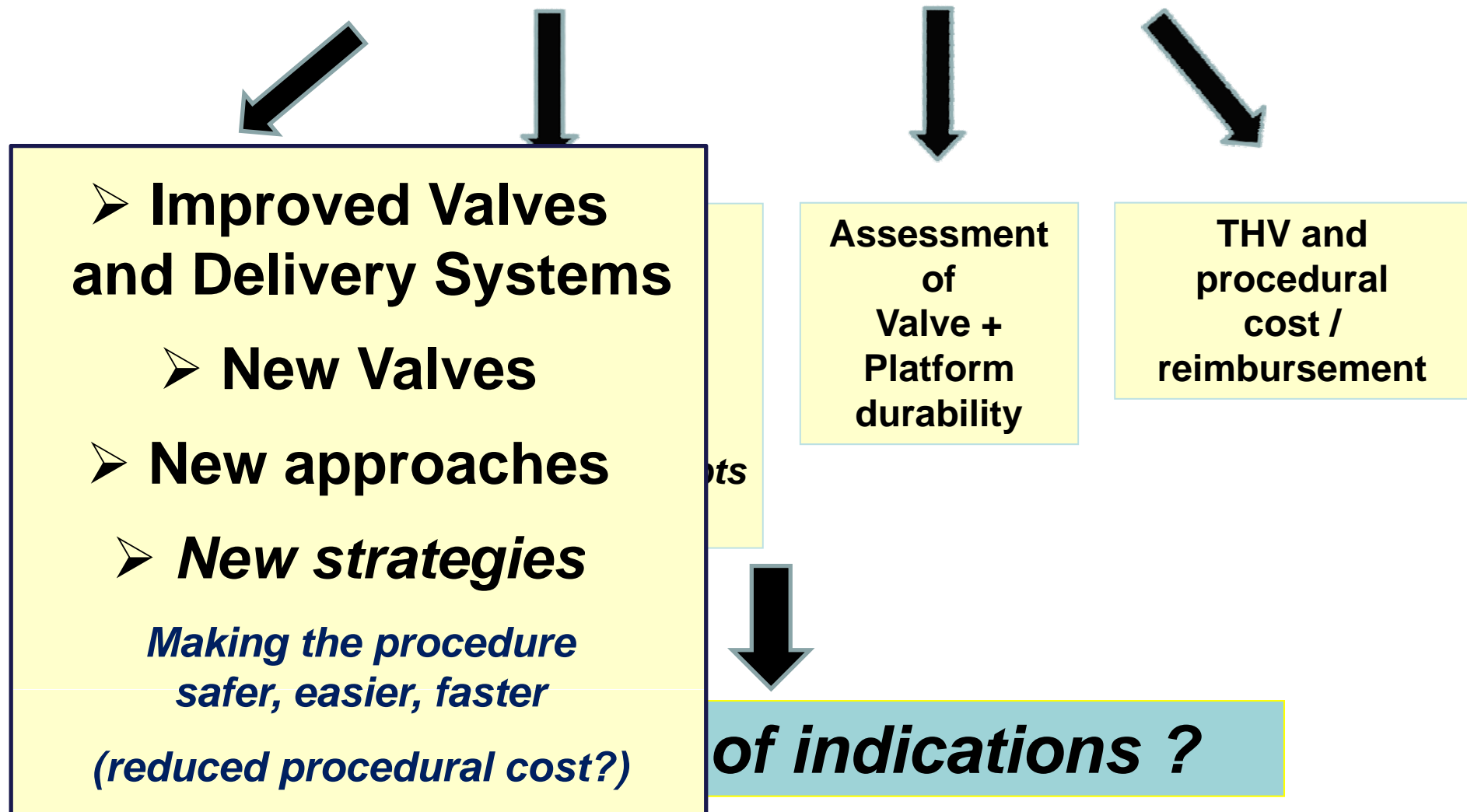
- 1) **Class I**
  - TAVI should not be performed in patients at intermediate risk
- 2) **Class IIa**
  - TAVI should not be performed if life expectancy is < 1 year
- 3) **Class IIb**
  - The good clinical sense is primordial (over Scores "numbers") in patient selection

Cardiologist / Surgeon / Anesthesiologist / Geriatrician



# *Perspectives*

**In the pipeline for the 10 coming years**



# Improved prosthetic heart valves balloon expandable valve

2000 (FIM 2002)

Percutaneous Heart Valve



2003

Cribier Edwards



2006

Edwards Sapien



Treated bovine peric.  
Stainl. steel frame .  
23 and 26mm

2009

T



Treated bovine peric.  
Cobalt Chrom. frame  
23, 26, 29mm  
20mm in evaluation

TF

24F

22F

22F, 24F

18F, 19F

A Perimount Magna Valve  
within a short stent



# Improved delivery systems

## Novaflex™

### RetroFlex 3 (Edwards Sapien)



Sheath size: 22F (23mm), 24F (26mm)

### e-Sheath

THV 23mm:

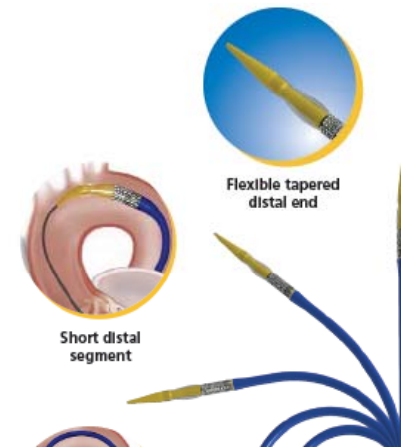
16 F



THV 26mm:

18 F

Sheath size: 18F (23mm), 19F (26mm)



**TF approach  
in  $\geq 80\%$**

Articulated delivery system

# *Improved valves and delivery systems*

**Launched  
in May 2012 month**

Extended annulus coverage  
in Transfemoral\*

The Edwards 29mm SAPIEN XT THV on the  
NovaFlex+ Transfemoral Delivery System\*

23mm

26mm

**29mm**



\*The 29mm NovaFlex+ delivery system is an Investigational device only. This product is currently not available for sale worldwide. CE Mark Pending.



## The Edwards 29mm SAPIEN XT THV



**Crimped over a 20F E-Sheath**

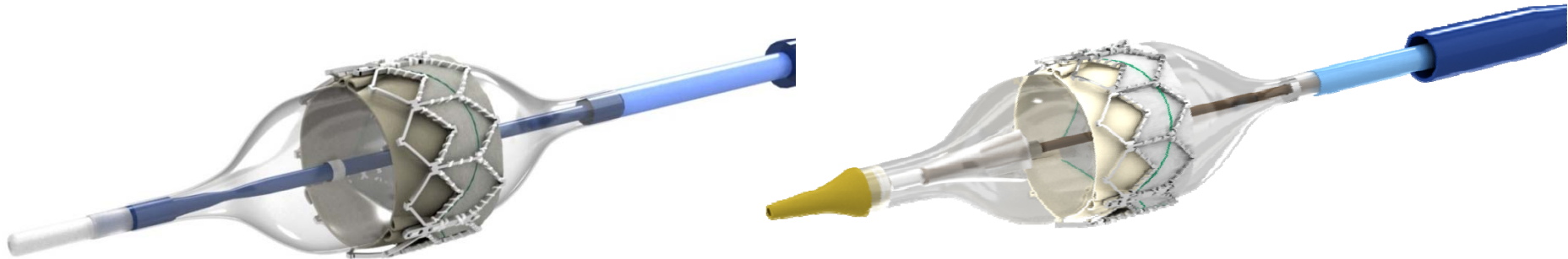
*Improved valves and delivery*

*systems* **Coming in 2012**

New TA & TAO delivery system\*<sub>1</sub>

**The New Edwards Ascendra+ Delivery System\*:**

For both antegrade (Trans-apical) or retrograde (Trans-aortic) delivery of the Edwards SAPIEN XT valve.



Ascendra2 Delivery System

**NEW** Ascendra+ Delivery System\*

- New balloon and nose cone to facilitate retrograde access
- Shortened delivery system length – Now only 55cm long
- 1 easy-to-use system for all valve sizes

\*Investigational device only. This product is currently not available for sale worldwide. CE Mark Pending. The trans-aortic indication is currently not approved with either Ascendra2 nor Ascendra+, CE Mark Pending. 1. As tested on bench and animal lab.

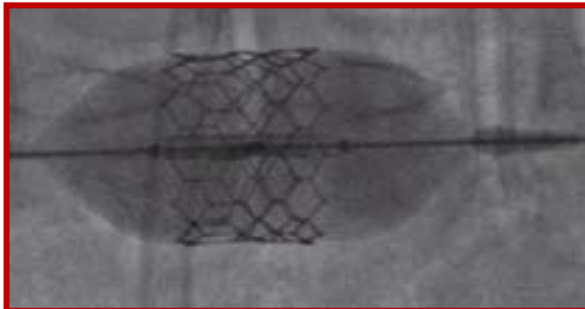


*Improved valves and delivery*

**Coming in 2012**

New Edwards SAPIEN 3  
Clinical Trial\*

***Ultra Low Profile Balloon-Expandable Platform***



- Designed to further **reduce PV leaks**
- Valve delivered through a **14 Fr eSheath**
- Reduced profile (**18F**) for TA approach
- Discrete valve that anchors in the annulus
- Treated bovine pericardial tissue leaflets
- TF, TA and Tao approaches,

\* The SAPIEN 3 Transcatheter Heart Valve system is an investigational devices only and not available for commercial sale.

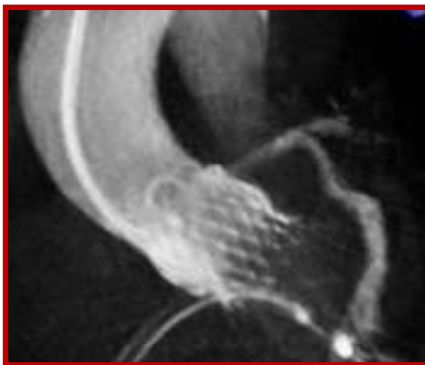
***First-in-Man Complete***

*Improved valves and delivery*

*systems* **Coming in 2012**

New Edwards CENTERA Clinical Trial\*

***Ultra Low Profile Self-Expanding Platform***



- **Motorized delivery system** for stable deployment and single operator use
- **Repositionable**
- Delivered through a **14 Fr eSheath**
- Seamless setup: **pre-loaded** onto delivery mechanism
- Discrete valve anchors in the annulus
- Treated bovine pericardial tissue leaflets
- Transfemoral and subclavian approach

***First-in-Man Complete***

\* The CENTERA Transcatheter Heart Valve system is an investigational device only and not available for commercial sale.

# *Improved valves and delivery systems*

## *Core Valve*

**Generation 1**  
**25F**

**Generation 2**  
**21F**

**Generation 3**  
**18F**

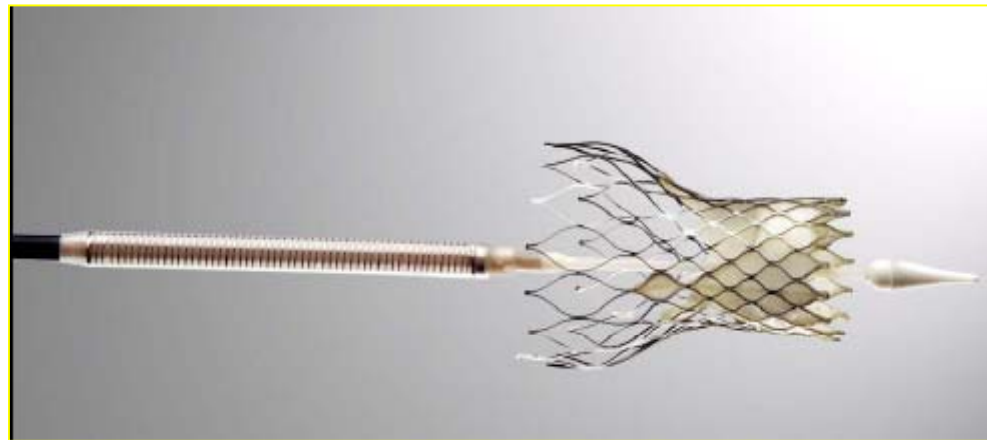
**Generation 4**  
**18F**

Sizes 26mm and 29mm

**2004-2005**

**From 2006**

**2010**



**NEW SIZE**  
**31mm**

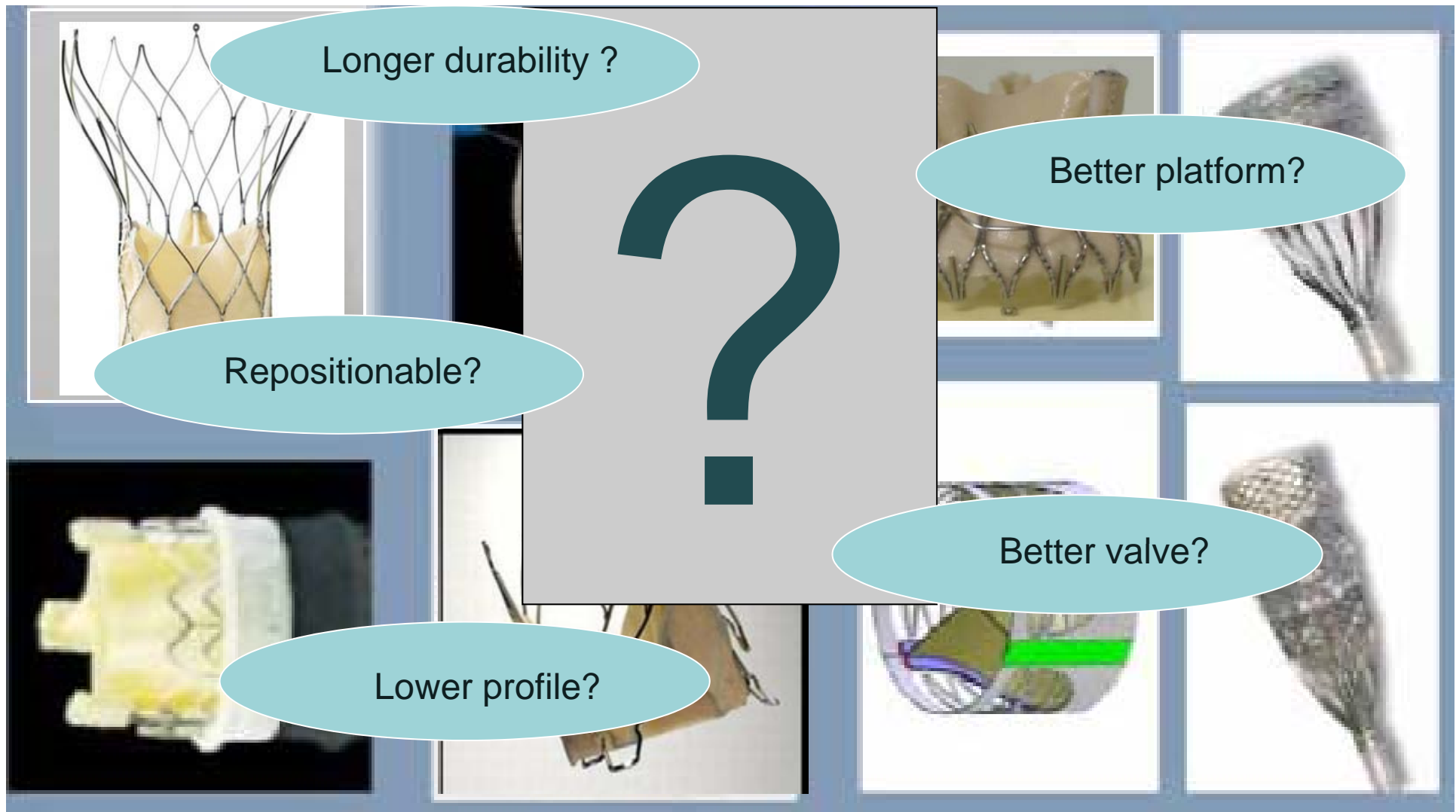
Pure percutaneous technique  
Preclosing with ProStar

**AccuTrak**  
**Delivery**  
**System**



# *New Valves*

Very early experience  
Short series



# New Approaches

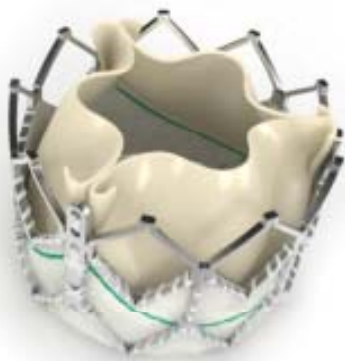


TRANSAORTIC

Axillary

Transapical

Transfemoral

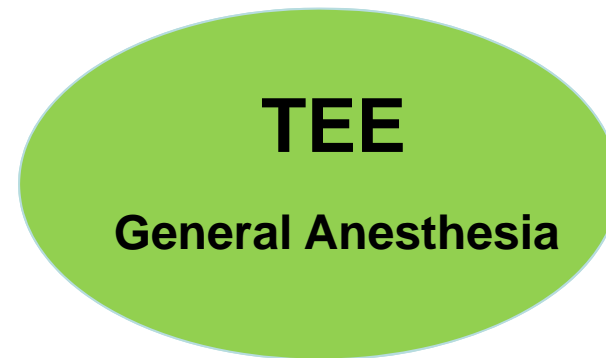


# New TF Implantation Strategies

Optimal X-Ray projection  
Accurate valve positioning  
Confirmation of valve size

## **Simplified procedure**

Local anesthesia  
Percutaneous approach  
Procedure duration: 45 min  
ICU < 24h  
Discharge Day 3  
Fluoroscopy used for  
valve sizing & positioning



*ations  
of results*





TF Edwards XT  
Maximalist approach  
General anesthesia  
TEE  
17 persons in room





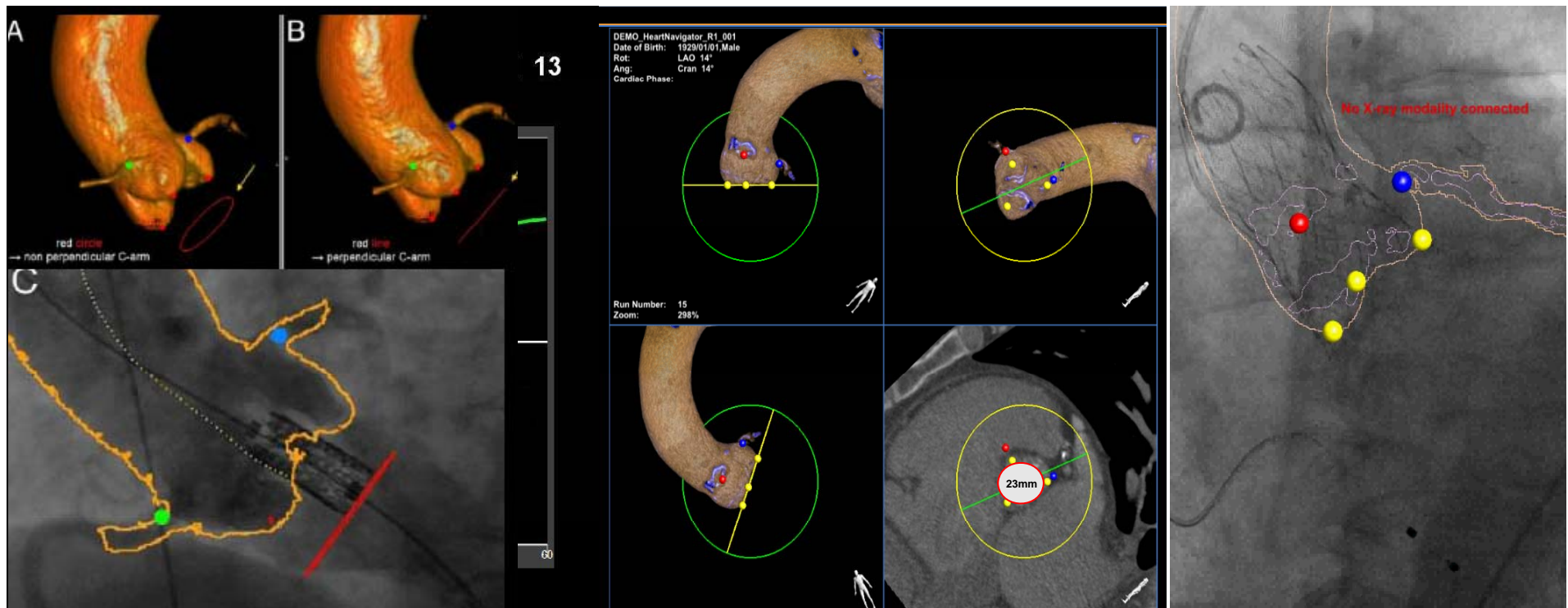


Rouen TF Edwardsd XT  
Minimalist approach  
5 persons in room



Conscious sedation  
ProStar  
Duration 45 min  
Discharge at Day3

# New Imaging technologies for improvement of valve sizing/ positioning



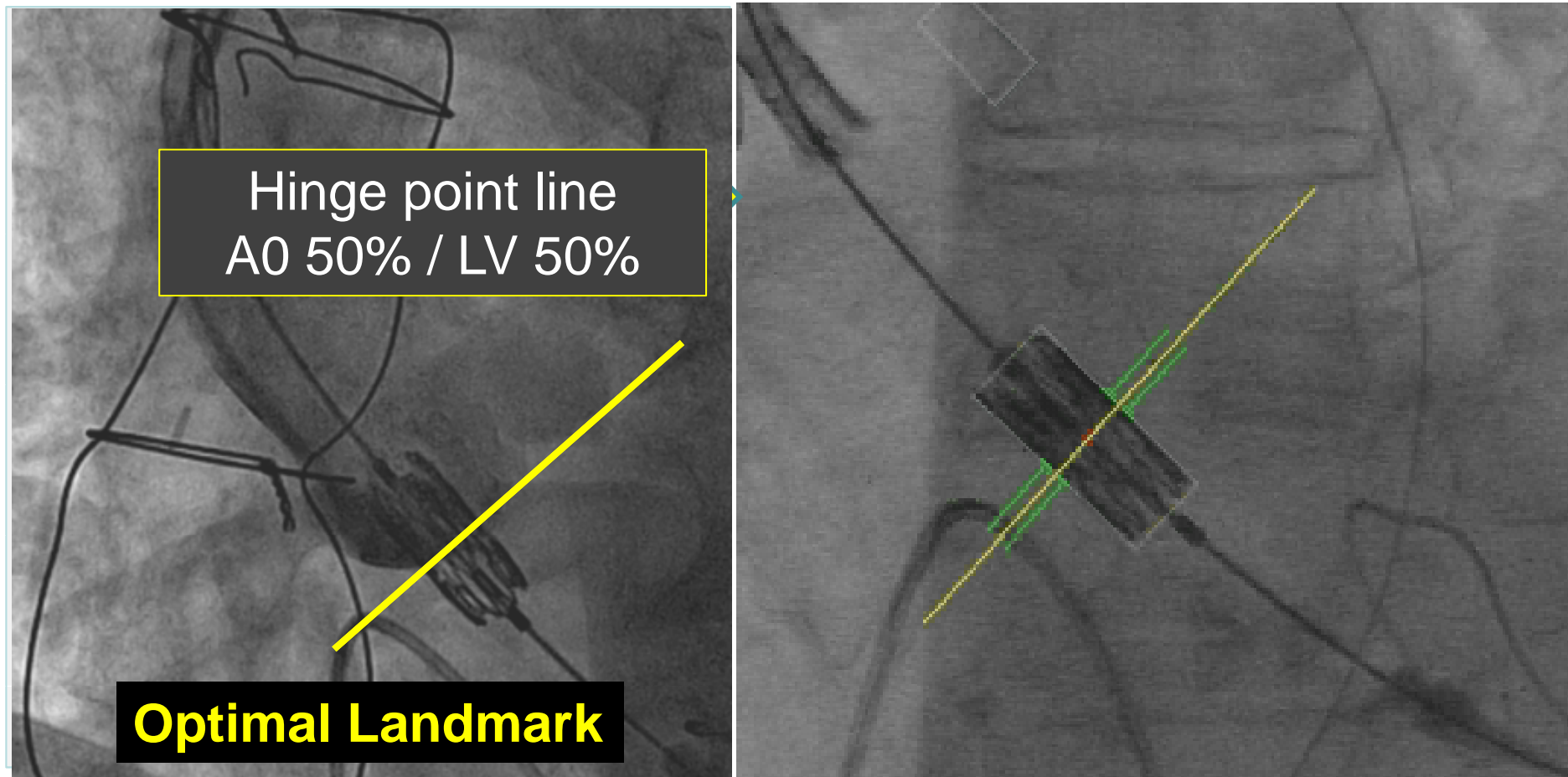
## CT and CT like reconstruction during TAVI



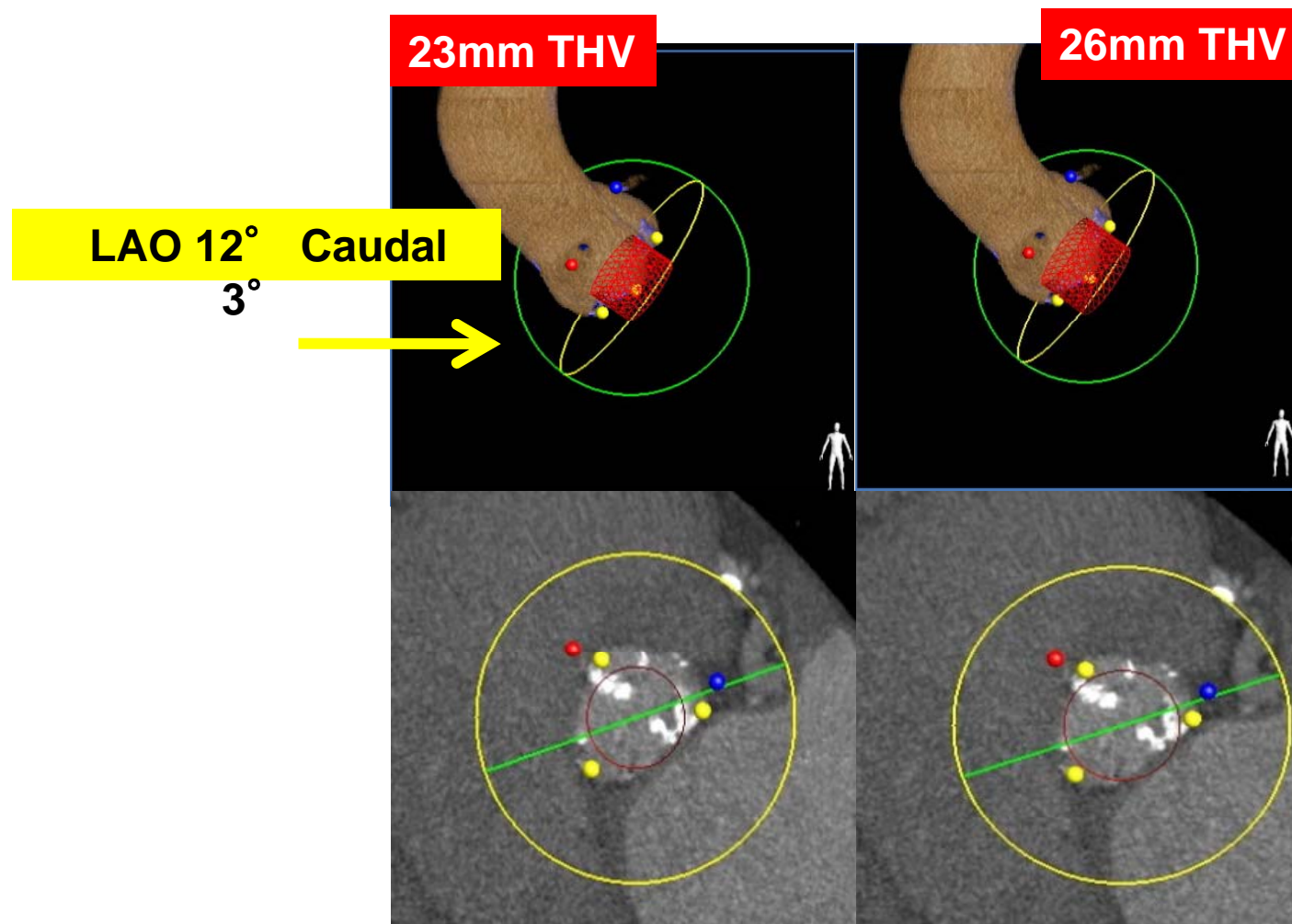
# New imaging technologies: Paieon C-TH

*Draws hinge point line (yellow line)  
and double green line over THV (50%)*

*Accuracy of valve positioning*



# PHILIPS HEART NAVIGATOR



**Accurate selection  
of optimal projection and valve size**

# *Perspectives*

**Where do we go?**

**Upcoming  
registries &  
controlled trials  
in specific  
subsets of pts:**

***Younger / less sick pts  
Valve in Valve***

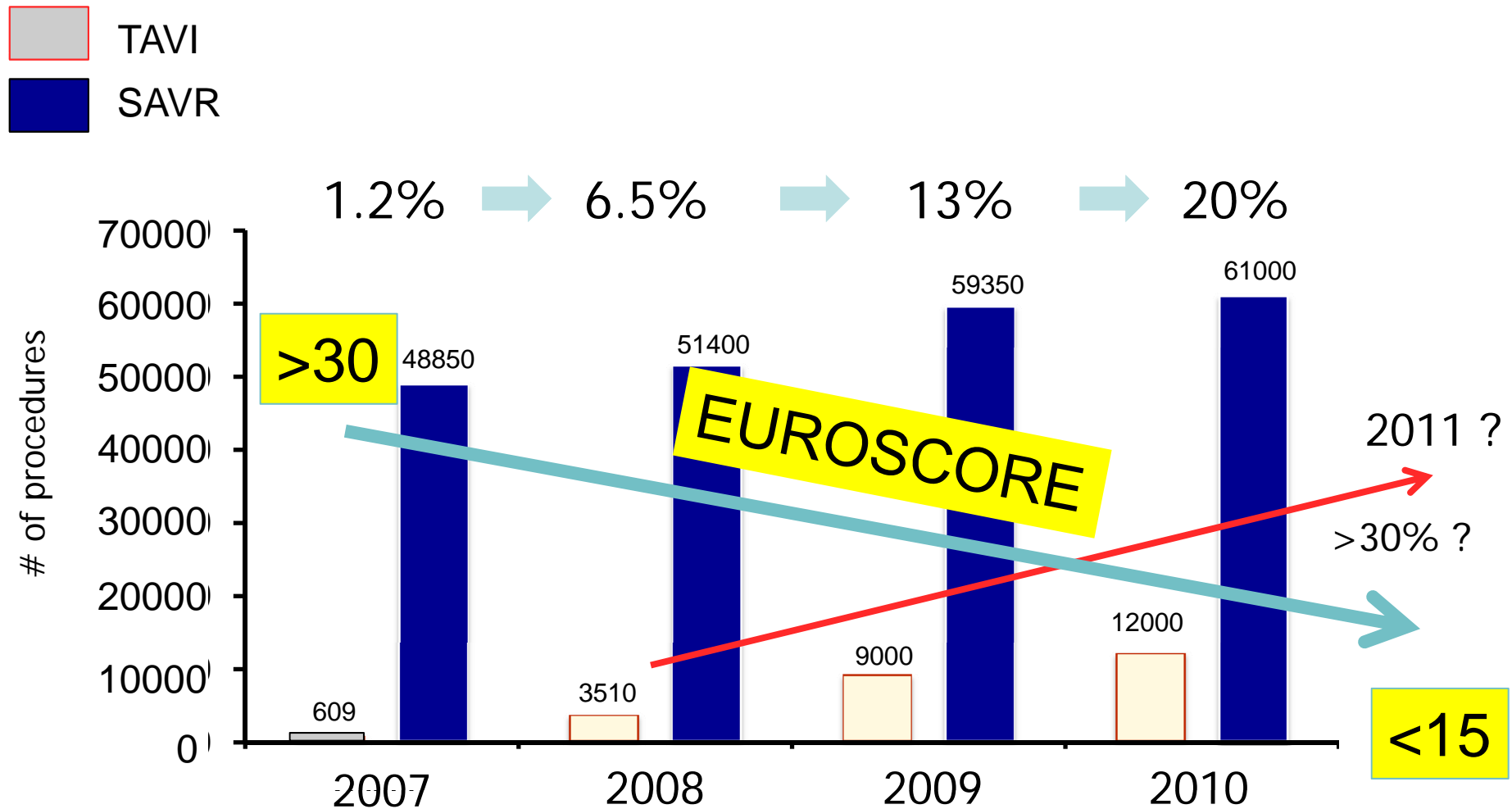
***Expanded clinical indications***

Improve  
THV  
and delivery  
System  
New THV

ment  
e +  
rm  
lity

THV and  
procedural  
cost /  
reimbursement

# TAVI: The current situation in Europe



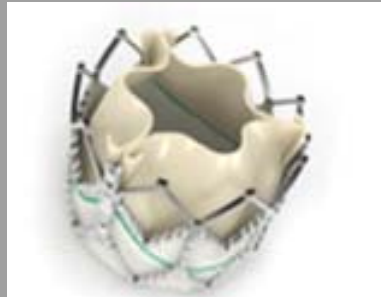


# The Issues of TAVI in Younger / Lower Risk Patients

Perimount Magna



Edwards XT



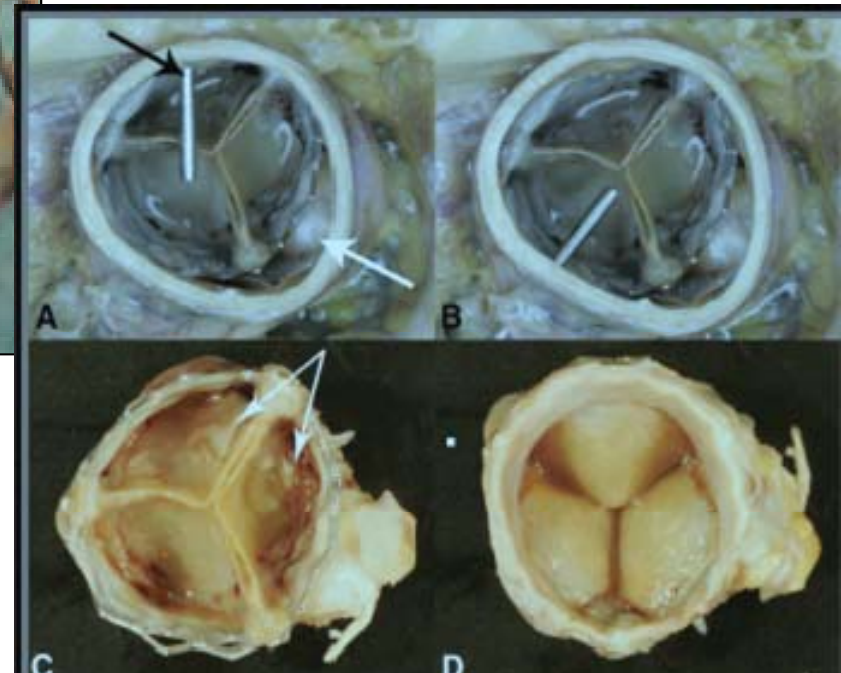
Why should the results be  
different on long term ?



How do TAVI  
results compare with  
**PARTNER – A**  
results ?  
Comparable at one year

# The Issues of TAVI in Younger / Lower Risk Patients

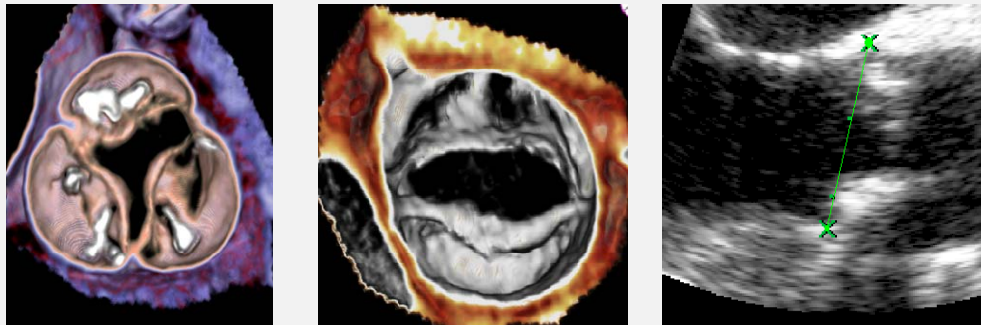
*Scarce reports on transcatheter heart failure*



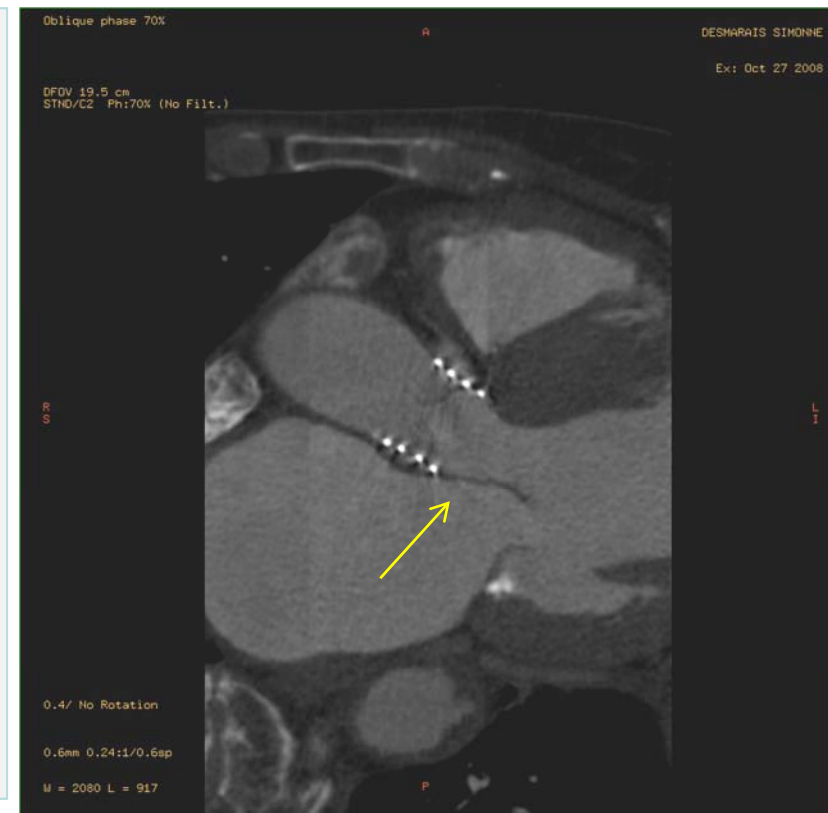
# Additional requirements in younger patients

Paravalvular regurgitation

Permanent pacemaker



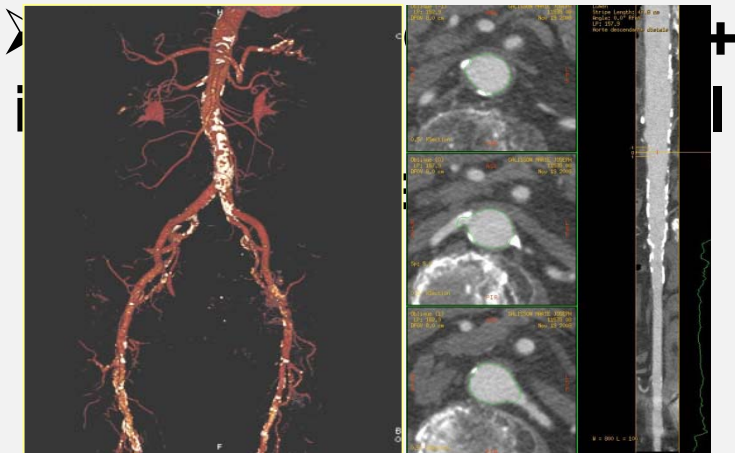
- Valve anatomy and calcium distribution
- Annulus measurements and valve sizing
- Accuracy of positioning, technical proficiency and adjunctive imaging techniques
- **New valves dealing with this issue (ex: Edwards SAPIEN 3)**



# Additional requirements in younger patients

## Vascular complications

- Lower size devices 16F, 14F....
- Improved closure devices



## Stroke (3 to 7%)



**CT screening of high risk patients**  
**Protection devices (filters)**  
**in selected cases**

**Umbrella device**

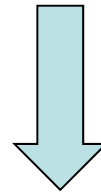


**Anticoagulant / antiplatelets Tt**



It is not time to expand the indications to younger / less sick patients **yet**

It is time to evaluate TAVI in new indications



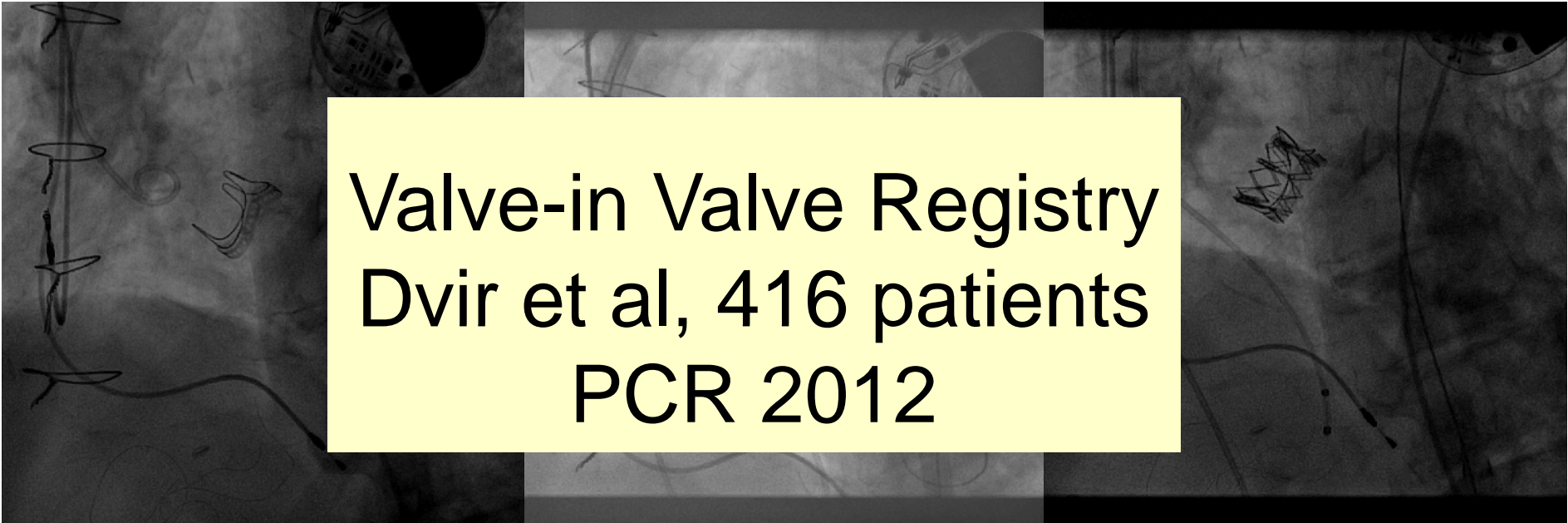
SURTA VI Trial  
Europe  
Core Valve

Randomized studies  
vs surgical AVR  
in lower risk / younger Pts  
(**Intermediate Scores**)

PARTNER 2  
USA  
Edwards

# A new promising indication: Valve in Valve

Rouen, Degenerated Perimount 21, F 92 yo

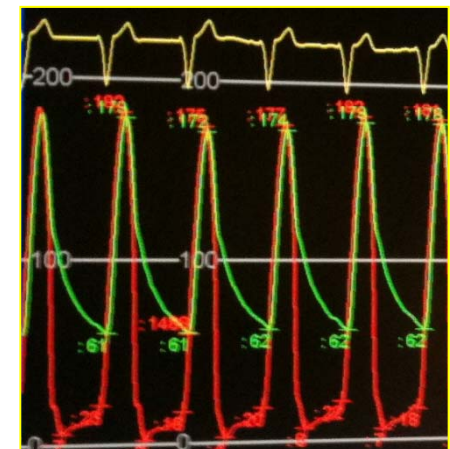


Valve-in Valve Registry  
Dvir et al, 416 patients  
PCR 2012



Edwards XT 23mm

Local anesthesia  
Prostar 10F  
Discharged at Day 3



## Cost of the Procedure

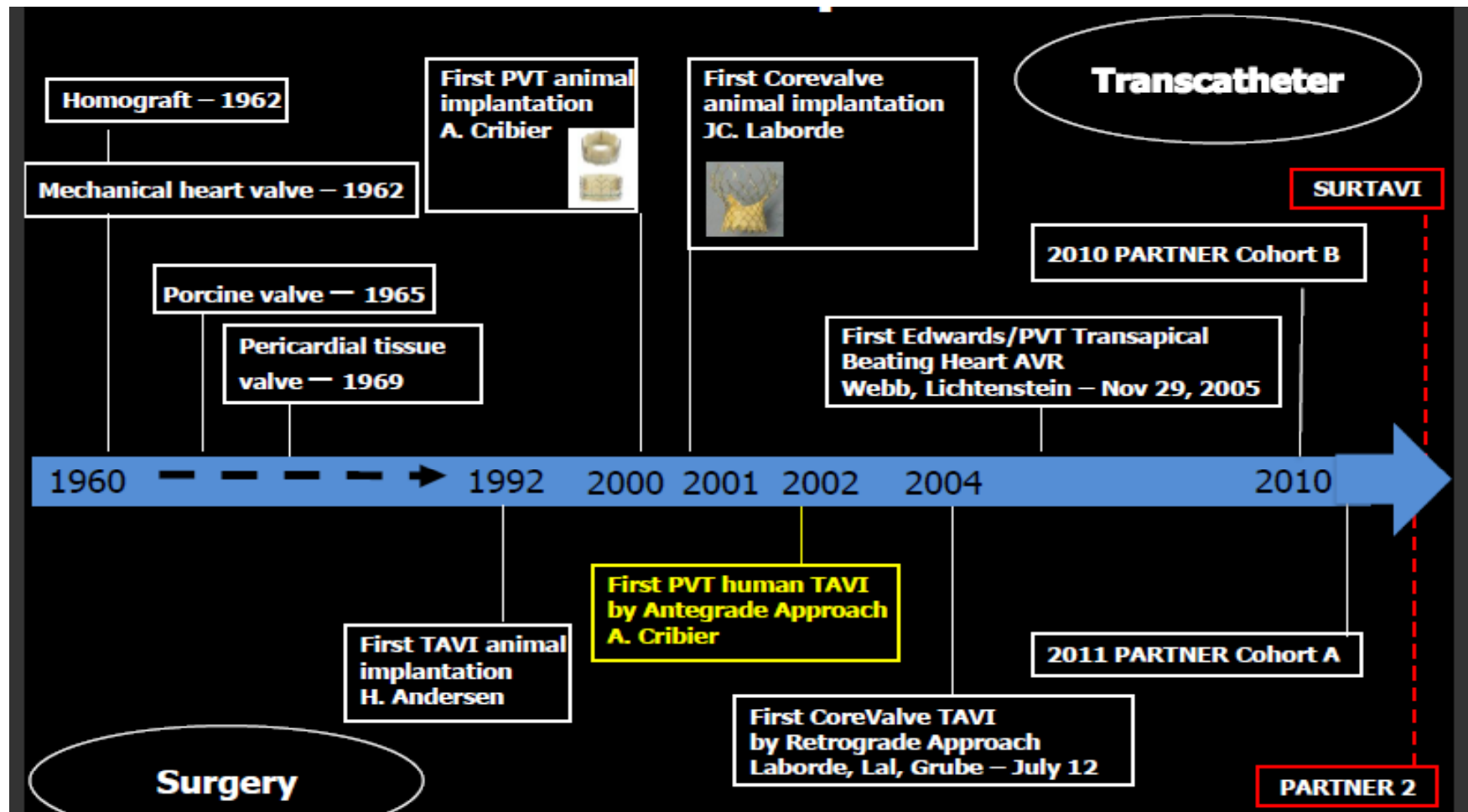
*A significant limitation to the expansion of TAVI worldwide*

High cost of the devices and procedures and lack of reimbursement programs do constitute one of the strongest limitation to TAVI expansion worldwide, and not only in developing countries !

*This might unfortunately favor cheapest new valves in many countries and institutions whatever the properties and medical results of the devices*

# Summary of the History of AVR

## *A 50 Years Moving Field*



From Serruys, ESC meeting 2012



# My views on the future

- **In 2012-2013**, with FDA approval, TAVI might explode in USA and worldwide in non-operable and high risk patients (> 400 centers in the US...)
- **Within 5 years**, expansion of indications to other subsets of patients such as less severely ill /younger patients can be expected. Controlled registries are requested. Less invasive procedures (stent like) might be used in > 70% of the cases

# My views on the future

- **Within 10 years**, actually, nobody knows! Probably used in a vast majority of patients with severe aortic stenosis... The future looks bright !...

2000-2002: negative comments of all experts.....

« Impossible! Major technical and anatomical issues »

« **Most stupid project ever heard!** »

Just a wink.....

