

# Why I select Balloon Expandable Valve ?

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# Disclosure Statement of Financial Interest

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

## Affiliation/Financial Relationship

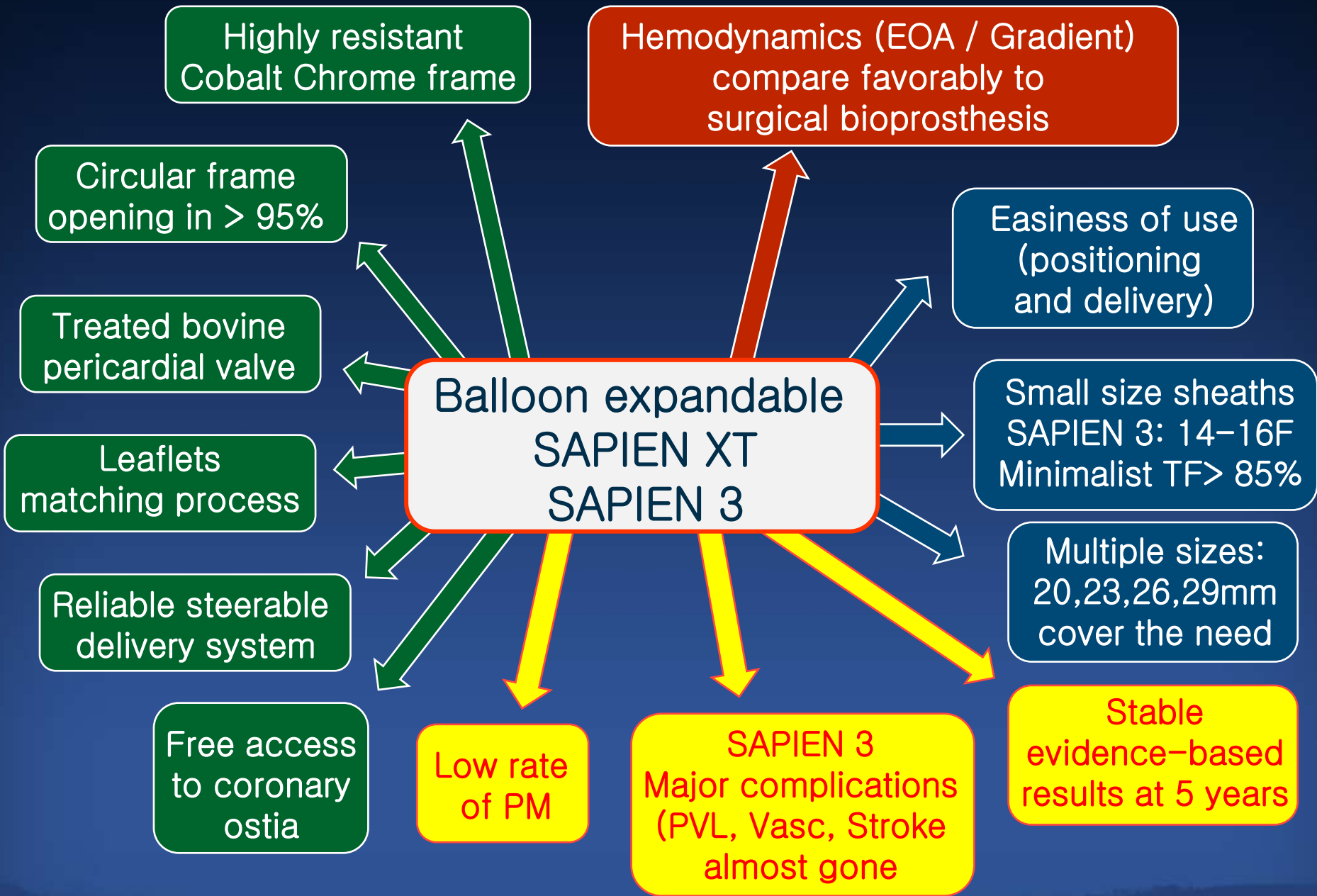
- Consulting Fees/Honoraria
- Proctoring–Training activities/Honoraria

## Company

- Edwards Lifesciences
- Edwards Lifesciences

# What is an ideal transcatheter valve?

- Hemodynamics and durability comparable to surgical bioprosthesis
- Frame with high radial force for circular opening
- Respect of surrounding anatomical structures
- Safe and predictable implantation
- Adapted to a majority of patients (access, sizes)



Highly resistant  
Cobalt Chrome frame



Circular frame  
opening in > 95%



Treated bovine  
pericardial valve

Balloon expandable  
SAPIEN XT  
SAPIEN 3

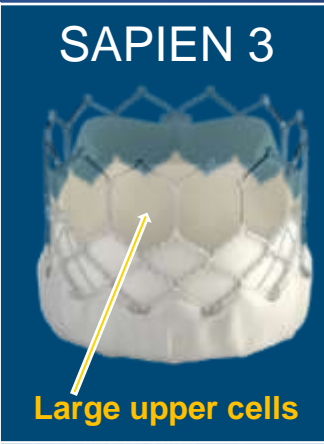


Leaflets  
matching process

Reliable steerable  
delivery system



Free access  
to coronary  
ostia

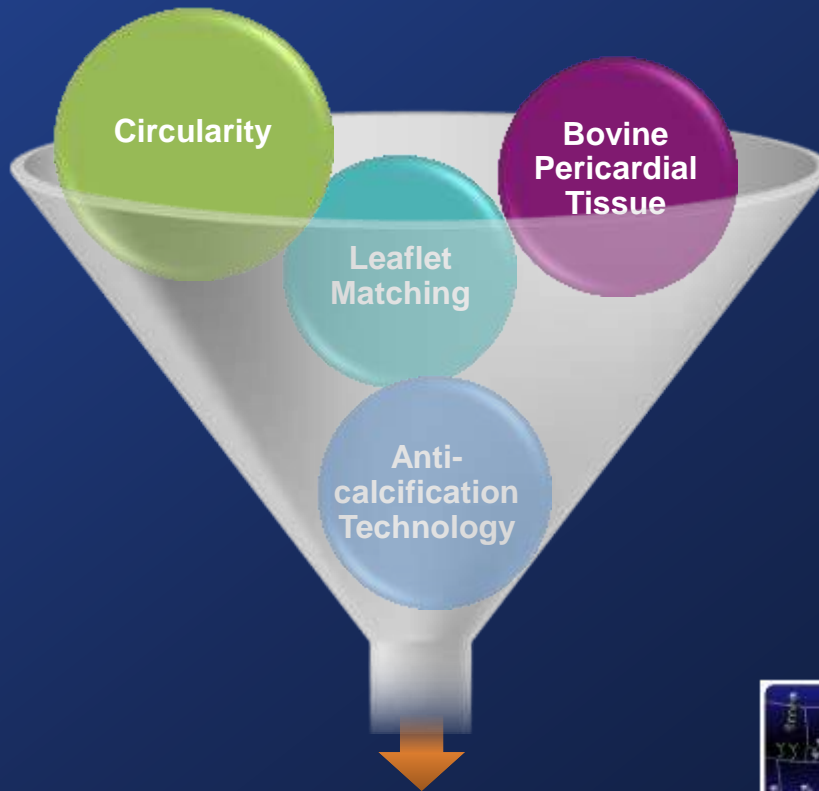


# Physical properties: critical elements for durability

## Circularity



Binder R., et al. Transcatheter Aortic Valve Replacement with the SAPIEN 3: A New Balloon-Expandable Transcatheter Heart Valve. JACC Cardiovasc Intv Vol. 6, No. 3, 2013.

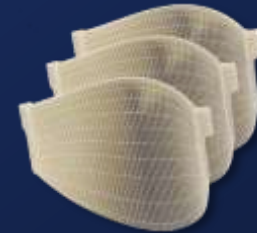


## Durability

## Bovine Tissue



## Leaflet Matching



## Carpentier-Edwards ThermaFix™ Process\*



1. Heat treatment  
removes unstable  
glutaraldehyde  
molecules

2. Patented  
chemical treatment  
removes 98% of  
phospholipids



# Ballon-expandable valve proven durability

## Mean Gradient & Valve Area (AT)



### PARTNER B at 5 years



Kodali, TCT 2014

Rouen, 2012: 10<sup>th</sup> year FIM celebration



**83 y/o patient  
9 years post – TAVR  
Normal valve function  
Normal life**

Hemodynamics (EOA / Gradient)  
compare favorably to  
surgical bioprosthesis

A Carpentier Edwards  
bioprosthesis  
mounted in a stent



Physical properties	Carpentier-Edwards PERIMOUNT Magna Surgical Valve	Edwards SAPIEN XT™ Transcatheter Heart Valve
1. Bovine Pericardial Tissue	✓	✓
2. Proprietary Leaflet Shape	✓	✓
3. ThermaFix™ Anti-Calcification	✓	✓
4. Non-interfering Frame Height	✓	✓
5. Circular Shape post-implant	✓	✓



Hemodynamics (EOA / Gradient)  
compare favorably to  
surgical bioprosthesis



Transcatheter valve

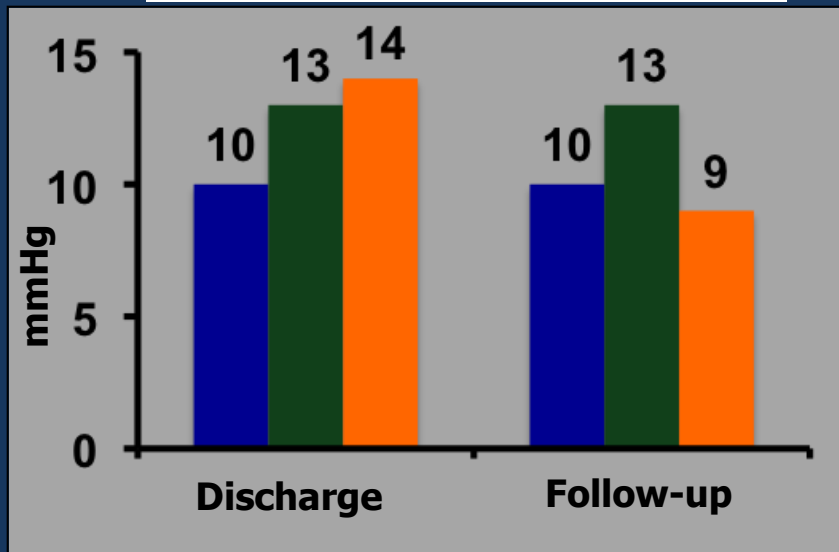


Surgical stented  
valve

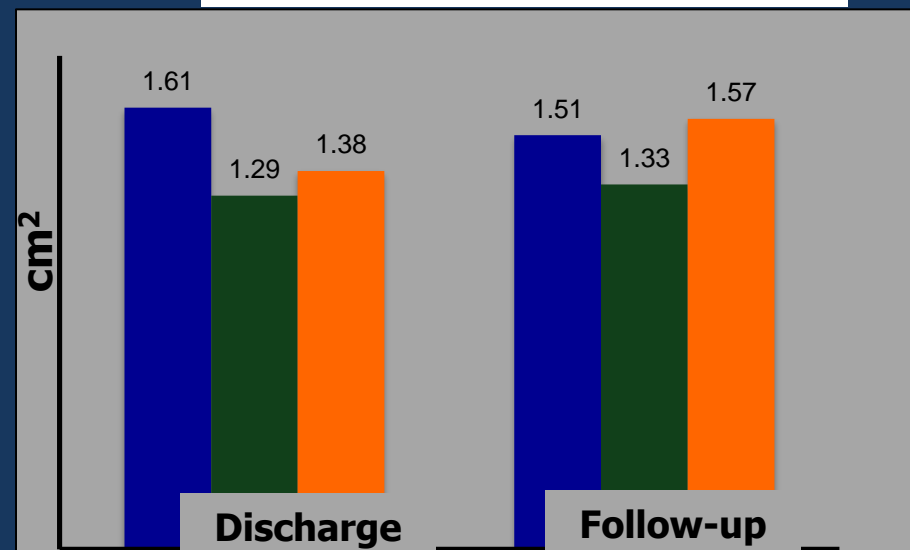


Surgical stentless  
valve

Mean Gradient (mmHg)

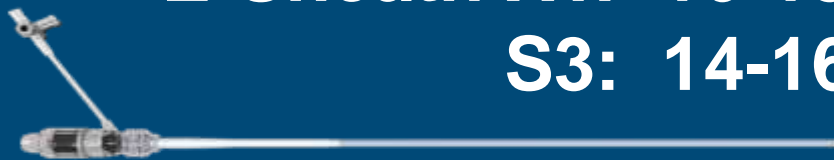


Mean Valve Area (cm<sup>2</sup>)



Clavel et al. J Am Coll Cardiol 2009; 53:1883-91

**E-Sheath XT: 16-18F**  
**S3: 14-16F**



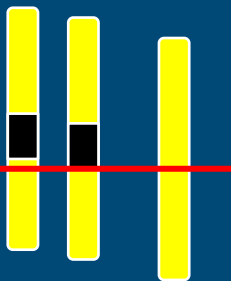
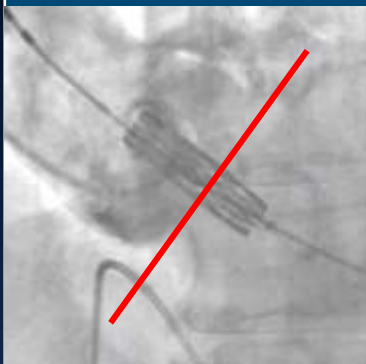
Ves  $\phi$  : 5.5mm

Easiness of use  
 (positioning  
 and delivery)

Small size sheaths  
 SAPIEN 3: 14-16F  
 Minimalist TF > 85%

Multiple sizes:  
 20,23,26,29mm  
 cover the need

Balloon expandable  
 SAPIEN XT  
 SAPIEN 3

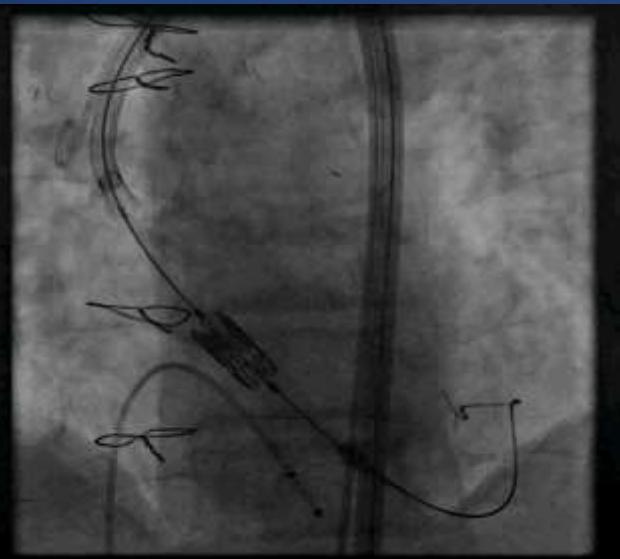


S3

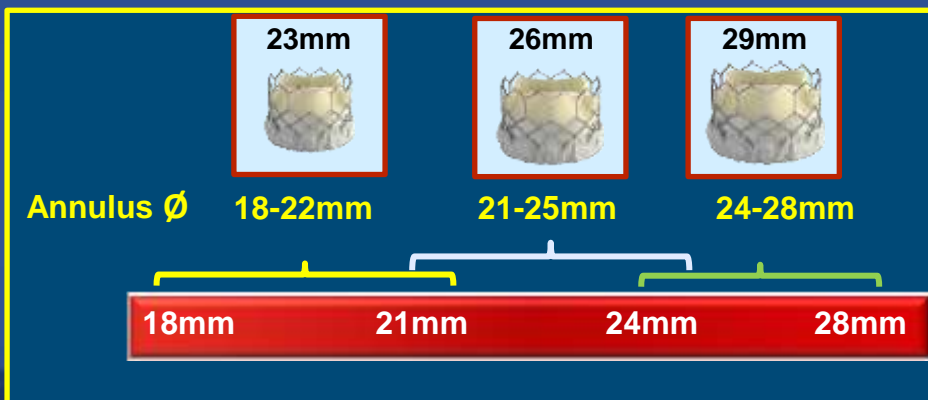
XT

Fine Positioning SAPIEN 3

S3: Easy positioning



XT: Easy delivery

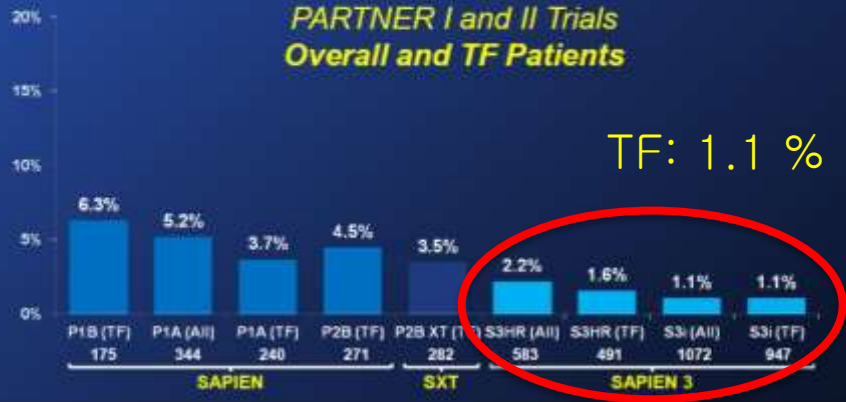


### All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)



*PARTNER I and II Trials  
Overall and TF Patients*

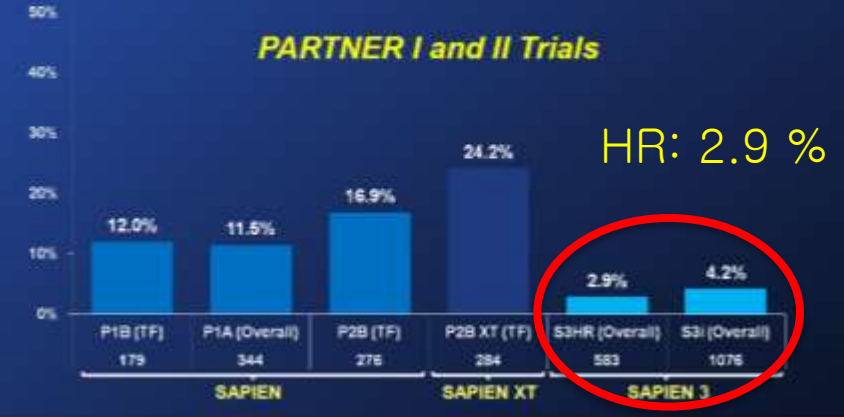


### Moderate/Severe PVL at 30 Days

Edwards SAPIEN Valves



*PARTNER I and II Trials*



Mortality at 30-D

PVL at 30-D

Balloon expandable  
SAPIEN XT  
SAPIEN 3

### Strokes SAPIEN 3

At 30 Days (As Treated Patients)

Disabling:  
S3 HR: 0.86%  
S3 IR: 1.02%

### PARTNER 1A: 5-y

SAPIEN 1st generation  
STS: 11.8%  
EuroScore: 29%

### Pace-Makers

2 to 3 Times less  
with balloon expandable  
vs Self expandable

### All-Cause Mortality (ITT) All Patients



# Sapien 3 in Rouen

Overall TAVI experience : ~ 900 patients (96% Edwards)

2015: 6 TAVI / week in 2 or 3 sessions

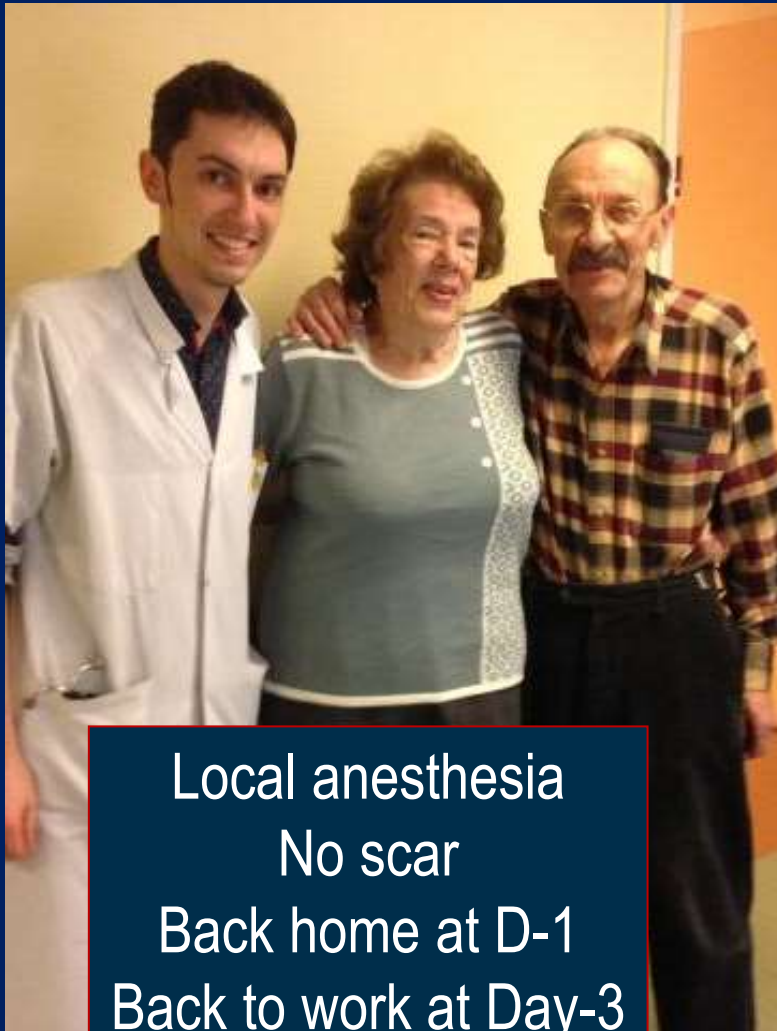
## Last 50 patients with Sapien 3 (since Nov 2014)

86% TF, 10% TA, 4% TA

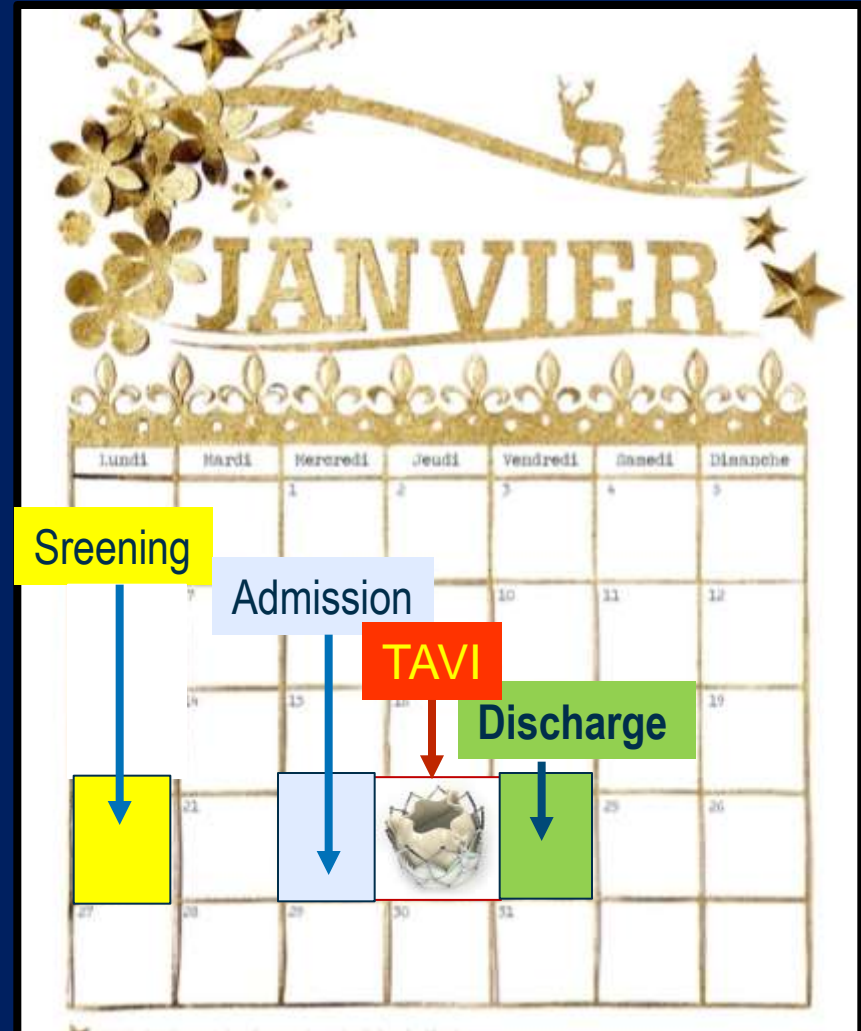
- Success: 100%
- PVL > 1: 0%
- Vascular complications: 0%
- PM: 6% (29mm valve)
- Discharge < D-3: 50%

CoreValve reserved to large size (> 28mm) annulus  
and small sizes bioprosthesis (now performed with the 20mm SAPIEN 3)

# Rouen: The “minimalist strategy” XT – S3 > 50% patients back home at < 3 Days



Local anesthesia  
No scar  
Back home at D-1  
Back to work at Day-3



Any good reason to use  
another valve?