

TAVI de demain

Dr DROGOUL Laurent

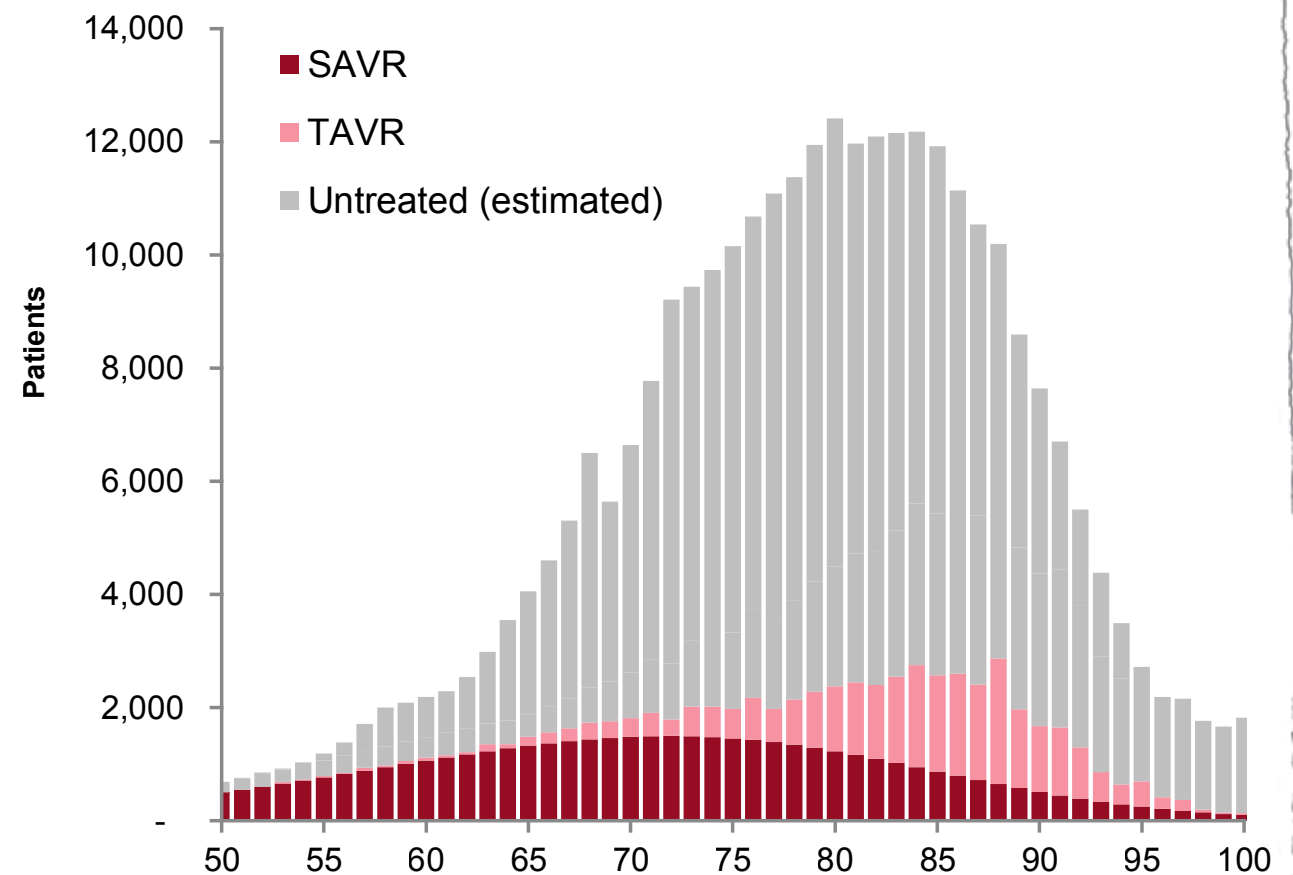
Global TAVR Opportunity Could Exceed \$5B in 2021

Observations

For Severe, Symptomatic AS Patients

- Age plays a significant role in the diagnosis and treatment of aortic stenosis
- Additional risk factors not captured in STS score become more important with patient age
- A safe interventional procedure has the potential to lift treatment rates in older age group

2015 Severe Symptomatic AS Patients in the U.S.¹



Avant le TAVI...

Mini-invasive Transradial Balloon Aortic Valvuloplasty: to SOFTLY and beyond

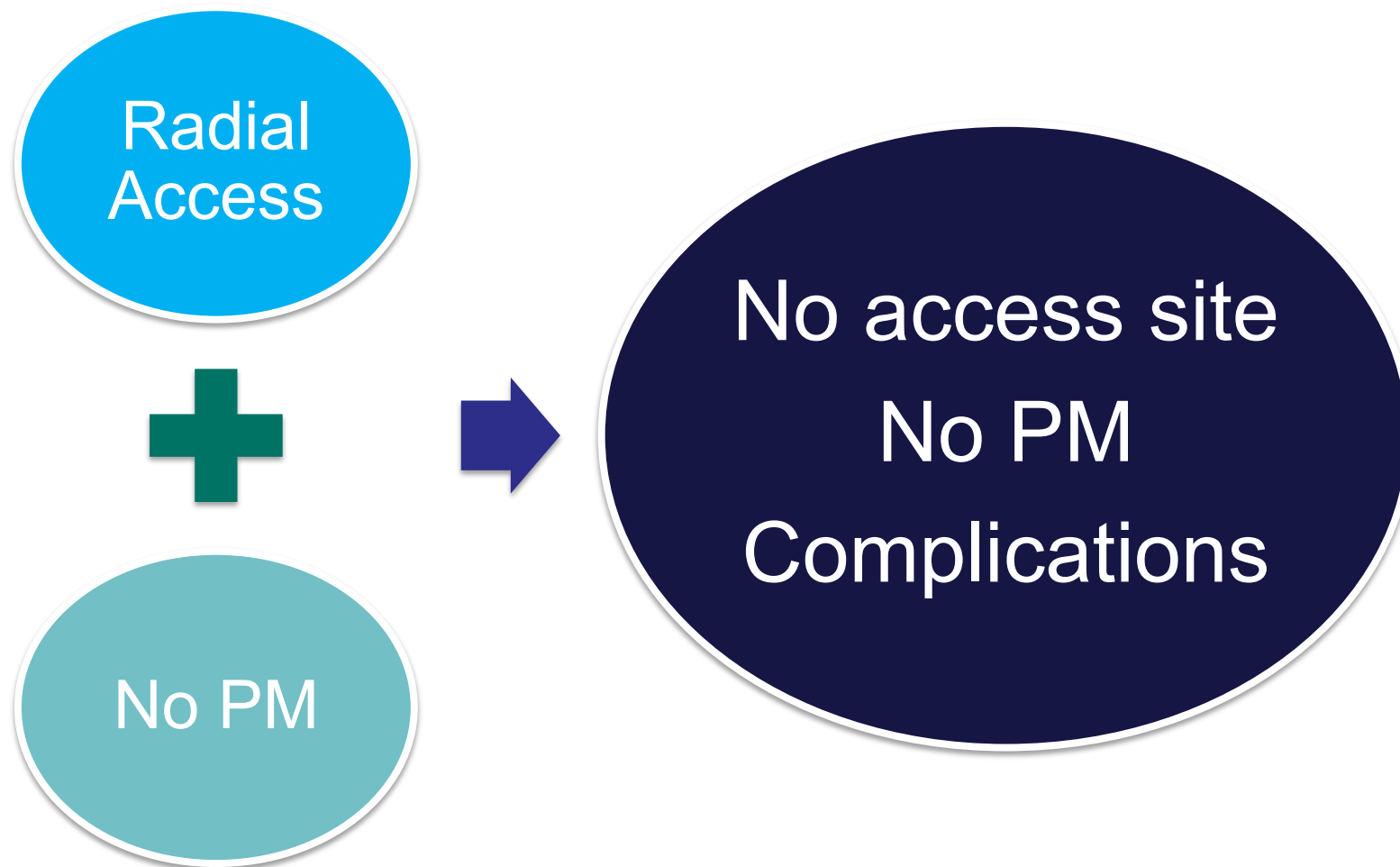
Simone Biscaglia

Medical Sciences Dpt, Ferrara University

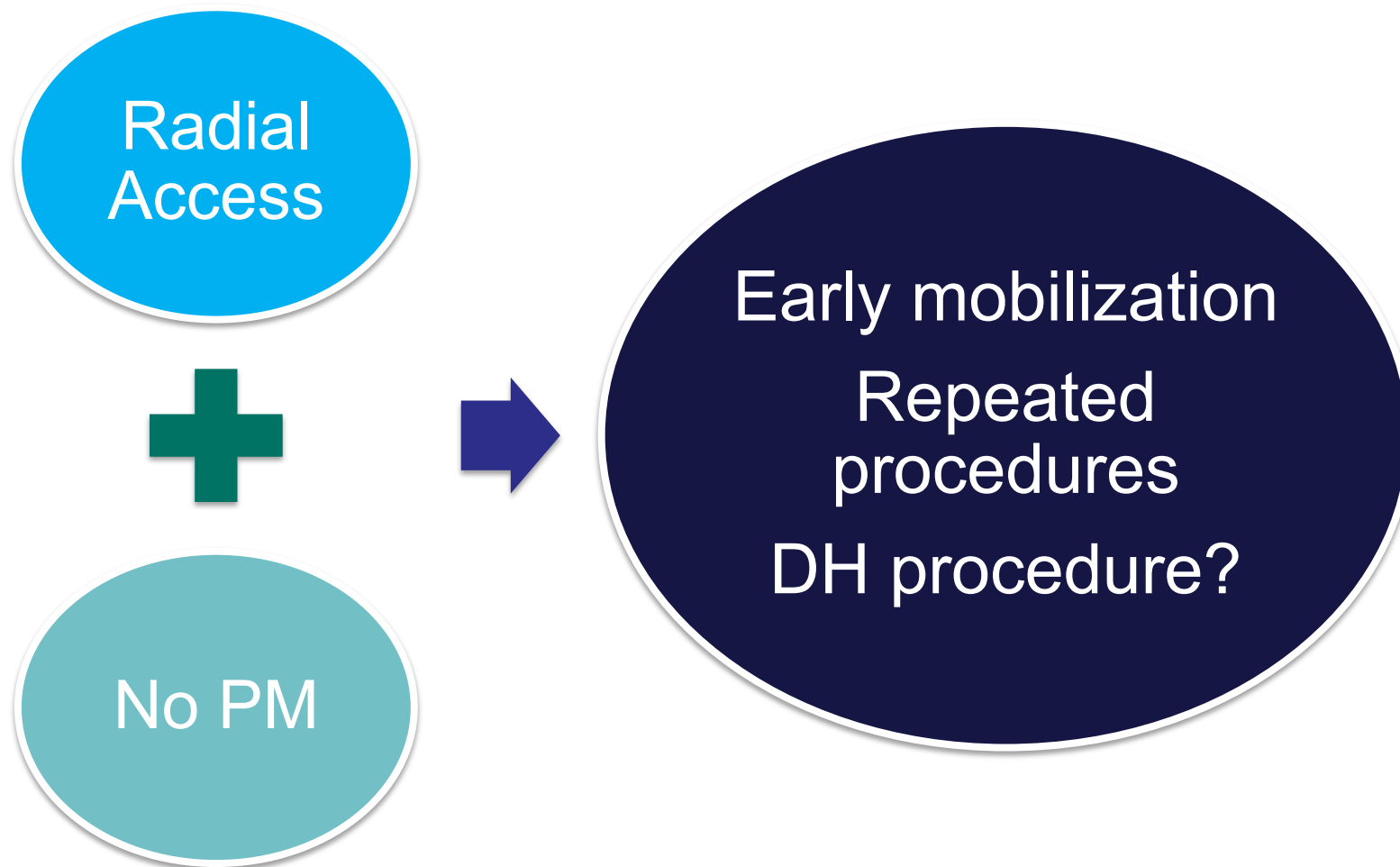


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DI FERRARA
- EX LABORE FRUCTUS -

Mini-invasive Transradial BAV



Mini-invasive Transradial BAV

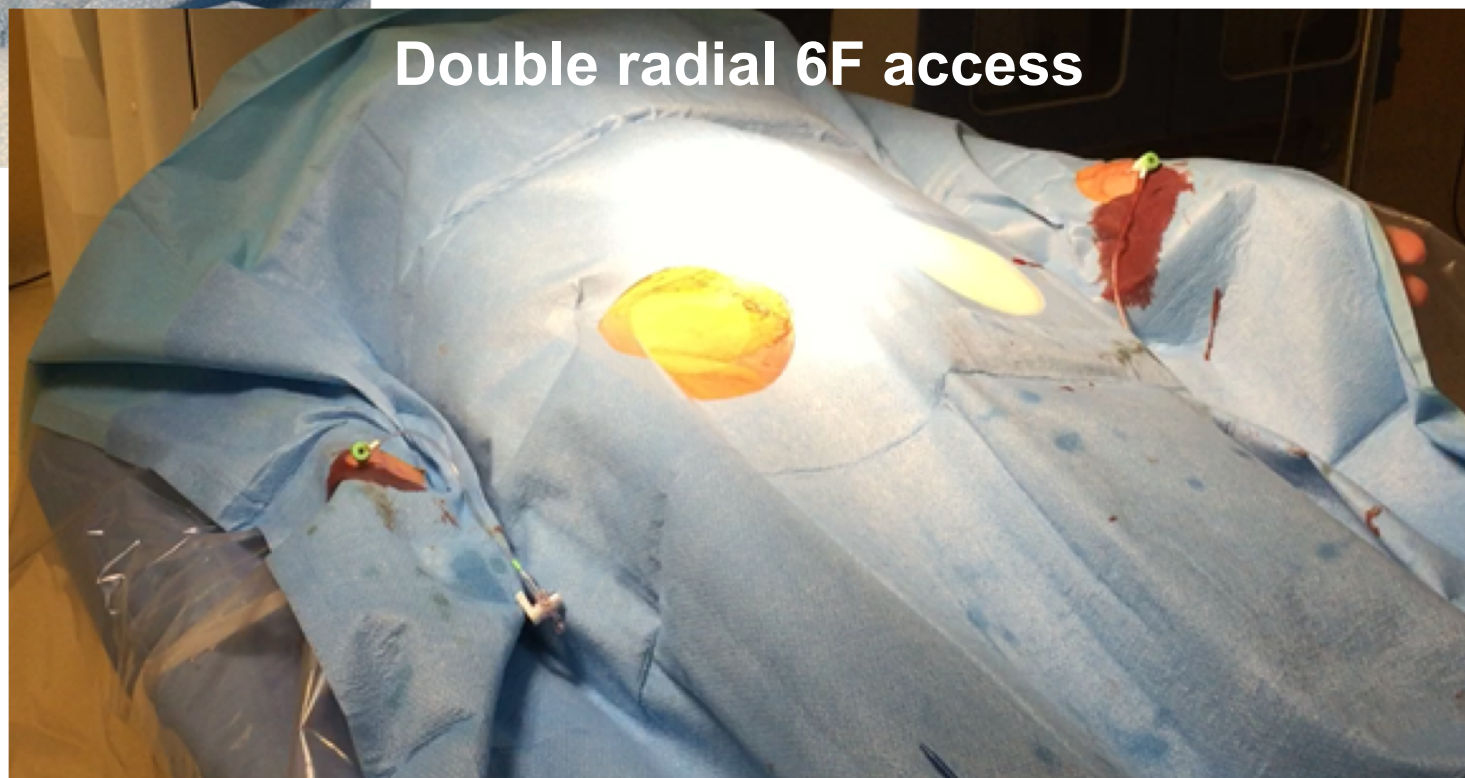


Mini-invasive Transradial BAV

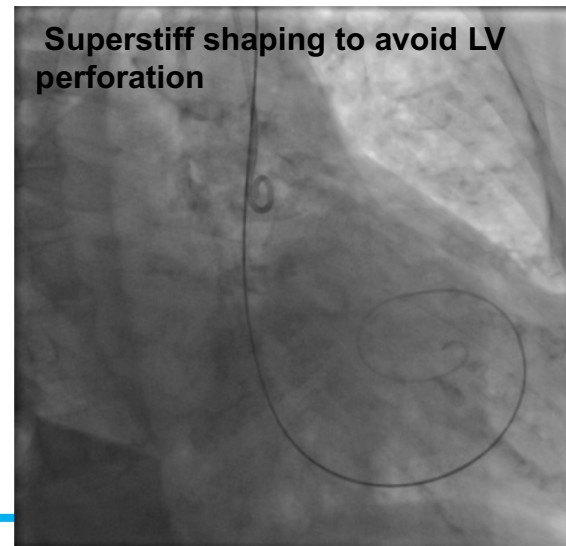
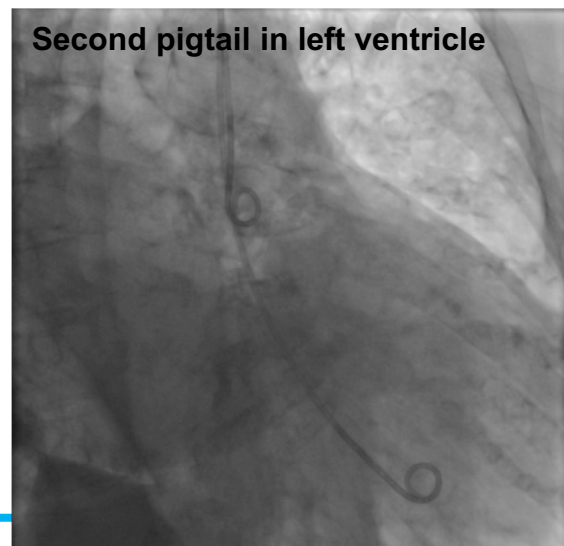
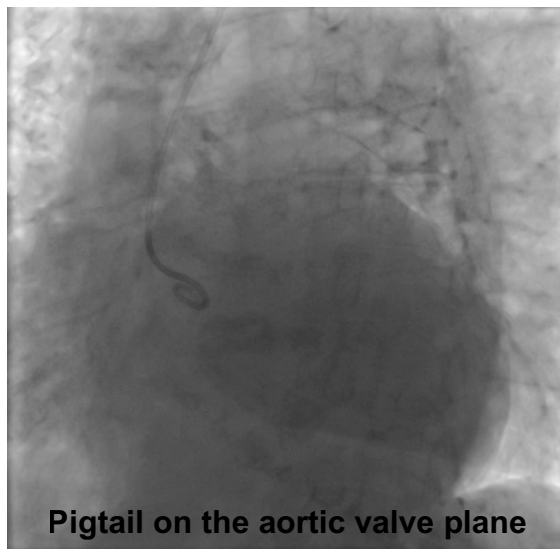
6F sheath in right radial artery



Double radial 6F access



Mini-invasive Transradial BAV

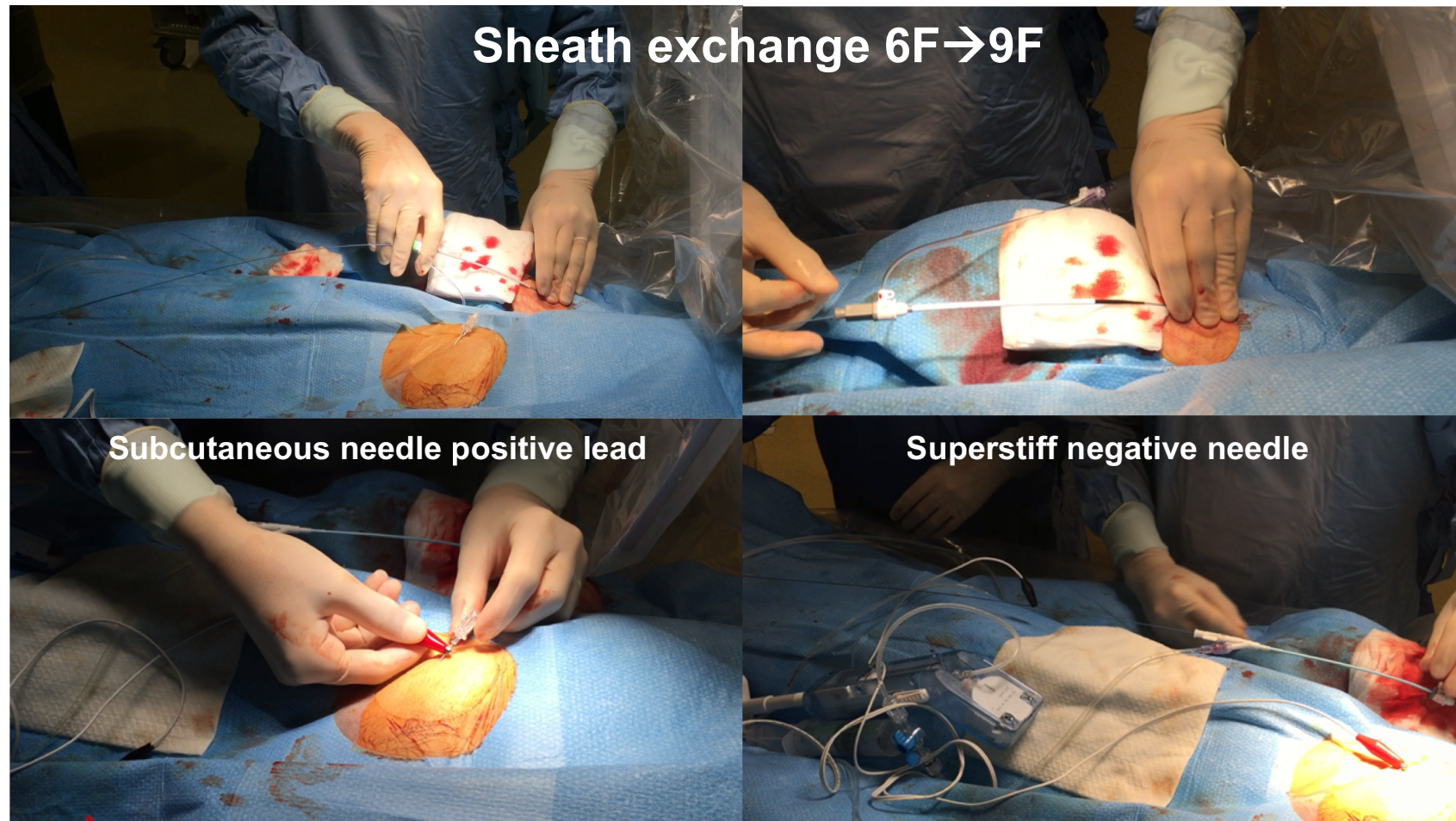


C Tumscitz, G Campo, M Tebaldi, F Gallo, L Pirani, S Biscaglia JACC CI 2017



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Mini-invasive Transradial BAV



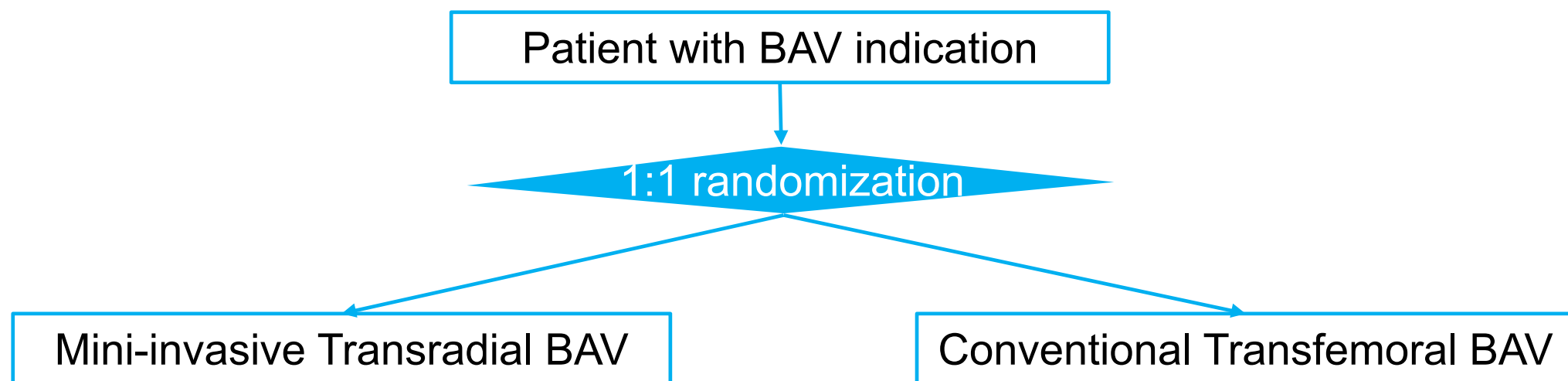
Sheath exchange 6F→9F

Subcutaneous needle positive lead

Superstiff negative needle

Leads connection to temporary PM

What could be next?



- **Primary Outcome:** 1-month serious adverse events rate
- **Safety endpoint:** Transradial balloon aortic valvuloplasty major complications rate

INDICATIONS DE DEMAIN

Five-Year Outcomes From the All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial in Patients with Severe Aortic Valve Stenosis

H. Gustav Hørsted Thyregod, MD, PhD

Department of Cardiothoracic Surgery
Copenhagen University Hospital, Denmark

On behalf of the NOTION Investigators



ACC.18

67th Annual Scientific Session, 8-12

Nordic Aortic Valve Intervention (NOTION) Trial

Objective:	To compare TAVR vs. SAVR in patients ≥ 70 years eligible for surgery (all-comers population/consecutive recruitment)
Primary outcome:	Composite rate of all-cause mortality, stroke or myocardial infarction at 1 year (VARC II-defined)
Secondary outcomes:	Safety and efficacy (NYHA), echocardiographic outcomes (VARC II-defined)
Design:	Prospective, multicenter, non-blinded, randomized trial
Enrollment period:	December 2009 - April 2013



ACC.18™

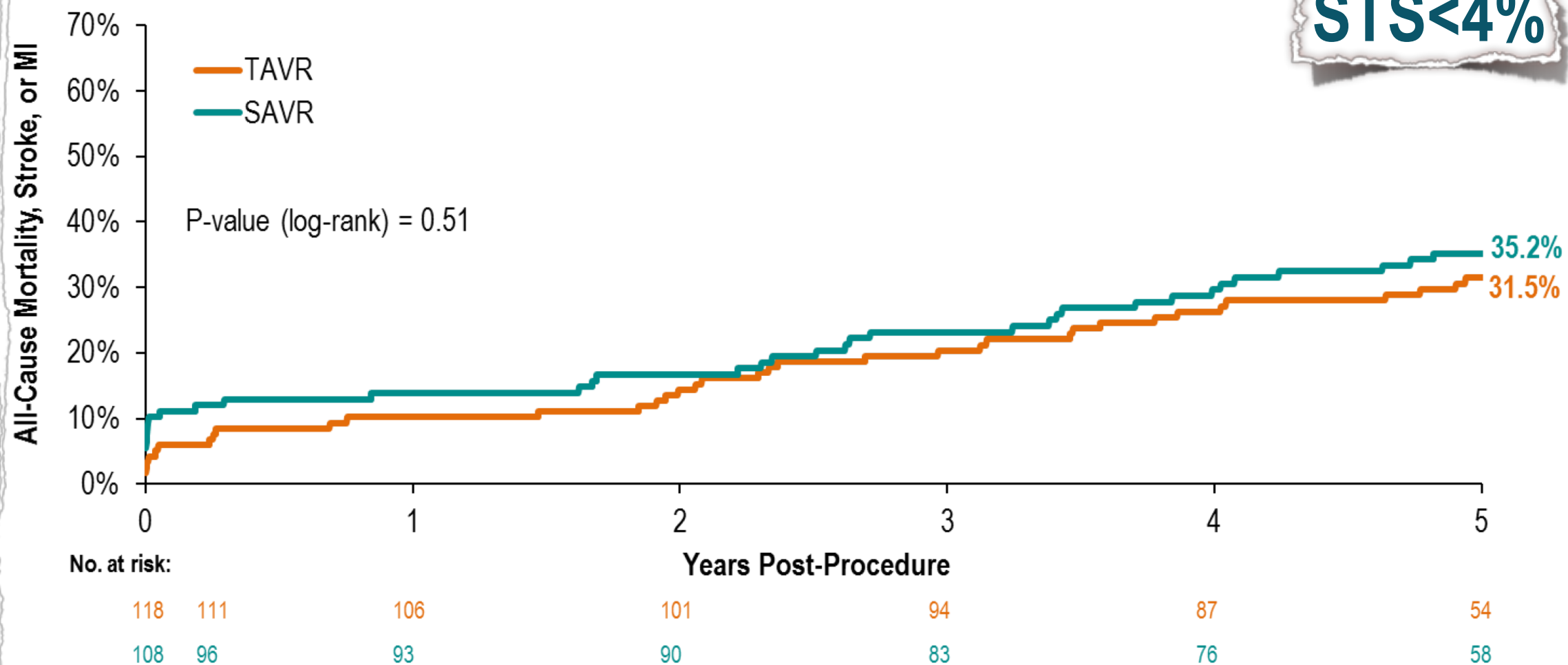
Baseline Characteristics

Characteristic, % or mean \pm SD	TAVR n=145	SAVR n=135	p-value
Age (yrs)	79.2 \pm 4.9	79.0 \pm 4.7	0.71
Male	53.8	52.6	0.84
STS score	2.9 \pm 1.6	3.1 \pm 1.7	0.30
STS score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 \pm 4.0	8.9 \pm 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61



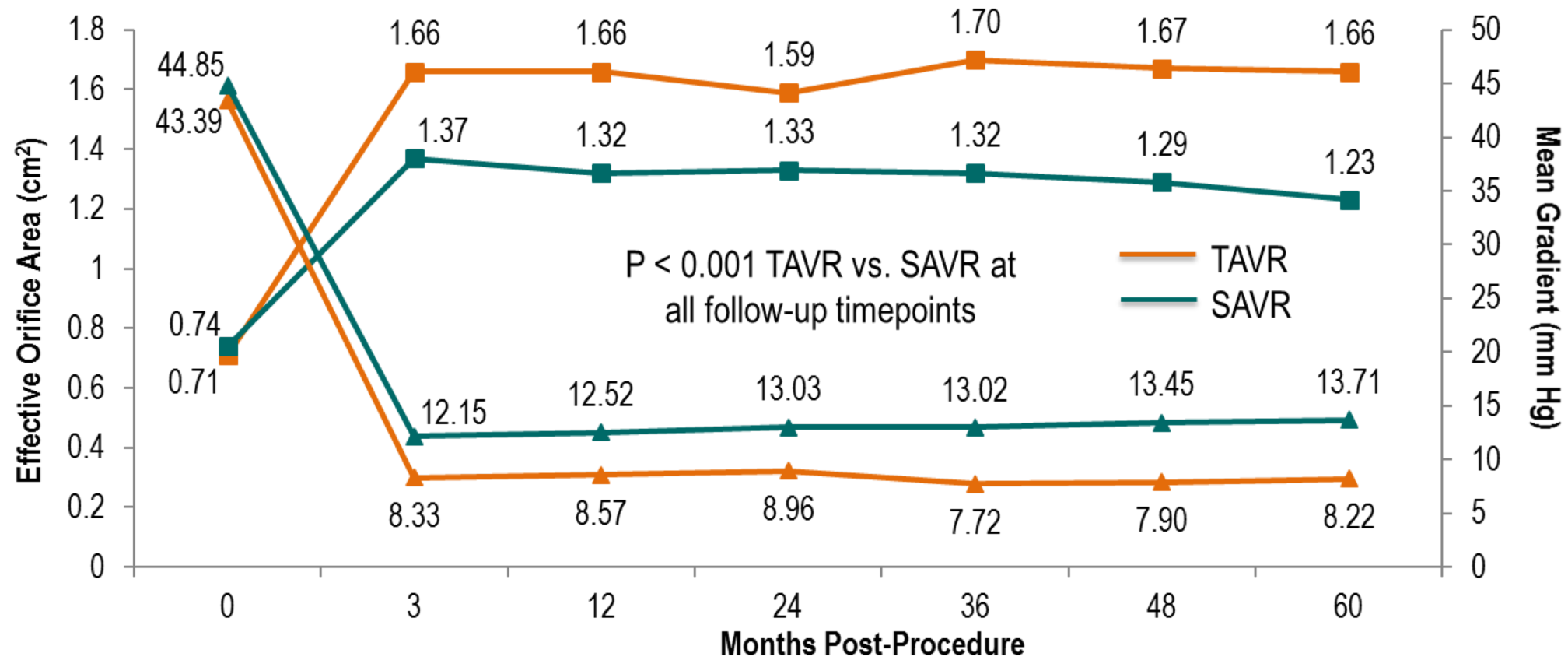
All-Cause Mortality, Stroke, or MI:

STS < 4%



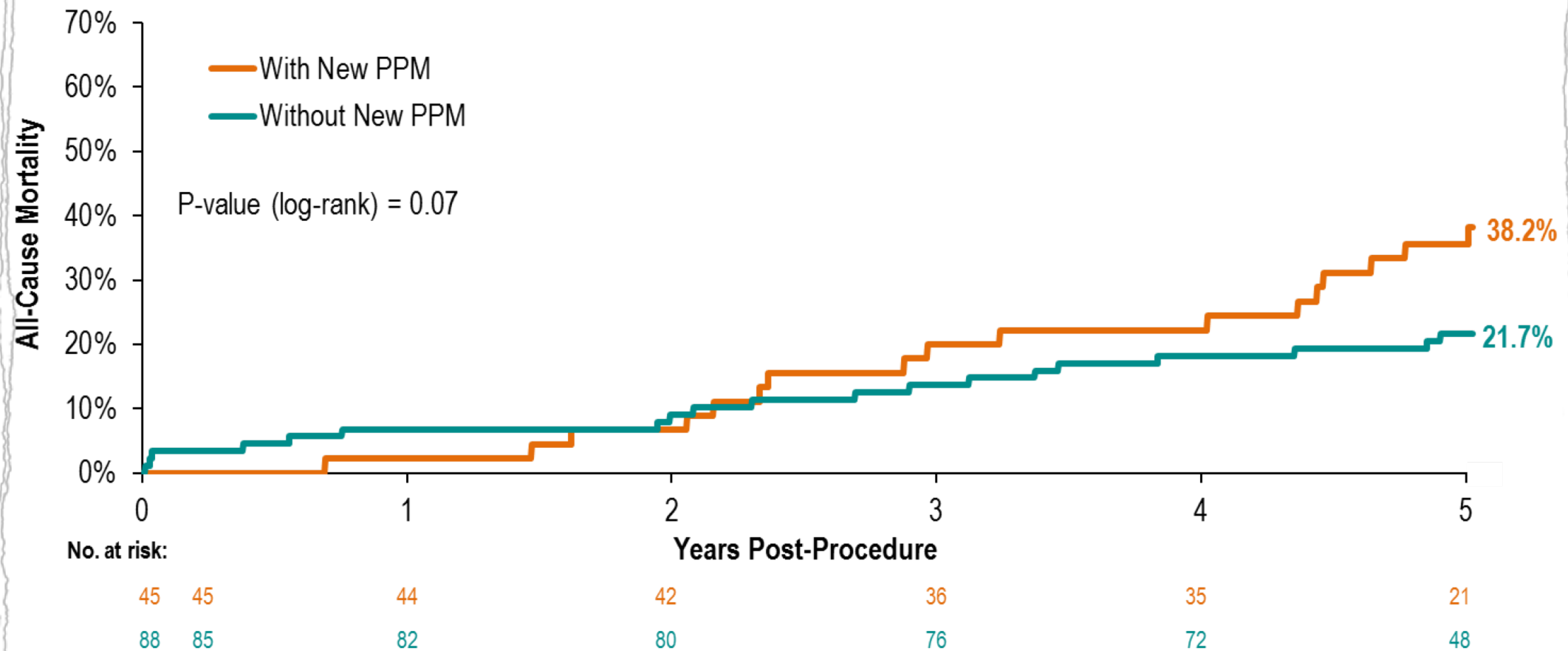
ACC.18

Aortic Valve Performance



ACC.18

Association of New Pacemaker with Mortality for TAVR



ACC.18

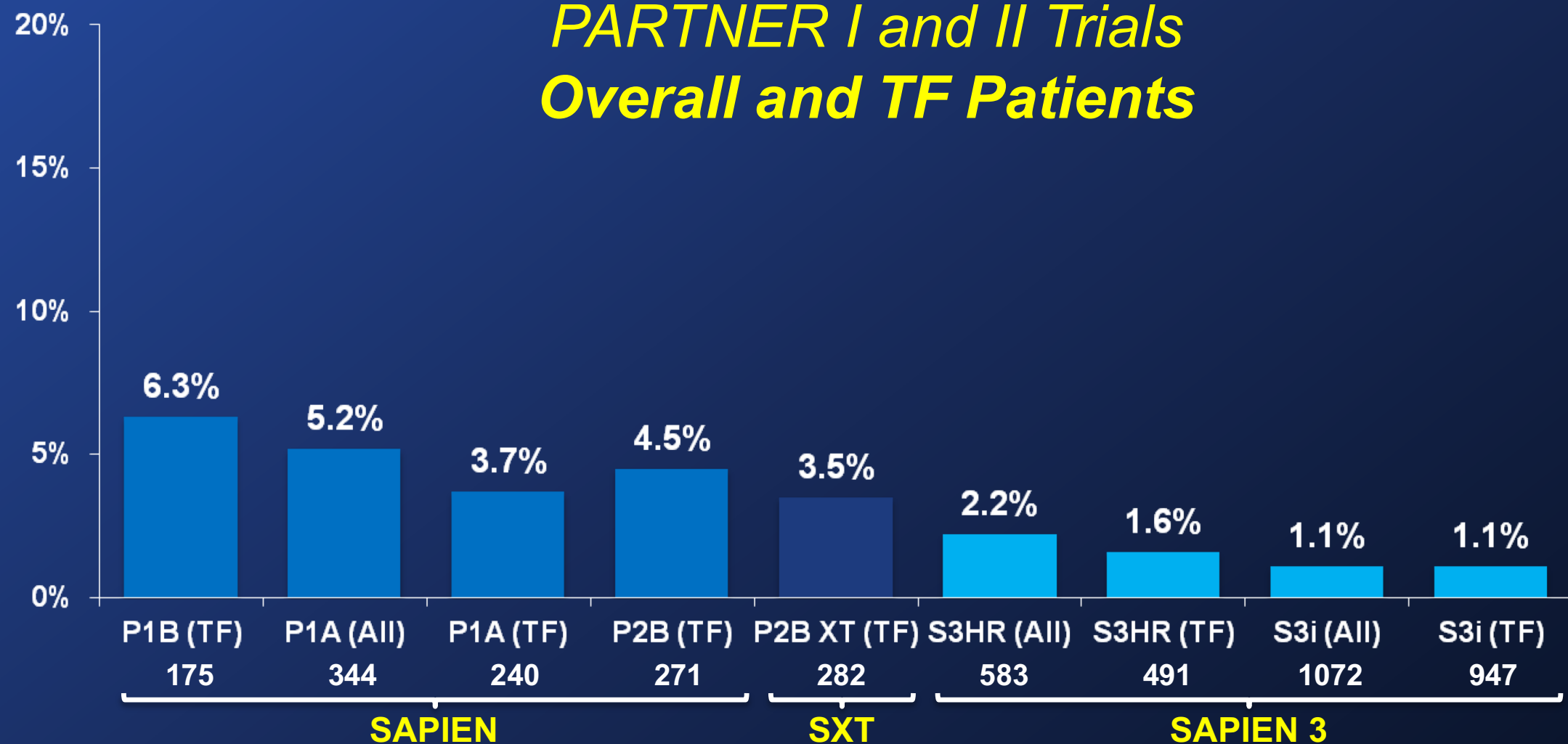
All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)



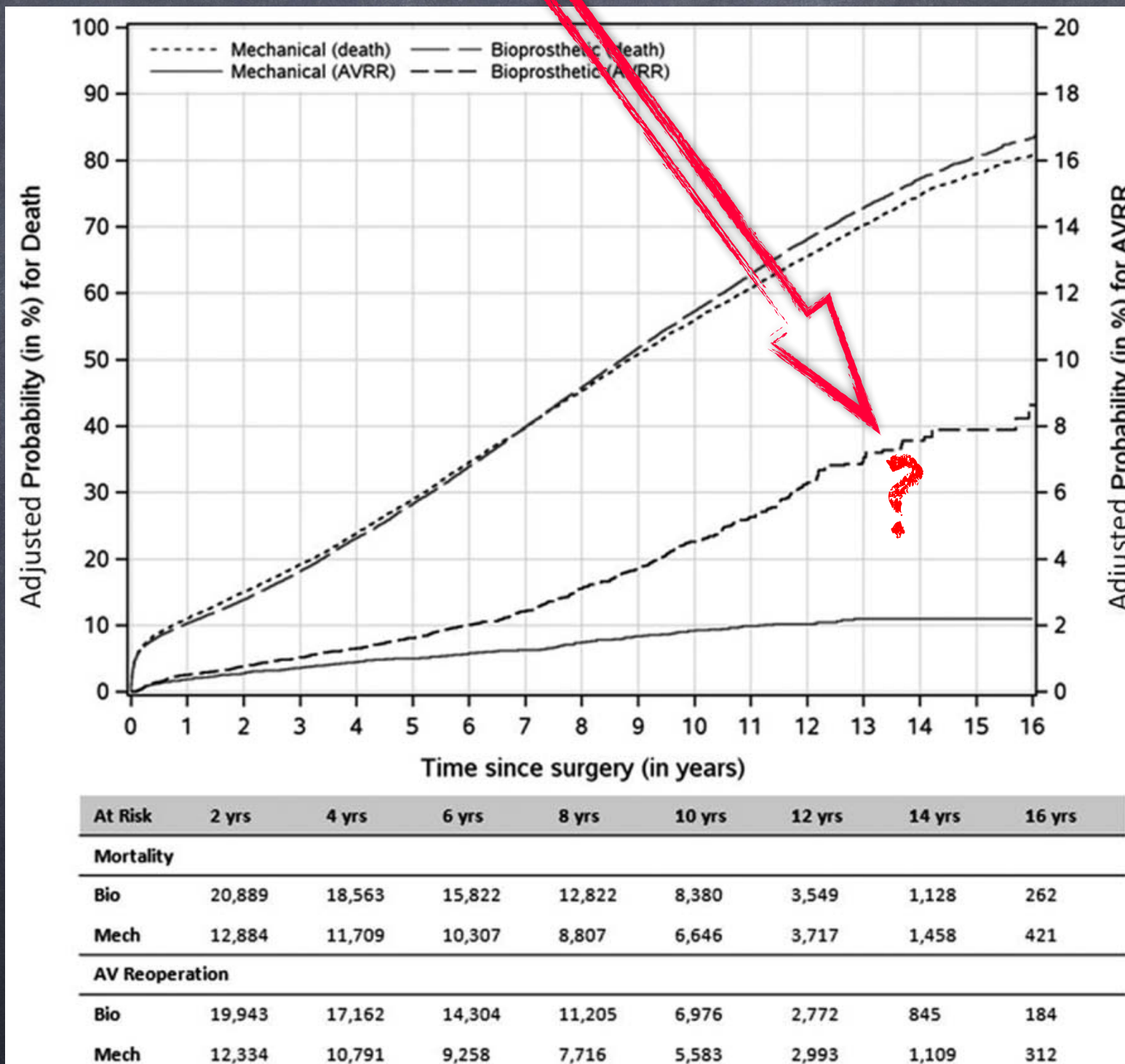
THE
PARTNER II
TRIAL

*PARTNER I and II Trials
Overall and TF Patients*



Indications des valves mécaniques ?

Résultats si on remplace le redox par
TAVI « V in V » ?

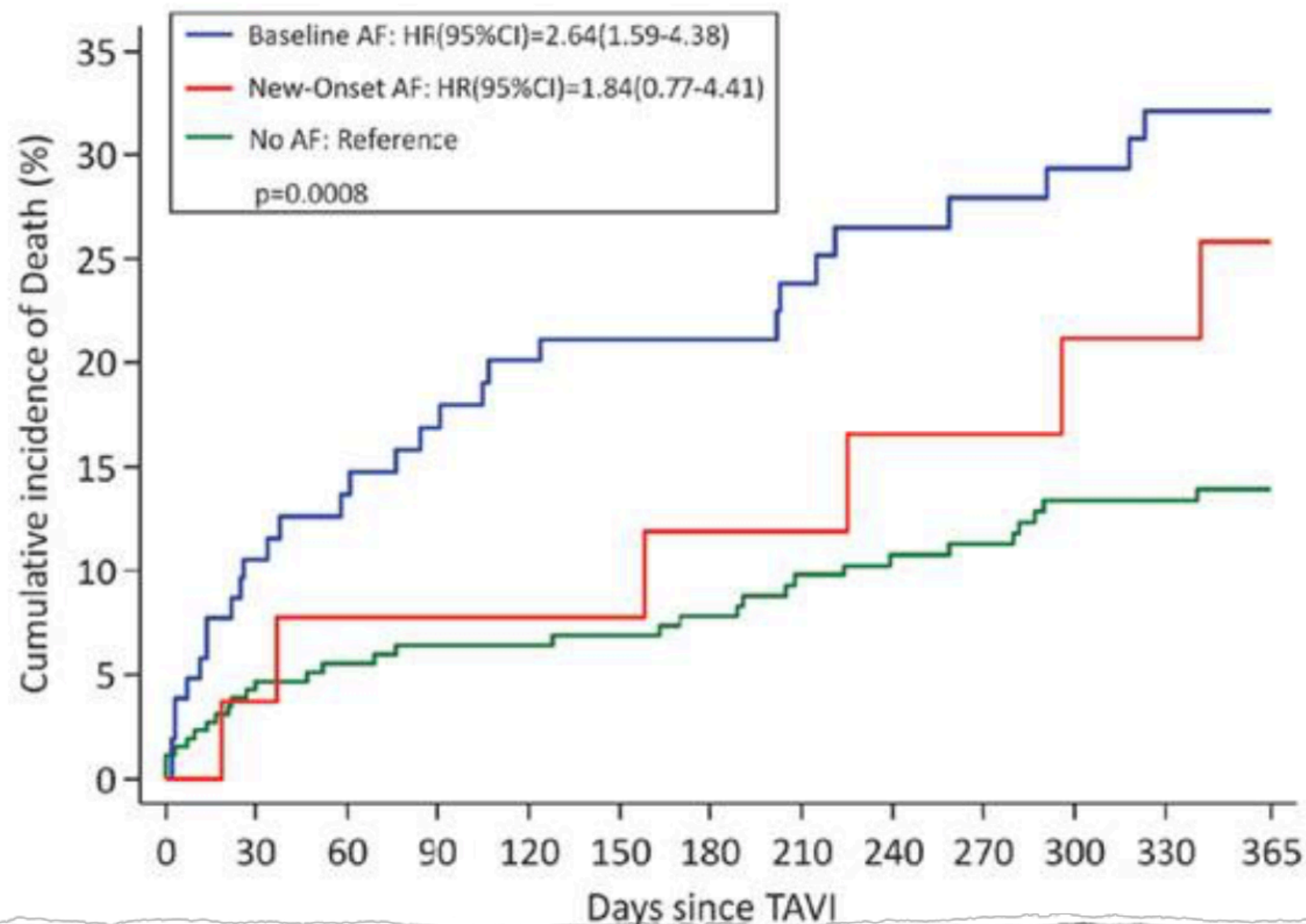


Traitement antithrombotique

AORTIC STENOSIS AND ATRIAL FIBRILLATION IN PATIENTS UNDERGOING TAVI

STORTECKY S ET AL. CIRC CARDIOVASC INTERV 2013; 6:77-84

BERN TAVI REGISTRY N=389; AGE 83 ± 6 YEARS; 58% FEMALE GEND



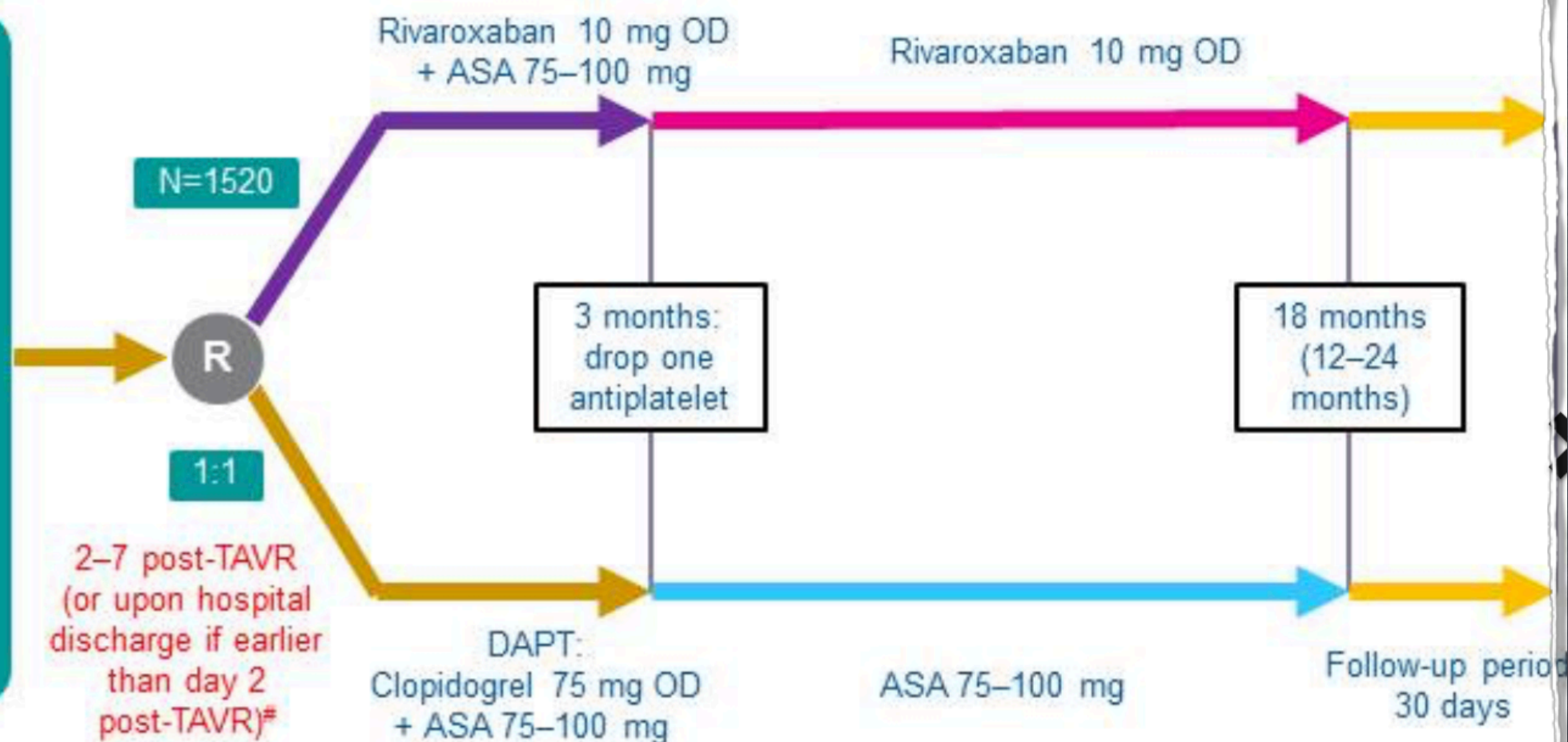
Prospective, randomized, open-label with blinded endpoint evaluation (PROBE), parallel-group, active-controlled, multicenter international study

Study population:

Patients with successful TAVR*

Key excl. criteria:

Ongoing indication for DAPT or anticoagulation, previous ischemic stroke, active peptic ulcer or upper GI bleeding, previous ICH, or severe renal insufficiency



*~110 sites in Europe & North America (15 countries)

Majority of patients will be on DAPT after TAVR
Gastric protection recommended throughout study



PI: Dangas G, Windecker S

Hartcentrum Hasselt

JESSA
ZIEKENHUIS

Traitement antithrombotique après TAVI

Pas d'indication d'anticoagulation au long court



Double antiagrégation plaquettaire (AAP)
Aspirine 75 à 100mg/j + Clopidogrel 75mg/j
3 à 6 mois

et/ou

Monothérapie AAP (*aspirine ou clopidogrel*) à vie
si risque hémorragique important
HAS-BLED ≥ 3

*Si suspicion de thrombose de valve :
↑ du grad moyen ≥ 10 mmHg ou nouveau grad moyen ≥ 20mmHg
Introduire AVK*

Indication d'anticoagulation (AC) au long court
*par AVK pendant les 3 premiers mois post implantation
puis NOAC ou AVK*



Coronaropathie associée avec
SCA ou pose de stent < 6 mois



OUI



Bithérapie:
AC+1 AAP
1 à 6 mois
Si NOAC : faible dose



Puis AC monothérapie
AVK ou NOAC

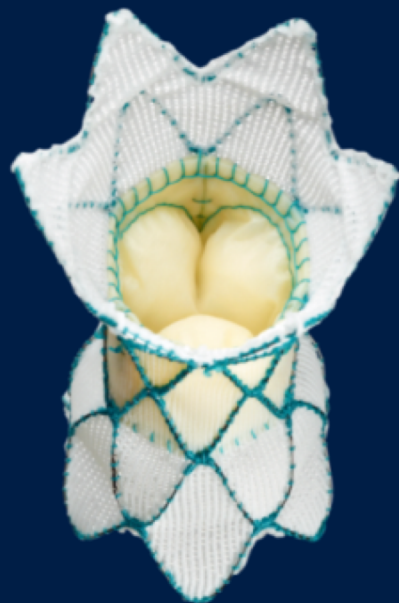
A venir...

PIONEERING TRANSCATHETER VALVE THERAPY

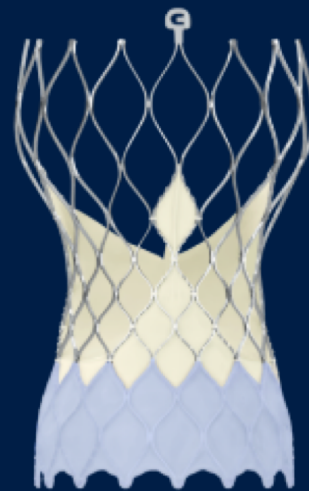
OUR FUTURE

Continued innovation with valves for specific disease states driven by patient anatomic and clinical needs

Pulmonary



Aortic



Mitral



EVOLUT PRO

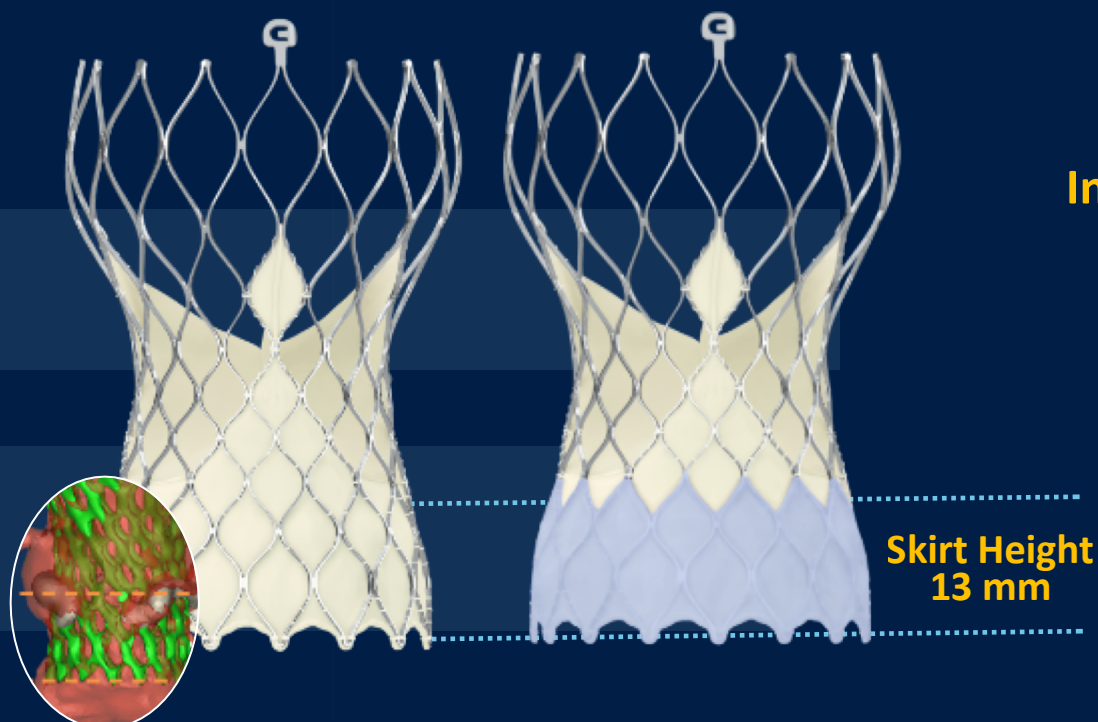
ADVANCED SEALING WITH PROVEN PLATFORM PERFORMANCE

Evolut™ R

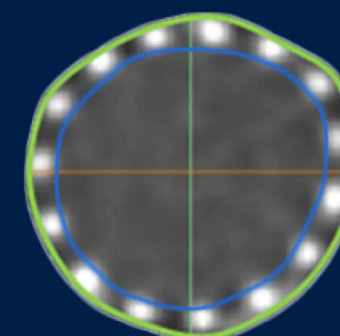
Evolut™ PRO

Supra-Annular Valve
Porcine Pericardial Tissue
Cell Size Enables Coronary Access

Self-Expanding Frame
Pericardial Skirt



**Pericardial Wrap
Increases Surface Contact
with Native Anatomy**

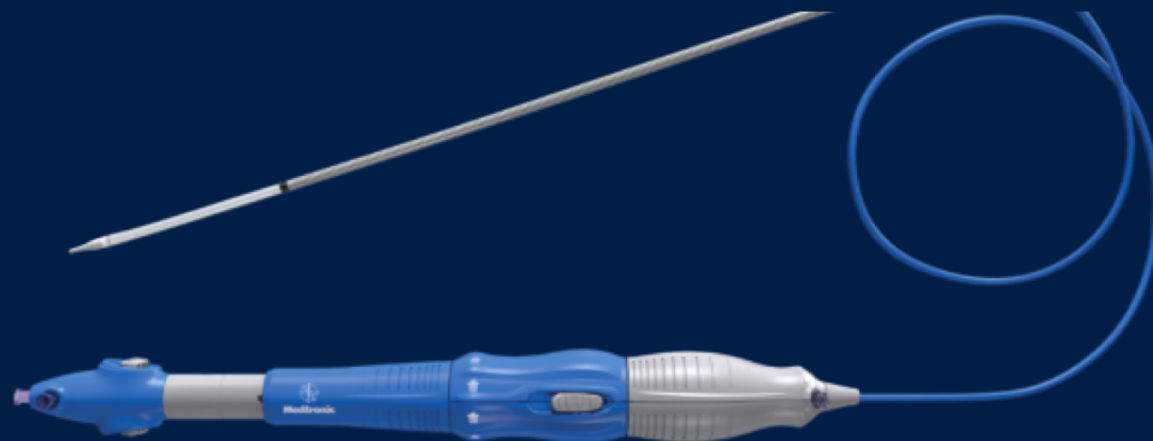


**Added Tissue Volume
between the TAV & native
anatomy to reduce gaps**

Sealing can occur at multiple levels;
including above and below calcification
with a self-expanding frame

EVOLUT PRO PROVEN PLATFORM PERFORMANCE

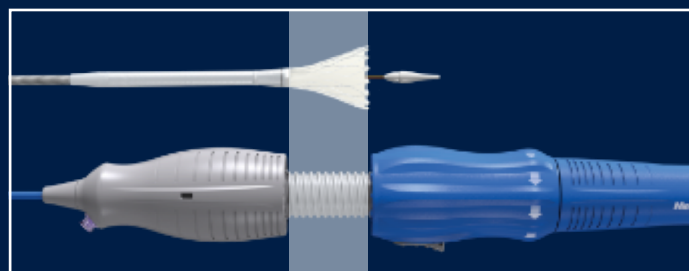
CONTROL DURING DEPLOYMENT WITH ABILITY TO RECAPTURE AND REPOSITION THE VALVE



Lowest Delivery Profile

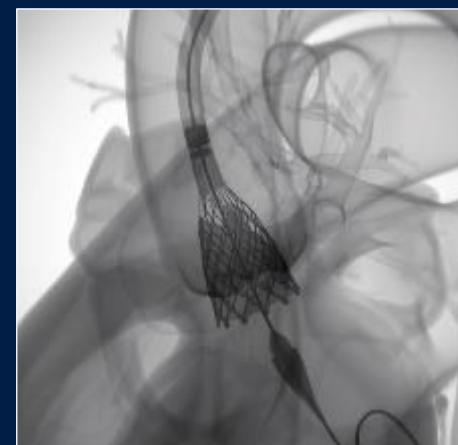
16Fr-equivalent

Vessel Access ≥ 5.5 mm (EvPRO 23, 26, 29)



Accurate Positioning

1:1 response provides immediate feedback between deployment knob and movement of the capsule



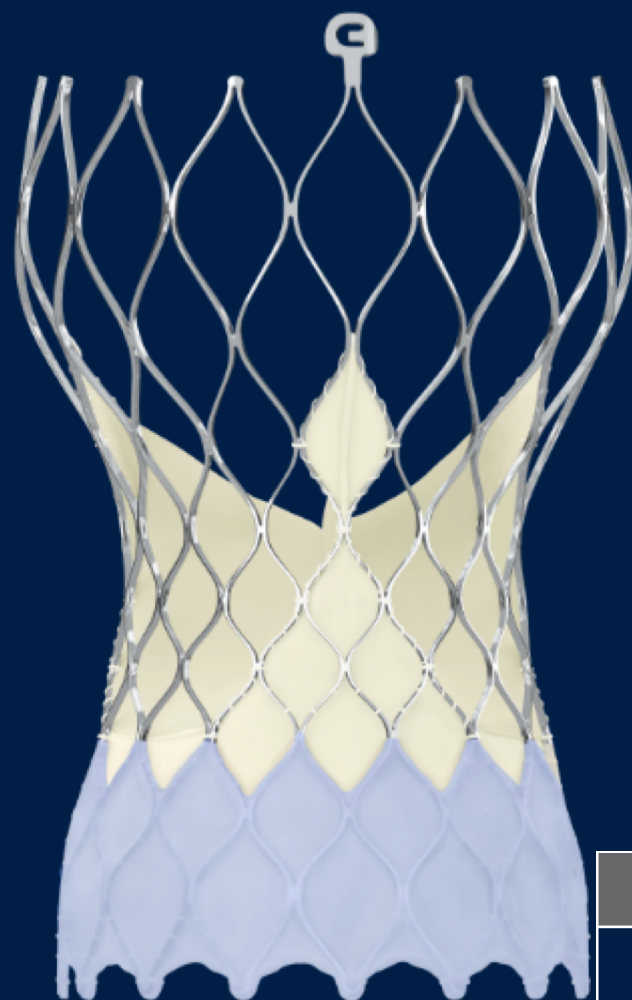
Recapture and Reposition

Provides option to recapture and reposition for accurate placement

EVOLUT PRO

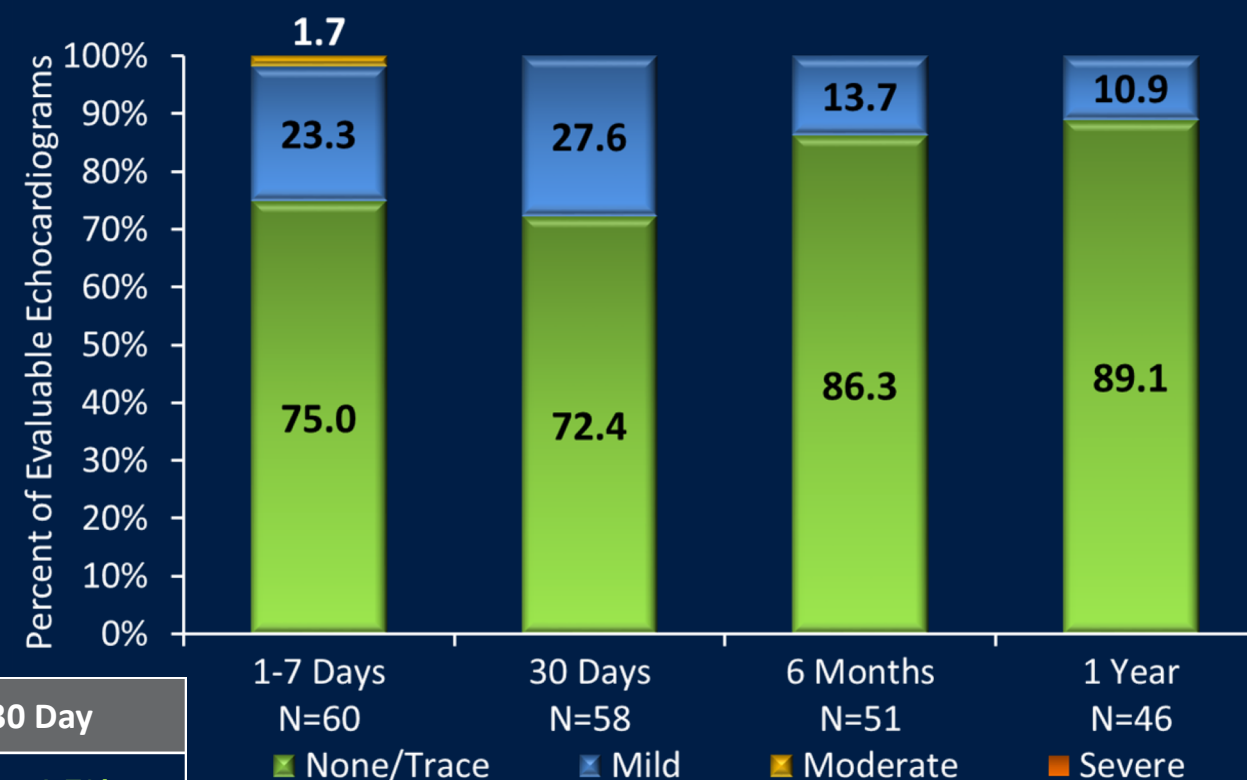
ADVANCED SEALING WITH PROVEN PLATFORM PERFORMANCE

Evolut PRO



Evolut PRO 30 Day	
Mortality	1.7%
Stroke	1.7%
Pacemaker	10.0%

Evolut PRO Paravalvular Regurgitation 1 Year – 89% None/Trace PVL



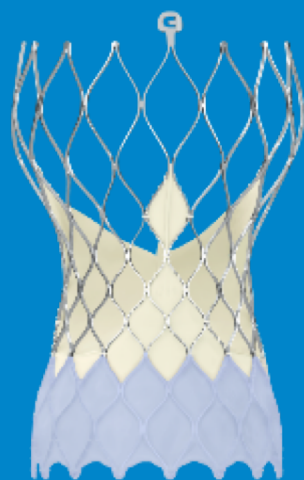
Williams et al., ACC, 2018

TAVI PIPELINE

CADENCE OF CONTINUOUS, MEANINGFUL INNOVATION

Evolut™ PRO

- Advanced Sealing



**FDA & CE-Mark
Approved**

EnVeo™ PRO

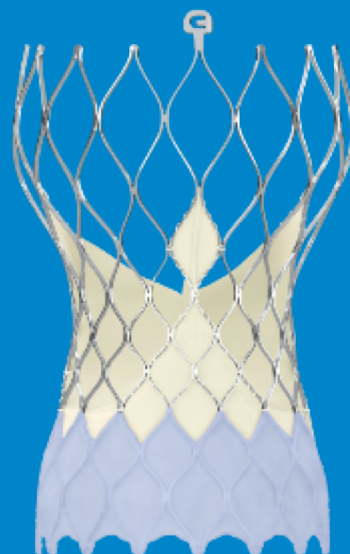
- Seamless Tracking



**FDA Approved &
CE-Mark pending**

34 PRO

- PRO Performance:
Large Valve



IN DEVELOPMENT

Next Gen

Evolut™

- Superior Ease of Use
- Positioning Accuracy
- Low Profile

IN DEVELOPMENT

Horizon

- Transformative
Aortic Platform



**IN
DEVELOPMENT**

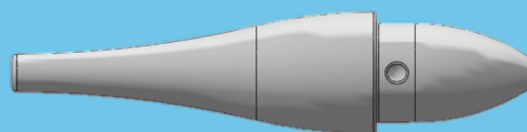
Investigational devices and not approved for sale

ENVEO PRO

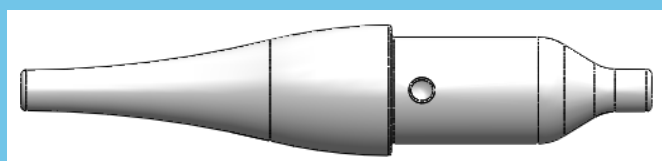
IMPROVE THE EVOLUT PLATFORM EXPERIENCE

SEAMLESS TRACKING

Especially in Tortuous Anatomies



EnVeo R



EnVeo PRO

SIMPLE LOADING

“Gator” System Prevents Misloads



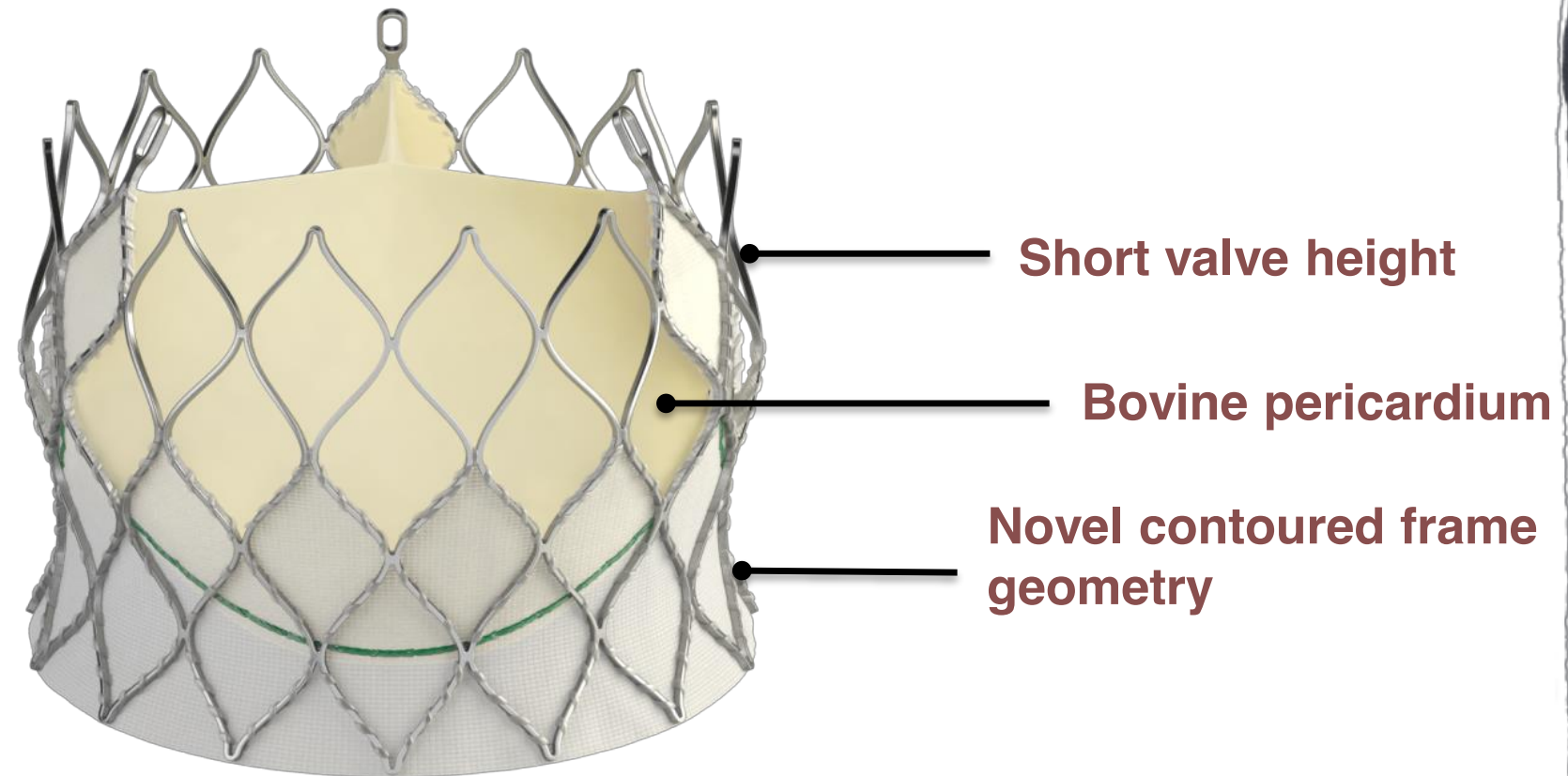
ENHANCED PRODUCT IDENTIFICATION

Color Coded Packaging and Labeling



Investigational device and not approved for sale

Edwards CENTERA Transcatheter Heart Valve System



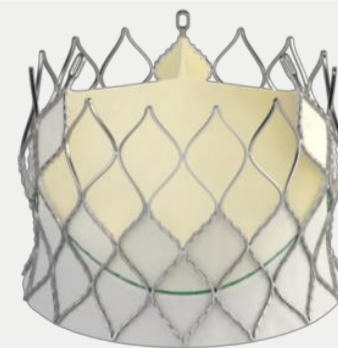
23 mm

18 mm



26 mm

21 mm



29 mm

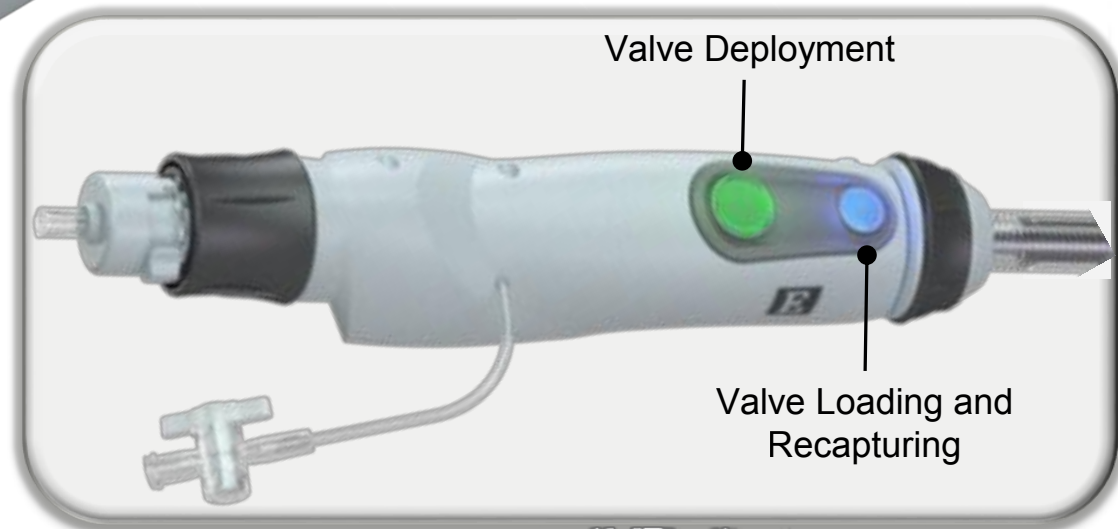
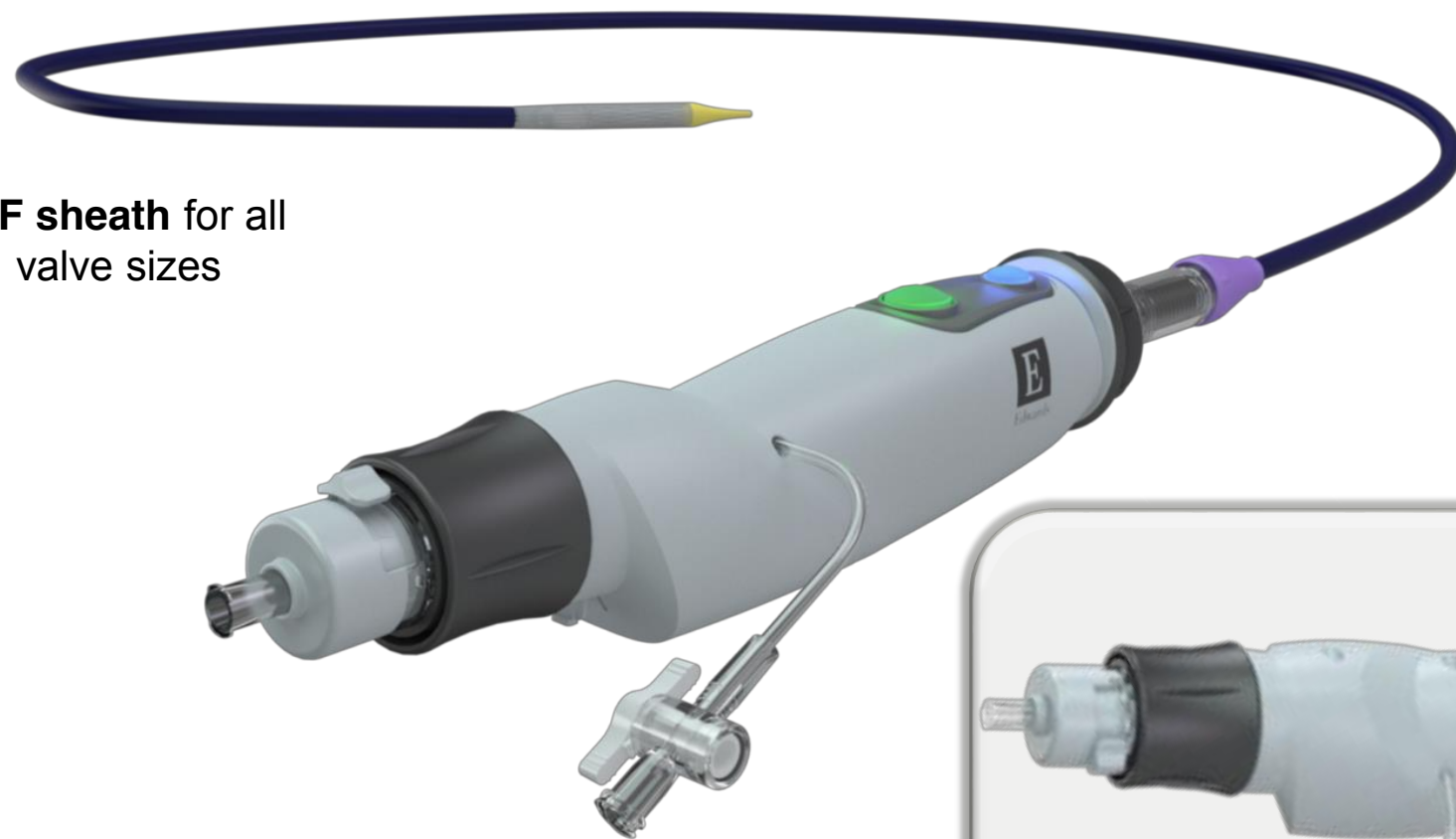
23 mm

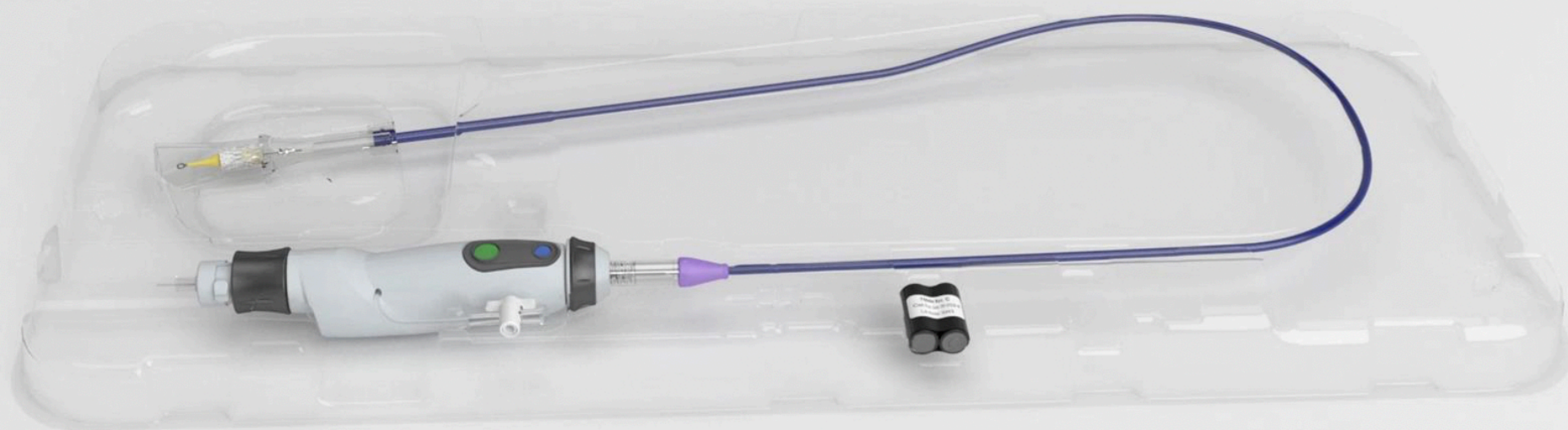
Fully pre-attached valve for rapid
device preparation

14F sheath for all
valve sizes

**Fully motorized delivery
system** for stable valve
deployment

**Repositionable and
recapturable** if needed





Parameters	As Treated (N=203) %
Recapturing and Repositioning (yes)	3.5
With Ventricular Injury	0
With Aortic Injury	0
Valve Embolization	0.5
Post-Dilatation	33.0
Required Intra-aortic Balloon Pump	0.5
Required Cardio-pulmonary Bypass	2.0
Technical Success	97.5
Device Success*	96.4

Primary Endpoint

O:E = 0.16

10

% of Patients

1%

0

All-Cause Mortality

n=203



Safety Endpoints	As Treated (N=203) %
Mortality	1.0
Cardiovascular Mortality	1.0
Stroke	4.0
Disabling Stroke	2.5
Myocardial Infarction	1.5
Coronary Artery Obstruction Requiring Intervention	0.5
Major Vascular Complications	6.4
Life-Threatening or Disabling Bleeding	4.9
Acute Kidney Injury (Stage 2 or 3)	1.0
New Onset Atrial Fibrillation	8.0
New Permanent Pacemaker	4.9
THV-related Dysfunction Requiring a Repeat Procedure	0

Future Sapiens Edwards...

12F

Système de fermeture prémontré dans
l'introducteur

ACURATE NEO™ TRANSCATHETER AORTIC VALVE

THE ULTIMATE SELF-SEATING, SELF SEALING TAVI VALVE

STABILIZATION ARCHES

Axial self-alignment of the valve within the native annulus

UPPER CROWN

Minimal Supra-annular anchoring
Caps native leaflets
Coronary clearance

WAIST

Lodges calcified leaflets

LOWER CROWN

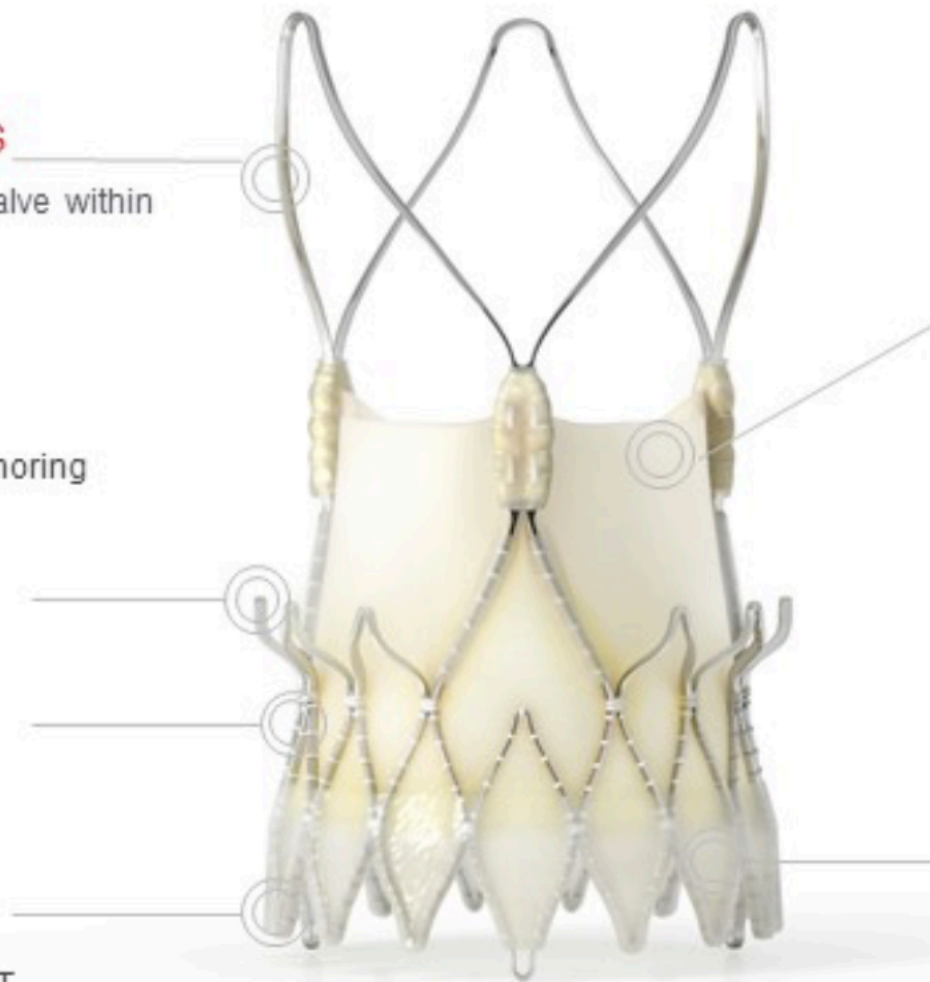
Minimal protrusion into LVOT
Low risk of conduction system interference

SUPRA-ANNULAR VALVE

Low gradient
Porcine pericardium leaflets
BioFix™ anti-calcification process

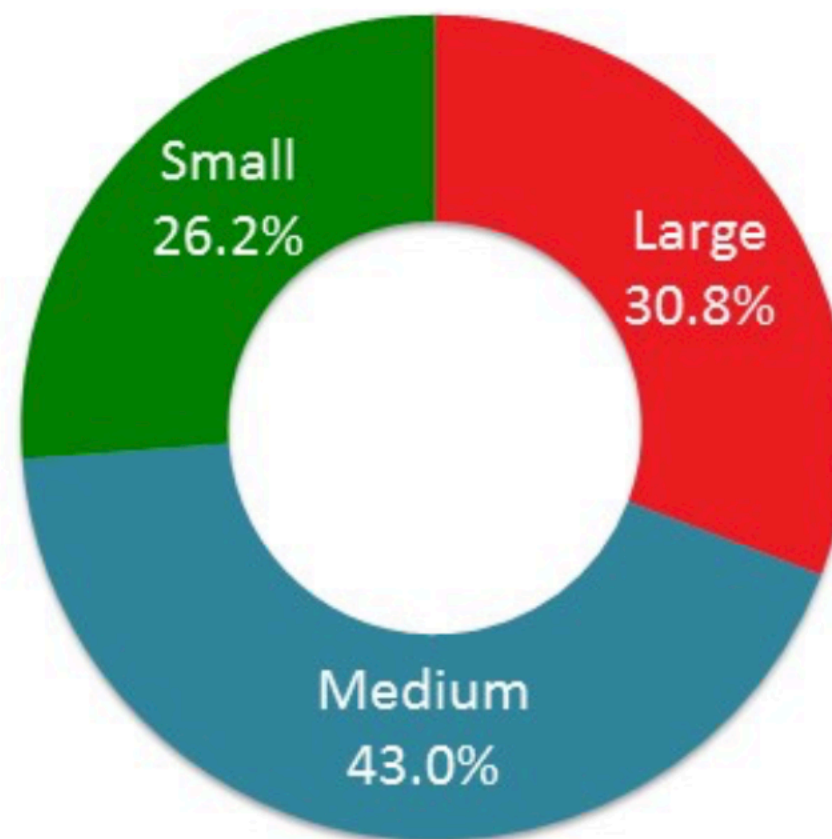
INNER & OUTER ANTI-PVL SKIRTS

Sealing against paravalvular leak



SAVI TF 1000

IMPLANTED VALVE SIZE



SAVI TF 1000

PERFORMANCE	7 DAYS
Population [n]	999*
Mean ∂P gradient [mmHg] (<i>n</i> =919)	8.3 \pm 4.0
Mean EOA [cm ²] (<i>n</i> =546)	1.81 \pm 0.5
PVL Grade	<i>n</i> =966
\leq Grade 1 (none to mild) [n]	926 (95.9%)
Grade 2 (moderate) [n]	39 (4.0%)
> Grade 2 [n]	1 (0.1%)

*One patient withdrew consent after treatment

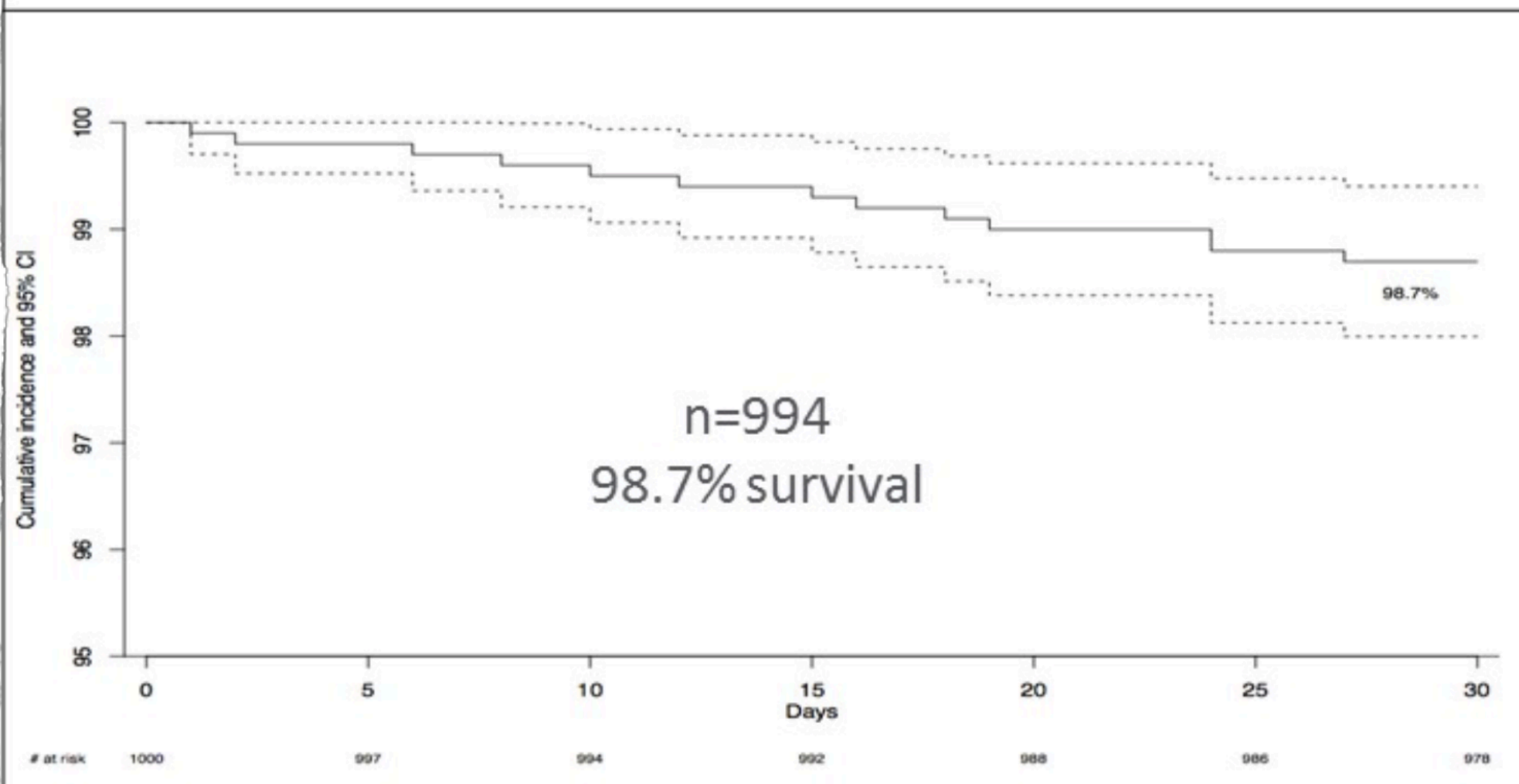
SAVI TF 1000

MACCE @ 30 DAYS	
Population [n]	994*
All-cause mortality [n]	13 (1.3%)
Stroke [n]	19 (1.9%)
MI [n]	3 (0.3%)
Re-intervention post-DC [n]	0 (0%)
Freedom from MACCE [n]	959 (96.5%)
New pacemaker implantation [n]	82 (8.2%)

* One patient withdrew consent after treatment, 3 patients lost to follow-up, and 2 did not return for 30D visit

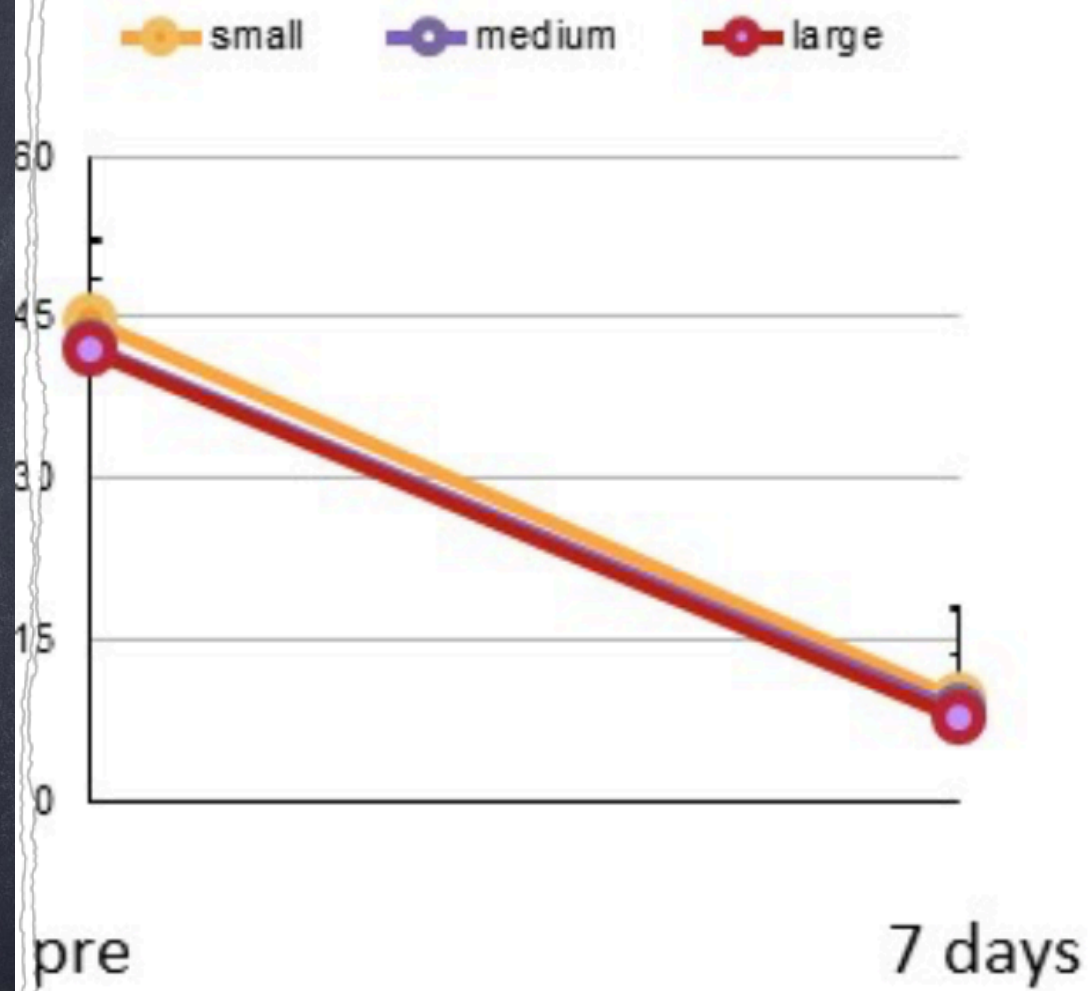
SAVITF 1000

KAPLAN-MEIER 30 DAY SURVIVAL

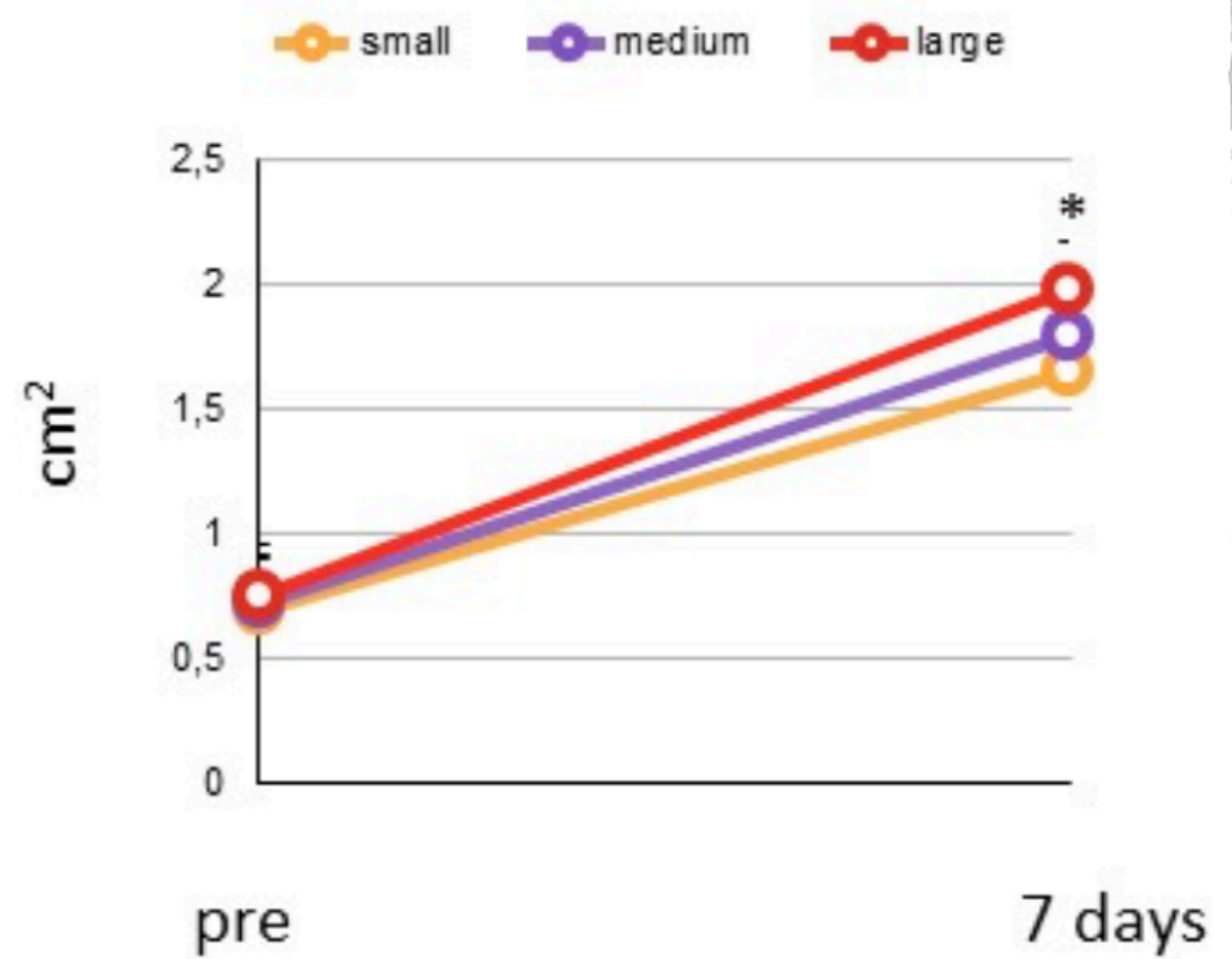


* One patient withdrew consent after treatment, 3 patients lost to follow-up, and 2 did not return for 30 days visit

mean transvalvular gradient



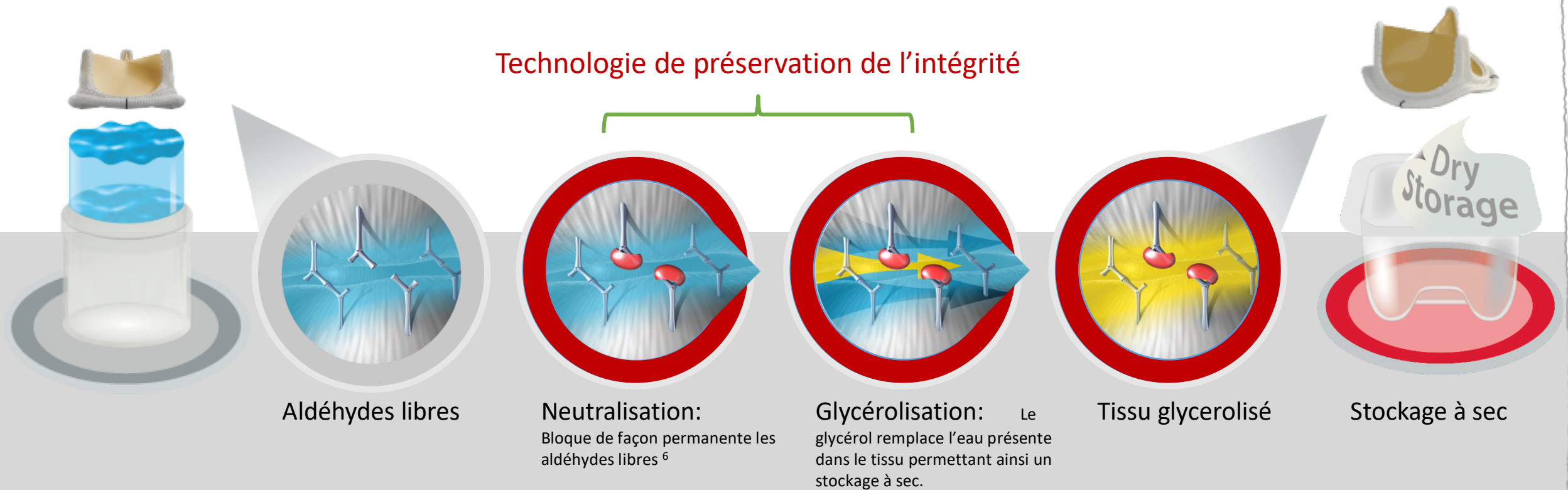
EOA



Durabilité

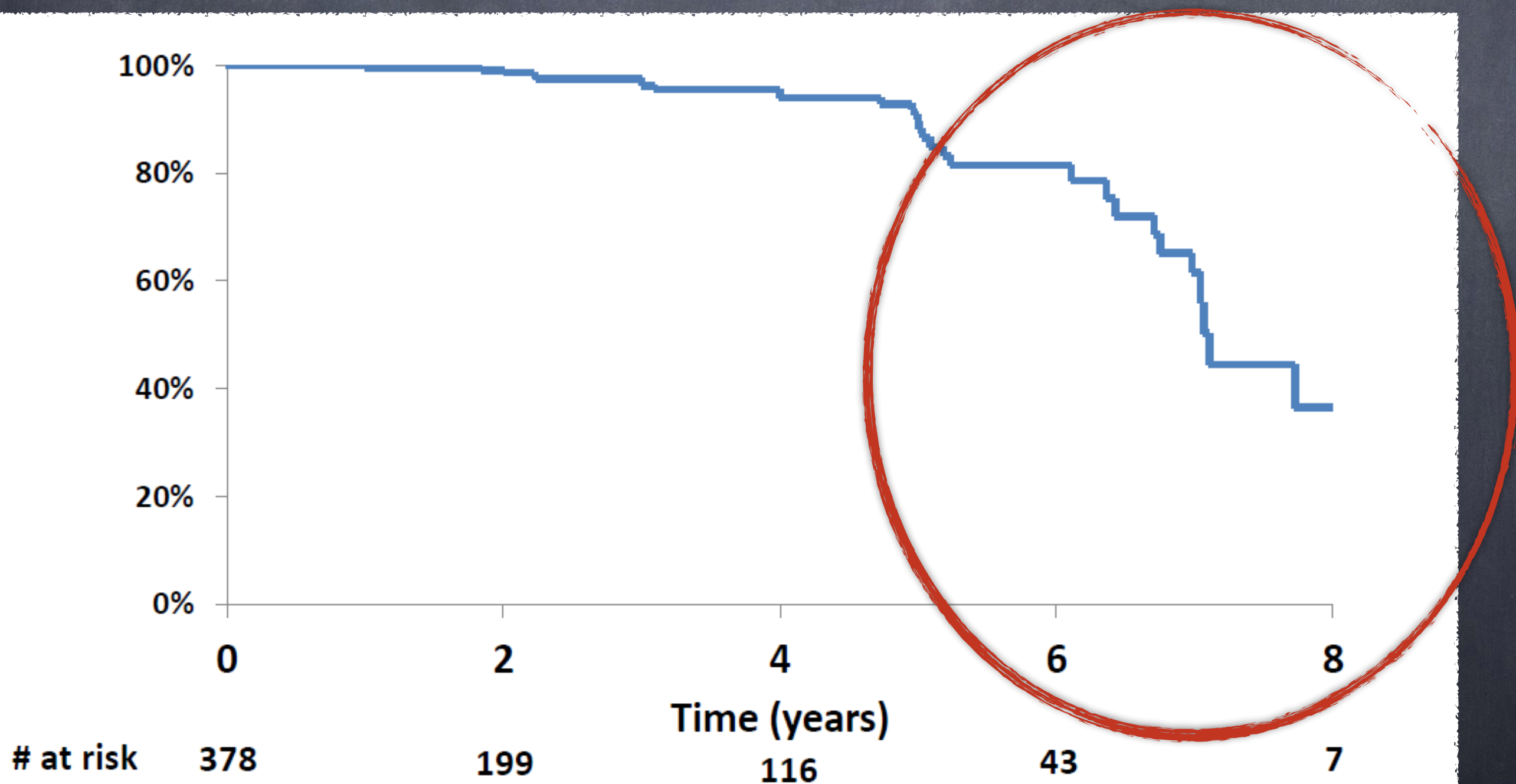
Le tissu RESILIA est du tissu péricardique bovin transformé par un procédé innovant préservant son intégrité

- La technologie de préservation de l'intégrité incorpore **deux nouvelles caractéristiques** qui élimine la quasi-totalité des aldéhydes libres tout en **protégeant et conservant le tissu**.



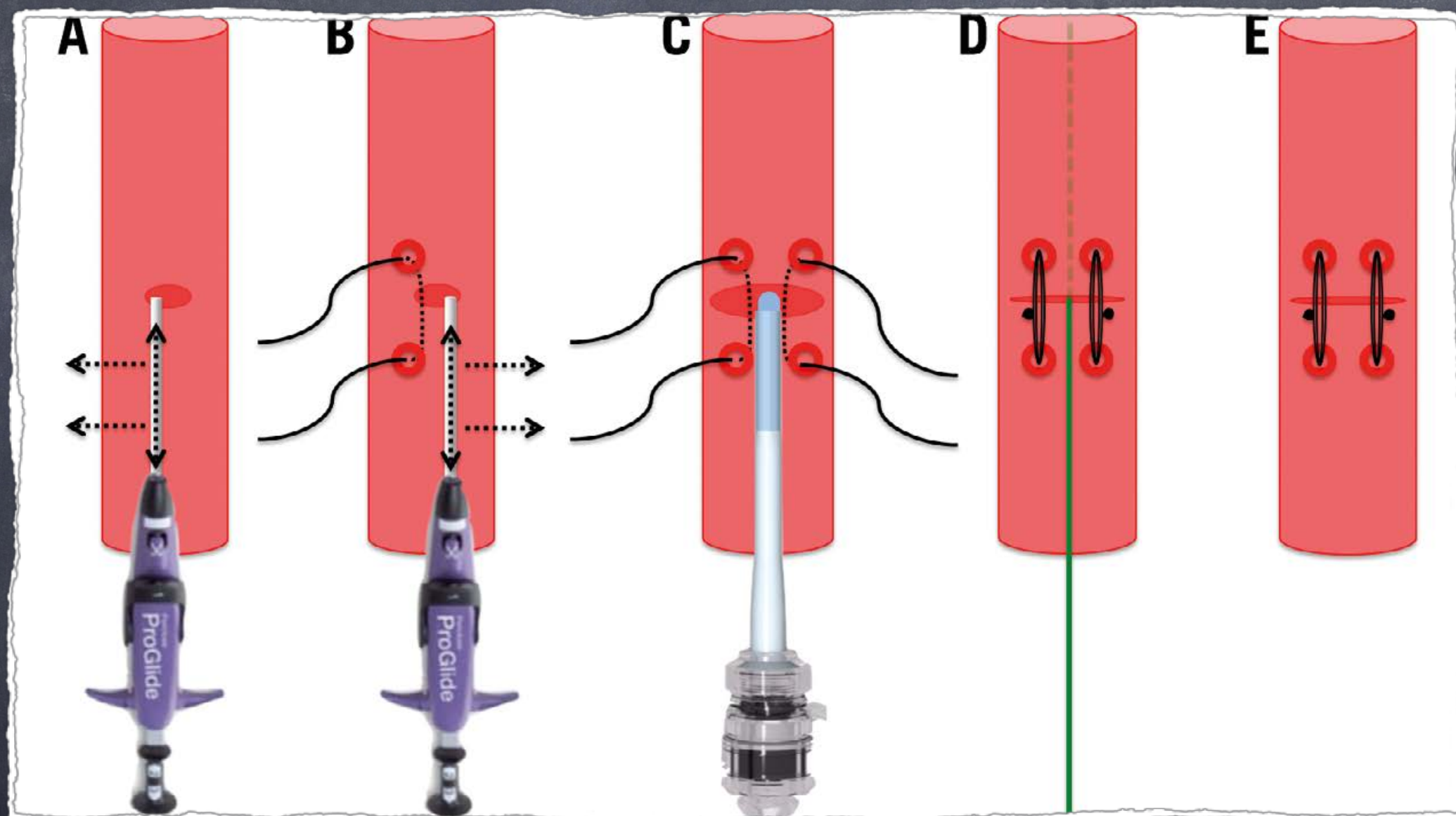
Freedom from TAVI degeneration

n=378



THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20 mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

Voies alternatives



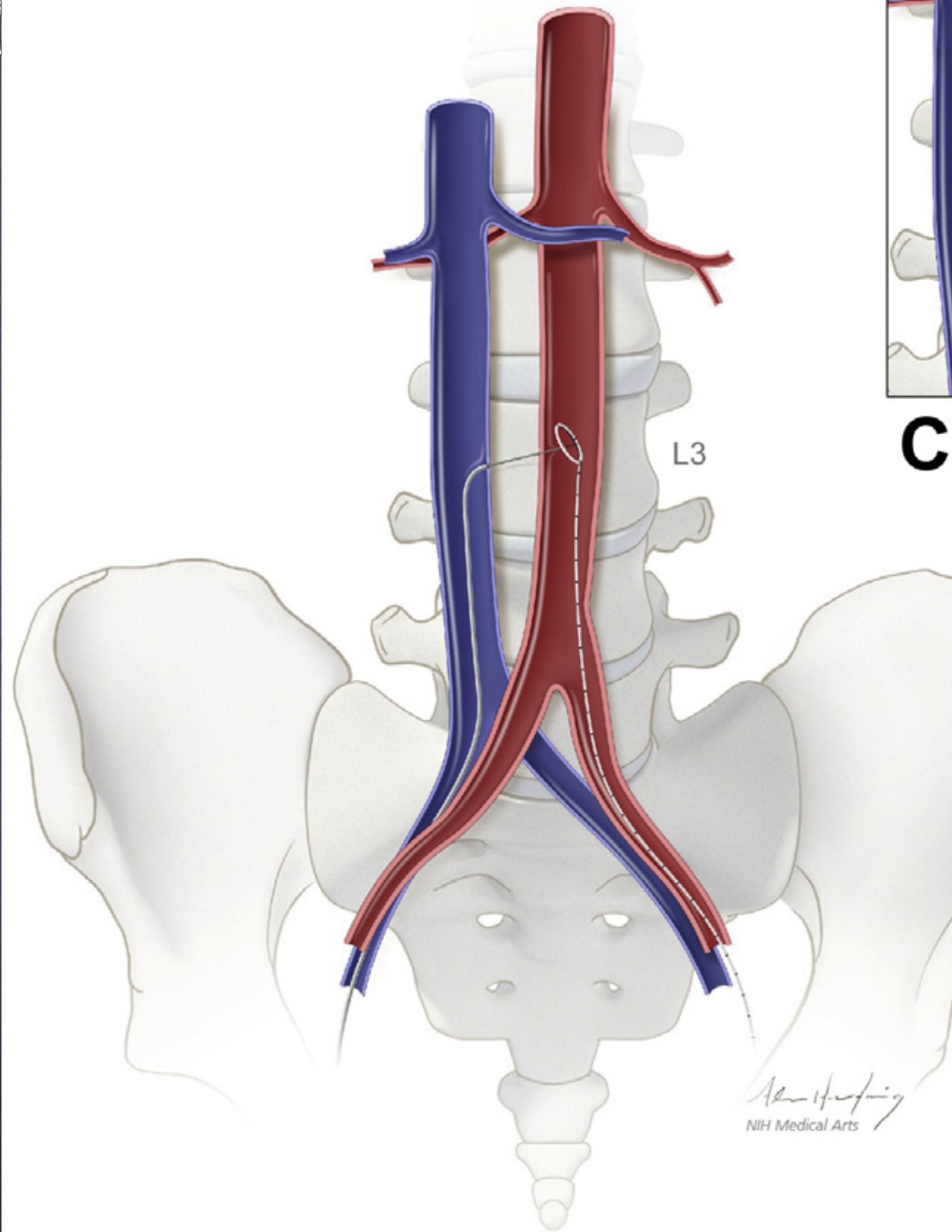
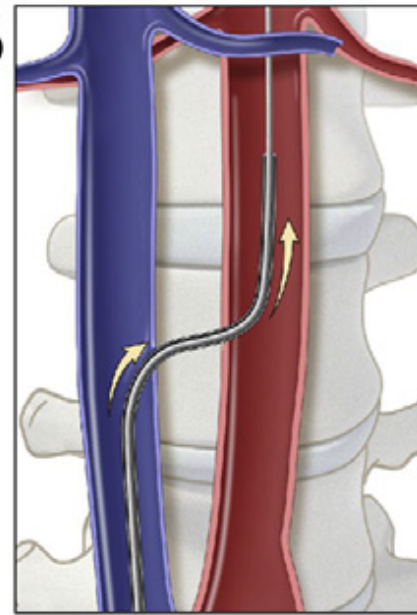
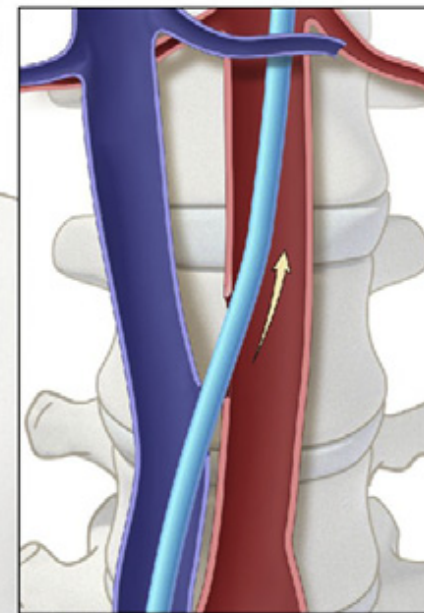
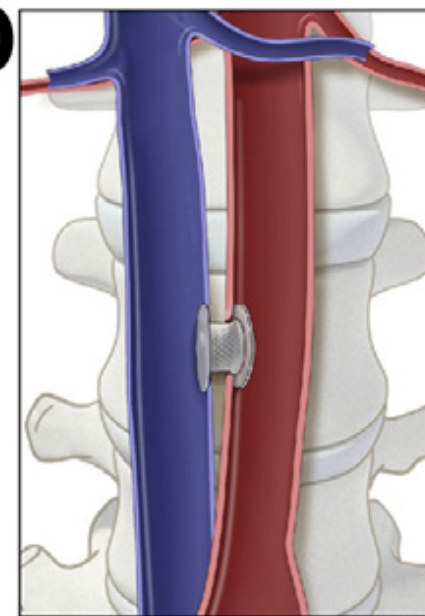
Caval-Aortic Access to Allow Transcatheter Aortic Valve Replacement in Otherwise Ineligible Patients

Initial Human Experience

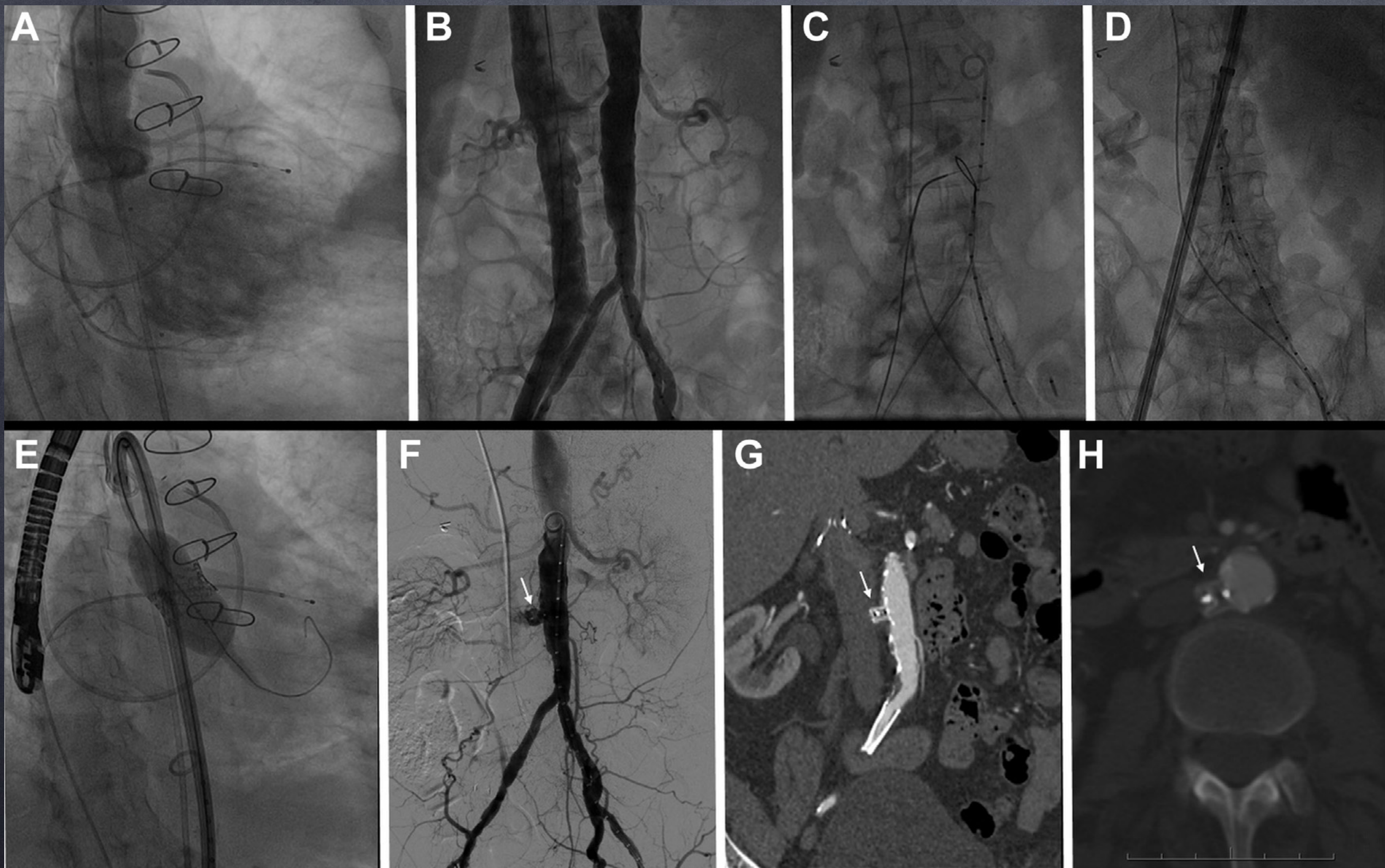
Adam B. Greenbaum, MD,* William W. O'Neill, MD,* Gaetano Paone, MD,†
Mayra E. Guerrero, MD,* Janet F. Wyman, DNP,* R. Lebron Cooper, MD,‡ Robert J. Lederman, MD§

Detroit, Michigan; and Bethesda, Maryland



A**B****C****D**

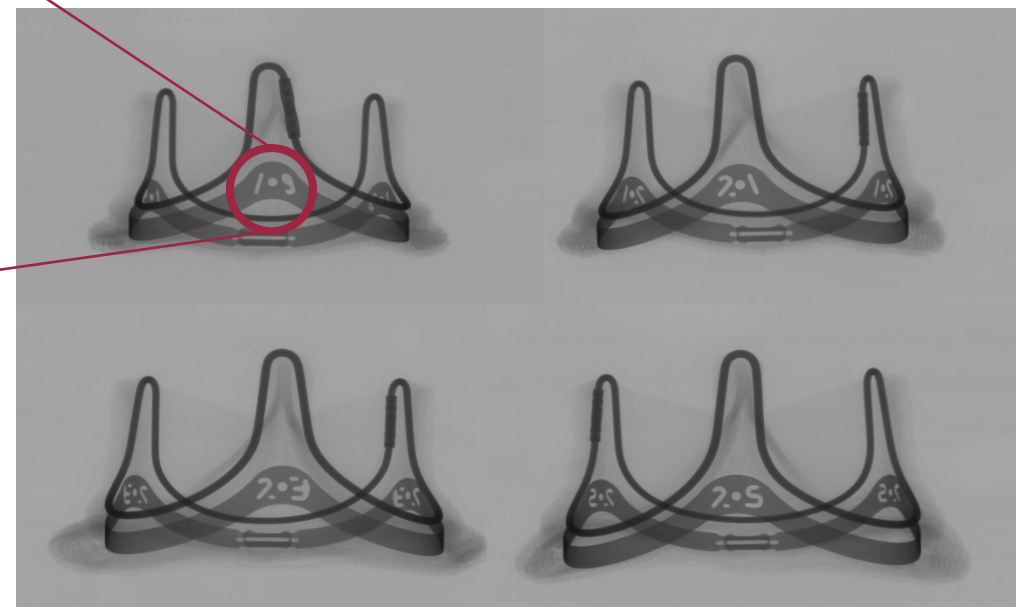
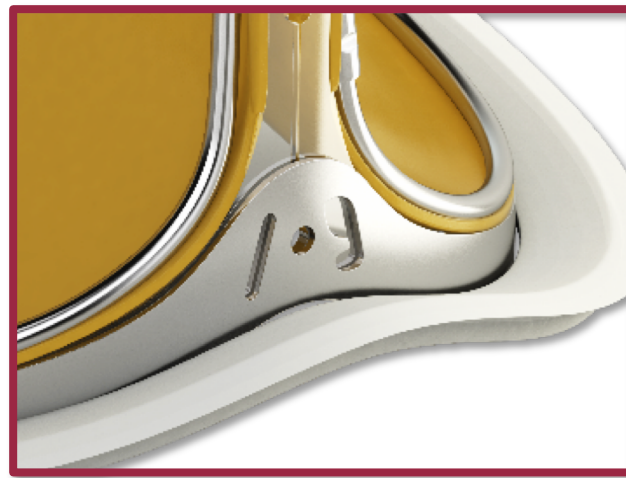
Alan H. Hurling
NIH Medical Arts



Valve in Valve

Technologie VFit* - intègre deux nouvelles caractéristiques conçues pour de futures potentielles procédures de “valve in valve”¹

Aucune donnée clinique existante ne permet d'établir la sécurité et l'efficacité du modèle 11500A dans le cadre des procédures "valve-in-valve"



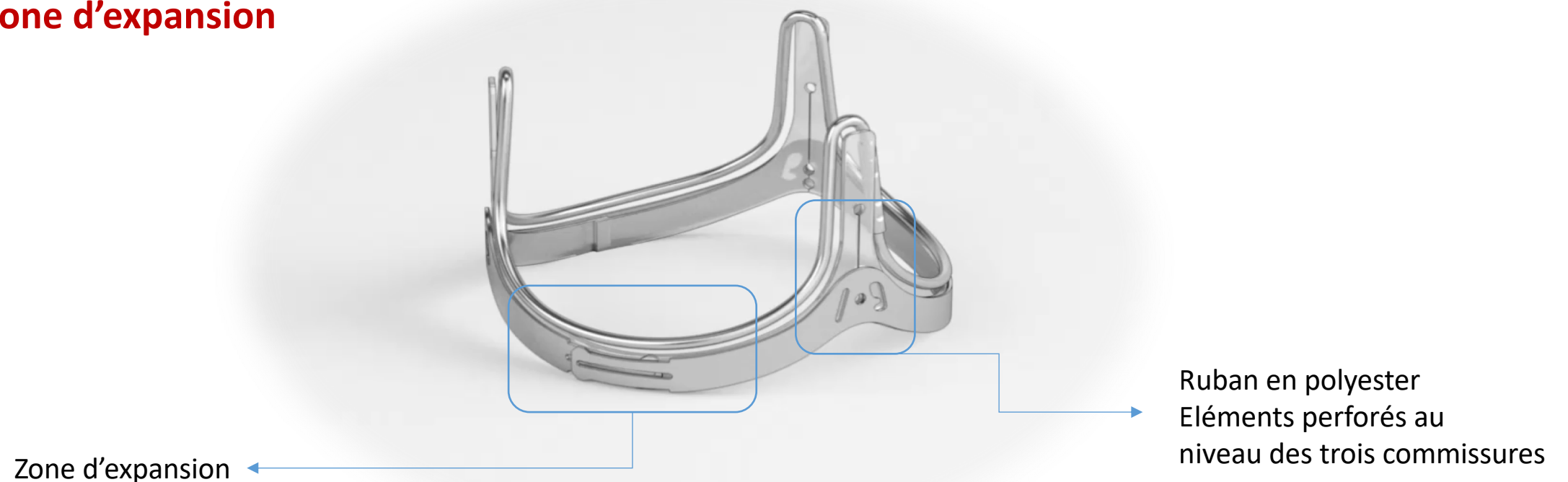
- **Marqueurs de tailles visibles par fluoroscopie**

disponible uniquement dans les tailles de 19 à 25 mm

* Se référer à la notice d'utilisation concernant les mises en garde relatives à la technologie VFit.

Technologie VFit* - intègre deux nouvelles caractéristiques conçues pour de futures potentielles procédures de "valve in valve"¹

- **Zone d'expansion**



*Se référer à la notice d'utilisation concernant les mises en garde relatives à la technologie VFit. Aucune donnée clinique existante ne permet d'établir la sécurité et l'efficacité du modèle 11500A dans le cadre des procédures "valve-in-valve". La technologie VFit est disponible dans les tailles de 19 à 25mm.

Mitrale

MEDTRONIC INTREPID™ TMVR

DUAL STENT DESIGN



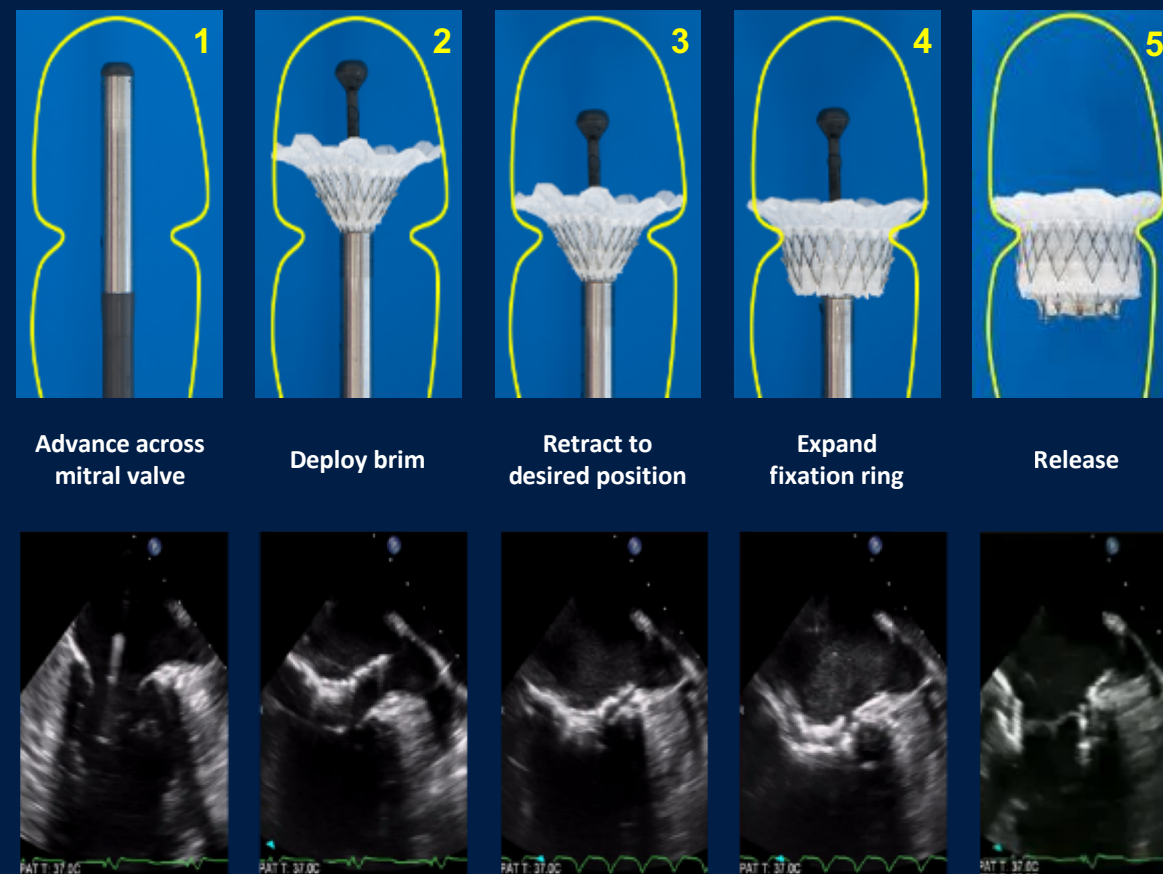
Conformable Outer Stent engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy

CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE.

MEDTRONIC INTREPID TMVR

CONTROLLED DEPLOYMENT

- Hydraulic mechanism provides for controlled deployment
- No need for rotational alignment
- No need to search for leaflets
- Accommodates tilt & lateral misalignment



CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE.

Combined CardiAQ-Edwards Platform Can Drive Leadership

- Focus on building clinical experience in TMVR
- CardiAQ platform complements the FORTIS program
 - One valve, multiple delivery systems
 - Unique anchoring mechanism
- Early patient experience is encouraging; more study needed
- Planned clinical timelines:
 - U.S. EFS underway; CE Mark trial to begin soon*
- Near-term product additions:
 - Lower valve profile, additional valve sizes, delivery system improvements, Edwards tissue



Merci pour votre attention