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Cardiac, Thoracic, Transplantation
and Vascular Surgery

Role of Sutureless Valves in the Surgeon's Armamentarium

Prof. Dr Malakh Shrestha

Vice Chair, Director of Aortic Surgery

Cardiothoracic, transplantation and Vascular Surgery

Hannover Medical School, Germany



STS/EACTS Latin America Cardiovascular Surgery Conference

Cartagena, Colombia

Hilton Cartagena

November 15 – 17, 2018



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Hannover Medical School

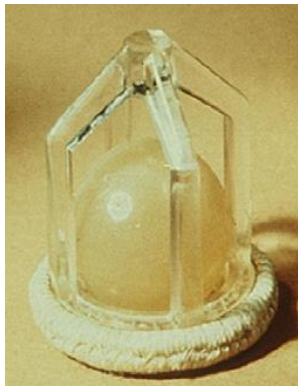
Disclosure

At present : none related to this presentation.

“First in man“ Implantation of Perceval (LivaNova) Sutureless Valve (24th April 2007).

“First in man“ Implantation of Elite Rapid Deployment Valve (Edwards) (20th Jan 2010)



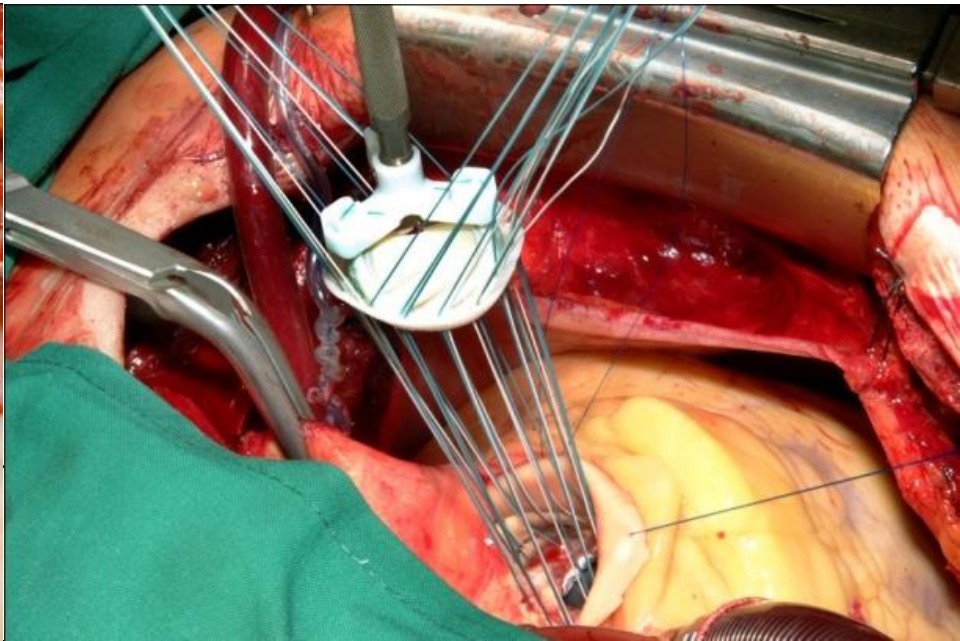
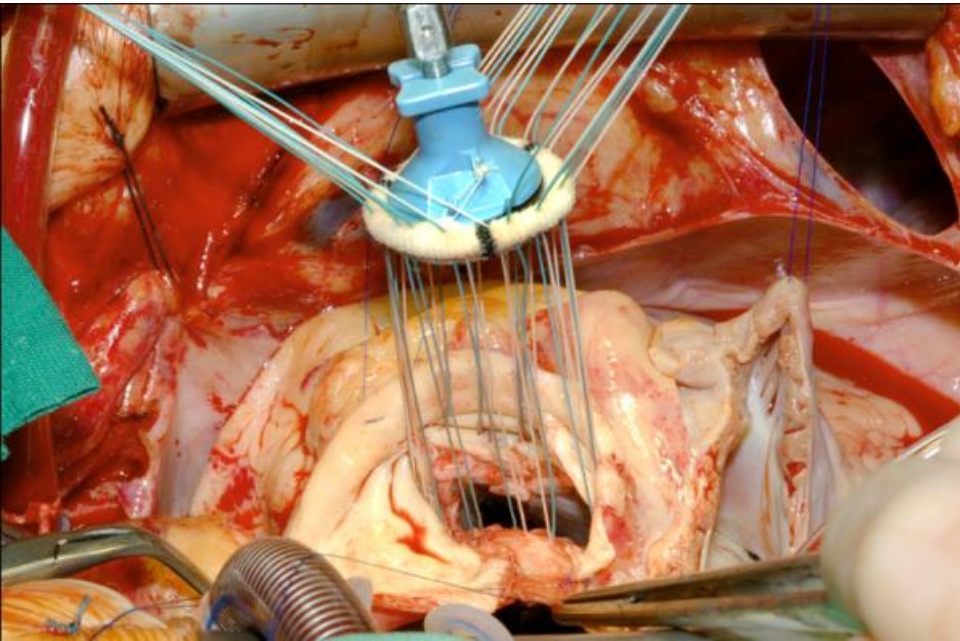


Albert Starr & Lowell Edwards

August 25, 1960



Holy Grail



Sutureless/ Rapid Deployment Valves

The concept

- Simplifies the surgical procedure
- Reduction of implantation time
- Concomitant procedures possible
- Minimally invasive AVR easier.



The McGovern Valve 1964

Native diseased aortic valve removed, Prosthesis not crimped: Better Durability

Rapid Deployment/Sutureless Valve Systems

Sorin Perceval S



Edwards Intuity Quick-connect System



Perceval – first clinical implant (Pilot trial)



April 24,
2007

Indications

1. Age \leq 75 years
2. Aortic valve stenosis at high surgical risk and candidate for a standard surgical intervention of aortic valve replacement with biological prosthesis
3. NYHA functional class III and IV
4. Small and calcific aortic root/annulus

Contra-indications:

1. Aneurysmal dilation or dissection of the ascending aorta requiring correction
2. Aortic annulus size (after decalcification) < 21 or > 23 mm by direct intraoperative measurement



MHH Hannover

- Male, 88 yrs, Logistic Euroscore 16.90%
- NYHA class III
- Perceval M and concomitant CABG
- X-clamp time: 53 min, CPB time: 83 min

A Staged Approach towards Interventional Aortic Valve Implantation with a Sutureless Valve: Initial Human Implants

M. Shrestha, N. Khaladj, C. Bara, K. Hoeffler, C. Hagl, A. Haverich

Thorac Cardiovasc Surg 2008; 56: 398–400

OBJECTIVE:

The purpose of this study was to assess a new sutureless aortic valve (Perceval Sorin).

METHODS:

Between April and September 2007, 16 high-risk patients (13 females, aged 81 [76 - 88]) were operated on (Euro Score 17 [8 - 73]). All patients had significant aortic valve disease and seven of these patients had concomitant coronary artery disease.

RESULTS:

One patient died during hospital stay for unknown reasons. Autopsy revealed no valve related pathologies. CPB time was 60 min (41 - 130), cross-clamping time was 36 (22 - 79) min. Intraoperative as well as postoperative echocardiography revealed neither aortic insufficiency nor paravalvular leakage in any of the patients.

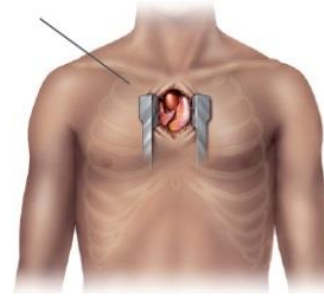
CONCLUSIONS:

The new approach is a technically simple alternative to conventional aortic valve replacement in high-risk patients and offers the potential of less invasive approaches.

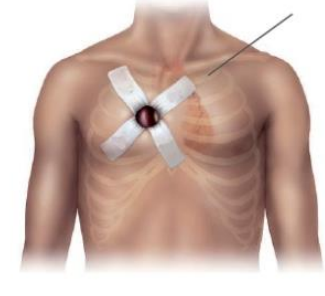
It appears especially useful in patients with severe calcification of the aortic root. CPB and cross-clamping times were markedly reduced compared with patients who underwent conventional operations.

Minimally invasive AVR

Mini-Sternotomy



Right Mini-Thoracotomy



Technical Difficulties

1. Small Aortic Root:
2. Calcified Aortic Root
3. Calcified Ascending Aorta

- ✓ **Sutureless valves make Minimally invasive AVR easier.**
- ✓ For right mini-thoracotomy approach, this is technically speaking, the easiest valve prosthesis for implantation.

Minimally Invasive Aortic Valve Replacement with Self-Anchoring Perceval Valve

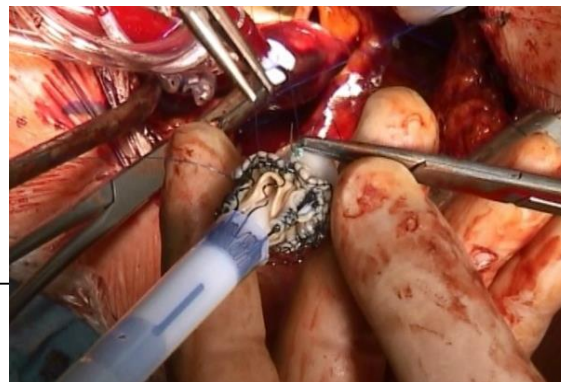
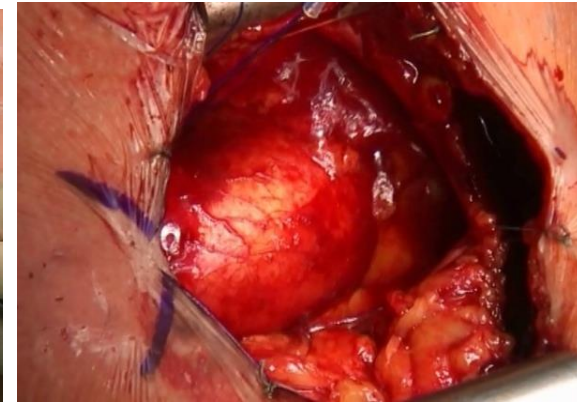
Malakh Shrestha, Rebecca Timm, Klaus Höffler, Nurbol Koigeldiyev, Nawid Khaladj, Christian Hagl, Axel Haverich, Samir Sarikouch

Shrestha, M., et al., J Heart Valve Dis, 2013. 22(2): p. 230-5

12/2006 – 2012, 35 Patients
Sizes 21, 23 + 25
Avg. Size = 22.1

Cross-clamp time (min)* 34 ± 10
Implantation time (min)* 9 ± 5

Parameter	Value
Age (years)*	80 ± 4
Height (cm)*	163 ± 8
Body weight (kg)*	73 ± 14
Body surface area (m ²)*	1.8 ± 0.2



Perceval facilitates and standardizes MICS procedures

Sutureless Valve Implantation via Mini J-Sternotomy: A Single Center Experience with 2 Years Mean Follow-up

Thorac Cardiovasc Surg



Fig. 1 Mini J-sternotomy approach.

Theodor Fischlein¹ Steffen Pfeiffer¹ Francesco Pollari¹ Joachim Sirch¹ Ferdinand Vogt¹
Giuseppe Santarpino¹

145 Perceval implanted via Mini J-Sternotomy

- Good clinical and hemodynamic results in the postoperative and at mid-term follow-up with no evidence of early prosthetic valve degeneration.
- mean implantation time of 7.8 minutes
- No PVL, 7.6% patients required PMI.

Clinical studies publications

Sutureless Perceval S Aortic Valve Replacement: A Multicenter, Prospective Pilot Trial

Malakh Shrestha¹, Thierry Folliguet², Bart Meuris³, Alain Dibie², Christoph Bara¹, Marie-Christine Herregods³, Nawid Khaladj¹, Christian Hagl¹, Willem Flameng³, Francois Laborde², Axel Haverich¹

¹Division of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany, ²Cardiac Medico-Surgical Department, Institute Mutualiste Montsouris, Paris, France, ³Cardiac Surgery, U.Z. Gasthuisberg, Leuven, Belgium

European Journal of Cardio-Thoracic Surgery (2015) 1-8

European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients[†]

Malakh Shrestha^{*,†}, Theodore Fischlein[†], Bart Meuris[†], Willem Flameng[†], Thierry Carrel[†], Francesco Madonna[†], Martin Misfeld[†], Thierry Folliguet[†], Axel Haverich[†] and Francois Laborde[†]

Aortic Valve Replacement and Concomitant Procedures With the Perceval Valve: Results of European Trials

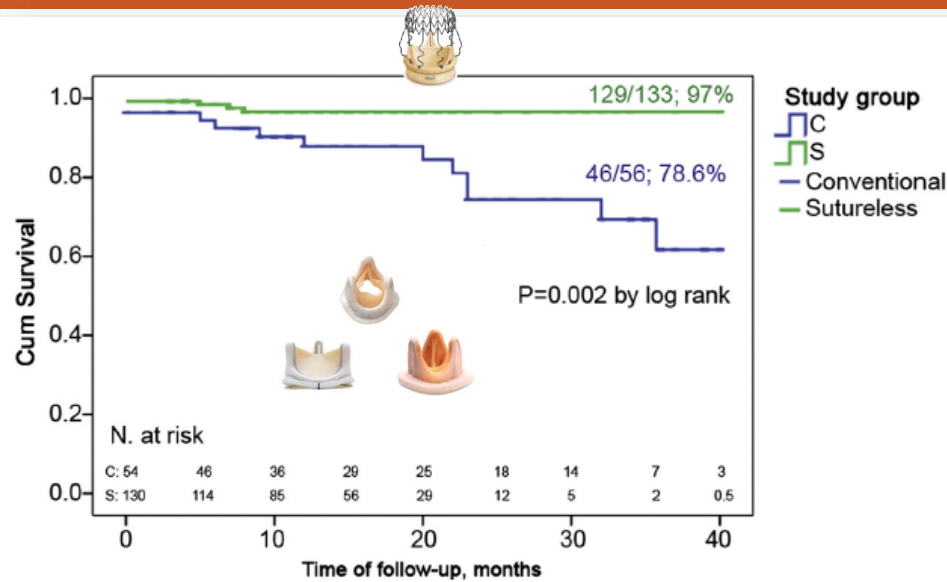
Malakh Shrestha, MBBS, PhD, Thierry A. Folliguet, MD, Steffen Pfeiffer, MD, PhD, Bart Meuris, MD, PhD, Thierry Carrel, MD, Matthias Bechtel, MD, Willem J. Flameng, MD, Theodor Fischlein, MD, PhD, Francois Laborde, MD, and Axel Haverich, MD, PhD

Cardiothoracic, Transplantation, and Vascular Surgery, Hannover Medical School, Germany; Cardiac Medicosurgical Department, Institute Mutualiste Montsouris, Paris, France; Klinikum Nuernberg, Center of Cardiac Surgery, Nuremberg, Germany; Cardiac Surgery, U.Z. Gasthuisberg, Leuven, Belgium; Inselspital, Bern, Switzerland; Ruhr University of Bochum, Department of Cardiothoracic Surgery, Bochum, Germany

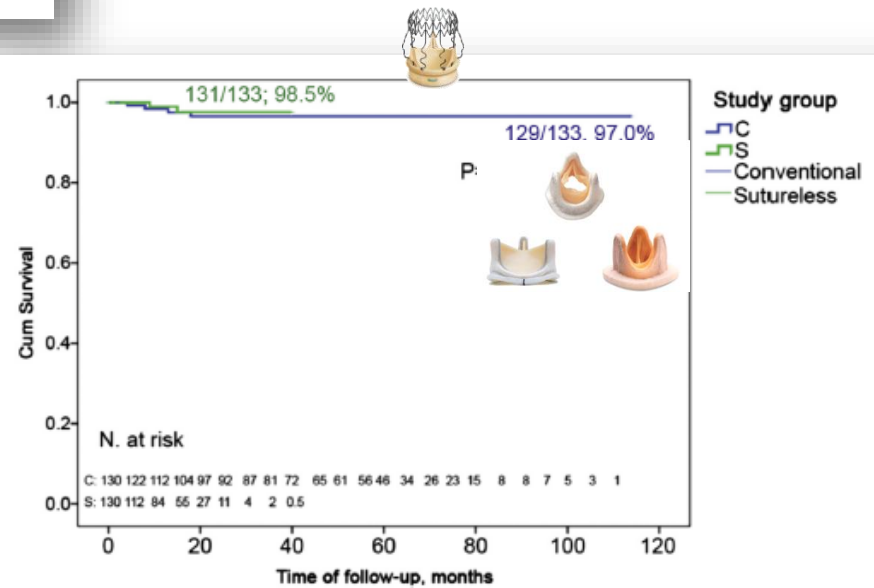
European Journal of Cardio-Thoracic Surgery (2015) 1-9

Clinical and haemodynamic outcomes in 658 patients receiving the Perceval sutureless aortic valve: early results from a prospective European multicentre study (the Cavalier Trial)[†]

Francois Laborde^{*,†}, Theodor Fischlein[†], Kavous Hakim-Meibodi[†], Martin Misfeld[†], Thierry Carrel[†], Marian Zembala[†], Francesco Madonna[†], Bart Meuris[†], Axel Haverich[†] and Malakh Shrestha[†], on behalf of the Cavalier Trial Investigators



40-months Survival Perceval vs. conventional AVR in RAT



Freedom from Reoperation at follow-up Perceval vs. conventional AVR in RAT

Aortic valve replacement through right anterior minithoracotomy: can sutureless technology improve clinical outcomes?
 Gilmanov D, Miceli A, Ferrarini M, Farneti P, Murzi M, Solinas M, Glauber M. - *Ann Thorac Surg.* 2014 Nov;98(5):1585-92.

First 100 Perceval implants!



AVR in small aortic annulus?

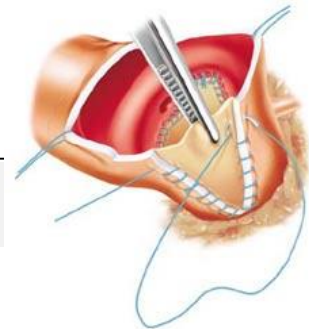
Patient-Prosthesis Mismatch?

No Suturing Ring: Perceval is stent-less Valve



Perceval prosthesis implantation is technically easy even in small aortic roots and has excellent gradients.

- ✓ Perceval implantation is easy to implant
- ✓ The gradients are excellent
- ✓ No PPM!!

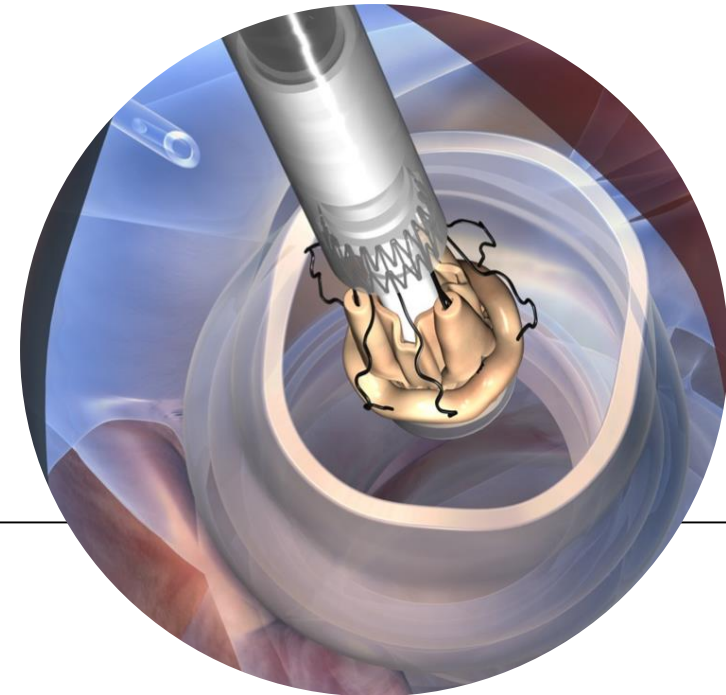
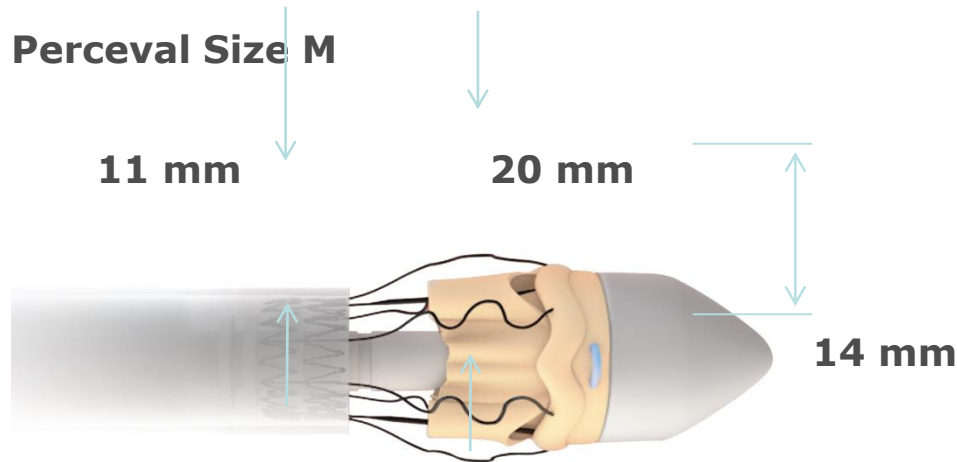


Patch enlargement of aortic annulus not necessary!

Features & Benefits: Collapsible

UNIQUE COLLAPSIBLE DESIGN

The valve diameter can be reduced prior to implantation, increasing visibility.



Features & Benefits: Collapsible

ATRAUMATIC COLLAPSING

The collapsing procedure does not affect the leaflets preventing any possible damage to the tissue



Published Experience

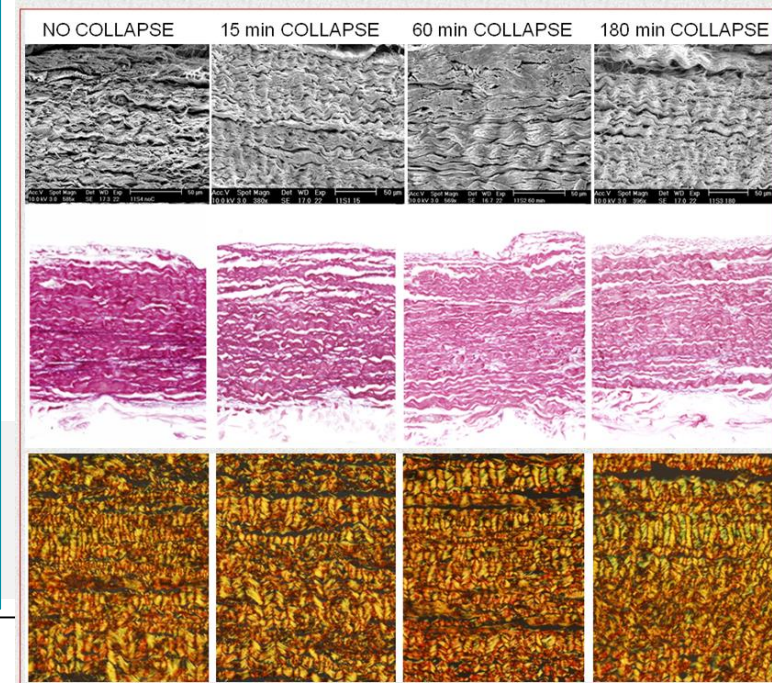
Lack of Evidence of Pericardial Injury Following Pre-implantation Collapse in the Sorin Perceval S Sutureless Prosthesis



Mila Della Barbera, Cristina Basso, Marialuisa Valente, Gaetano Thiene
Department of Medical and Diagnostic Sciences and Special Therapies, University of Padua Medical School, Padova, Italy

CONCLUSIONS:

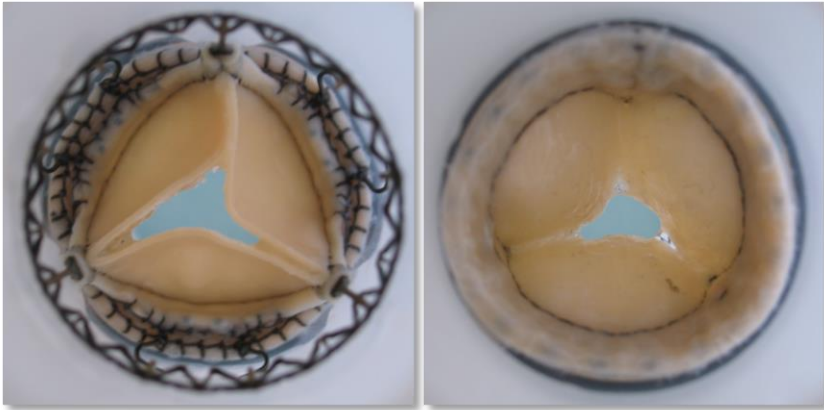
Pre-implantation collapse and ballooning does not affect the structural integrity of the collagen network of the pericardial cusp tissue in LivaNova Perceval S Sutureless prosthesis.



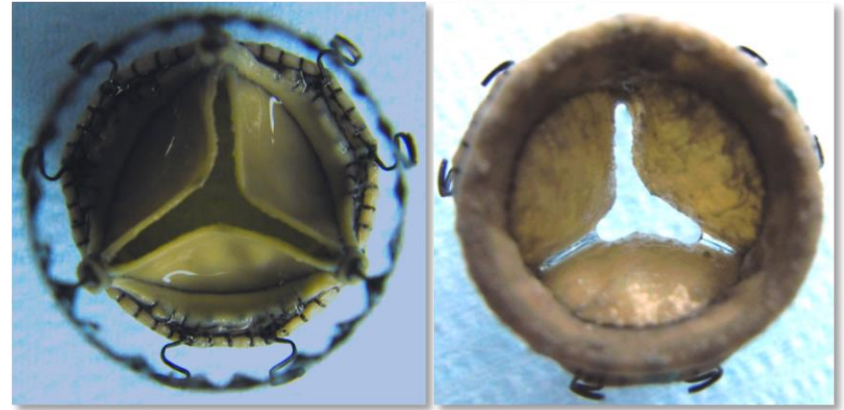
Durability: Design Tests

- ISO5840 and FDA guidance require 200 million cycles for tissue valves
- Perceval valve was tested up to 600 million cycles (15 years equivalent)

Before test



After 600 Mcycles

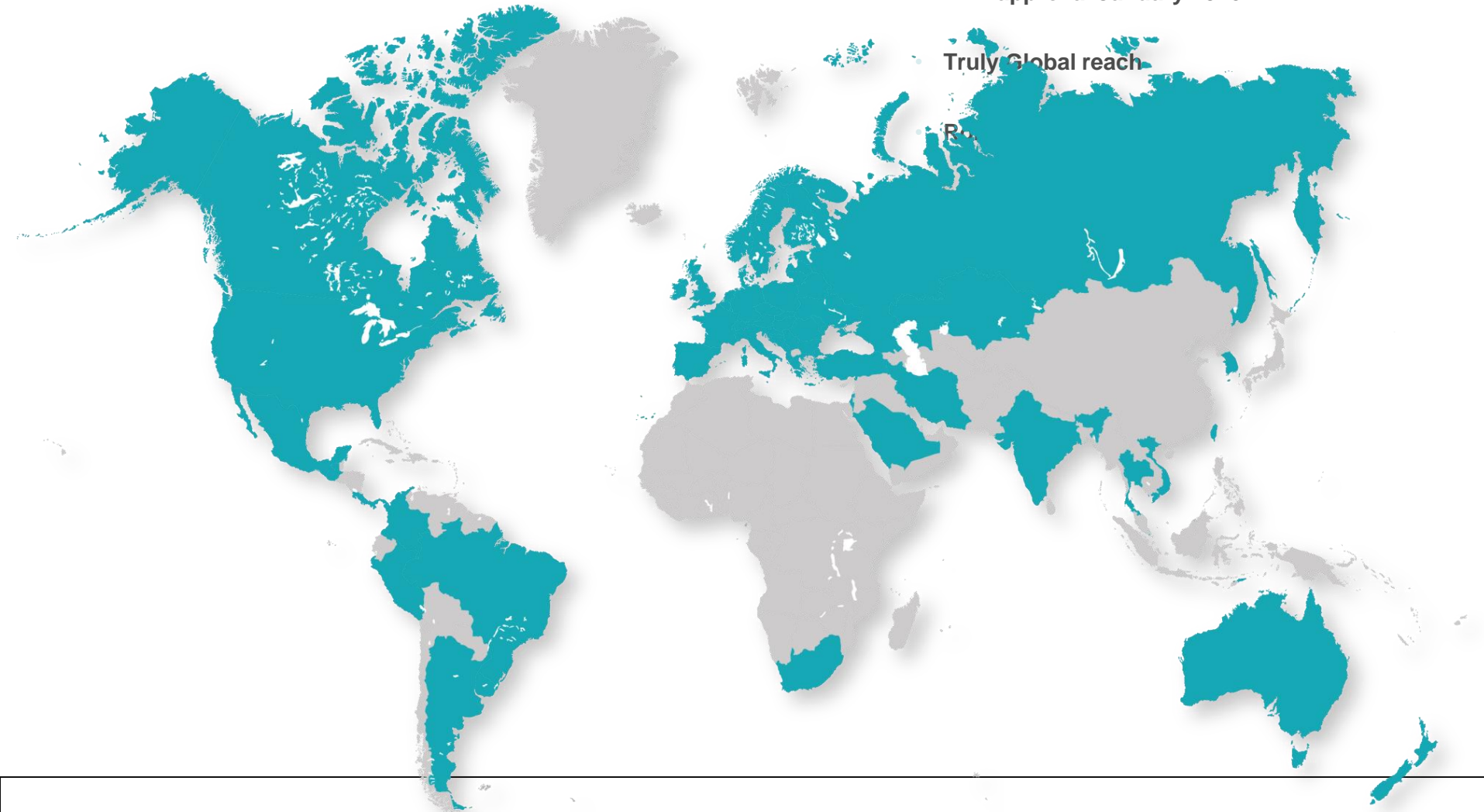


Testing performed in compliant chamber to mimic worst case in vivo condition

Perceval over-achieved three times the FDA guidance

Facts: Perceval Worldwide

- First-in-Human performed in 2007
- CE mark January 2011
- FDA approval January 2016
- Truly Global reach



PERSIST-AVR

CLINICAL TRIAL

1,234 patients to be randomized (1:1)

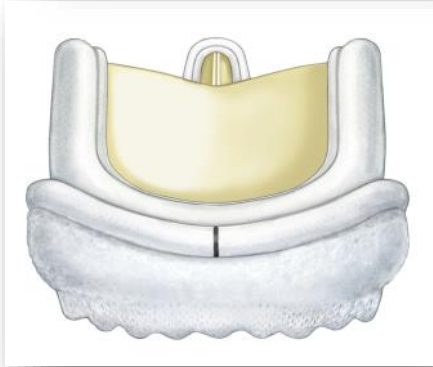
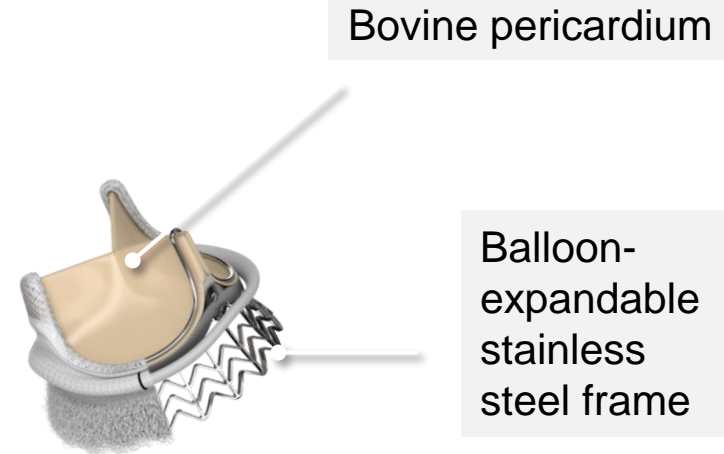
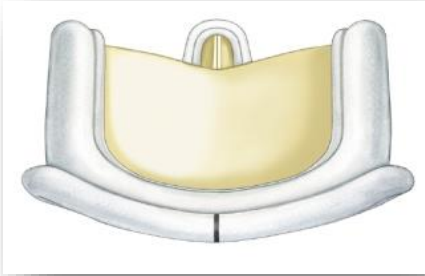
In countries where Perceval is approved

International, multicenter controlled randomized trial

Approximately 60 centers be selected

Follow up to 5 years

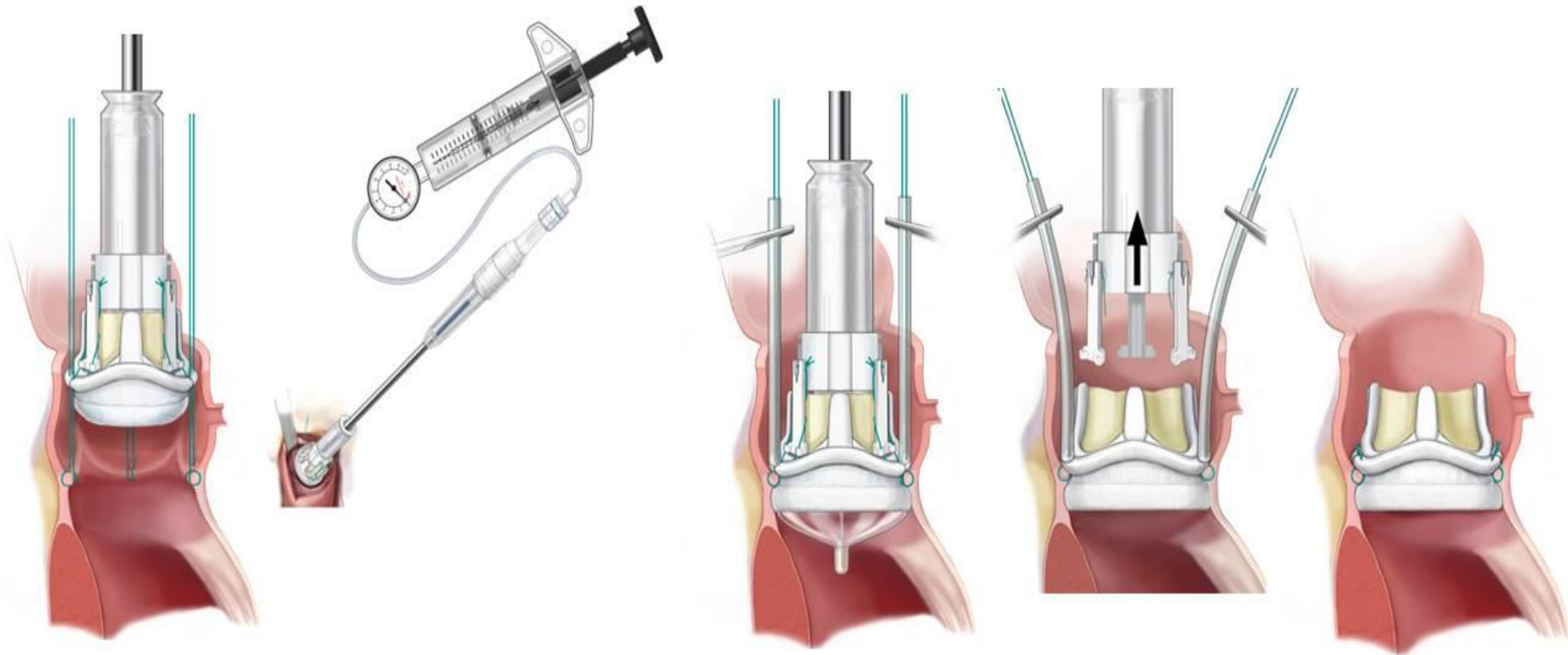
Odyssey (Elite) Valve and Delivery System



- Designed to simplify and facilitate MIS
- Built upon proven valve technology
- Leverages innovation from transcatheter heart valves

- Balloon-expandable frame
- Sub-annular fixation
- Complete size range – 19 mm to 27 mm

Edwards Rapid Deployment Valve (Elite)



Three fixation sutures: No migration or dislodgment of valve!

Triton trial (CE Certification)

Major Inclusion Criteria

- Patient is 18 years or older
- Aortic stenosis or stenosis-insufficiency requiring planned replacement
- Planned aortic valve replacement with or without concomitant CABG
- Informed consent and patient agrees to all post-procedure follow-up

Major Exclusion Criteria

- Pure aortic insufficiency
- Aneurysm of the aortic root or ascending aorta
- LVEF of < 25%
- Congenital bicuspid aortic valve
- Concomitant valve disease requiring repair or replacement
- Evidence of AMI \leq 1 month before intended treatment
- In situ mitral, tricuspid, or pulmonic replacement valve or ring
- Non-cardiac life expectancy < 12 months

Center	Investigator
AKH Vienna – Universitätsklinik für Chirurgie - Vienna, Austria	Prof. Dr. Günther Laufer
MHH Medizinische Hochschule Hannover - Hannover, Germany	Prof. M.D. Axel Haverich Dr. Malakh Lal Shrestha
Universitaet Leipzig, Herzzentrum, Klinik fuer Herzchirurgie - Leipzig, Germany	Prof. Friedrich Mohr M.D. Ph.D. Prof. Michael Borger M.D. Ph.D.
Klinikum der Universität München - Munich, Germany	Prof. Bruno Reichart M.D.
Kerckhoff Klinik - Bad Nauheim, Germany	Prof. Thomas Walther
Hopital Universitaire de Berne - Berne, Switzerland	Prof. Thierry P. Carrel

One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System

The Journal of Thoracic and Cardiovascular Surgery • January 2013

Alfred A. Kocher, MD, PhD,^a Günther Laufer, MD, PhD,^a Axel Haverich, MD, PhD,^b Malakh Shrestha, MD, PhD, MBBS,^b Thomas Walther, MD, PhD,^c Martin Misfeld, MD, PhD,^d Joerg Kempfert, MD,^c Linda Gillam, MD, MPH,^e Christoph Schmitz, MD,^f Thorsten C. Wahlers, MD, PhD,^g Jens Wippermann, MD,^g Friedrich W. Mohr, MD, PhD,^d Matthias Roth, MD,^c Adalbert Skwara, MD,^c Parwis Rahmanian, MD,^g Dominik Wiedemann, MD,^a and Michael A. Borger, MD, PhD^d

Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve

The Journal of Thoracic and Cardiovascular Surgery • Volume 151, Number 6

Thorsten C. W. Wahlers, MD, PhD,^a Axel Haverich, MD,^b Michael A. Borger, MD, PhD,^c Malakh Shrestha, MBBS, PhD,^b Alfred A. Kocher, MD,^d Thomas Walther, MD, PhD,^c Matthias Roth, MD,^c Martin Misfeld, MD,^c Friedrich W. Mohr, MD, PhD,^c Joerg Kempfert, MD,^c Pascal M. Dohmen, MD, PhD,^f Christoph Schmitz, MD,^g Parwis Rahmanian, MD,^a Dominik Wiedemann, MD,^d Francis G. Duhay, MD,^h and Günther Laufer, MD^d

Long-term outcomes of a rapid deployment aortic valve: data up to 5 years[†]

ORIGINAL ARTICLE

Günther Laufer^{a*}, Axel Haverich^b, Martin Andreas^a, Friedrich W. Mohr^c, Thomas Walther^d, Malakh Shrestha^b, Parwis Rahmanian^e, David Holzhey^c, Matthias Roth^d, Christoph Schmitz^f, René Schramm^f, Christophe Giot^g and Thorsten C.W. Wahlers^e

European Journal of Cardio-Thoracic Surgery 52 (2017) 281–287

Case 1:

80 Year Old Female

Symptomatic Severe Aortic Valve Prosthesis Stenosis

(Gradient: 73/49 Hg mm, EOA: 0.73 cm²)

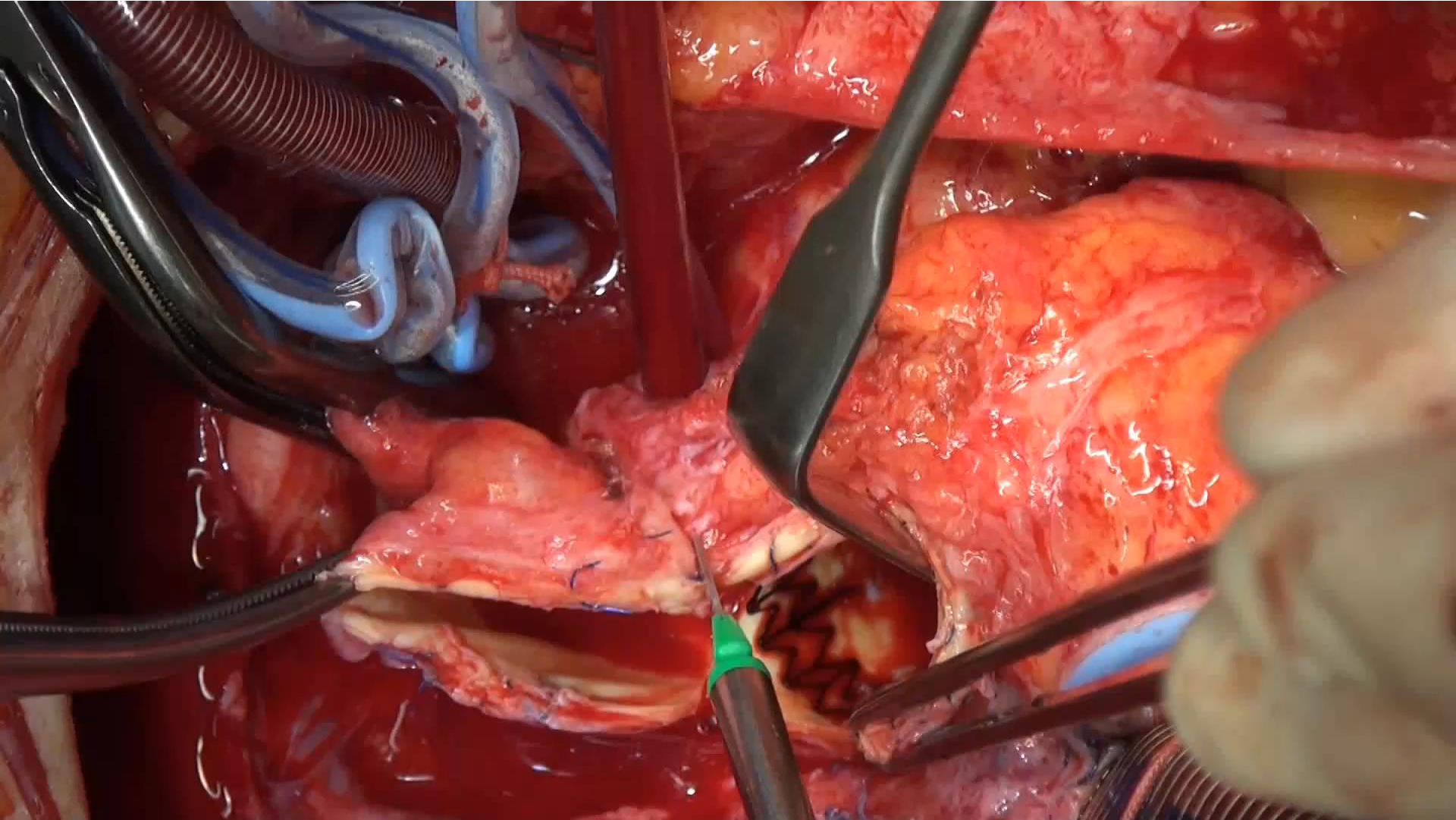
EF:58%

Past History:

Aortic Valve Replacement (Sutureless Perceval Valve, 21mm) in 2011.

“ReDo “ Aortic Valve Replacement

(Perceval Sutureless Valve, 21 mm)



PHILIPS

TIS0.5 MI 0.9

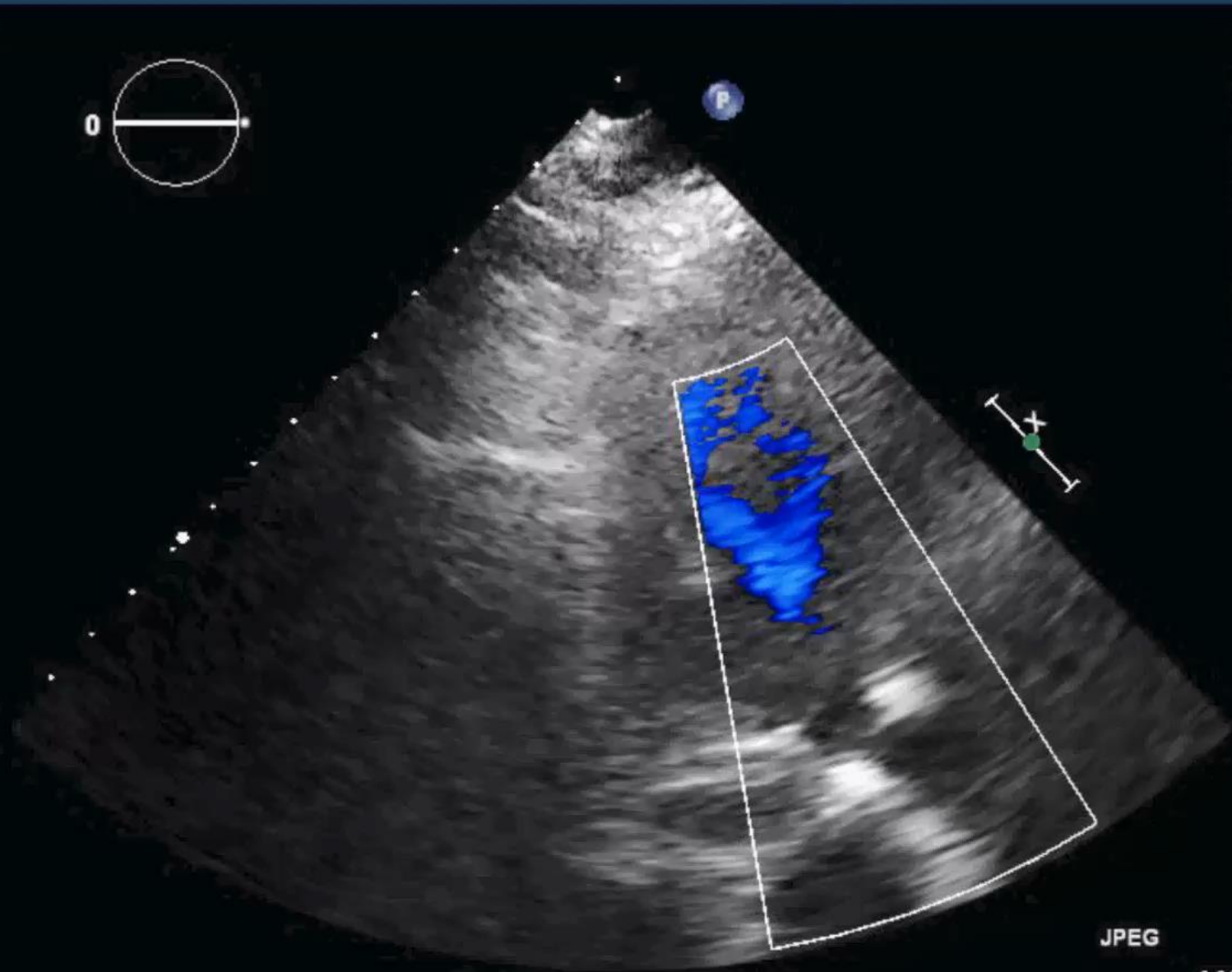
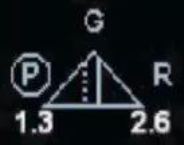
X5-1/Echo

BF 21Hz
15cm

2D
60%
K 50
M Mittel
HPen

FD
63%
2.5MHz
WF Hoch
Mittel

S3 S4
+61.6



JPEG

110 /min

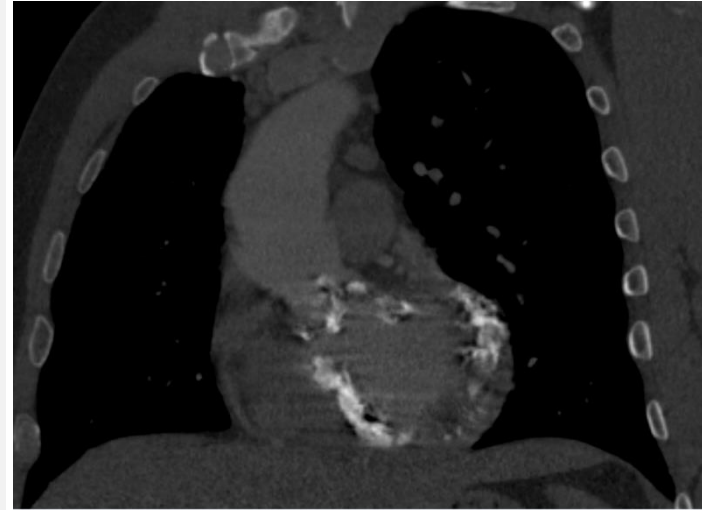
Case 2:

56 Year Old Male

Symptomatic Severe Aortic Valve Stenosis

Aneurysm of the ascending Aorta

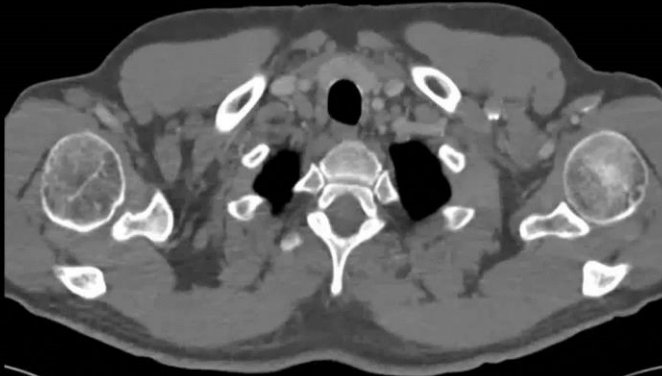
X-ray, CTScan: Extreme Calcification in the aortic root and Myocardium

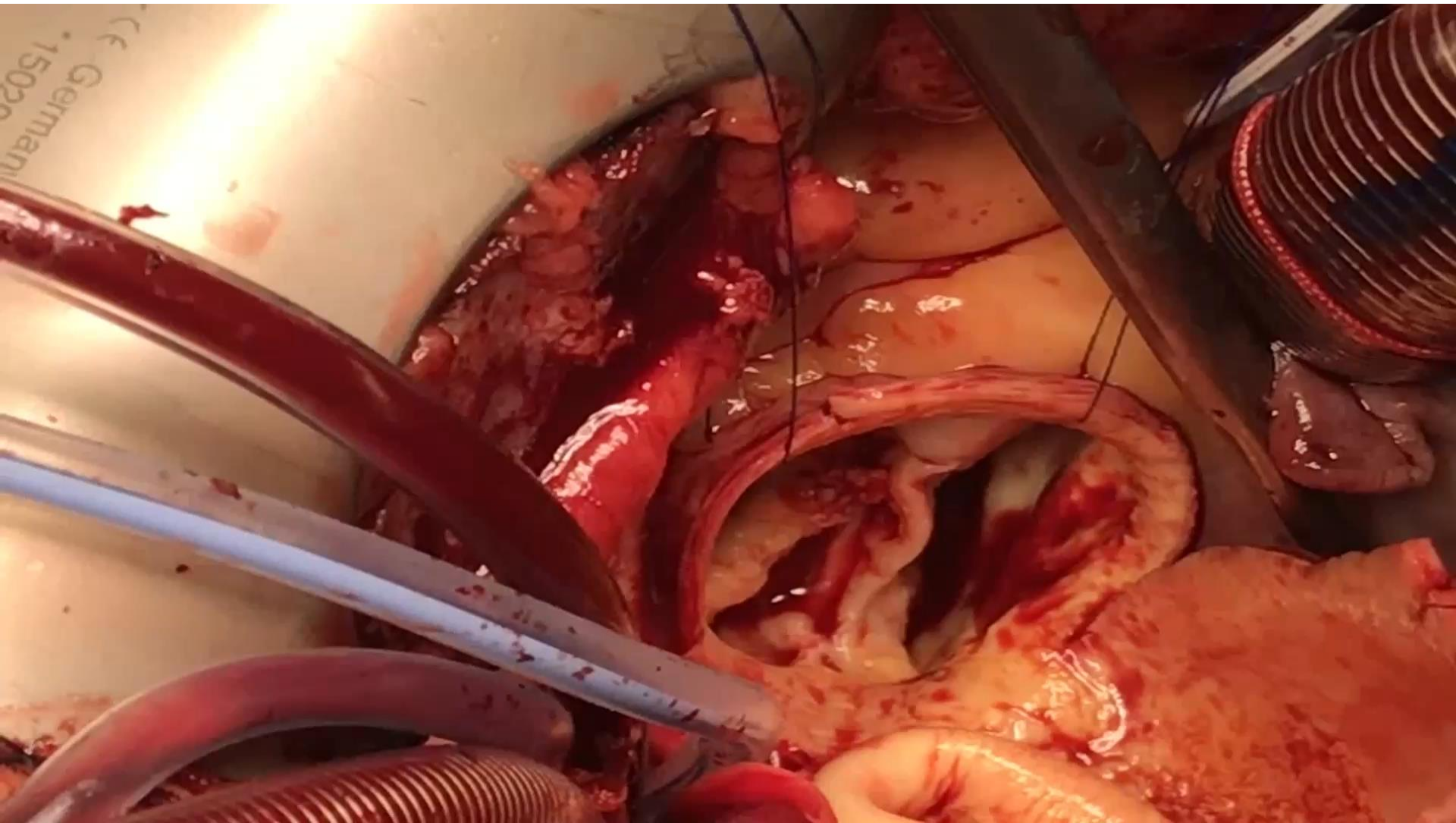


Aortic Valve Replacement :(Edwards Elite Valve, 27 mm)

Ascending aortic replacement with a Dacron Graft (30mm Diameter)

Post-op mean Gradient: 6mm mm Hg





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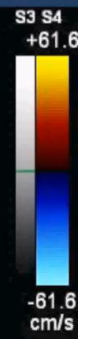
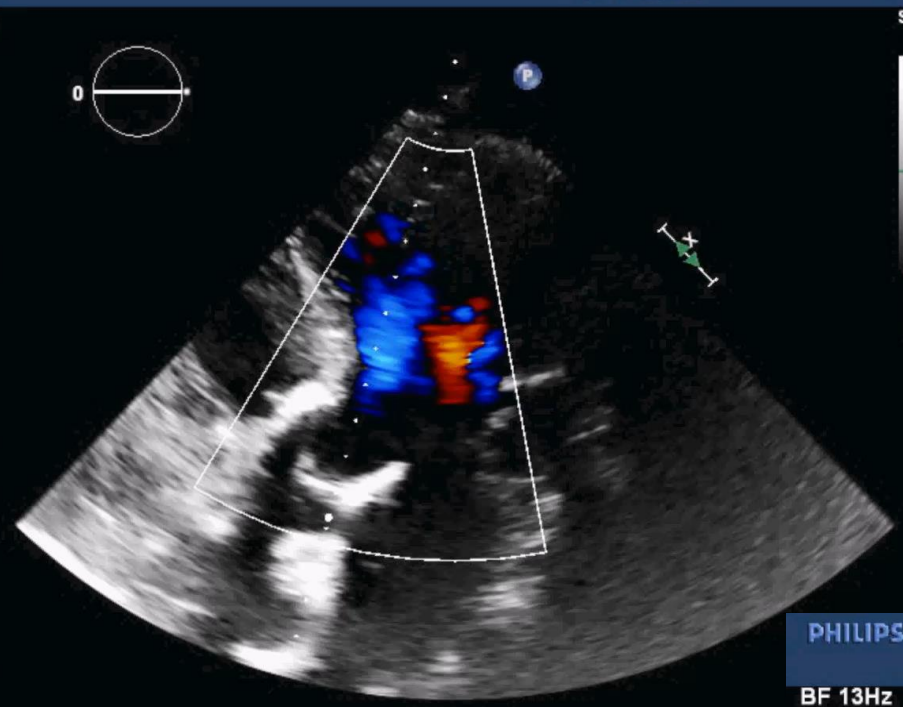
Cardiac, Thoracic, Transplantation
and Vascular Surgery

X5-1/Erw.

BF 14Hz
17cm

2D
69%
K 50
M Niedrig
HAllg

FD
63%
2.5MHz
WF Hoch
Mittel

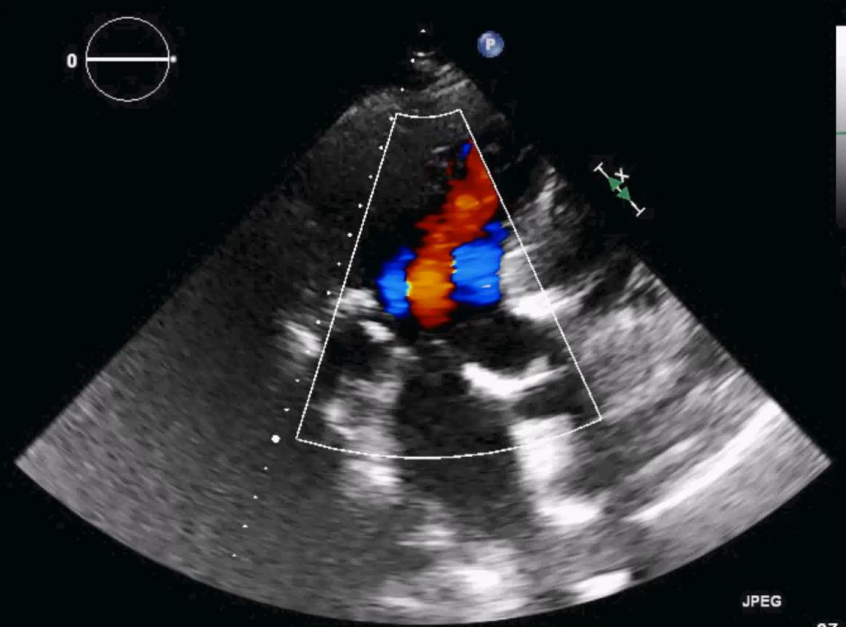


X5-1/Erw.

BF 13Hz
19cm

2D
73%
K 50
M Niedrig
HAllg

FD
63%
2.5MHz
WF Hoch
Mittel



Aortic Cross-Clamp Time, New Prostheses, and Outcome in Aortic Valve Replacement

Marco Ranucci¹, Alessandro Frigiola², Lorenzo Menicanti², Serenella Castelvechio¹, Carlo de Vincentiis², Valeria Pistuddi¹, for the Surgical and Clinical Outcome Research (SCORE) Group

Departments of ¹Cardiothoracic and Vascular Anesthesia and Intensive Care and ²Cardiac Surgery, IRCCS Policlinico San Donato, Milan, Italy

The Journal of Heart Valve Disease 2012;21

Results: The AXCT was an independent predictor of severe cardiovascular morbidity, with an increased risk of 1.4% per 1 min increase. Patients with a left ventricular ejection fraction $\leq 40\%$, and also diabetic patients, showed the most relevant clinical benefits induced by a reduction in AXCT.

Perceval vs Intuity

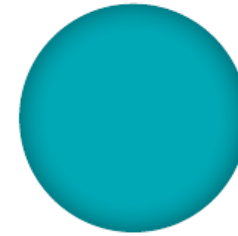
LivaNova PERCEVAL



PERCEVAL size M
Approximately 20mm
Overall valve dimension during implantation

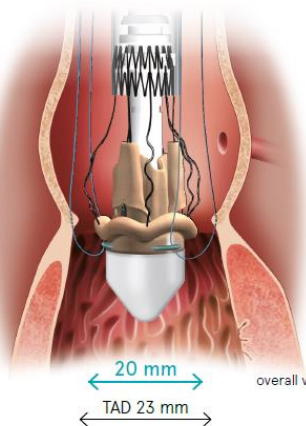
PERCEVAL is the smallest valve available for surgical implantation.⁷

Edwards INTUITY ELITE



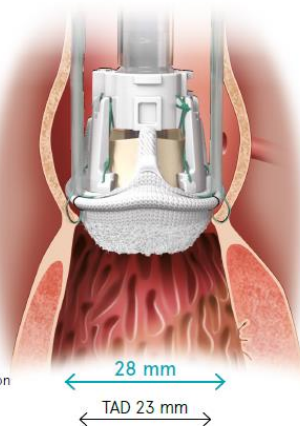
INTUITY size 23
Approximately 28mm
Overall valve dimension during implantation⁸

LivaNova PERCEVAL



overall valve dimension during implantation

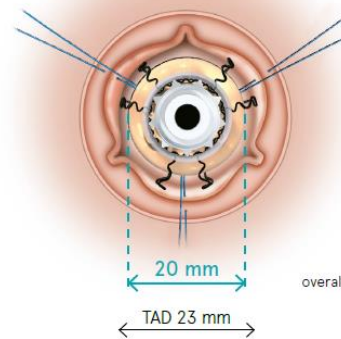
Edwards INTUITY ELITE



overall valve dimension during implantation

LivaNova PERCEVAL

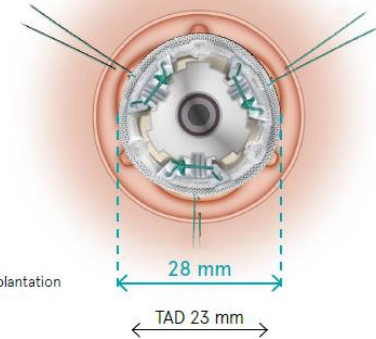
24% Visibility
Collapsible design allows for visibility of critical structures during Implantation



overall valve dimension during implantation

Edwards INTUITY ELITE

No Visibility
Valve design limits visibility of critical structures during implantation



overall valve dimension during implantation

Current Clinical Evidence on Rapid Deployment Aortic Valve Replacement *Sutureless Aortic Bioprostheses*

Glenn R. Barnhart, MD* and Malakh Lal Shrestha, MBBS, PhD†

(*Innovations* 2016;11:7–14)

The growing adoption of percutaneous AVR likely will compel more surgeons to explore minimal access approaches for isolated AVR, if it is not currently part of their surgical toolbox.

Importantly, the learning curve for rapid deployment heart valves cannot be discounted, which highlights the importance of device-specific training, whether sponsored by industry or by the professional societies.

Finally, although the early clinical outcomes seem satisfactory and comparable with conventional heart valves, the important issue of long-term valve durability remains unanswered.

In expert hands, conventional and minimal access AVR is associated with low risk and outstanding long-term results that were unheard of even a decade ago.

The transition from conventional surgical AVR to rapid deployment AVR by our specialty must be performed in a deliberate and methodical fashion so that the benefits accrued during the last 55 years will not be squandered.

OPEN

International Expert Consensus on Sutureless and Rapid Deployment Valves in Aortic Valve Replacement Using Minimally Invasive Approaches

Mattia Glauber, MD, Simon C. Moten, MD,† Eugenio Quaini, MD,* Marco Solinas, MD,‡
Thierry A. Folliguet, MD, FACS,§ Bart Meuris, MD, PhD,|| Antonio Miceli, MD, PhD,*
Peter J. Oberwalder, MD,¶ Manfred Rambaldini, MD,# Kevin H. T. Teoh, MD,**
Gopal Bhatnagar, MD,†† Michael A. Borger, MD, PhD,‡‡ Denis Bouchard, MD,§§
Olivier Bouchot, MD,|||| Stephen C. Clark, FRCS (CTh),¶¶ Otto E. Dapunt, MD, PhD,##
Matteo Ferrarini, MD,* Theodor J. M. Fischlein, MD,*** Guenther Laufer, MD,†††
Carmelo Mignosa, MD,‡‡‡ Russell Millner, MD,§§§ Philippe Noirhomme, MD,|||||
Steffen Pfeiffer, MD,††† Xavier Ruyra-Baliarda, MD,¶¶¶ Malakh Lal Shrestha, MBBS, PhD,###
Rakesh M. Suri, MD, DPhil,**** Giovanni Troise, MD,†††† and Borut Gersak, MD, PhD‡‡‡‡*

- To gain evidence-based consensus on the use of sutureless and rapid deployment valves in minimally invasive isolated aortic valve replacement
- To define the role of minimally invasive aortic valve replacement with sutureless and rapid deployment valves.

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International Expert Consensus on Sutureless and Rapid Deployment Valves in Aortic Valve Replacement Using Minimally Invasive Approaches

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Key recommendations regarding PATIENT INDICATIONS:

Sutureless or rapid deployment:

- Use of sutureless and rapid deployment valves in minimally invasive approaches in patients candidates for AVR and not for TAVI
- Suitable annular size (after decalcification) ranges from 19 to 27 mm
- Not indicated for Bicuspid valve type 0
- Can be implanted in bicuspid valves type 1 and 2 if:
 - Coronary ostia do not have 180° position
 - Rounded annulus
 - Uniform height of the commissures (in type 2)
- Not indicated in annular abscess or deconstruction due to endocarditis

It is important to find the right balance in life!



AVR: we need the whole range of Armementarium!



Conclusion

'Rapid Deployment and Sutureless Valves' are technically easier to implant and more reproducible even in Calcified/ small annulus.

Min. Inv. AVR: Limited Exposure not a disadvantage

Reduces of the X-clamp time and CPB time.

No Suturing Ring: Perceval is stent-less Valve: No PPM!

Safety:

Good durability (Follow-up >10 year)

Effectiveness:

Hemodynamics are excellent!

Re-do AVR: not a problem.

Valve of choice for the geriatric Pt.s! Especially in combined AVR