

Saturday, 28th October 2013

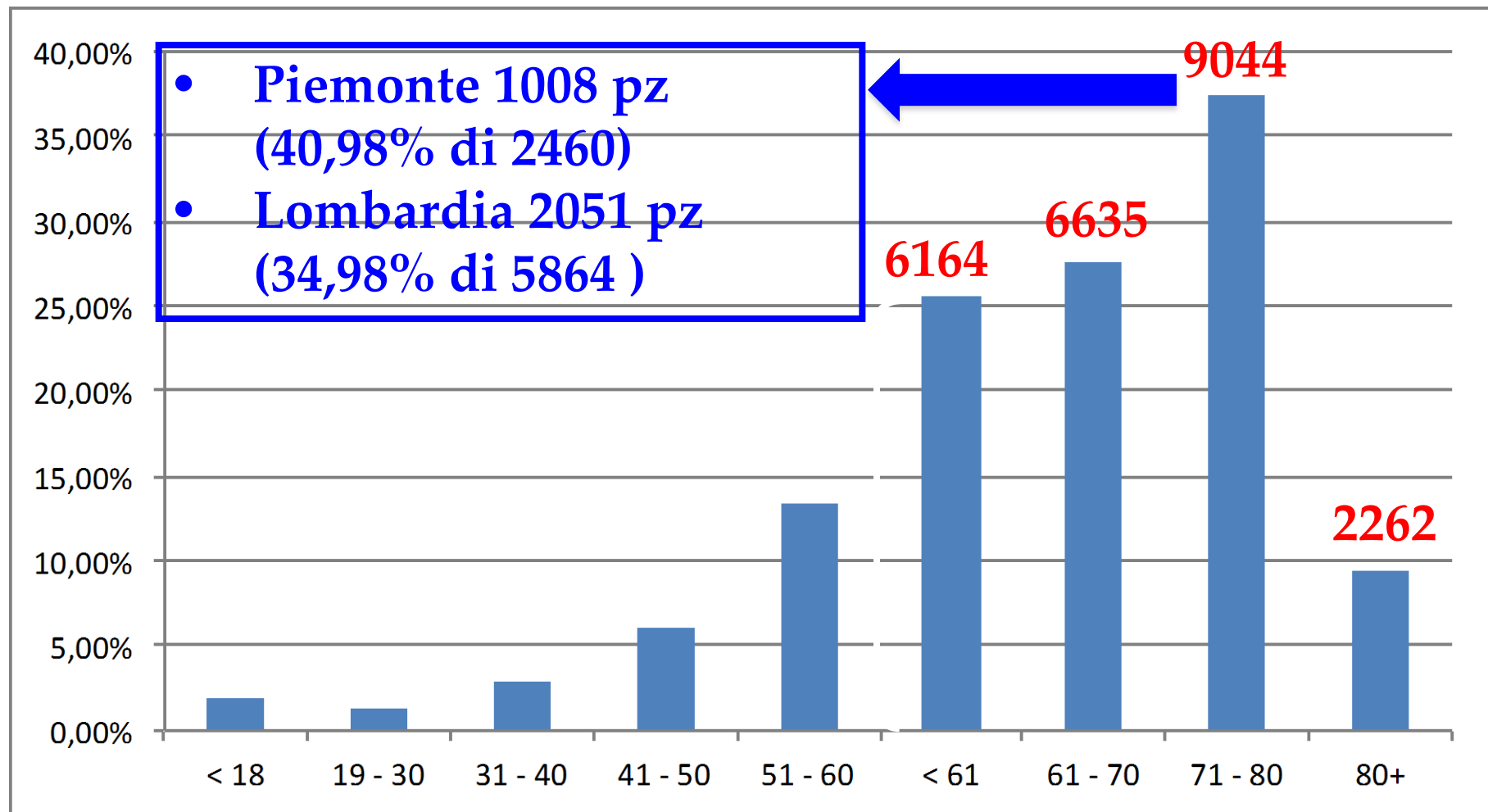
**TAVI today:
a new technology for
an old pathology**

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***CITTA' DELLA SALUTE E DELLA SCIENZA
TORINO***

DISTIBUZIONE PER ETÀ DEI RICOVERI PER INTERVENTI ALLA VALVOLA AORTICA IN ITALIA



Prohibitive surgical patients treatable

2.9%

≥ 75 years old have severe aortic stenosis

Lindroos et al. JACC 1993

84.6%

with severe AS are symptomatic

Lung et al: Curr Probl Cardiol. 2007

31.8%

do not undergo surgery

Lung et al. EHJ 2003

45.9%

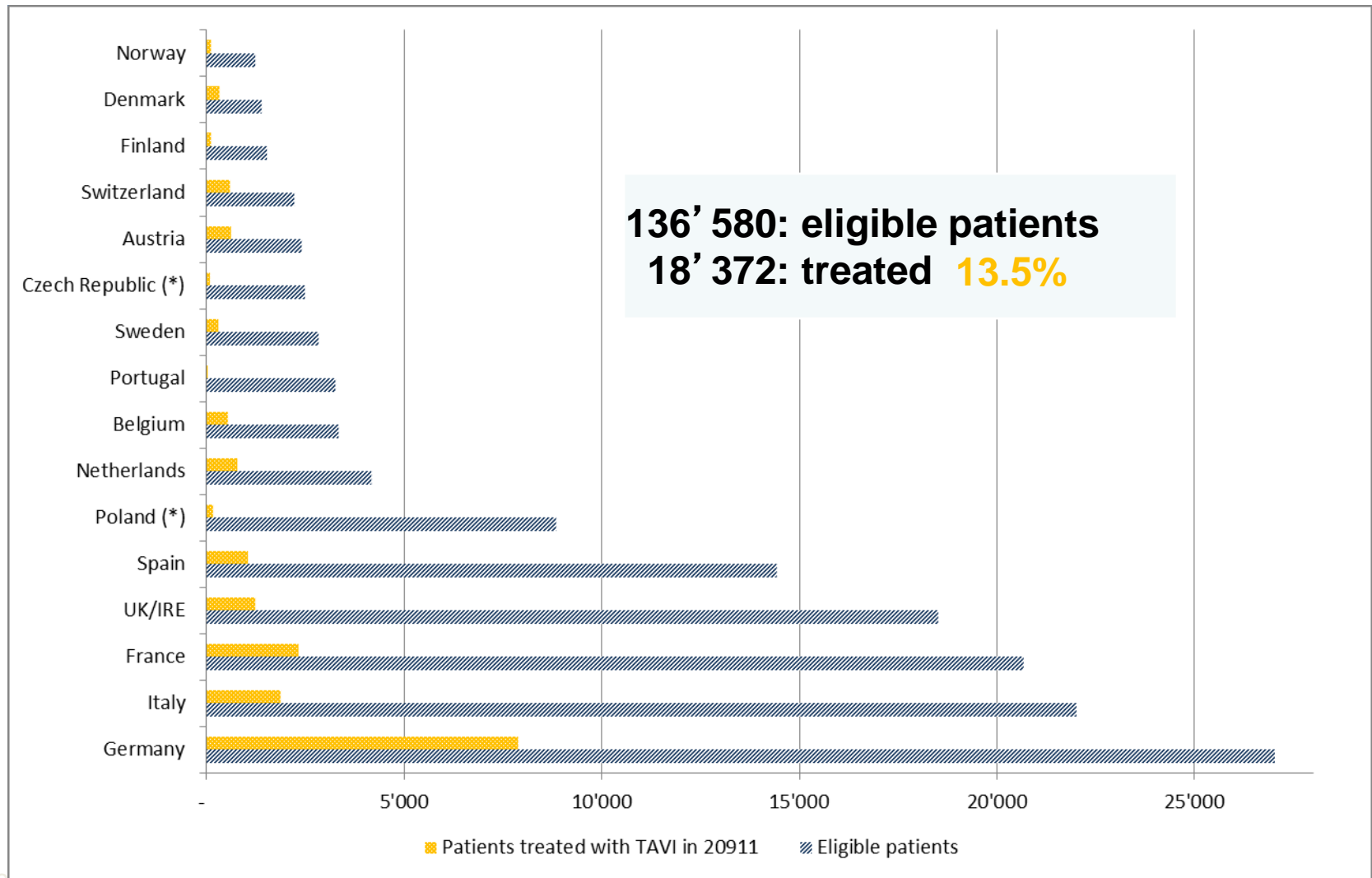
TAVI eligible patients

Saia et al, 2011

Eligible TAVR Patients using Pooled Estimates

| Countries | Total population 75 years and above | Prevalence of severe AS in persons ≥ 75 yrs (SAS) 2.67%** | Prevalence of SAS diagnosed persons with symptoms (sSAS) 80.9% | Persons with sSAS that are deemed High risk and SAVR ineligible 31.8% | Persons with sSAS that were ineligible for SAVR but deemed TAVR eligible 57.9% |
|-----------------|-------------------------------------|---|---|--|---|
| Belgium | 940,727 | 25,117 | 20,320 | 6,462 | 3,741 |
| Czech Republic | 699,879 | 18,687 | 15,118 | 4,807 | 2,783 |
| Denmark | 391,138 | 10,443 | 8,449 | 2,687 | 1,556 |
| Germany | 7,546,760 | 201,498 | 163,012 | 51,838 | 30,014 |
| Ireland | 225,364 | 6,017 | 4,868 | 1,548 | 896 |
| Spain | 4,031,995 | 107,654 | 87,092 | 27,695 | 16,036 |
| France | 5,771,830 | 154,108 | 124,673 | 39,646 | 22,955 |
| Italy | 6,147,116 | 164,128 | 132,780 | 42,224 | 24,448 |
| The Netherlands | 1,166,868 | 31,155 | 25,205 | 8,015 | 4,641 |
| Austria | 674,365 | 18,006 | 14,566 | 4,632 | 2,682 |
| Poland | 2,472,267 | 66,010 | 53,402 | 16,982 | 9,832 |
| Portugal | 916,033 | 24,458 | 19,787 | 6,292 | 3,643 |
| Finland | 435,549 | 11,629 | 9,408 | 2,992 | 1,732 |
| Sweden | 799,946 | 21,359 | 17,279 | 5,495 | 3,181 |
| United Kingdom | 4,943,066 | 131,980 | 106,772 | 33,953 | 19,659 |
| Norway | 351,700 | 9,390 | 7,597 | 2,416 | 1,399 |
| Switzerland | 625,338 | 16,697 | 13,507 | 4,295 | 2,487 |
| TOTAL | 38,139,941 | 1,018,336 | 823,834 | 261,979 | 151,686 |

Therapy uptake in 2011



Aortic Valve Stenosis: AN OLD PATHOLOGY

Surgery for Aortic Stenosis in Elderly Patients **A Study of Surgical Risk and Predictive Factors**

Y. Logeais, MD; T. Langanay, MD; R. Roussin, MD; A. Leguerrier, MD; C. Rioux, MD;
J. Chaperon, MD; C. de Place, MD; P. Mabo, MD; J.C. Pony, MD; J.C. Daubert, MD;
M. Laurent, MD; C. Almange, MD

Methods and Results Between 1976 and February 1993, we performed 2871 operations for aortic stenosis. This study concerns 675 patients (278 men and 397 women) who were

Circulation. 1994;90: 2891-2898

Aortic Valve Stenosis: AN “OLD” PATHOLOGY

- **Prevalence of AS** and comorbidities that increase the risk of surgical aortic valve replacement **increase with age³**
- Mortality for untreated, symptomatic severe AS is up to 50%-60% at 2 years in high risk patients⁴

1. Iung B, et al. *Eur Heart J*. 2003;24:1231-1243.

2. Background: Severe Aortic Stenosis. Detroit Medical Center Cardiovascular Institute Web site. <http://www.dmccvi.org/aortic>. Accessed 7/13/11.

3. Iung B, et al. *Eur Heart J*. 2005;26:2714-2720.

4. Spaccarotella C, et al. *Circ J*. 2010;75:11-19.

Aortic Valve Stenosis: AN “OLD” PATHOLOGY

- SAVR is the gold standard for treatment of severe AS¹
- **However, 33% of all patients ≥ 75 years of age with severe AS are declined for surgery²**
 - Of these patients who ultimately undergo SAVR, a portion are at high risk for morbidity/mortality from the procedure

SAVR=surgical aortic valve replacement.

1. Bagur R, et al. *Eur Heart J*. 2010;31:865-874.

2. Iung B, et al. *Eur Heart J*. 2005;26:2714-2720.

Aortic Valve Stenosis: AN OLD PATHOLOGY

Ballon Aortic Valvuloplasty (BAV)

...for improving the quality of life for elderly patients in whom a surgical alternative is a poor or unacceptable option

- 1950' s Intraoperative dilatation for valve conservation
- 1982 Pulmonary Valve in Children (Kan; Pepine)
- 1983 Hypoplastic PV and PA' s – Lock
- Coarctation – Lock
- 1984 Aortic stenosis in Children – Lababidi
- 1985 Acquired Aortic stenosis in 3 pts– Cribier
- 1987 Aortic stenosis in Children - Choy
- 1987 Cribier - 92pts and Block - 55pts
- 1986 Mansfield Registry
- 1987 NHLBI Registry

Aortic Valve Stenosis: AN OLD PATHOLOGY

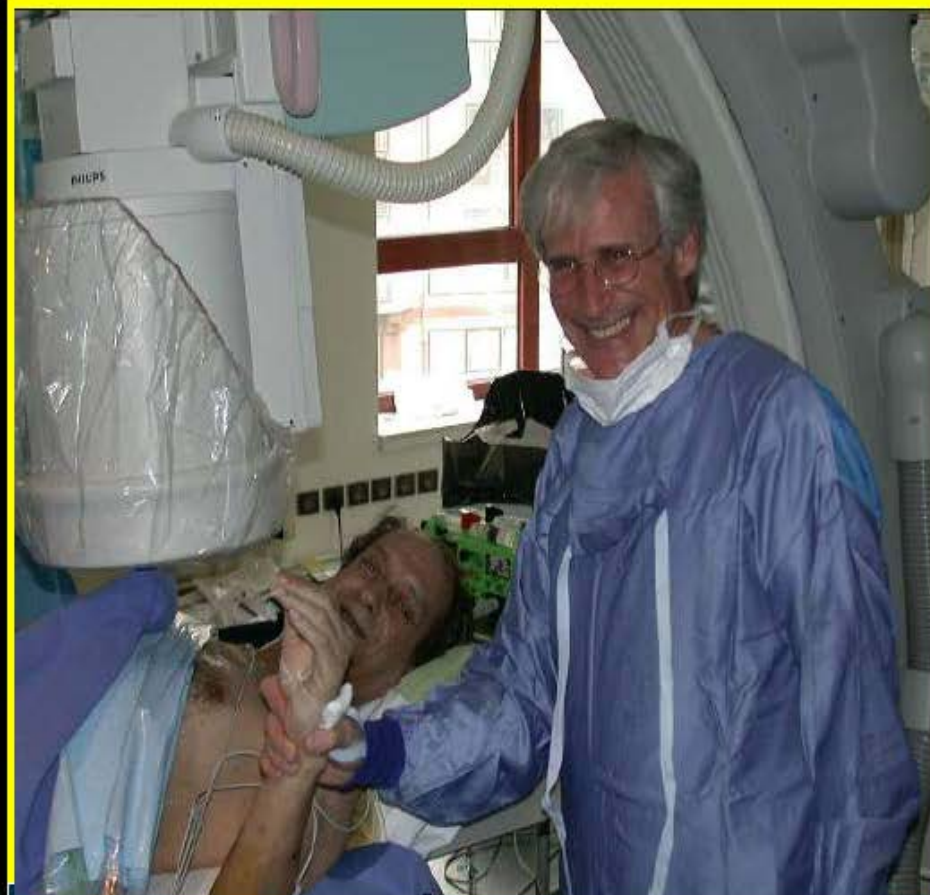
BAV Failure

Recommendations for Aortic Balloon Valvoplasty in Adults With Aortic Stenosis

Bonow et al. 1998 ACC/AHA Task Force

| Indication | Class |
|---|--------------|
| | I |
| A bridge to surgery in hemodynamically unstable patients who are at high risk for AVR | IIa |
| Palliation in patients with serious comorbid conditions | IIb |
| Patients who require urgent non cardiac surgery | IIb |
| As an alternative to AVR | III |

Rouen, April 16, 2002: F.I.M THV implantation Trans-septal approach



30 min post-implantation



8 days post-implantation

Aortic Valve Stenosis NEW TECHNOLOGY

Trascatheter

Aortic

Valve

Implantation



Medtronic CoreValve



Edwards Lifesciences

Aortic Valve Stenosis

NEW TECHNOLOGY

Aortic Valve Stenosis

NEW TECHNOLOGY

Evolution of existing valves

New valves

New approaches

Bicuspid valves

Prosthetic valve

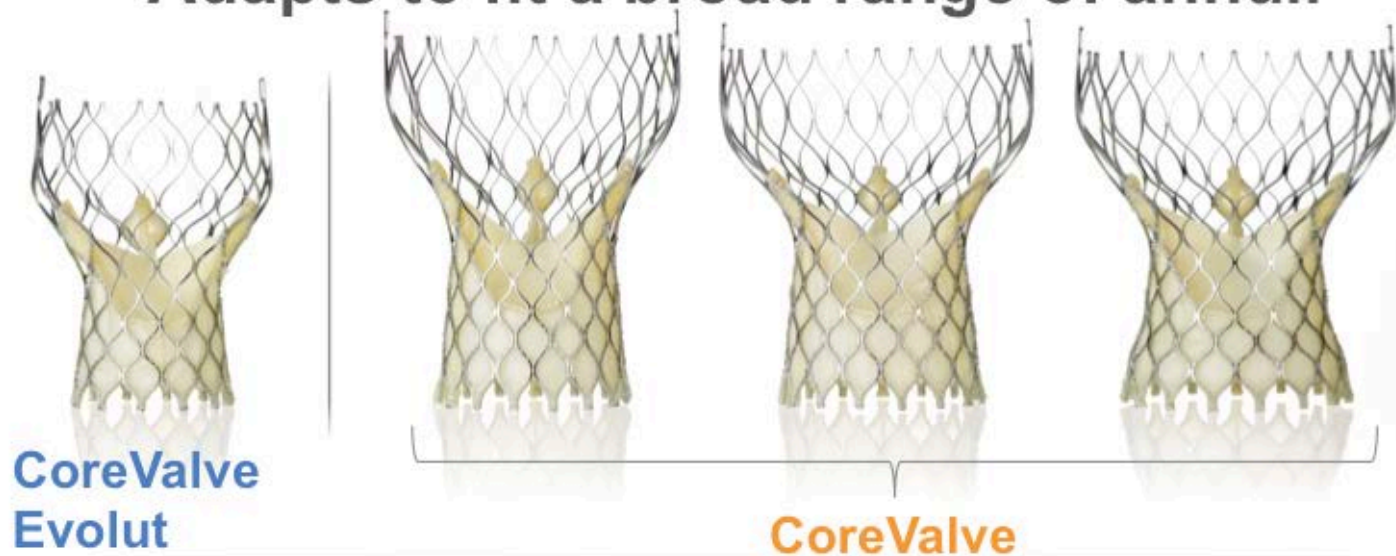
Intermediate risk patients

Imaging technology

hybrid room

Aortic Valve Stenosis: NEW TECHNOLOGY

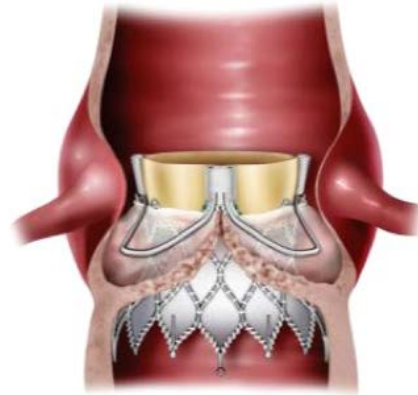
Adapts to fit a broad range of annuli



Aortic Valve Stenosis: NEW TECHNOLOGY

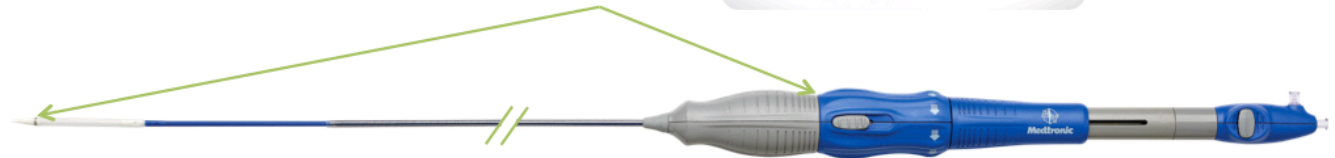


Engager



TRANSAPICAL AND
DIRECT AORTIC

- 1 **Enables predictable deployment** through an intuitive handle with 1:1 response and improved valve release



- 2 **Enhances insertion and tracking** via a low profile, 18Fr catheter with hydrophilic coating
- 3 **Facilitates delivery** with an optional shorter-length catheter for subclavian and direct aortic access
- 4 **Resheath & Reposition**



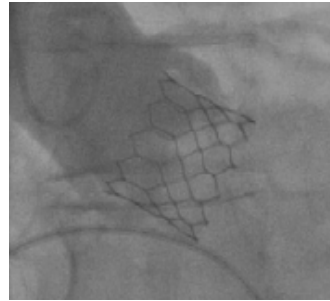
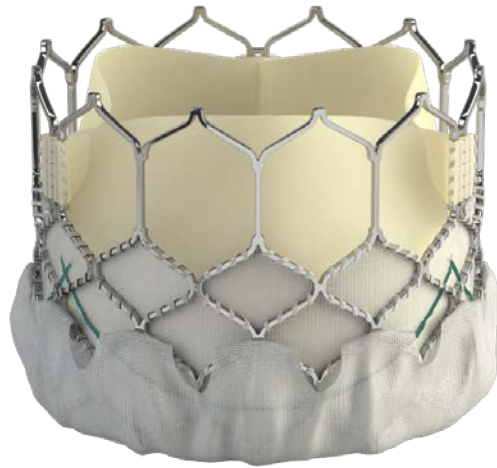
Edwards SAPIEN 3

Transcatheter Heart Valve

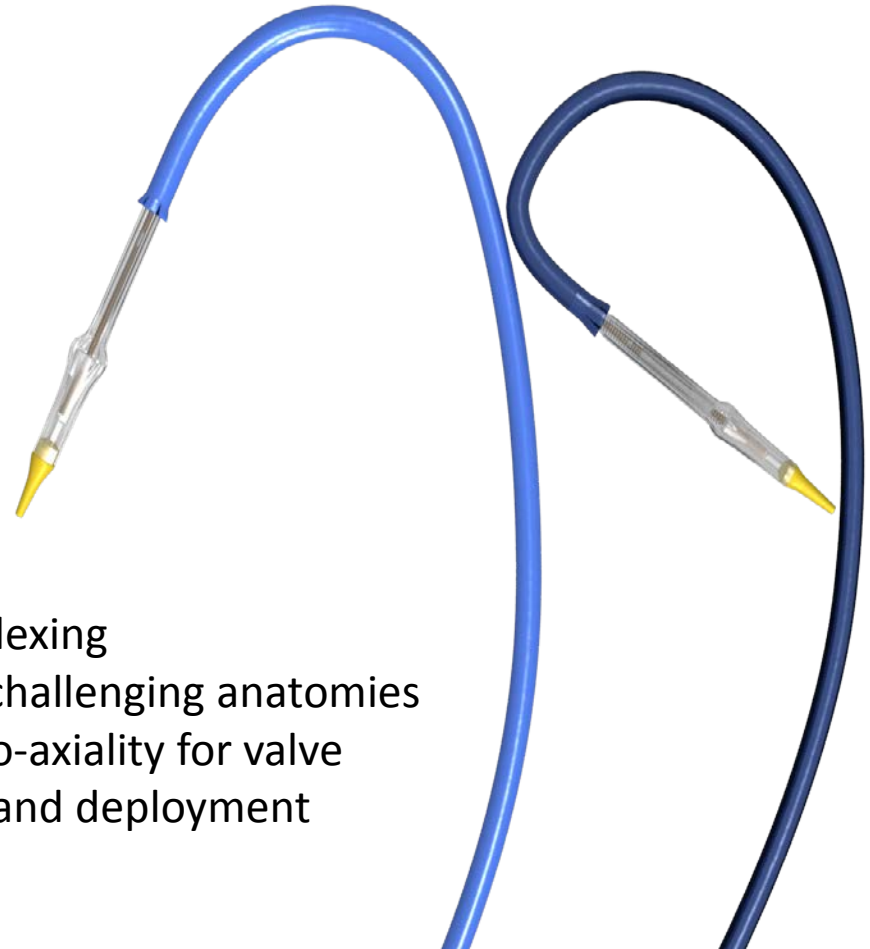
Commander Delivery System

Refined Flex Catheter

20, 23, 26 and 29 mm sizes



Improved distal flexing
Crossing in challenging anatomies
Control of co-axiality for valve
positioning and deployment



Balloon-expandable
Cobalt Chromium Frame
External Sealing Ring

The Edwards SAPIEN 3 is an investigational device and not available for commercial sale

NovaFlex+

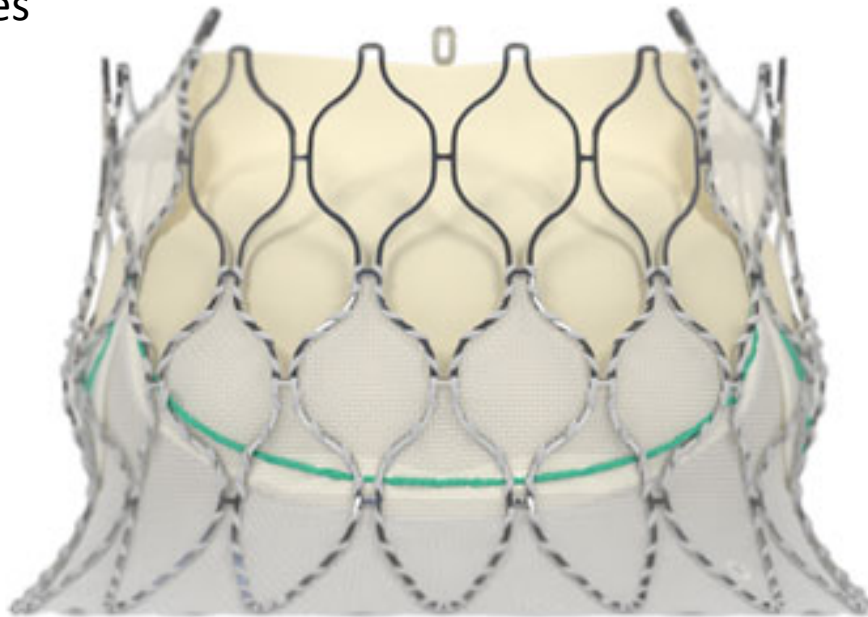
Commander

Edwards CENTERA

Transcatheter Heart Valve

23, 26 and 29mm sizes

Bovine Pericardial
Tissue Leaflets



Discrete Valve
Anchors in the Annulus

Self expanding
Nitinol Frame

LOTUS VALVE SYSTEM



DIRECT FLOW



JENA VALVE

FEELER GUIDED,
ANATOMICAL
POSITIONING

No rapid pacing required during
prosthesis release & maintains
hemodynamic flow during
prosthesis placement

WIDE RANGE
OF SIZES

3 sizes covering
annuli from
21 to 27 mm

RETRIEVABLE &
REPOSITIONABLE

Puts heart teams
in control



LOW PROFILE
PROSTHESIS
DESIGN

Ensures open flow
to coronaries

JENACLIP™
ANCHORING
MECHANISM

Provides active
fixation, resistance
to migration

PORTICO VALVE St Jude



Aortic Valve Stenosis: NEW TECHNOLOGY

- ✓ **Bicuspid aortic valve**
- ✓ **Prosthetic aortic valve “valve in valve”**
- ✓ **Intermediate risk patients**



Munich

Partner IIA

SURTAVI



Montreal

STS score

$\geq 4\%$

$\geq 4\% \leq 10\%$

**Coronary artery disease -
Syntax score**

$\leq 33\%$

$\leq 22\%$

Primary endpoint

Mortality & major
stroke at 2 years

Randomized arms

TF, TA, TAO

1:1 TAVI vs SAVR

TF, SC, TAO

Statistics

Non-inferiority, (Δ) 20%; $\alpha = 0.05$ and power = 80%

Sample size (n)

2000
(event rate 30%)

2500
(Bayesian Adaptive Design)

Location

US only
50 sites

Europe, US, Canada
75 sites

Current status

32 sites selected, 525
patients enrolled

30 European sites selected,
ongoing in US/Canada
2 centers enrolling in Europe

HEART TEAM

Cardiologist

Radiologist

Heart Surgeon

Geriatrist

Anaesthesiologist

Pulmonologist

Imaging specialist

Vascular surgeon

Nurses



RISK SCORES
COMORBIDITIES

Aortic Valve Stenosis: NEW TECHNOLOGY

THE HYBRID ROOM



Aortic Valve Stenosis: NEW TECHNOLOGY

THE HYBRID SUITE

Interventional disciplines

- Interventional radiology
- Interventional neuroradiology
- Interventional cardiology
- Interventional oncology



**More
complex**

Surgical disciplines

- Vascular surgery
- Cardio-thoracic surgery
- Neurosurgery
- Trauma/orthopedic surgery



**Less
invasive**

Define the clinical use of the Hybrid Suite

Typical disciplines and procedures in the Hybrid Suite

Vascular procedures

- EVAR (TEVAR, FEVAR and F-TEVAR)
- Below the knee, carotid stenting, visceral, and other peripheral vascular

Cardiac procedures

- TAVR
- Transcatheter Mitral Valve
- Other structural heart procedures
- PCI procedures
- Hybrid EP procedures
- Combined procedures

Neuro and spine procedures

- Minimally invasive surgical spinal fixation
- Kyphoplasty/vertebroplasty
- 3D navigated spinal instrumentation
- AVM treatment, stroke treatments, aneurysm clipping/coiling

Other applications

- Trauma surgery
- Thoracic surgery
- Orthopedic surgery
- Oncology procedures
- Urology procedures

New concepts

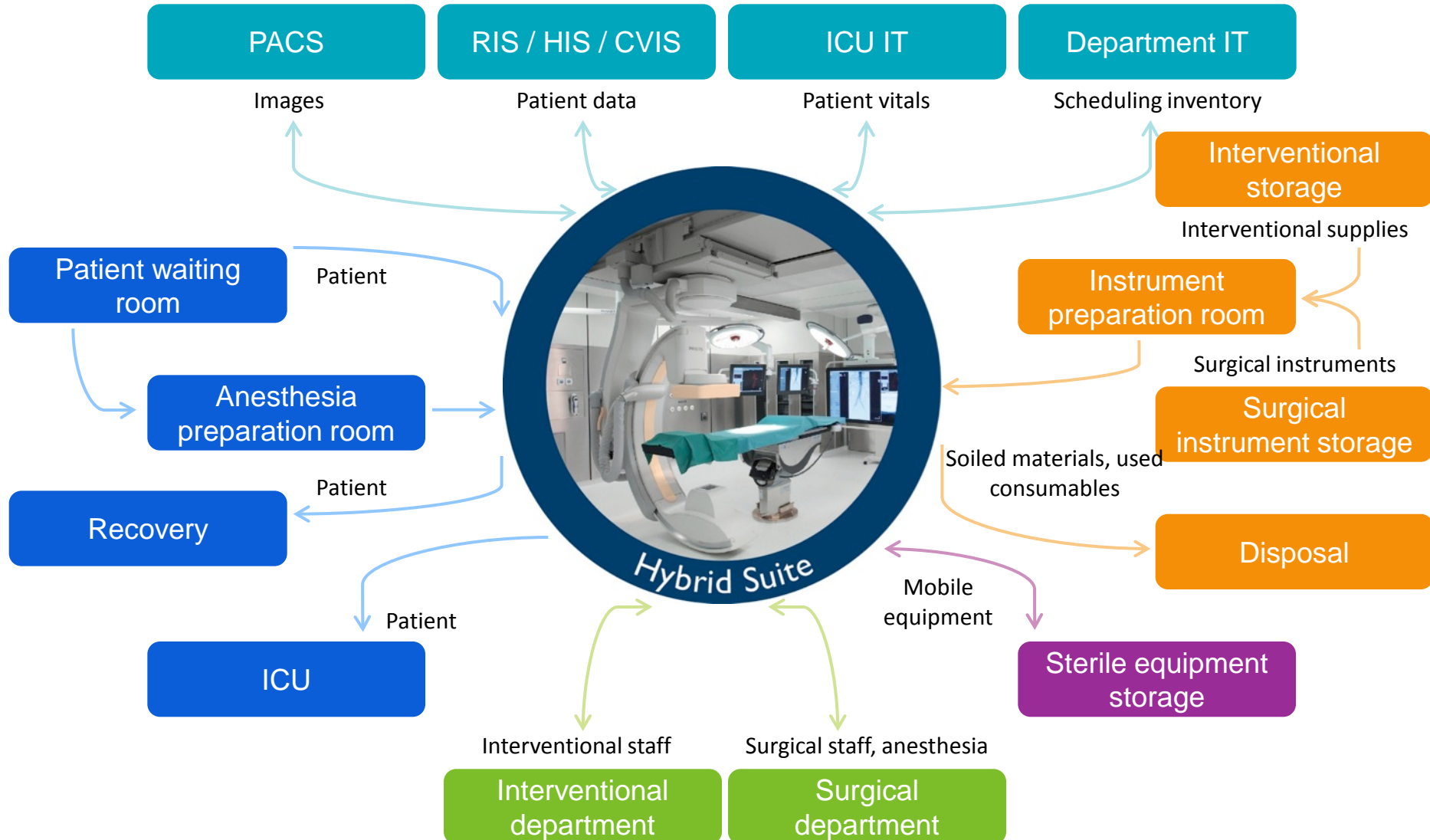
- Robotic Hybrid Suite
- MR OR
- CT OR

Mature

Developing

Pioneering

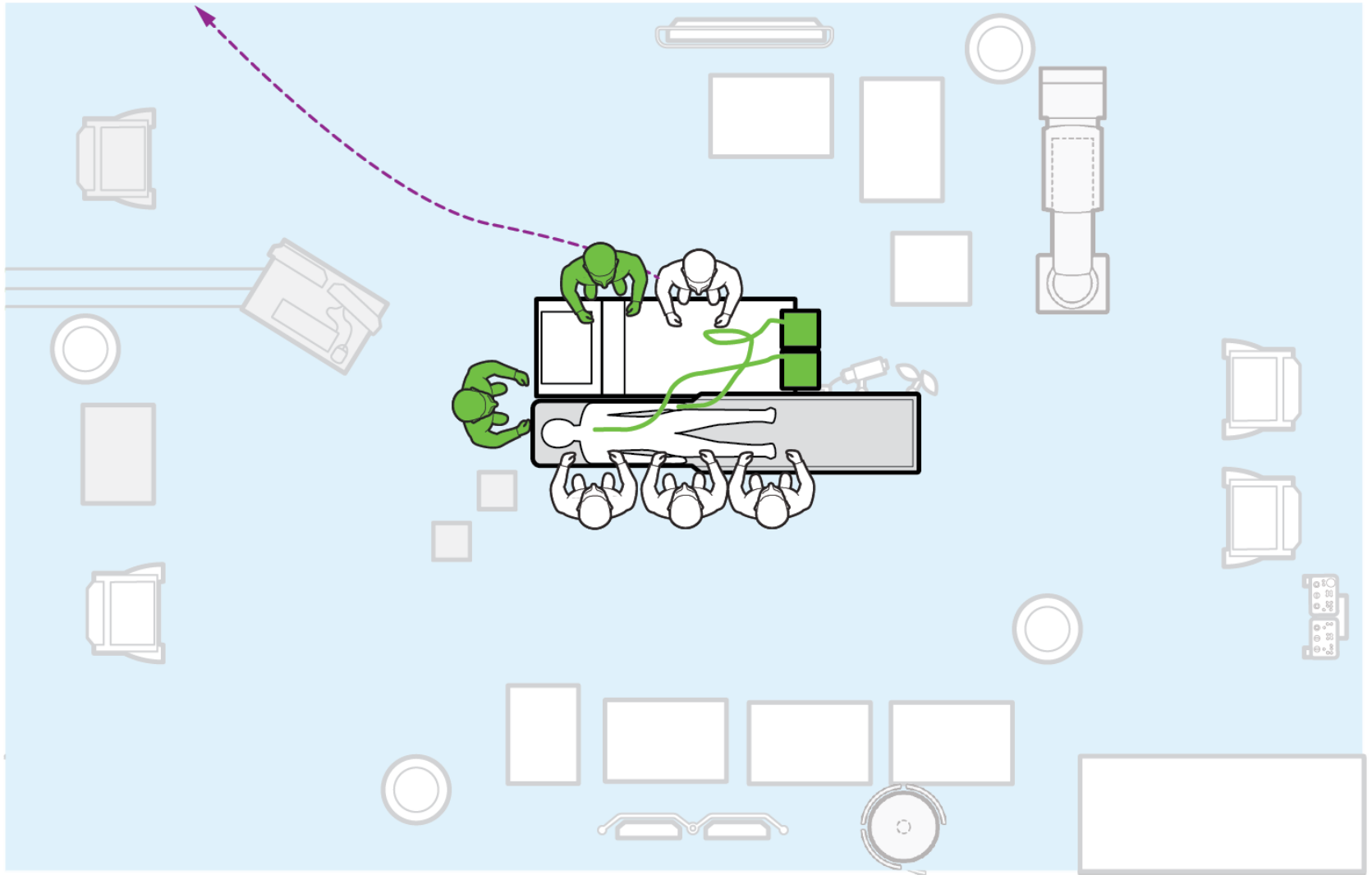
Define workflow and user requirements



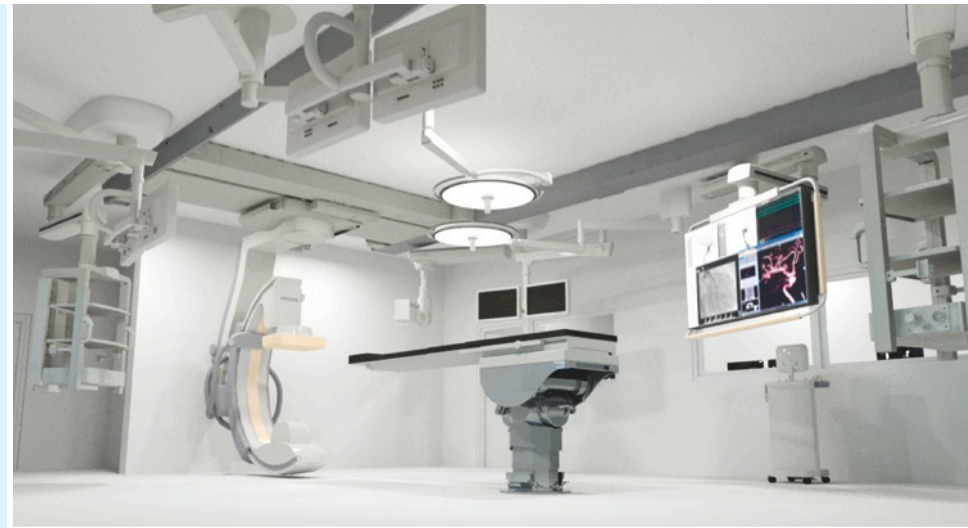
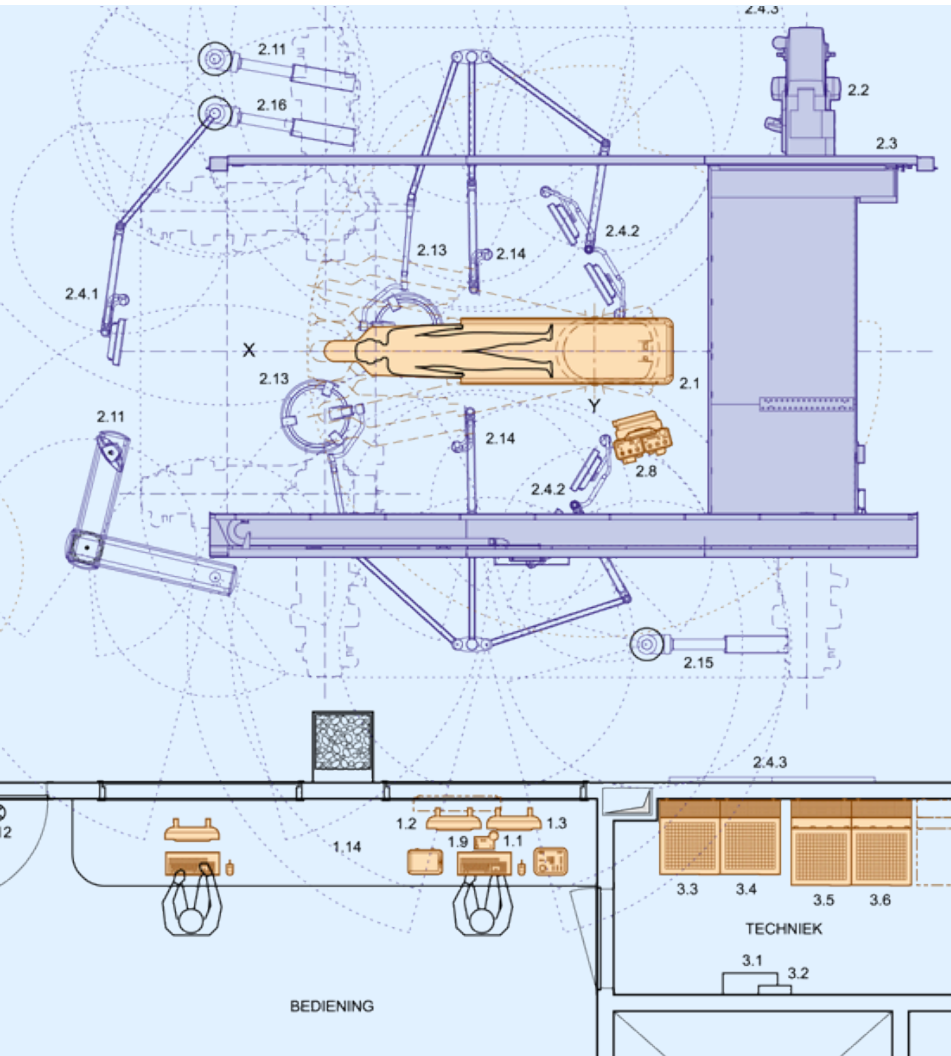
Define the imaging requirements

| Imaging requirements for procedures | | |
|---|--|--|
| Vascular | Cardiac | Neuro |
| 2D X-ray imaging <ul style="list-style-type: none"> • DSA • 2D roadmapping • Bolus Chase • Perfusion imaging | 2D X-ray imaging <ul style="list-style-type: none"> • Coronary angiography • Stent visualization | 2D X-ray imaging <ul style="list-style-type: none"> • DSA • 2D roadmapping • Perfusion imaging |
| Intra-procedural 3D X-ray imaging <ul style="list-style-type: none"> • 3D rotational angiography • Cone-beam CT (XperCT) | Intra-procedural 3D X-ray imaging <ul style="list-style-type: none"> • 3D coronary angiography • 3D rotational angiography of aorta | Intra-procedural 3D X-ray imaging <ul style="list-style-type: none"> • 3D rotational angiography • Cone-beam CT (XperCT) |
| Live 3D image guidance <ul style="list-style-type: none"> • Fusion of pre-procedural CT/MR or intraprocedural 3DRA images with fluoroscopy | Live3D image guidance <ul style="list-style-type: none"> • Fusion of pre-procedural CT with live fluoroscopy or live 3D TEE | Live 3D imaging guidance <ul style="list-style-type: none"> • Fusion of pre-procedural CT with fluoroscopy |
| Other imaging modalities <ul style="list-style-type: none"> • Ultrasound imaging • IVUS | Other imaging modalities <ul style="list-style-type: none"> • Live 3D echocardiography • IVUS • ICE • OCT • FFR | Other imaging modalities <ul style="list-style-type: none"> • Surgical microscopy |

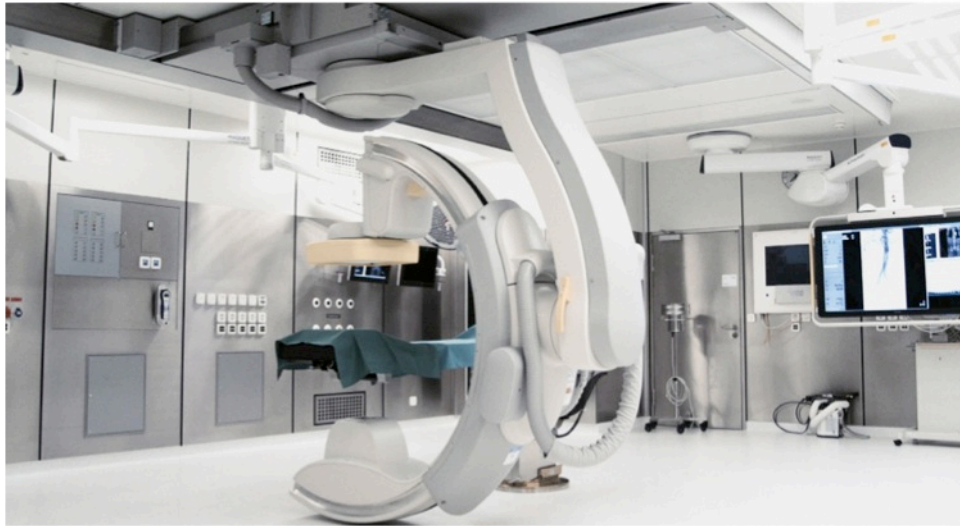
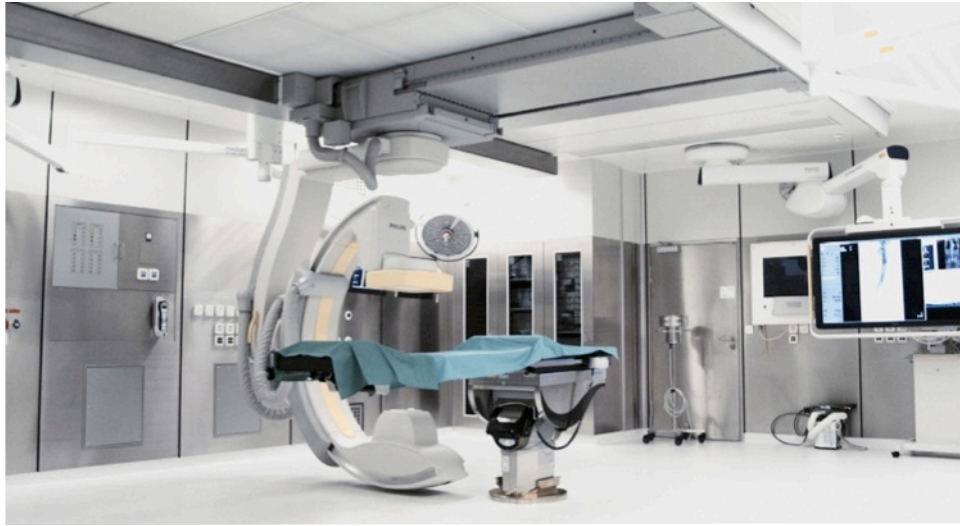
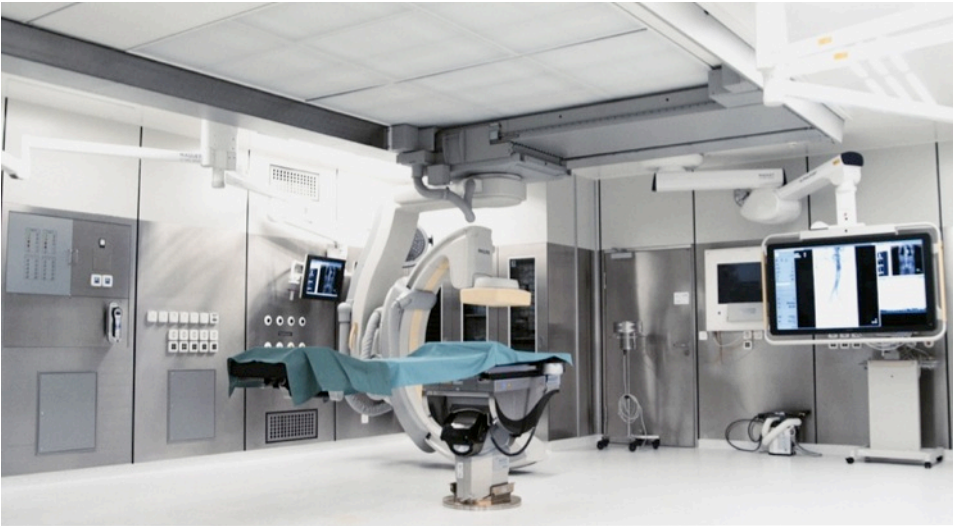
Consider all the equipment and workflows involved



Map out different options

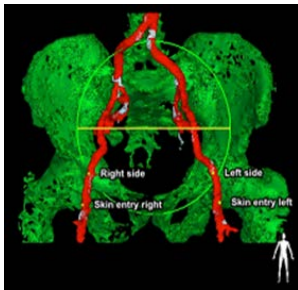


Making the working area flexible

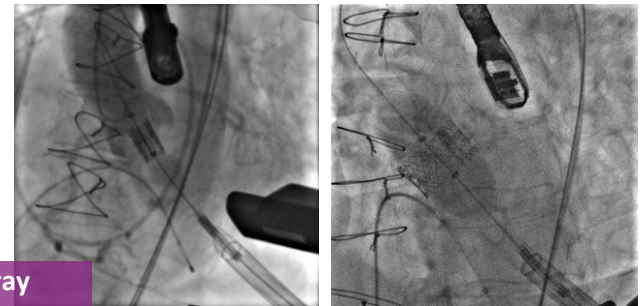
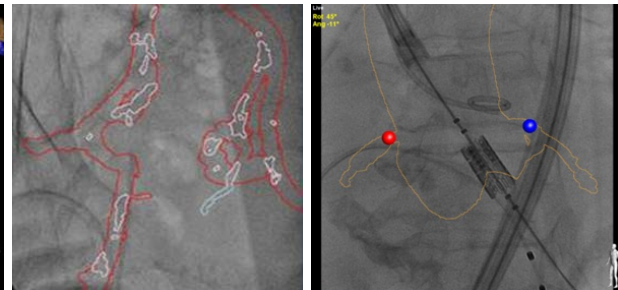
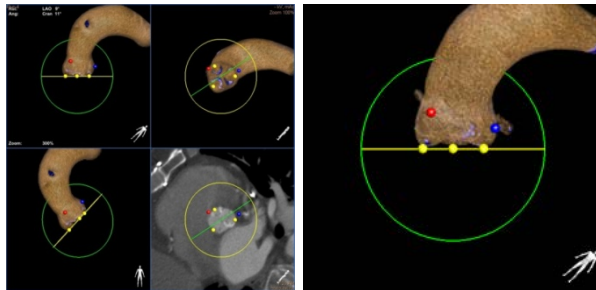


TAVR Image guidance

| Select Access | Plan Access | Select device | Size device | Plan X-ray views | Guided access | Device Positioning Deployment | Check regurgitation |
|---------------|-------------|---------------|-------------|------------------|---------------|----------------------------------|---------------------|
|---------------|-------------|---------------|-------------|------------------|---------------|----------------------------------|---------------------|



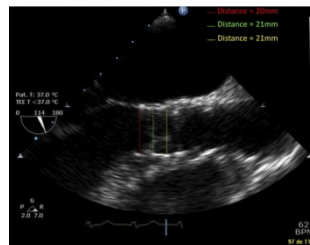
HeartNavigator



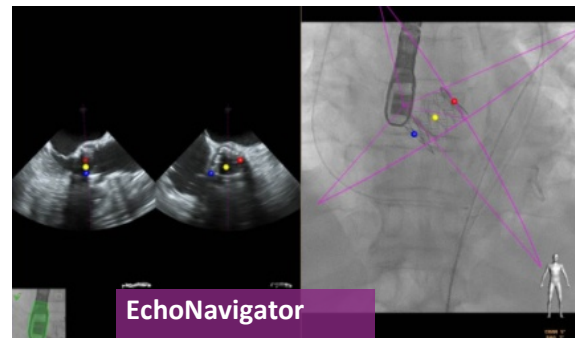
X-ray



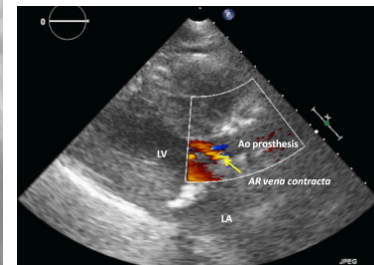
CT



Echo

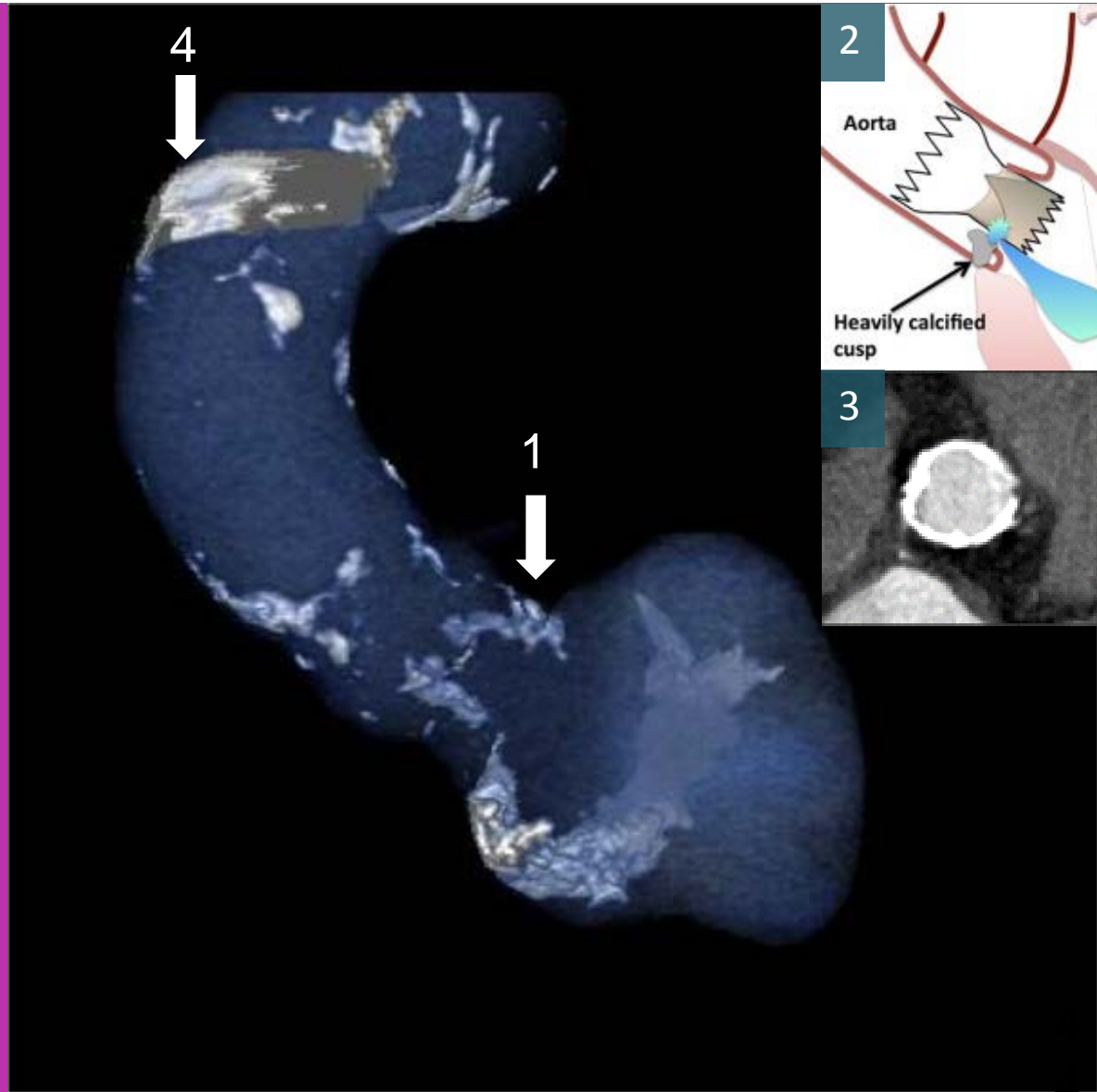


EchoNavigator

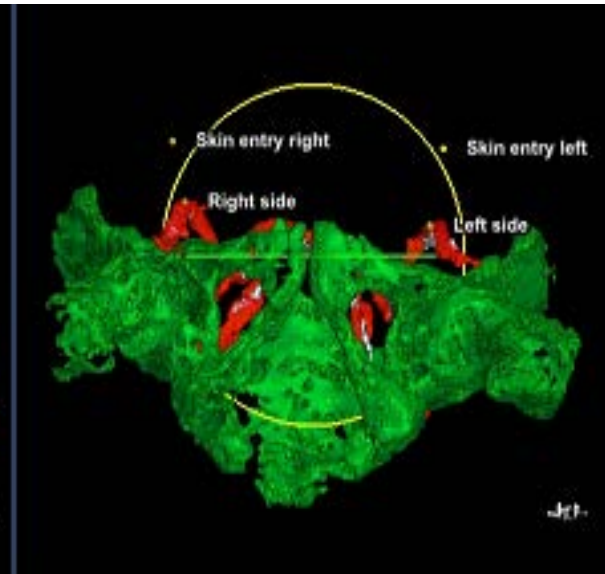
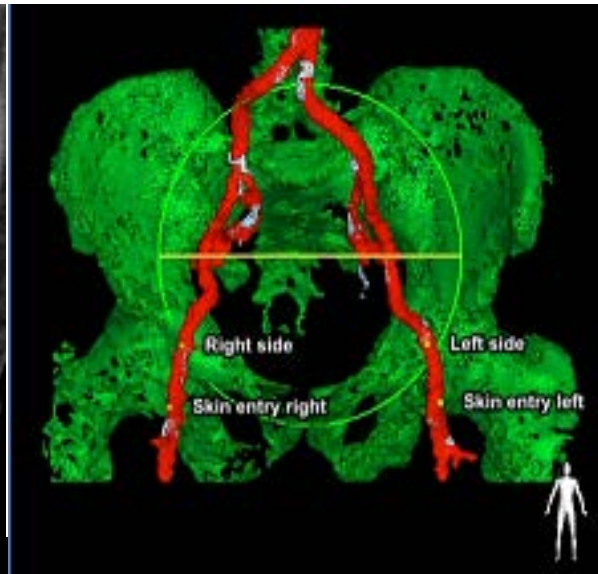
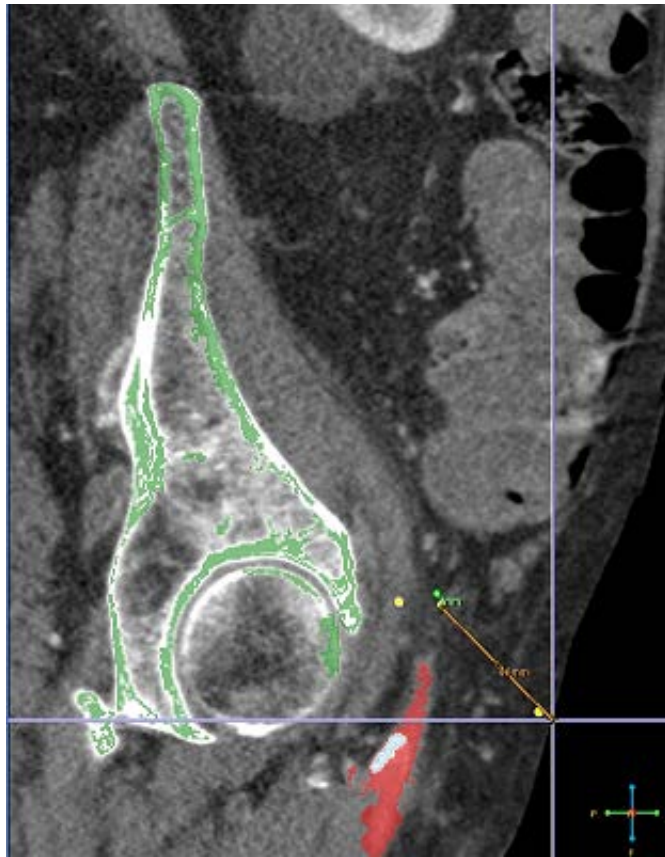


HeartNavigator with calcium visualization

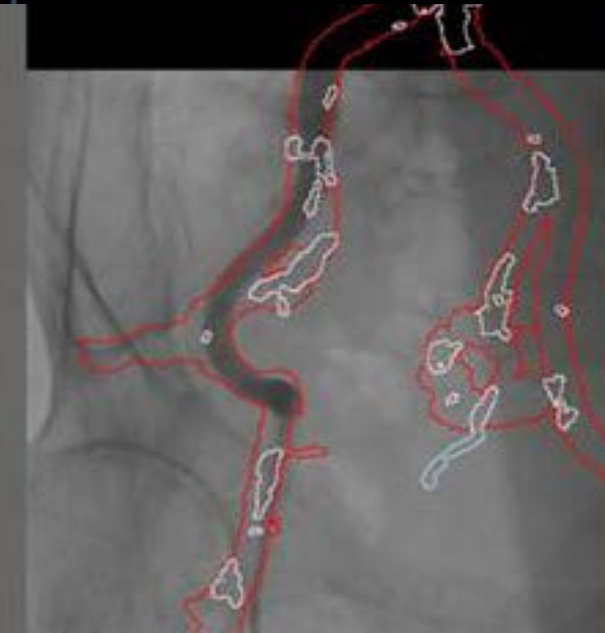
- Calcium in Left ventricular outflow tract¹ or on valve² → prevent full deployment of device and cause regurgitation
- Extensive annular calcification³ → risk of annular rupture with high radial forces
- Extensive calcium on valve leaflet → may block coronary ostia
- Calcium on aorta⁴ → need to work around for direct aortic access



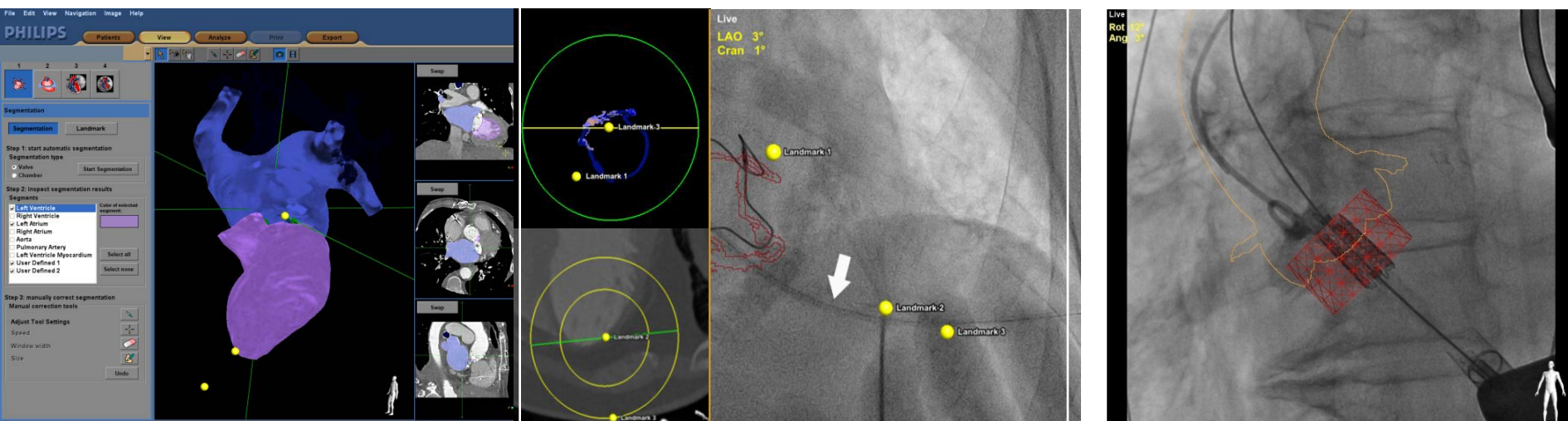
HeartNavigator Flexibility: Access Planning



“Ensure that calcifications are avoided during vessel puncture to reduce the risk of vascular access complications”



HeartNavigator paravalvular leak

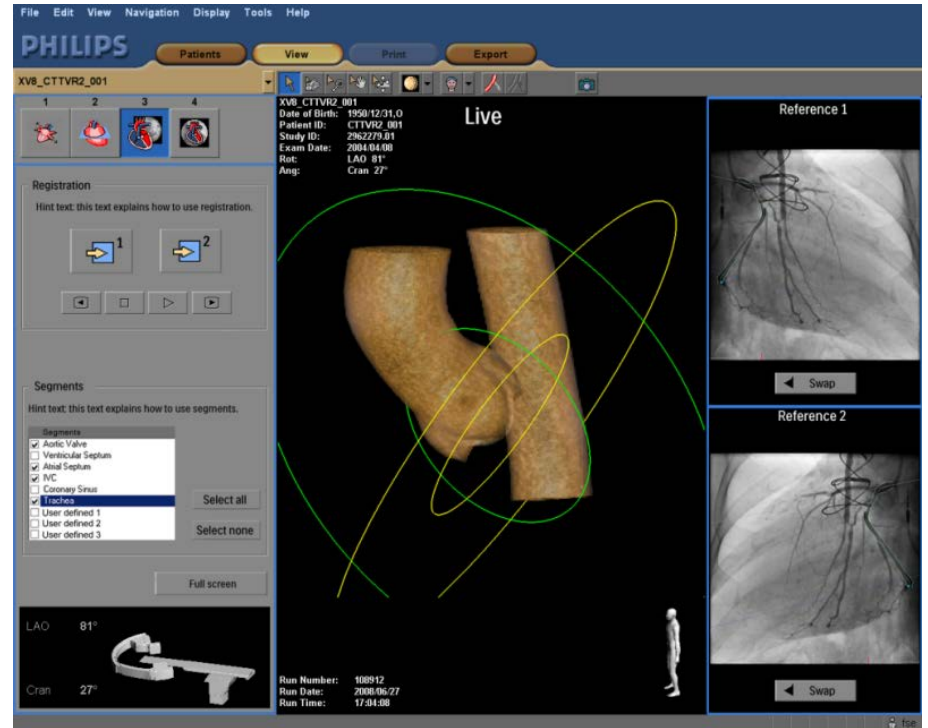
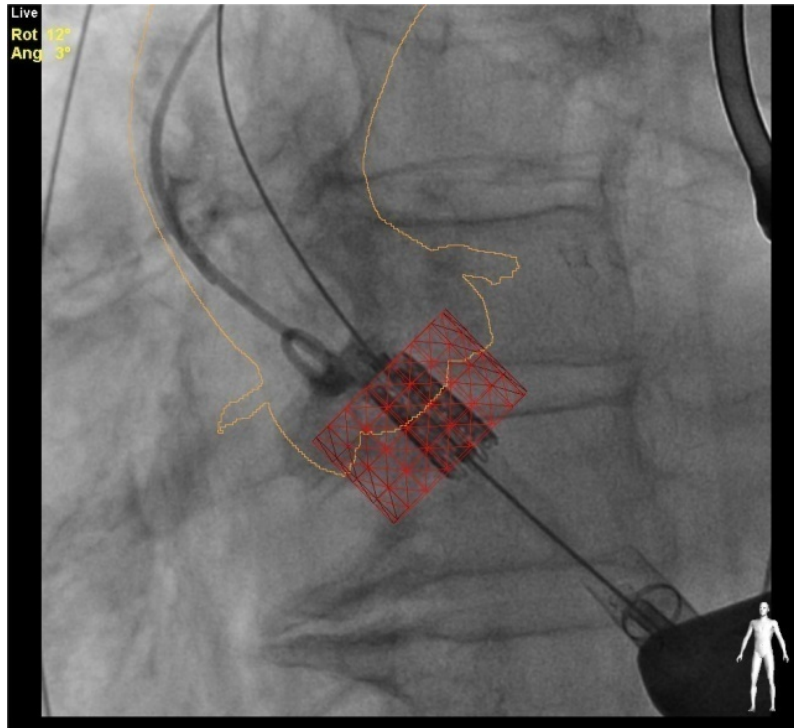


Automatic + manual segmentation

User defined landmarks

Live fluoro-CT fusion

HeartNavigator 3D image guidance for TAVI



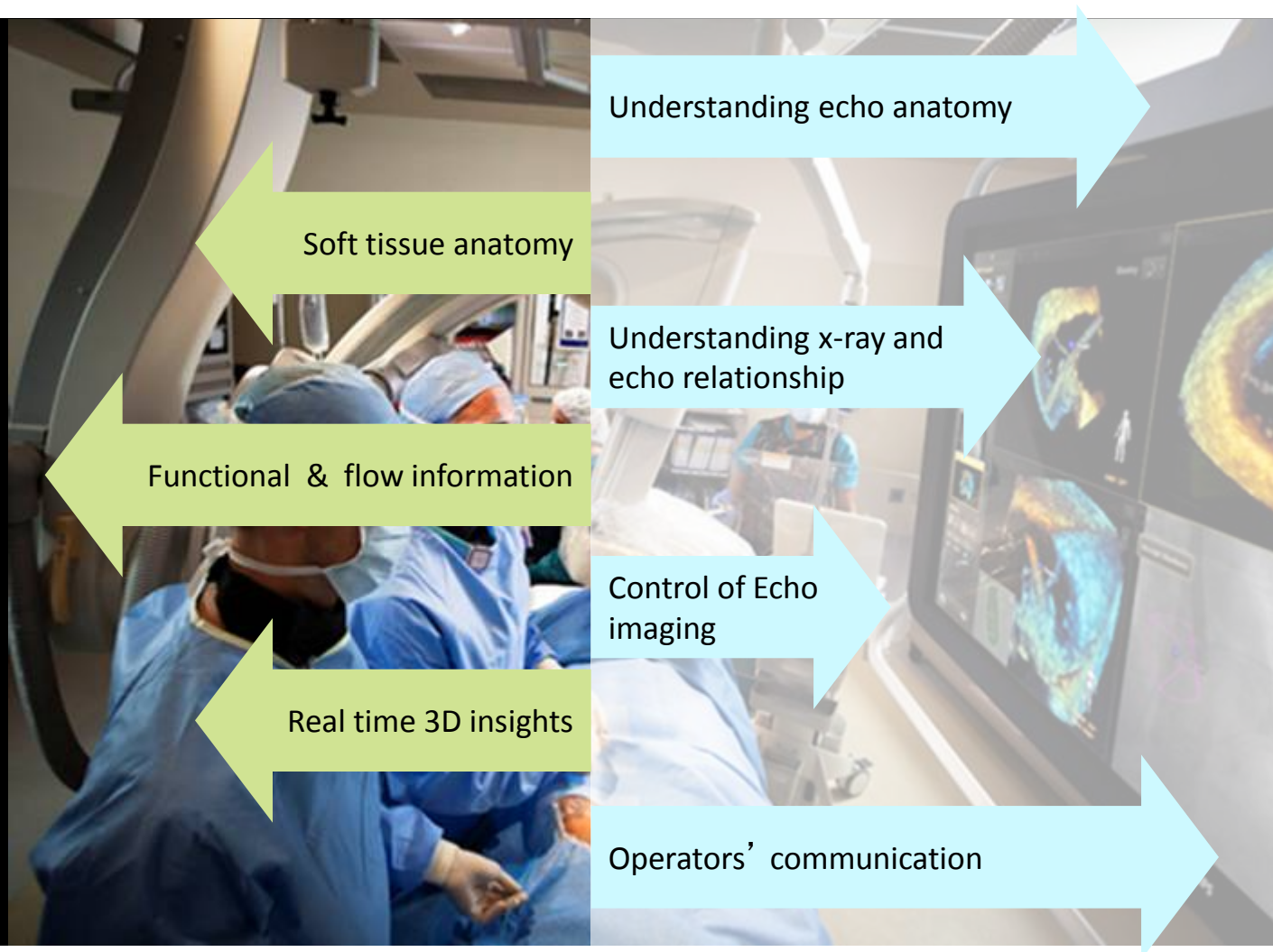
Today's cathlab scenario

Benefits and Challenges of Echo



Today's cathlab scenario

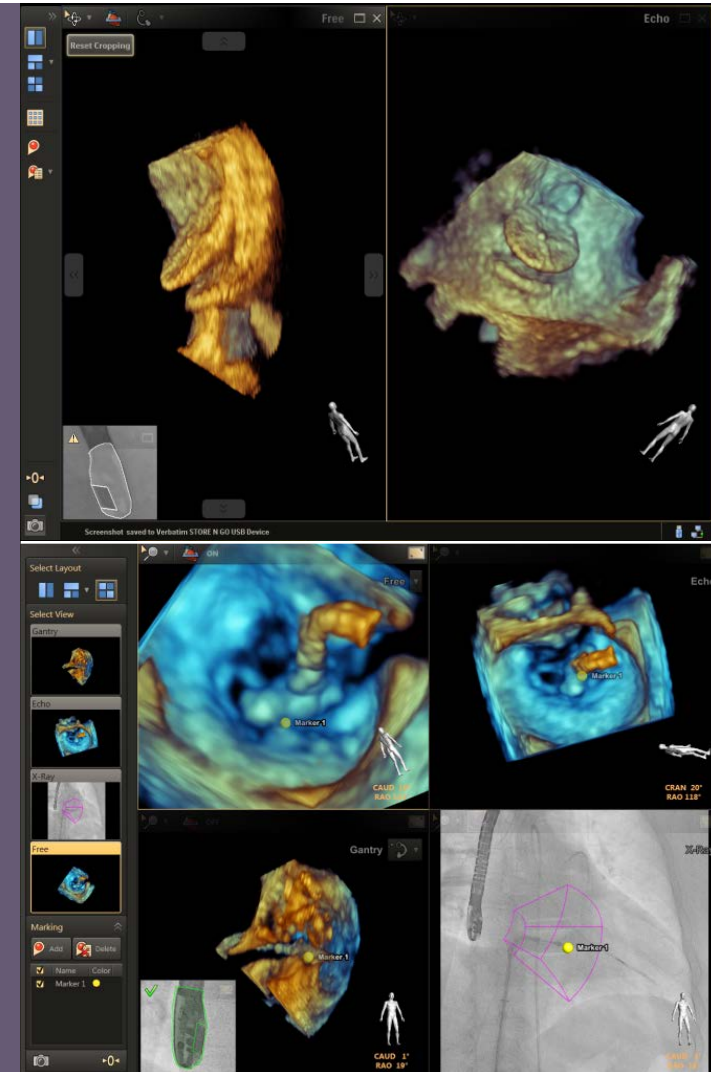
Benefits and Challenges of Echo



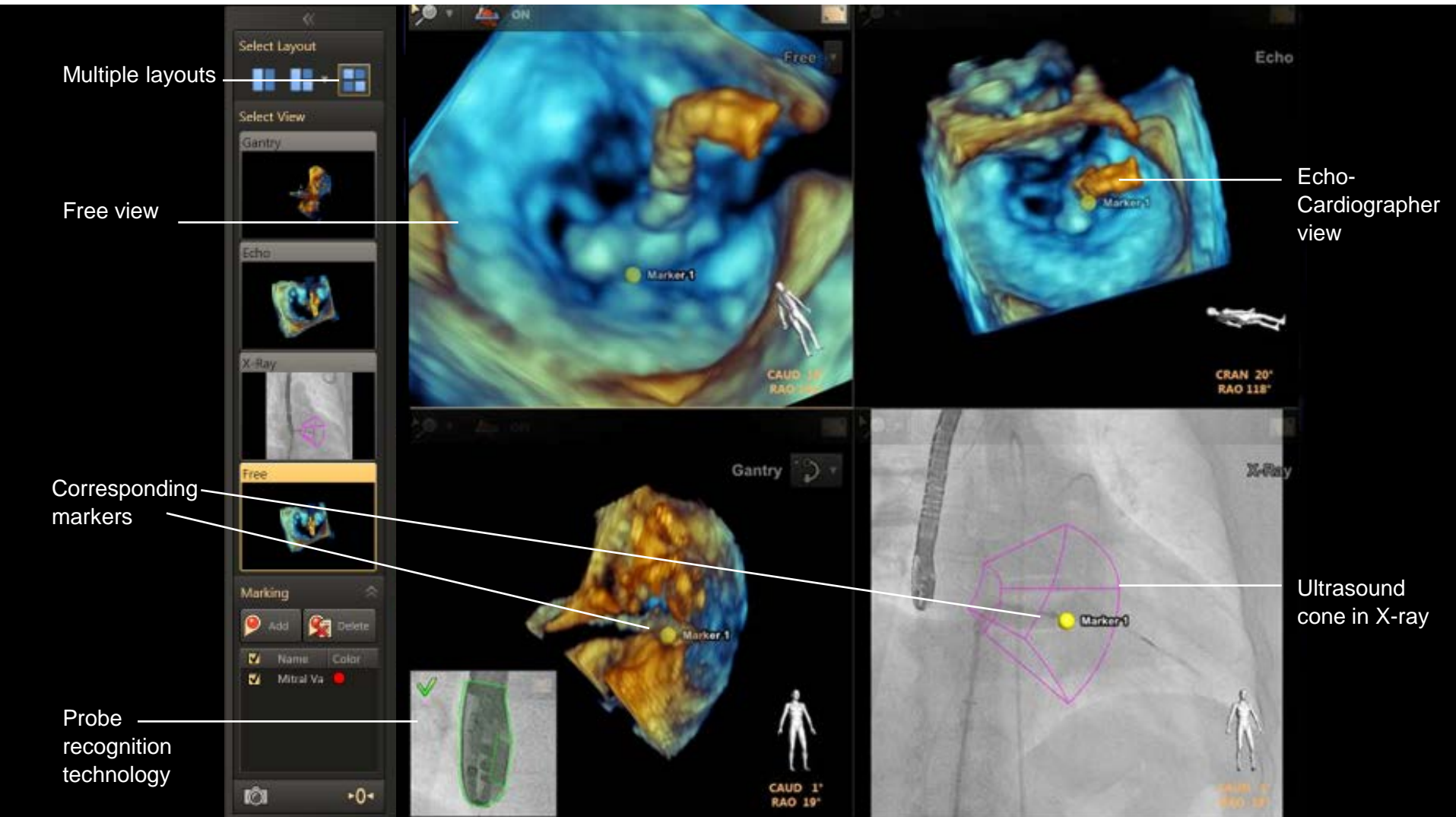
Applications

- Trans Aortic Valve Replacement*
- Mitral valve clipping
- Left Atrial Appendage (LAA) closure
- Paravalvular Leak (PVL)
- Pulmonary valve repair
- Septal closure (VSD, ASD)
- Patent Foramen Ovale (PFO) closure
- (Mitral) Valvuloplasty

**when 3D TEE Echo is used for guidance*



EchoNavigator



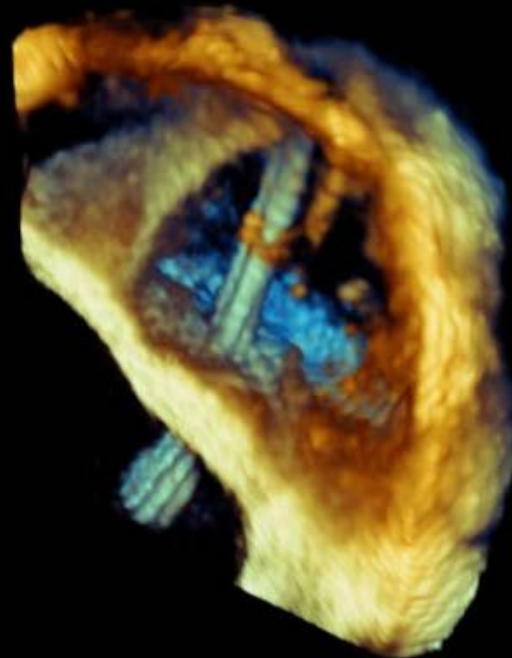
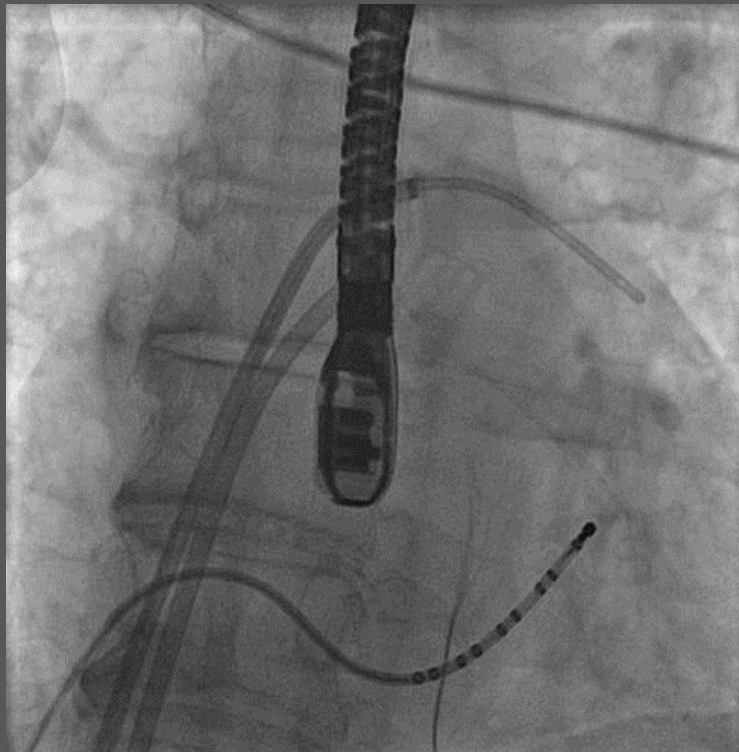
All EchoNavigator functions are unique

- TEE field of view (Ultrasound cone) visible as an outline in the X-ray view
- Automated and intuitive link between X-ray and Echo image orientation
- Echo image orientation automatically follows as the C-arm gantry is repositioned
- Mark soft tissue anatomical structure in Echo, appear in X-ray for context and guidance
- Quickly browse anatomy in the Echo data from the table side (e.g. change views, zoom)



EchoNavigator

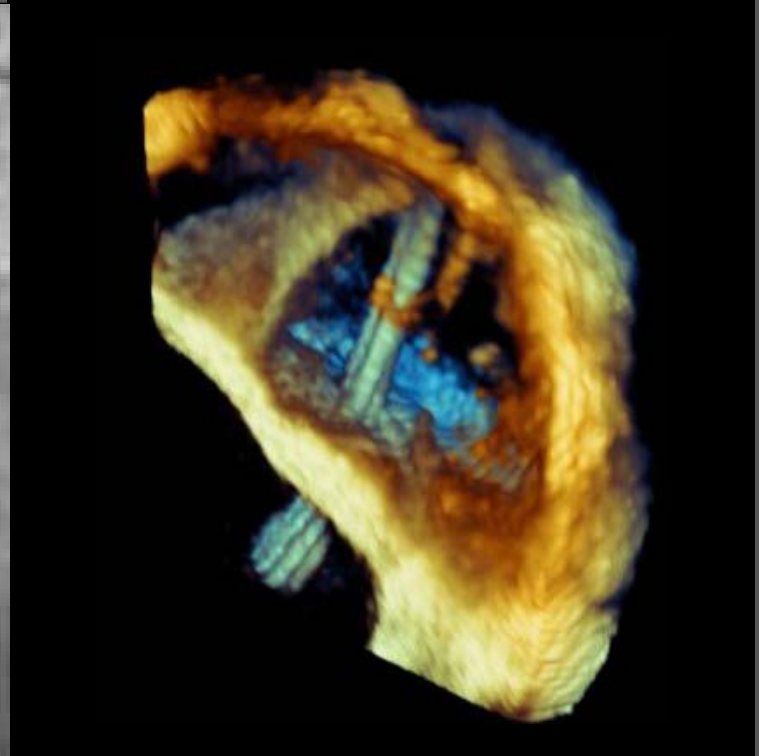
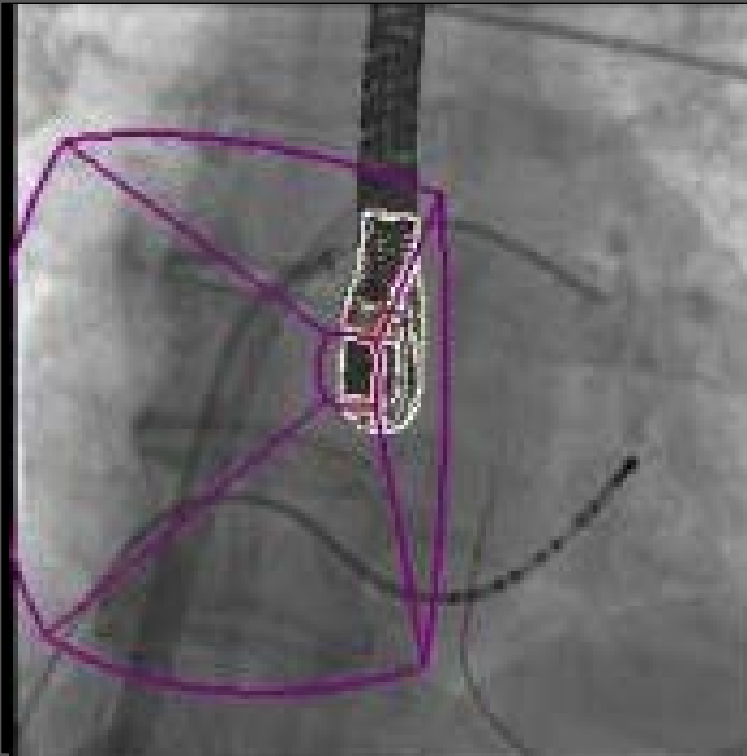
Key clinical functionality



EchoNavigator

Key clinical functionality

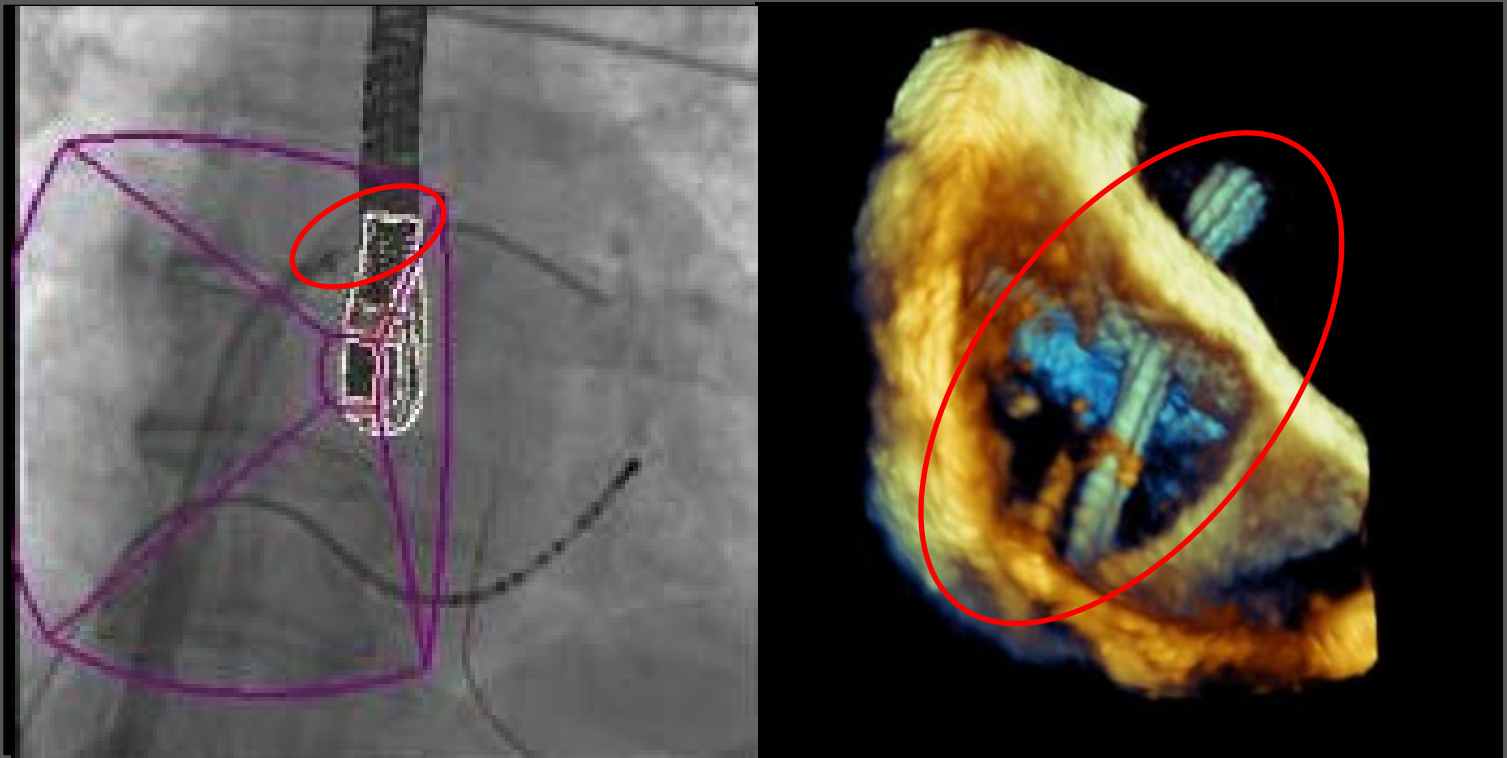
TEE field of view (Ultrasound cone) visible as an outline in the X-ray view.



EchoNavigator

Key clinical functionality

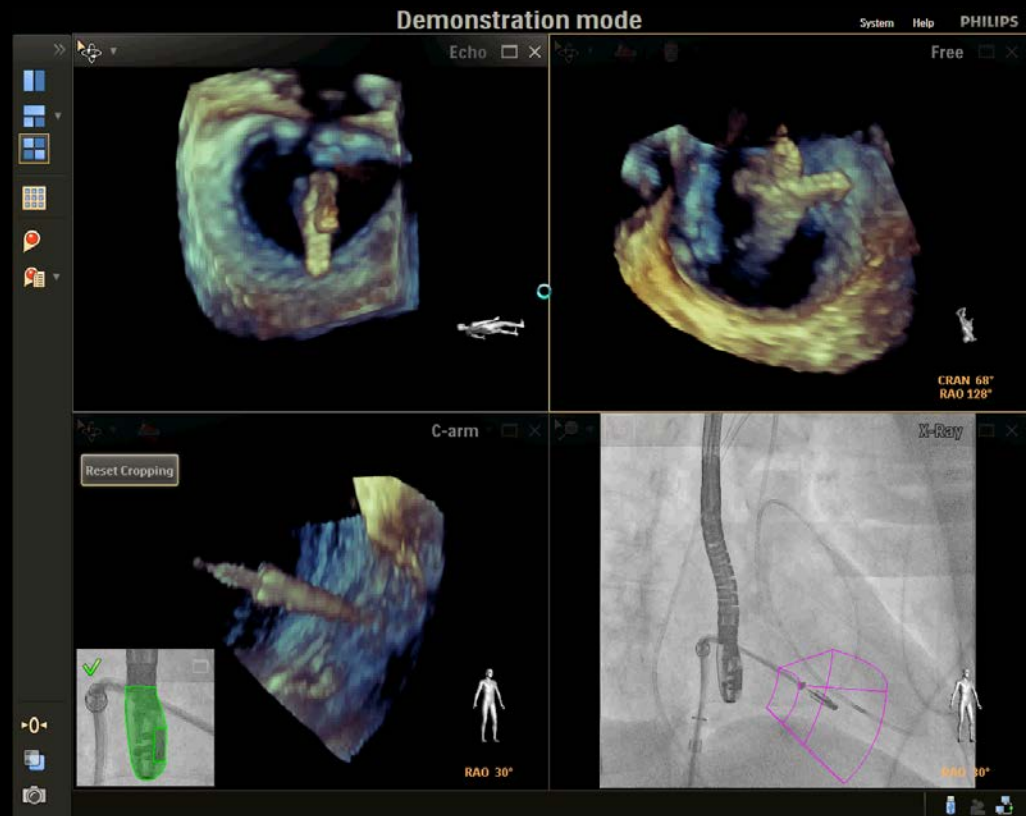
Automated and intuitive link between X-ray and Echo image orientation



EchoNavigator

Key clinical functionality

Quickly interrogate the anatomical structures (e.g. change views, zoom) in the Echo data from the table side



TAVI results depends :

- ✓ Heart Team experience in patients selection
- ✓ Experience of Echo. and Interv. Cardiologists,
Anesthesiologist, Cardiac surgeon, Vascular people
- ✓ Devices technologies
- ✓ Novel aortic imaging tools for more safe e fast procedures
- ✓ Echo heart navigation
- ✓ Acces site management
- ✓ Avoid procedurs in too sick patients

OUR INTENTION OF TREATMENT

TO PROLONG SURVIVAL IN OUR POPULATION ?

TO IMPROVE THE QUALITY OF LIFE IN OUR OLDER ELDERLY ?

TO REDUCE HOSPITAL ADMISSIONS IN THOSE VERY SICK PEOPLE ?

OR

TO IMPROVE QUALITY OF LIFE AND SURVIVAL IN ALL PATIENTS WHEN THIS TREATMENT IS FEASIBLE BY A HEART TEAM APPROACH

