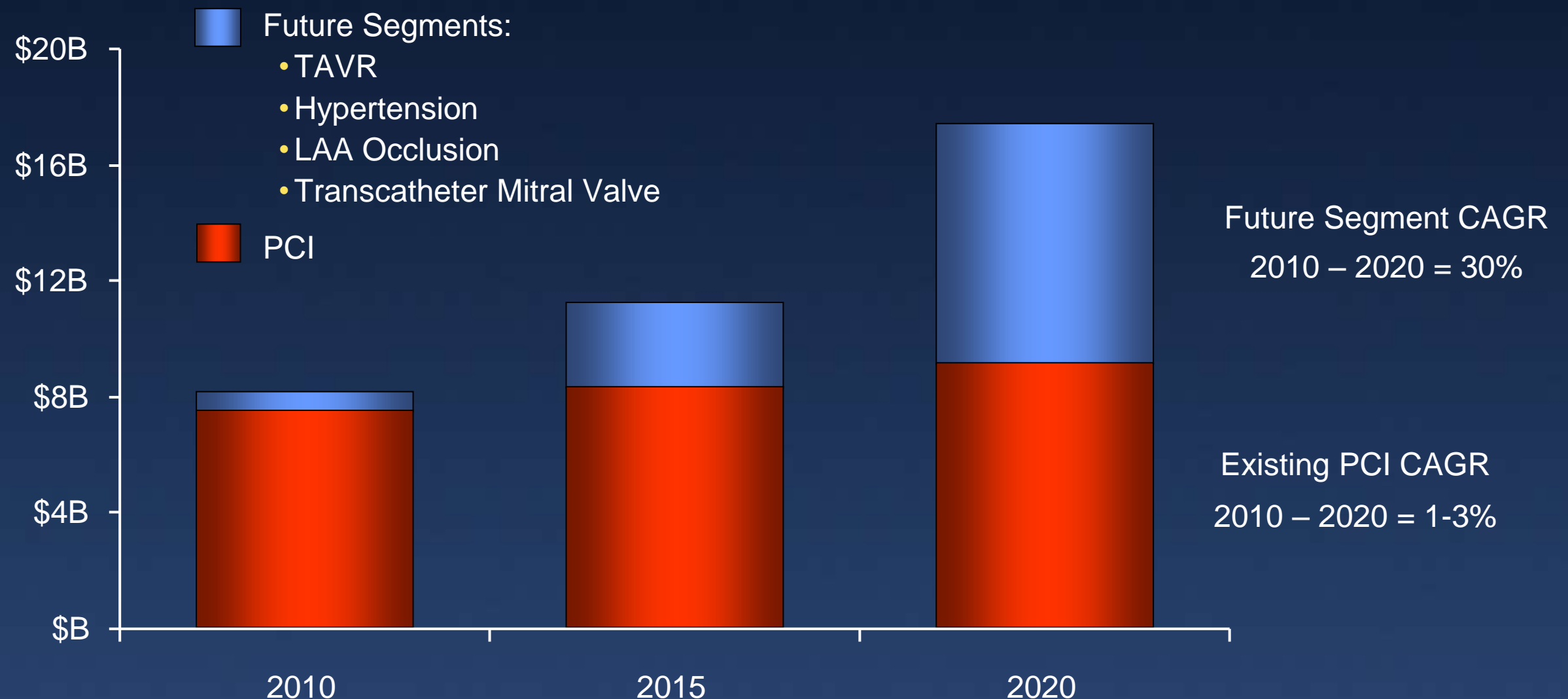


Introduction of the **Navigator system** for successful structural heart disease procedure

Seung Hoon Lee RT

**Cardiovascular center, Seoul St. Mary's Hospital
The Catholic University of Korea**

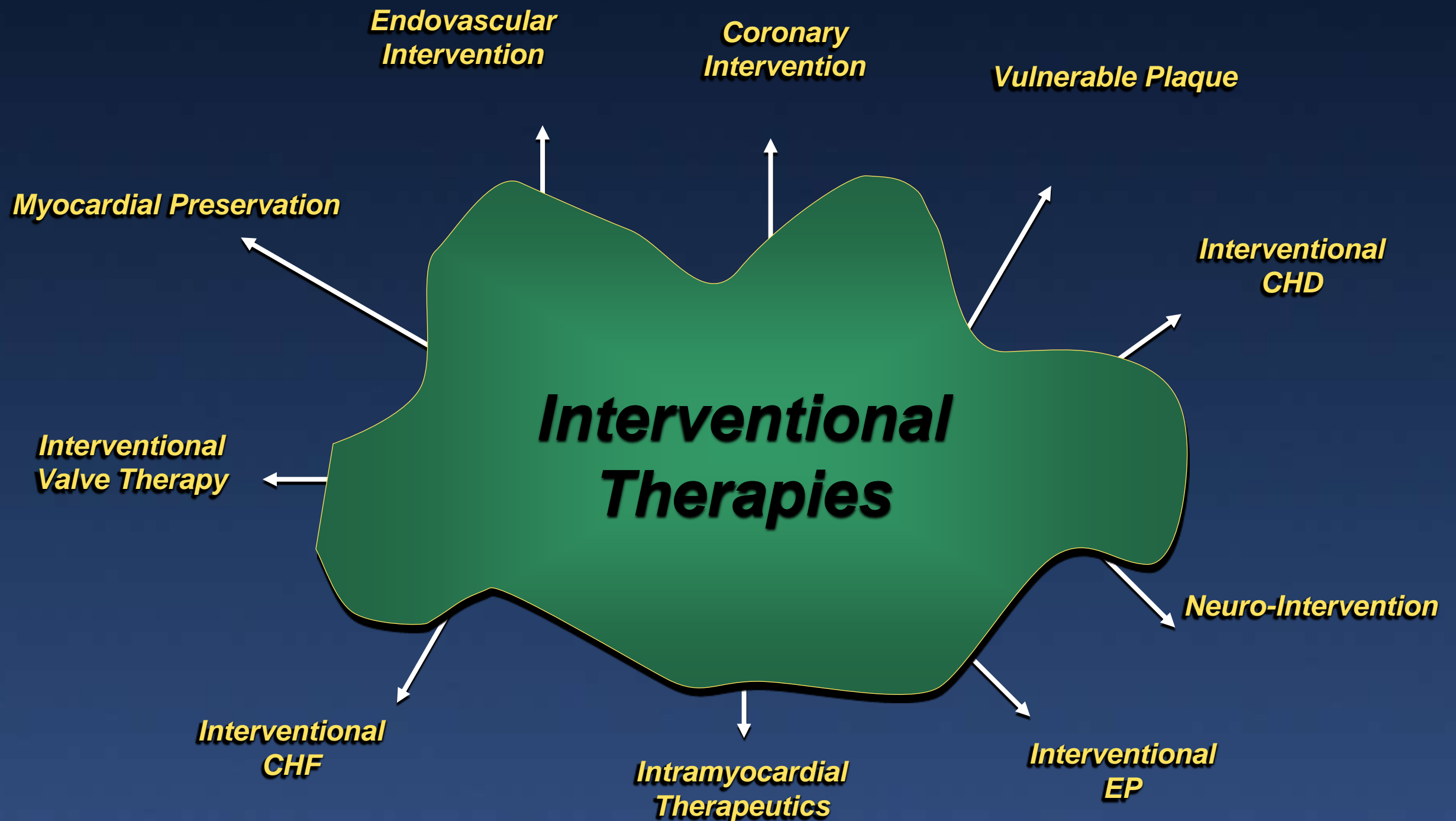
WW Cardiology Market Trends



- New market segments may exceed PCI market size by 2020
- Emergence of future segments relies on technology and clinical data
- OUS markets will lead and exceed the size of US markets

Source: Industry, May 2011

Blue Ocean in Cardiology



Blue Ocean in Cardiology

Aortic Valve for TAVI

AS is the most prevalent valve disease.
Prevalence of AS and comorbidities increased with age.
Mortality of symptomatic severe AS is 50-60% at 2 years.



Edwards Sapien Valve:
Balloon-expandable



Medtronic Core Valve :
Self-expandable



Case# 2013.07.06 F/75

Transcatheter LAA Occlusion

35% of patients with AF have stroke in their lifetime!!

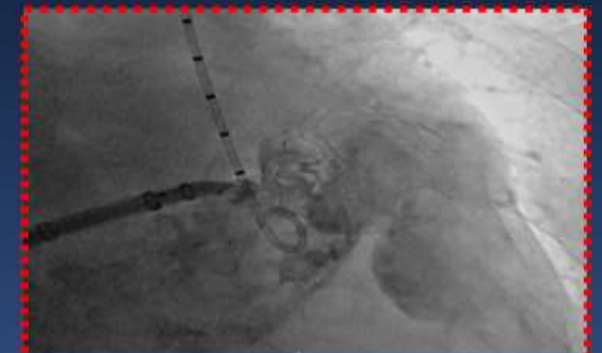
→ **LA appendage** : 90% of thromboembolic source in non-rheumatic AF
Warfarin: A cornerstone of stroke prevention
However, warfarin is not always tolerable.



Watchman (Boston Scientific)



Amplatzer Cardiac Plug (SJM)

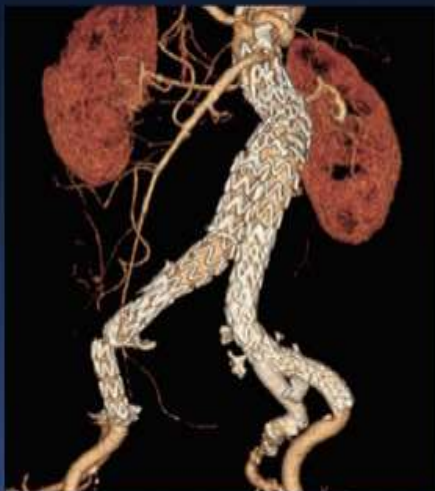


Case# 2012.11.22 F/84

EVAR

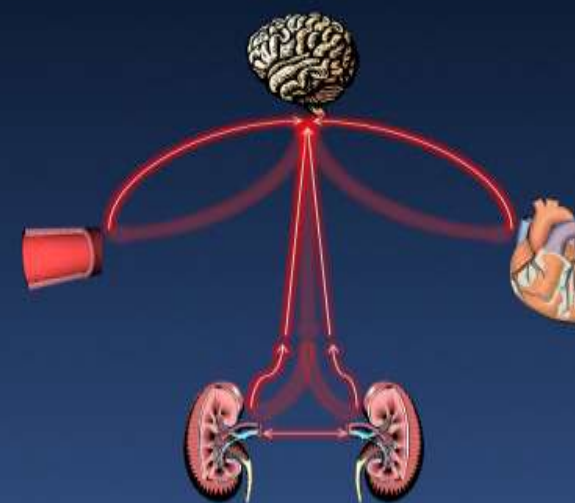


Aorfix (Lombard Medical)



Case# 2013.10.22 F/82

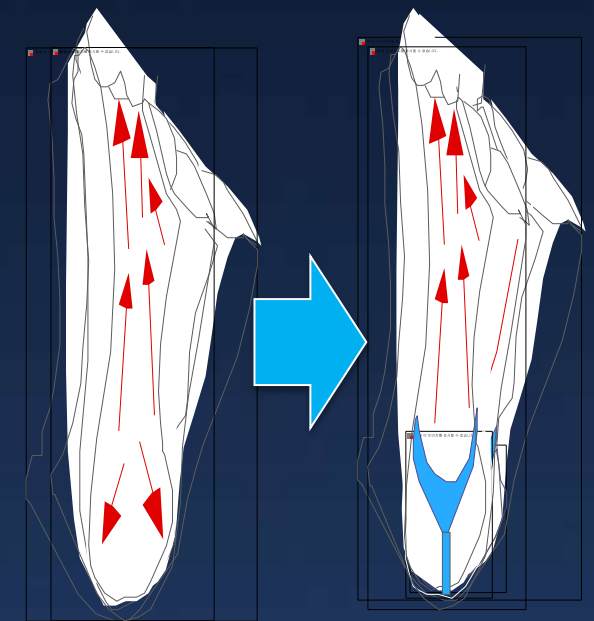
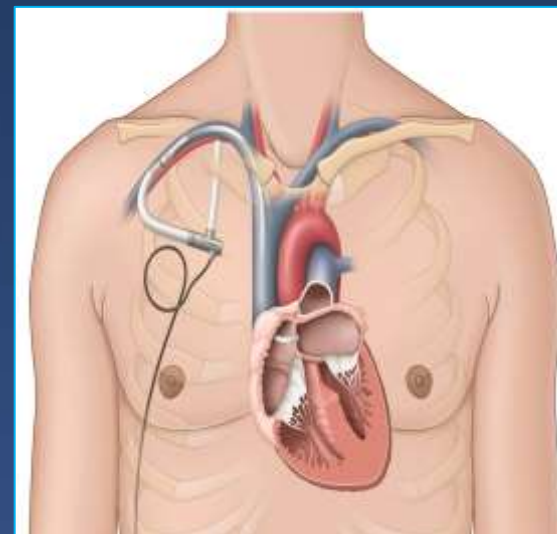
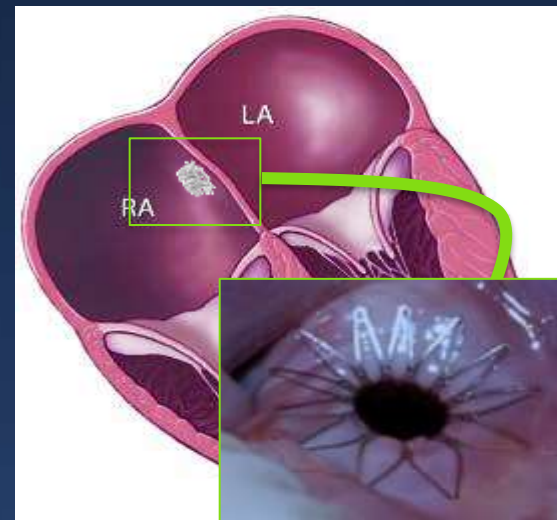
RDN



Case# 2012.05.02 M/69

New CHF Therapies

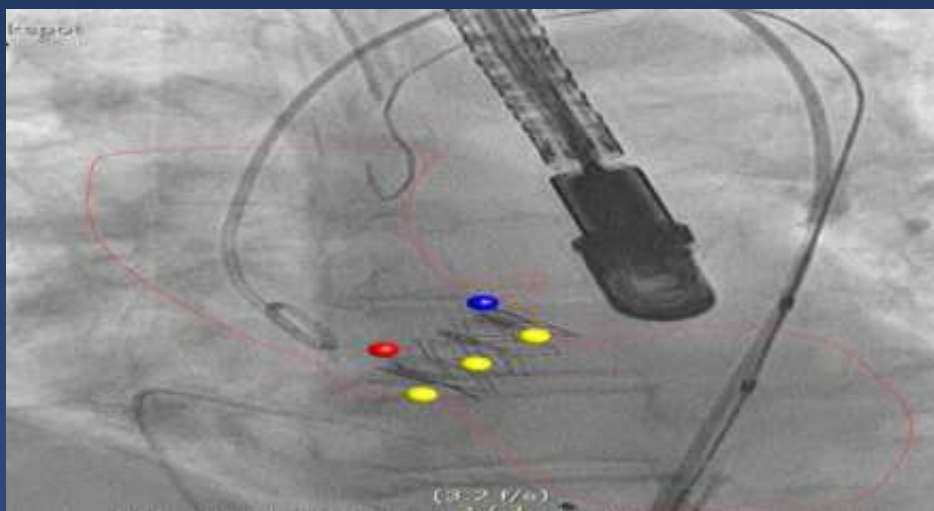
- Sensors to monitor therapy
- LV remodeling devices
- Contractility modulation
- Micro-VADs (interventional)
- Inter-atrial shunt implants
- Stem cell therapies



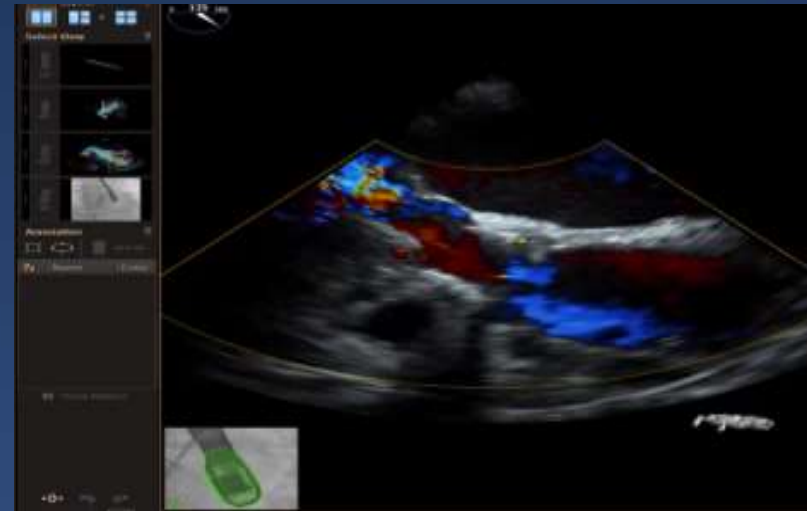
Seoul CMC Hybrid Room



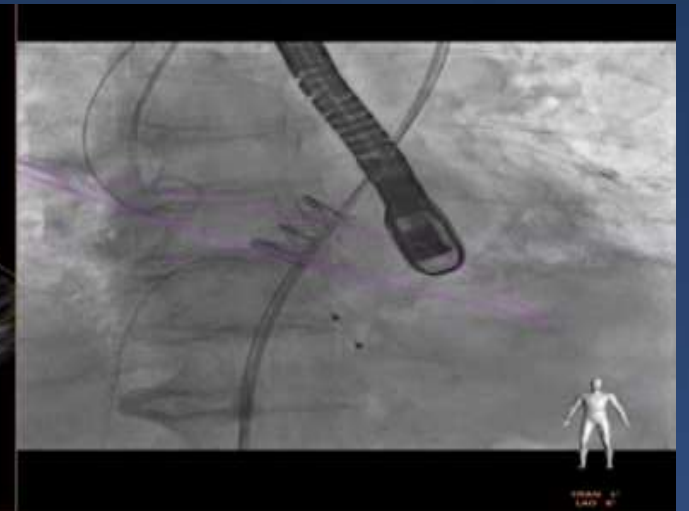
<PHILIPS Bi PLAN ANGIO>



<HEART NAVIGATOR>



<ECHO NAVIGATOR>



Introduce Navigator System



- Heart Navigator
- Echo Navigator
- Vessel Navigator

innovation  you

PHILIPS

What is HeartNavigator?

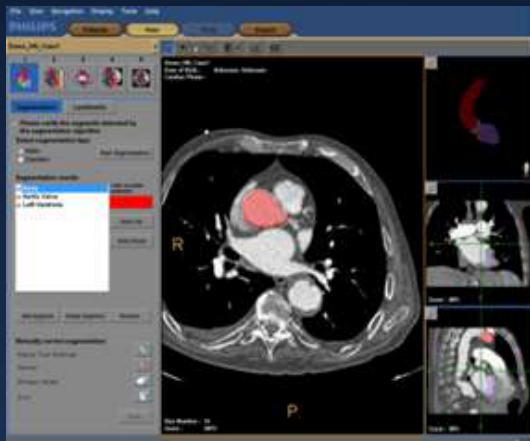
HeartNavigator is a tool that is used in combination with a previously acquired cardiac CT data set to optimize the preparation of structural heart disease treatment, such as correct sizing and positioning of an implant in the patient's body.

Clinical benefits

- Identify and visualize relevant anatomical structures in the CT data set
- Device selection (virtual devices, automatic measurements etc.)
- Plan optimal X-ray projection angles for use during the procedure
- The overlay can be used as a 3D roadmap to help the user with the navigation of the catheter and device in the patient's body

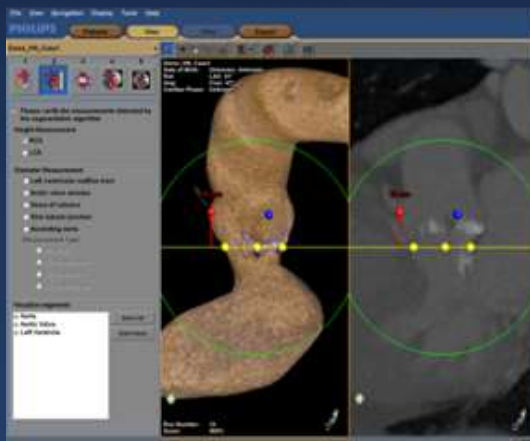
HeartNavigator Workflow steps

From 4 to 5 workflow steps



Step 1. Automatic segmentation

A DICOM CT dataset is automatically segmented to show anatomical structures and landmarks.



Step 2: Automatic Measurements

With one click, automatic measurements relevant for TAVR/TAVI procedures are provided.



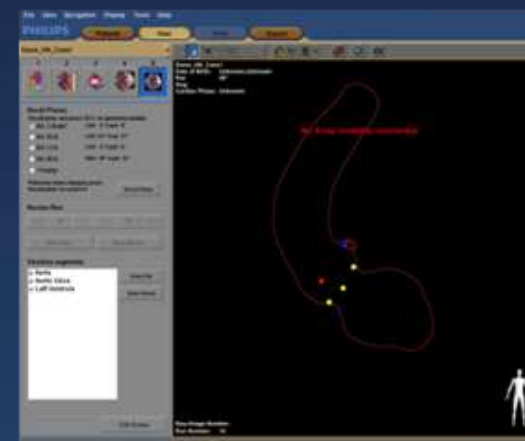
Step 3. Device selection and view planning

Commonly used projection angles (based on the calculated planes and landmarks) are automatically provided. Different virtual device can be inserted.



Step 4. Import and match CT volume to X-ray

The software automatically imports the live X-ray images. The user manually matches the 2D X-ray images with the 3D dataset.

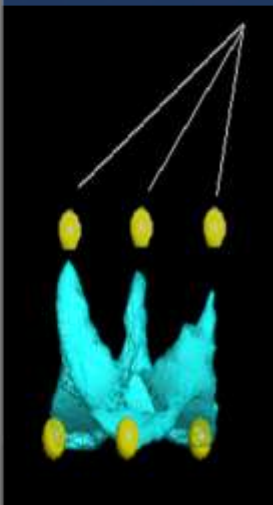
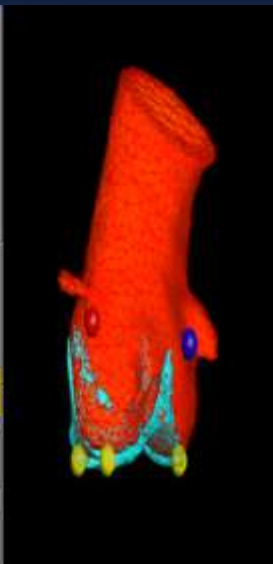
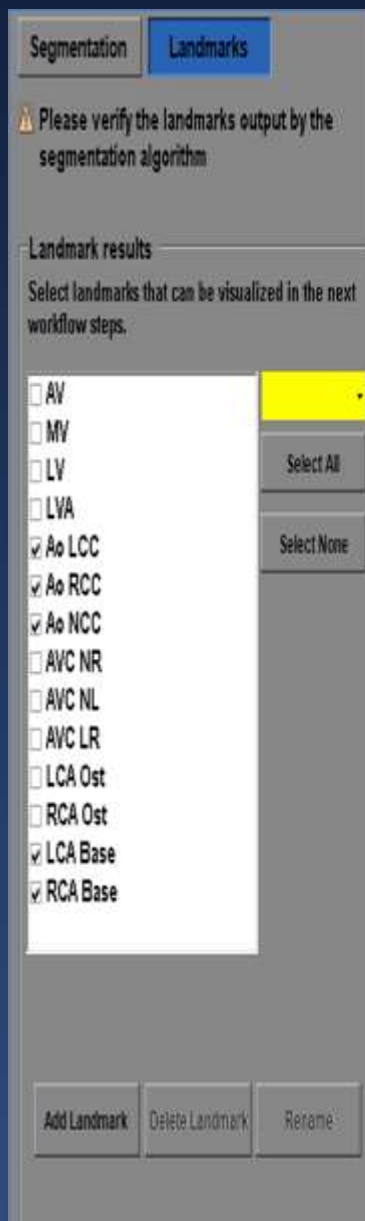


Step 5. Live overlay image

During the procedure, the 3D volume can be overlaid on the live X-ray image to get real-time feedback.

Major Function 1

Additional landmark functionality

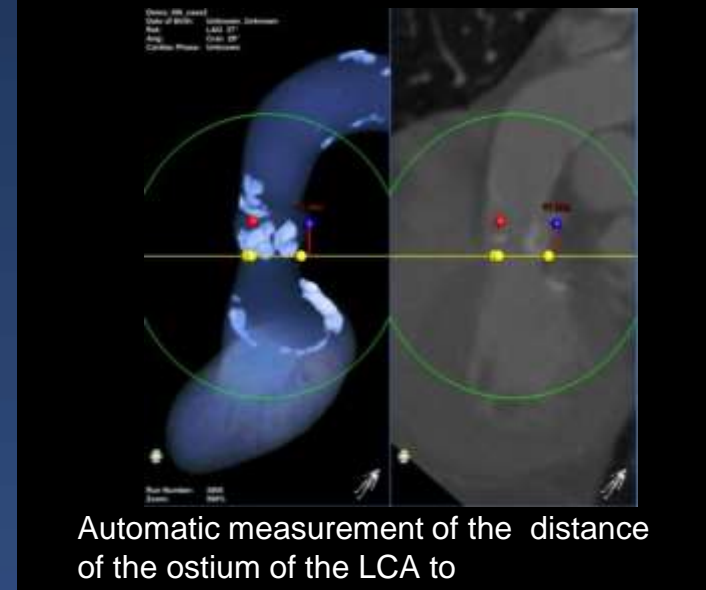


- Additional commissures landmarks
 - Important for placement of certain types of valves
- Additional manual landmarks
 - to mark additional point of interest
- Change color of the landmarks
 - The color of the different landmarks can be changed individually

Automatic measurements



Automatic measurement of the aortic valve annulus diameter



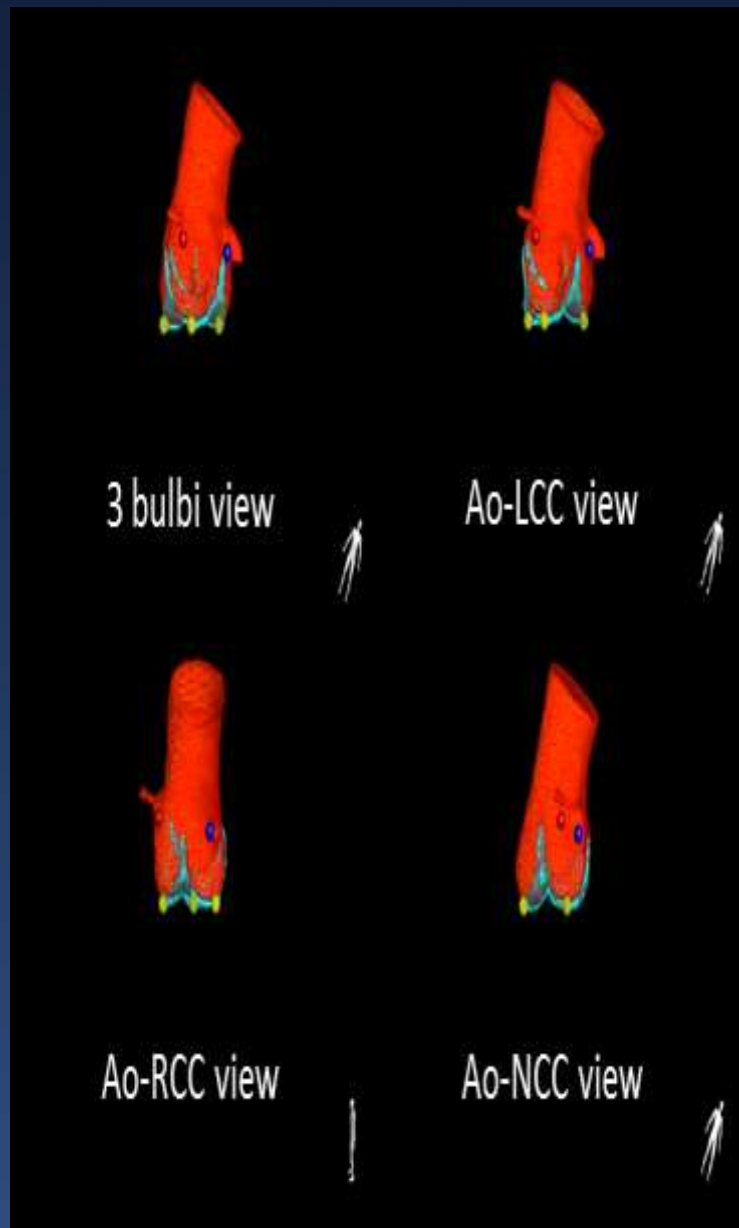
Automatic measurement of the distance of the ostium of the LCA to

Major workflow improvement for TAVR/TAVI

- Fast and fully automated measurements for typical anatomical distances and diameters of aortic valve structures
- Offered as 2nd step in the integral high level workflow
- Automatically generated in the correct plane
- More reproducible than manual measurements

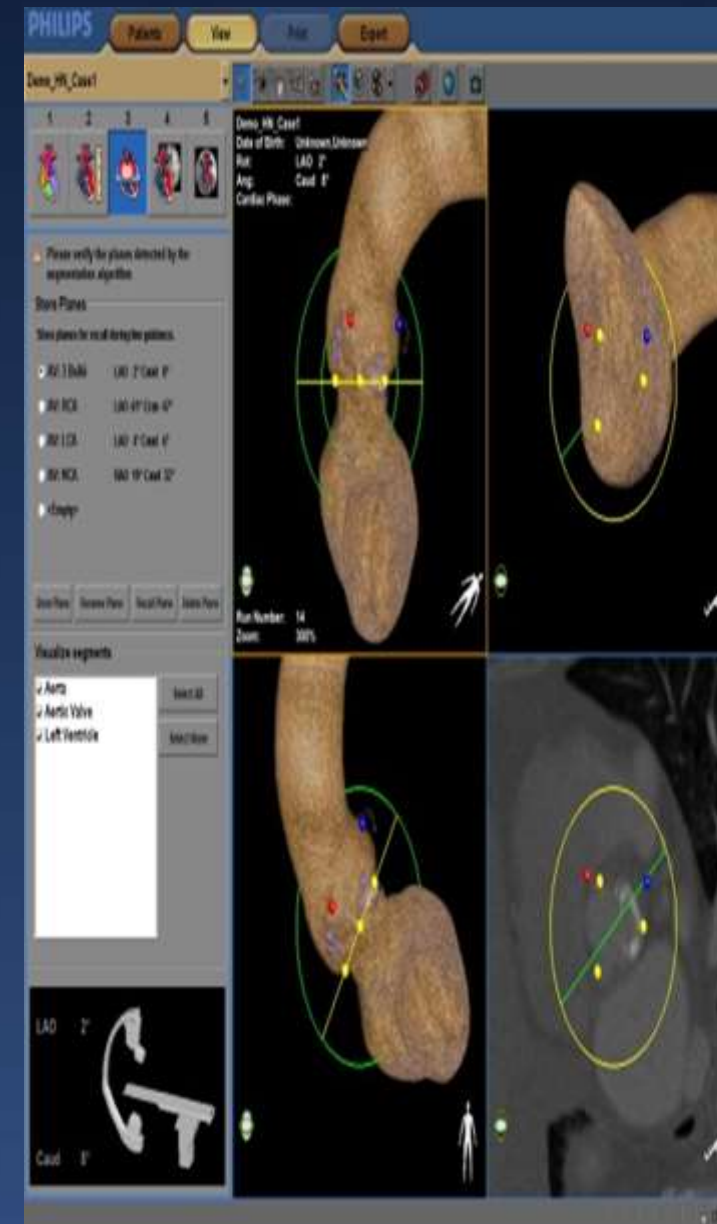
Major Function 2

Automatic optimal view planes



Commonly used
projection angles are
automatically
provided that can be
recalled at tableside.
Less manual
manipulation needed
to find the correct
angle for treatment

Real X-ray view

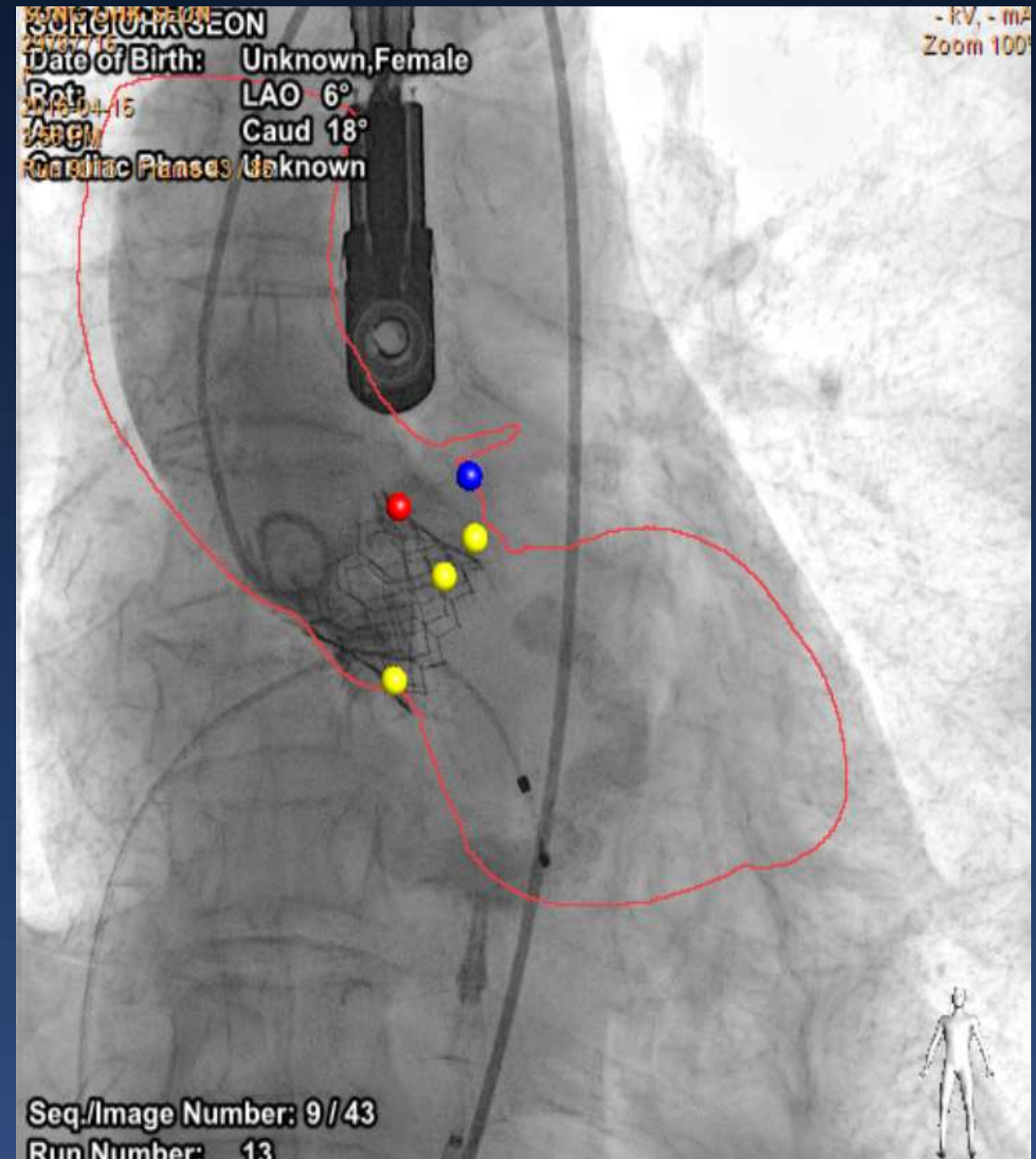
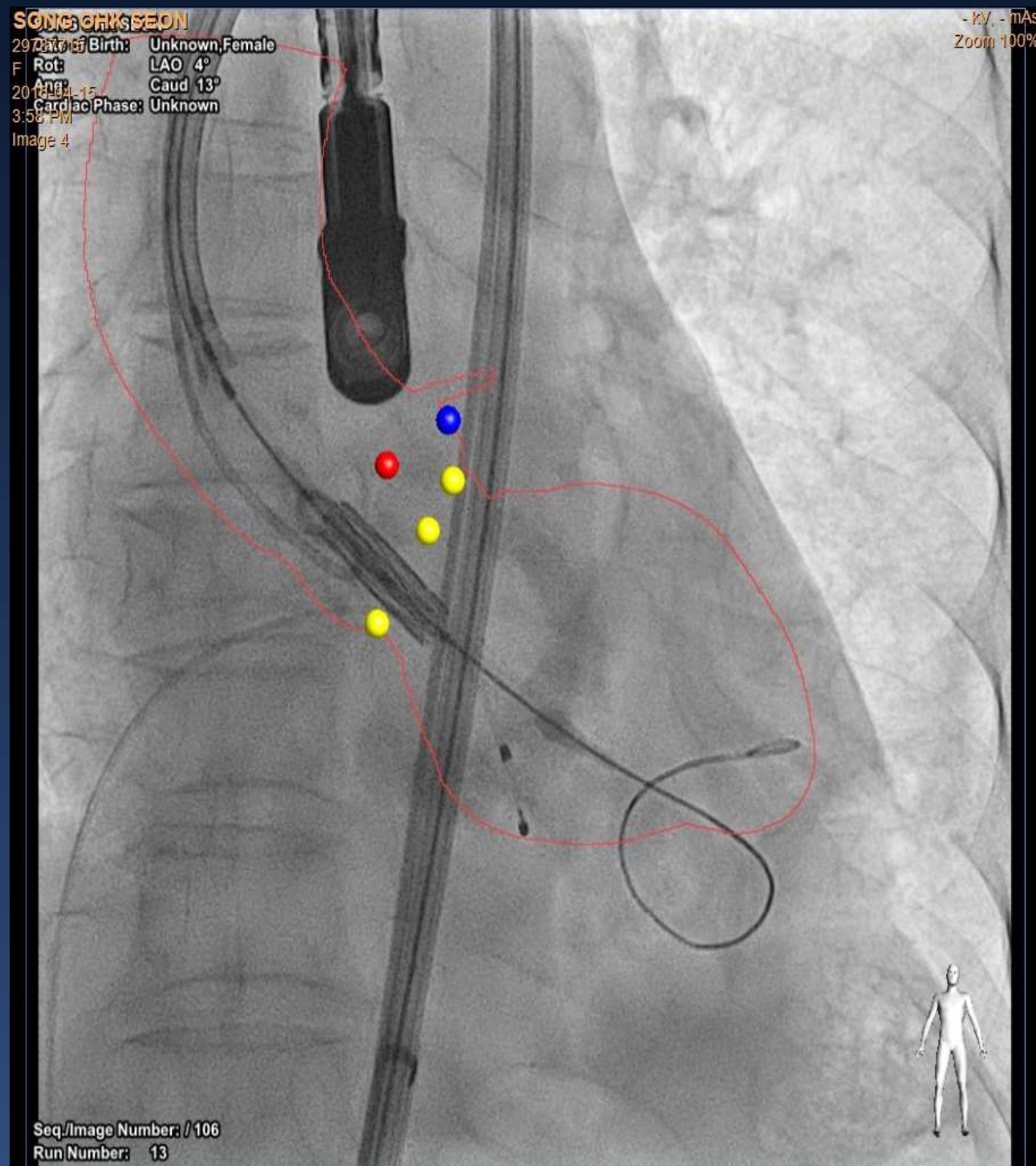


In planning step:

- Same orientation than the X-ray view in the lower left window

Requested since the introduction
of the HeartNavigator

HeartNavigator - Live Image Guidance



What is Echonavigator?

Echonavigator Real-time fusion of live Xray and live echo images for intuitive guidance during structural heart disease procedures.



The EchoNavigator R2 is compatible with:


- Initial delivery for Allura Xper Release 8.x & AlluraClarity systems
- Field Extension for Allura Xper Release 7.6/7.7/7.8/8.1 & AlluraClarity systems

EchoNavigator R2 pre-requisites – iXR (initial & field extension)

- FlexVision XL or EP cockpit XL
- iE33/EPIQ Video Coupling (**NCVB867**) or CX50 Video & UI Coupling (**NCVB868**)
- 2 x dedicated WCBs (Wall Connection Box)

What is Echonavigator?

Making Structural Heart Disease procedures more straightforward



Easy understanding of X-ray
and echo relationship

Get control over critical X-ray and
Echo functionality at table side

Enhance confidence of targeting +
positioning of interventional devices

Enhance communication
between operators

Enhance understanding anatomical
structures imaged by TEE

<Typical procedures >

- 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

Courtesy of University Hospital Denver, Colorado, USA

EchoNavigator Workflow steps

1.Connectivity

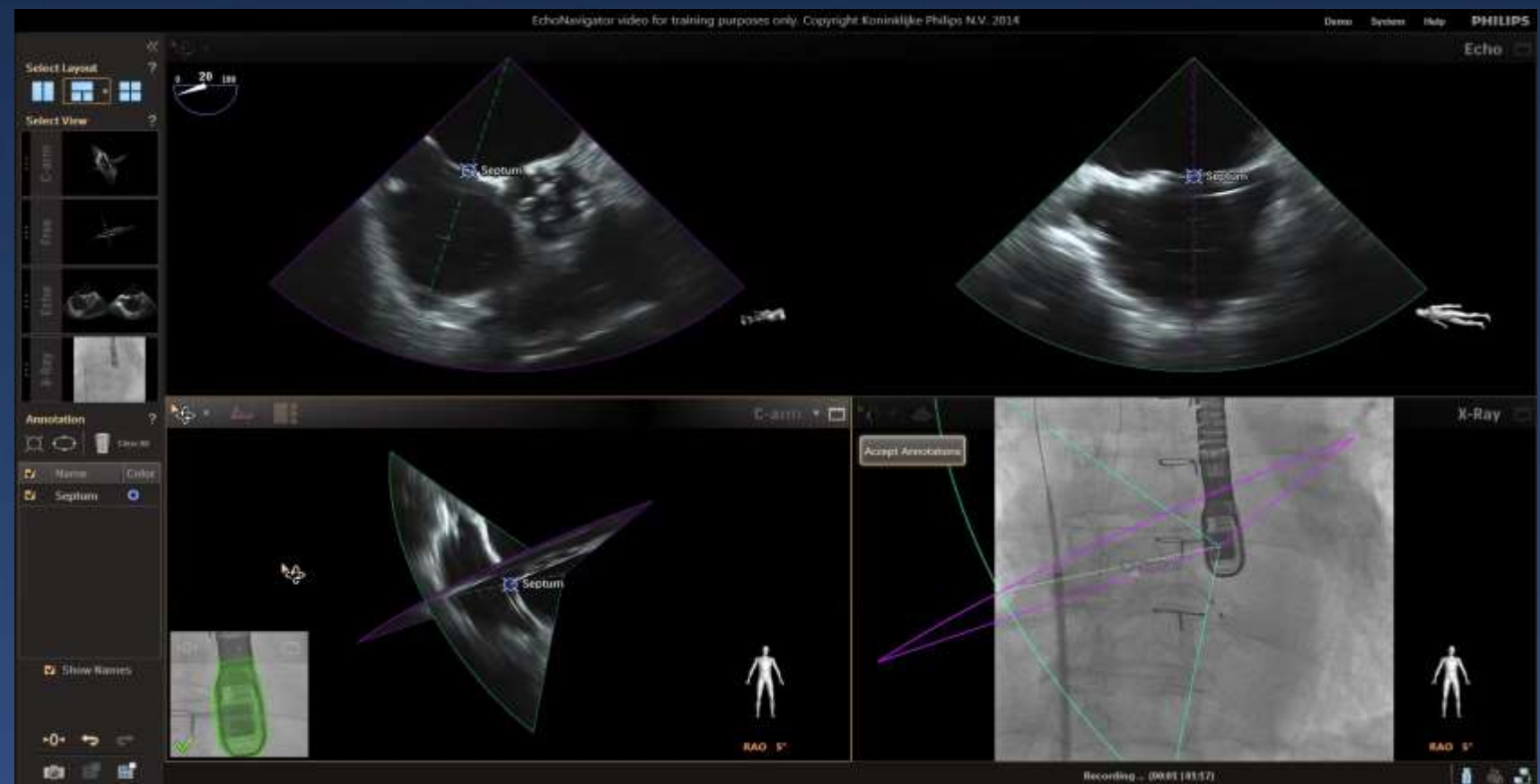
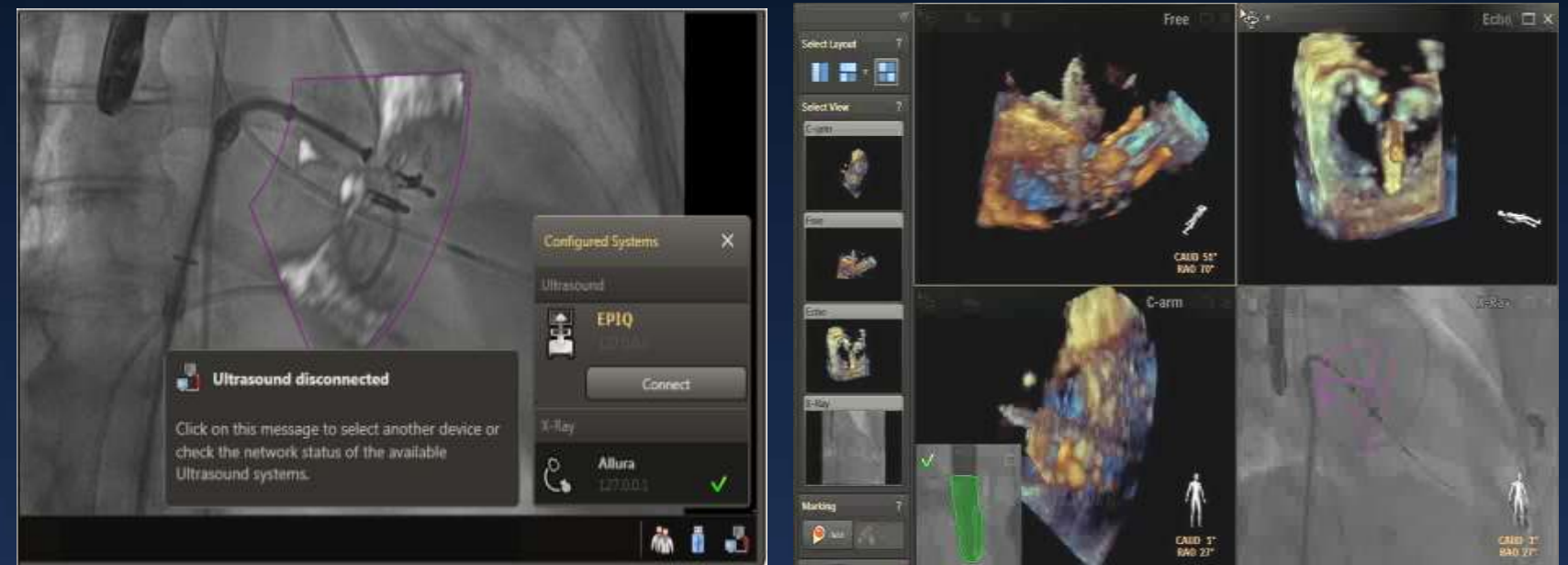
2.Layout

3.View Ports

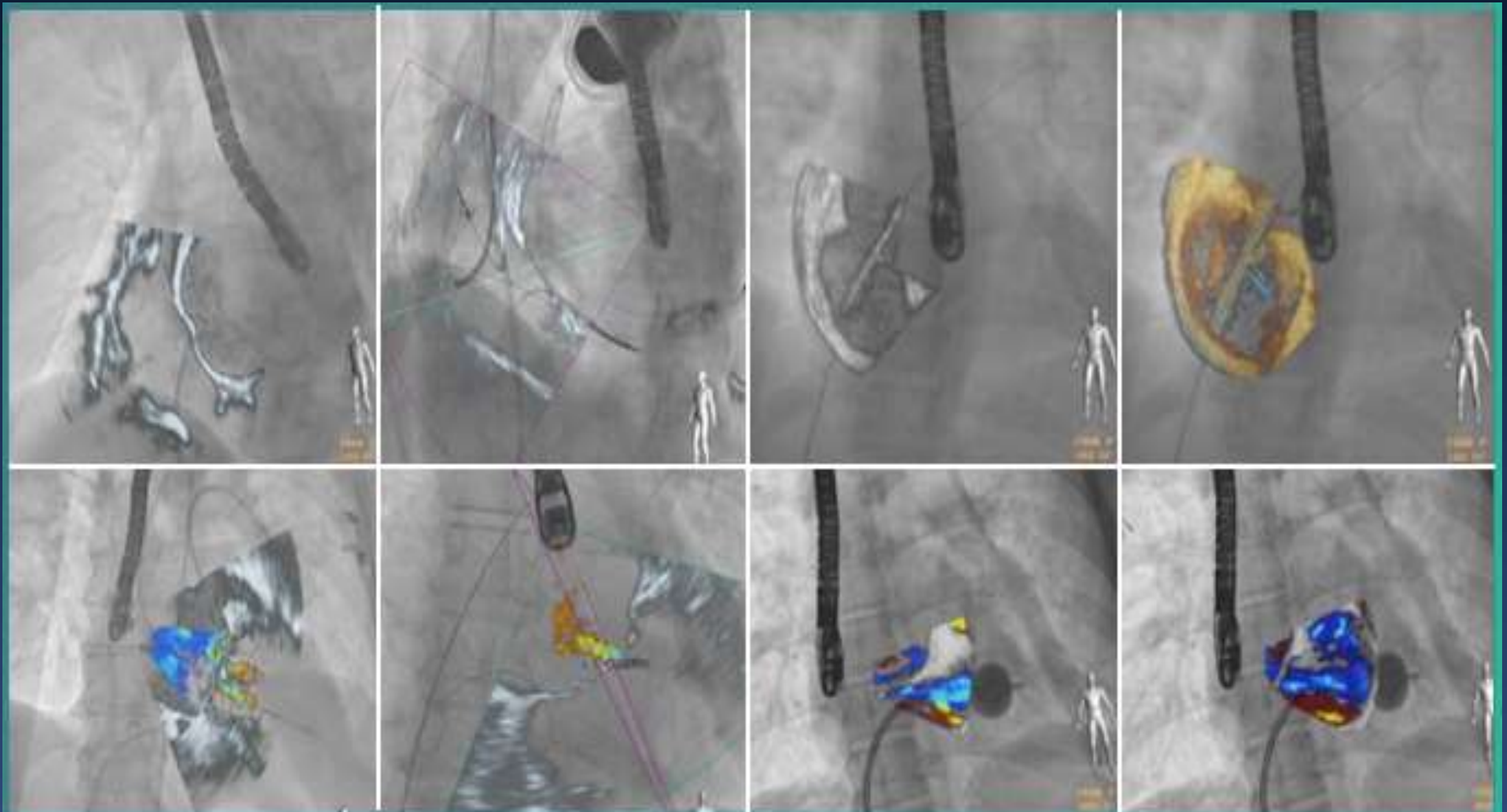
4.Registration

5.Annotation

6.SmartFusion



EchoNavigator - Live Image Guidance



2D Echo Fusion

xPlane Echo Fusion

3D Echo Fusion SLICE 3D Echo Fusion VOLUME

What is Vesselnavigator?

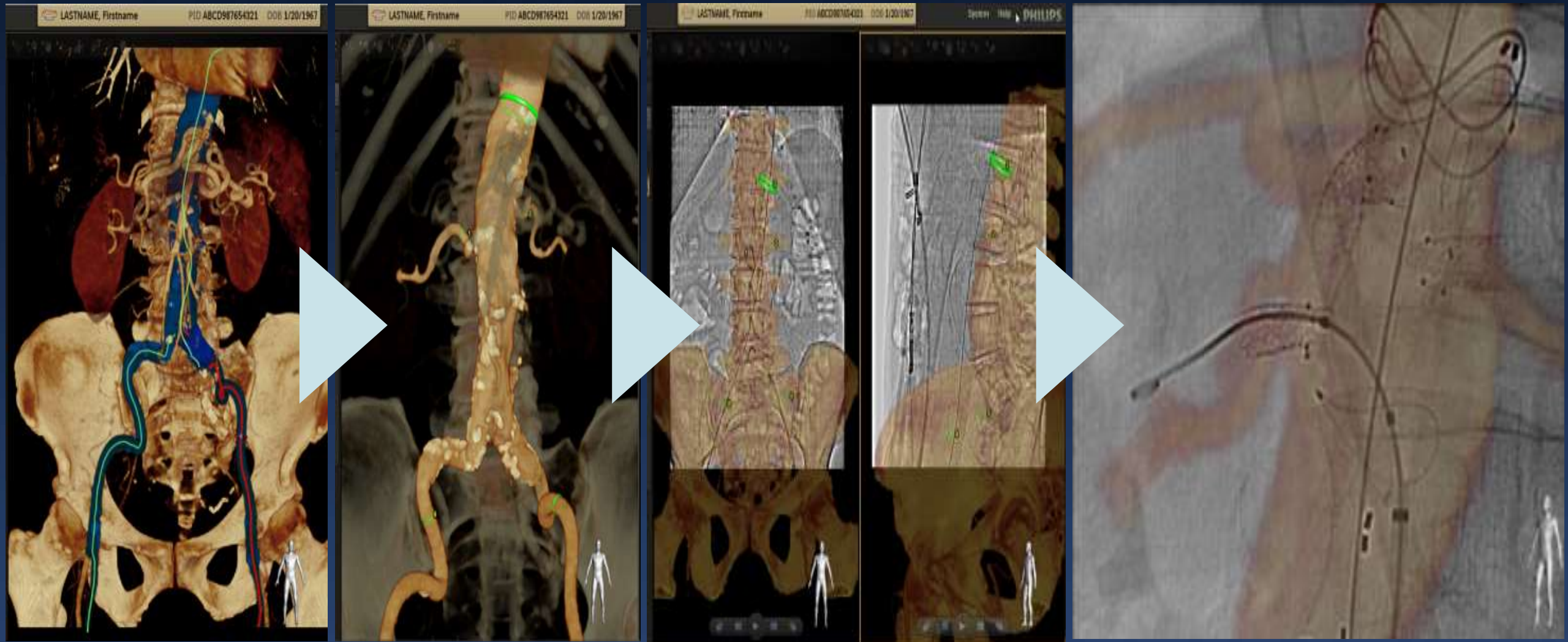
It provides live 3D image guidance for navigating endovascular devices through intended vascular structures in the body, reusing previously acquired CT or MR data.

VesselNavigator is intended to assist in the treatment of endovascular diseases during procedures such as AAA, TAA, carotid stenting, iliac interventions.

An improvement of Multi Modality Matching

- One-click to segment your MR and CT data in the interventional workstation
- 2D -3D Registration; bone registration with use of fluoroscopy runs in 2 different angles (>30 degrees)
- Improvement of 3D-3D Registration; calcification registration
- Intuitive and easy to use by providing step by step workflow guidance
- First iAPP, new interface with interventional workspot 1.3
- Placement of landmarks to indicate ostia and landing zone or optimal projection angles
- New visualization presets with Vessel Outline during live navigation

VesselNavigator workflow steps



Segmentation

- Select vasculature of interest

Planning

- Add ring markers
- Plan optimal angle

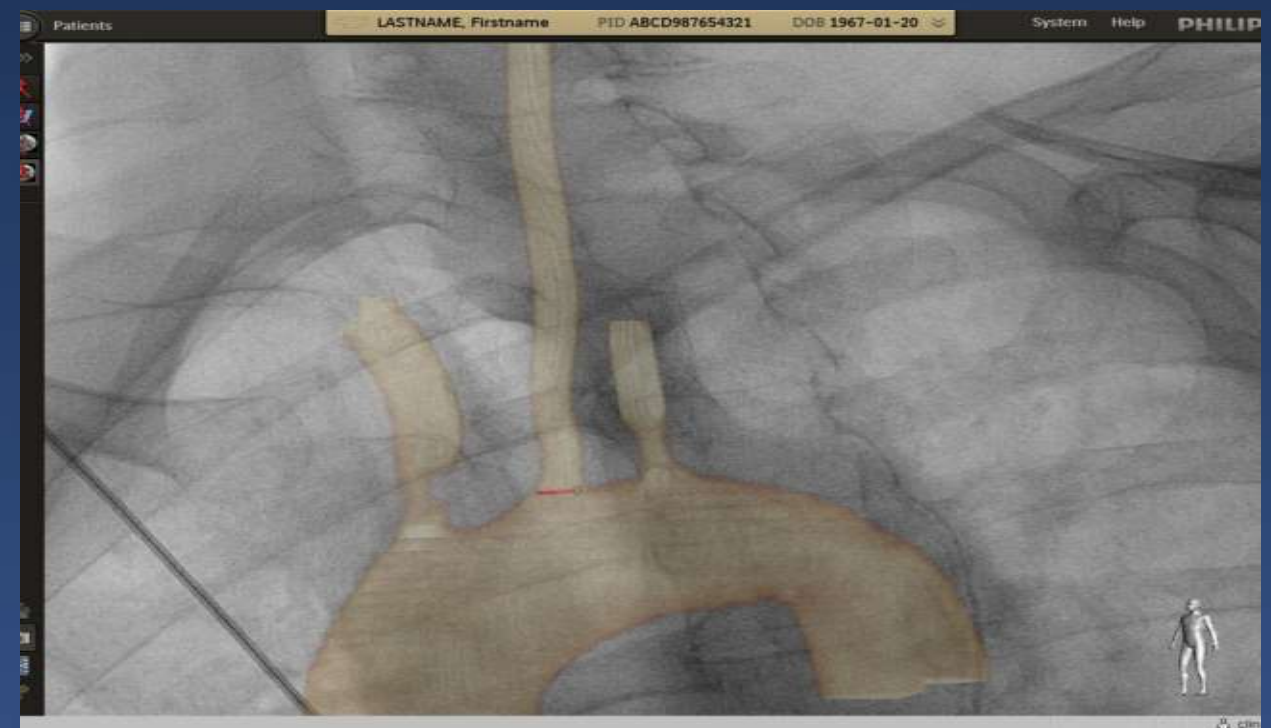
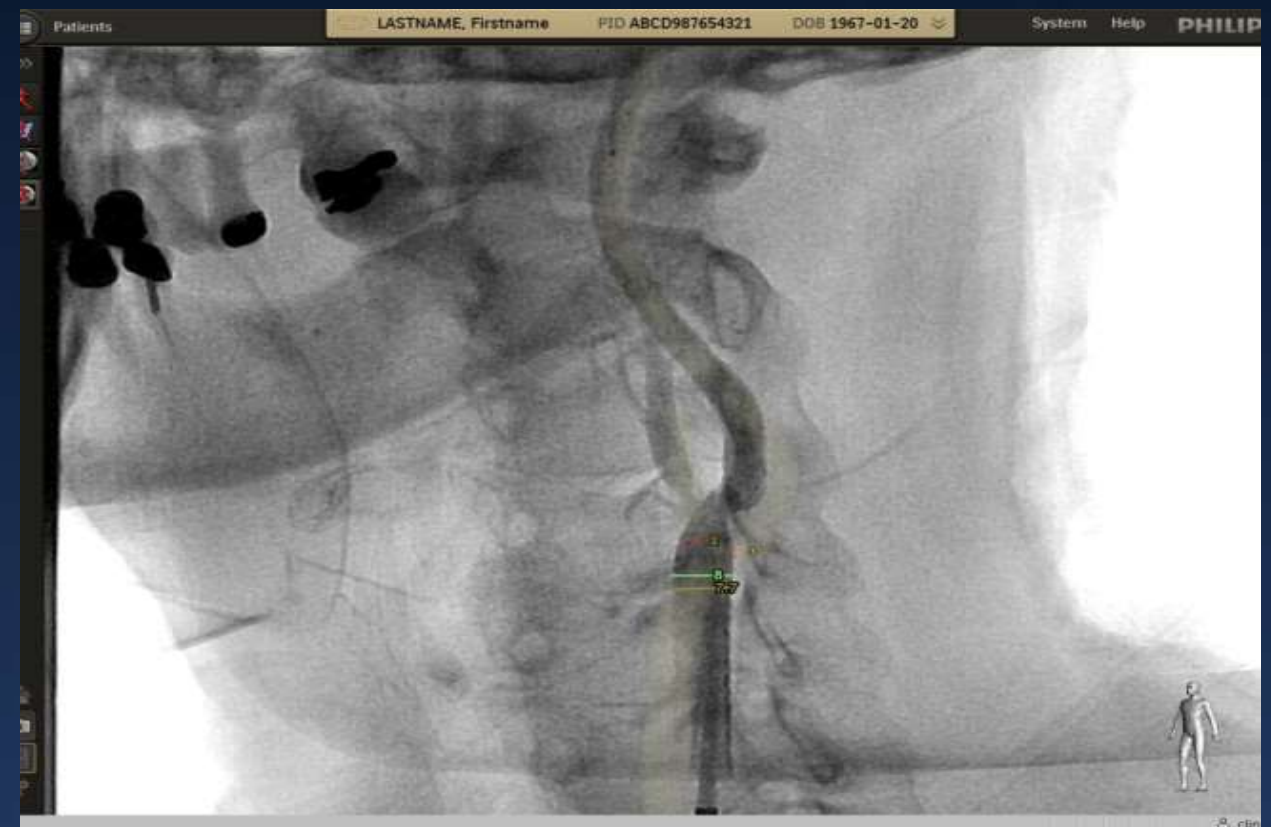
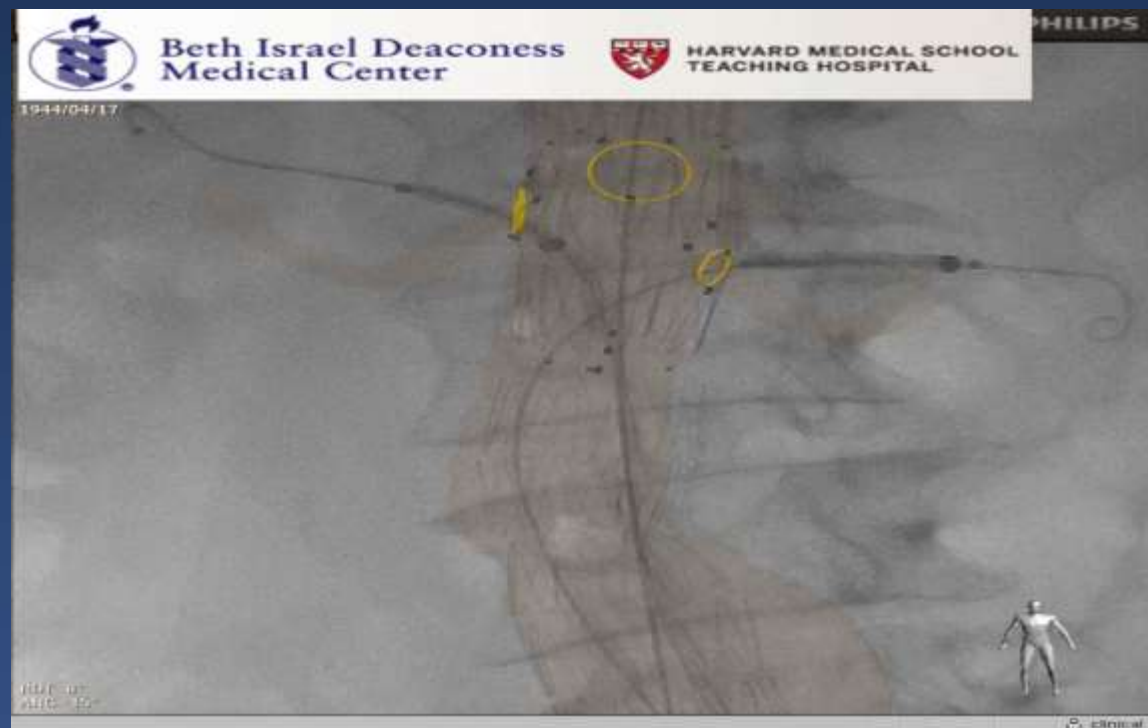
Registration

- 2D-3D: bony landmarks
- 3D-3D: calcifications

Live Image Guidance

- Select preferred visualization
- Follow C-arm and table movements

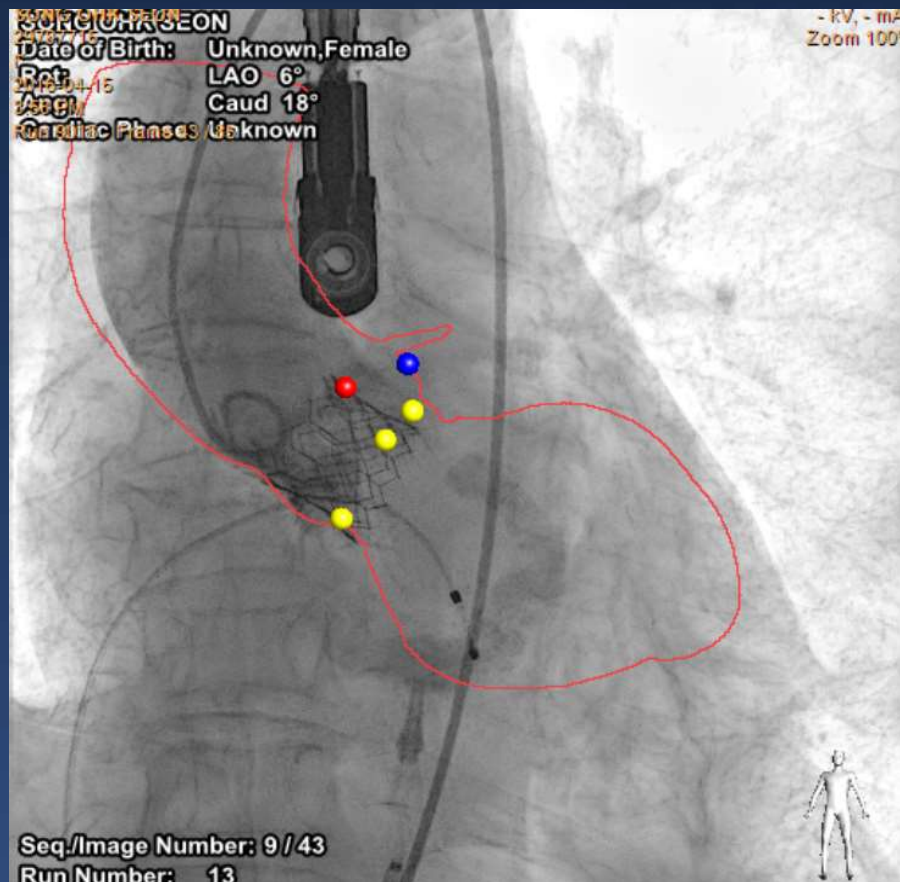
VesselNavigator- Live Image Guidance



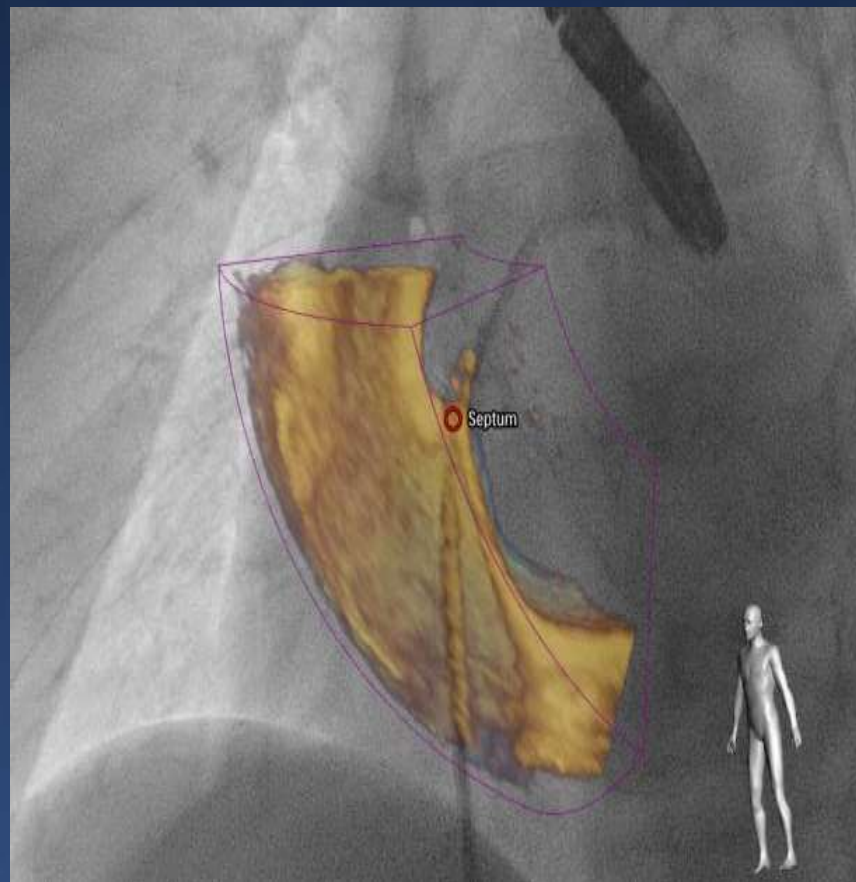
Benefit of Navigator System

Benefit

- Easy to find anatomical structure (especially SHD)
- Reduce Contrast & Radiation Dose
- Enhance the Success rate



Heart Navigator



Echo Navigator



Vessel Navigator

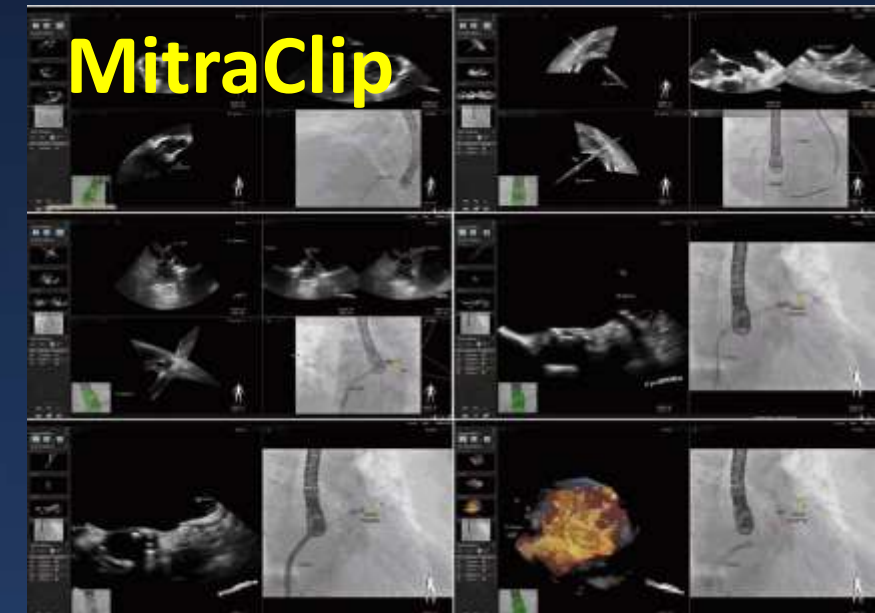
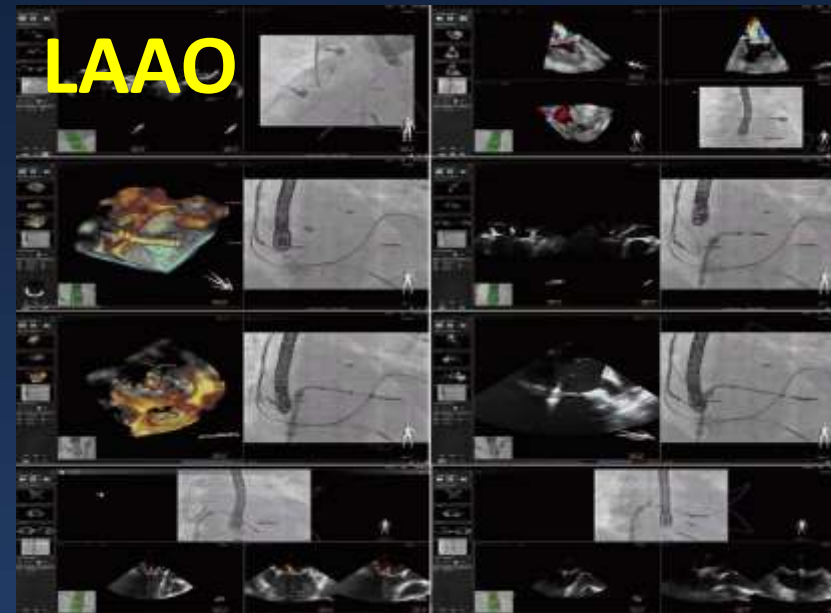
Benefit of Navigator System

ORIGINAL ARTICLE

Basic Study

Initial clinical experience using the EchoNavigator®-system during structural heart disease interventions

Jan Balzer, Tobias Zeus, Katharina Hellhammer, Verena Veulemans, Silke Eschenhagen, Eva Kehmeier, Christian Meyer, Tienush Rassaf, Malte Kelm



<RESULTS>

The application of the novel **image fusion technology** was safe and led to a better appreciation of multimodality imaging guidance due **to improved visualization** of the complex relationship between catheter devices and anatomical structures.

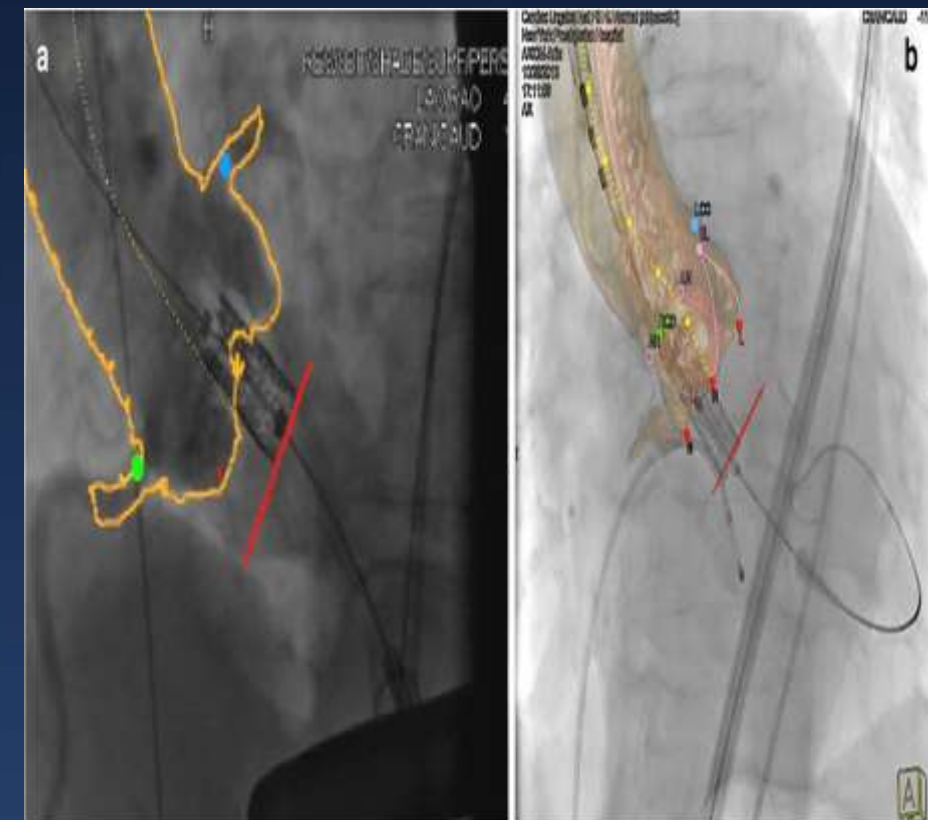
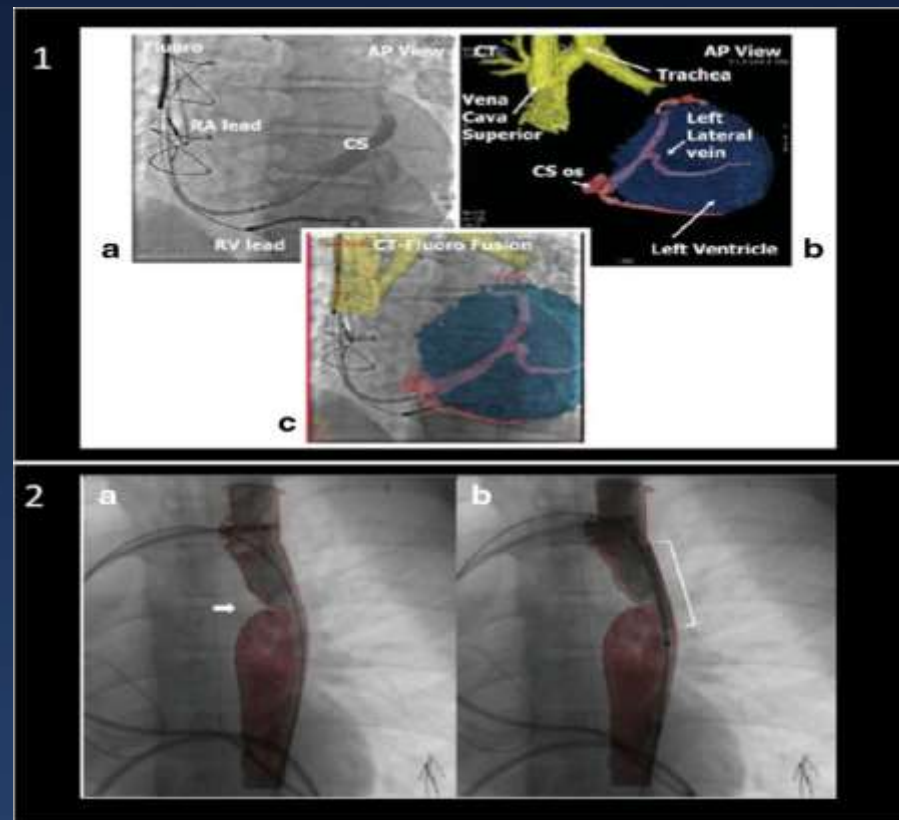
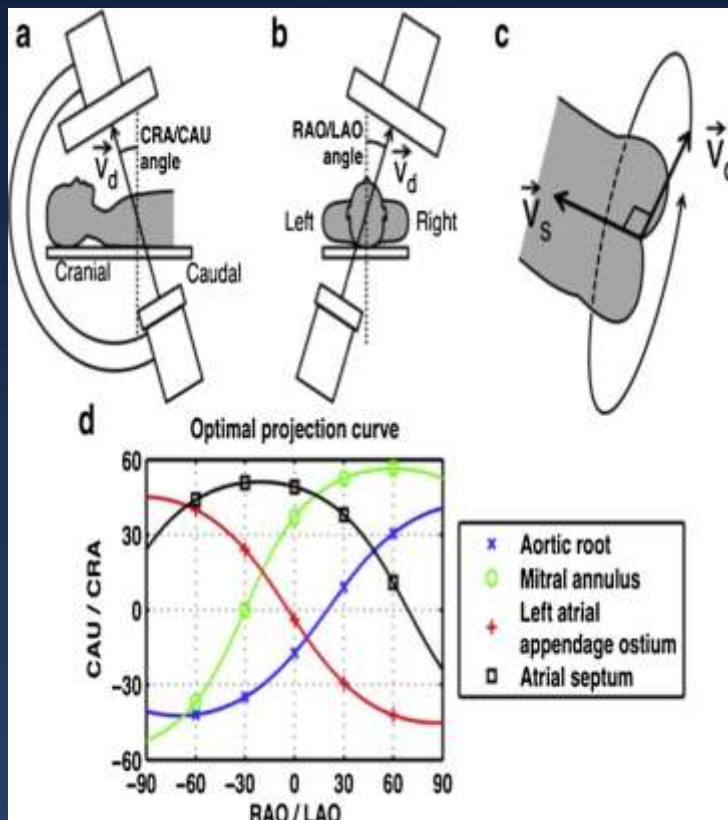
<CONCLUSION >

The EchoNavigator(®)-system is a feasible and safe tool for guidance of interventional procedures in structural heart disease. This innovative technology may improve confidence of interventional cardiologists in targeting and positioning interventional devices in order **to increase safety, accuracy, and efficacy** of percutaneous interventions in the catheter laboratory.

Benefit of Navigator System

Hybrid Imaging During Transcatheter Structural Heart Interventions

Patric Biaggi¹ • Covadonga Fernandez-Golfin² • Rebecca Hahn³ • Roberto Corti¹



<Conclusion>

The use of fusion imaging leads to a **reduction of radiation dose**, **faster and safer** interventions, and higher interventional **success rates** remains to be seen.

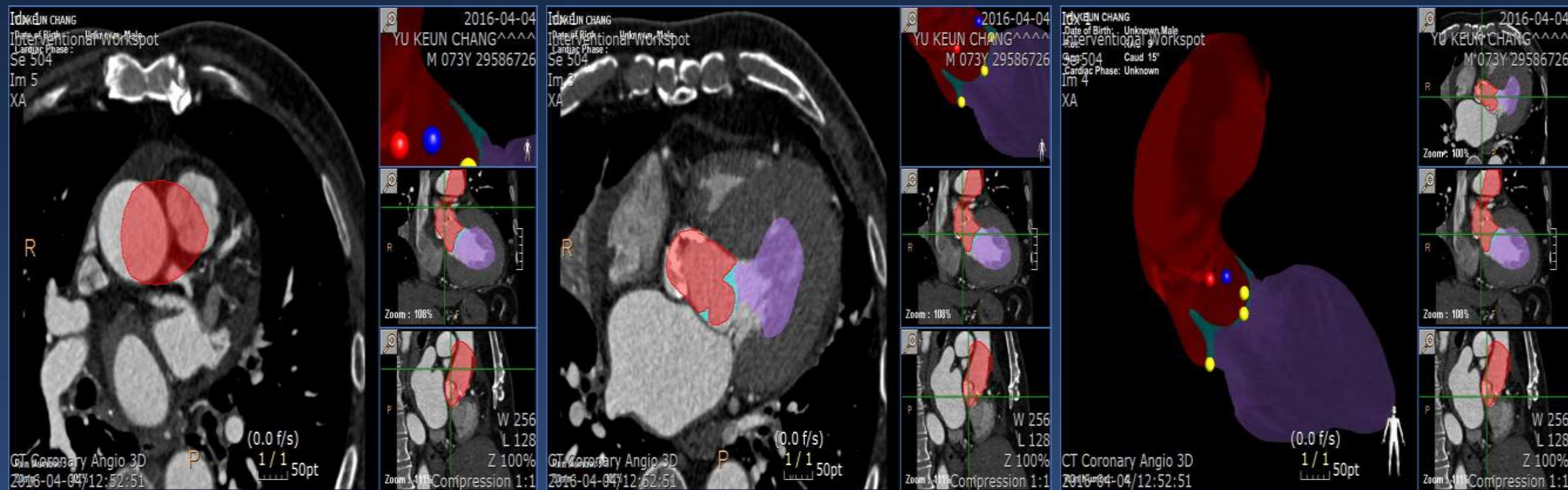
<Limitation>

This system was installed only in very few hospitals. As a consequence, there is very little data

Limitation of Navigator System

Limitation

- Incorrect Segmentation
- Hard to find landmark & Registration
- Fusion image does not match



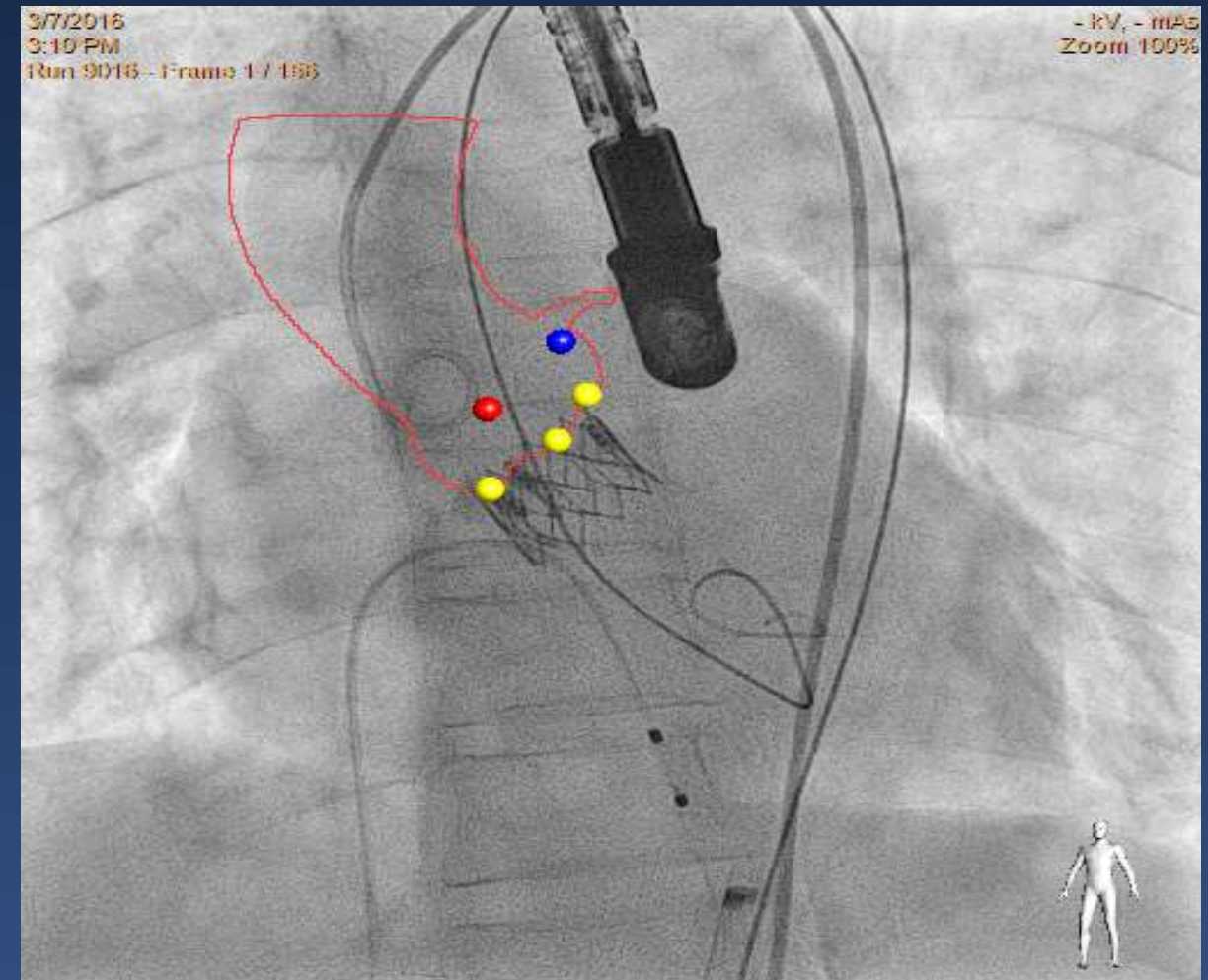
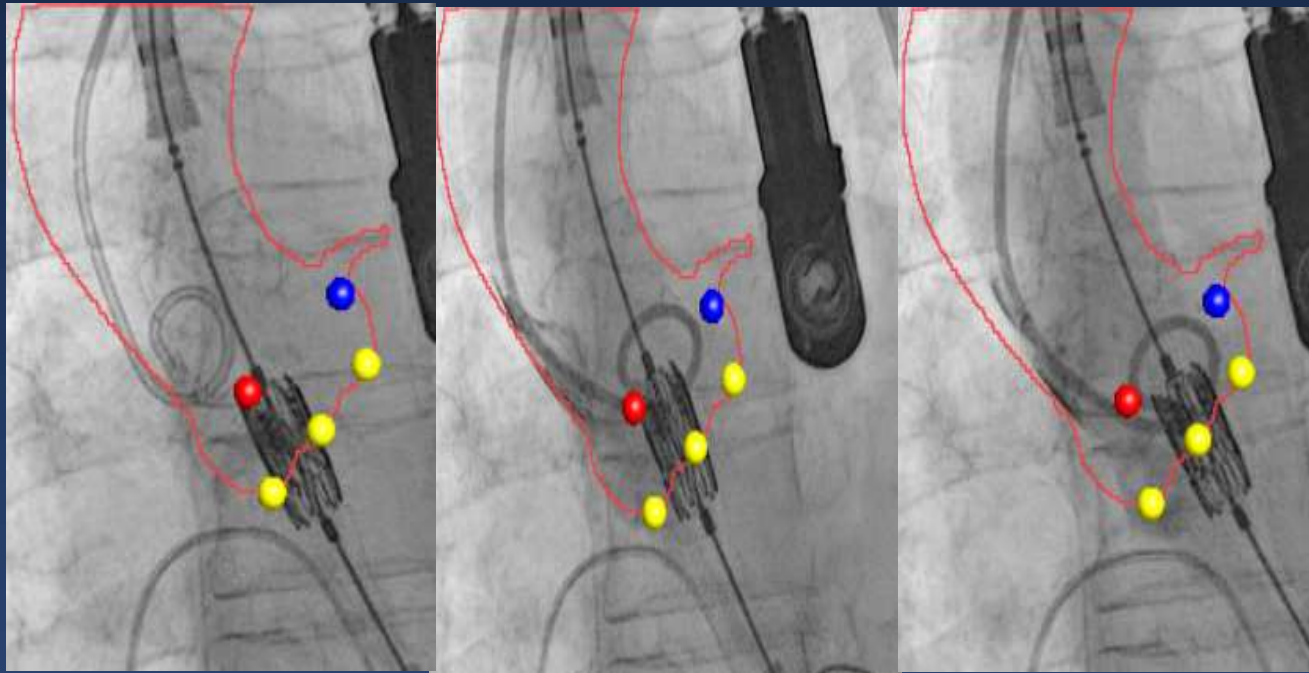
Incorrect segmentation
Different patient position (Raw data)

→ **Miss match**

Limitation of Navigator System

Limitation

- Incorrect Segmentation
- Hard to find landmark & Registration
- Fusion image does not match



Cardiac Motion & Fixed Landmark



No effect during Implantation

How to overcome ??

R & D

Clinical
Experience

Share of
Clinical Data

Overcome
Learning Curve



사업명	2017년도 서울성모병원 R&D 동반성장 지원사업	
과제명	국문	Structural Heart Disease 시술시 Hybrid Room의 각종 Navigation 장비 활용을 위한 Protocol 구축 및 효용성 평가
	영문	Construction and Evaluation protocols for navigators equipment utilization in the hybrid room in the structural heart disease

ORIGINAL ARTICLE

Basic Study

Initial clinical experience using the EchoNavigator[®]-system during structural heart disease interventions

Jan Balzer, Tobias Zeus, Katharina Hellhammer, Verena Veulemans, Silke Eschenhagen, Eva Kehmeier, Christian Meyer, Tienush Rassaf, Malte Kelm

1st PVL Echo Navigator Guided

Paravalvular Leakage Closing using Amplatzer plug

History

F/75 박 O 자

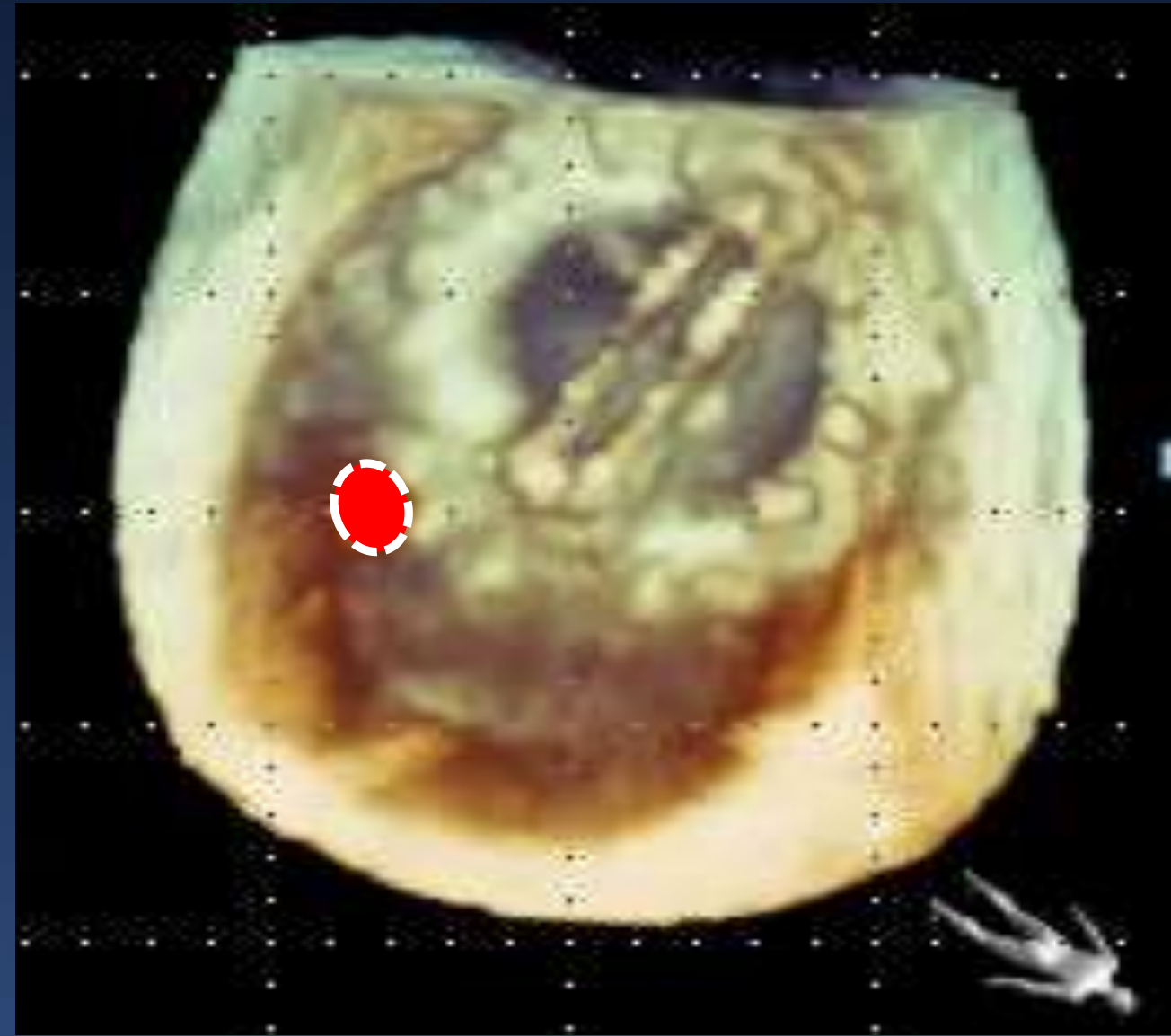
- C.C : Dyspnea, Syncope
- Past hx. : DM/HBP (+/+), AF
- MVR state (1988,2000 at 부천 세종병원)
- V/S 130/85 - 75
- Lab : BUN/Cr 30.9/1.74 mg/dl Hb 10g/dL

pro BNP 4084 pg/ml

T n-T/CK-MB 0.037/2.29



TEE

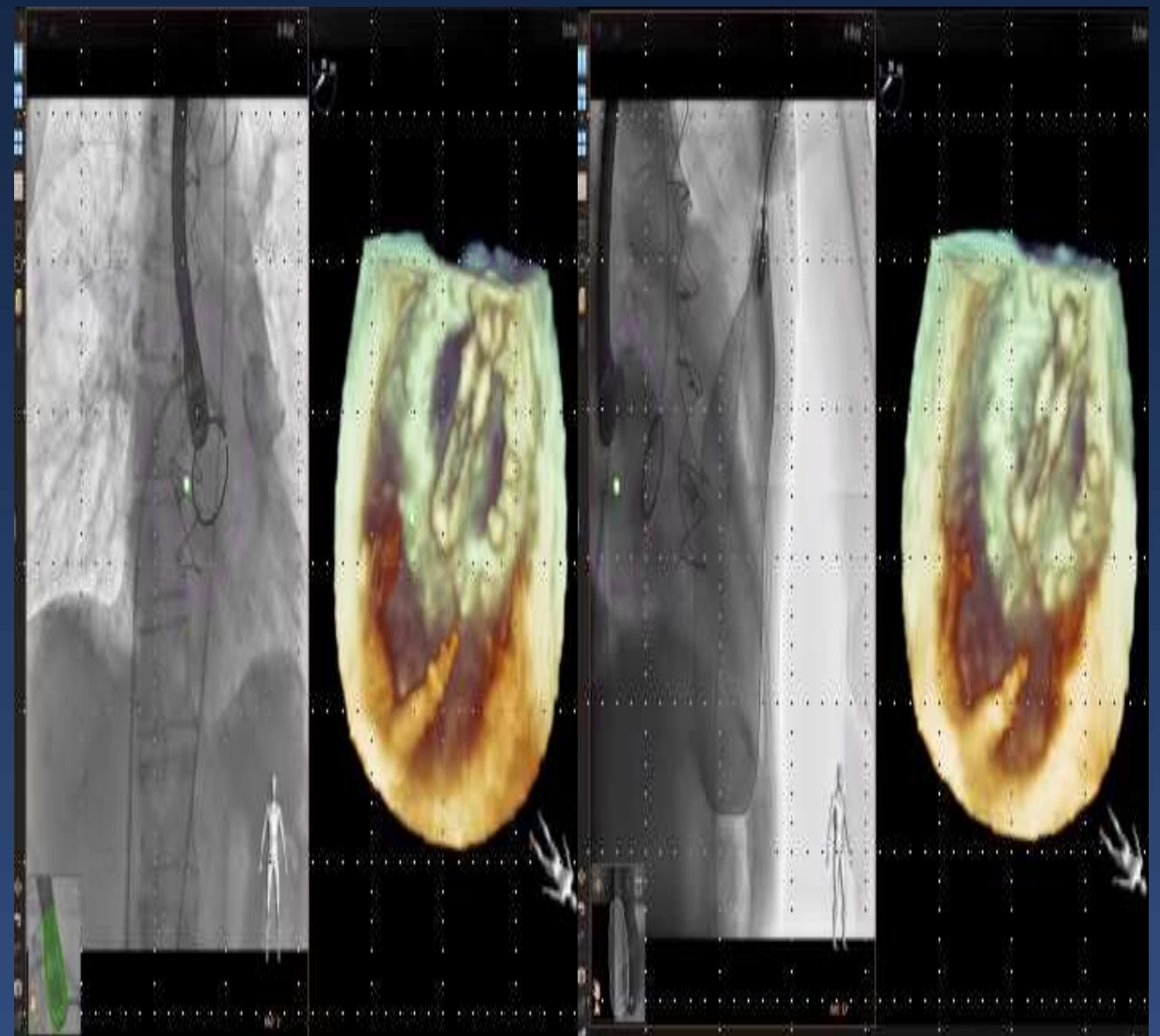


ECHO Navigator guided MVL plug in

ECHO navigator targeting

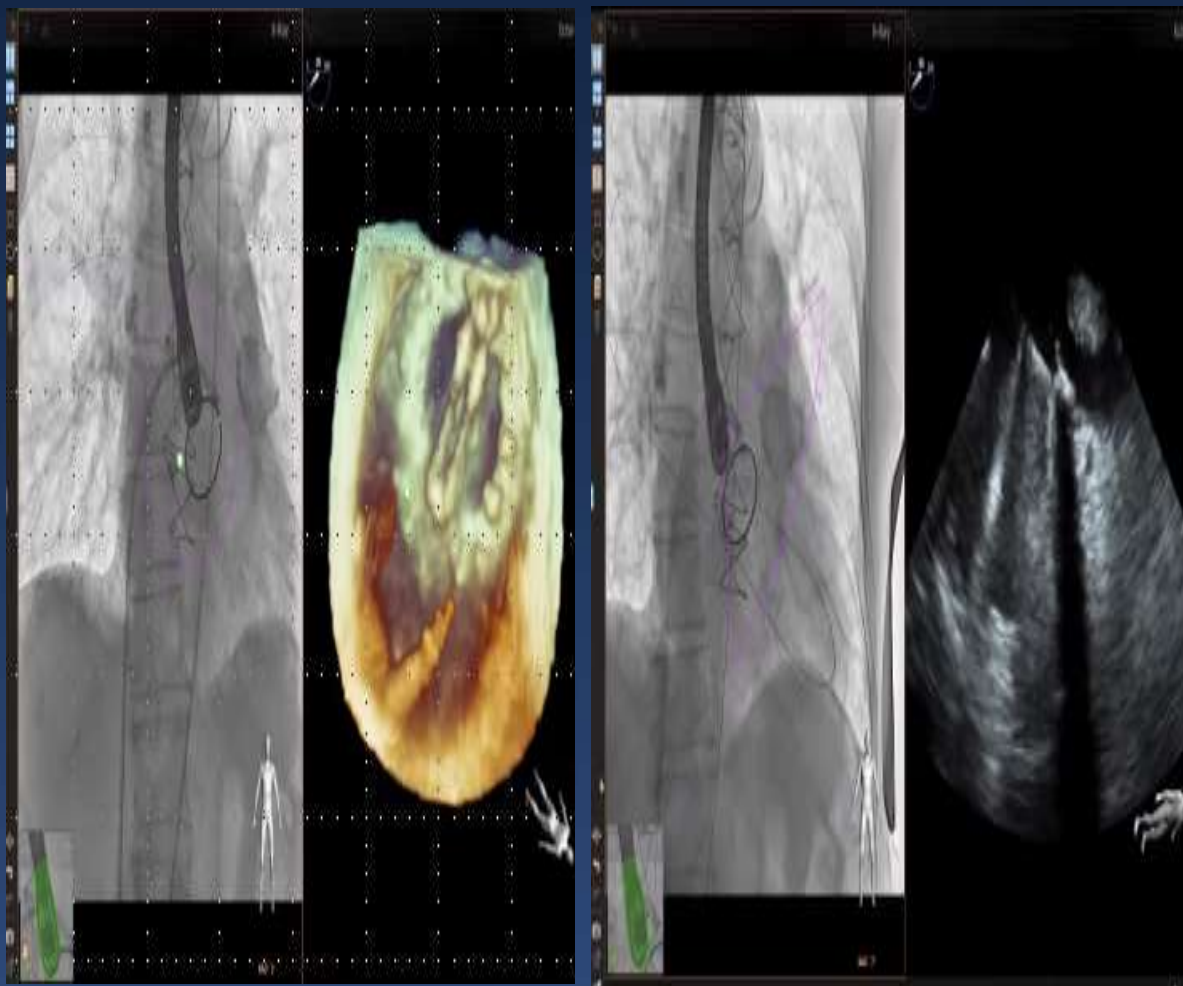


Septal puncture, Wiring



ECHO Navigator guided MVL plug in

Lt. femoral a. approach, Wiring



Amplatz Extra Stiff wire
Multipurpose catheter

Shuttle Catheterization



Glide catheter

ECHO Navigator guided MVL plug in

Plug-in deployment



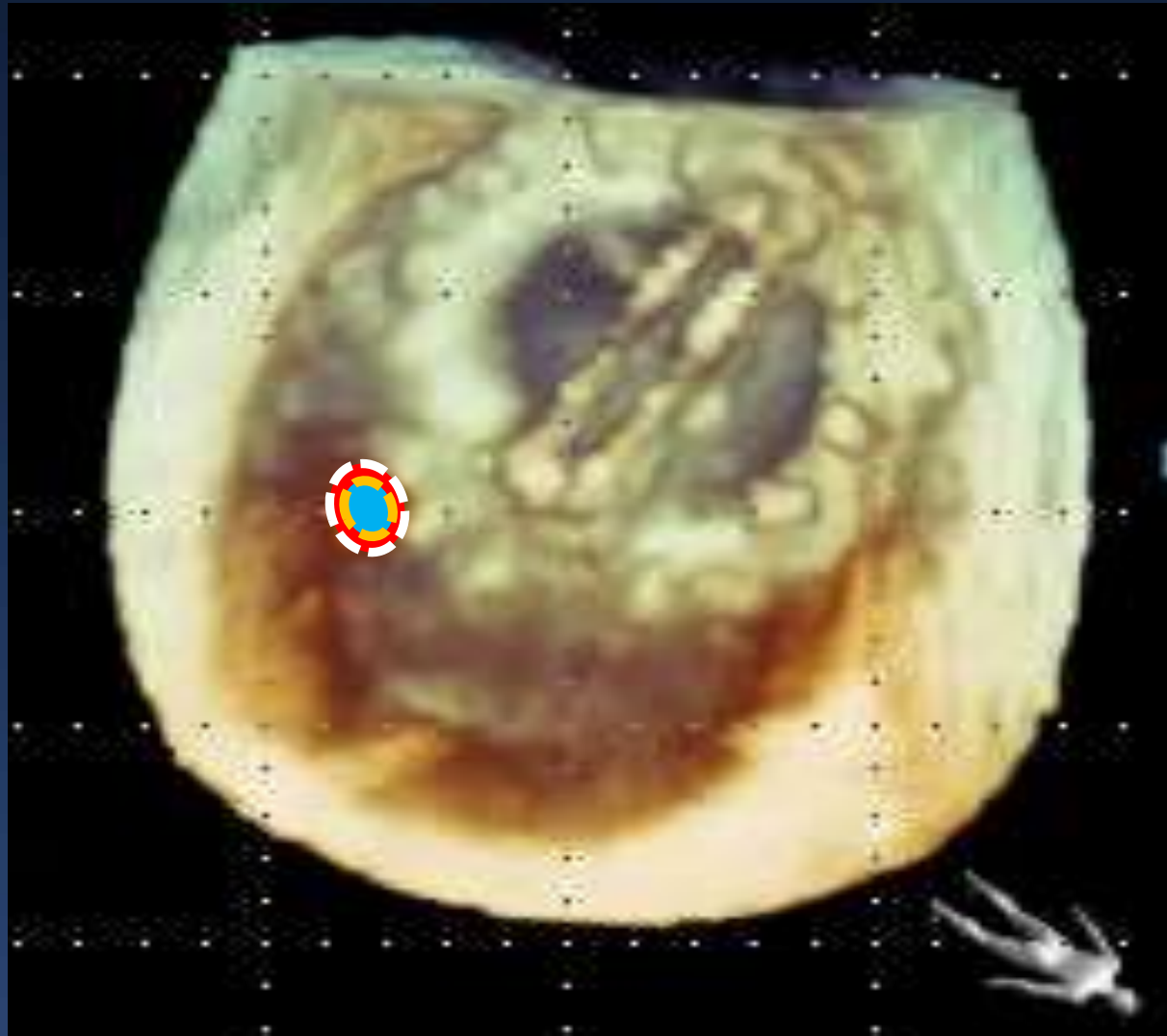
Amplatzer vascular plug 8mm

MV leakage remain

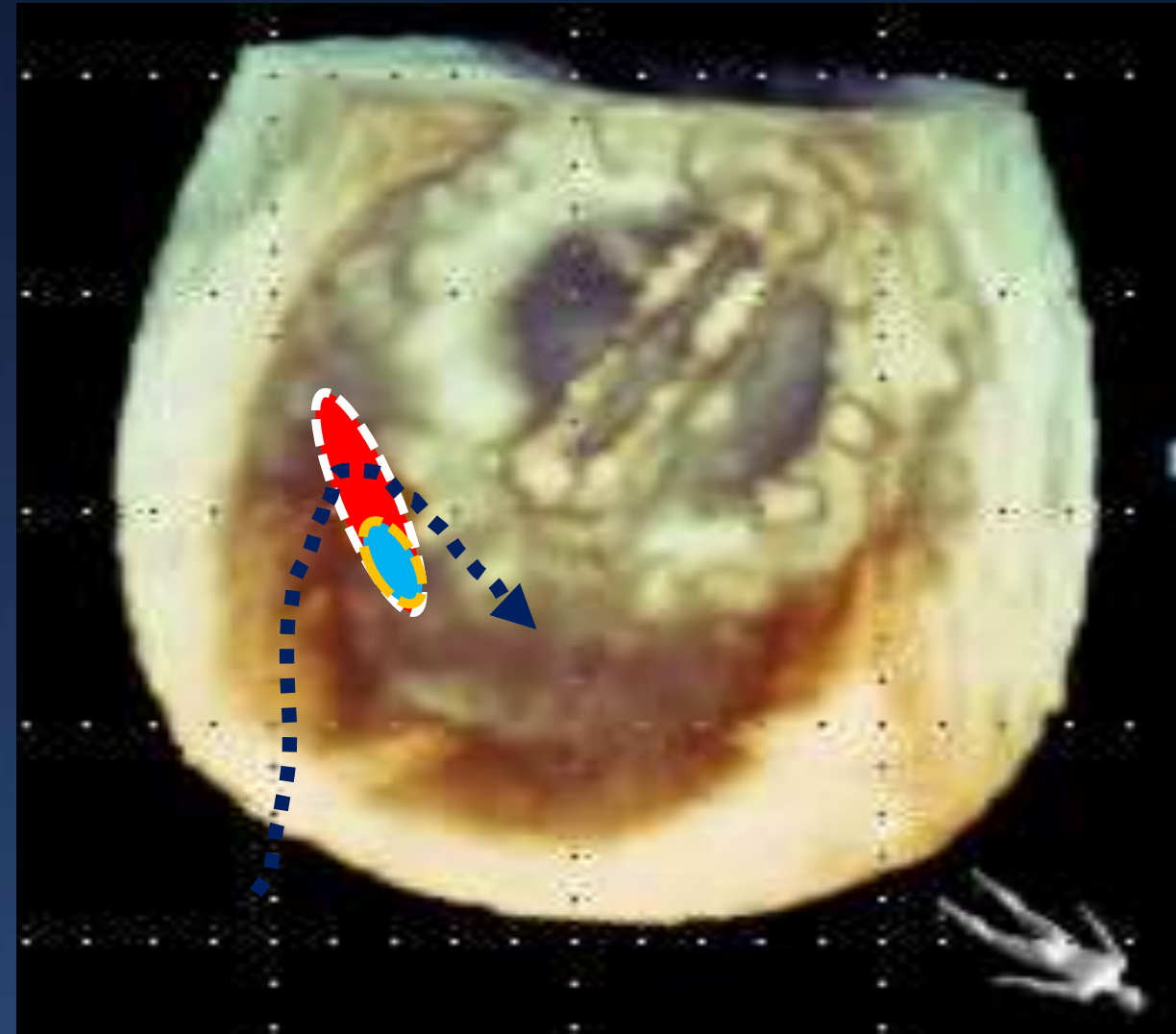


Rewiring

ECHO Navigator guided MVL plug in



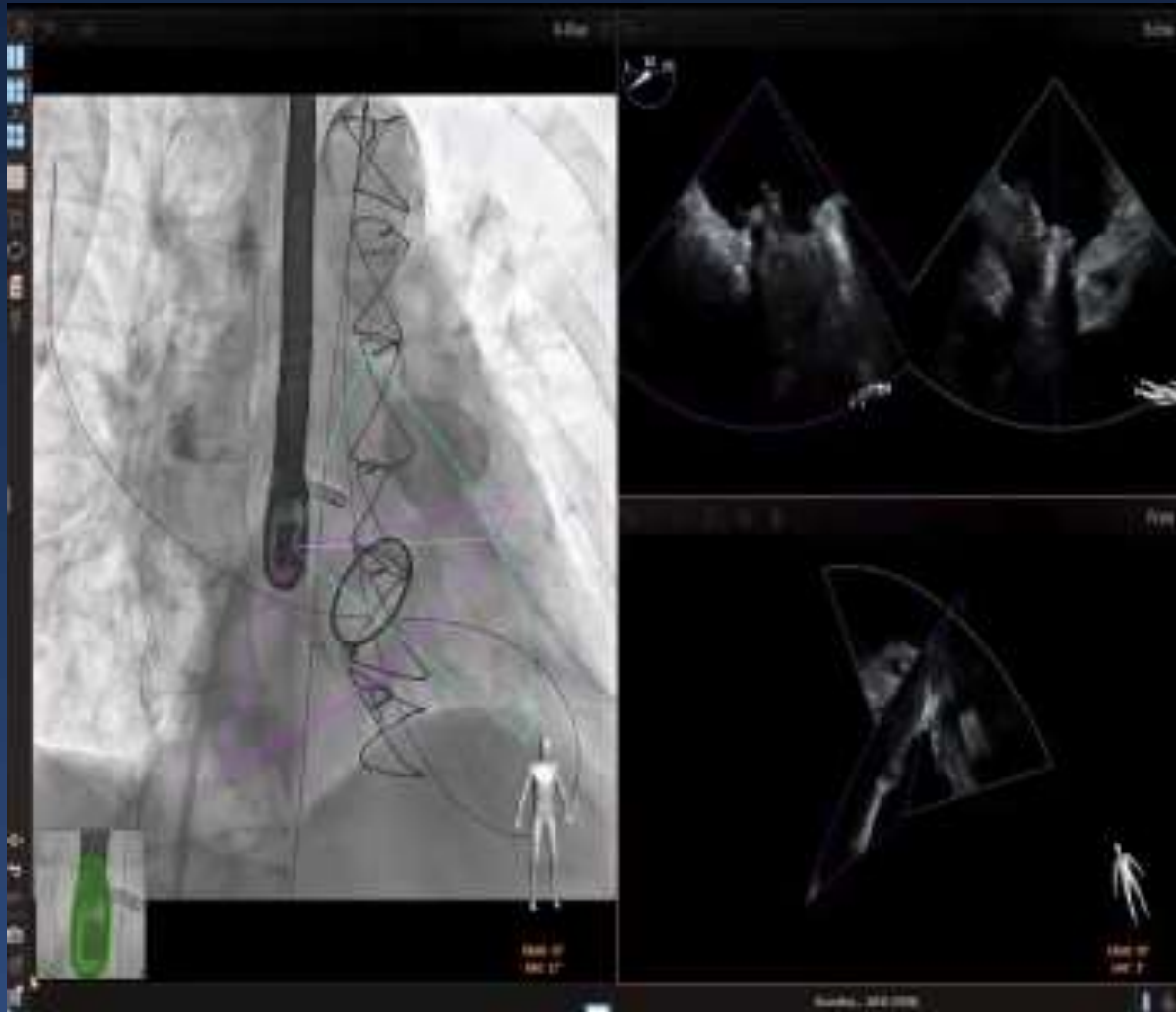
Initial Plugging Plan
8 mm



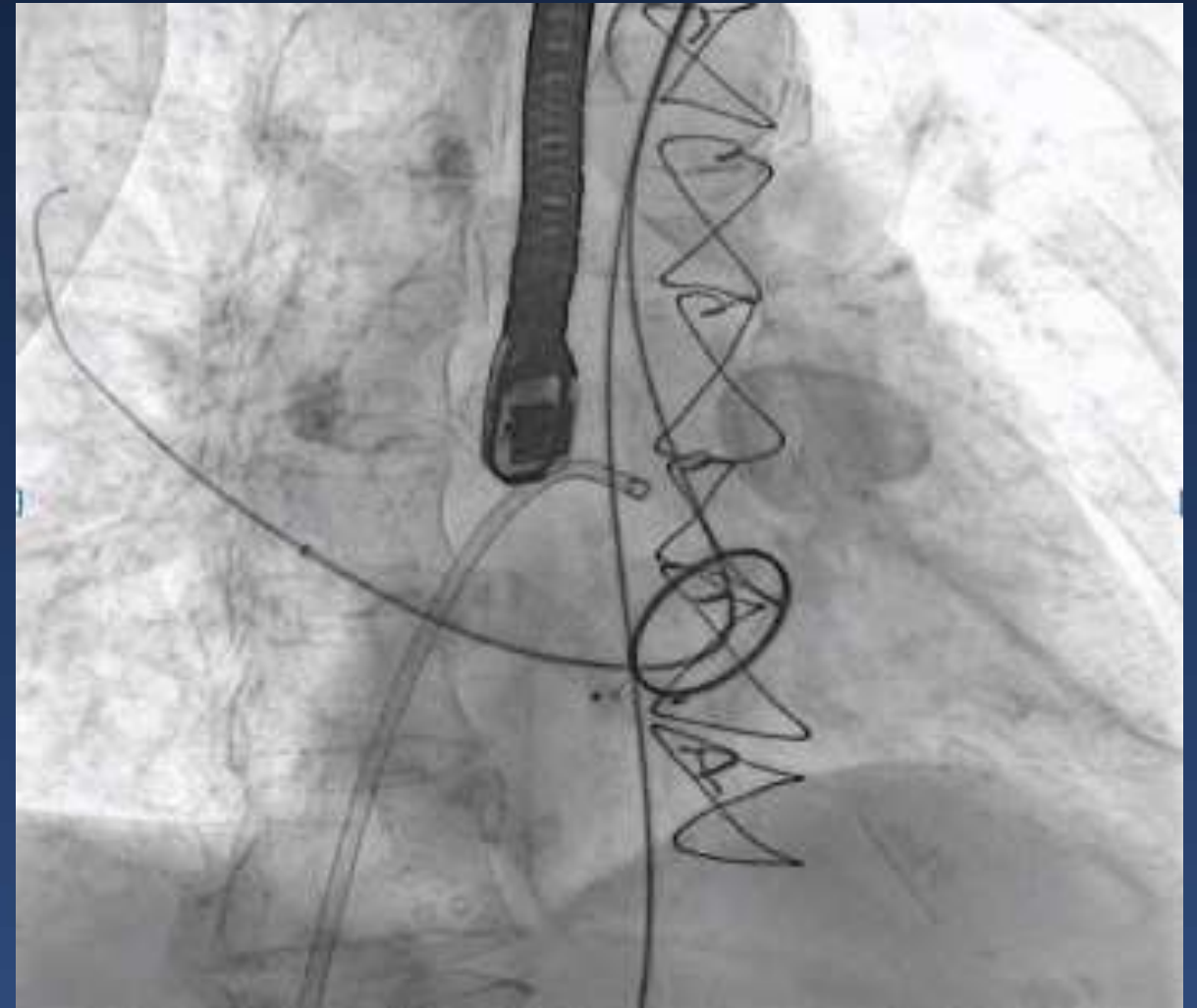
Additional Plugging
10 mm

ECHO Navigator guided MVL plug in

Wire reengagement



2nd MV plug in deployment



Amplatzer vascular plug 10mm

ECHO Navigator guided MVL plug in

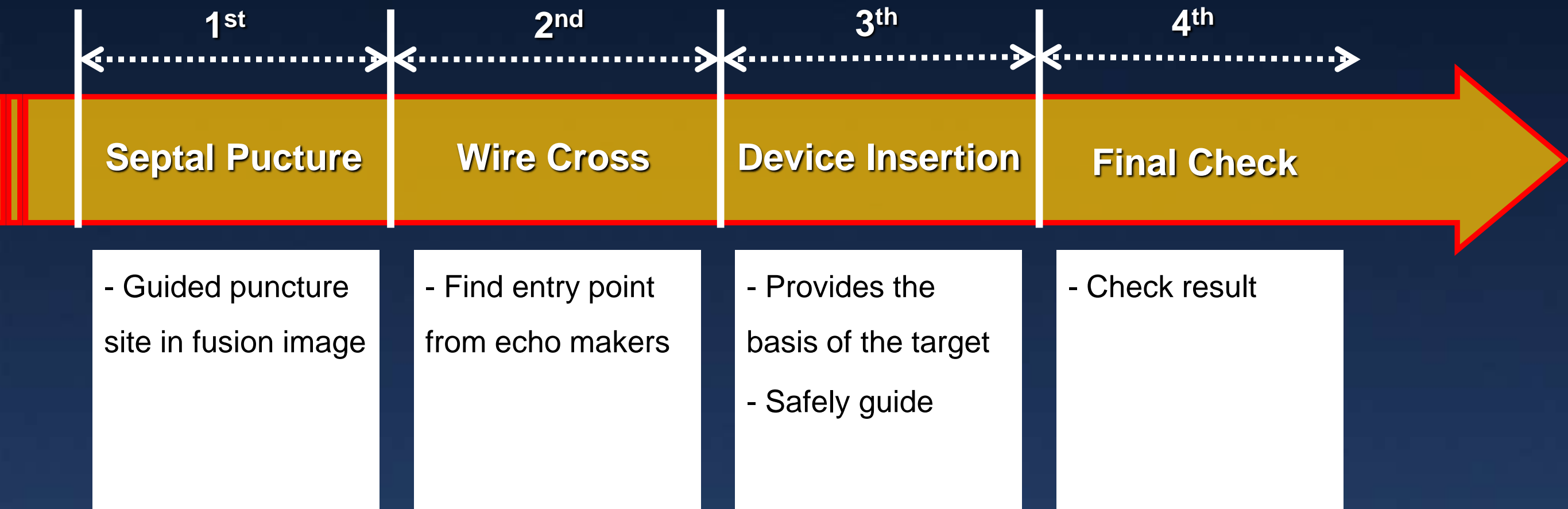
Final ECHO



Final



1st CASE SUMMARY



- Easy to find cardiac structure
- Easy to find leakage site
- Safely guide



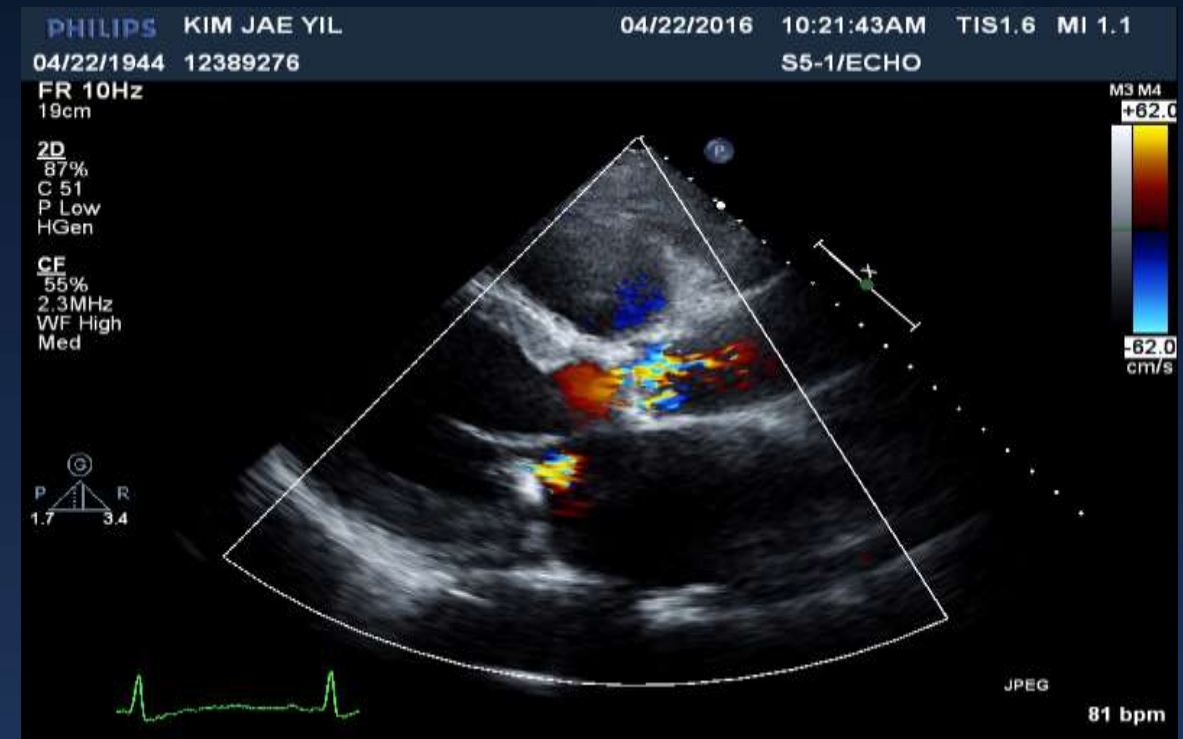
2nd TAVI Heart Navigator Guided

History

M/75 김 O 일

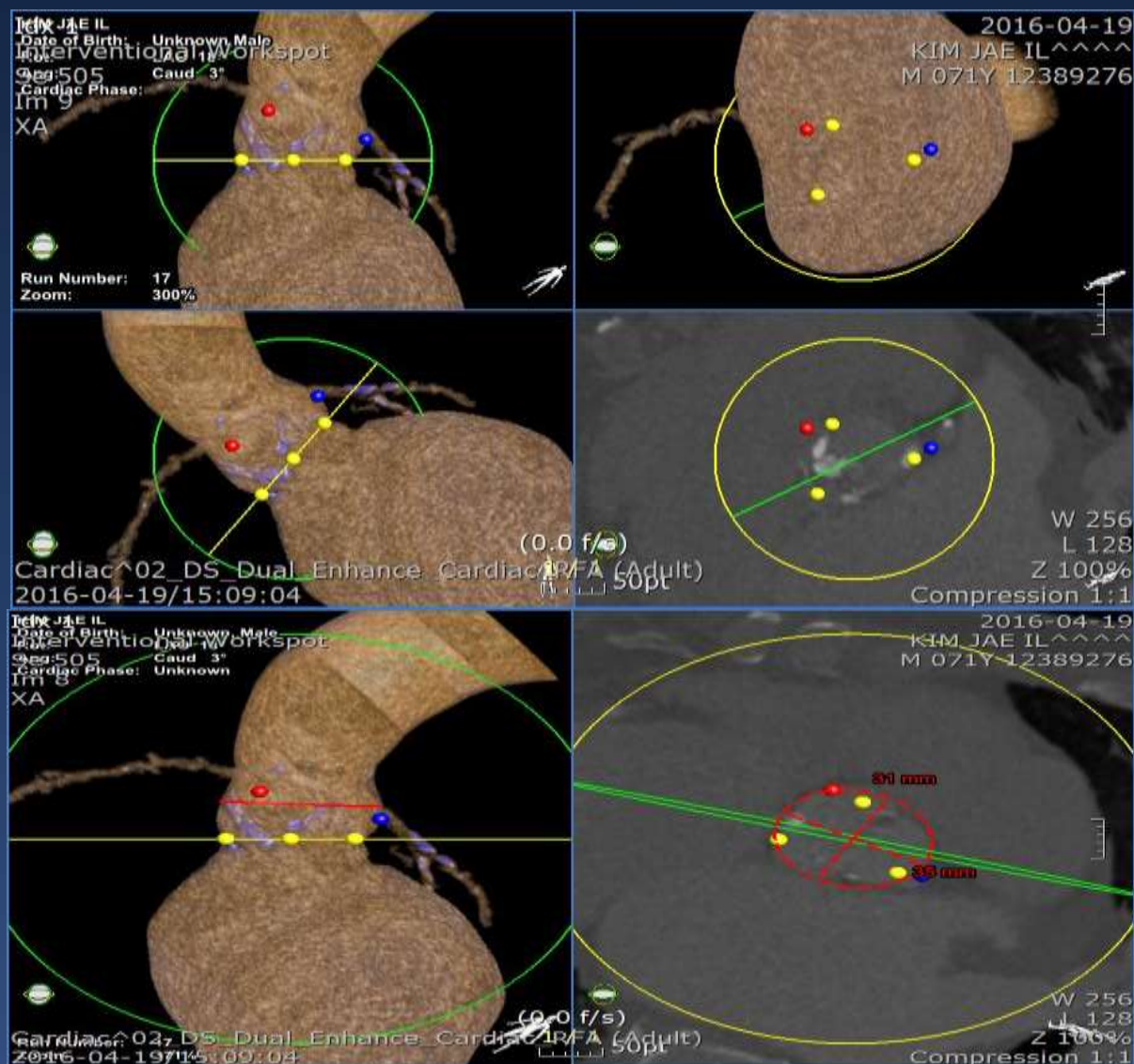
- C.C : Severe AS
- Past hx. : AKI on CKD, AF
- V/S 110/70
- Lab : BUN/Cr 112.9 / 1.88

pro BNP 14412 pg/ml

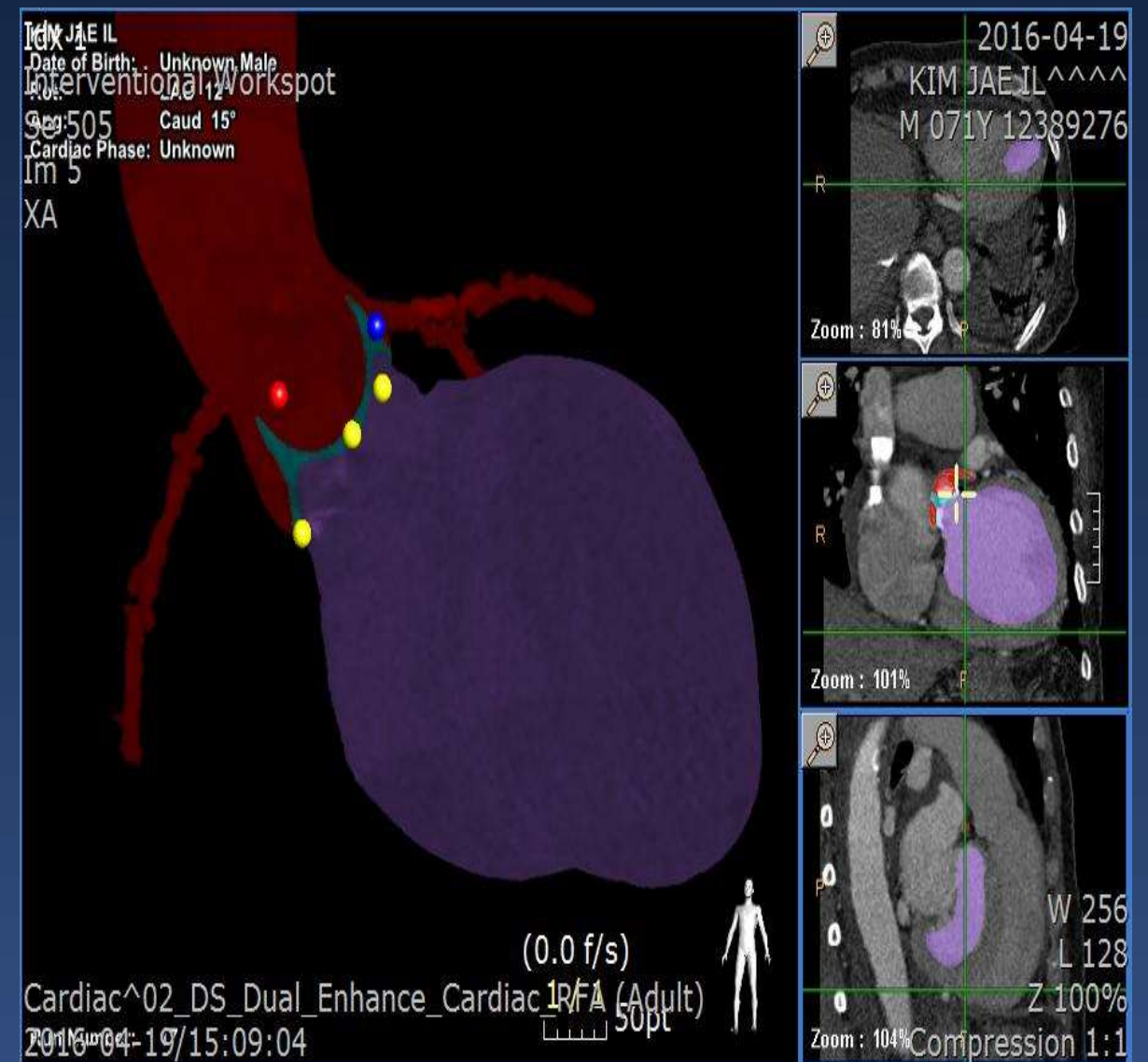


Heart Navigator guided TAVI

Size Measure

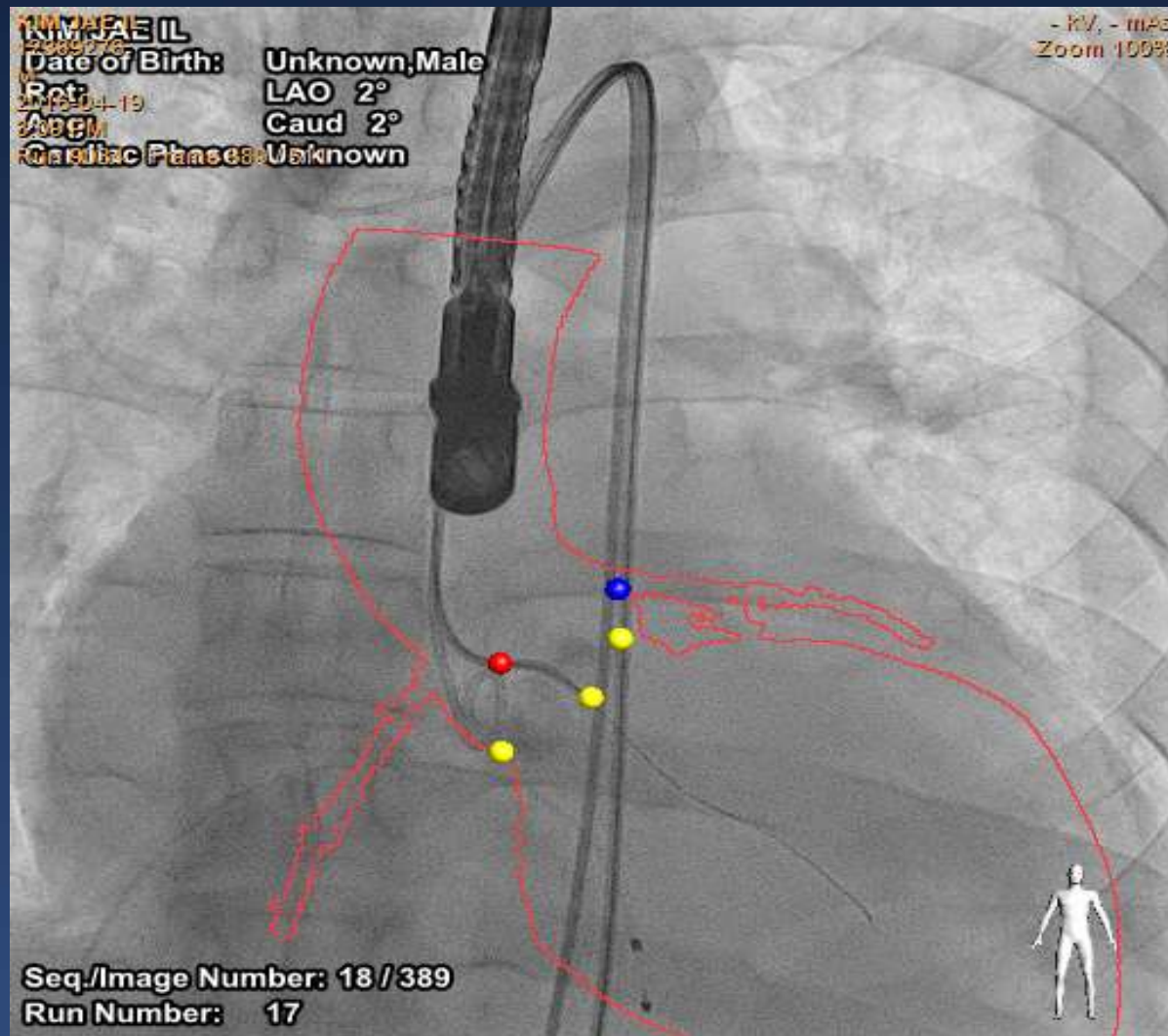


Segmentation & Registration

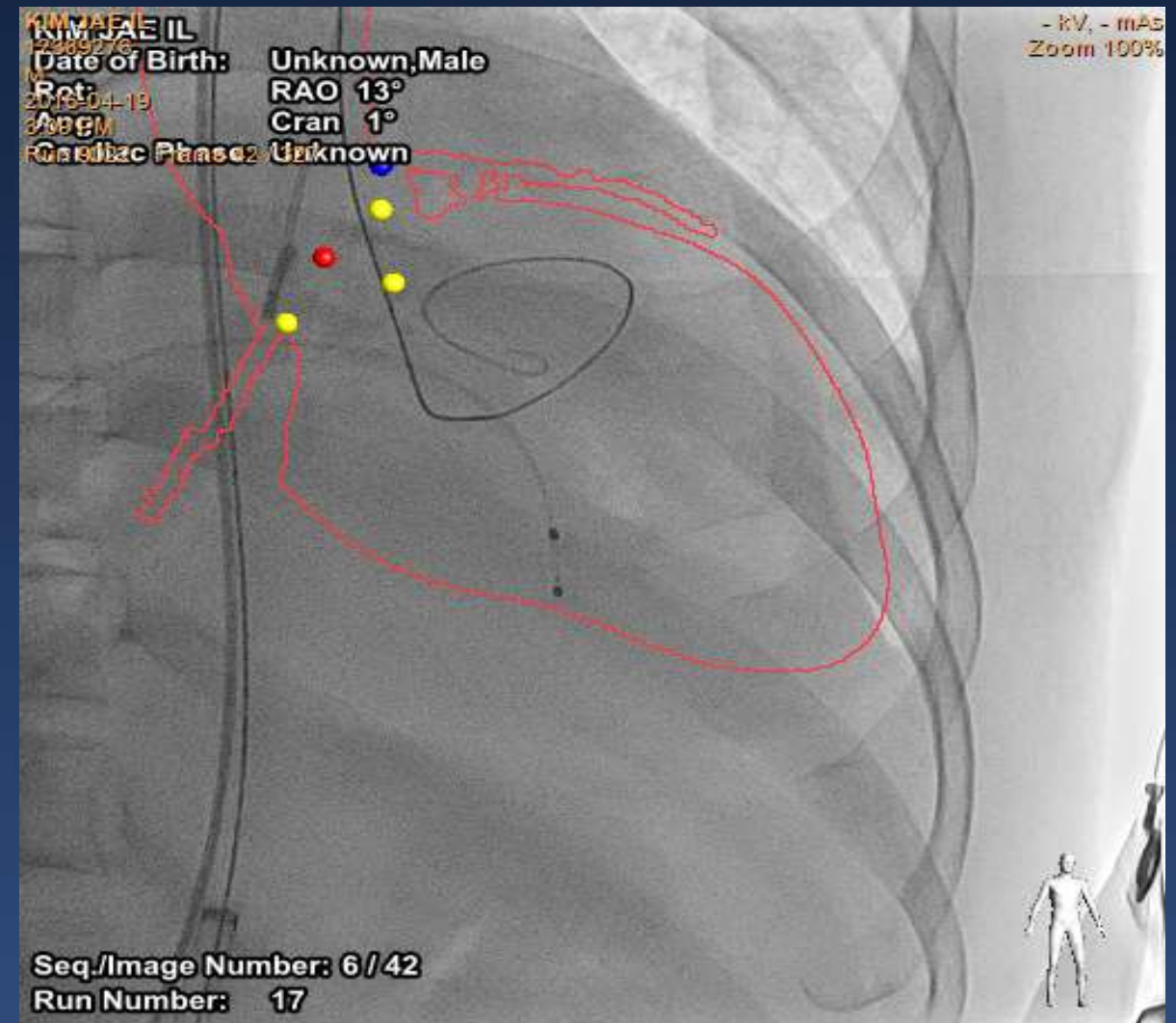


Heart Navigator guided TAVI

Wire Cross Ao to LV

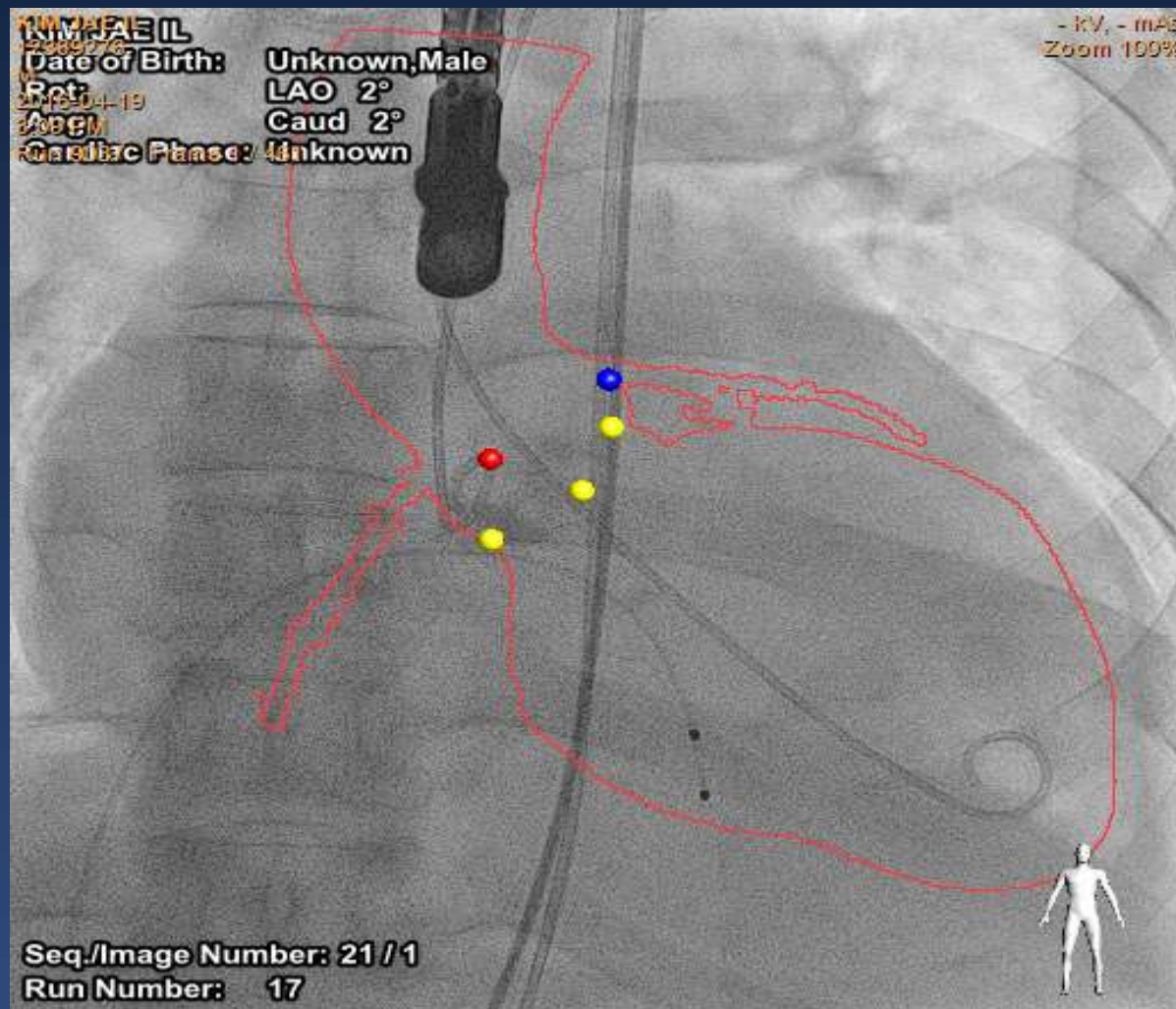


1st Wire Position

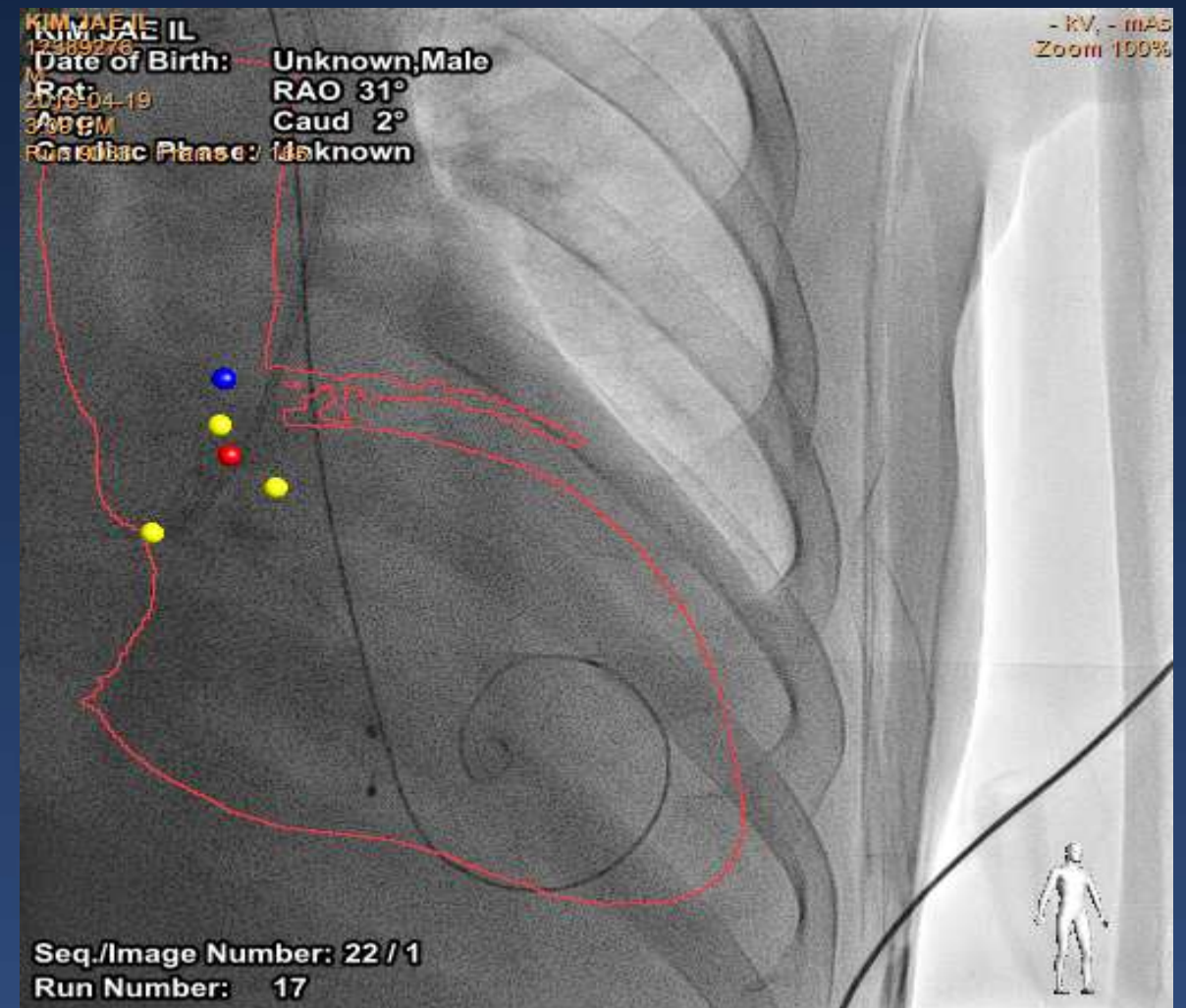


Heart Navigator guided TAVI

2nd Wire Position

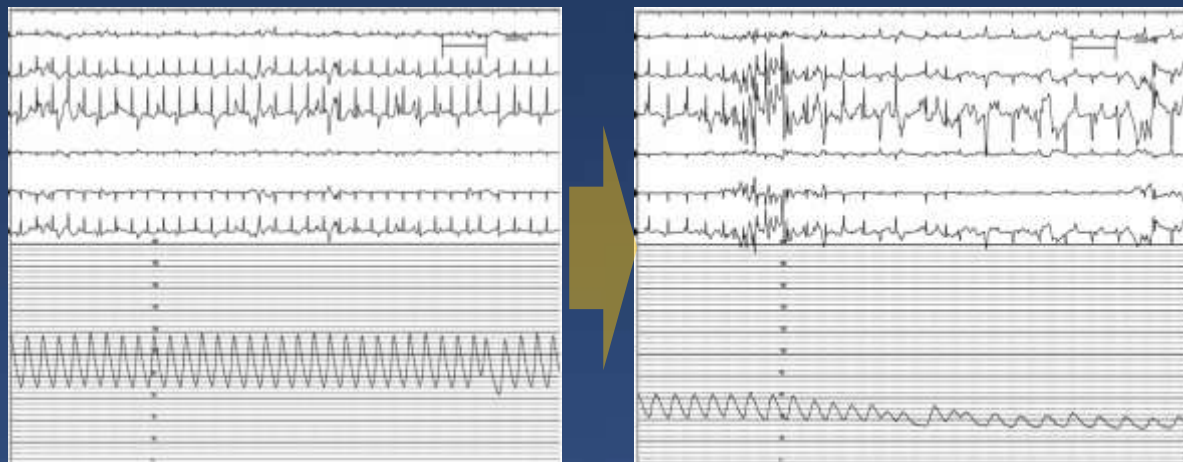


Position Check

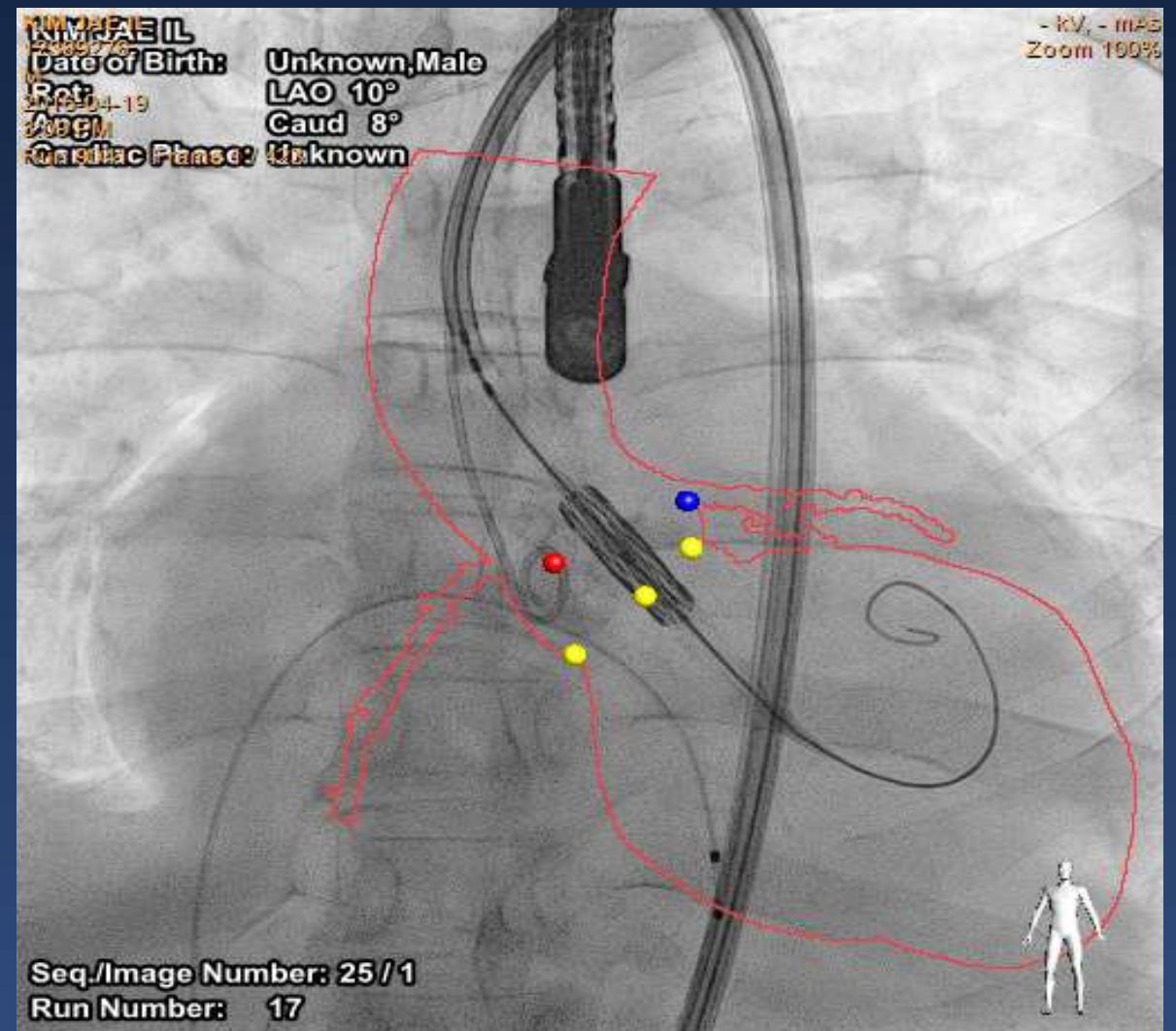


Heart Navigator guided TAVI

Balloon position → BP down

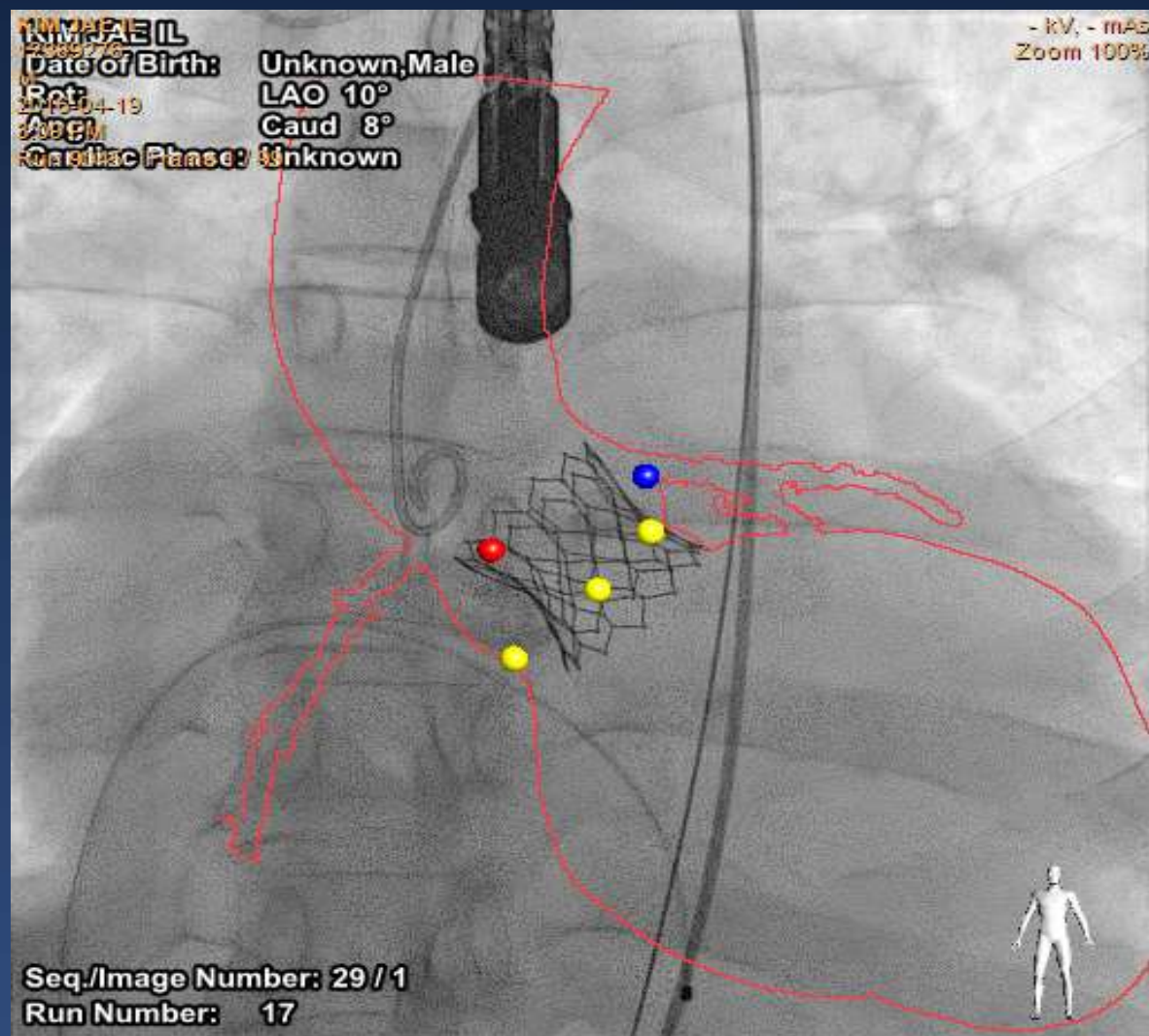


Direct TAVI Insertion

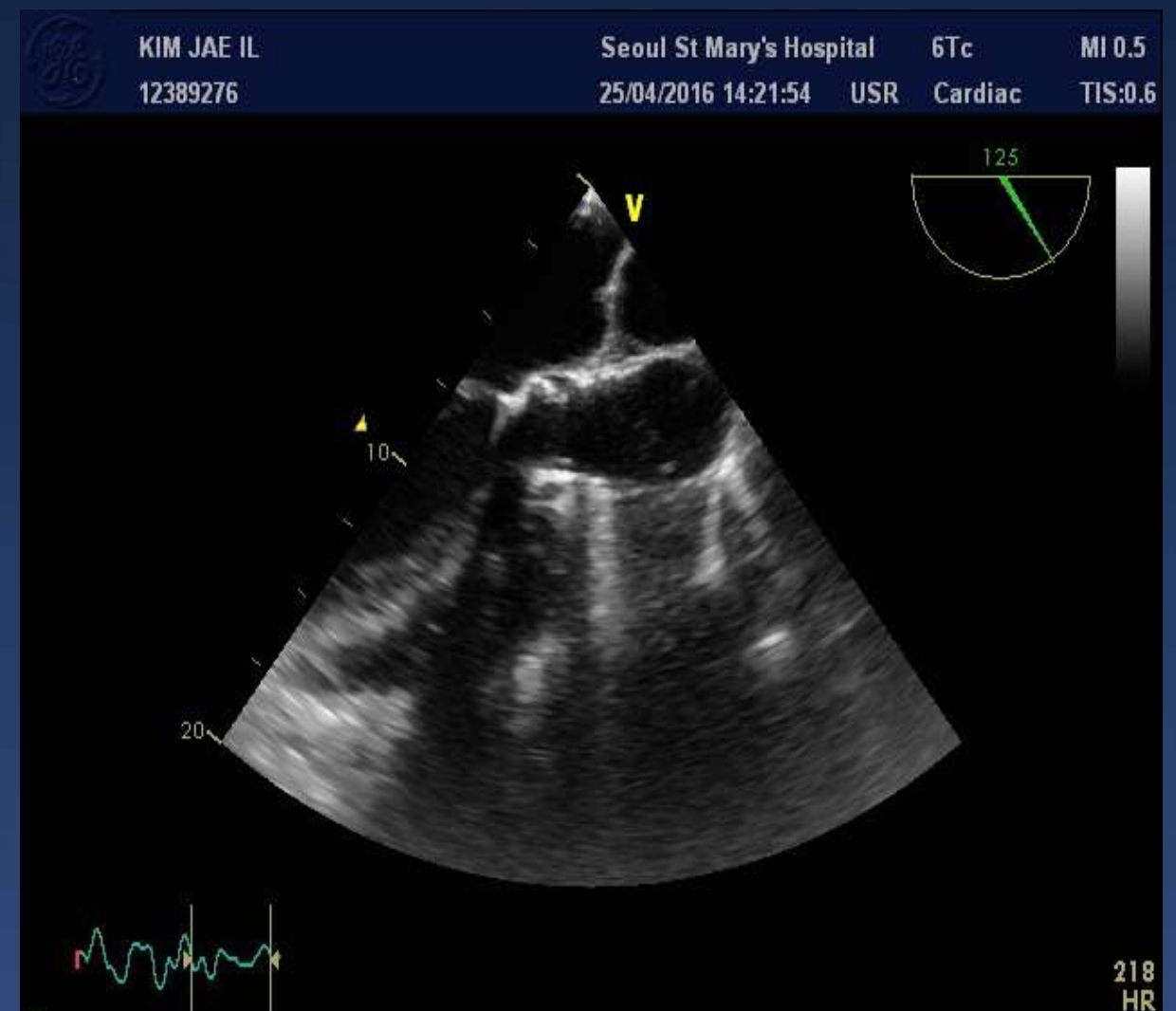


Heart Navigator guided TAVI

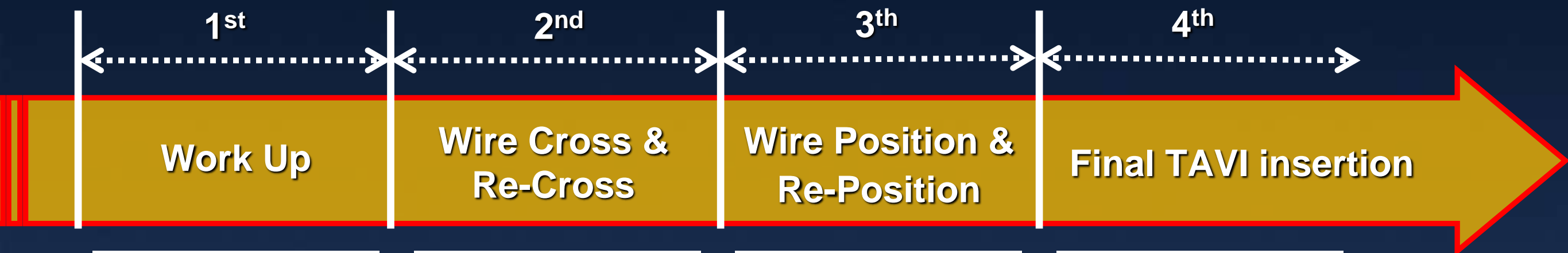
Final Angio



Final Echo



2nd CASE SUMMARY



- Check Annulus Diameter
- Recommend Projection angle
- Registration

- Find entry point from cuspid markers
- Check coaxial position

- Find LV volume from LV chamber makers
- Prevent LV damage

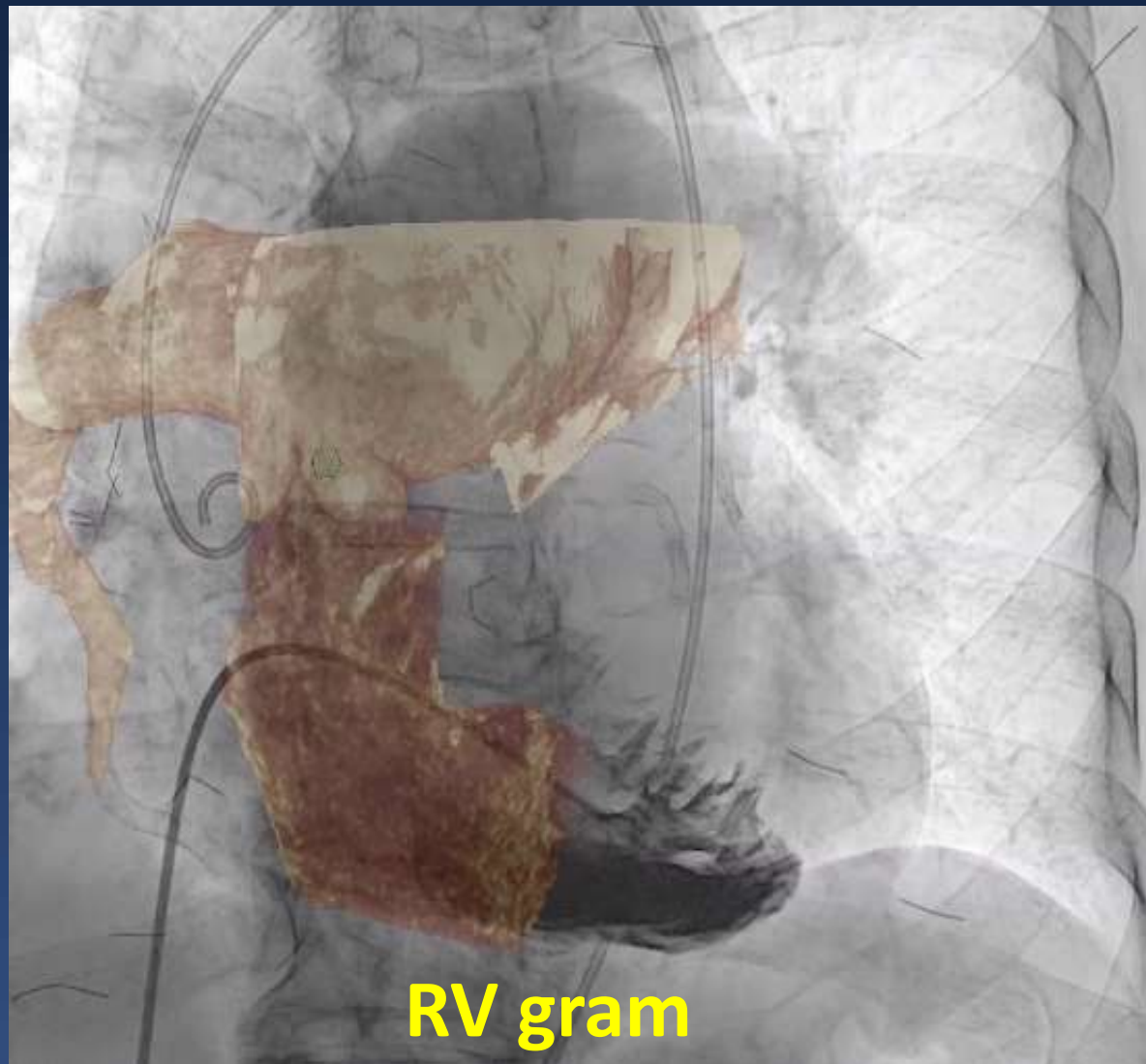
- Provides the basis of the target
- Safely guide

- Easy to find aortic valve & lv chamber
- Check to wire entry & position easily
- Reduce Contrast & Radiation Dose
- Safely guided

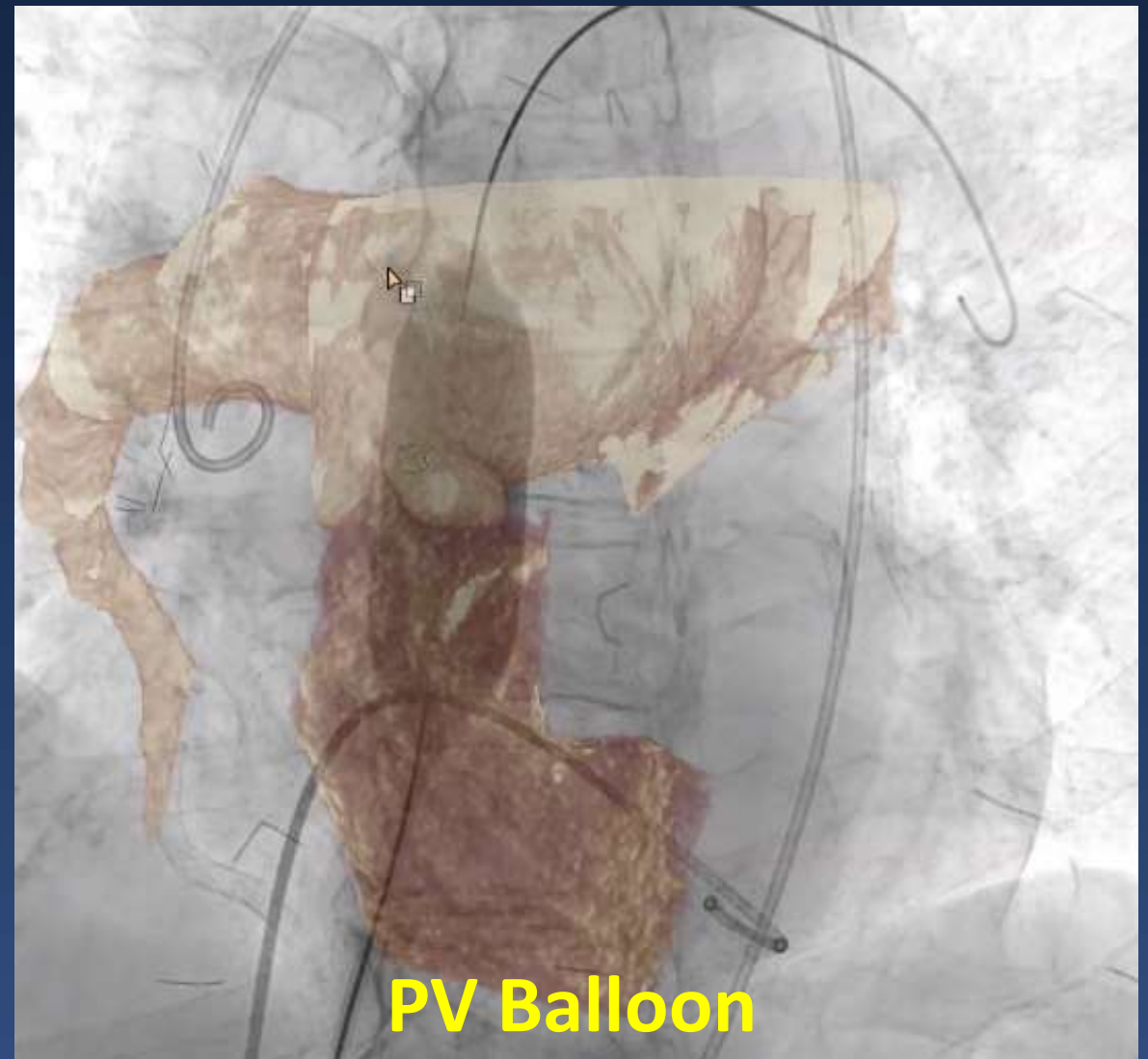


3th CASE Vessel Navigator guided PVB

RV gram with Fusion Image



Pulmonary Valve Balloon



4th CASE Vessel Navigator guided BPA

CTEPH : Chronic Thrombo Embolism Pulmonary Hypertension

B P A : Balloon Pulmonary Angioplasty

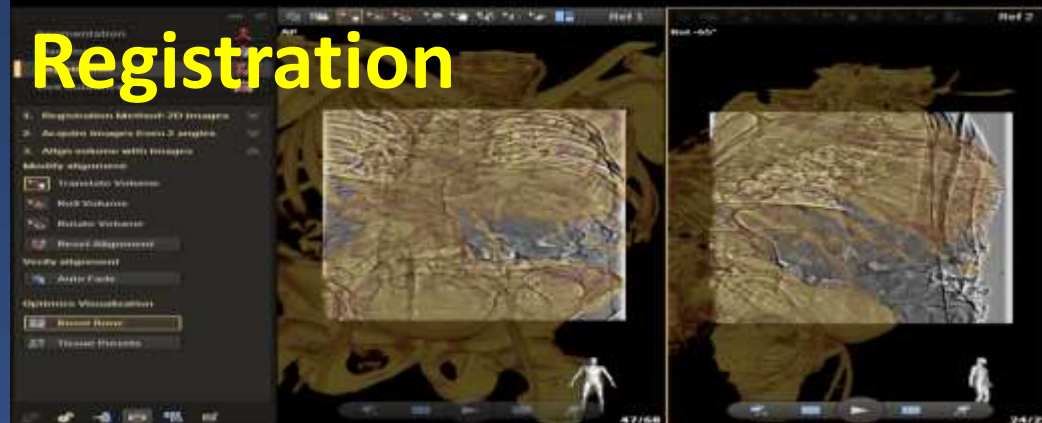
Segmentation



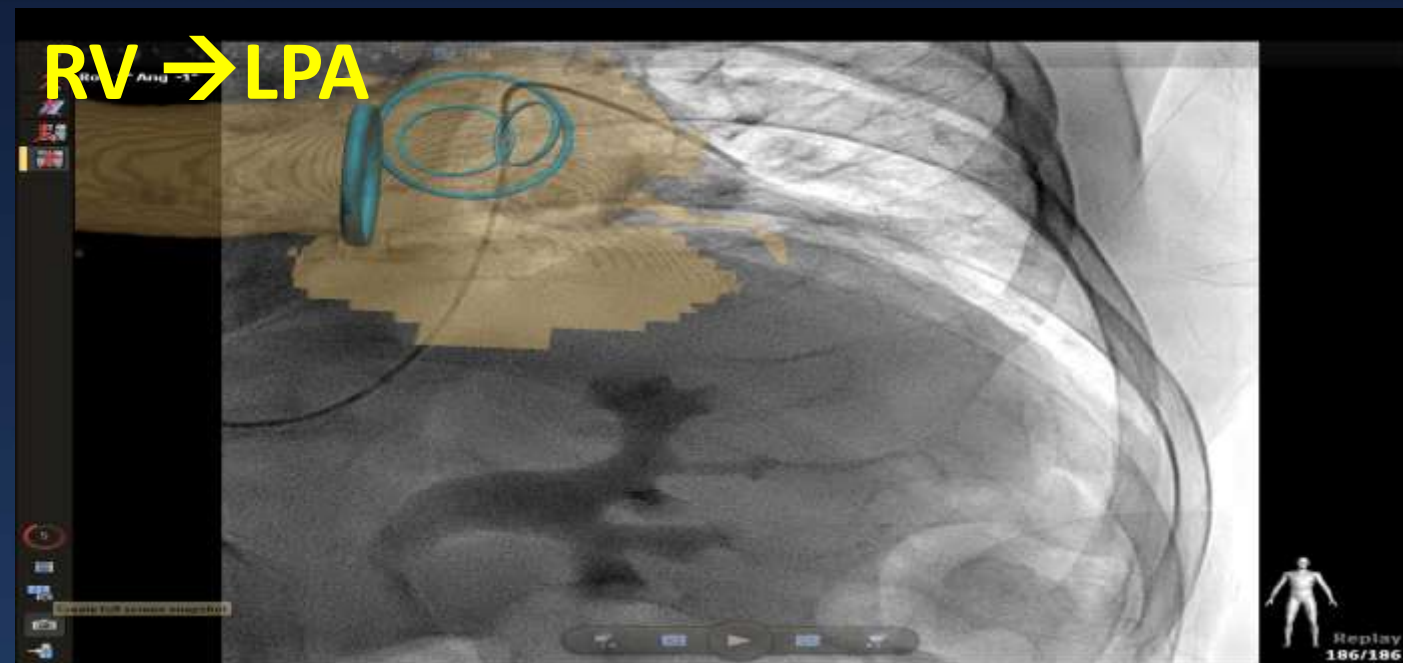
Landmarks



Registration



RV → LPA



RV → RPA



Take Home Message

Definition

Heart
Echo + Fluro → Fusion Image → Navigator
Vessel

Benefit

- Easy to find cardiac structure
- Reduce Contrast & Radiation Dose
- Enhance the Success rate

Limitation

- Incorrect Segmentation & Hard to find landmark
- Fusion image does not match
- System was installed only in very few hospitals

Take Home Message

Overcome

- R & D
- Single or Multi Center Trial
- Share of early clinical experience

Apply

- **Easy to find cardiac structure**
 - Know the anatomical structures in real time
 - Fusion image helps the understanding of the fluoro & cine
- **Reduce Contrast & Radiation Dose**
 - It can be a quick procedure time
 - It can reduce the contrast medium through the usage landmark
- **Enhance the Success rate**
 - It can significantly reduce the learning curve



Thank you for your attention