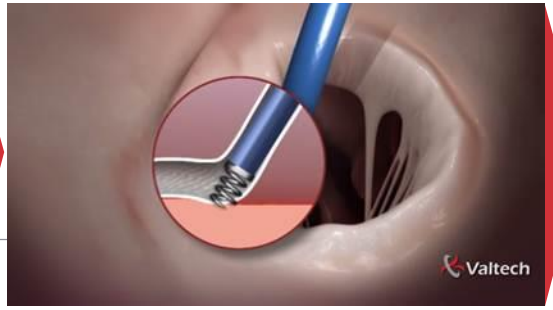
Valtech

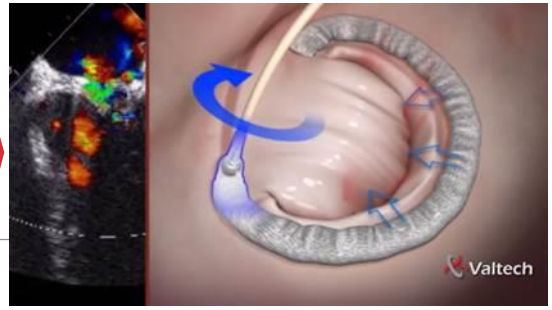
TRANS FEMORAL Cardioband

Cardioband
Procedure steps









General Preparations

Imaging Views

Transseptal Puncture



TSS Insertion

IDS Insertion

Implant Deployment

IDS removal

SAT Insertion & Implant Adjustment

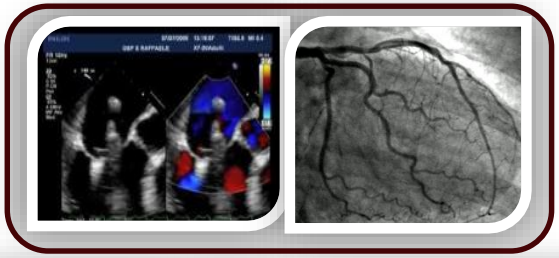
System Removal

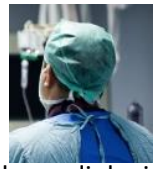
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Cath Lab – Overview

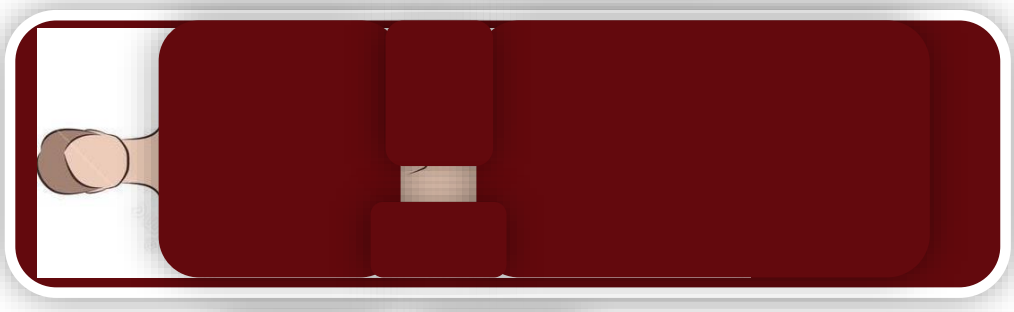
TEE





Echocardiologist

Fluoroscopy







Anesthesiologist

Respiratory Machine









Anchor Drives Equipment

Cardioband System preparation table (280x65)

Patient Positioning

Place Booster **support plate** under patient's leg in the region between the area of the upper leg and the knee

Place the **booster** on the booster support plate so the front edge of the booster is **90-100 cm** from the patient's heart

Adjust height of the booster to minimal height above the leg

Prepare the patient for hemodynamic monitoring, per institution's standard practice.

Device preparation performed in the Cath Lab prior to the procedure



Procedure steps

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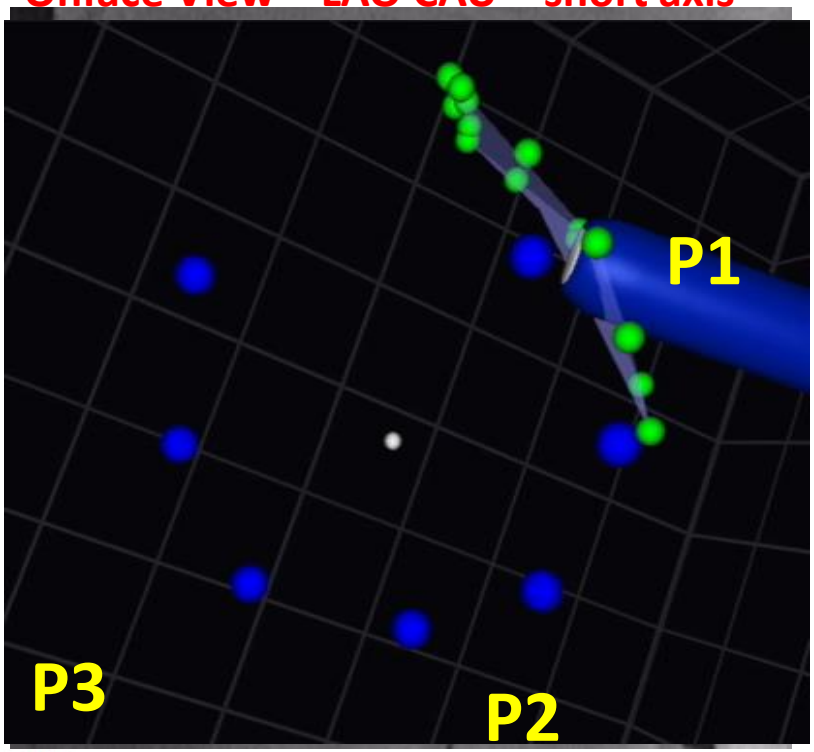
Valtech

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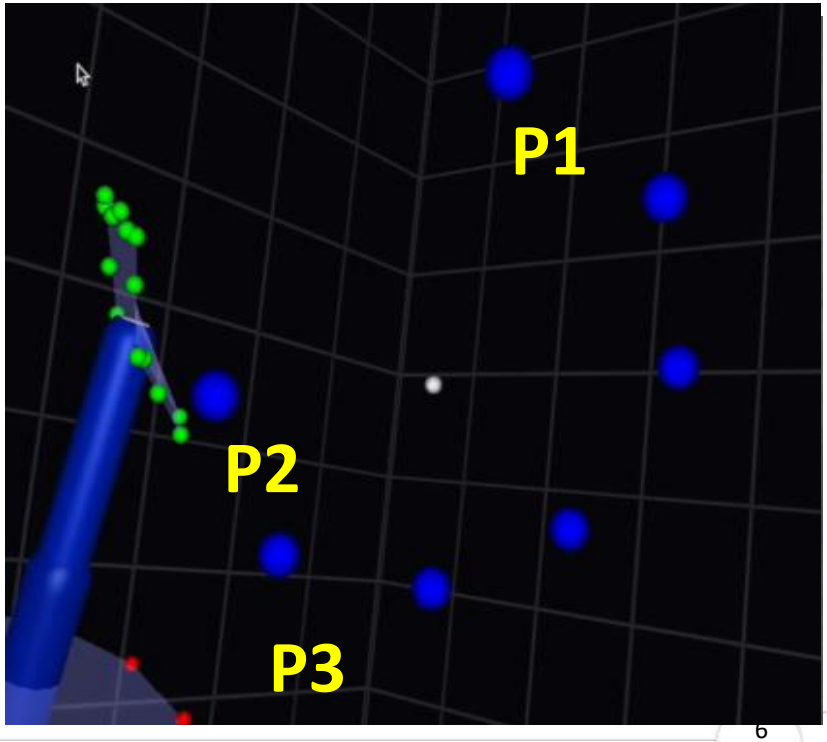
Imaging Views – Fluoroscopy

- During the procedure, two fluoroscopy projection views of the mitral valve are used
- The views are pre planned based on CT scan
- Onface - LAO/CAU to see the “C” path
- Perpendicular - RAO/CRA to see the single anchor path

Onface View – LAO CAU – short axis



Prependicular View – RAO CRA – long axis

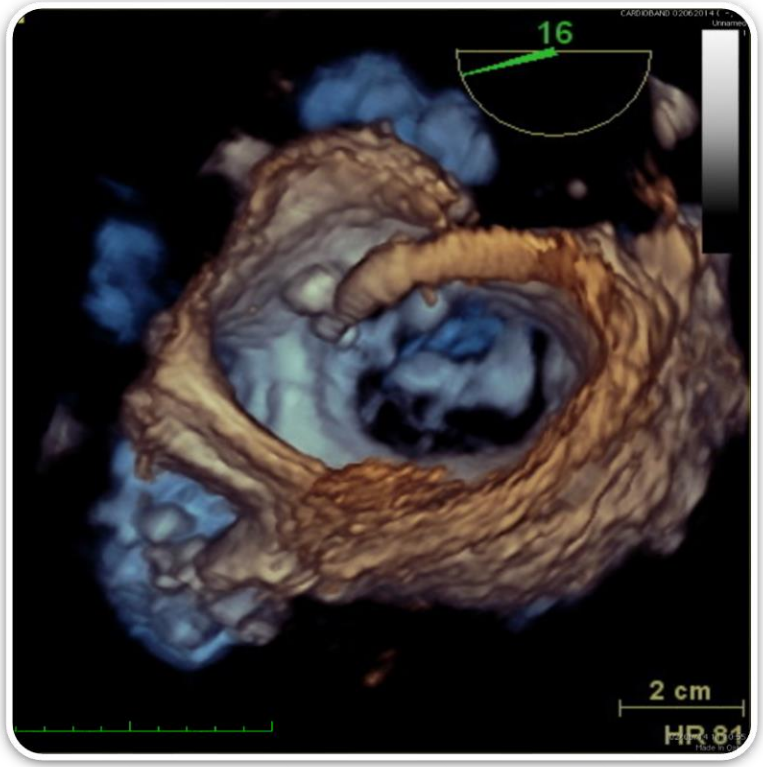


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Imaging Views - Echo Views – 3D Surgical View

3D surgical view is used for general orientation, gross tip positioning and catheter angulation



Keep the same 3D orientation throughout the procedure

- Aorta at 12 o'clock
- Lateral commissure at 9 o'clock

Valtech

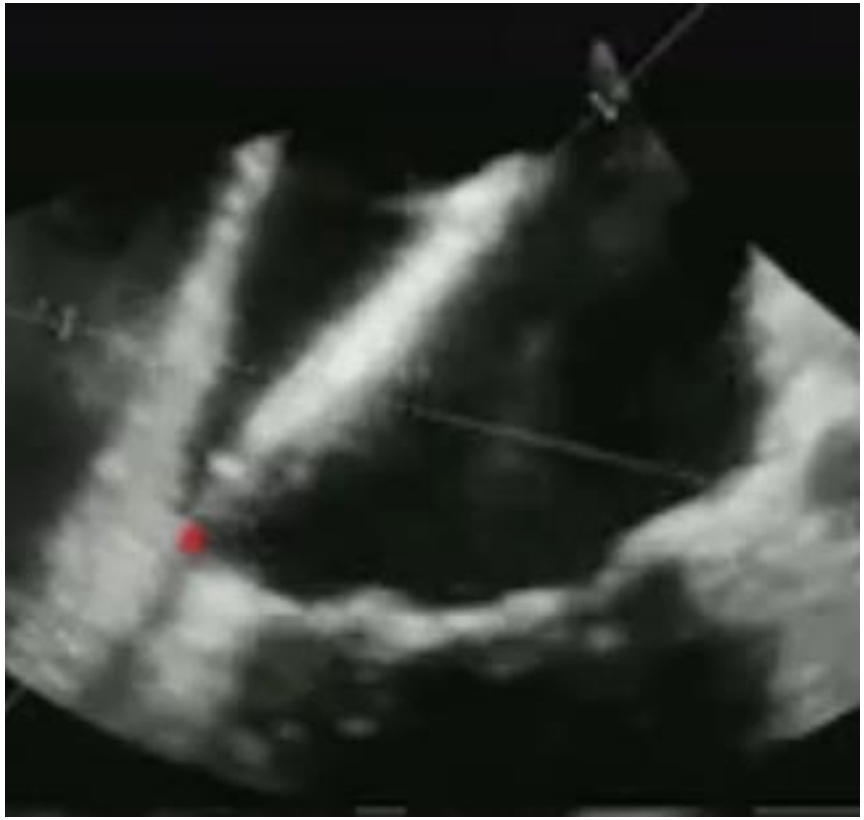
CLD1142

Imaging Views - Echo View – 2D

2D and x-plane view:

1. Distance from the hinge point

2. Assessment the angle of approach to the annulus
(according to the procedure planning)



Cardioband implantation – Imaging sequence

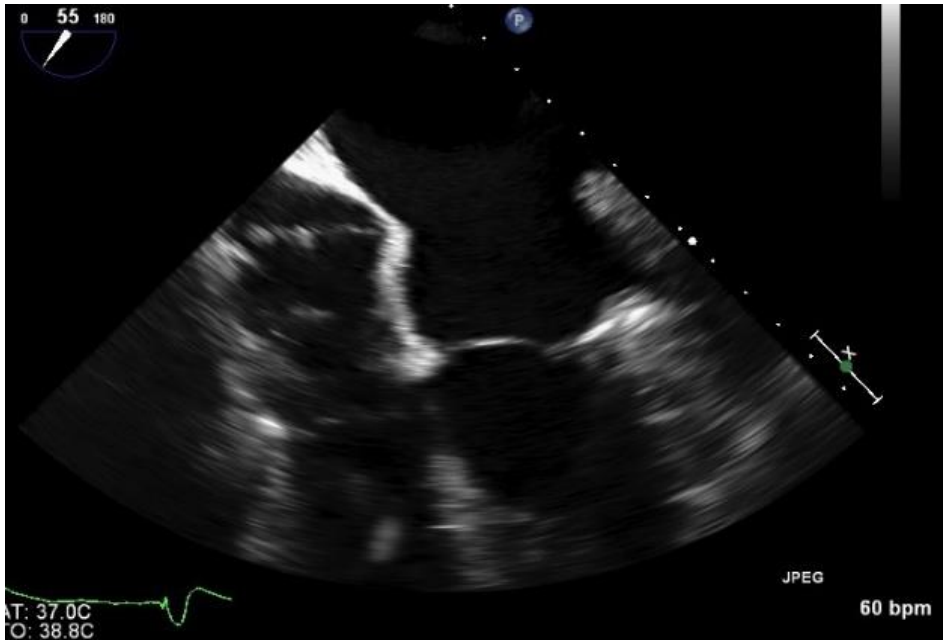
- LAO - General position of the tip of CB
- 3d Echo - General position of the tip of CB
- X-plane - final check
- RAO - Anchor deployment

Procedure steps

General Preparations

Imaging Views

Transseptal Puncture



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IDS removal & SAT insertion

Implant Adjustment

System Removal

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Transseptal Puncture

Puncture is performed in the Fossa Ovalis

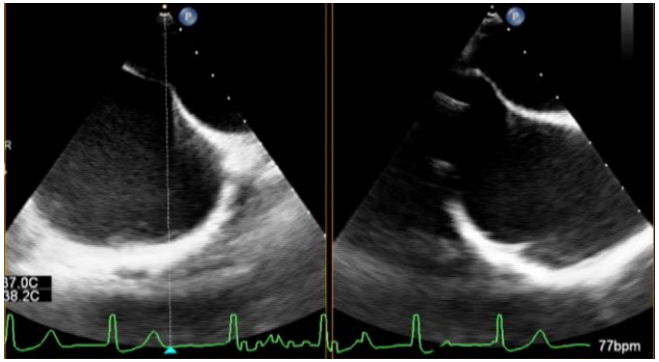
TSP height: 3.5-4.5 cm

Puncture site is chosen during the procedure planning

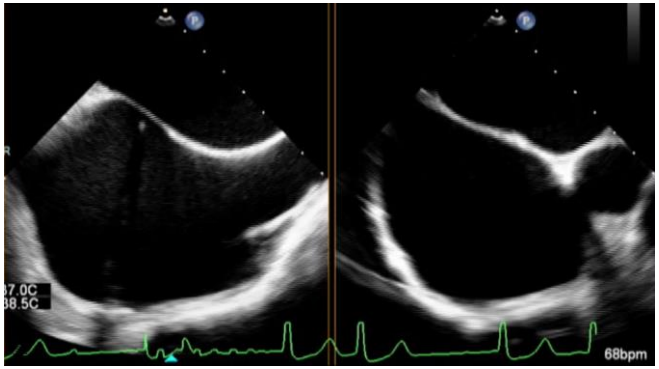
Accurate puncturing is essential for a successful Cardioband implantation.

Echo Views

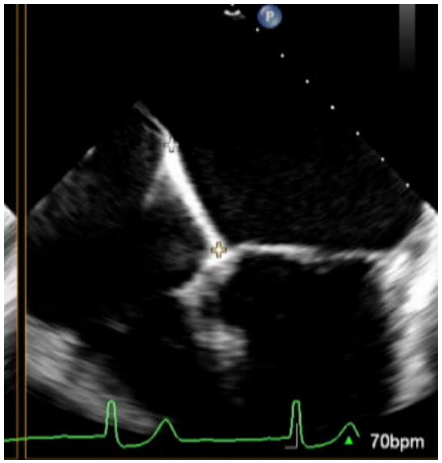
Bicaval (inf - sup)



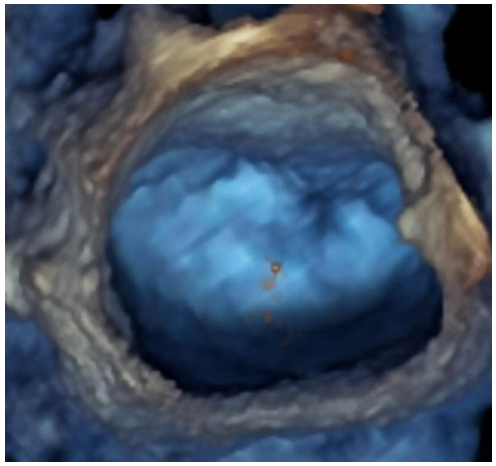
SAX at the base (ant-post)



4 chamber view (height)



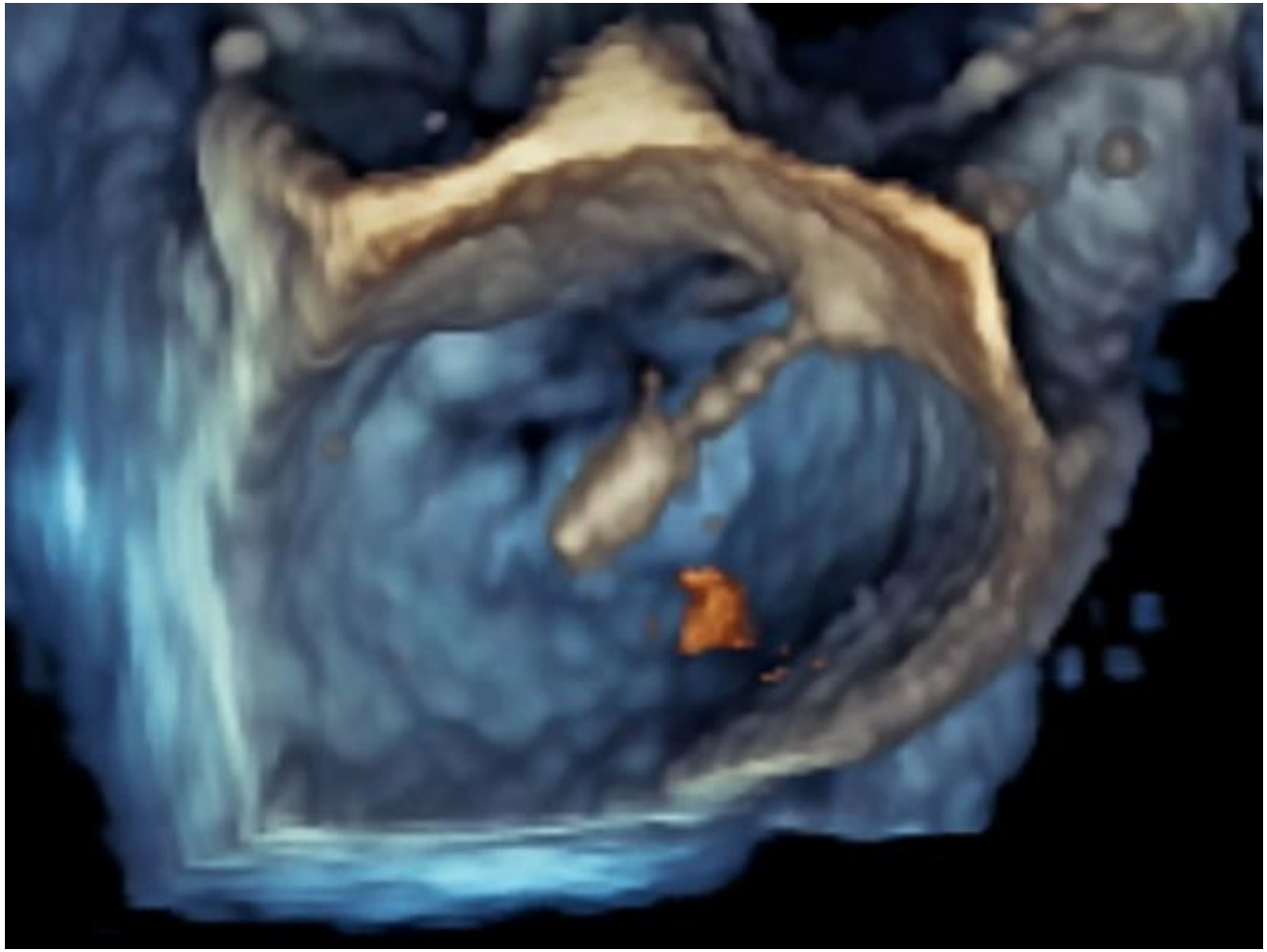
3D Surgical view



After Transseptal Puncture

- Advance the Mullins sheath into left PV
- Heparinize the patient – ACT to be maintained >250
- Advance extra stiff Amplatz exchange length guidewire in LA or PV
- Retract sheath

After Transseptal Puncture



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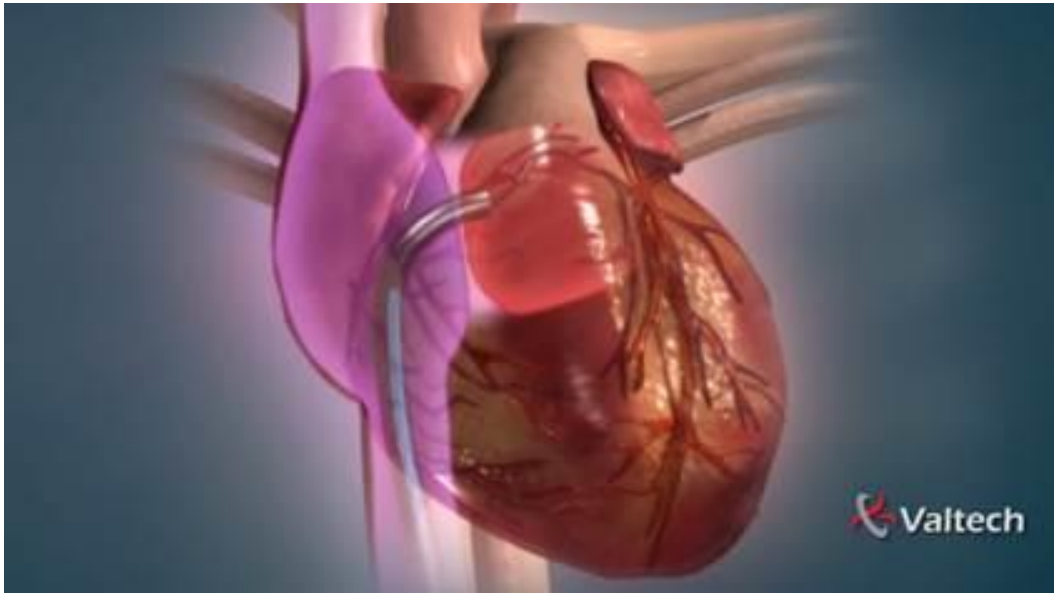
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Procedure steps - Presentation Overview

General Preparations

Imaging Views

Transseptal Puncture



TSS Insertion

IDS Insertion

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IDS removal

SAT Insertion & Implant Adjustment

System Removal

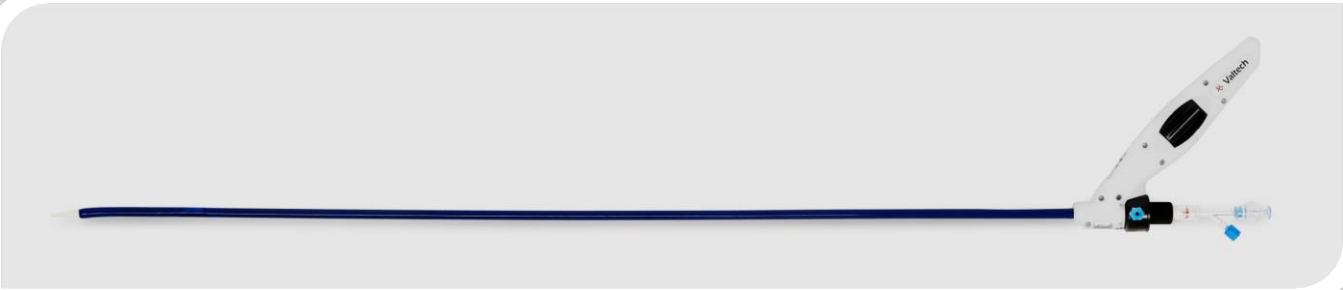
TSS Insertion- 1\2

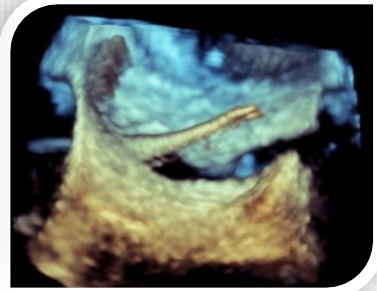
Pre dilate femoral access with at least 18F dilator

Insert the straighten TSS with the Dilator through the femoral vein over the high support guidewire

Observe Echo and Fluoroscopy, consider applying “+” on TSS steering once in the RA

Advance TSS across the septum. While maintaining slight forward pressure on TSS (tenting), gentle rotation of TSS may be needed. Avoid pushing TSS aggressively across septum





Recommended Echo Views: 2D -Bicaval view or short axis at the base view, 3D - surgical view

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TSS Insertion- 2\2

Retract the dilator into the TSS, keep the wire in LA or PV and confirm that the TSS is at least 2cm in the LA.

Pull back the wire inside the dilator, close the dilator valve to secure the wire.

Remove the dilator and Guidewire together.

Consider to apply "+" to the TSS to prevent it from escaping out of LA

Once dilator is out – De-Air the TSS & renew min flushing

Place the stand over the silicon mat above the booster

Connect the TSS to the stand cradle

Steer the TSS to 90° by applying "+" on the steering knob.

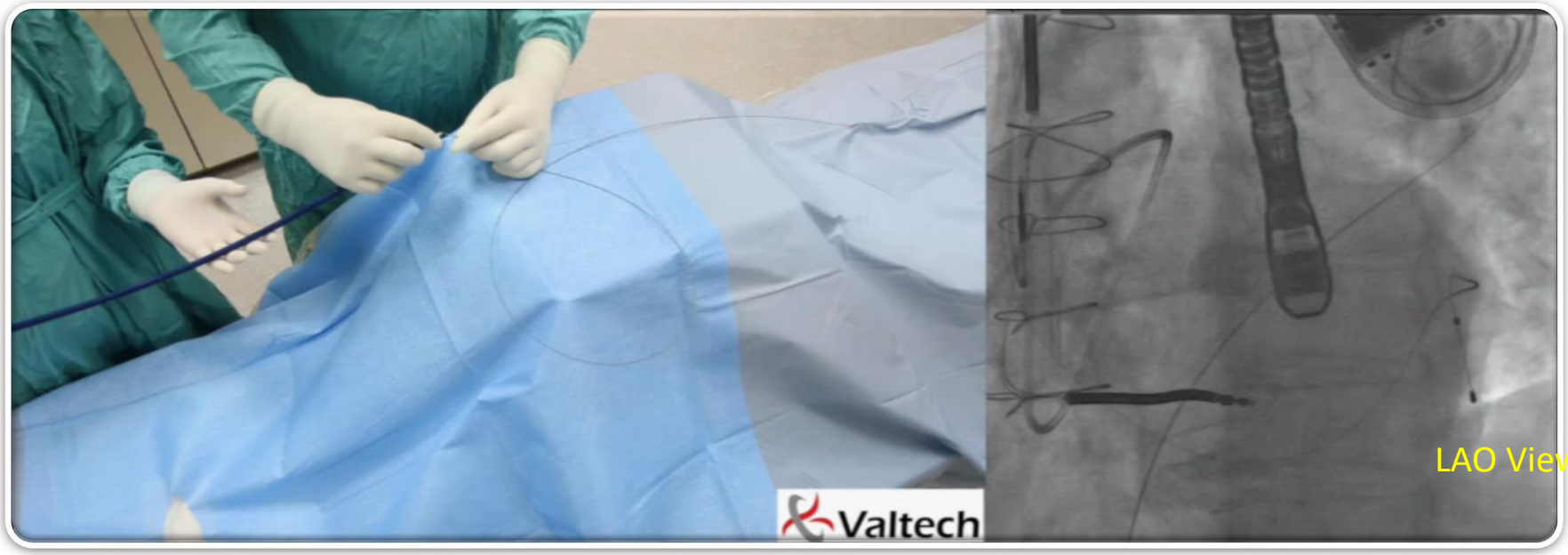
The tip of the TSS should be placed above the middle of the MV

Use 3D surgical view and RAO to aim the TSS tip in the direction of the apex by rotating the TSS handle CCW\CW

Recommended Echo Views: 2D -Bicaval view or short axis at the base view, 3D - surgical view

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TSS Insertion



Procedure steps

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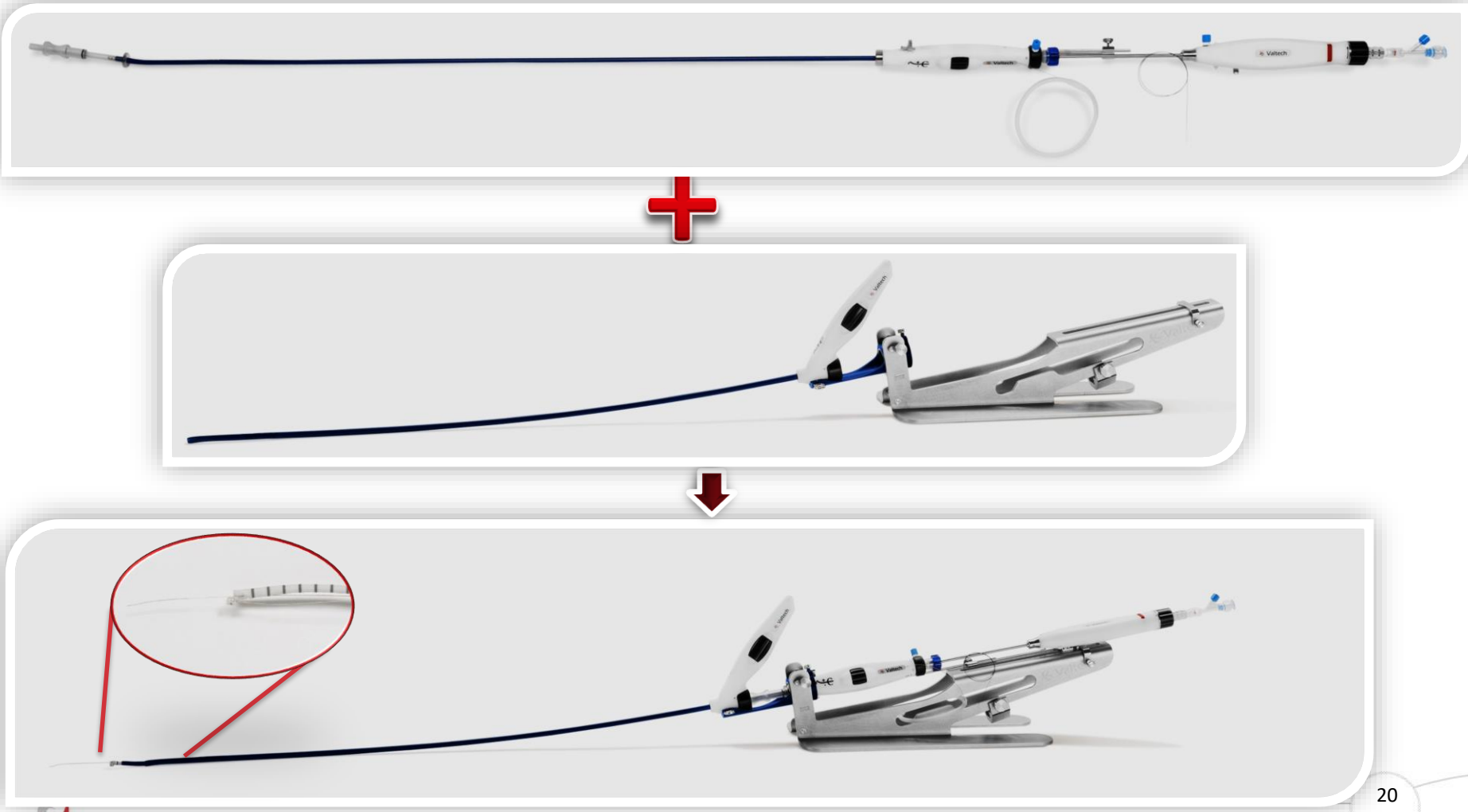
IDS removal

SAT Insertion & Implant Adjustment

System Removal

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IDS Insertion



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IDS Insertion

Flush the IDS until water fills the Implant protection funnel, close with your finger the locking opening

Verify the funnel hole is facing up

Attach the funnel tip to the TSS valve for a few seconds allowing dripping through the funnel hole.

Carefully pull the distal part of funnel all the way through the TSS valve “pulling & not pushing”

Advance the IDS into the TSS



IDS Insertion

Once the locking mechanism crossed the TSS valve, lower the IDS, de-air the GC by allowing back flush through the stopcock. Make sure to temporarily eliminate TSS & GC flushing.

Once blood is seen through GC line, close the stopcock and restart Min flushing in GC, remove funnel lock.

Advance the IDS into the TSS while keeping the IDS locking pin in the direction of the cradle insertion hole, stop advancing about 5 cm from the cradle engagement point



IDS Insertion – Iron Man GW deployment

3D surgical echo & Fluoroscopic RAO views

advance the IDS further into the TSS

Watch the ironman GW exiting from the TSS tip through the MV into the LV

When feeling resistance to the advancement execute the following sequence repeatedly:

1.Straighten a bit the TSS by applying “-” steering

2.Simultaneously pull the entire system back to maintain the position of the wire tip (exchange over GC)

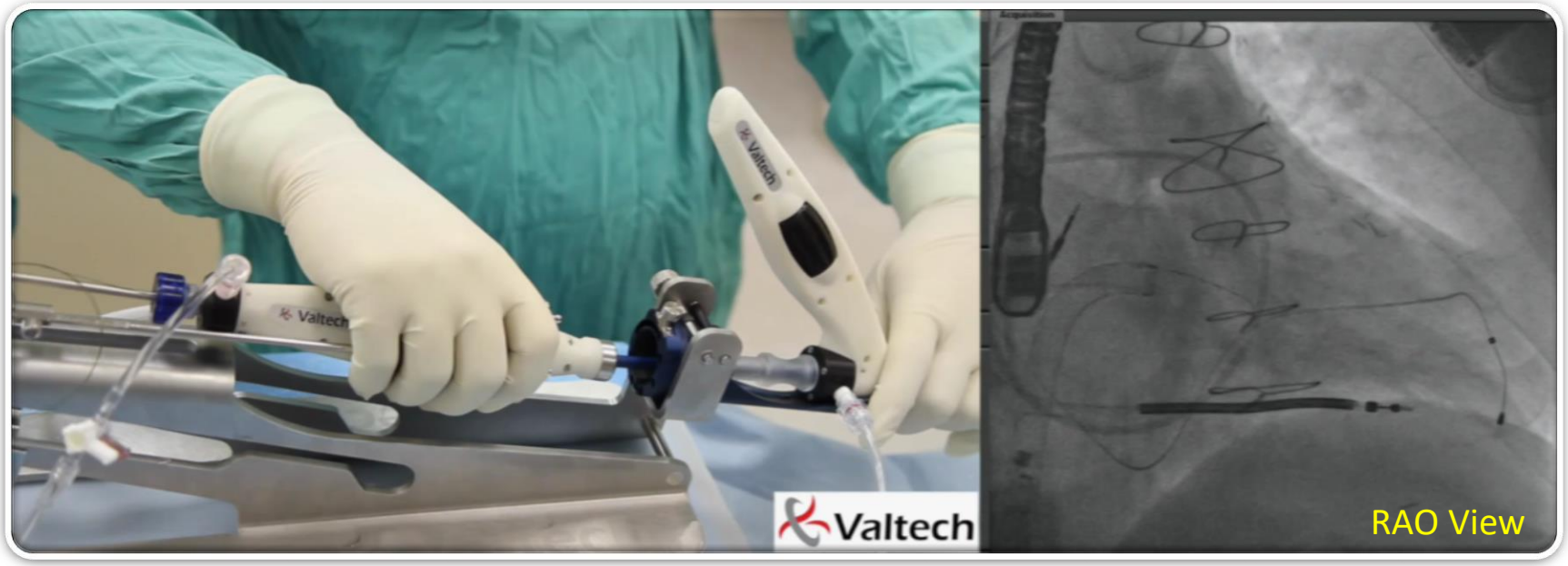
3.Advance the IDS

When the GC handle reaches the cradle, insert the GC pin forward and rotate the GC CW while pushing forward, double check locking. Lock the IC into the stand.

Confirm on RAO that the Iron Man remains in the LV

IDS Insertion – Iron Man GW deployment

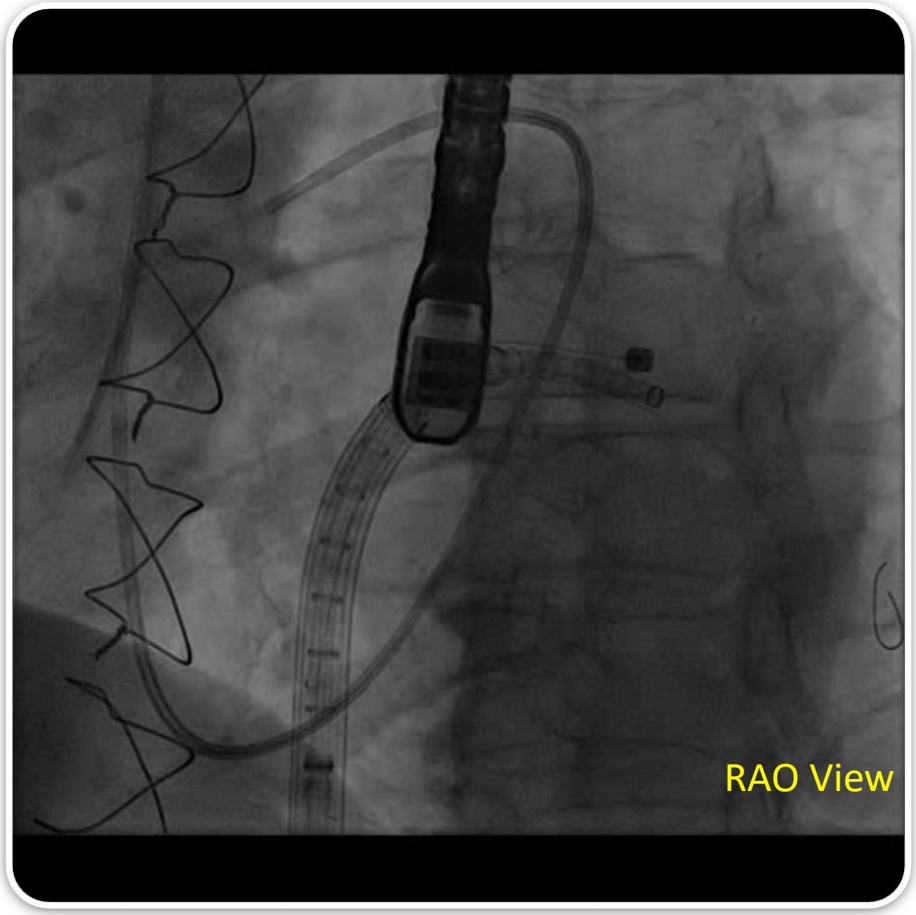
- Confirm that the IDS tip doesn't advance into the LV – if it is getting into the LV pull back the system
- 4CH 2D view to be used to confirm wire deployment



IDS Insertion – Implant Position

IC Tip in the LV –

- Arrhythmias
- IDS moving with the heart beats
- Diretion towards the apex
- Ironman and IDS parallel



“go shallow” → retract the system out

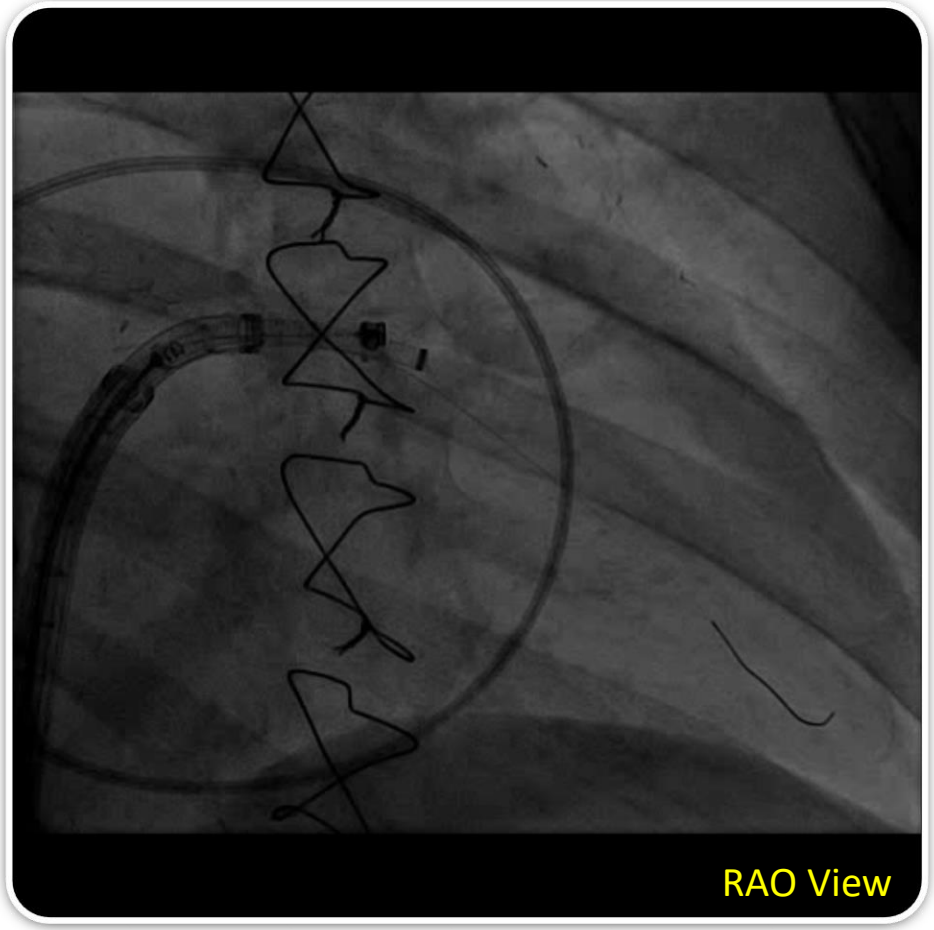
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IDS Insertion – Implant Position

IC Tip lays on the annulus –

- Angle separation between Iron Man and IDS
- The implant tends to go lateral and the Ironman bring it medial



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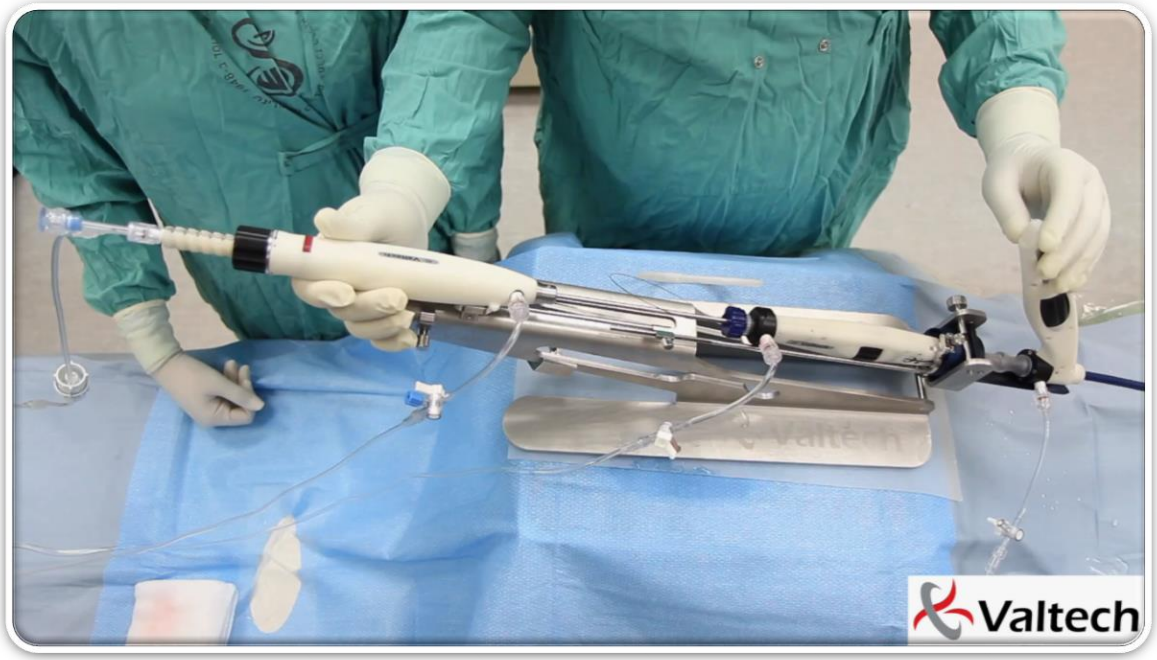
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IDS Insertion – IC GC Fixator Removal

Connect the IC to the stand

Remove the IC-GC Fixator by pushing forward at the two arrow marked points.

Place the implant GW hoop in the stand slot, release blue hemostatic valve to allow IC movements

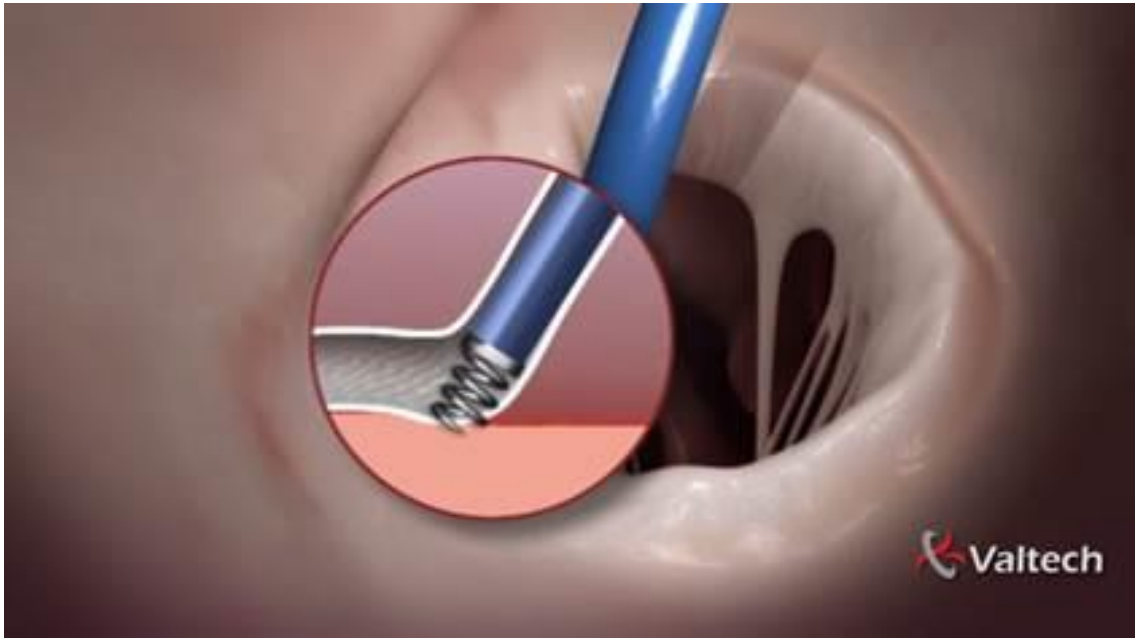


Procedure steps

General Preparations

Imaging Views

Transseptal Puncture



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IDS removal

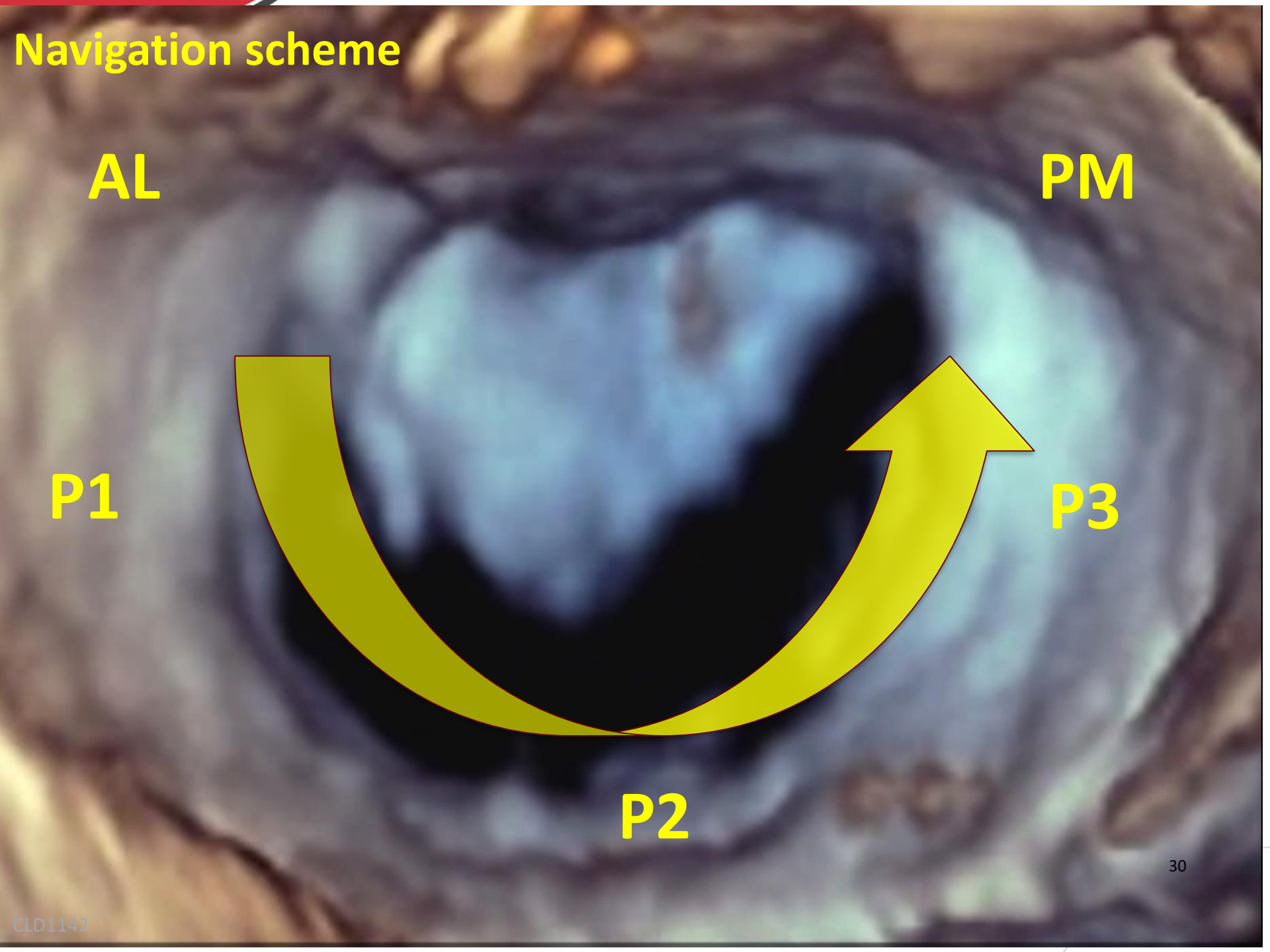
SAT Insertion & Implant Adjustment

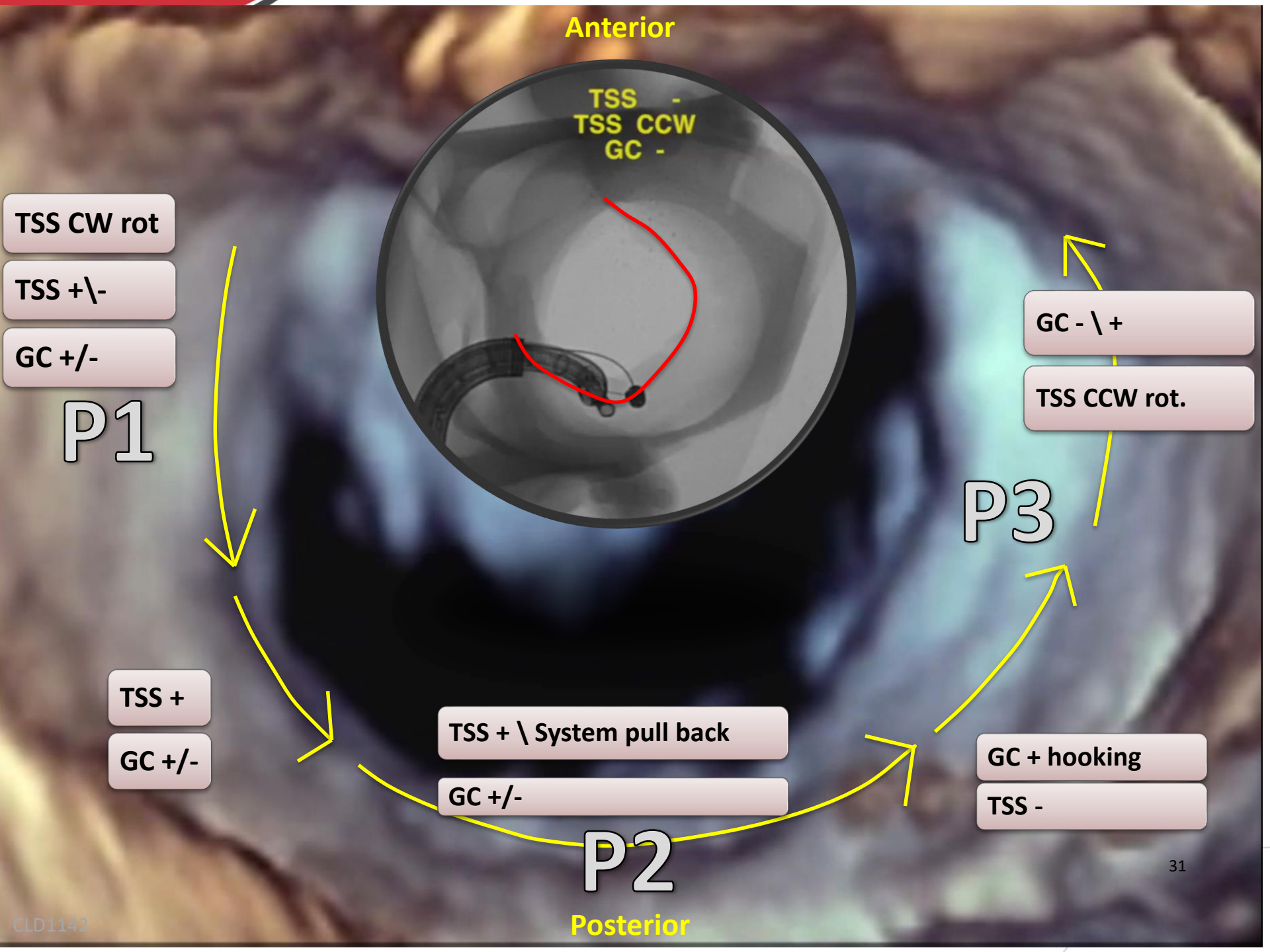
System Removal

Navigation – general

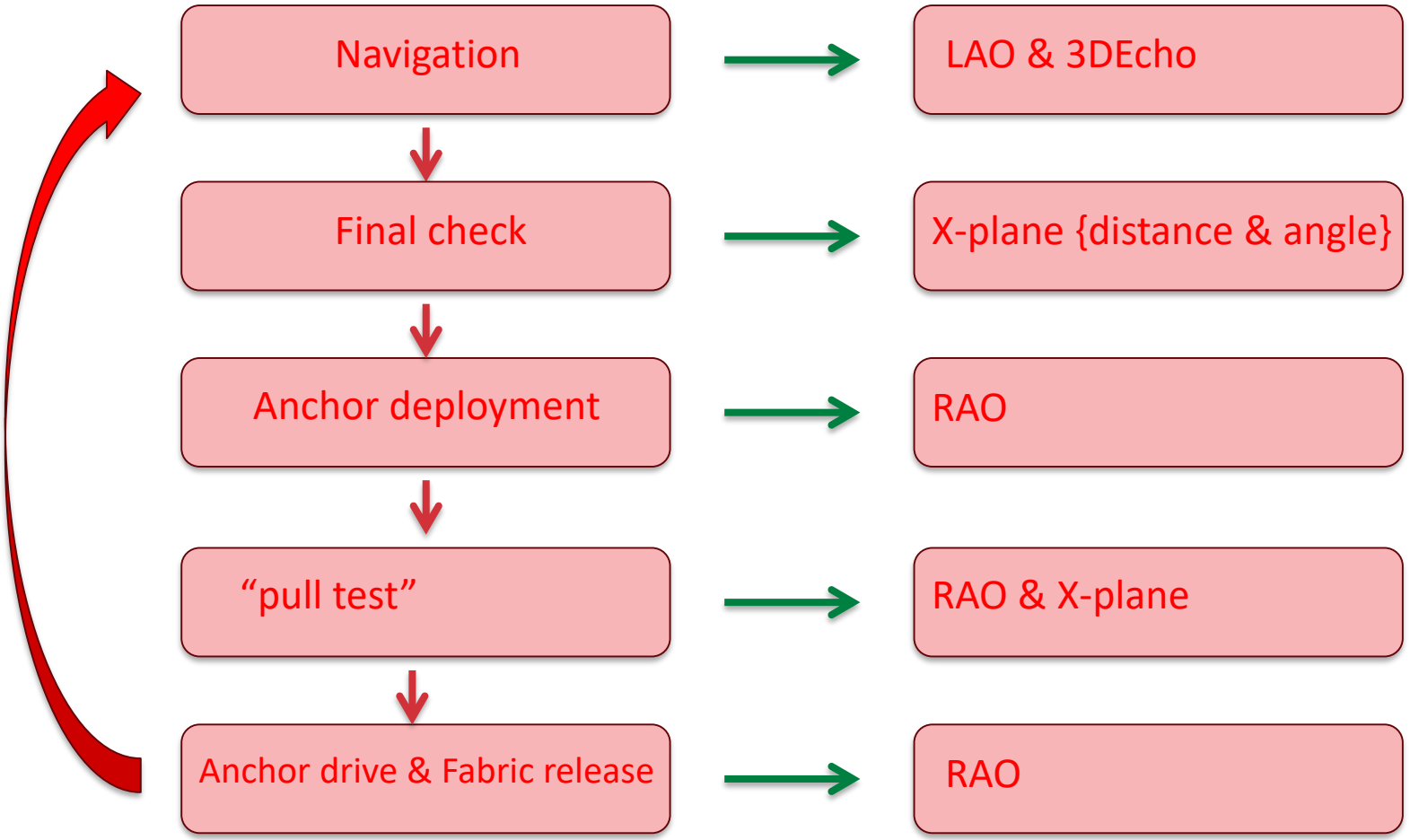
- Navigate the system according to the current P Area
- Gain Tissue contact by pushing in the IC – make sure to avoid over pushing.
- Each degree of freedom must be followed by visual check – 3D echo or fluoroscopy
- IC tip must not touch the tissue during navigation
- IC tip must touch the tissue during anchoring
- Avoid more than 3 IC segments out of the GC

Navigation scheme




Anterior
TSS -
TSS CCW
GC -
TSS CW rot
TSS +\-
GC +/-
P1
TSS +
GC +/-
TSS + \ System pull back
GC +/-
P2
GC + hooking
TSS -
P3
GC - \ +
TSS CCW rot.
Posterior

Cardioband Implantation Sequence



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Implant Deployment – 1st Anchor Positioning

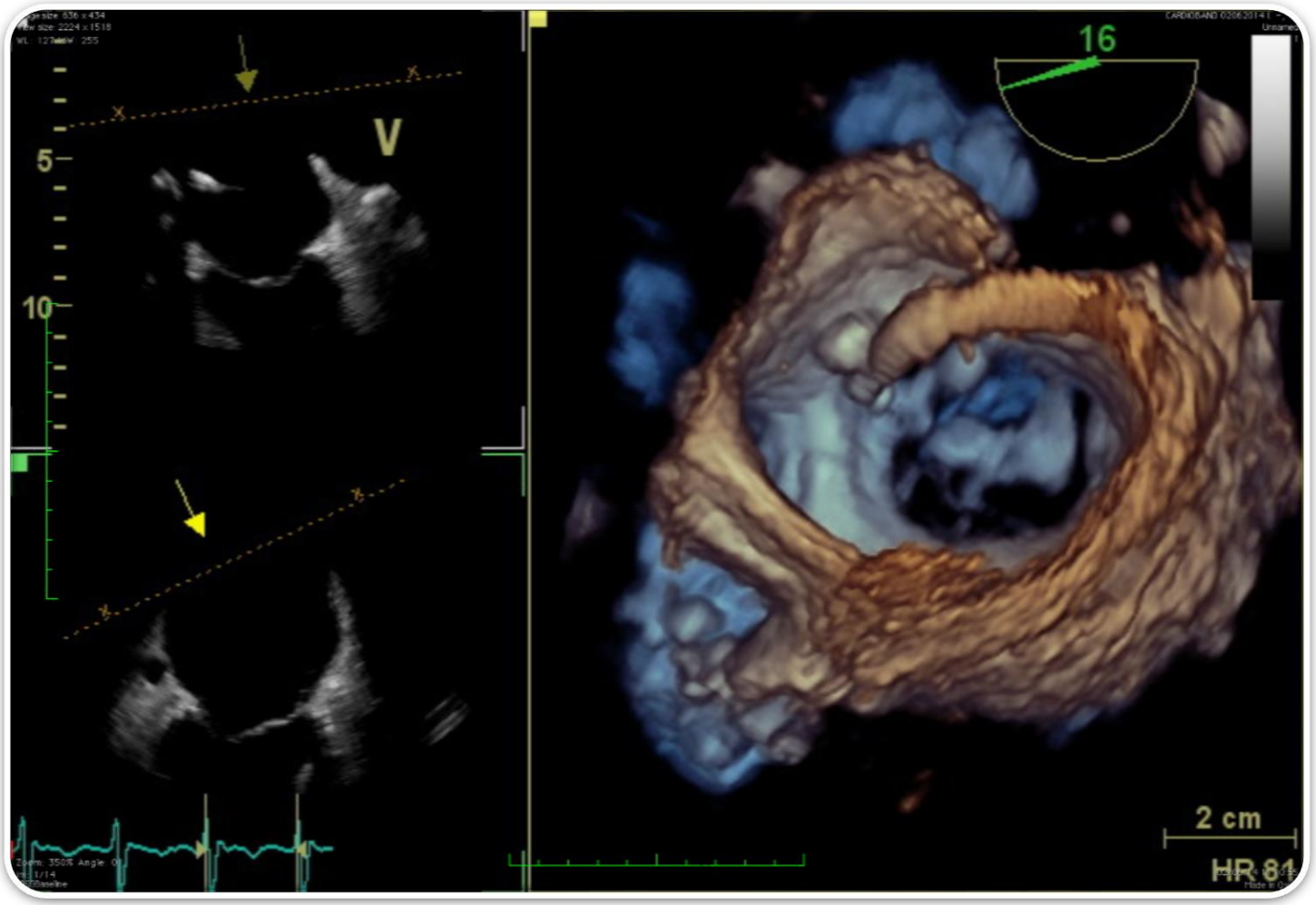
2D X-Plane & RAO

Move the Implant guidewire to distinguish (in echo) between the IC tip and the adjustment mechanism {Spool}

Check the angle and compare it to the required angle of the procedure planning

Perform **angiography** \ view Cx wire to clear doubts of Circumflex proximity

Implant Deployment – 1st Anchor Positioning – 2D & 3D

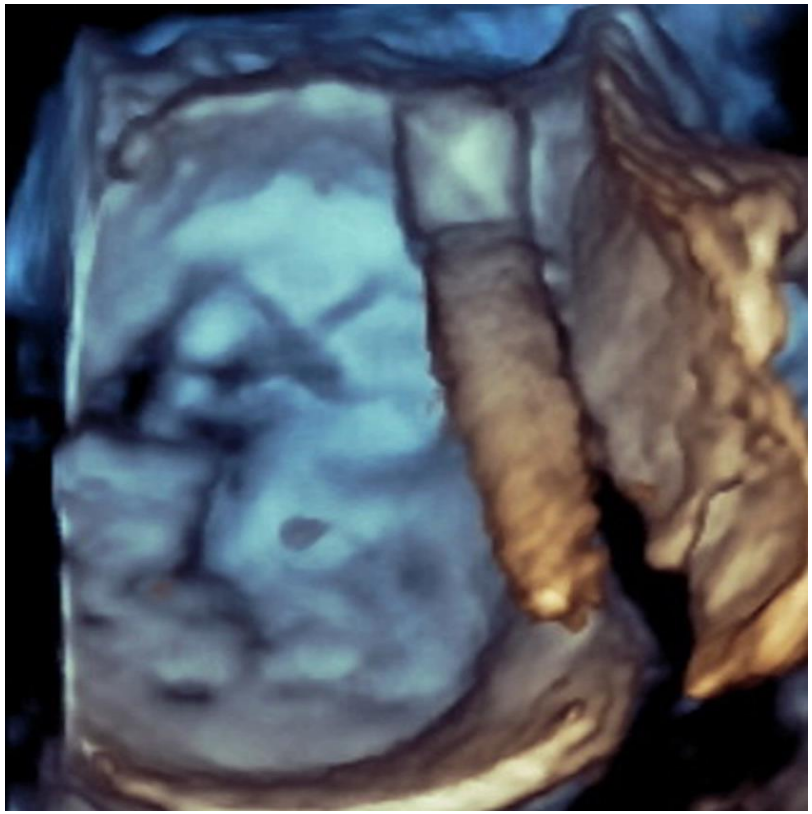


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Implant Deployment – First anchor navigation – 2D x-plane



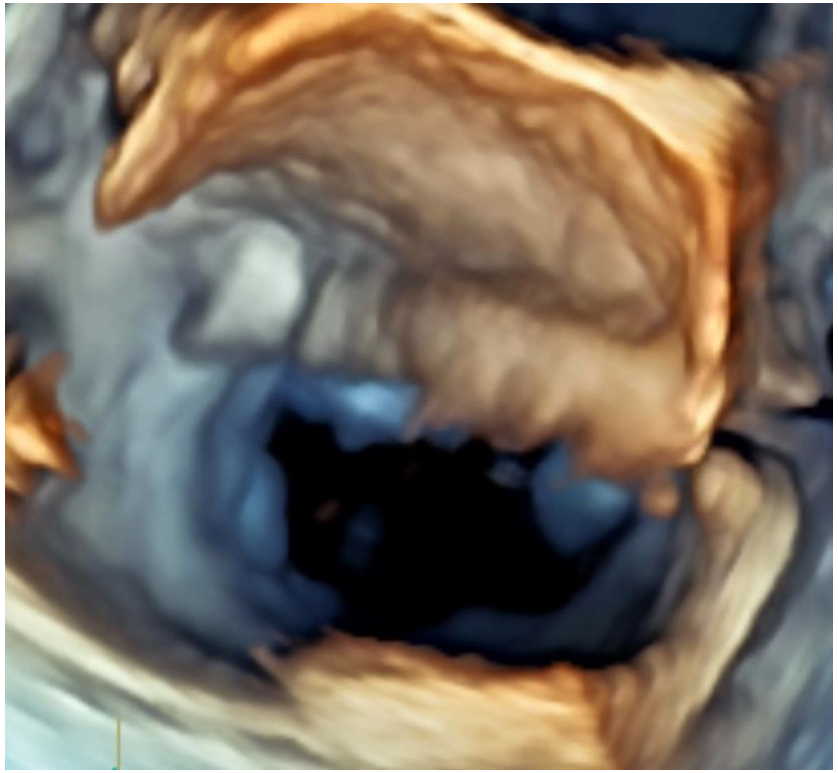


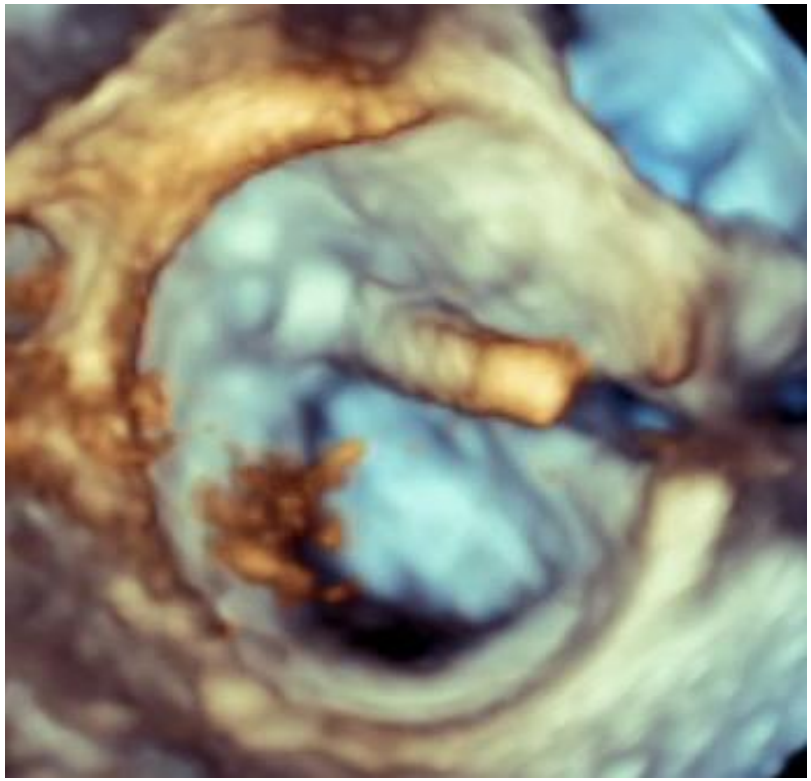
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Implant Deployment – First anchor navigation – Spool check



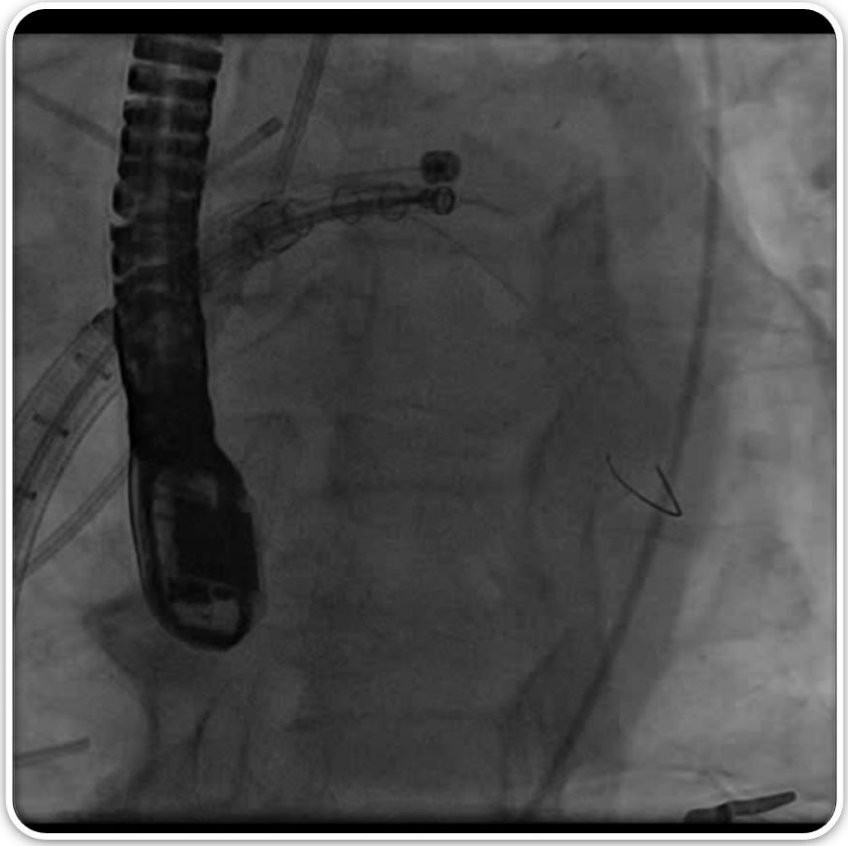


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Implant Deployment– 1st anchor– Angiography

Perform Left Coronary Artery angiography to ensure that there is no risk of damaging the Circumflex Artery with the anchor





Implant Deployment – Anchoring

RAO and 2Dx-plane

Introduce the anchor drive with torque limiter through the IDS

Rotate the torque limiter, make sure:

1. The anchor is fully outside the IC.
2. Anchor stepped advancing

Implant Deployment –1st Anchor Pull test

2D X-plane and RAO

Push forward the spool using the implant GW.

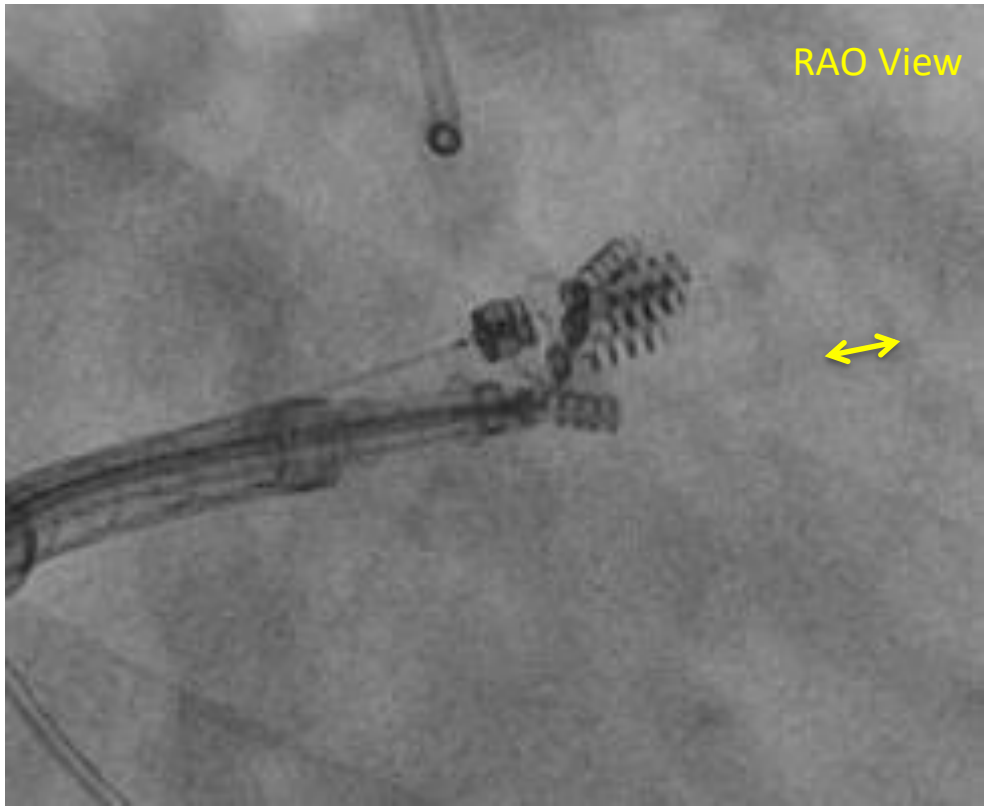
Verify the spool is stopped at the level of the anchor head (annulus)

Push / Pull IC to verify the anchor is firmly fixed according to the following indications:

- **system arching**
- **the spools moves with the anchor**
- **identify tissue movement with the IC tip - not always feasible**

Extensive movement of the anchor indicates sub optimal anchoring

Pull test – After each anchor



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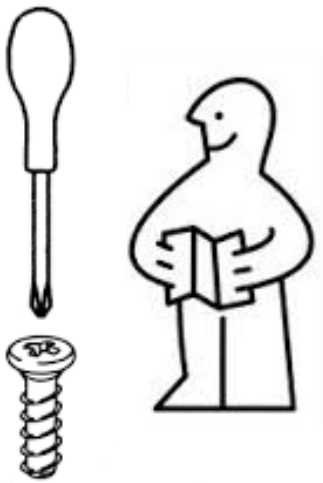
CLD1142

Release VS Unscrew

Release !

When anchoring quality is confirmed to be satisfying

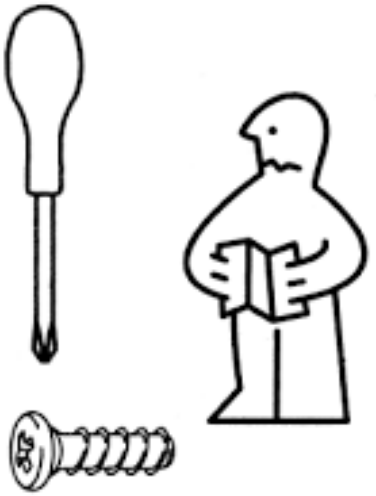
{Retrieve IronMan}



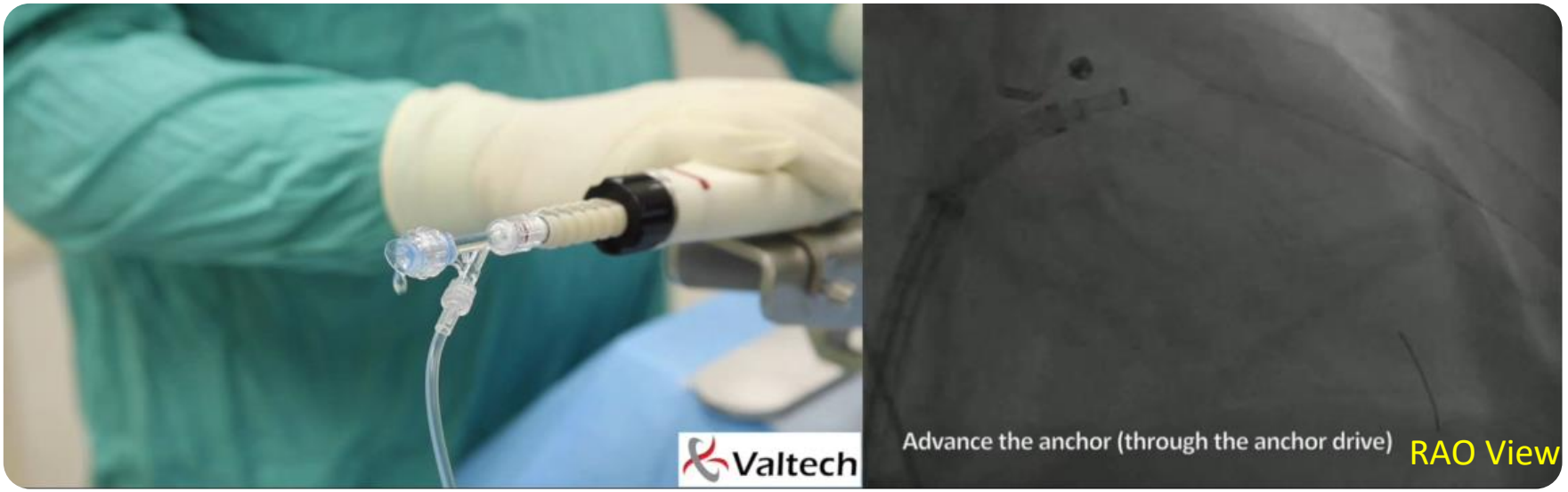
Unscrew !

Unsatisfying anchor deployment

- Rotate the anchor CCW using the TL while gently pulling.
- After a few turns the anchor will be disconnected from the tissue
- Continue rotating till the anchor is fully retrieved inside the IC.

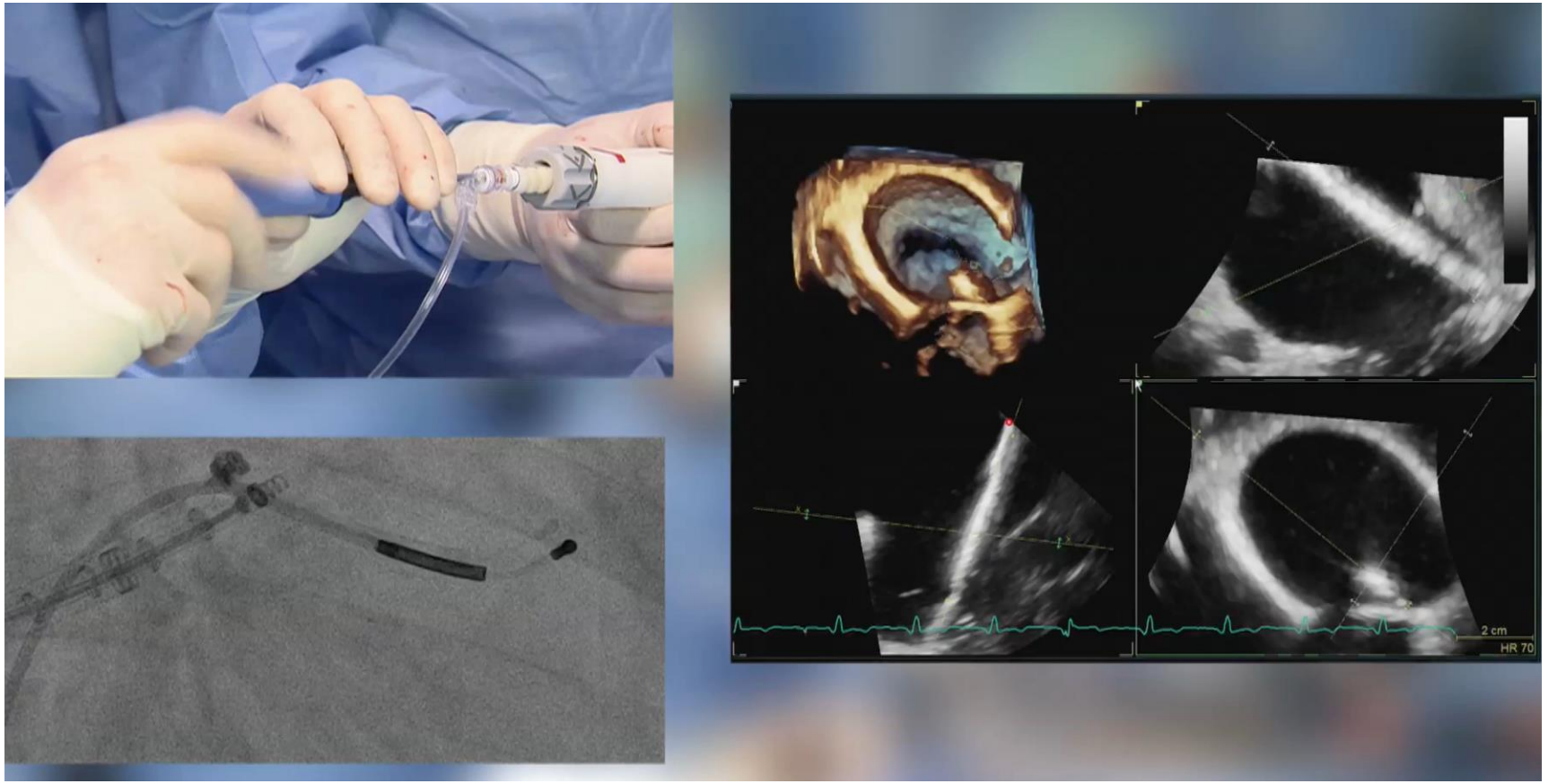


Implanting the First anchor



1st anchor – double check Echo 3D before releasing

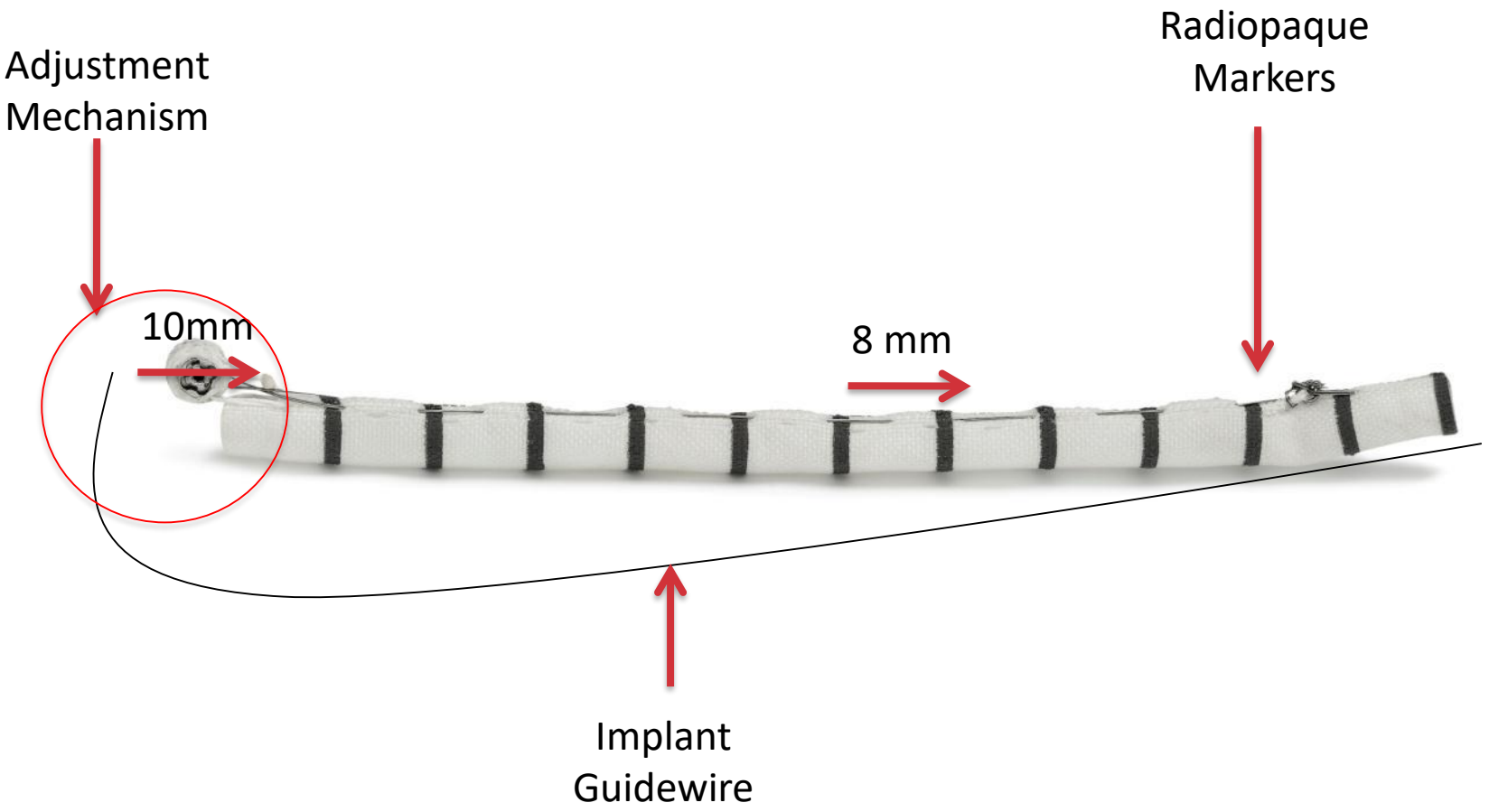
Implant Deployment – Anchoring & Ectopic beats



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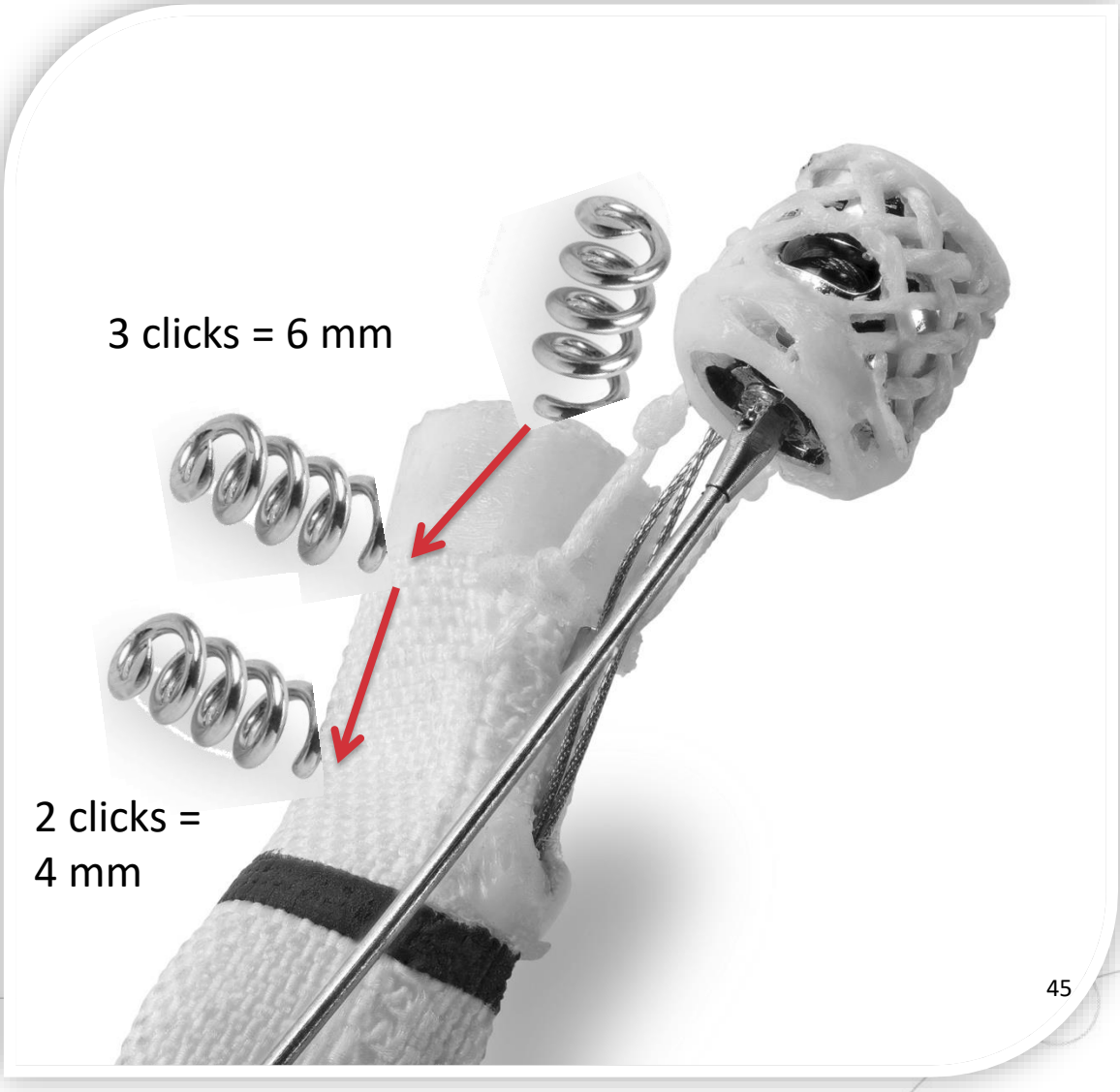
CLD1142

Cardioband Implant – 2nd & 3rd anchor



Cardioband Implant – 2nd & 3rd anchor

First three anchors act as the root foundation of the Procedure



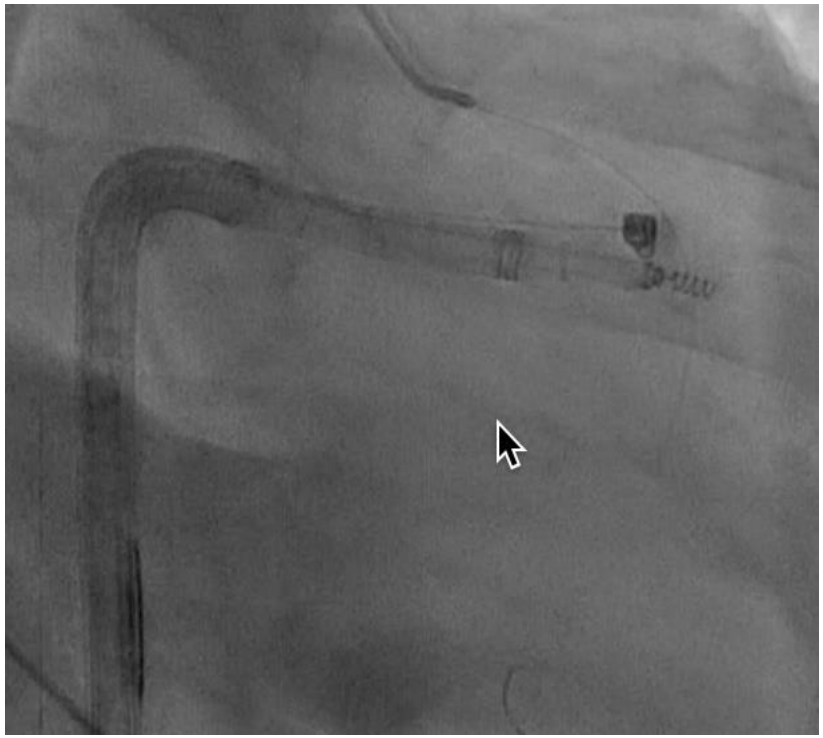
Valtech

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Cardioband implantation – 2nd & 3rd anchor

- 2nd anchor – 3 clicks – “half segment”
- 3rd anchor – 2 clicks – alignment with first radio pack marker

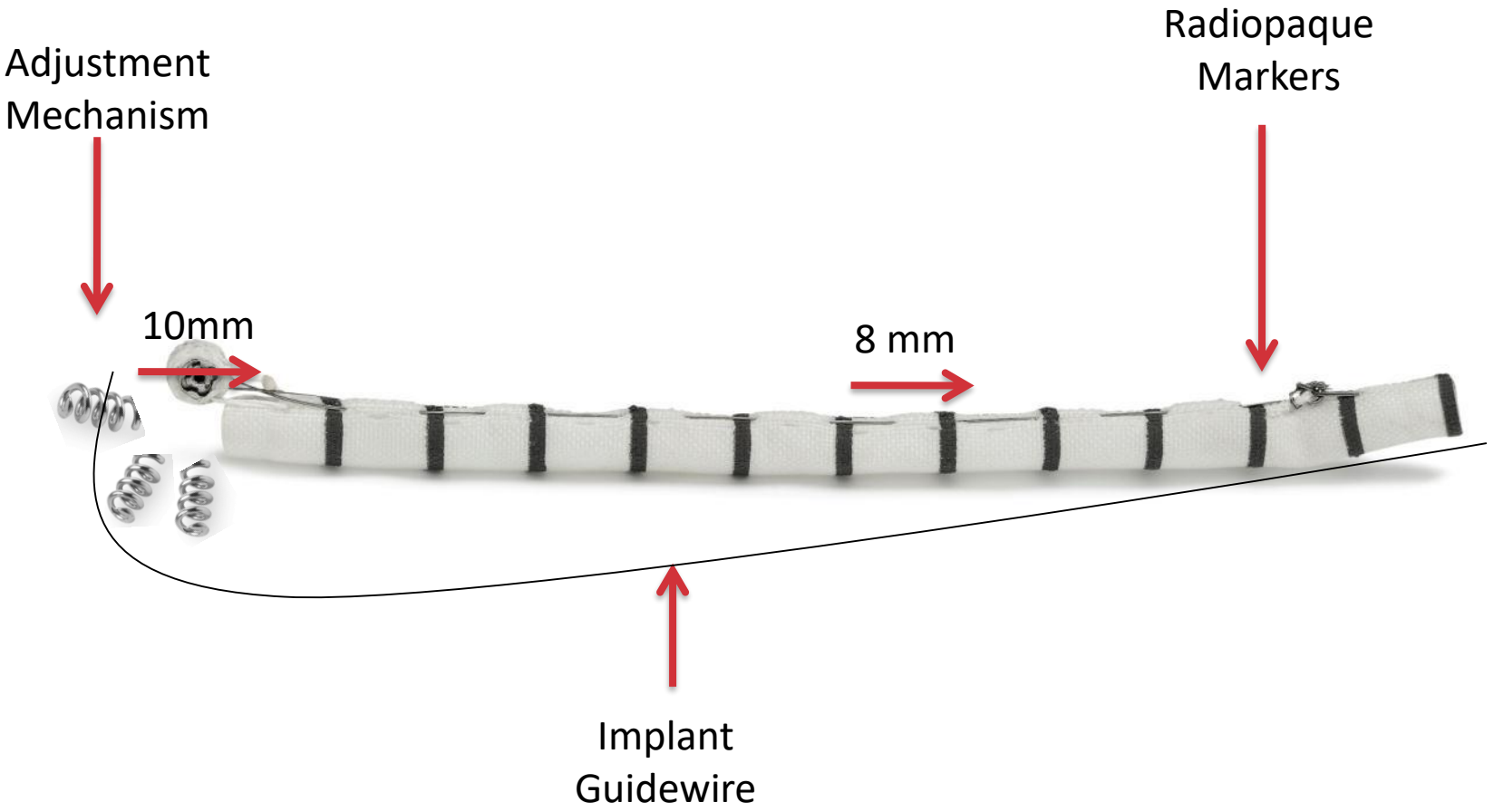




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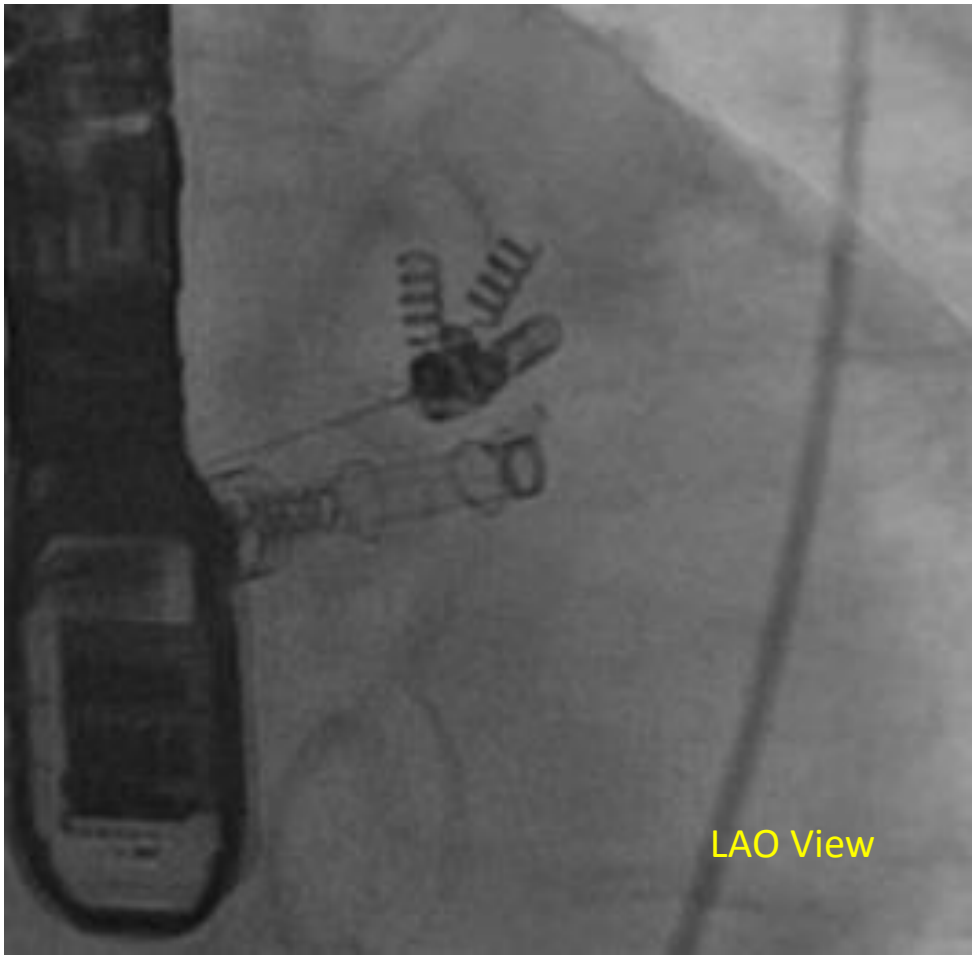
Cardioband Implant – second and third anchor



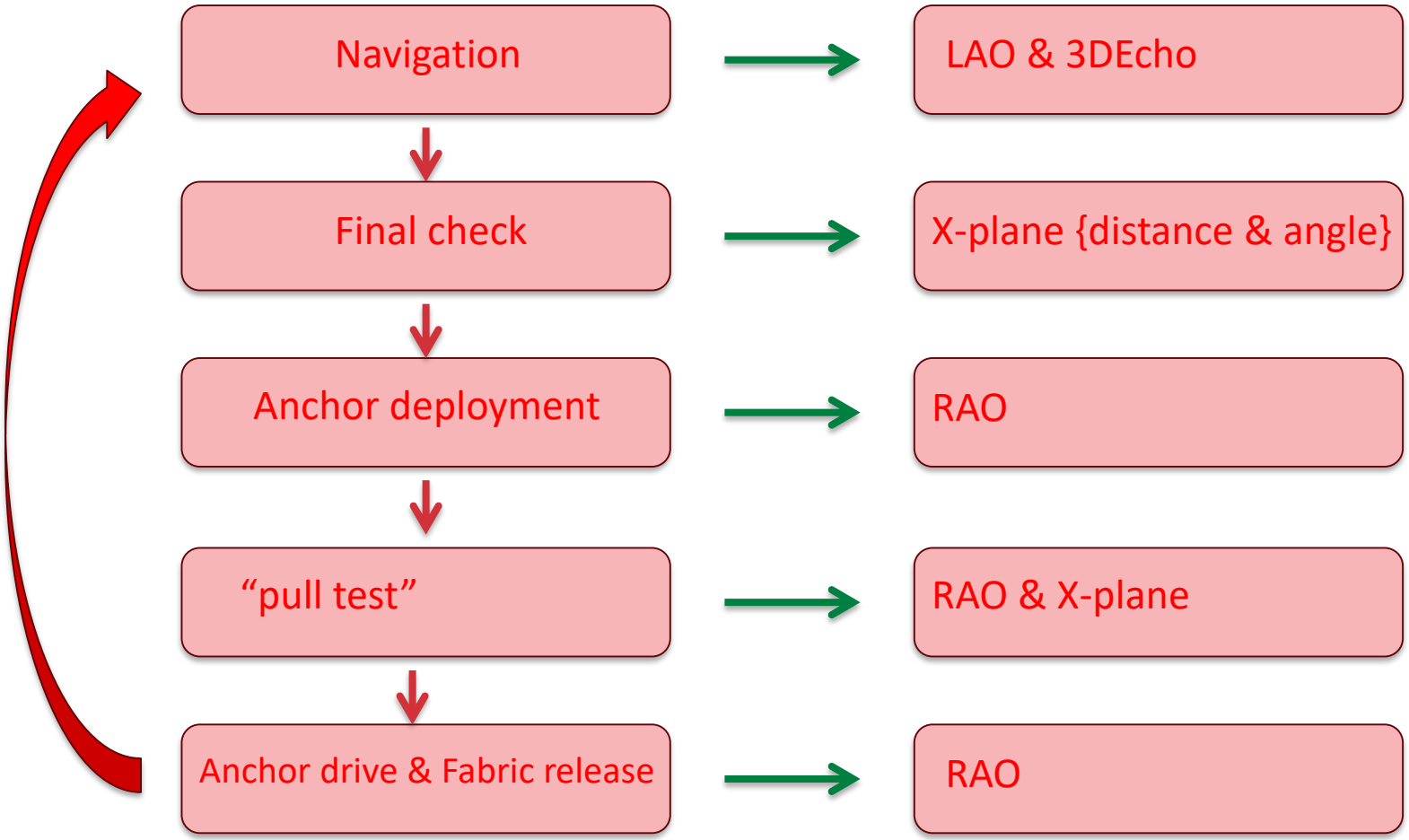
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Cardioband Implant – Typical RAO View



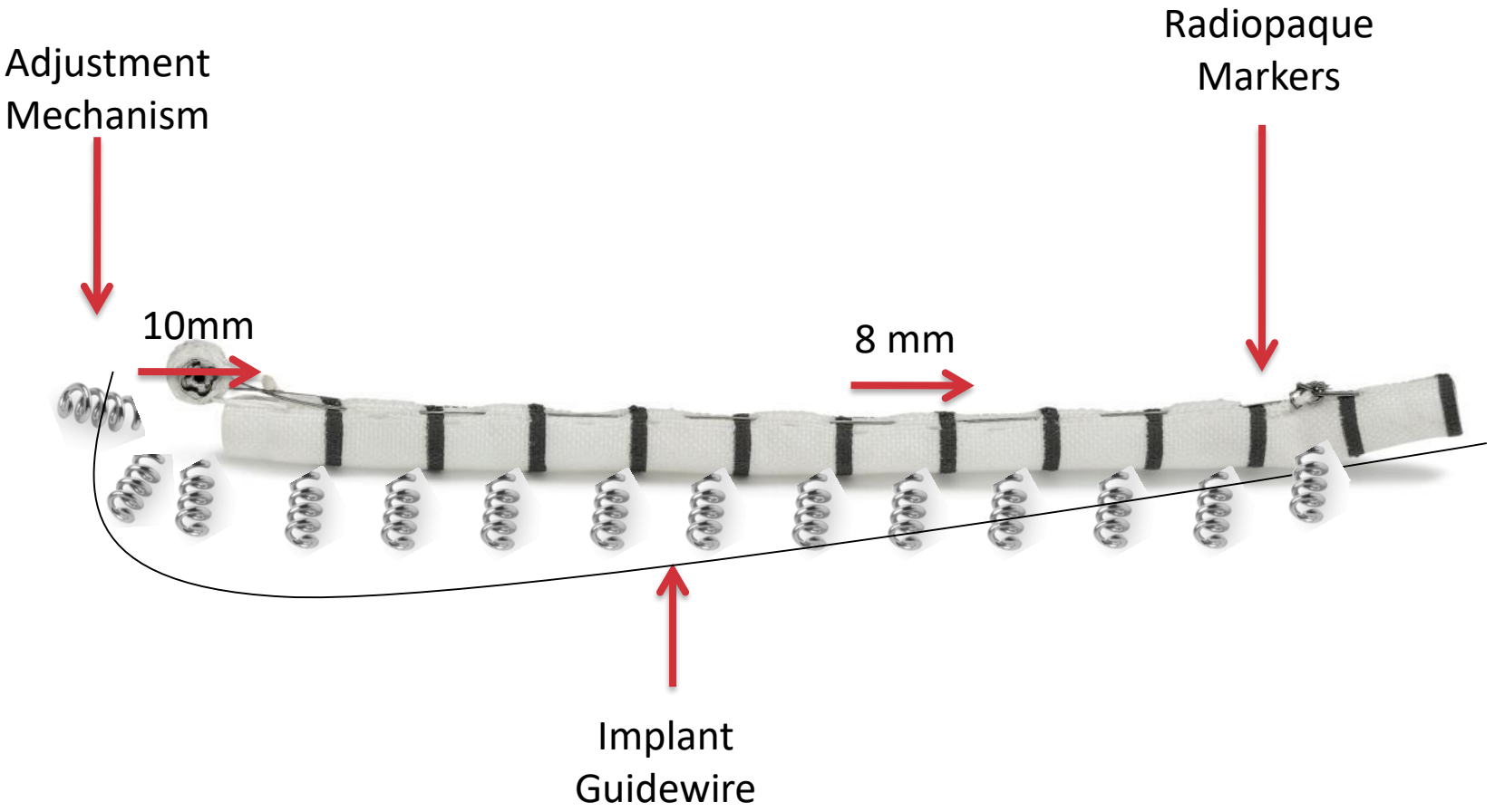
Cardioband Implantation Sequence



Valtech

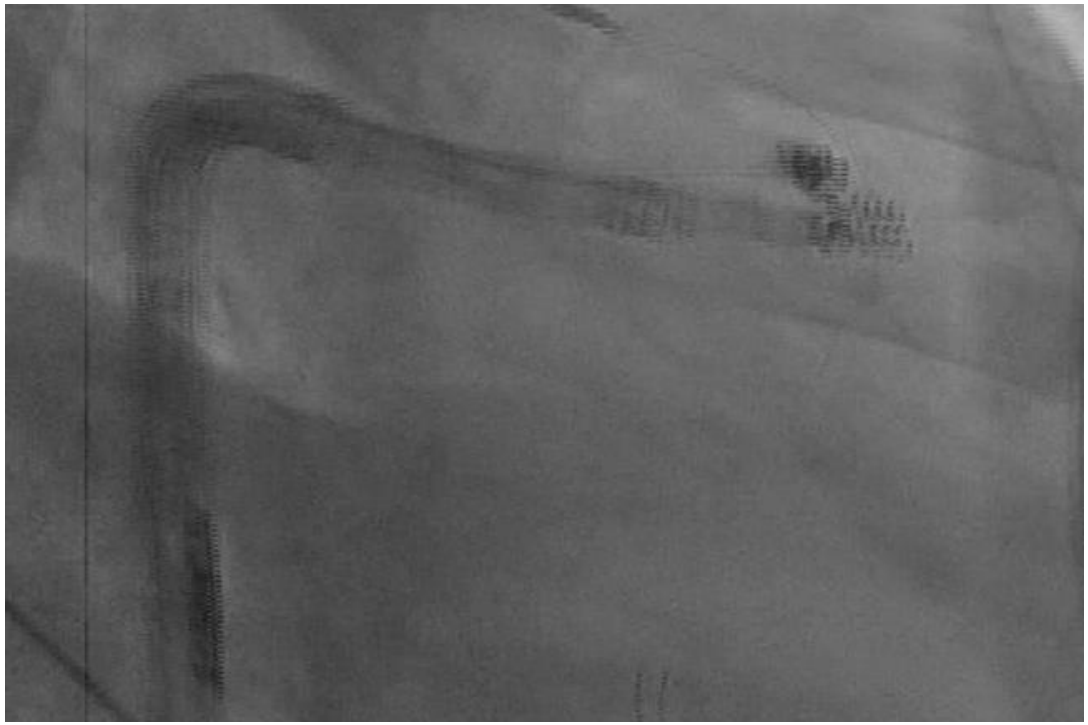
CLD1142

Cardioband Implant – Anchors Over View



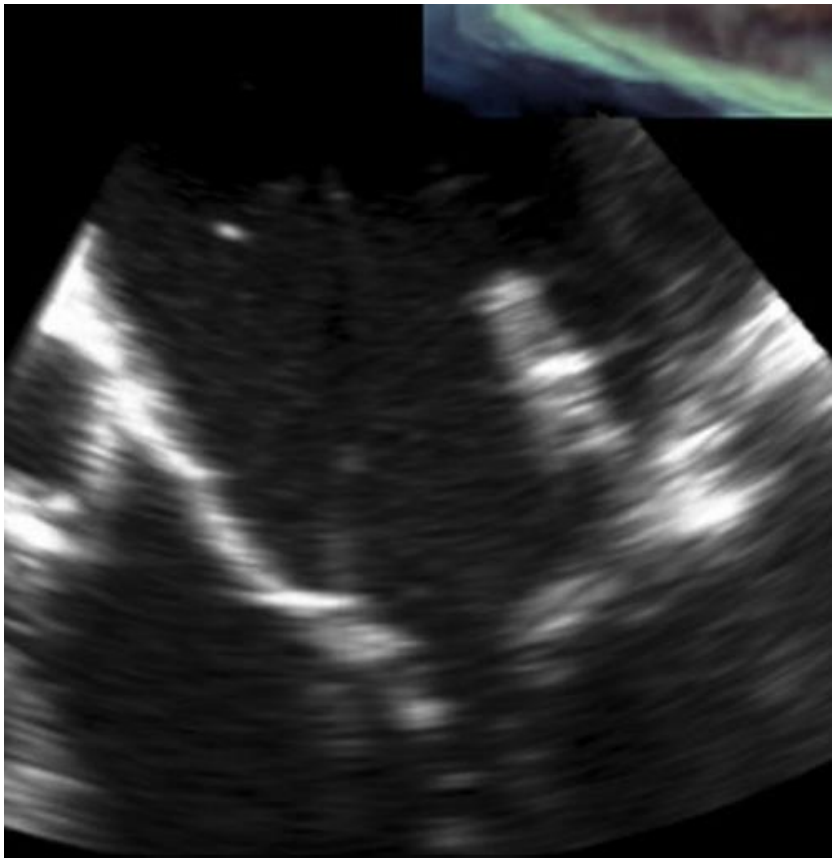
Cardioband implantation – 2nd & 3rd anchor

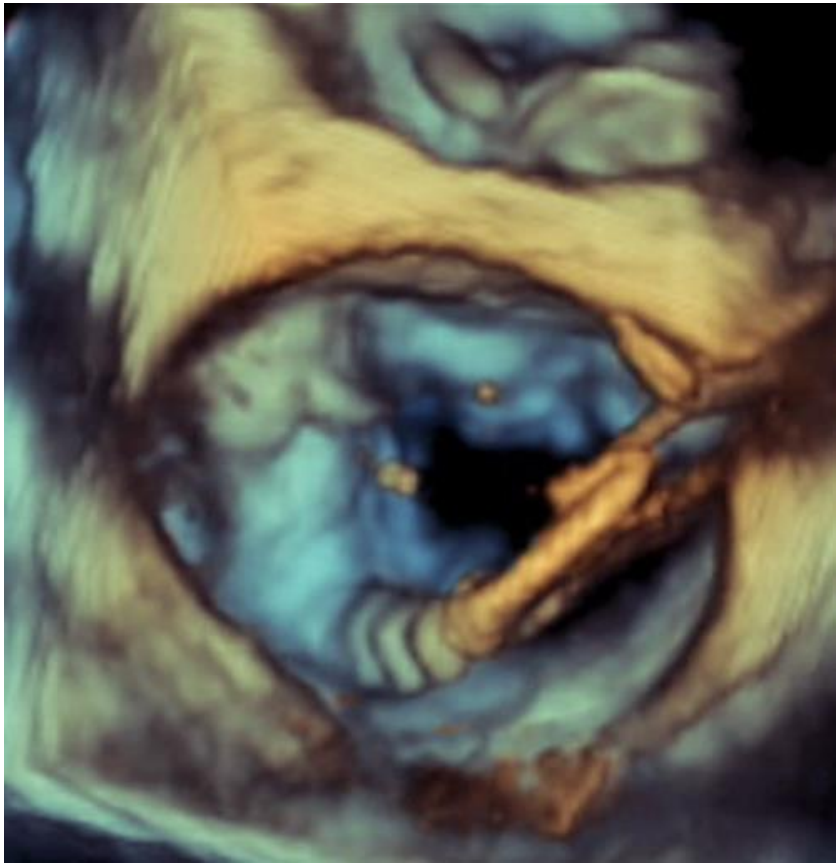
- 2nd anchor – 3 clicks – “half segment”
- 3rd anchor – 2 clicks – alignment with first radio pack marker
- 4th anchor – 4 clicks – alignment with the radio pack marker



Valtech

Location example #1

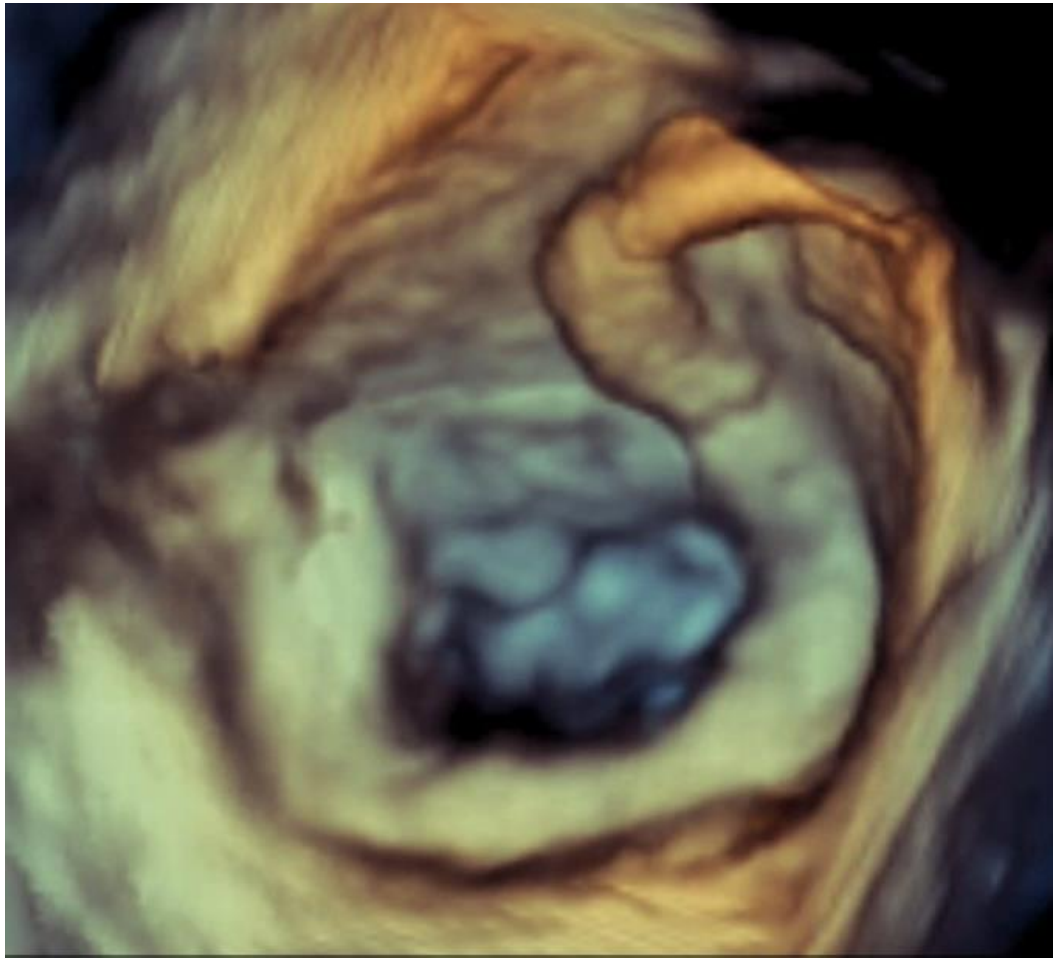




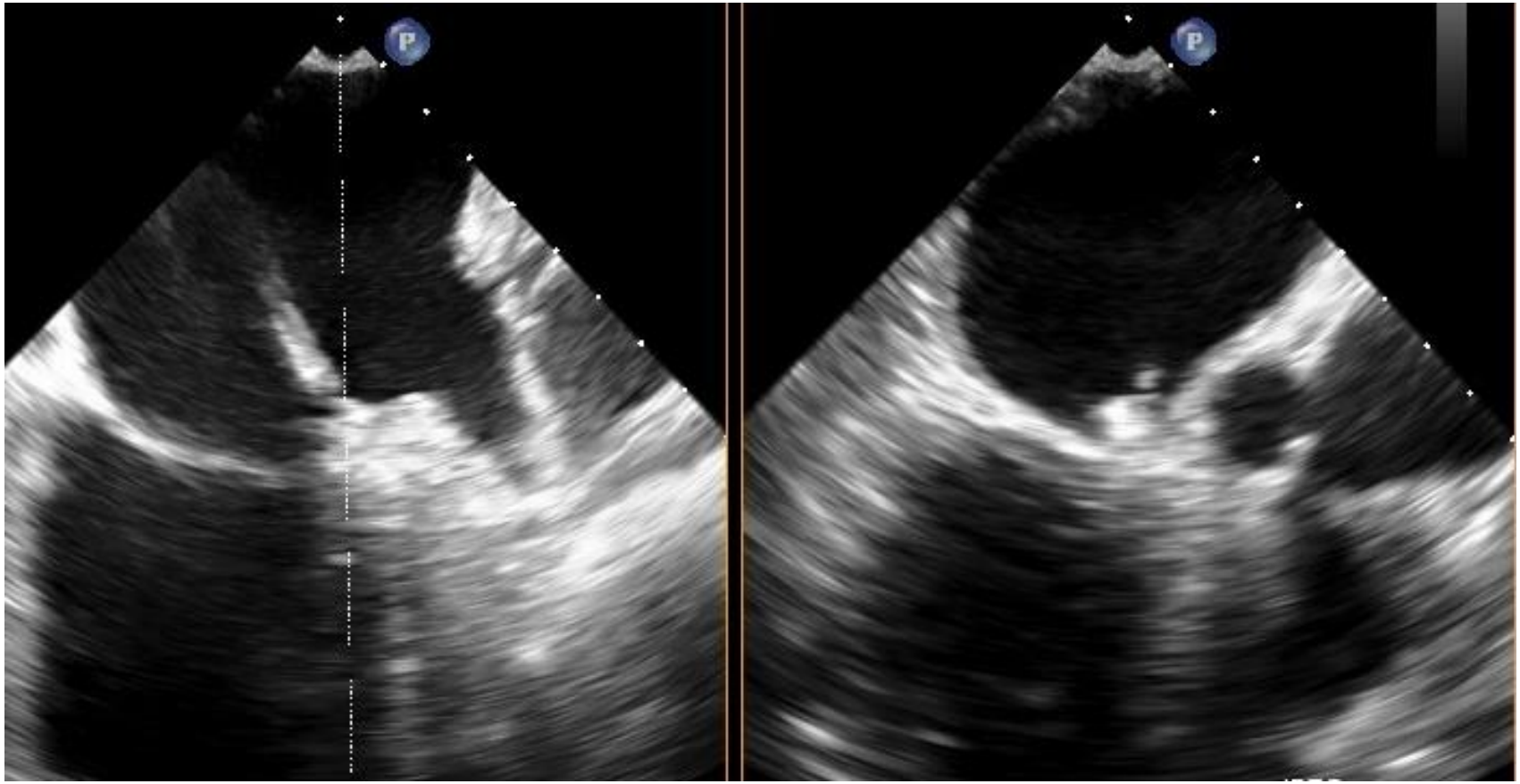
Valtech

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Location example #2



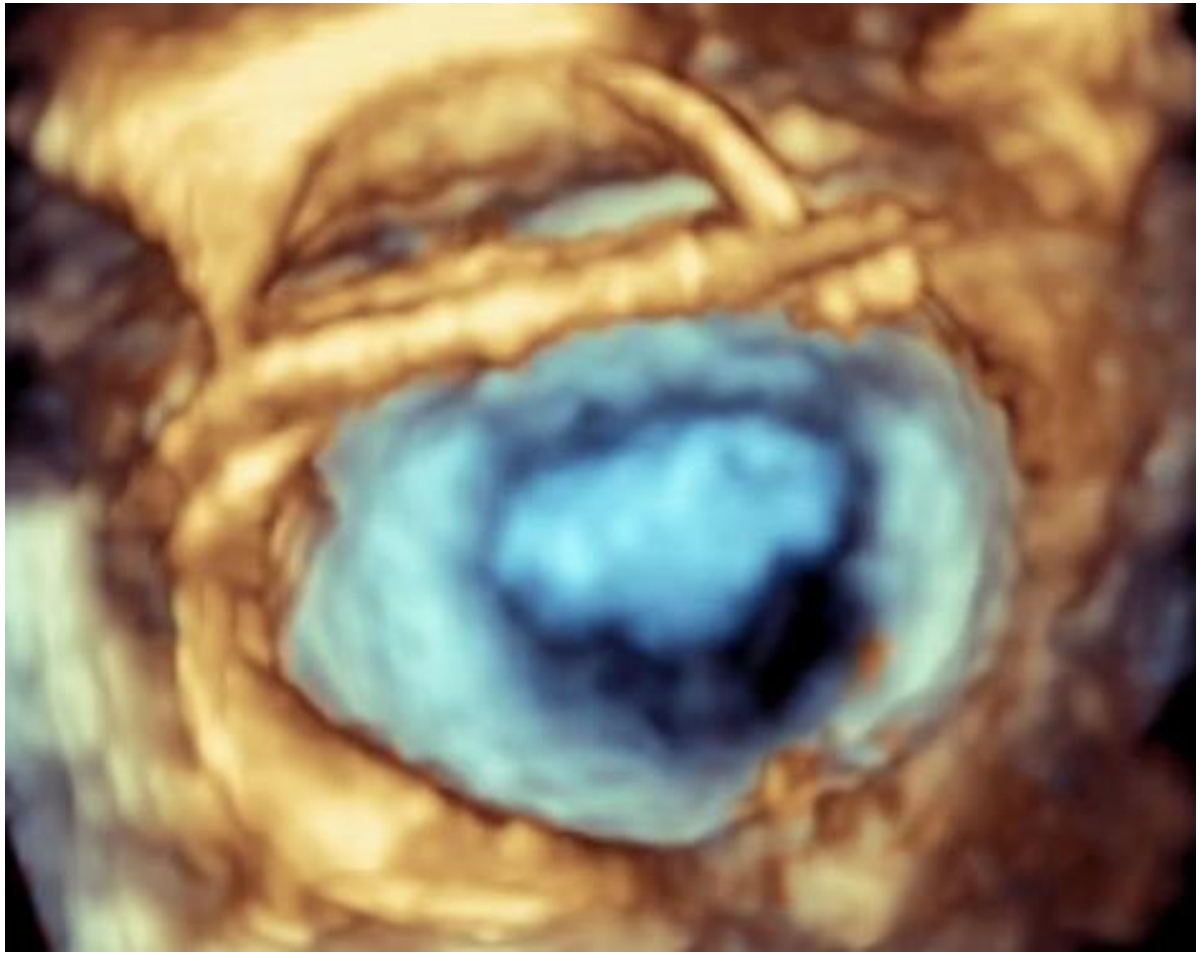
Location example #3



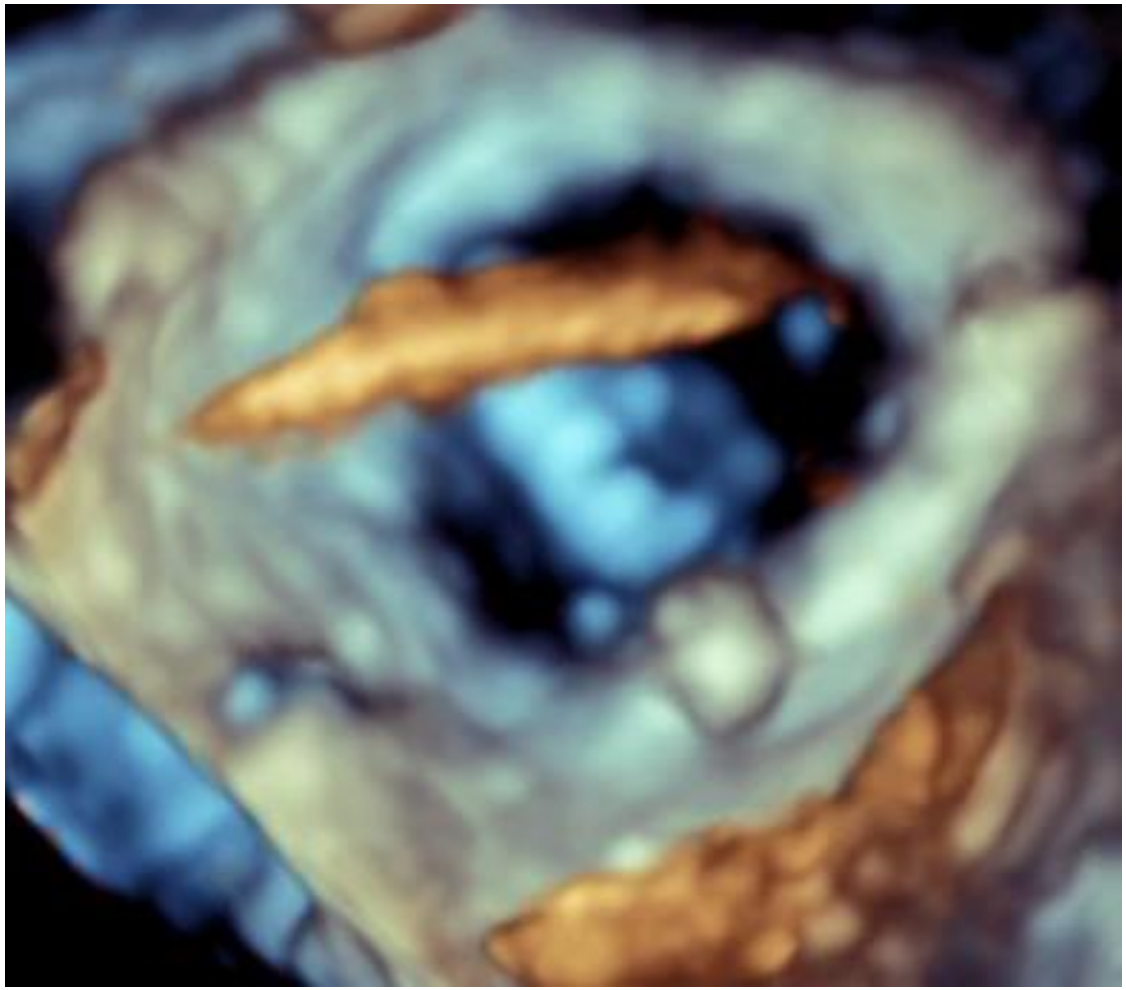
Valtech

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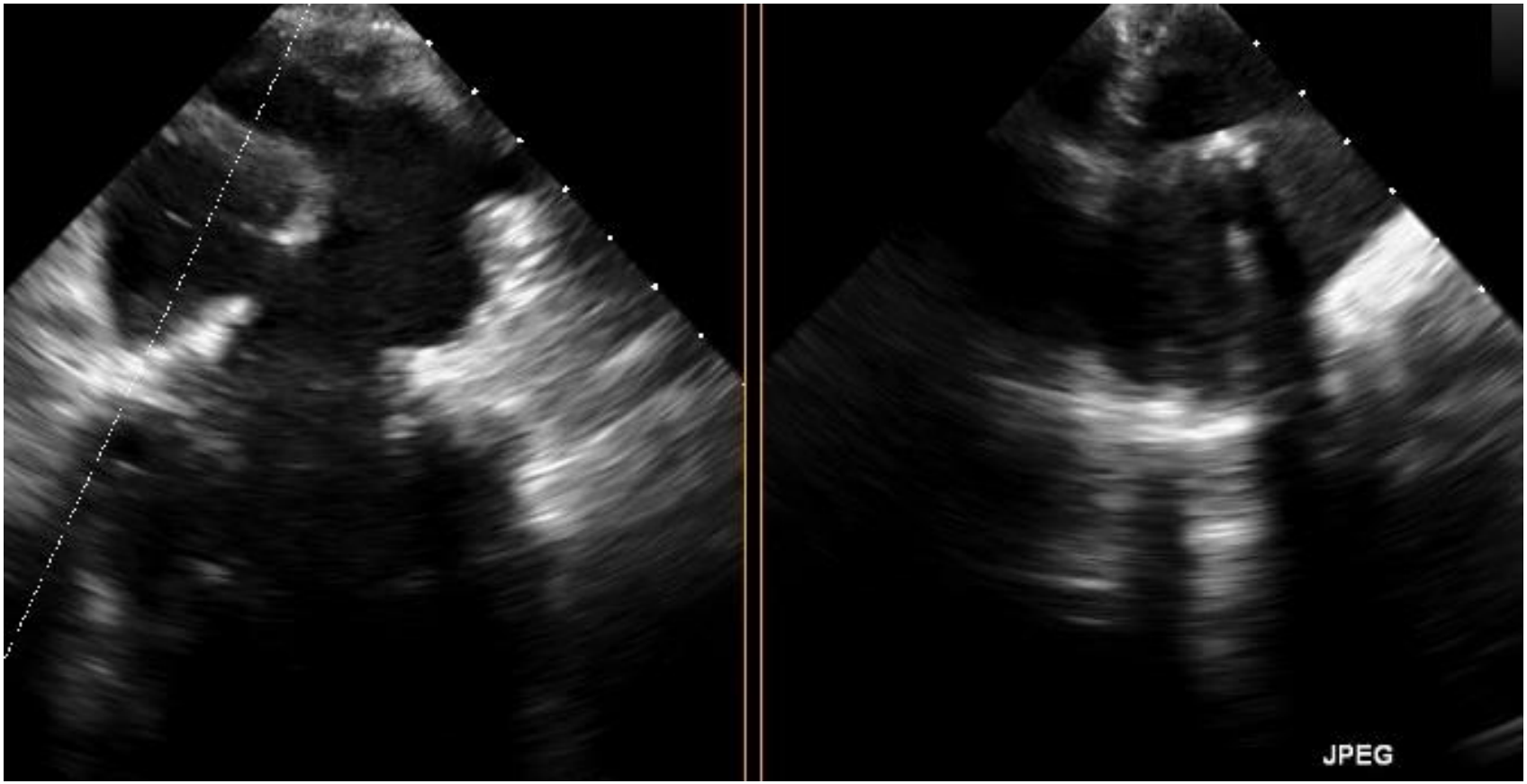
Location example #4



Location example #5



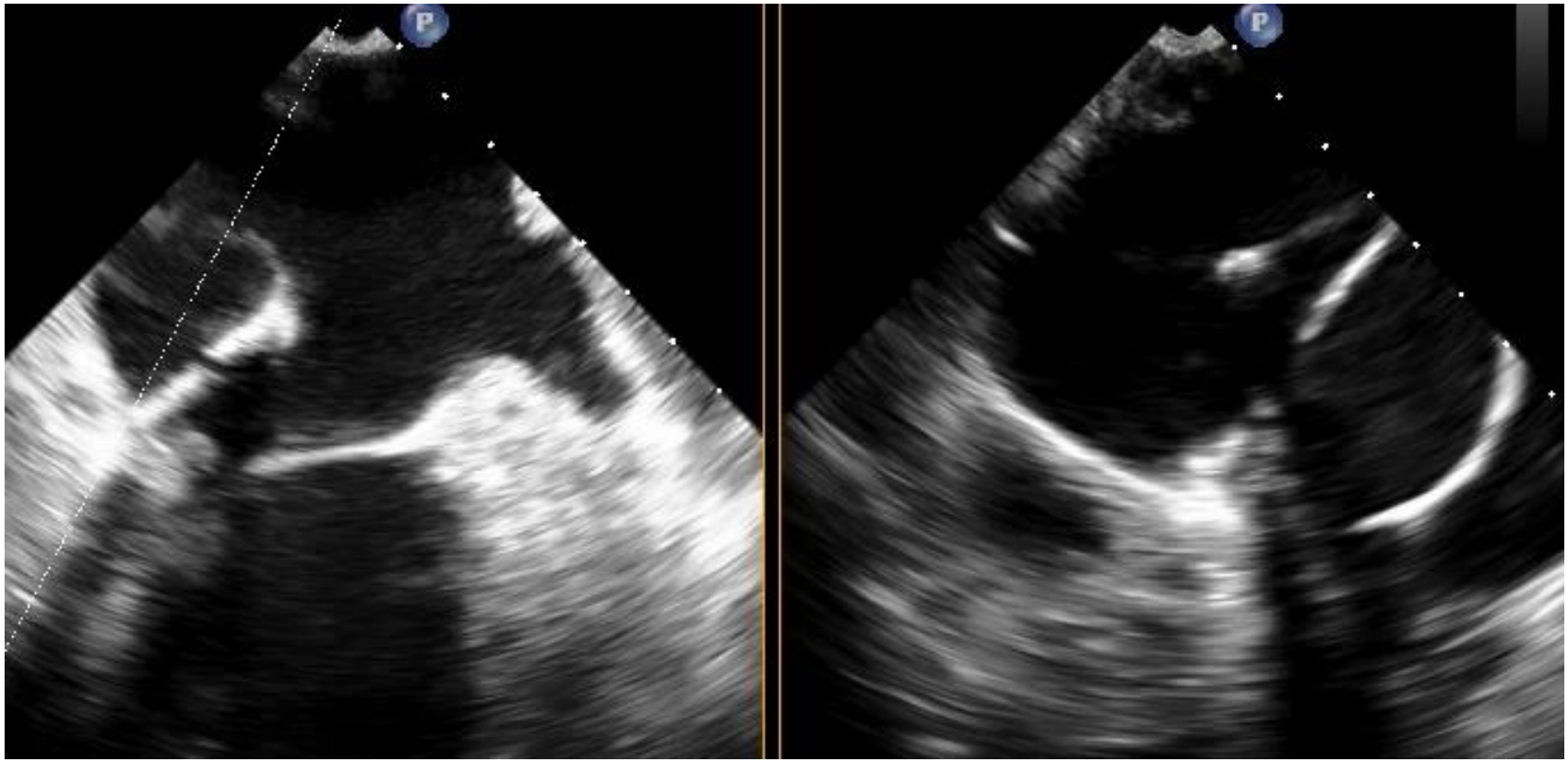
Location example #6



Valtech

CLD1142

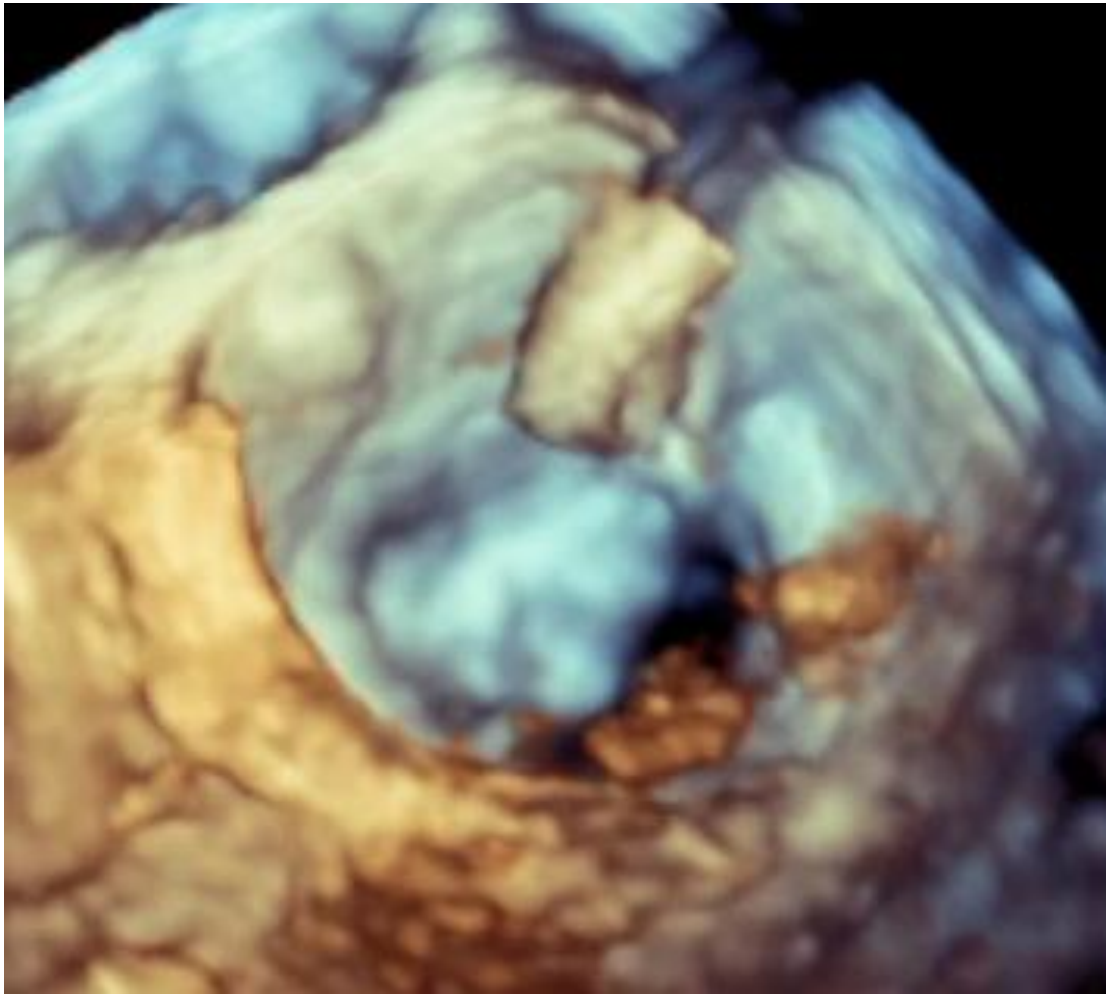
Location example #7



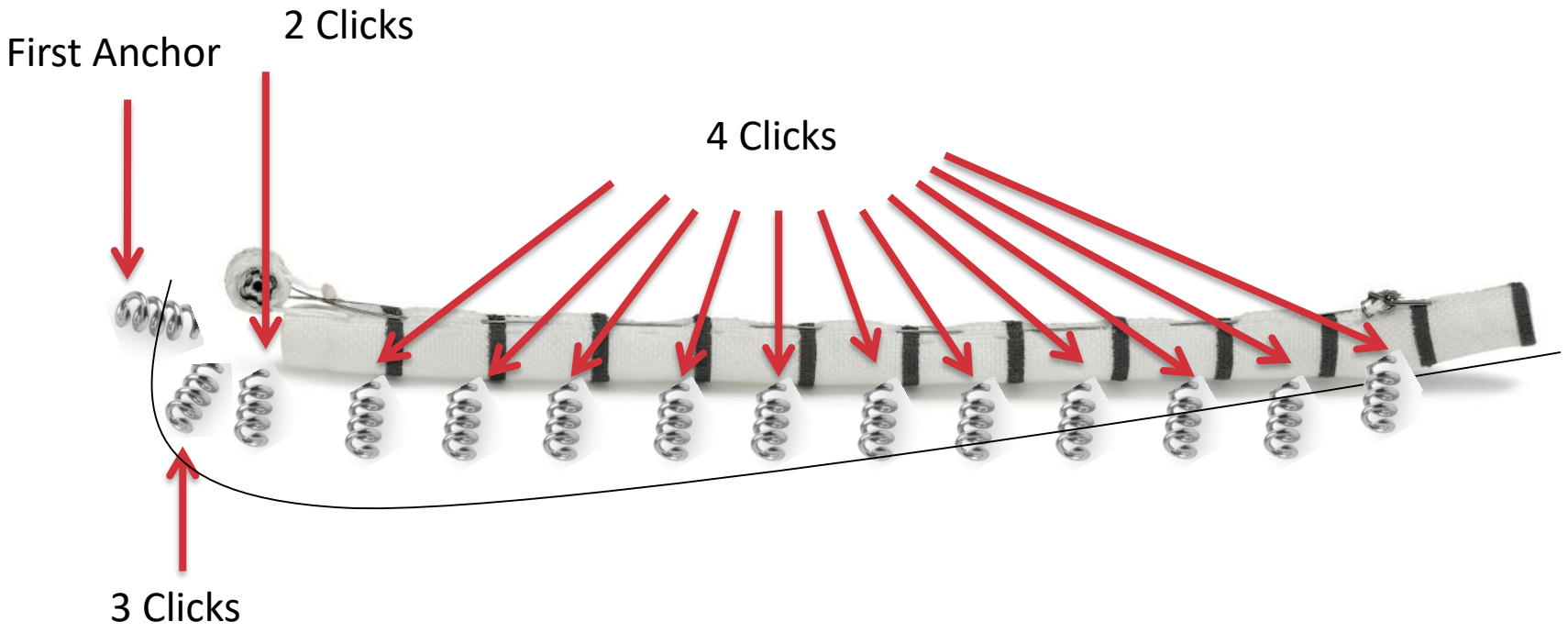
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Location example #8



Cardioband Implant – Anchors Interval



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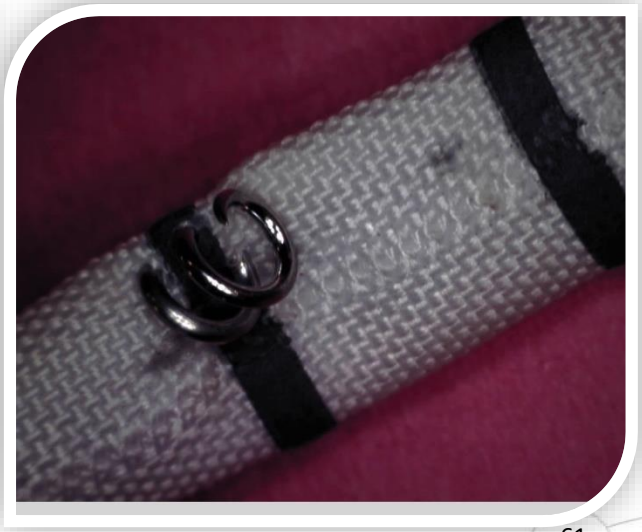
CLD1142

Implant deployment – “EF” – Early feedback

- Early feedback is a situation in which high torque is required to implant an anchor.
- Due to the high torque the TL clutch is activated not allowing to continue with anchor implantation
- EF usually happen when an anchor is deployed twice through the fabric due to wrong deployment angle







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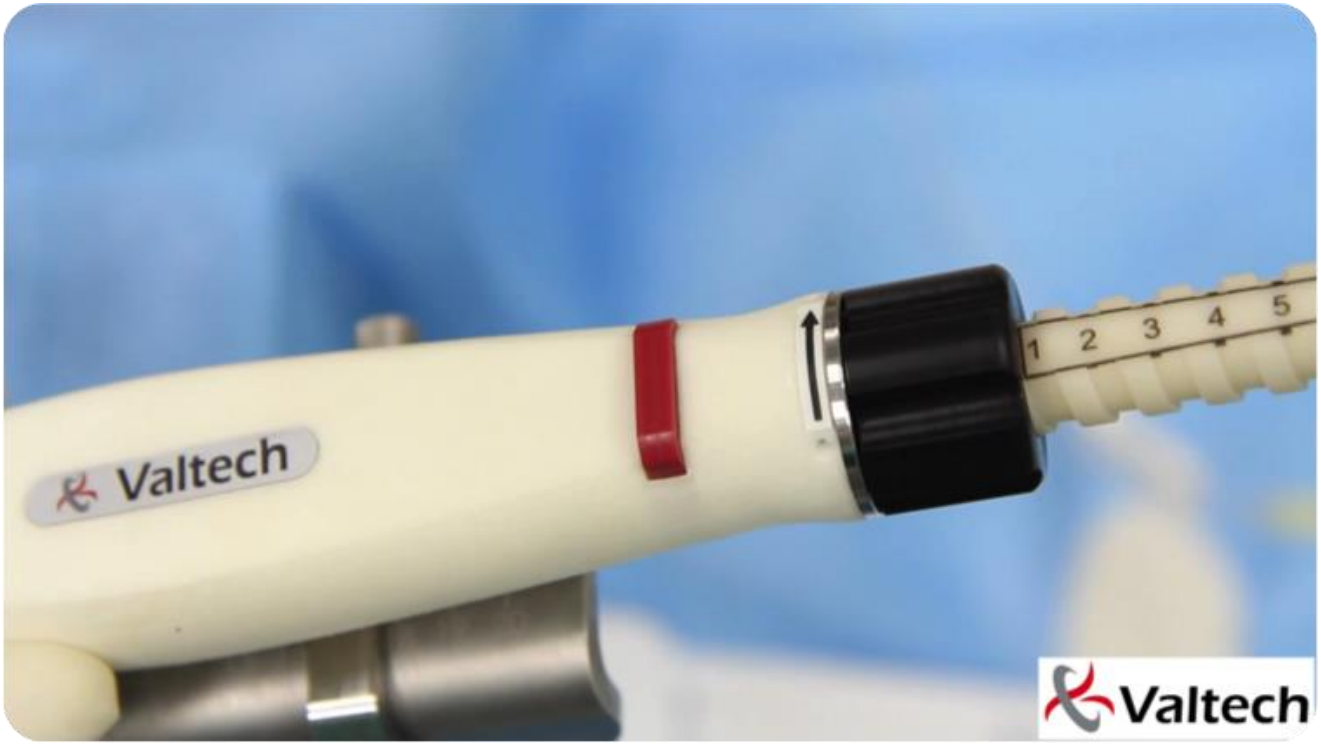
Avoiding Early feedback

Early feedback

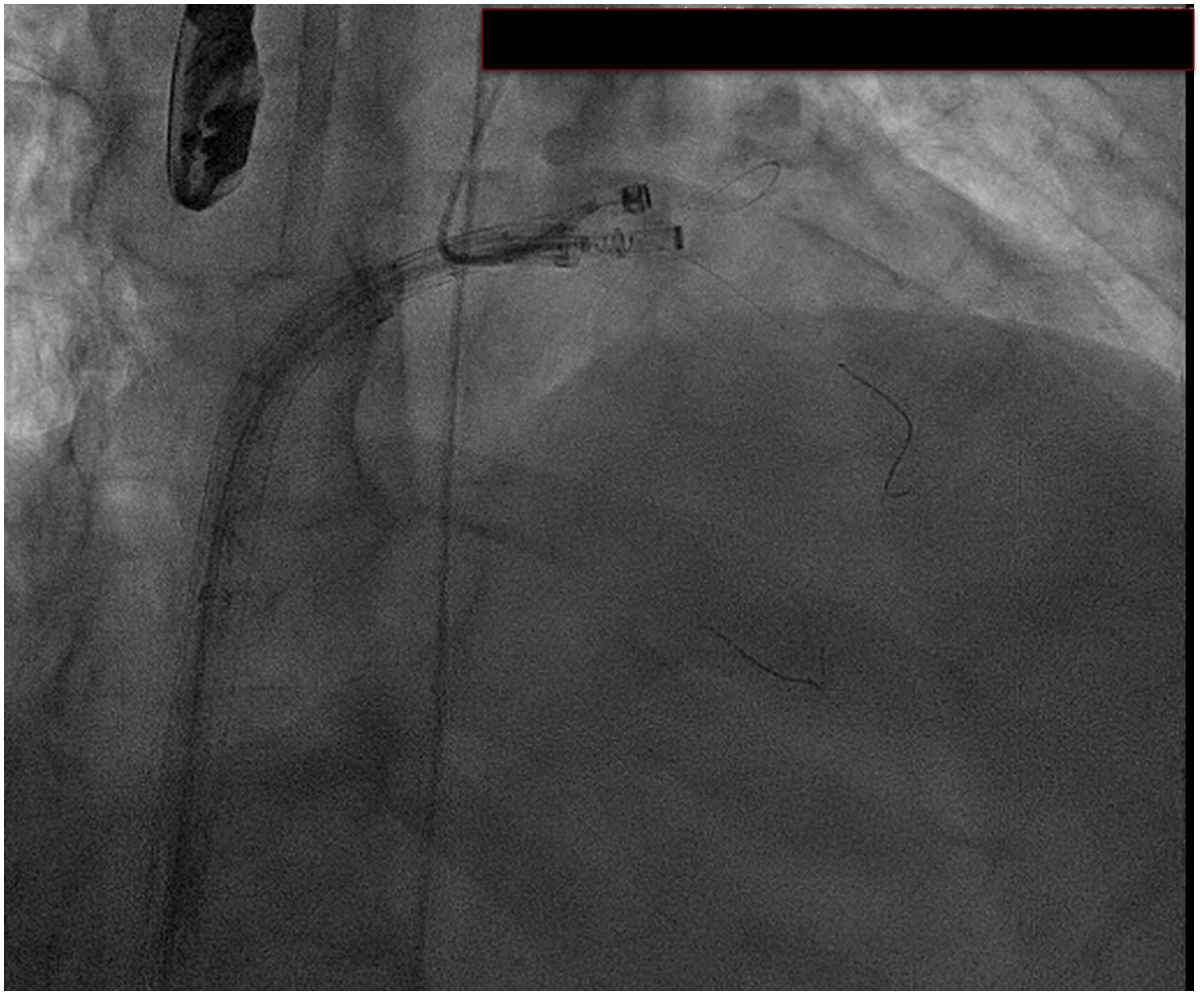


Cardioband implantation – Last 2 Anchors Deployment

- Do not cross “2” on the IC scale without placing the an anchor
- Once reaching “1” on the IC scale – red safety latch will pop up automaticity – place the last anchor



Cardioband implantation – Navigation LAO



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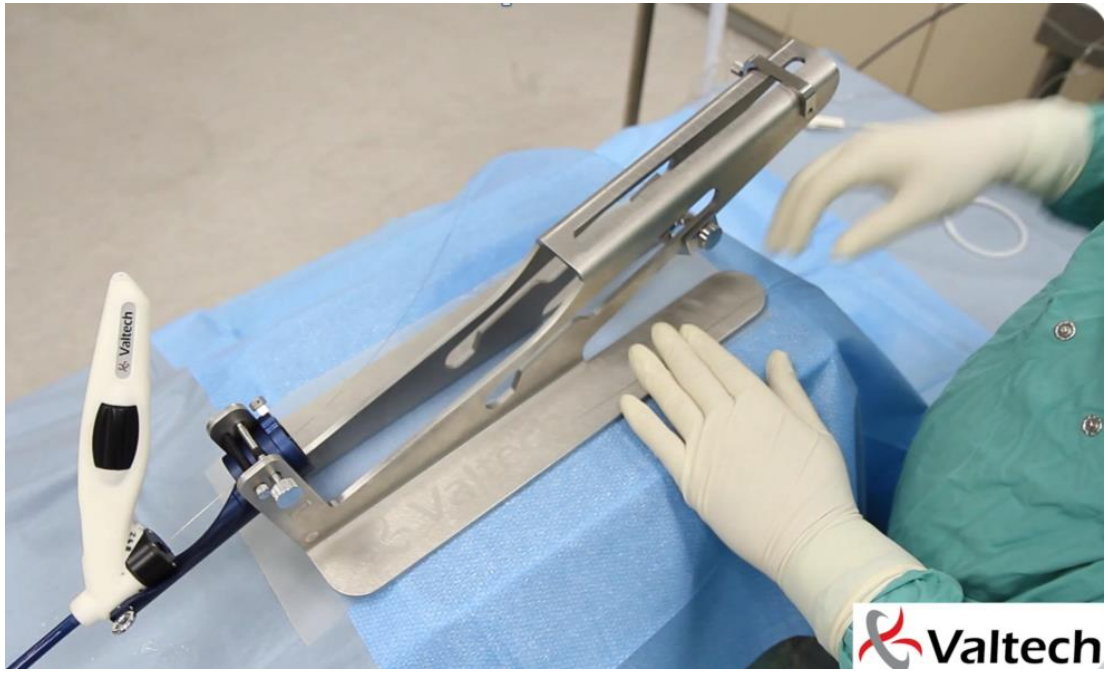
CLD1142

Procedure steps

General Preparations

Imaging Views

Transseptal Puncture



TSS Insertion

IDS Insertion

Implant Deployment

IDS removal

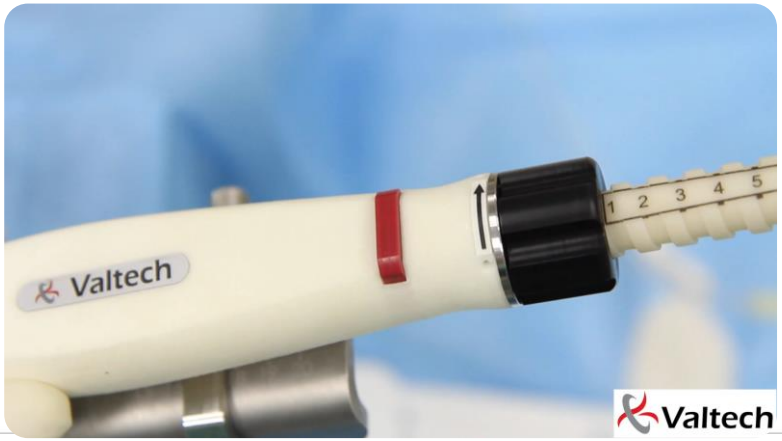
SAT Insertion & Implant Adjustment

System Removal

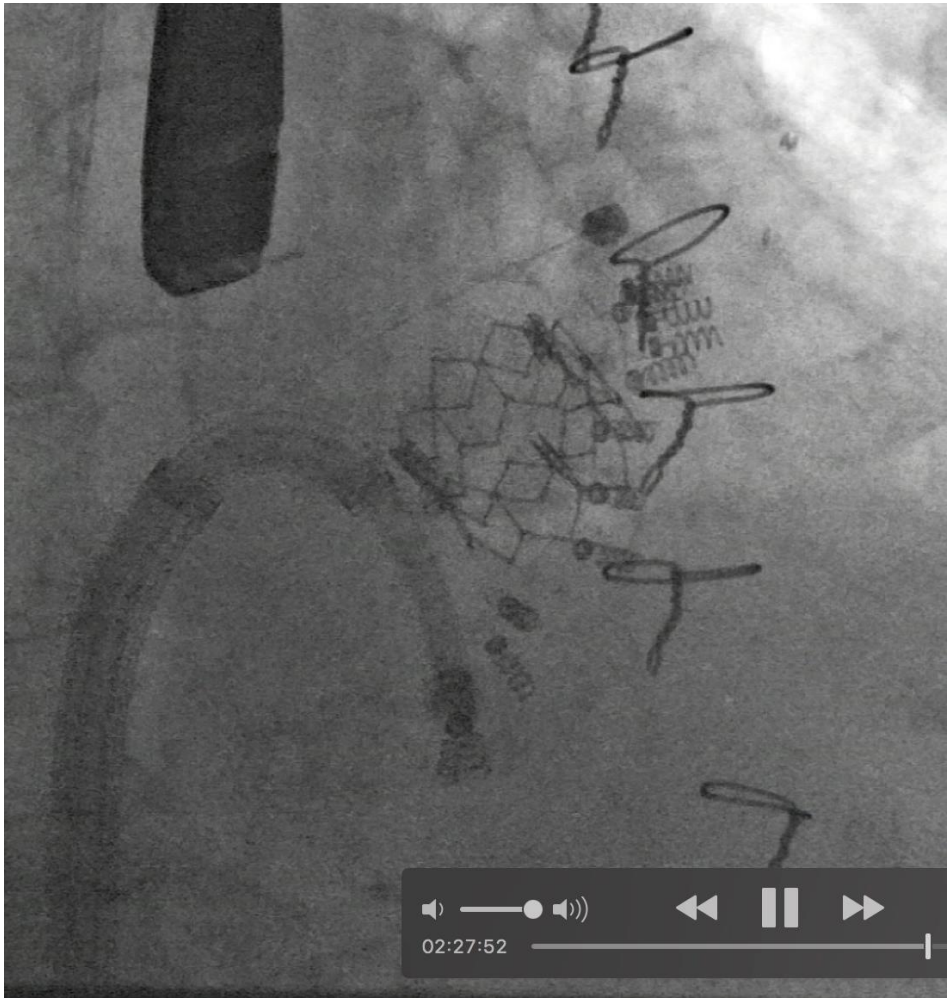
IDS removal 1\2– IC disconnection

RAO View

- Press the safety latch down and continue to **turn the implant release knob** CW to disconnect the IC from the implant. Once the safety latch will pop up again; **implant is released**
- Pull the IC inside the GC
- Lock the blue GC hemostatic valve
- Release GC & TSS tips curve
- Make sure that spool ds free by manipulating the implant guidewire



IDS removal 1\2– IC disconnection



IDS removal 2\2

Lift the IC from the stand slot & Unlock the GC handle from the cradle

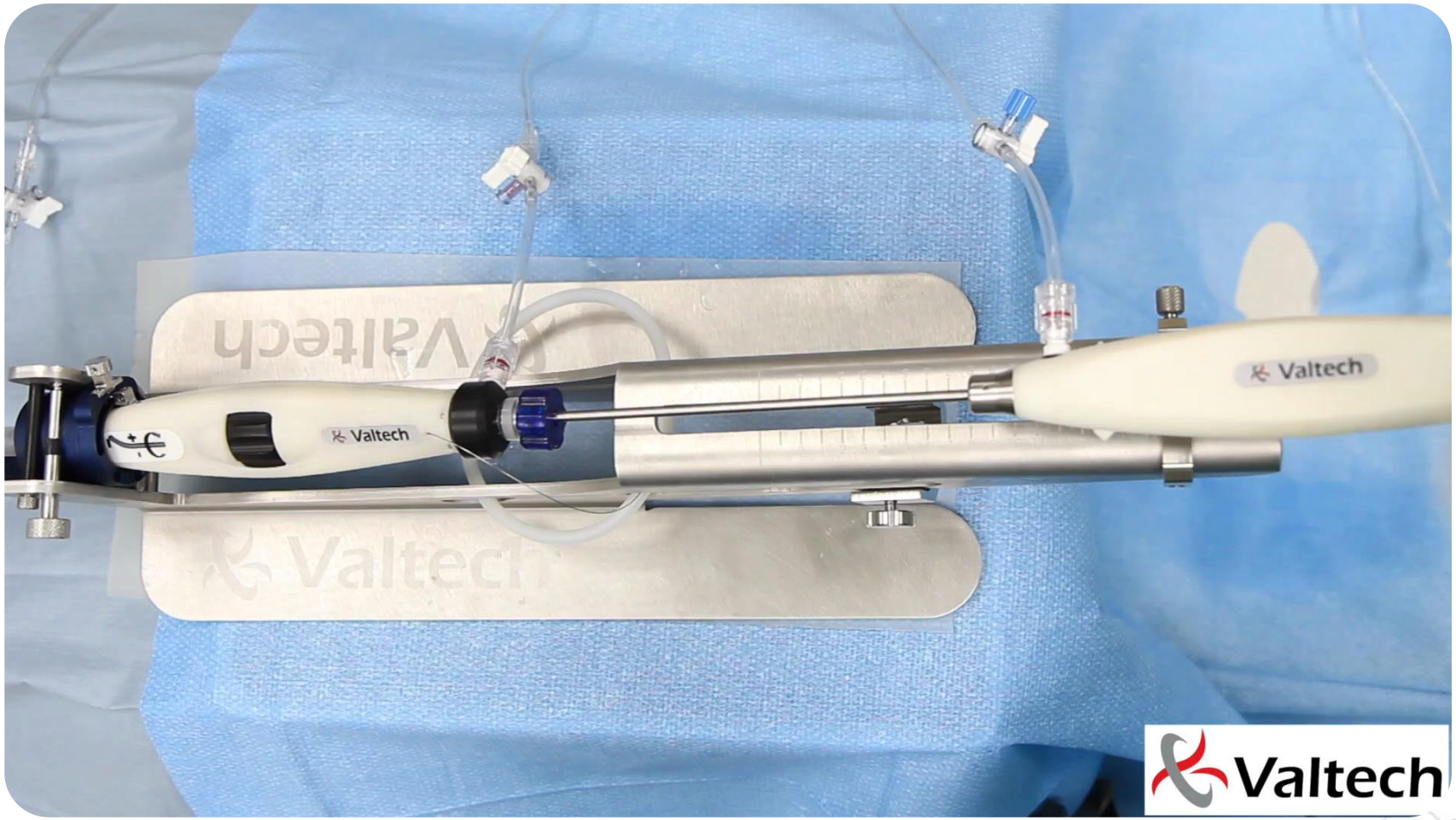
Pull back the IDS out of the TSS until the GC locking segment reaches the Implant protection funnel

Pull the funnel out of the TSS valve

Secure the implant GW and remove the IDS completely

De air the TSS

IDS Removal



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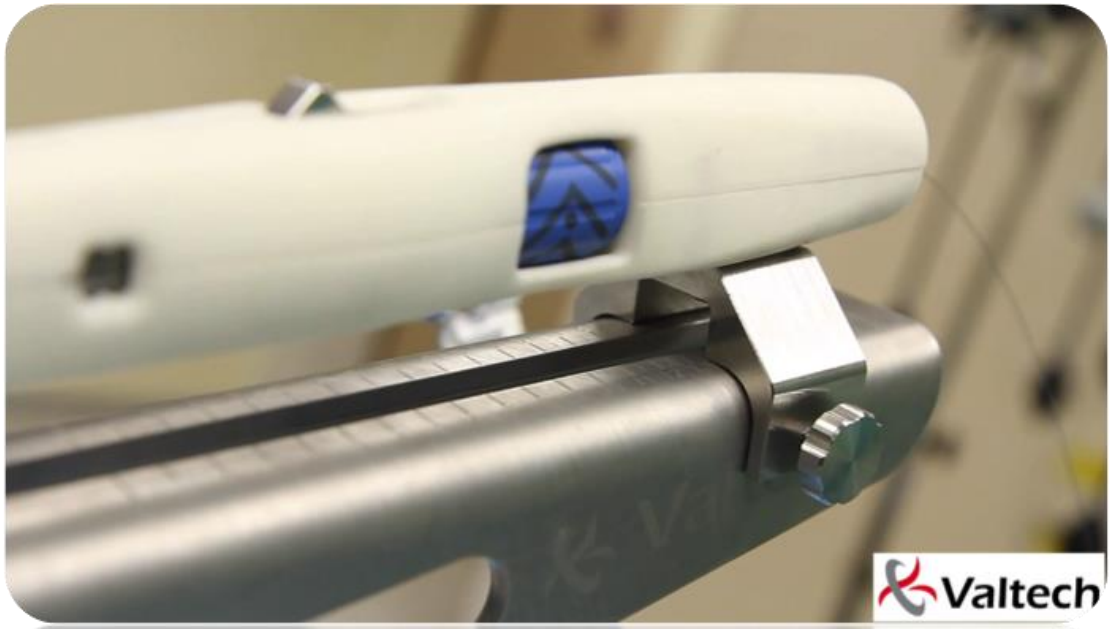
CLD1142

Procedure steps - Presentation Overview

General Preparations

Imaging Views

Transseptal Puncture



TSS Insertion

IDS Insertion

Implant Deployment

IDS removal

SAT Insertion & Implant Adjustment

System Removal

SAT insertion and Engagement

- Remove the IC stopper & Mount the SAT-Stand adaptor over the stand
- Insert the SAT over the Implant guide wire, through the TSS
- **At all time: Advance SAT slowly & gently, Avoid extra slack of the Implant guidewire**
- Insert the SAT funnel through the TSS hemostatic valve
- Connect the SAT to the SAT-Stand adaptor
- Maintain the adjustment mechanism 5 mm away from the first 3 anchors (RAO) by manipulating the implant guide wire.
- Push the SAT in until its tip is adjacent to the Implant adjustment mechanism
- Make sure black mark on the implant GW is fully exposed behind the SAT handle
- Place the SAT tip & adjustment mechanism 5 mm above the first anchors (RAO) & posterior and above the first 3 anchors (LAO)
- Lock the SAT-stand adaptor screw
- Activate the SAT with the Activation Latch. Verify the latch is at the most forward position
- Unscrew the SAT-Stand adaptor screw

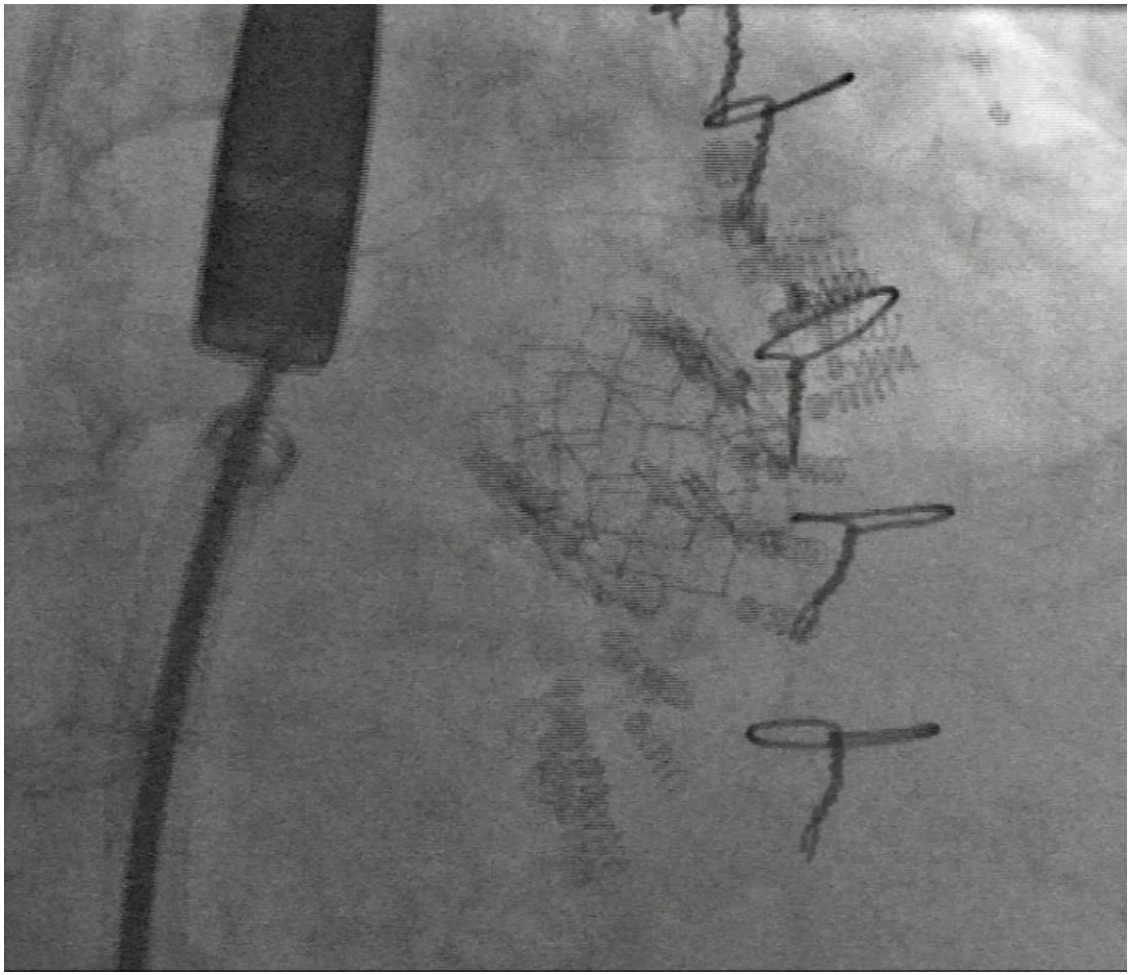
Avoid SAT\GW manipulations exerting on the anchors – check LAO & RAO

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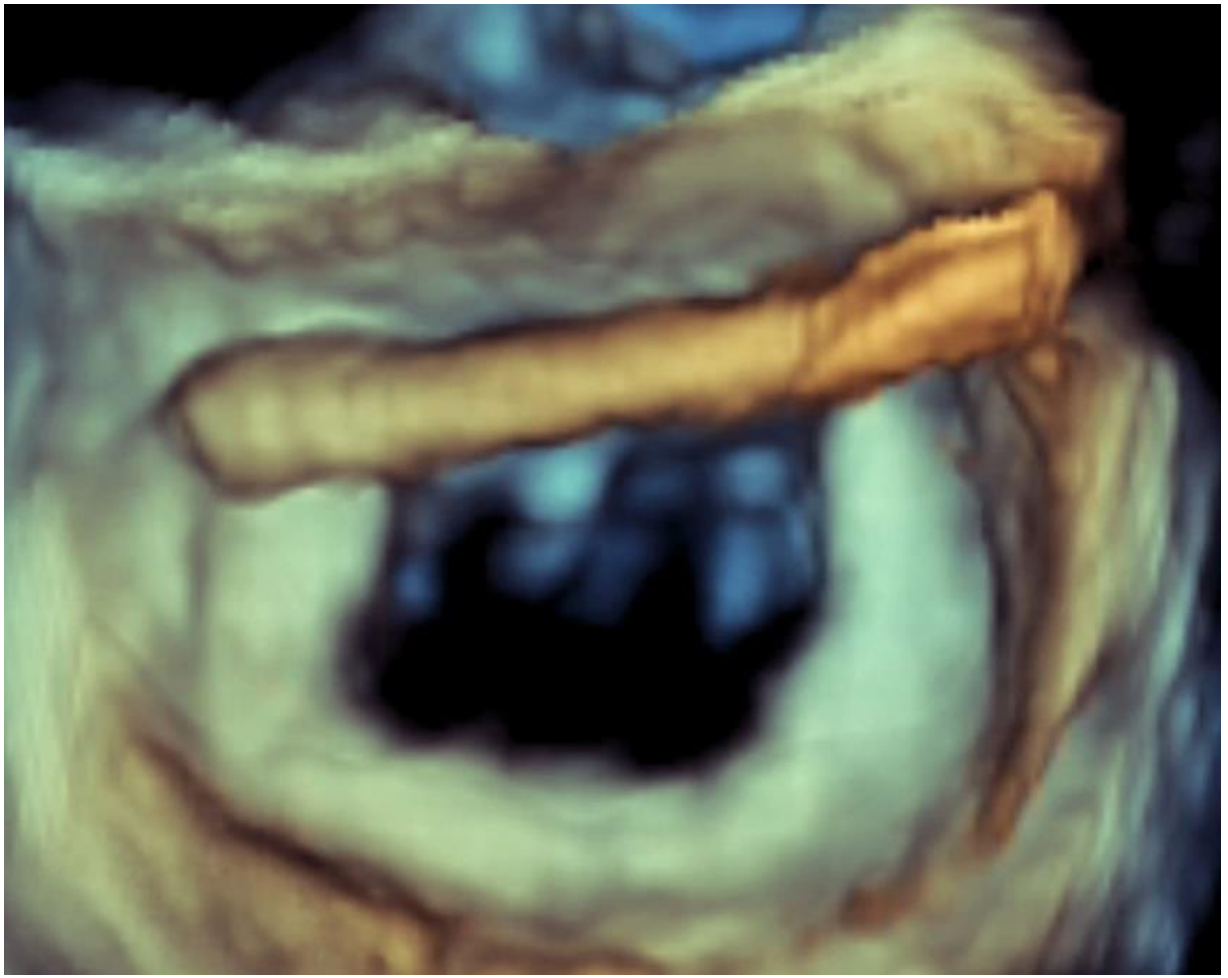
SAT insertion and engagement



SAT insertion and engagement



SAT insertion



Implant adjustment

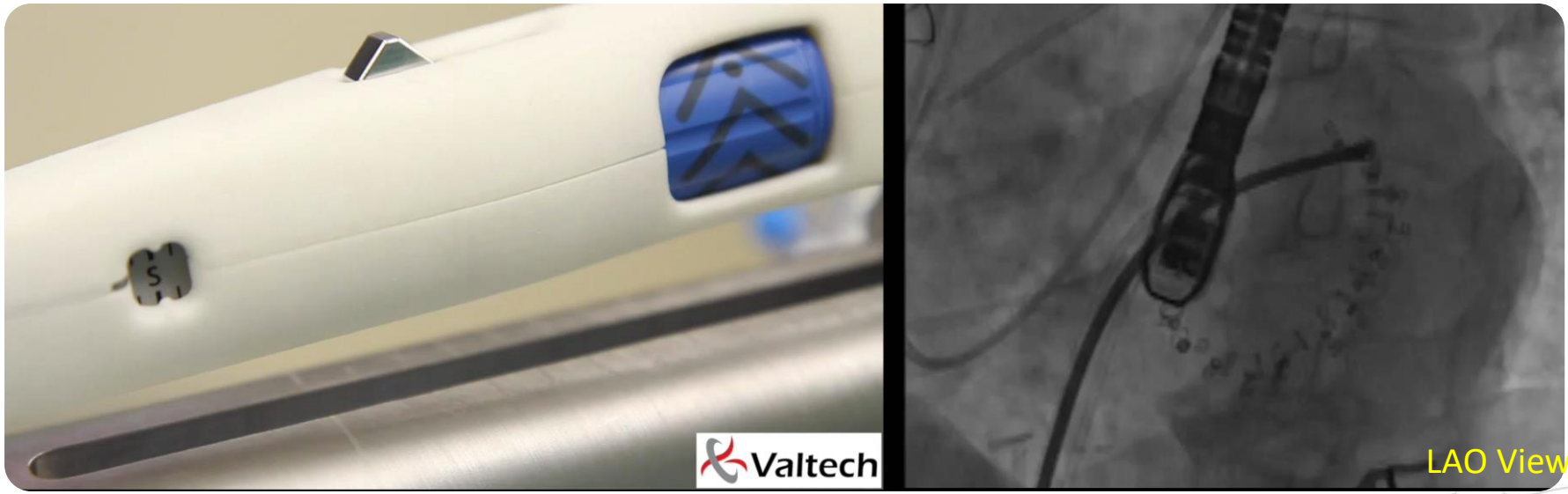
- **“S” → “0” – non active contraction**
- **“0” → “5” – an active contraction**

Record base line (LAO)

Rotate the Adjustment roller CW for implant contraction under (LAO)

Adjustment is shown quantitatively by the Adjustment counter window

Rotate the Adjustment roller CCW for implant expansion under (LAO)

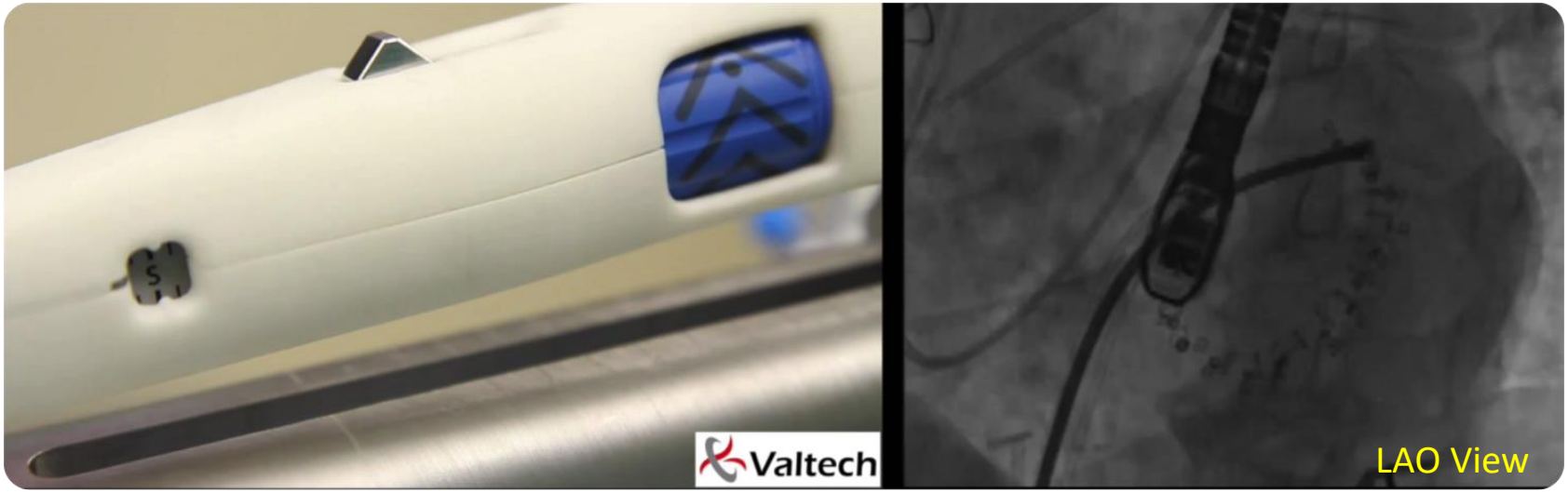


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Implant adjustment – Do's & Don'ts

- Once passing "0" – incase of expanding the implant – do not go below "0"
- Starting "2" and above – 4 Min in between each CM
- Implant Expansion must be followed by active contraction

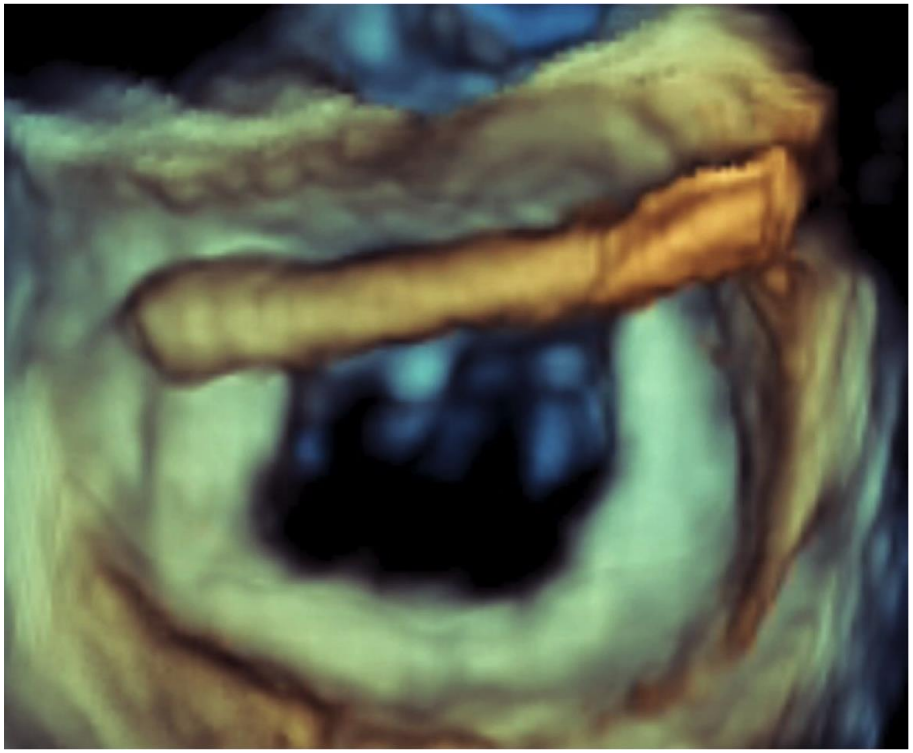


Cinching evaluation: Before & After

- Before cinching:
  - Record 3d view of the annulus
  - Take gradient
- Take measurements before and after each degree of cinching;
- Record each view with an without color;

Views: 0°, 60°, 120°

- Measurements:
  - Annulus diameter (SL distance measured in 2ch inter-commisural and Lvot)
  - Coaptation depth
  - Coaptation length
  - MV area
  - MR severity

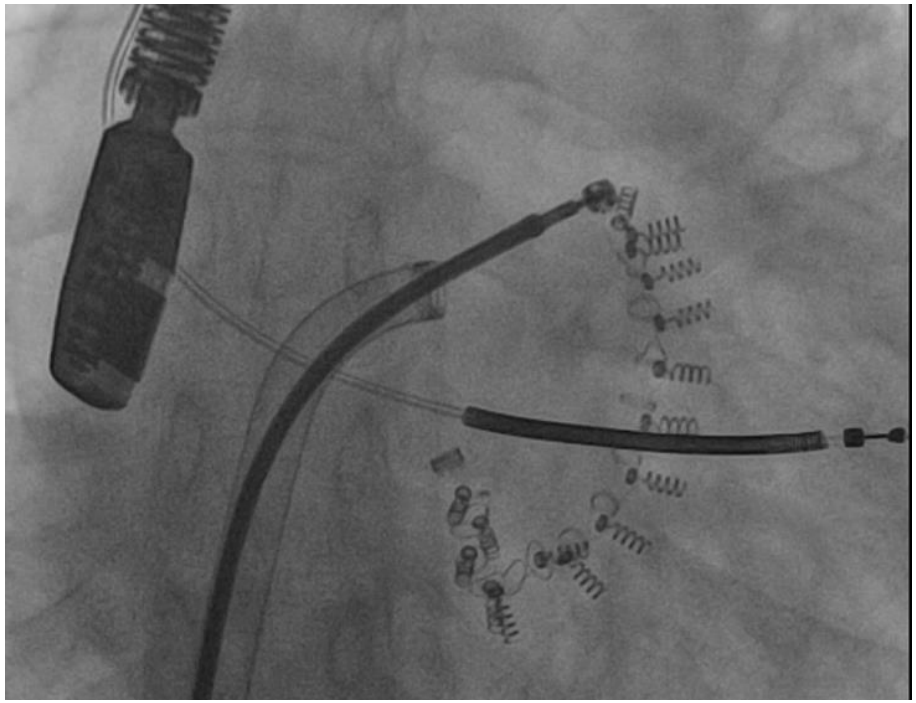


Procedure steps

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SAT Disconnection 1\2

Aim the TSS tip towards the implant adjustment mechanism

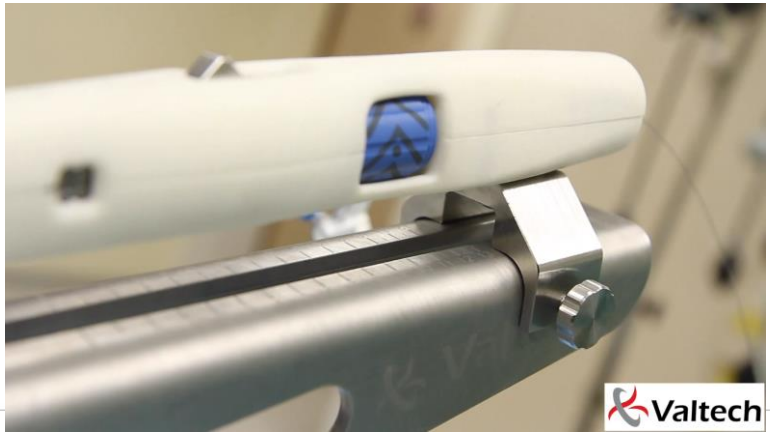
Expose the Detachment Roller, by sliding the Adjustment roller distally

Rotate the Detachment roller CCW at least 10 full turns, to release the SAT with the implant guide wire from the implant

If the SAT doesn't disconnect reveal the blue knob back and rotate it 3-10 clicks CCW for disconnection

Retract the SAT into the TSS. **Draw back the SAT funnel** from the TSS valve

Remove the SAT



TSS Removal 2\2

Steer the tip of the TSS to a straight position and retract it into the right atrium

Unlock the TSS from the stand by retracting the securing element

Remove the TSS carefully from the patient

Immediately after detachment AND 10 minutes after

- Record 3d view of the annulus
- Record each view with an without color;
- Views: 0°, 60°, 120°
- Measurement:

✓ Annulus diameter (SL distance measured in 2CH inter-commissural and Lvot)

✓ Coaptation depth

✓ Coaptation length

✓ MV area

✓ Mr severity

✓ Change of residual jet geometry and presence of new jet (new jet occurrence)

✓ Check leaflet integrity (echo drop out – absence of perforations)

✓ Asence of pericardiac effusions

✓ Check no new wall motion abnormalietes in cx terriotry

- Take gradient
- Check fossa at SAX and Bicaval, 2D and 3D

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Thank you