

*Progress Toward a Percutaneously  
Adjustable Mitral Ring: Micardia*

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# Disclosure

Speaker's name: **Maurice Buchbinder, MD**

I have the following potential conflicts of interest to report: **Micardia Inc**

Consulting

Employment in industry

Stockholder of a healthcare company

Scientific Advisory/ Board Member

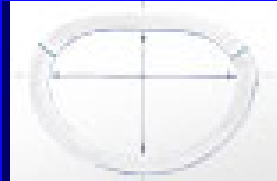
I do not have any potential conflict of interest

# Ischemic MR

- Following Mitral valve repair with annuloplasty surgery recurrent (>2+) MR is seen in 10-30% of patients (McGee; J. Thorac Cardiovasc Surg 2004;128:916-24)
- Recurrent MR appears within the first year following surgery with increasing incidence over time. (McGee; J. Thorac Cardiovasc Surg 2004;128:916-24)
- Unlike in degenerative disease or non ischemic dilated cardiomyopathy, IMR is associated with **asymmetric deformation** of the mitral annulus (Kwan; *Circulation*. 2003;107:1135.)

# Current technology does not cope well with such ischemic changes

- Residual > 2+ post-op MR (6-10%)
- 6 month, recurrence (15%-25%)
- 3 Years, recurrence (30% to 50%)



Edwards Physio



Medtronic Duran



SJM Tailor



ATS Simulus

# The MiCardia Dynamic Ring:

enCor™

- Without activation this NITINOL device functions as a “standard” annuloplasty ring
- However with its Pre-attached electrodes it can be ACTIVATED using RF energy making the ring Adjustable or **Dynamic**
- **Available in sizes from 28 through 36 mm**



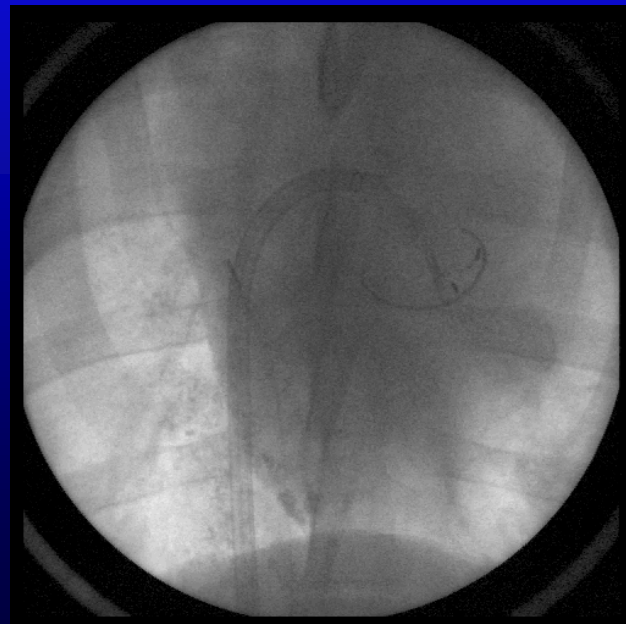
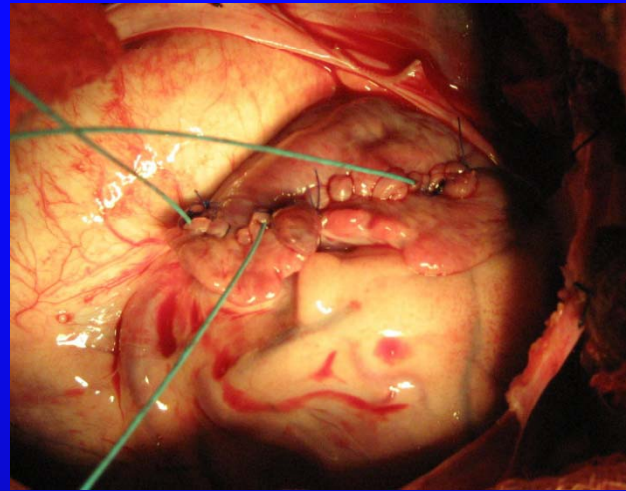
# Intra-Operative Re-shaping

- Following surgical implantation  
Once the electrodes are connected to a proprietary MiCardia RF generator.
- The NITINOL ring can be activated to reshape the ring and treat residual MR.
- Echocardiography usually confirms the need and effectiveness of activation during and post re-shaping.



# Dynamic Ring - Activation

- Although reshaping or ring activation can be done intra-operatively at the time of implantation
- Reshaping can be done at a later date (months after implantation) upon recurrence of MR using minimally invasive/ percutaneous techniques.



# Dynaplasty™ : enCor™

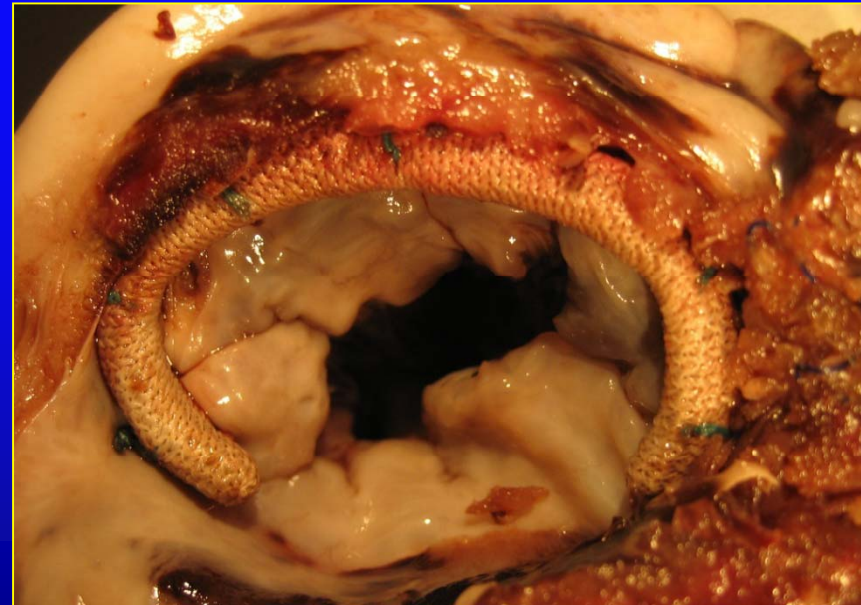


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# Extensive Pre-clinical experience (has shown reliable activation)

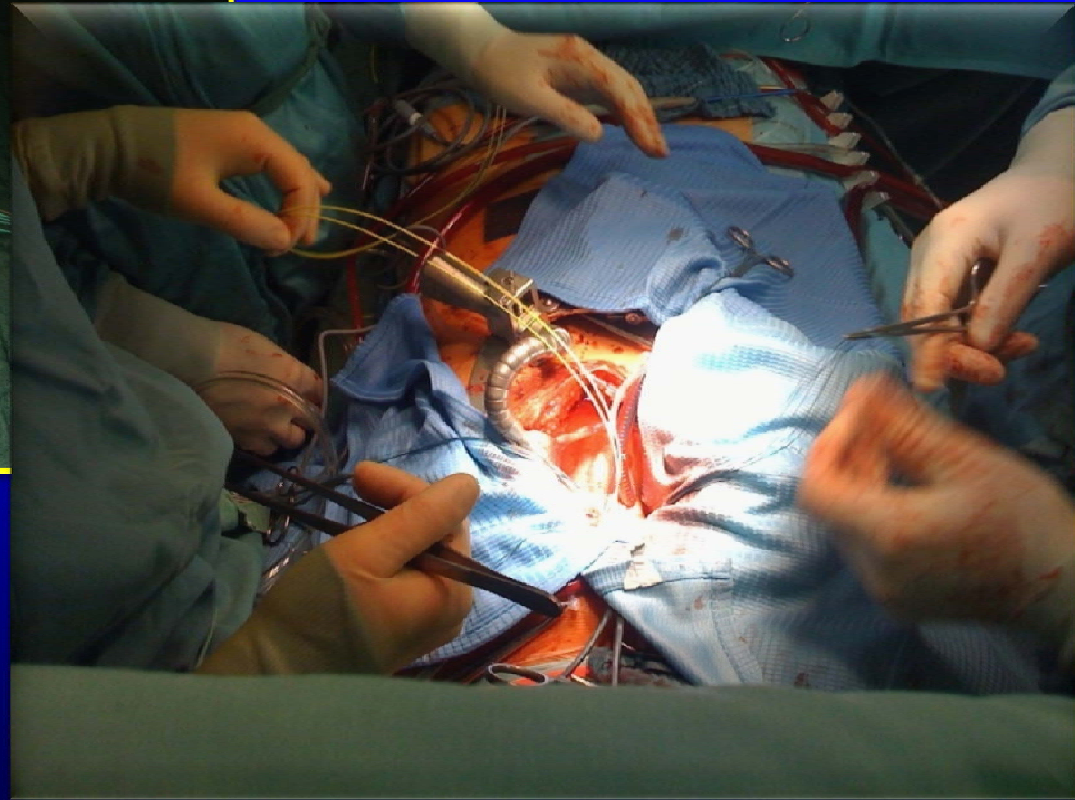
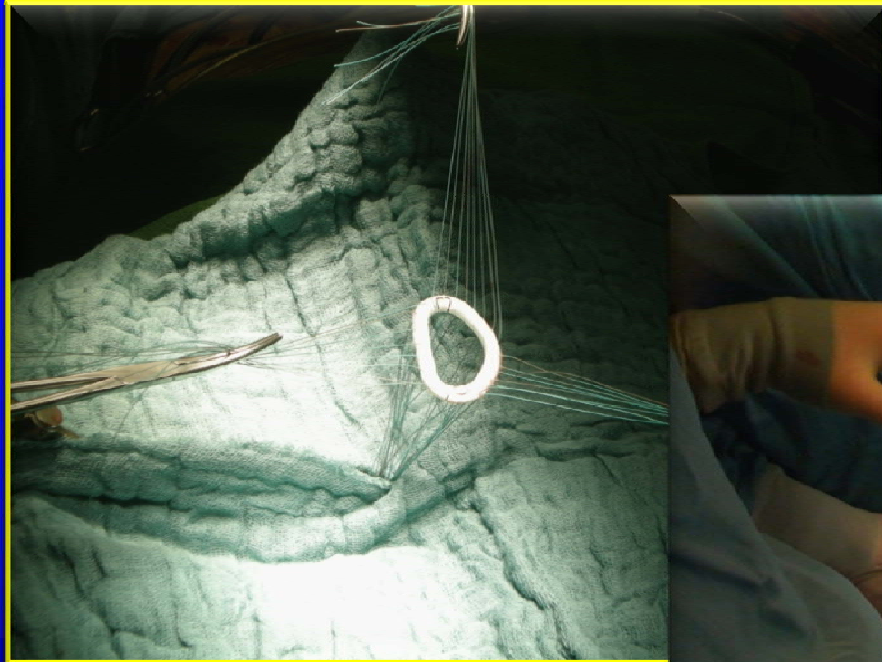
- Consistent A-P distance shortening by 0.5-3.0mm
- Inter-Commissural distance contracted by 1.0-3.5mm
- No heat damage to the surrounding tissue



Postero-Medial commissure  
activation

Courtesy Dr. Alex Marmureanu

# Human Experience : DYANA study



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# Clinical Experience: European DYANA Study (Endpoints)

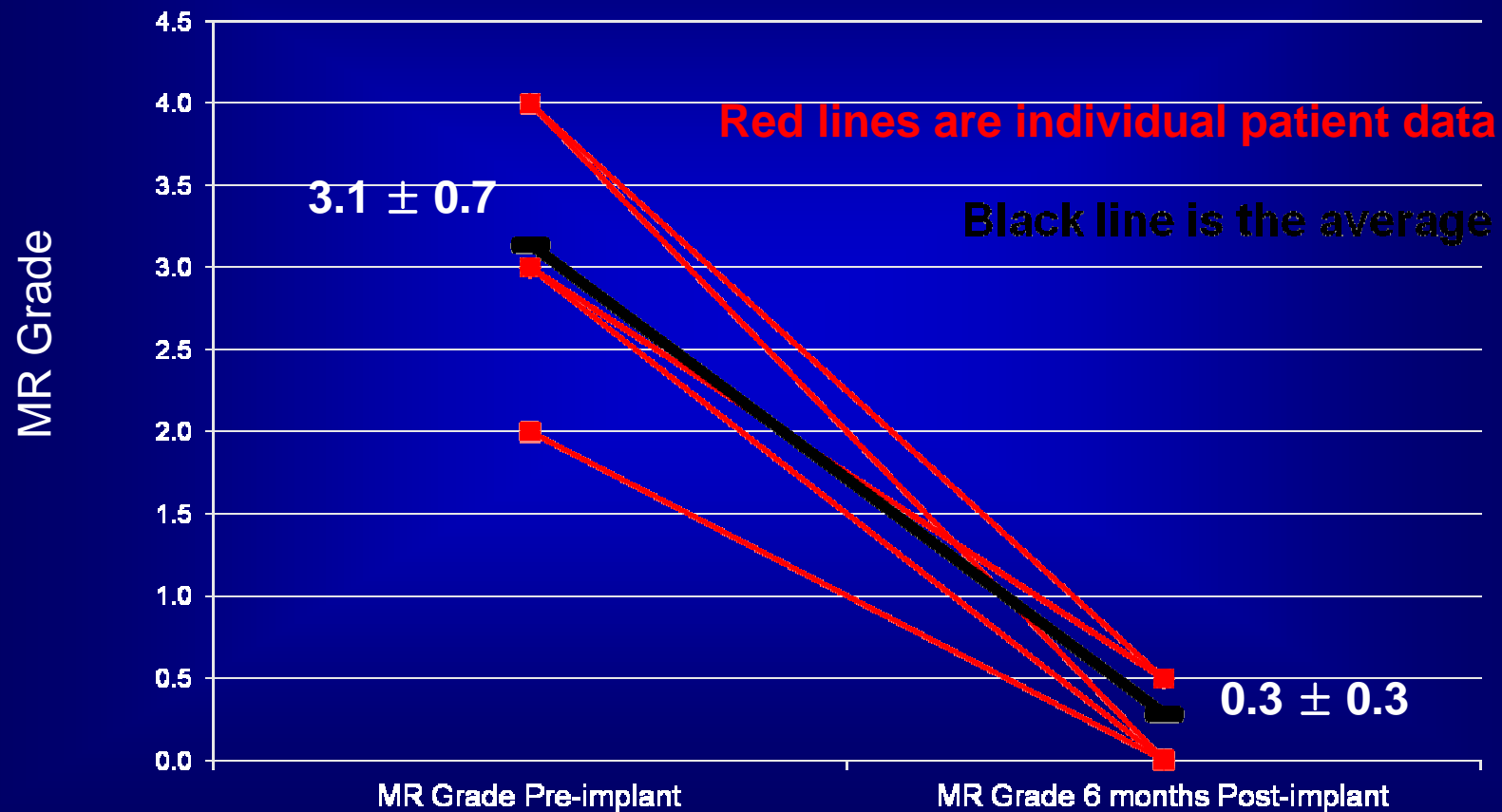
- Primary Efficacy
  - Procedural success with  $<2+$  MR Or  $<1+$  with activation
- Primary Safety
  - Comparison of early and late adverse events to literature references

# 30 Human Implants Completed

Site	Implants	Activations
University Hospital of Homburg	7	4
Leipzig University Heart Center	11	1
Sana Herzchirurgie, Stuttgart	8	2
University Hospital, Kiel	4	0
<b>Total</b>	<b>30</b>	<b>7</b>
No adverse effects due to intra-operative activation noted		

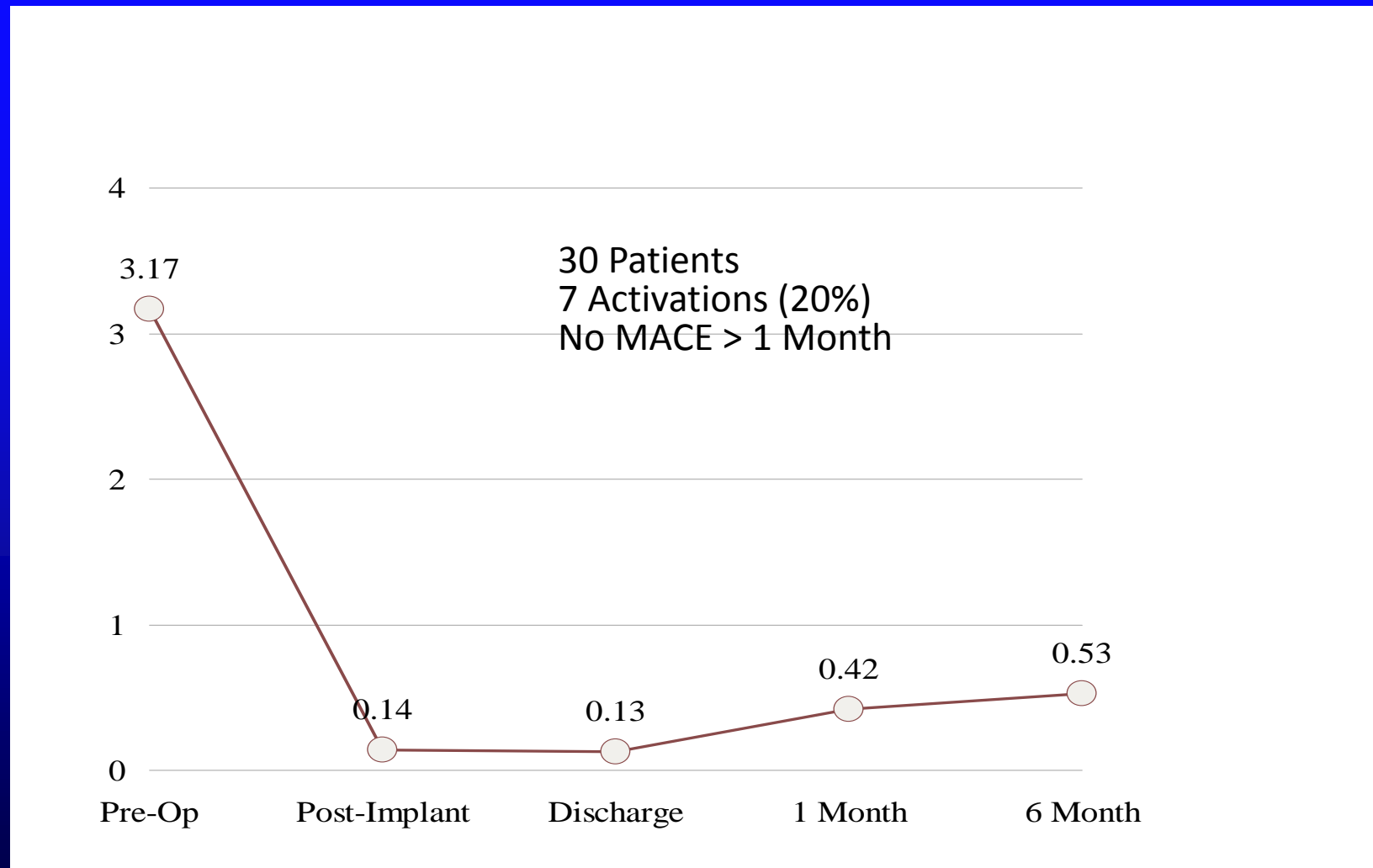
# Clinical Experience

## Activated Patients

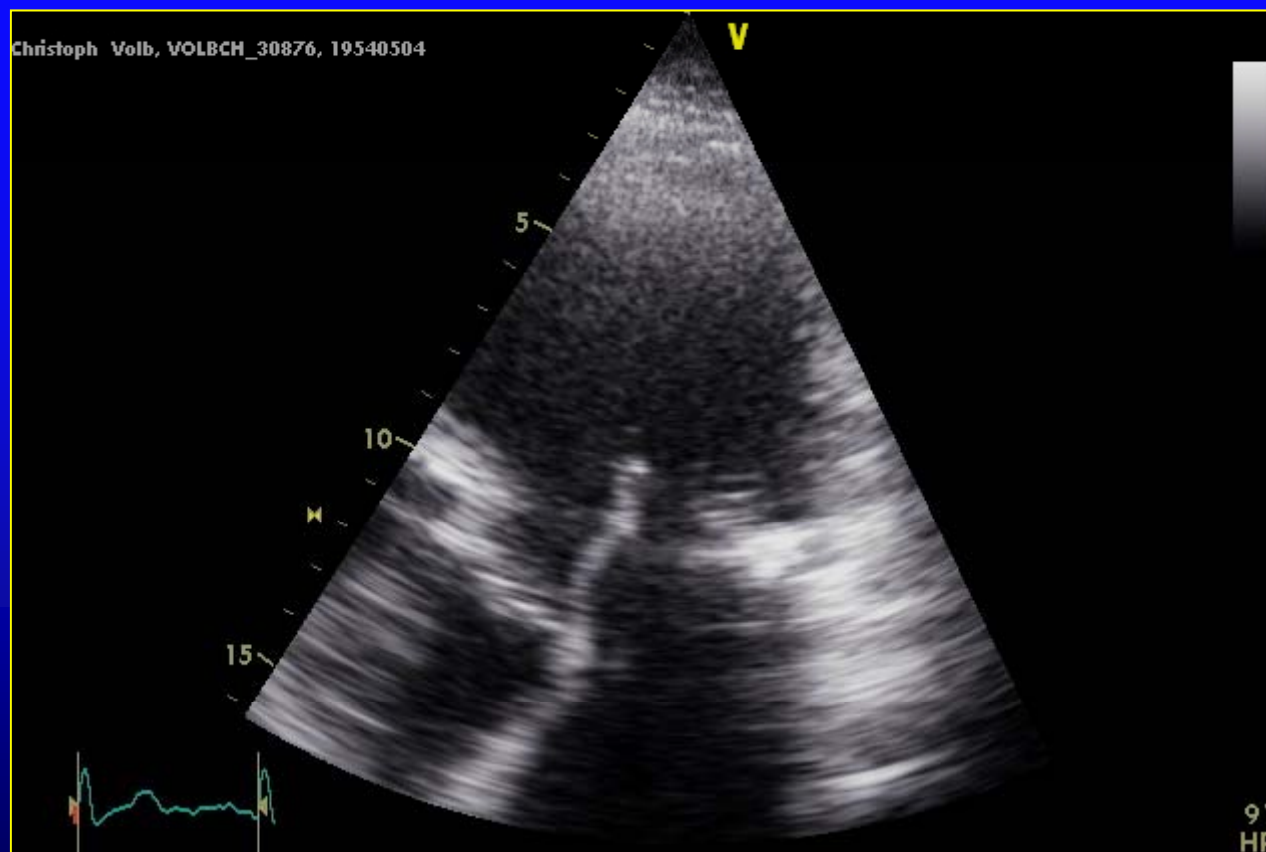


# Intra-Operative activation

## Intermediate follow up

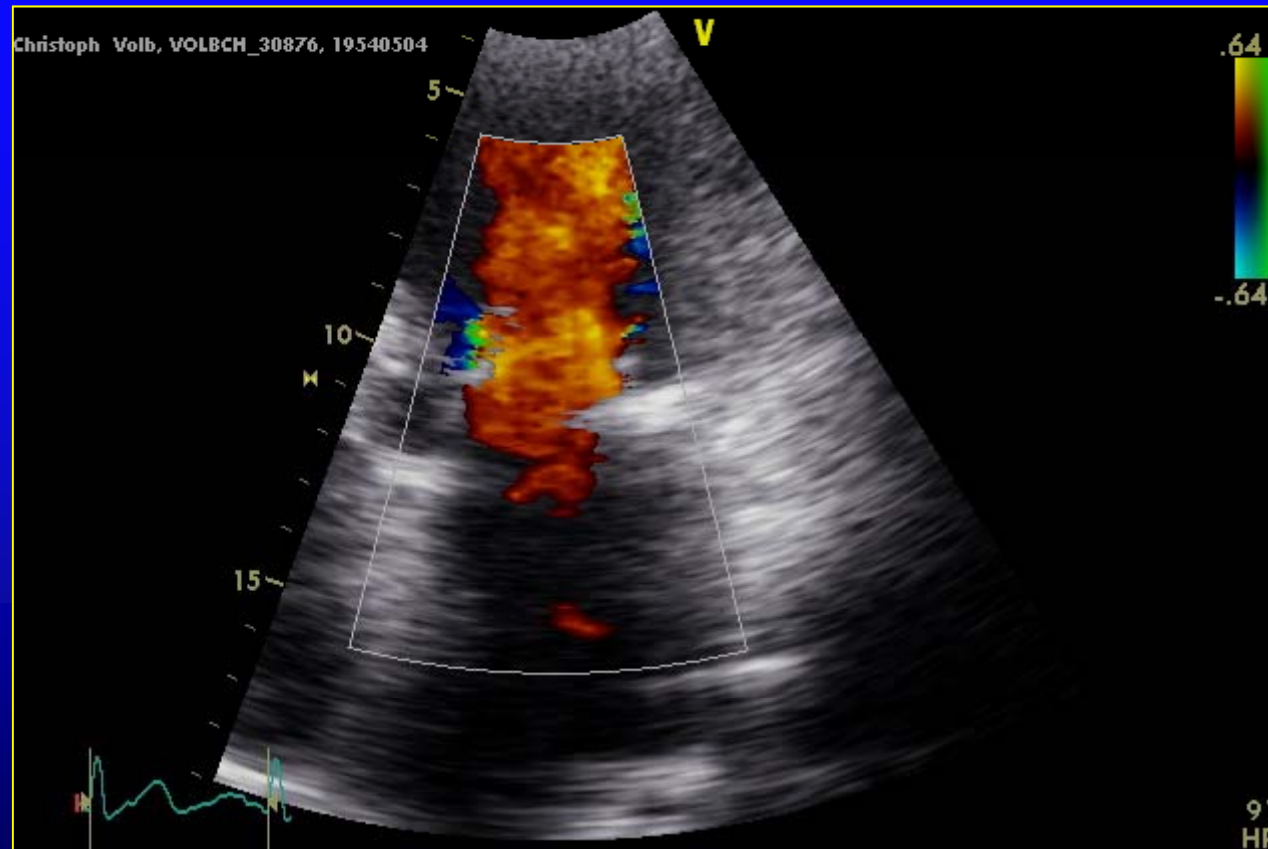


# TTE 2D pre-procedure Bi-leaflet Prolapse



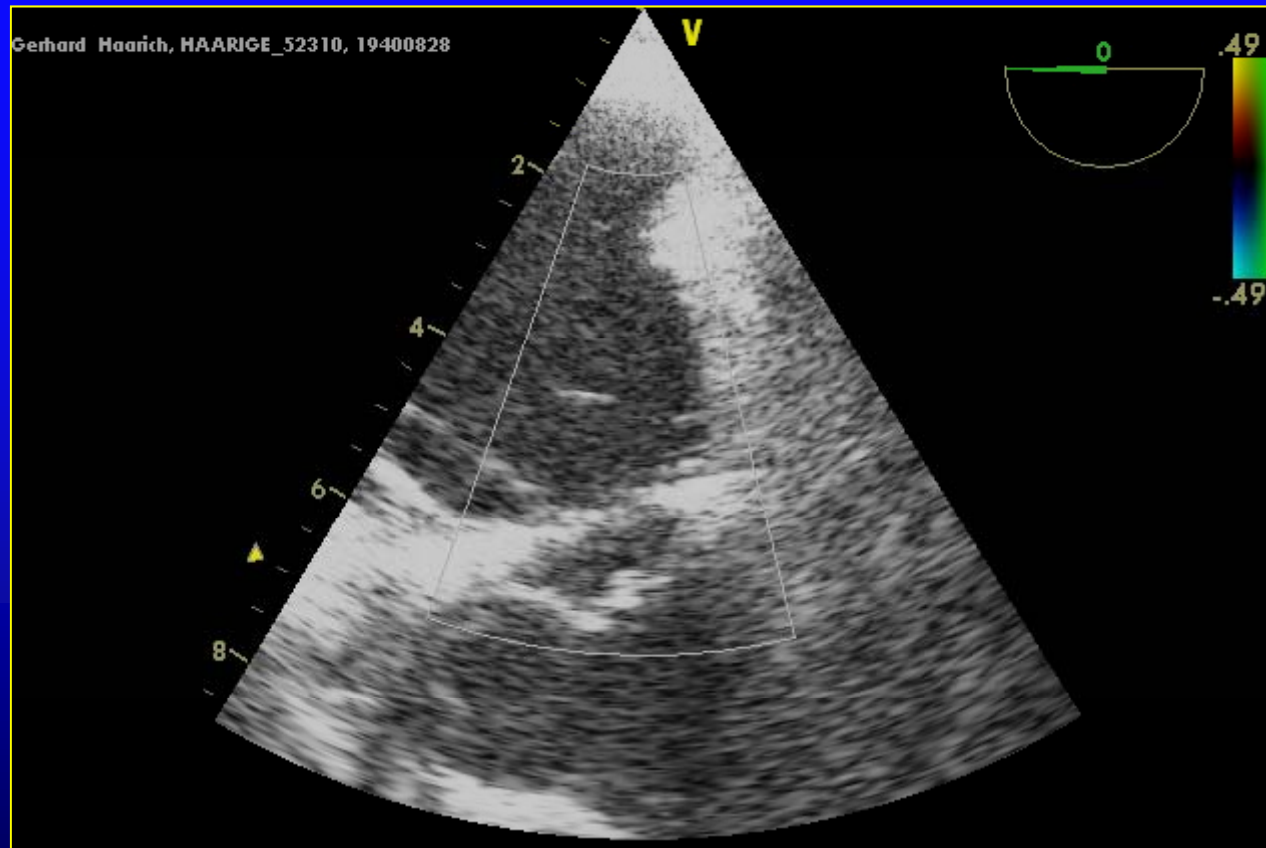


# TTE 4-chamber Pre-procedure





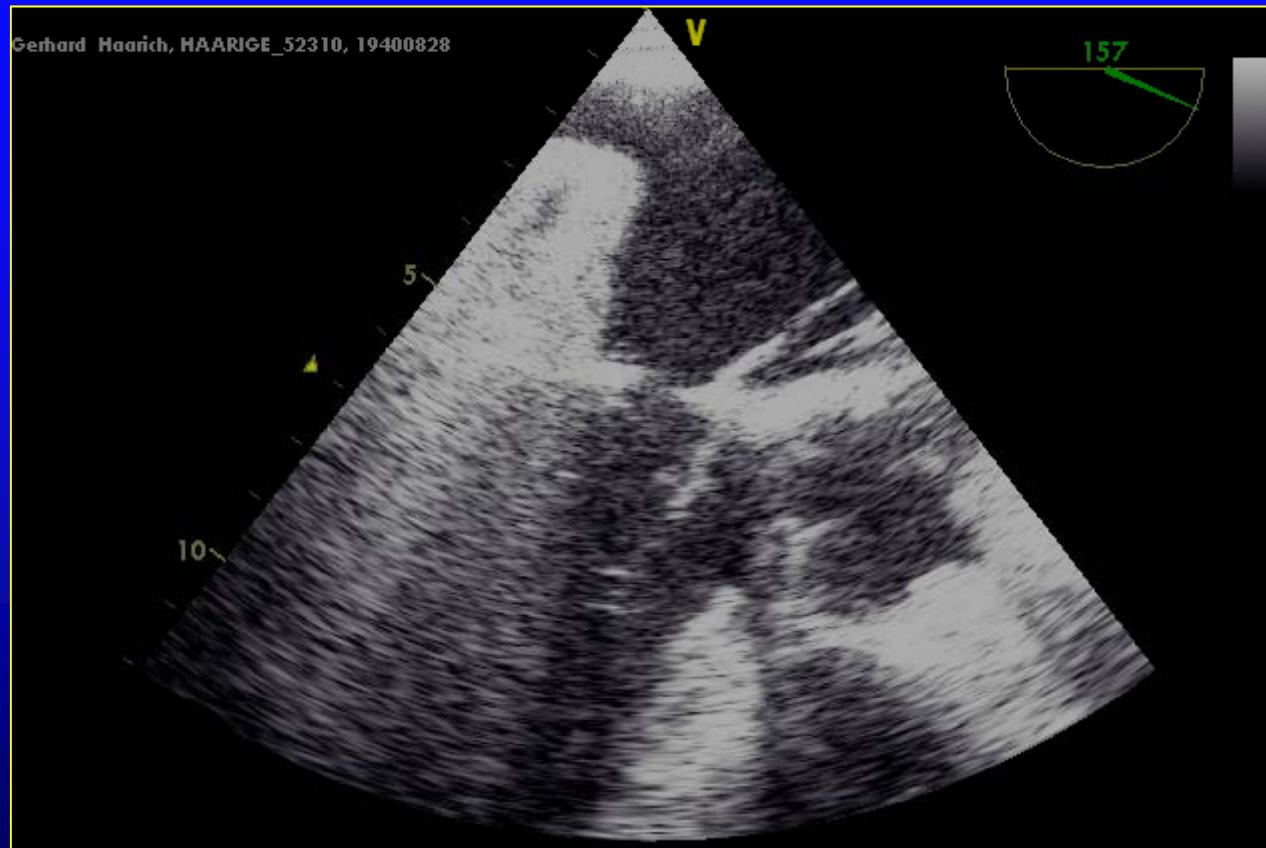
# TTE 4-chamber post ring implant prior to activation



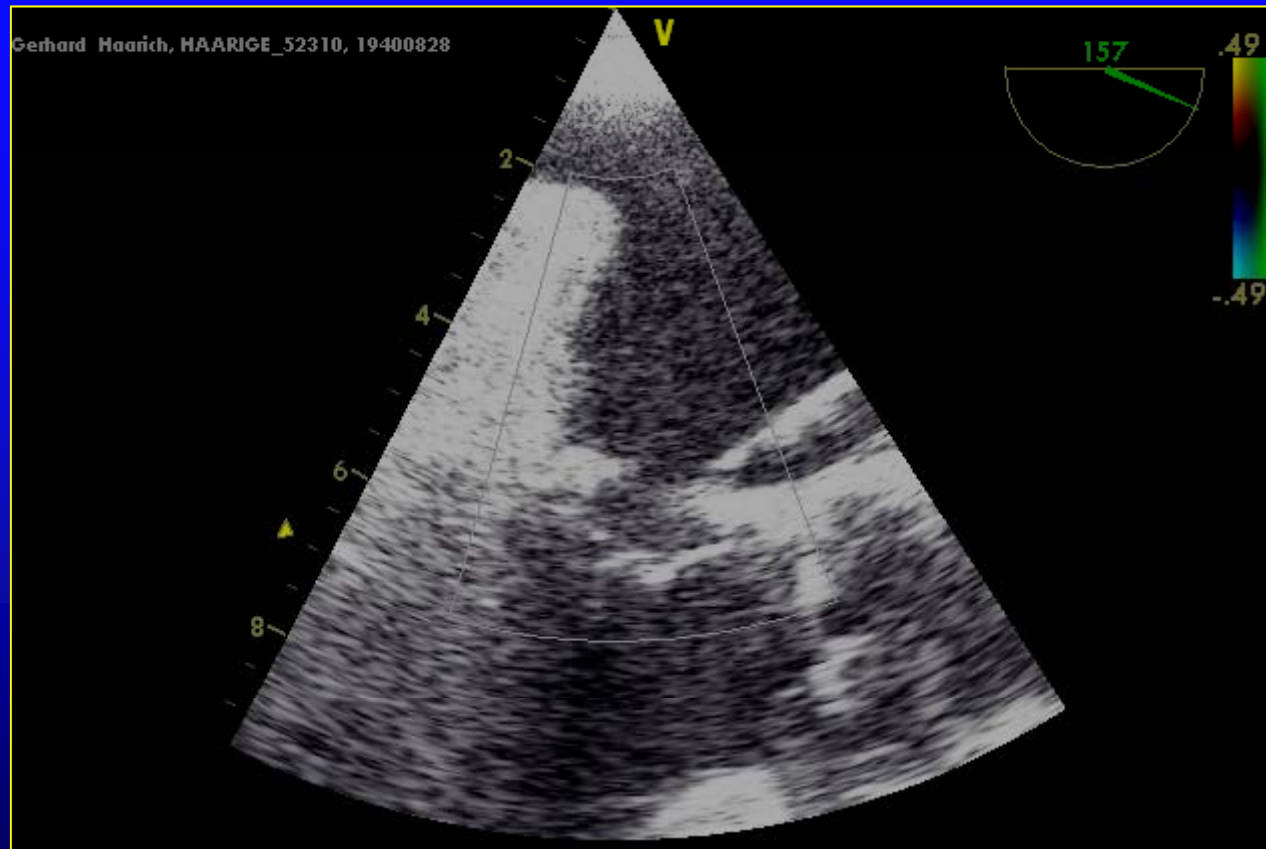
# TTE 2-chamber post ring implant prior to activation



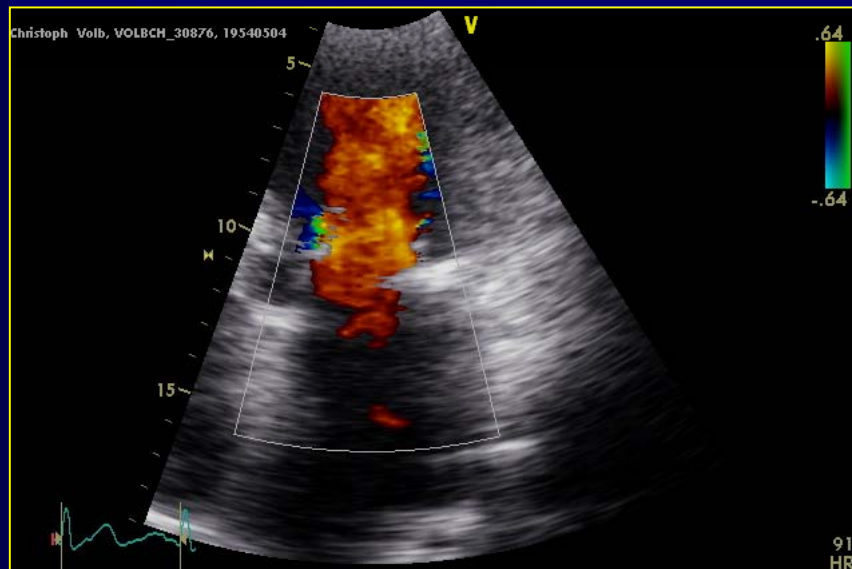
# RF connecting cable in place



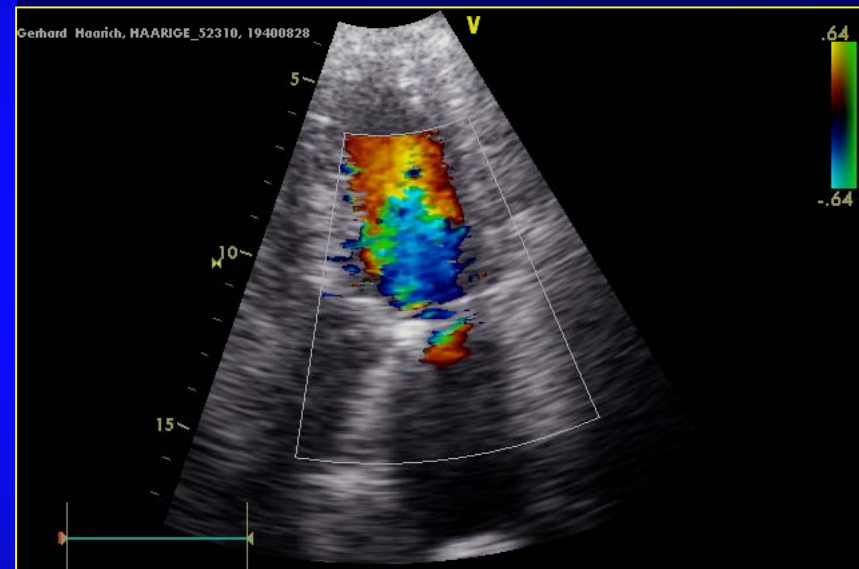
# TEE 3-chamber Post-activation



## PRE- Procedure TTE



## Post-Procedure TTE



# 6-Month F/U, TTE 4-chamber



# Clinical Experience

- 3 Cardiac related SAE's in 3 patients (None were device related)
  - 1 pt unstable angina pectoris day 74 post op
    - Required hospitalization.
  - 1 pt heart block day 12 post op
    - Pacemaker implantation
  - 1 pt Bypass spasm -> Hemodynamic instability → Multi organ failure
    - Patient expired on day 2 post op
    - Annuloplasty ring + coronary bypass x2

# Ultimate Valve Repair Modality : late activation



enCor<sup>sq</sup>

## LATE activation: Sub Q device platform



- From a two lead system the device has evolved into a Single lead unit with atrial exit of the lead upon implantation and pacemaker like Subcutaneous “pocket“ implantation
- This allows Simple percutaneous access for outpatient activation when needed

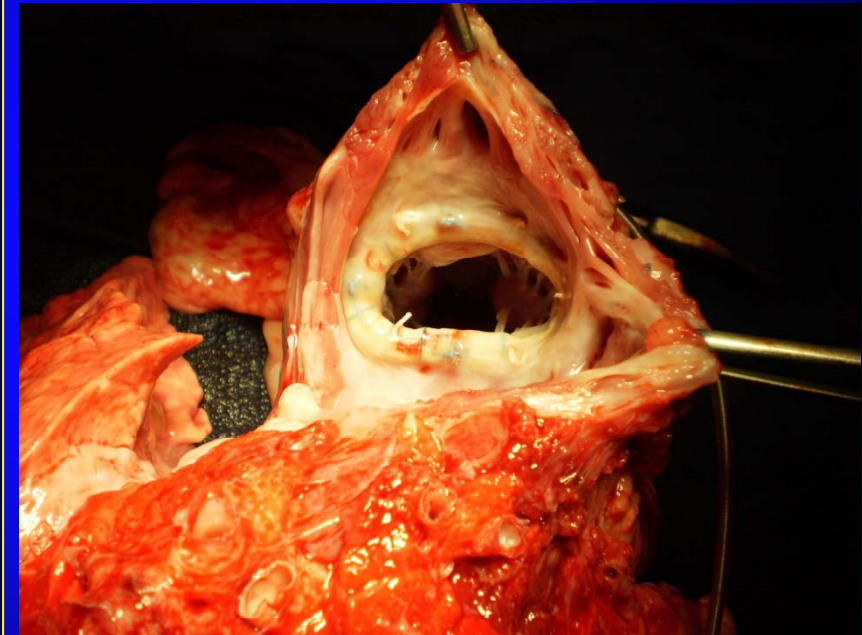
# Pre clinical Percutaneous Reshaping: Sub-Q Device Platform @140 days

- Full activation within 60 seconds

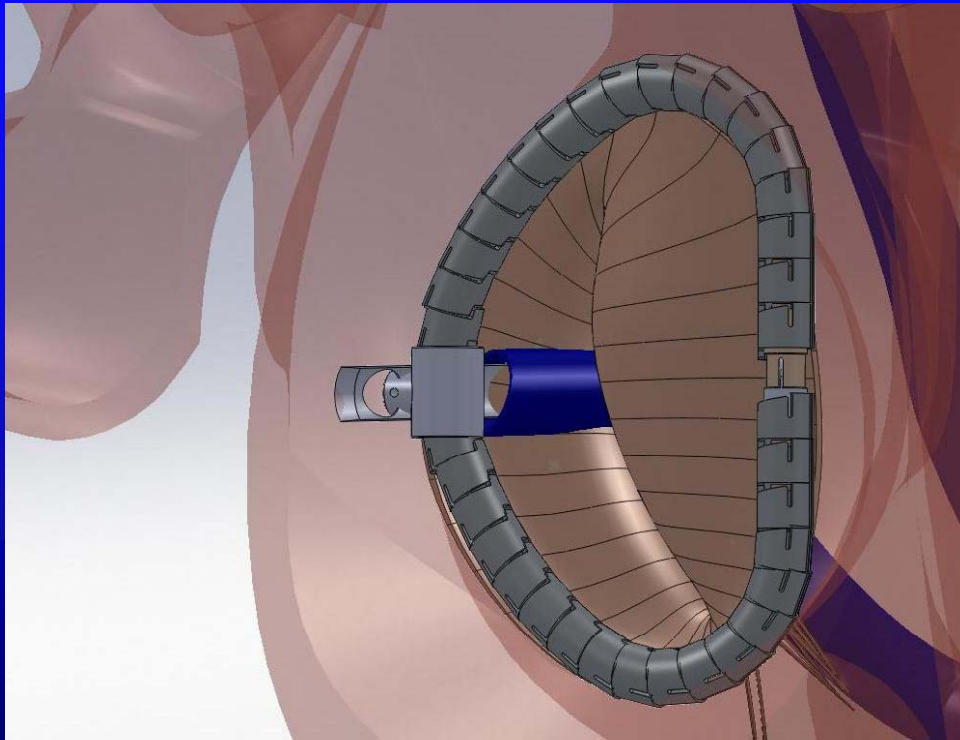


# Pre clinical Percutaneous Reshaping: Sub-Q Device Platform @140 days

- No infection
- No dehiscence
- Full activation @ 140 days, despite 100% in-growth

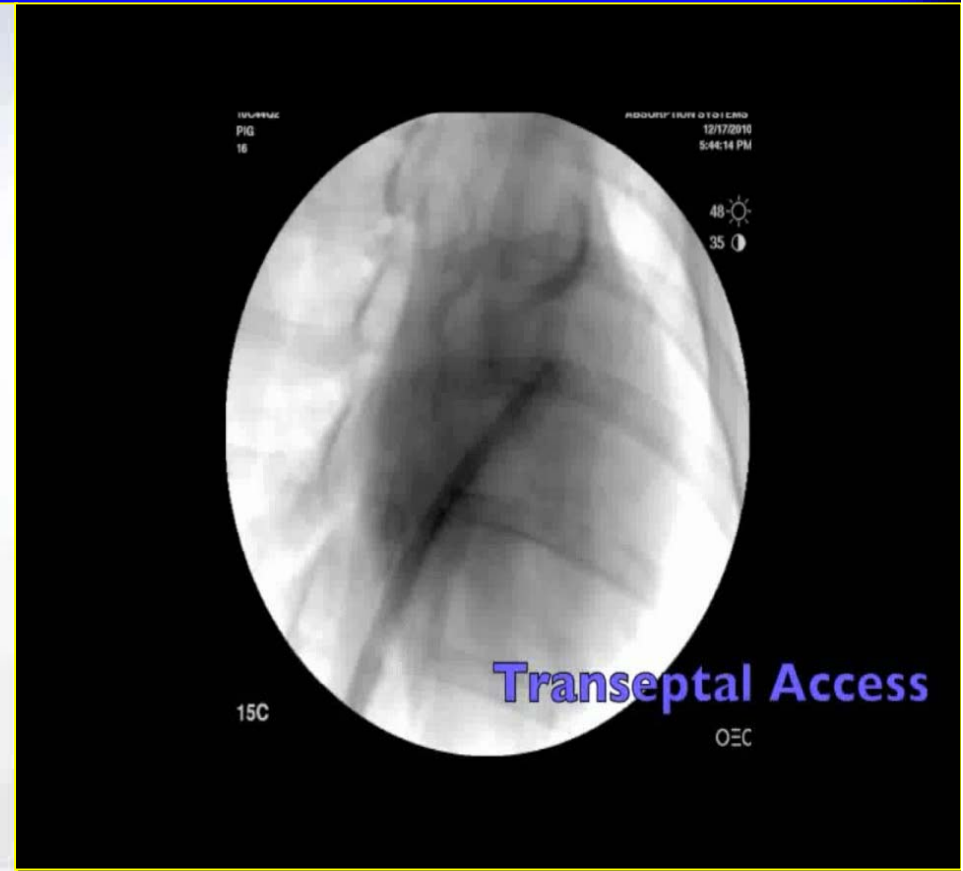
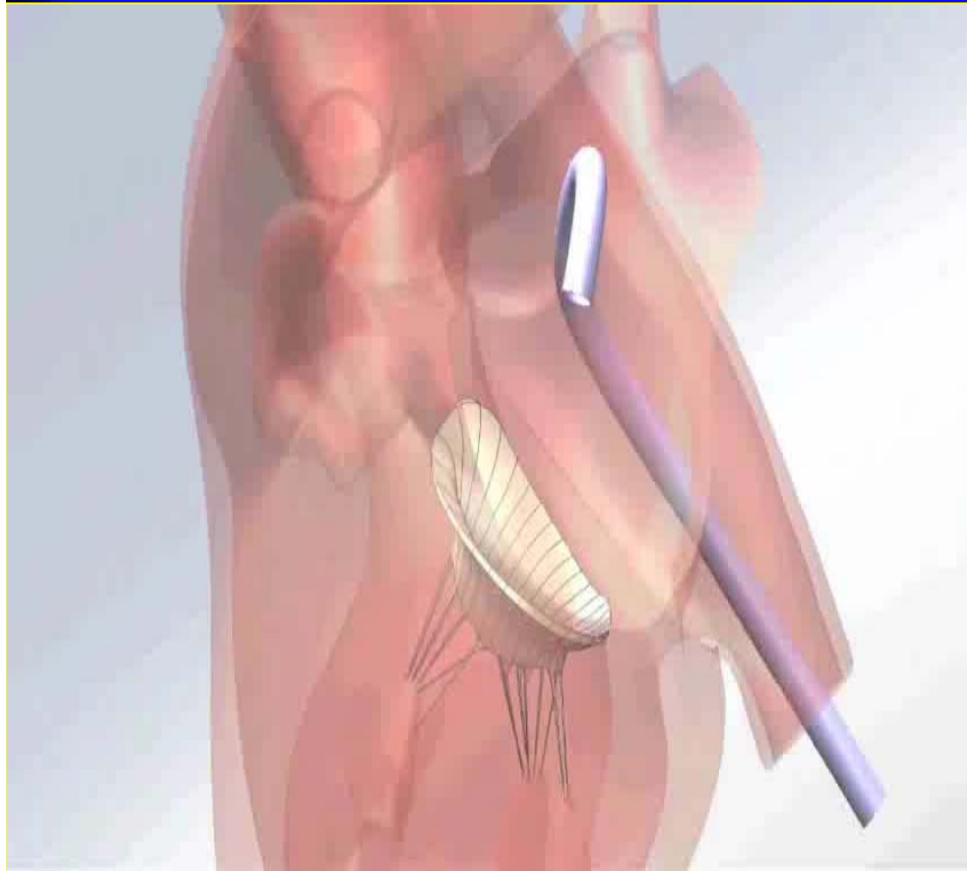


# Trans-Catheter Device Platform



- Steerable Delivery Catheter
- Ring “Snaps Together” after delivery
- Built in Anchors for Fixation
- Delayed Activation with “Wireless” Percutaneous Catheter

# Percutaneous Trans-Catheter Device Platform



# Conclusions

- From this early clinical experience the MiCardia Dynamic Annuloplasty Ring appears to be a promising device for surgical treatment of Mitral regurgitation.
- The Intra-operative adjustable feature may be an extremely valuable tool for optimization of surgical results
- Further minimally invasive adjustments in ring geometry in the follow up phase could be a compelling advantage for its use .
- Early experience with a percutaneous Trans- catheter dynamic ring implantation system appears encouraging .