

2018 | euro  
PCR

The heart team in structural interventions:

# Continuous innovation resolving complexity

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*Heart Center and Heart Valve Unit  
University medicine Mainz Germany*



Speaker's name:

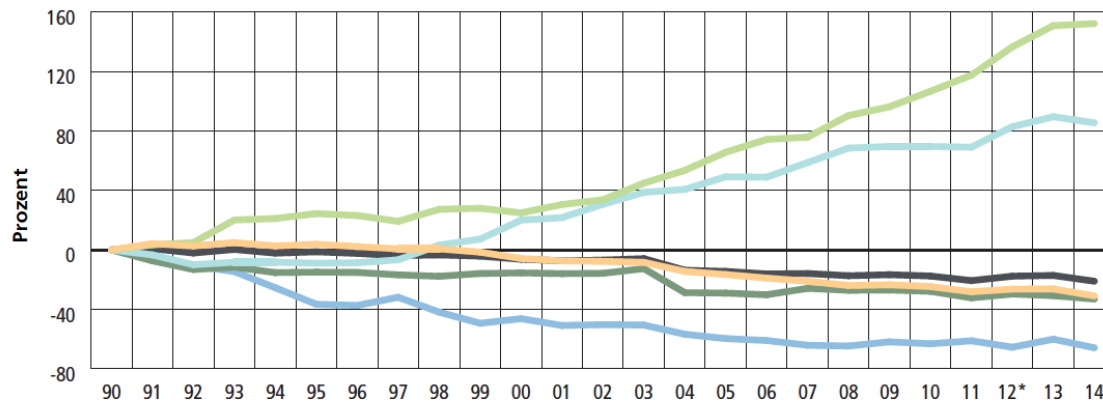
- I have the following potential conflicts of interest to report:

RCT Study Activity and Speaker boards:

- RESHAPE-2 HF (IIT), TRILUMINATE (Abbott SH), Tendyne (Abbott)  
TRIC (IIT Munich), TRI Repair (Edwards), Matterhorn (IIT Cologne)  
Abbott, Cardiac Dimensions, GE Health Systems, Edwards LS, Philips

## Mortality numbers indexed in 1990 in Germany Heart Valves become more important

### Entwicklung der Sterbeziffer insgesamt in Deutschland



← **Heart Valves**

← Rhythm disorders / Afib

← Heart Failure

← Grown up congenital HD

\* ab 2012 Bevölkerung auf Grundlage des Zensus 2011

Jahr

ischämische Herzkrankheiten

Herzinsuffizienz

Herzrhythmusstörungen

Herzklappenkrankheiten

angeborene Fehlbildungen

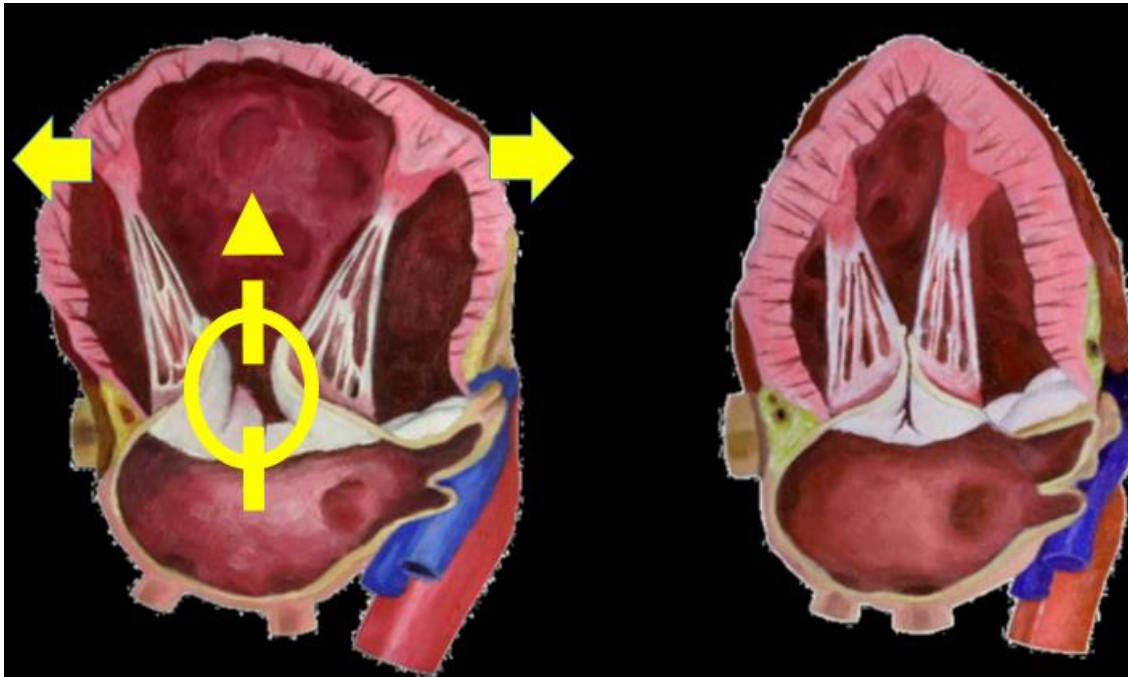
Summe

Berechnung auf Grundlage von Daten des Statistischen Bundesamtes.  
Die Daten 1990 – 2009 wurden mit freundlicher Genehmigung dem Herzbericht 2010 entnommen.

Abb. 2/9: Entwicklung der Sterbeziffer der ausgewählten Herzkrankheiten insgesamt in Deutschland von 1990 bis 2014

# LV/LA dilatation: chordal and PM displacement

- Dilatation of the ring and MV apparatus causes regurgitation

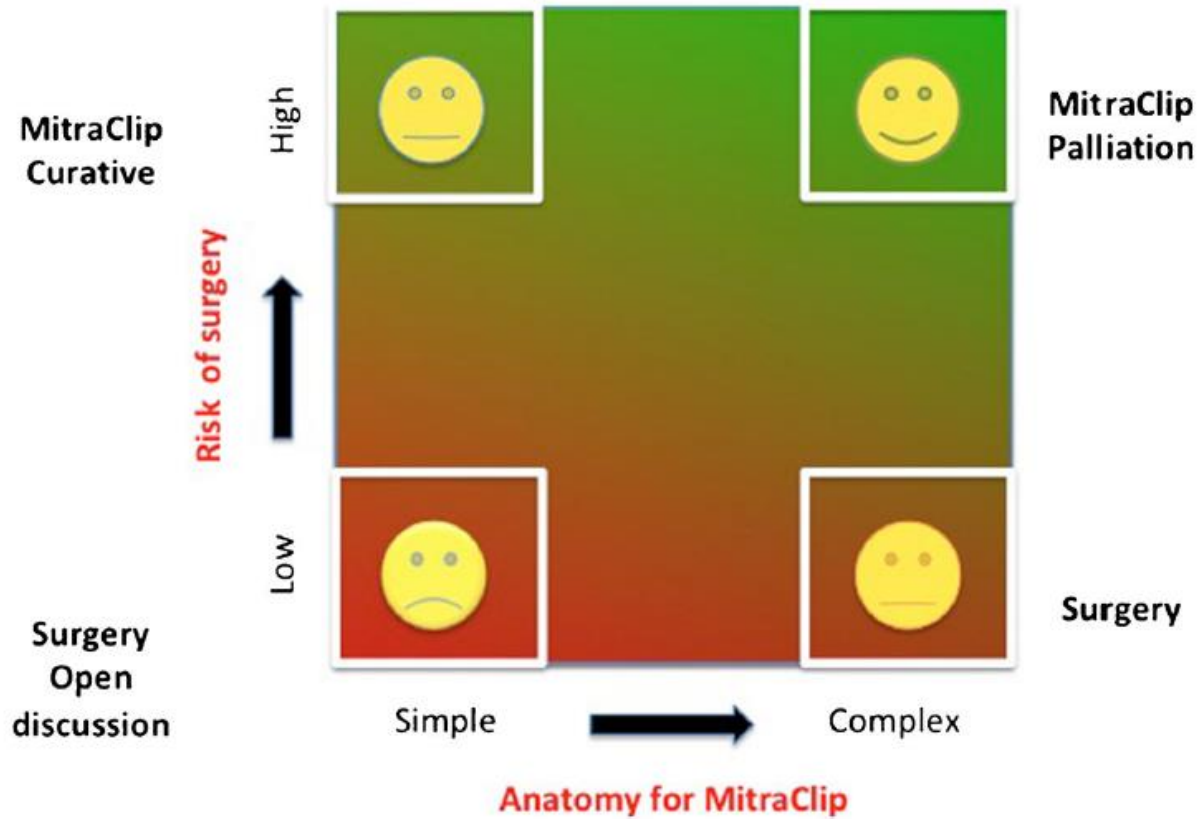


Dilatierter LV

Normaler LV

# Maisano: Heart Team Patient selection 2016

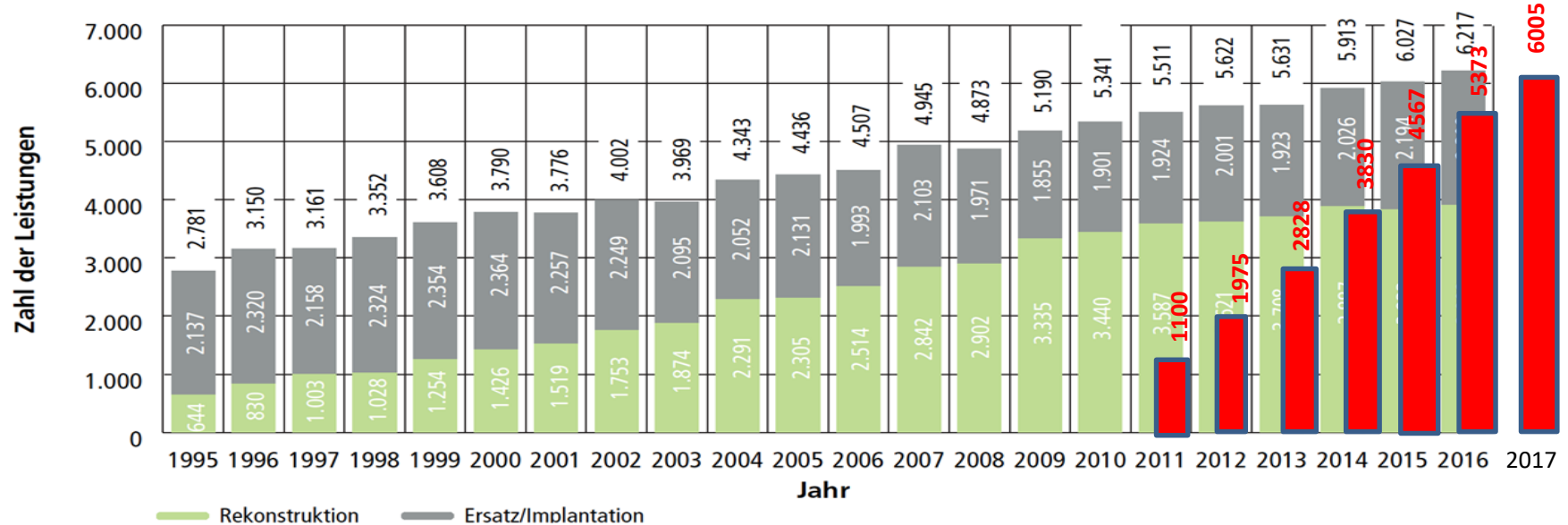
Curr Cardiol Rep (2016) 18: 129



## Mitral Valve repair transcatheter MitraClip (red) and heart surgery (green), Mitral Valve replacement surgical (grey)

(Data Heart report Germany 2017 and Apollo DB Germany Abbott)

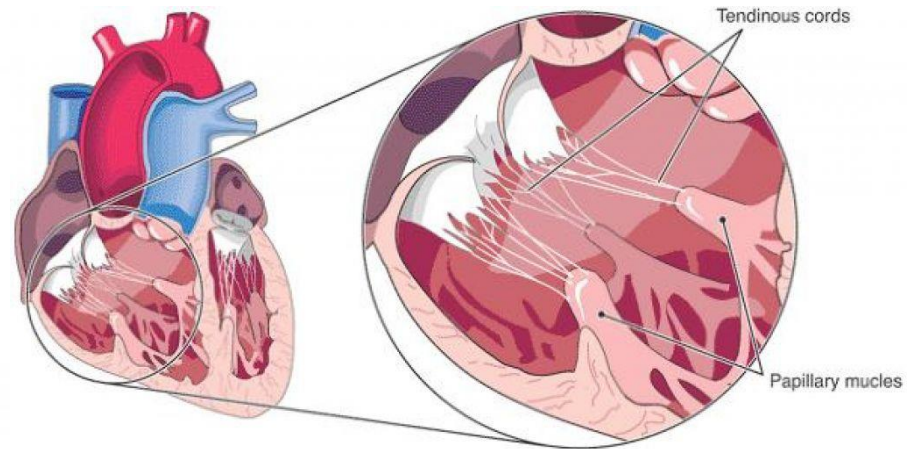
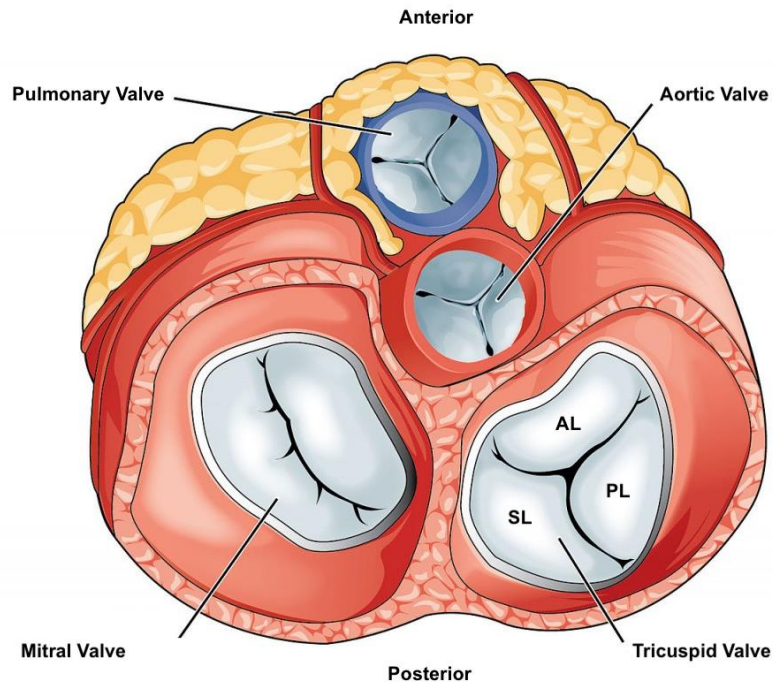
### Entwicklung der isolierten Mitralklappenchirurgie nach Operationsverfahren



Darstellung auf Grundlage der DGTHG-Leistungsstatistik.  
Die Daten 1995 – 2010 wurden mit freundlicher Genehmigung dem Herzbericht 2010 entnommen.

Abb. 4/13: Entwicklung der isolierten Mitralklappenchirurgie von 1995 bis 2016

# Anatomy of Mitral and Tricuspid Valve





# Valve morphology and TMVR: Size matters

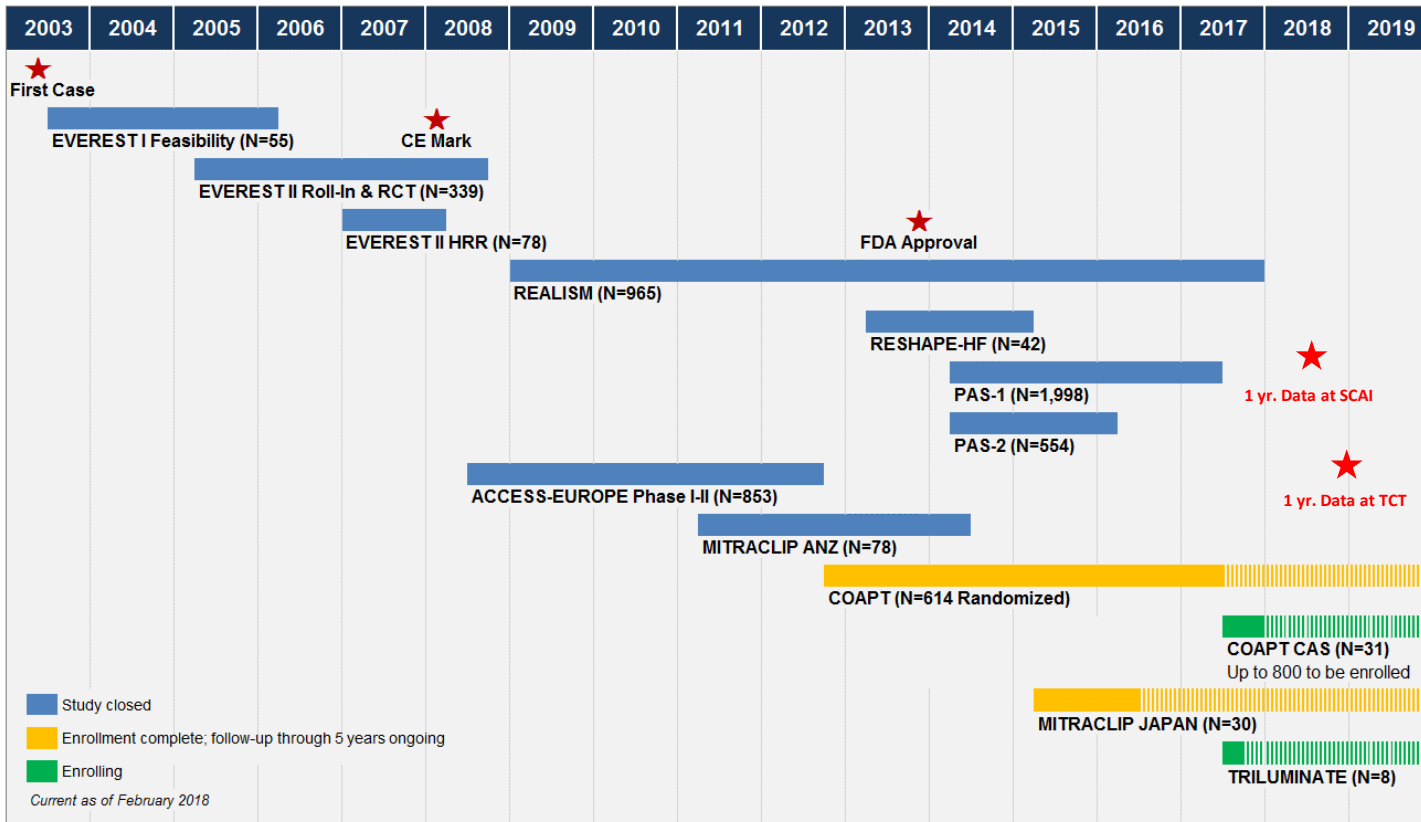
!

## MitraClip NTR and MitraClip XTR





# 2003 – 2018 15 yrs of TMVR with MitraClip



>15 YEARS  
OF EVIDENCE  
BUILDING

65,000+  
PROCEDURES  
WORLDWIDE

1000+  
PUBLISHED  
ARTICLES

# WORLDWIDE EXPERIENCE AND RCT FOR MITRAL VALVULAR HEART DISEASE



## MITRAL VALVE STUDIES

### • Register

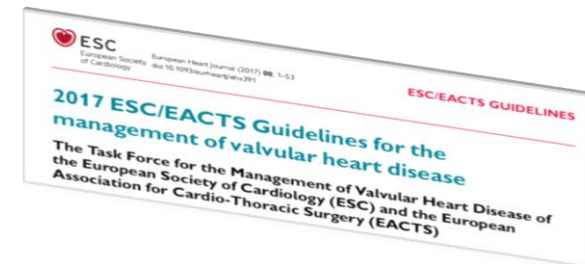
- TRAMI 1366 pat
- REALISM
- ACCESS EU 566 pat

### • Real World Experience

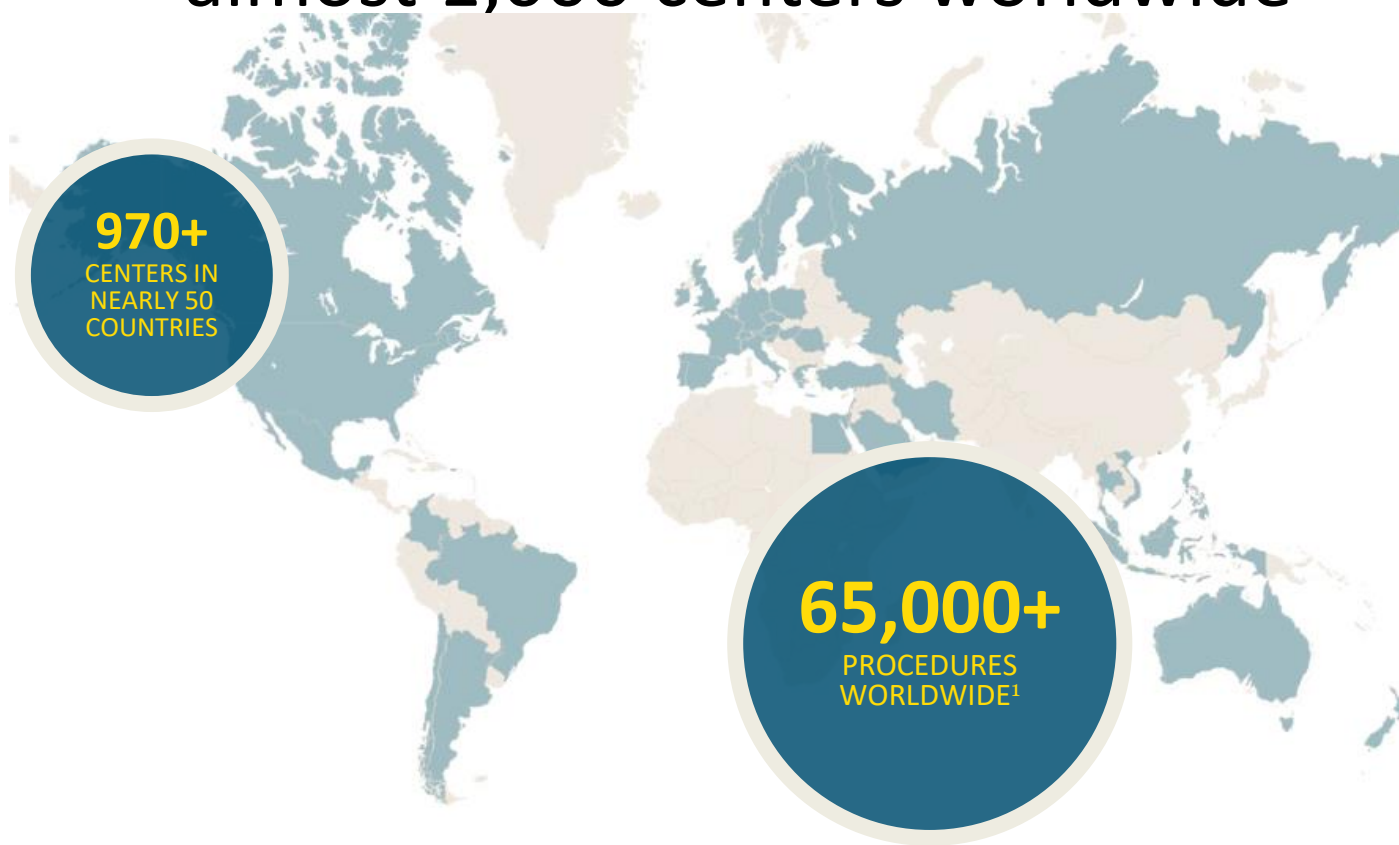
- 65.000+ patients treated

### • RCT

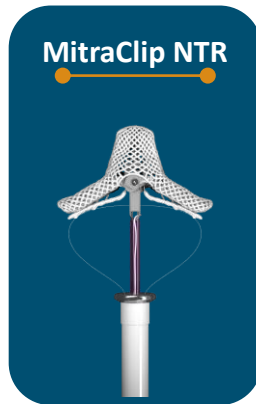
- MitraFR 288 pt randomized 1/17 closed results: ESC Munich 8/2018
- COAPT US 660 pt. Randomized closure 06/17 results: TCT San Diego 10/2018
- RESHAPE 2 EU 330/410 pts. enrolling
- MATTERHORN 65+/190 pt enrolling



2003 – 2018: 65,000 MitraClip procedures in almost 1,000 centers worldwide

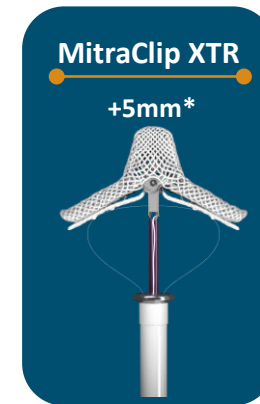


## TWO CLIP SIZES EXPANDING TREATMENT OPTIONS



**MitraClip NTR**

The original MitraClip NT size, with an improved Clip Delivery System.

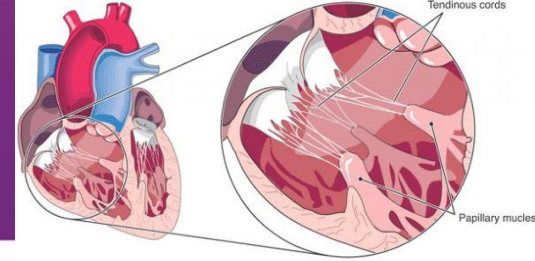


**MitraClip XTR**

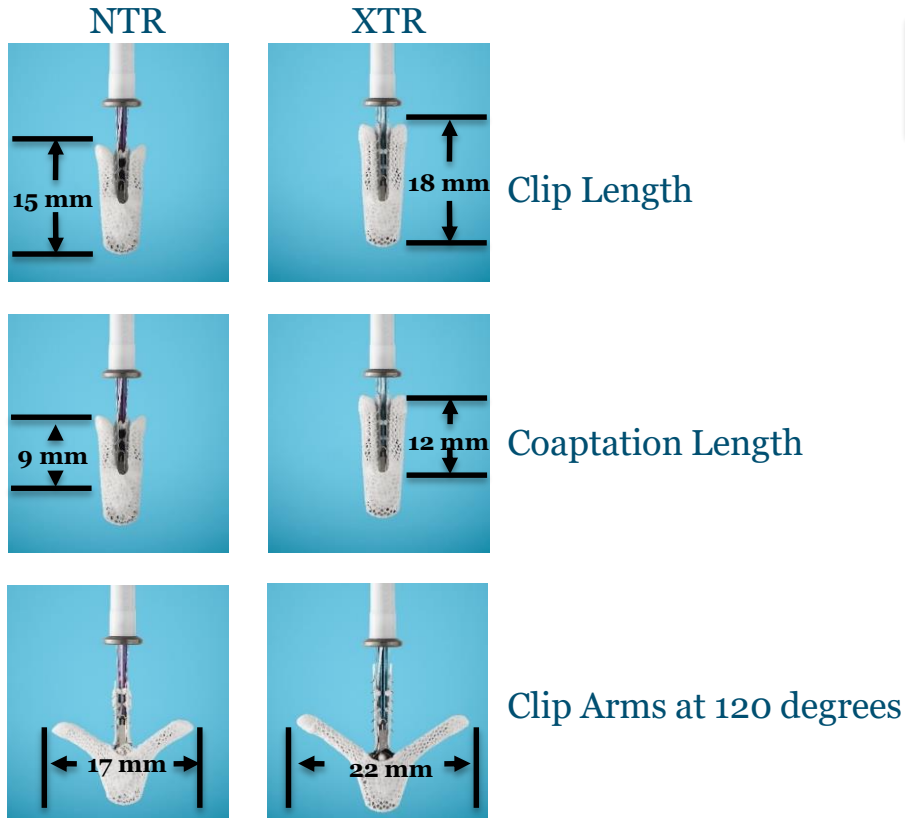
Longer arms for easier grasping and better reach<sup>1</sup>, with an improved Clip Delivery System.

### MitraClip 3<sup>rd</sup> Generation Design Intent:

- Achieve further MR reduction
- Expand the range of MV anatomies treatable with MitraClip
- Increase steering precision, deliverability and ease of use
- Reduce device time and clip rate



# Anatomy of AV Valves now treatable



## Improved Ease of Leaflet Grasping

MitraClip XTR Clip: 3mm longer  
 Clip Arms & Grippers

–Increased leaflet coaptation length

–Grippers with 6 rows of frictional elements with spacing identical to MitraClip NT

–Longer Clip and Gripper covers to support longer Clip Arms

## TWO CLIP SIZES EXPANDING TREATMENT OPTIONS

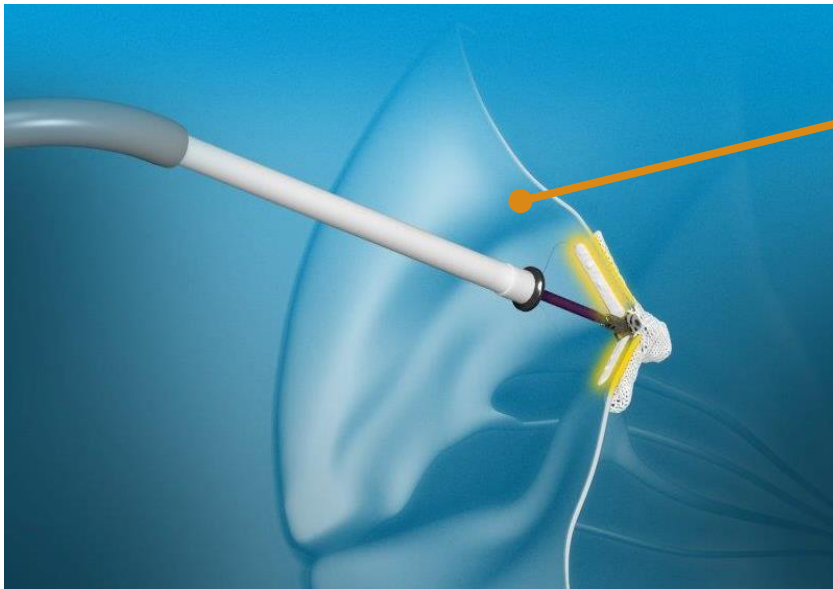
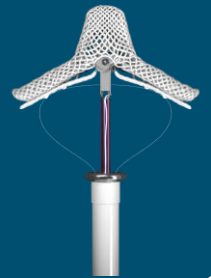
MitraClip NTR



With the MitraClip® NTR system and MitraClip® XTR system, a customized size device repair based on each patient's mitral valve anatomy is now possible.

MitraClip XTR

+5mm\*



**44%**  
more restored  
coaptation surface area  
with **3 mm** of  
additional Clip arm length  
of MitraClip XTR<sup>1</sup>

Source: Data on file at Abbott.

\*This figure reflects the additional grasping width achieved with the MitraClip XTR Clip.

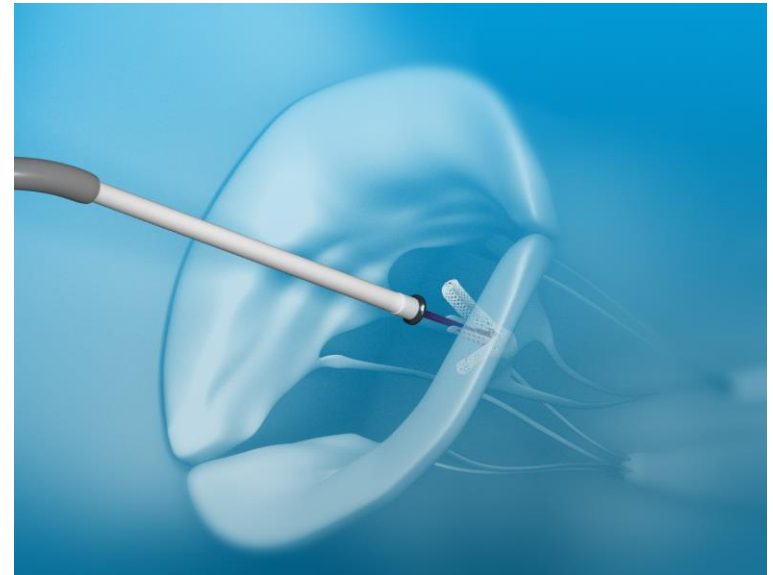
1. Tests performed by and data on file at Abbott



## TWO CLIP SIZES EXPANDING TREATMENT OPTIONS

### Redesigned catheter with new features<sup>1</sup>:

- Straight trajectory into the left ventricle
- Improved torque response
- **Stable Clip arm** orientation when crossing
- **Longer catheter** that allows for an expanded target area of the transseptal puncture
- Ability to leave **Clip unlocked** for the duration of procedure resulting in fewer steps



NOTE: the new delivery system is available with both clip sizes

Source: Data on file at Abbott.

\*This figure reflects the additional grasping width achieved with the MitraClip XTR Clip.

1. Tests performed by and data on file at Abbott

# EXPAND Observational Study

The **EXPAND** (A Contemporary, Prospective Study Evaluating Real-world **Ex**perience of **P**erformance **an**d Safety for the Next Generation of MitraClip® **D**evices) observational study will generate current, marketable clinical evidence for MitraClip® NTR and MitraClip® XTR.

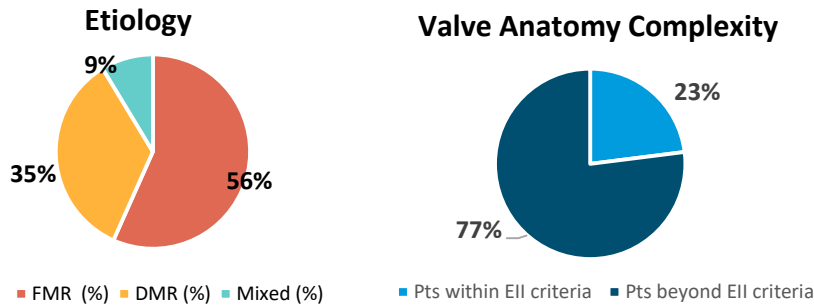
- Enrollment goal: 1000 patients
- 50+ centers across EMEA and US
- CEC adjudicated for major adverse events
- Independent echo core lab
- First patient in: April 2018
- Last patient in: December 2018

# Early Experience with MitraClip NTR and XTR

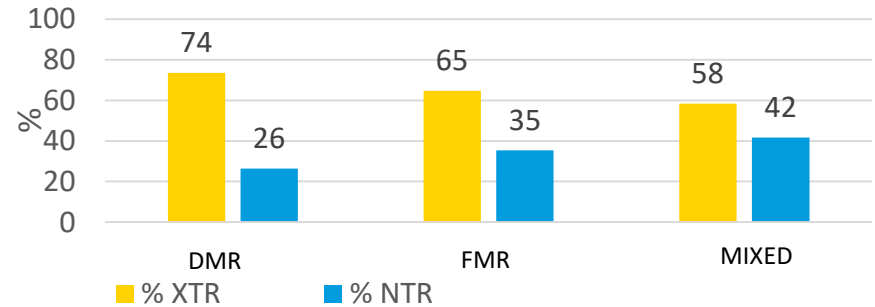
## Experience from early commercial use following CE Mark

- 24 European centers
- 150 procedures

### Patient Baseline Characteristics

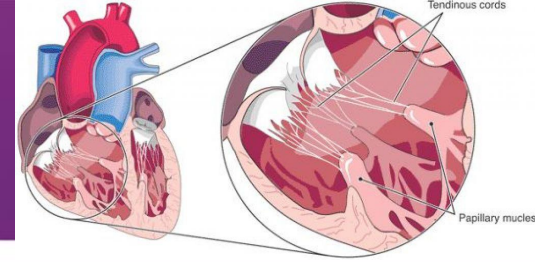


### NTR/XTR Use



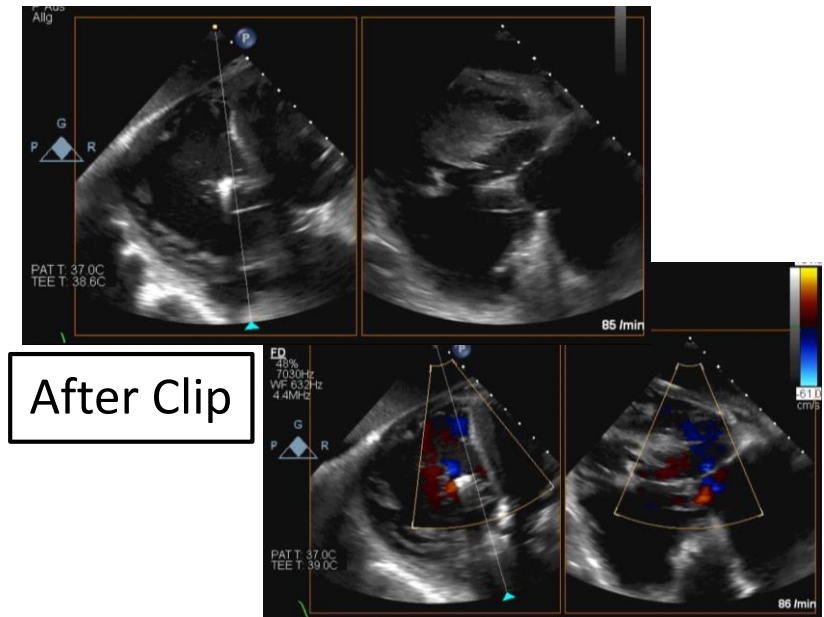
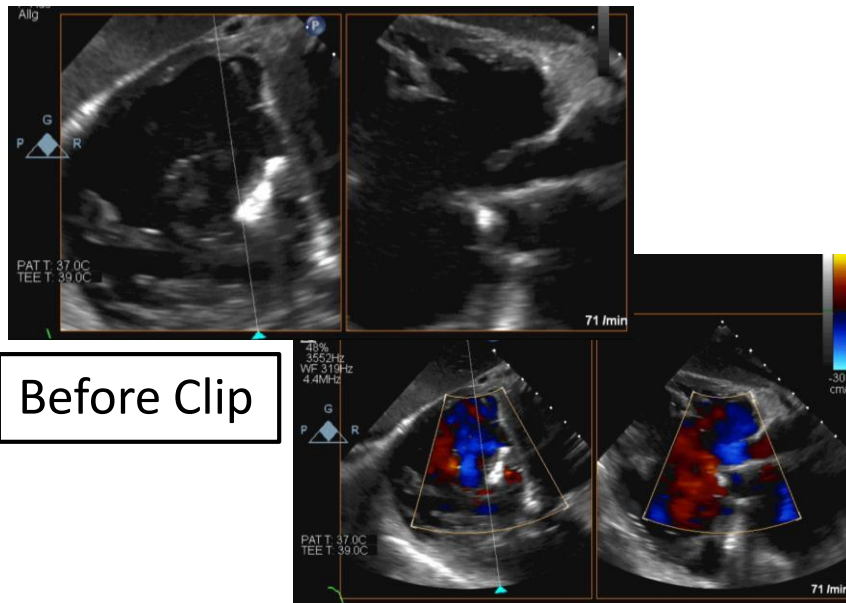
### Early Experience

- **MR Reduction**
  - **Steering performance of NTR/XTR vs NT**
  - **Grasping/Capture performance of NTR/XTR vs NT**
- 84% MR $\leq$ 1+**  
**73% better**  
**100% better**



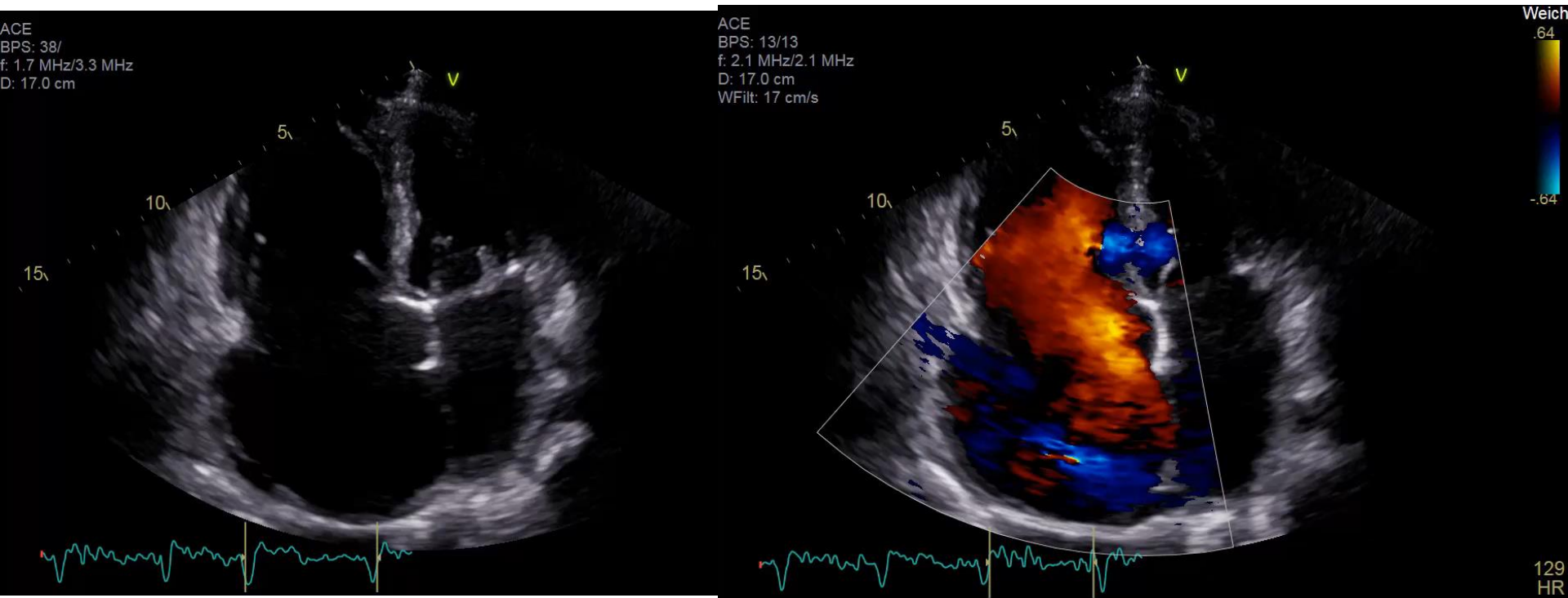
# Anatomy of AV Valves now treatable

# Imaging TRILUMINATE NT Transcatheter Procedures



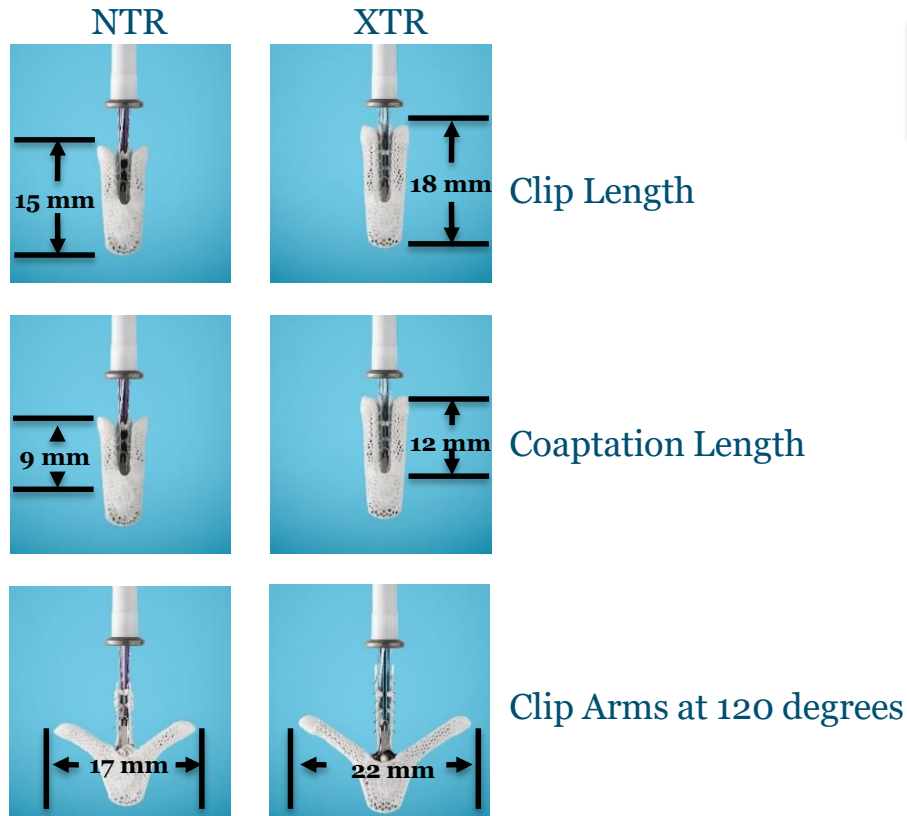
TOE-Guiding of Edge-to-Edge Repair (MitraClip®) in a Patient with severe TR after surgical Ring-Reconstruction – transgastric En-Face & orthogonal View

# The Combination of functional MR III medial gap and massive (OMG) functional TR IV - gap 16mm Treatable?





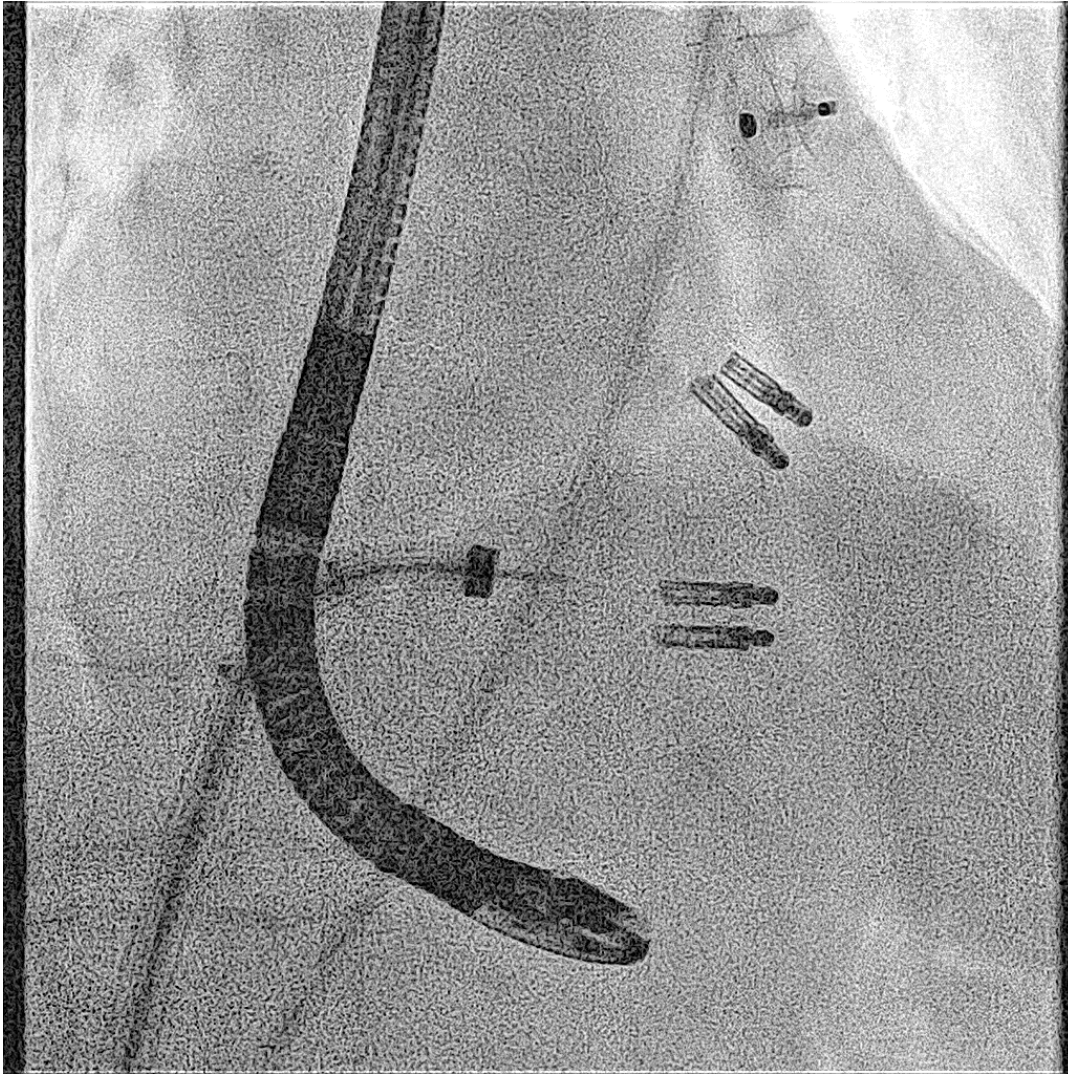
# MITRACLIP NTR / MITRACLIP XTR - NEW GEN



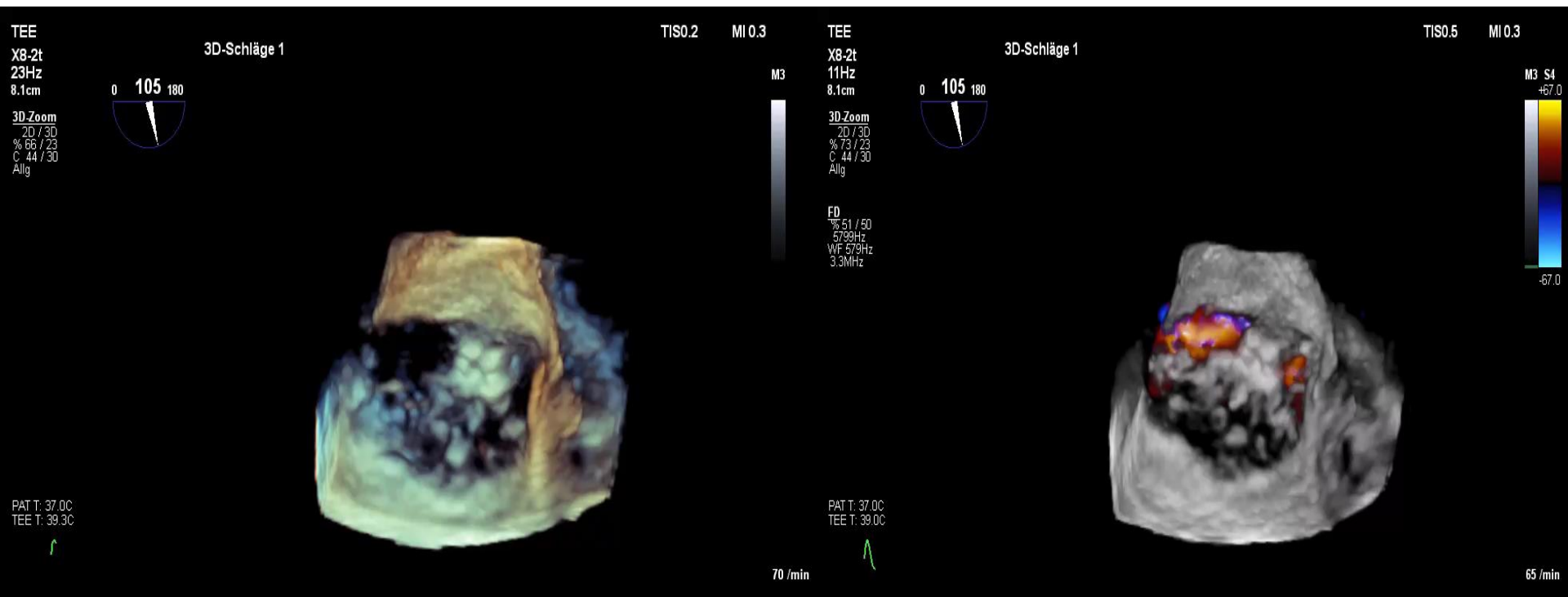
## Improved Ease of Leaflet Grasping

MitraClip XTR Clip:  
3mm longer Clip Arms  
& Grippers

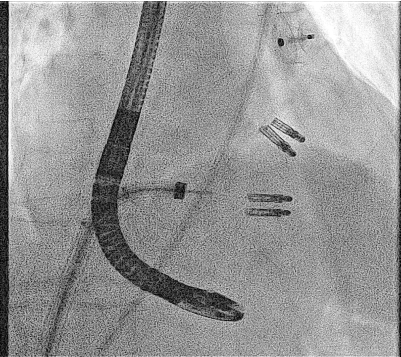
- Increased leaflet coaptation length
- Grippers with 6 rows of frictional elements with spacing identical to MitraClip NT
- Longer Clip and Gripper covers to support longer Clip Arms



# Tricuspid Valve interventions free TV gap 16mm Post Tx with 2 MitraClip XTr in TV







TEE  
X8-2t  
10Hz  
11cm

xPlane  
56%  
56%  
44dB  
P Mittel  
Allg

FD  
48%  
5799Hz  
WF 521Hz  
3.3MHz

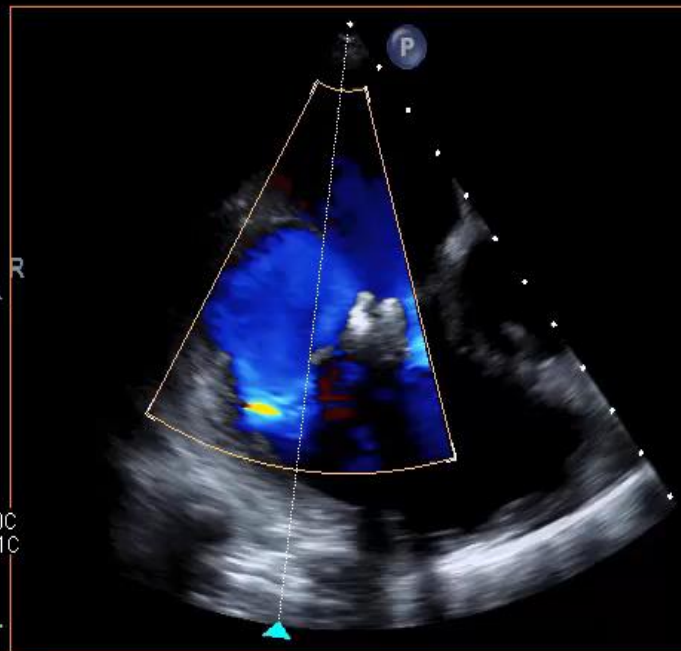


PAT T: 37.0C  
TEE T: 39.1C

TIS 0.5 MI 0.4



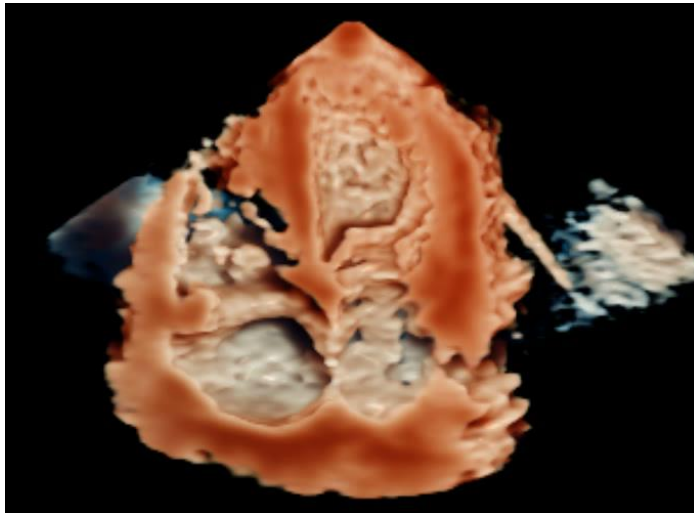
M3 S4  
+67.0



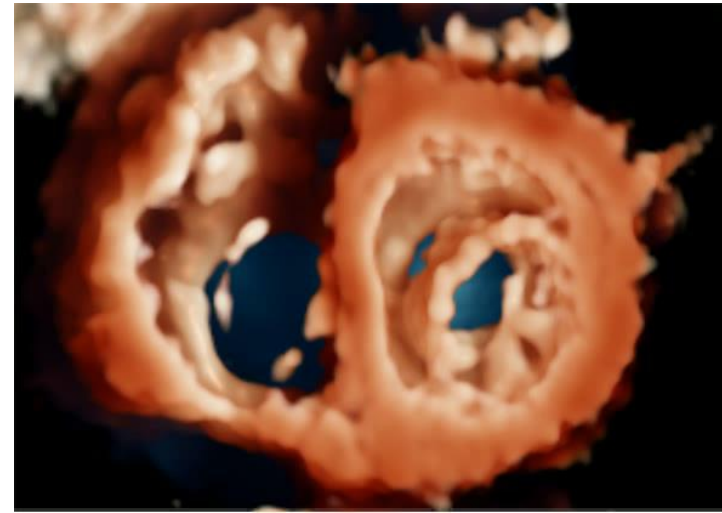
63 /min

# Innovation in Transthoracic Echocardiography – What's next?

## High resolution photo-realistic rendering in 3D TTE



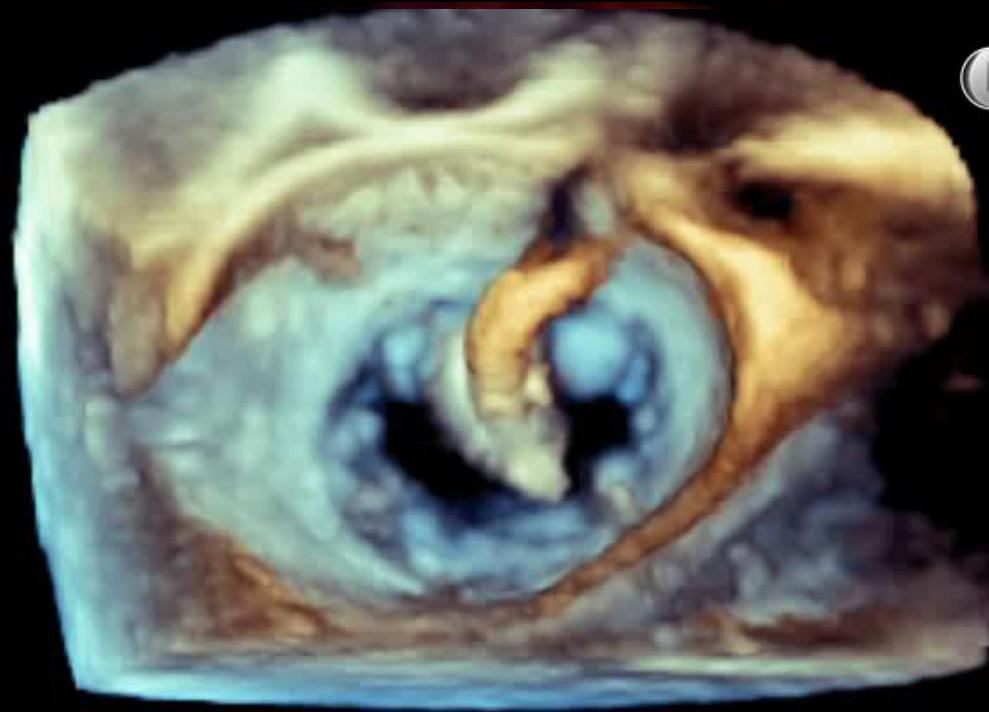
Visualization of Volumes, Texture and Heart Wall Motion



Visualization of Mitral and Tricuspid Valves and short axis LV shape

Rendering: Philips

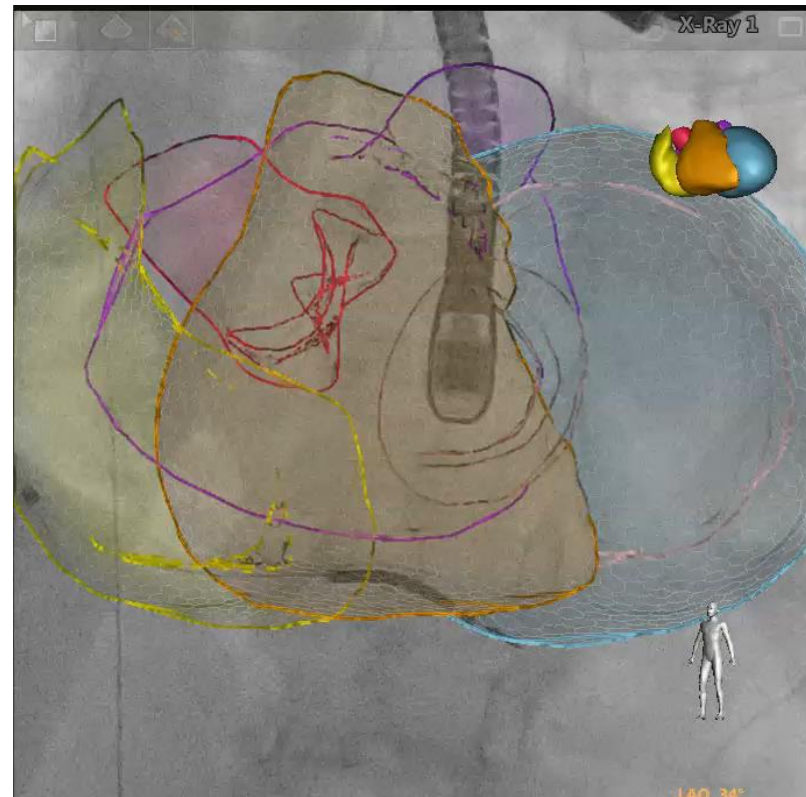
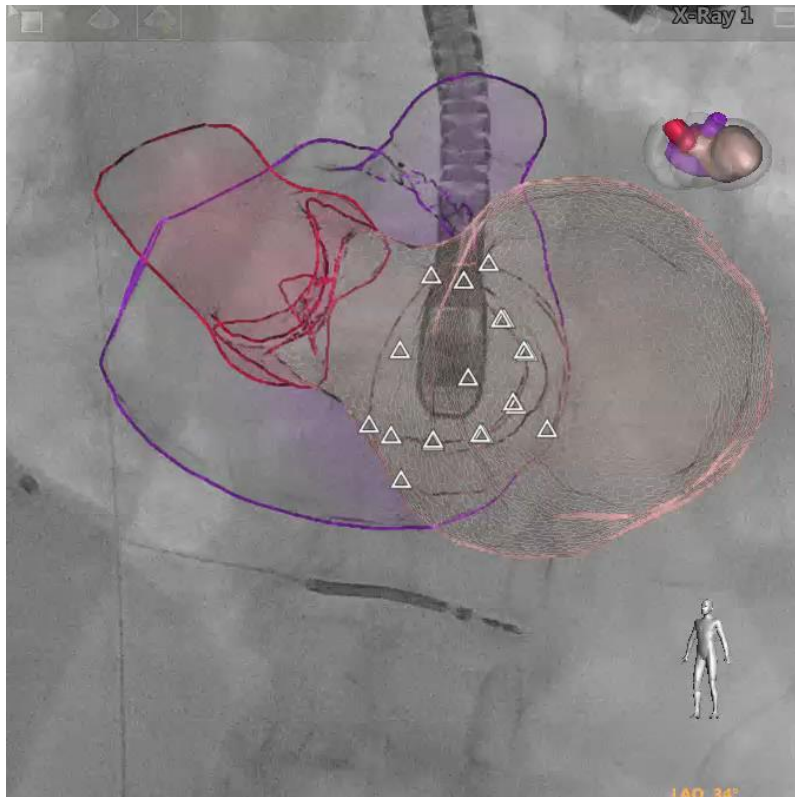
# Photorealistic Visualisation MitraClip NT® (Software influenced by PIXAR)



© von Bardeleben, RS UM Mainz Germany 2018



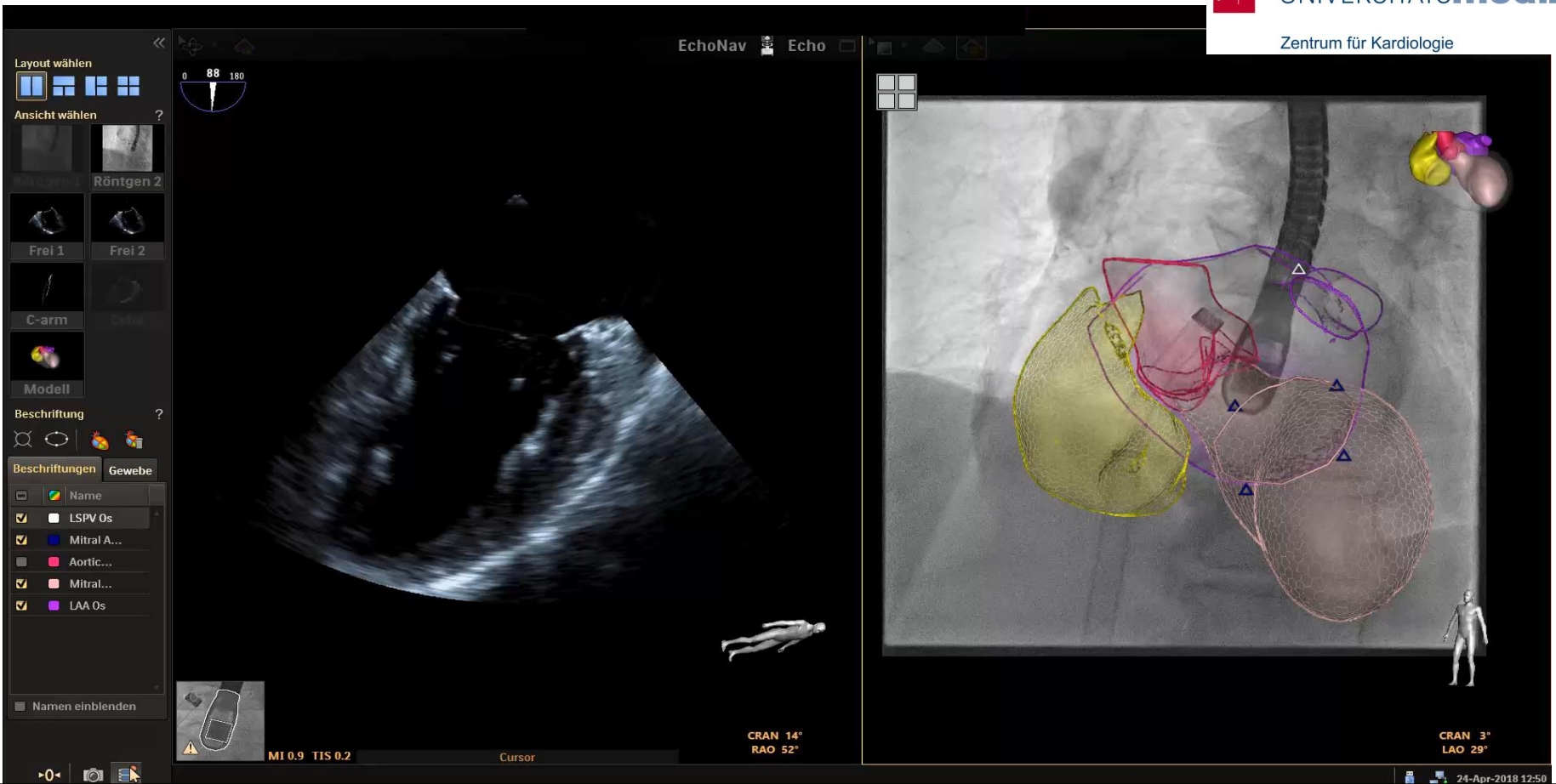
# Innovation in Interventions: EchoNavigator AI Heart Model 3.0 realtime beating heart SHD overlay



# Innovation in Interventions: | EchoNavigator AI Heart Model 3.0 realtime ECHO SHD overlay

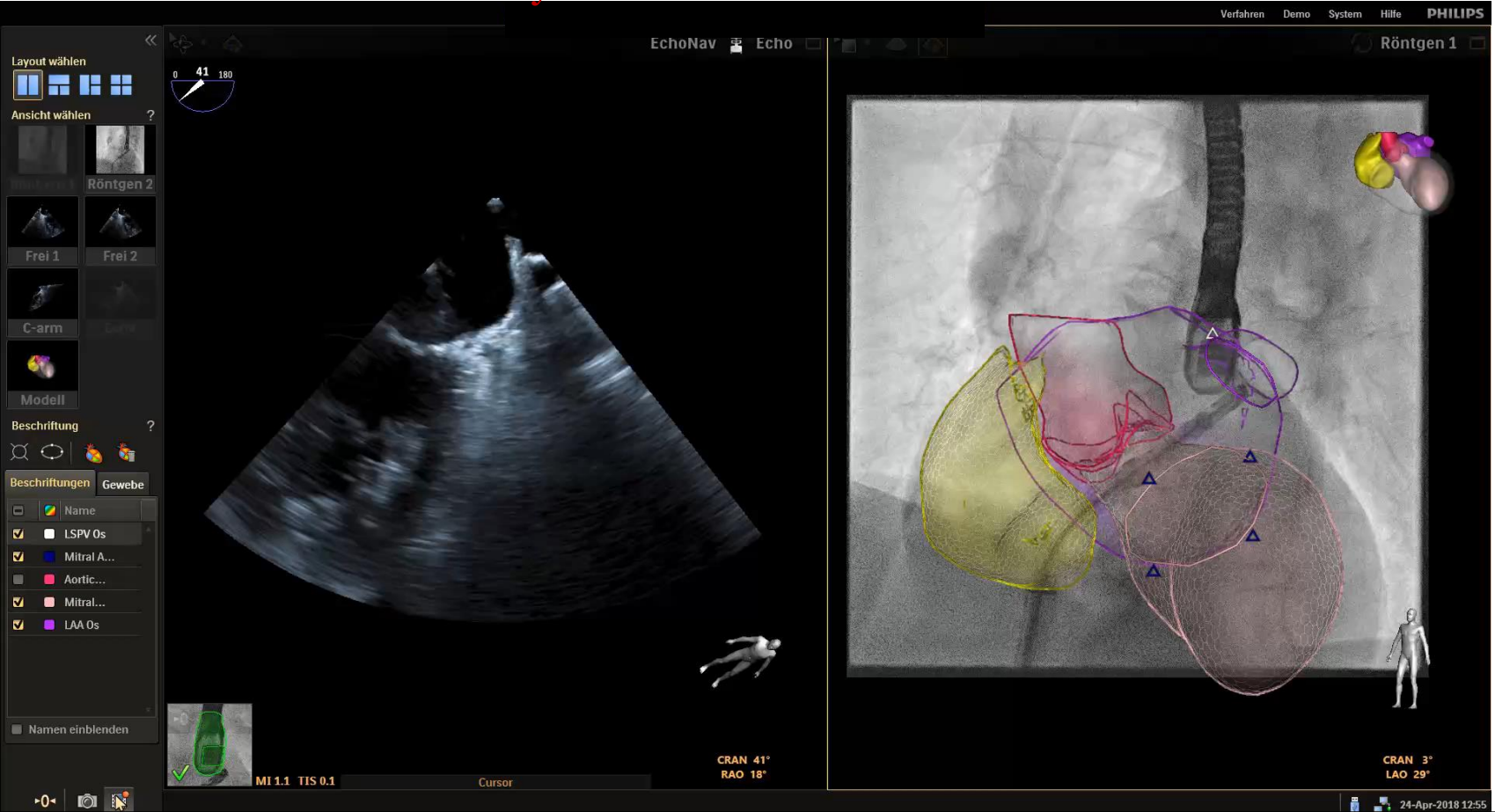


# Innovation in Interventions: | EchoNavigator AI Heart Model 3.0 realtime ECHO SHD overlay



© von Bardeleben, RS UM Mainz Germany 2018

# Innovation in Interventions: | EchoNavigator AI Heart Model 3.0 realtime ECHO SHD overlay

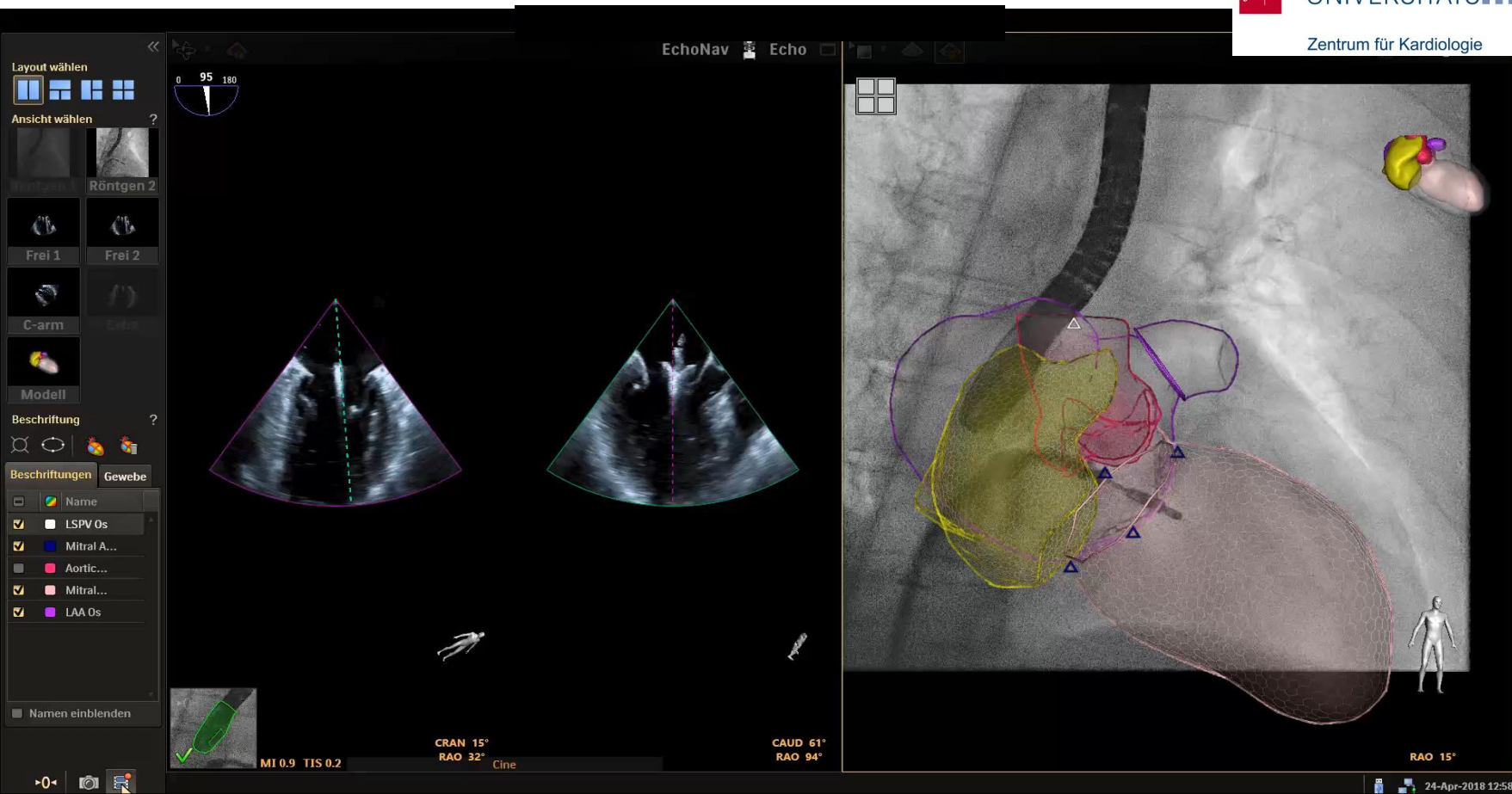


© von Bardeleben, RS UM Mainz Germany 2018

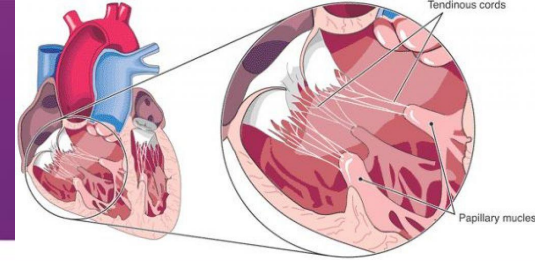


# Innovation in Interventions: | EchoNavigator AI Heart Model 3.0

realtime ECHO SHD overlay



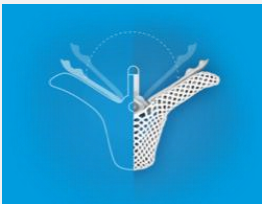
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# New Generation of MitraClip devices

## GEN 2—2016

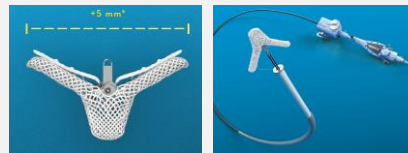
### MITRACLIP NT



**DESIGN FOCUS:**  
Leaflet grasping and steering enhancements

## GEN3—2018

### MITRACLIP NTR & XTR



**DESIGN FOCUS:**  
Improved grasping, greater reduction in mitral regurgitation, complex valve anatomy

Enhanced steering accuracy and ease of use

## GEN 4

### MITRACLIP GEN 4\*



**DESIGN FOCUS:**  
Improved ease-of-use  
Improved leaflet grasping  
Greater MR reduction  
Complex cases

## GEN 5

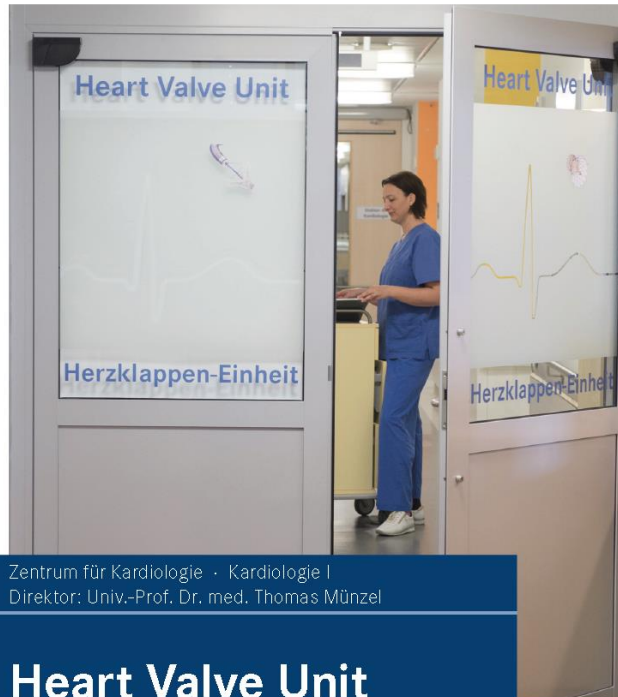
### MITRACLIP GEN 5\*



**DESIGN FOCUS:**  
Enhanced Steering accuracy  
Improved ease-of-use

\*Currently in development at Abbott. Not currently for sale. Image for illustration purposes only.





Zentrum für Kardiologie · Kardiologie I  
Direktor: Univ.-Prof. Dr. med. Thomas Münzel

## Heart Valve Unit Herzklappen-Einheit

Die Heart Valve Unit  
am Zentrum für Kardiologie

# Mainz April 2018: 1st Heart Valve Unit worldwide:

- integrated patient support 25 patients
- intermediate care level 8 patients
- recompensate, plan, intervene and discharge with same Heart Valve Team

**Heart Valves** @unimedizin-mainz.de

Stephan.von\_Bardeleben@unimedizin-mainz.de

- Structural valve interventions rely on innovations in imaging and device maturity – **NEW options for the Heart Team**
- Use of Abbott MitraClip to treat **mitral regurgitation is safe** and feasible, tricuspid regurgitation treatment is under way
- Device innovations include improvements in **steerability, ease of use** and extended valve pathology open for intervention
- **XTr provides longer Clip arms** needed in prolapse (primary MR), larger gaps in MR and TR
- ***Imaging, Fusion and holographic display*** will enter SHD Tx
- **Further studies and implant experience is warranted** to validate these promising results