



# Prediction of cardiac regenerative therapy response by imaging and modeling

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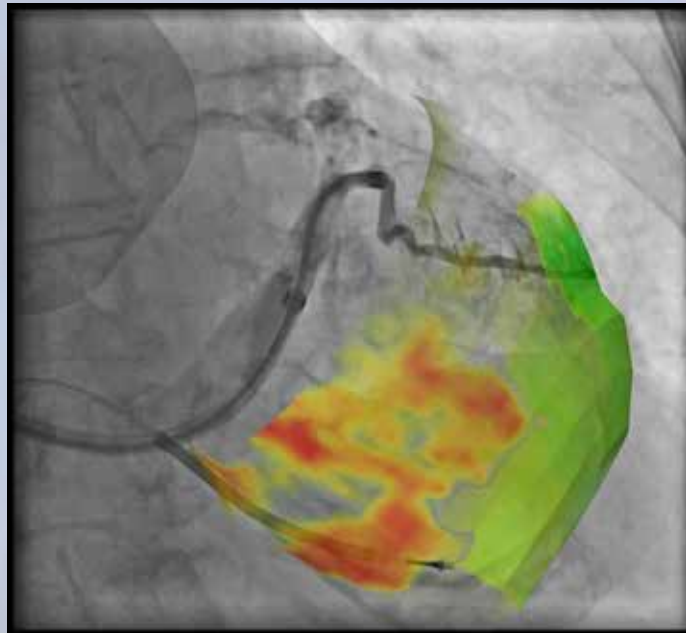
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## Our solution

Show the tissue characteristics on the fluoroscreen before you start!



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## One imaging modality: MRI

- Gold standard technique for infarction visualization (LGE)
- Dyssynchrony assessment based on feature tracking (CINE)
- High resolution 3D anatomical information
- All available prior to the implantation
- No ionizing radiation

### CARTBox software for

- Target selection
- Fluoroscopy fusion and guided LV lead placement



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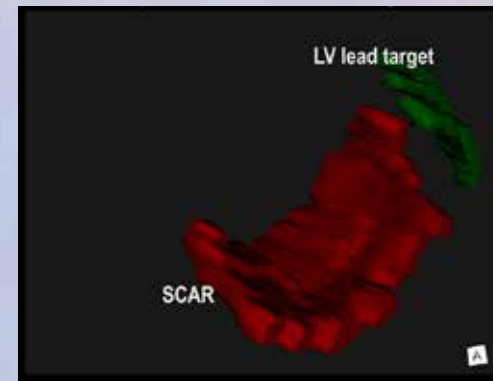




## Safety & feasibility study: ADVISE-CRT



- PI Mathias Meine MD PhD
- Safety and feasibility of real-time image fusion during CRT implantation
- Fifteen patients included
  - In 9 patients: conventional CRT implantation
    - CARTBox workflow performed in parallel
    - no image guidance
  - In 6 patients: image guided LV lead implantation
    - Scar
    - Dyssynchrony
    - Left phrenic nerve
    - Coronary sinus ostium



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## Results

- Successful implantation in all patients
- CARTBox guidance platform successful in all patients
- No (serious) adverse events



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	TARGET group (n=6)	Conventional group (n=9)	p-value
Distance to target (mm)	8 [0-22]	26 [17-46]	0.04
LV lead implantation duration (min)	46±18	55±28	0.57
Radiation dose (mGy/m <sup>2</sup> )	9140 [3276-11522]	6669 [4215-9472]	0.64
ΔQRSd (ms)	-12±13	9±27	0.10

Values are in mean ± SD, median [interquartile range]

Unpublished data





## Study conclusions



- CRT implantation using CARTBox is safe and feasible
- Enhances LV lead delivery
- Supports decision making for branch of venous system:
  - SCAR
  - Dyssynchrony
  - Left phrenic nerve
  - Coronary sinus ostium
- Clinical outcome needs to be further investigated

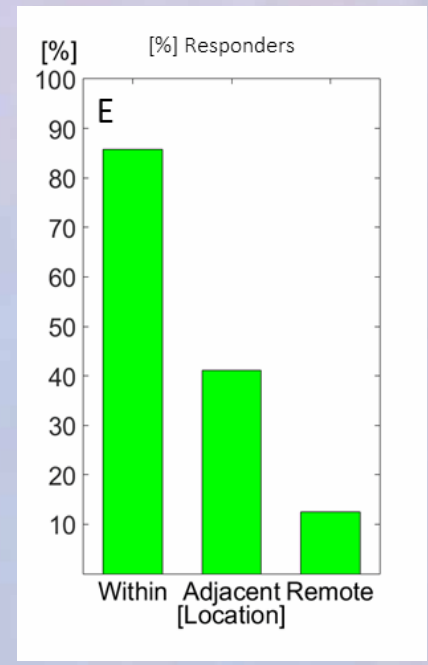


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## CARTBox retrospective study

- 32 (ischemic) HF patients (UMC Utrecht)
- LGE-MRI (myocardial infarction assessment)
- CINE-MRI (dyssynchrony assessment)
- LV divided in 36 segments
- Echo Follow-up (6 months)
- Responder > 15%  $\Delta$ ESV reduction



Unpublished data



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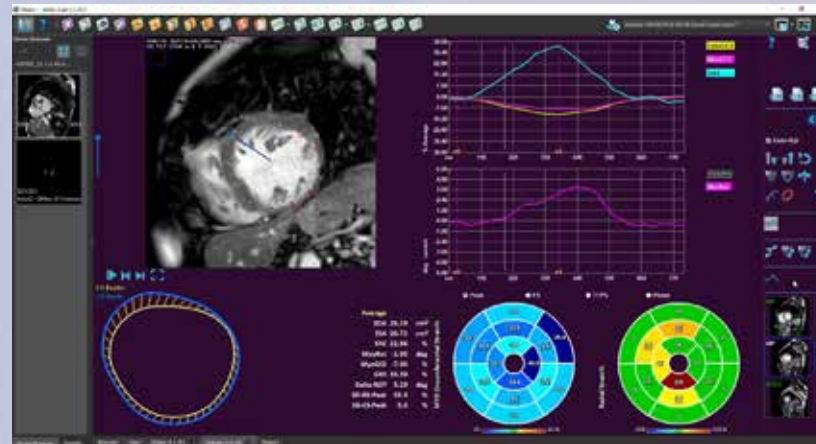


## Progress for CARTBox widespread clinical use

EU regulatory approval

- Class II b medical device
- CE certified

Collaboration with MEDIS and AMID for Feature Tracking and more advanced image processing



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## Untill then

Position of LV lead is crucial!

- SCAR = wasted
- Late activated tissue = well placed > evidence for efficacy needed

CARTBox software:

- Supports implantations
- Gold standard cardiac MRI
- Safe and Feasible
- Vendor independent
- Easy to use
- CE Certified



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- Paul Leufkens, PharmD
- Filippo Brogi
- David Sparks

We are looking for EU CRT  
implanting centers for clinical  
studies

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