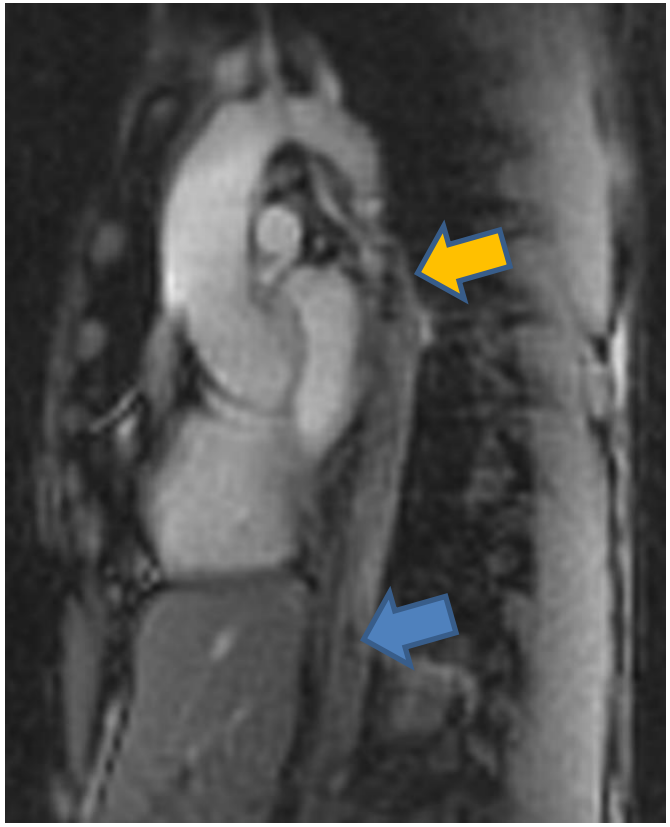
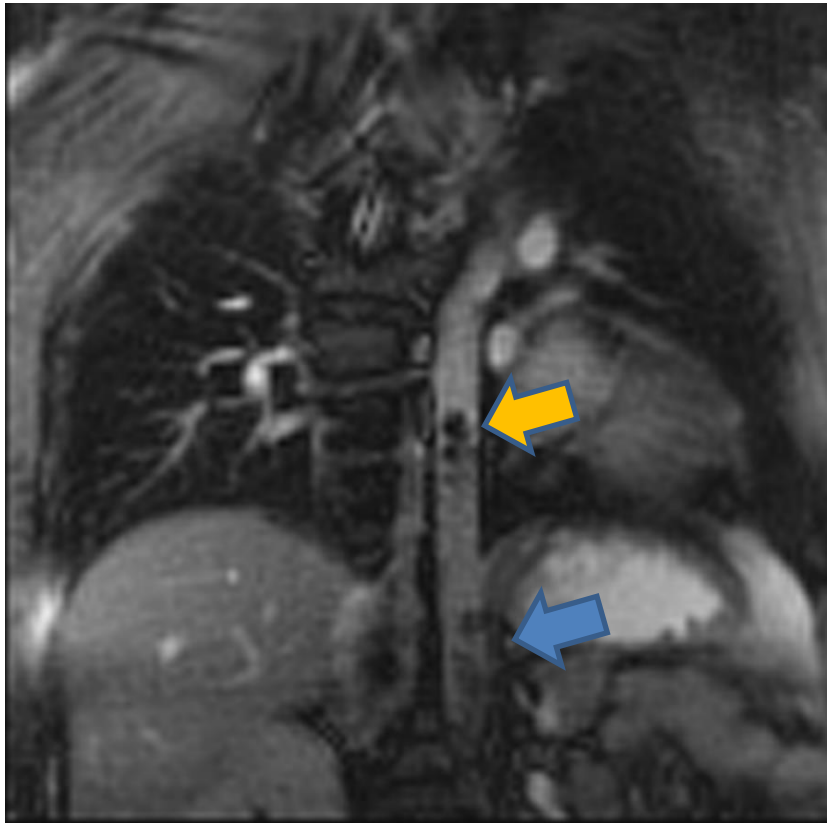
Nano4Imaging: empowering MRI interventions

SCMR- Nice, February 2015, Booth #11

Nano4Imaging , Aachen, Germany
www.nano4imaging.com (new website since Feb 1st)
E-mail: info@nano4imaging.com

SCMR/EuroCMR
Joint Scientific Sessions





Insertion of MRWire within Berman catheter into aortic arch in patient with CHD under MRI (1.5 T, GRE-real time images)
Passive markers indicated by

Images courtesy Dr Sohrab Fratz (DHZ)

SCMR/EuroCMR
Joint Scientific Sessions

Status and vision

Key Milestones	Achievements and planning
MRWire production	Own production robot and facilities, flexibility. Production at CMI-Dresden
CE Certification	Since October 31th 2014 PMCF to start on March 15th (DHZ, GOSH)
FDA 510(k) approval	Animal studies and additional bench testing ongoing Approval expected December 2015
MRWire clinical studies	Multi-center study immediately after PMCF; no permission to run studies simultaneously
MRWire sales in EU	MRWire available for non-clinical work (animals, phantom)

PMCF

Title	**Post-market clinical follow-up study with MRWire**
Study design	Prospective, consecutive patient study
Purpose	Confirm safety and performance of the MRWire and the acceptability of identified risks in the CER and to detect emerging risks on the basis of factual evidence
Intended use	The introduction and/or the placement of diagnostic or interventional devices in the central circulatory and/or peripheral vasculature using MRI techniques.
Inclusion/Excusion criteria	**Inclusion**: Patients with clinical indication for CMR and conventional diagnostic catherization. Body weight > 40 kg and introduction of introducer > 5 F is possible. Informed consent. **Exclusion**: Major surgery last 42 days, contraindication to MRI, CTO, no negative pregnancy test; history of bleeding disorder
Sample Size	Up to **25 subjects**
Number of sites	**DHZ (Munich) and GOSH (London)**
Patient follow-up	Assessment prior to hospital discharge. Telephone contact at 2 days post-procedure/discharge and 30 days telephone follow-up
Study endpoints	**Primary endpoint:** – Procedural success defined as “was procedural success reached?”: yes/no **Success during procedure means that all following questions are answered with yes** – Could the MRWire be inserted successfully through the introducer device (**handling**)? – Could the MRWire be advanced successfully to the target region (**steerability**)? – Was the MRWire sufficiently visible under MRI to enable steering (**conspicuity**)
Study duration	Total duration 6 months; follow-up of 30 days for each patient.

Multicentre study:
Kiel, Munich, Bad Oyenhausen, Leipzig and Leuven (BE)
Start after PMCF and review (june/july 2015). Similar targets
As in PMCF

Ongoing product development:
- Introducer kit (MR compatible)
- Procedure kit (MR compatible)
- Steerable catheter (MR compatible)
- Myocard biopsy catheter kit
- Provide integral MRI solutions and support

Please come and visit us at Booth #11