Safety and Performance of MR-Conditional Pacing Systems with Automated MRI Mode at 1.5 and 3 Tesla

RESULTS FROM THE CAPRI STUDY

Dacher, JN., Langguth, P., Adam, D. et al. Safety and performance of MR-conditional pacing systems with automated MRI mode at 1.5 and 3 Tesla. Eur Radiol (2023). https://doi.org/10.1007/s00330-023-09650-9

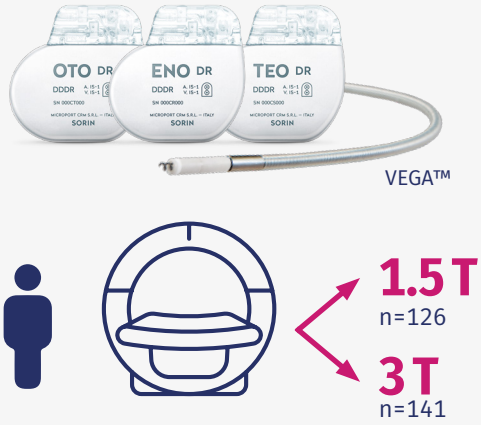
Background & objective

28.5% of Pacemaker patients will have at least 1 MRI scan within 4 years post-implantation.

→ Clinical need for development of MRI conditional pacing systems.

Objective: Evaluate at 1.5 T and 3 T MRI the safety and performance of trademarked ENO™, TEO™ or OTO™ pacing systems with automated MRI Mode and the image quality of non-enhanced MR examinations.

Methodology



267 implanted patients
underwent MRI examination
(brain, cardiac, shoulder, cervical spine).

› **CAPRI is an interventional, prospective, multicenter,** open label, two arms parallel non-comparative non-randomized study conducted in **Europe and Asia-Pacific** to confirm the clinical safety and performance of the ENO™, TEO™ or OTO™ MRI conditional single or dual chamber rate response pacemakers with VEGA™ pacing leads in the MRI environment.

AUTOMRI™

› MRI mode of pacemaker was activated and set to 'Auto' by the cardiologist, allowing automatic switch to programmed asynchronous pacing mode when the magnetic field of the MRI scanner is detected and **back to initial configuration, 5 minutes after the patient gets away from magnetic field.** Patients eligible at the inclusion visit underwent an MRI scan at either 1.5 or 3 T.

Results

MicroPort MR Conditional Pacemakers ENO™, TEO™ and OTO™ are SAFE under 1.5 and 3 Tesla MRI scan.

› **Freedom from MRI-related complications** at 1-month post-MRI was **100% in both 1.5 and 3 T arms** (both p<0.0001).

› The stability of pacing capture threshold was respectively at 1.5 and 3 T [ventricular: both 100% (p<0001); atrial: 98.9% (p=0.001) and 100% (p<0.0001)].

› The stability of sensing was respectively at 1.5 and 3 T [ventricular: 100% (p<0.0001) and 99.1% (p=0.0001); atrial: 100% (p=0.0001) and 96.9% (p=0.01)].

100% AUTOMRI™ mode proper functioning.

› **All devices switched automatically** to the programmed asynchronous mode in the MRI environment and resumed to normal mode, post MRI exam.

› Even if artefacts were noticed in a subset of examinations, overall **interpretability was preserved**.

Conclusion

This Study demonstrated the **clinical safety and performance of the ENO™, TEO™ or OTO™** MRI conditional pacing systems at 1-month post-MRI with no scan exclusion zone under **1.5 and 3T**. This study confirmed **the proper functioning of the automated MRI mode**. 100% of MRI images were assessed as interpretable and image quality was assessed as good or excellent in > 90% of the scans.

MicroPort®