

Safety and Performance Evaluation of a New Catheter Range for Lead Implantation At Interventricular Septum

NCT06453850

Status	RECRUITING
Phase	Not Applicable
Sponsor	MicroPort CRM
Enrollment	216 participants

Key Eligibility Criteria

Inclusion (10)

- Patient indicated for cardiac pacing according to the most recent guidelines from the European Society of Cardiology (ESC)
- Patient planned for a de novo implantation of any Single Chamber (SR) or Dual Chamber (DR) CE marked pacemaker
- Patient planned for a catheter-guided implantation in the interventricular septum area
- Patient planned for the implantation of any CE marked ventricular pacing lead compatible with the FLEXIGO delivery catheter
- Patient reviewed, signed and dated the Informed Consent Form (ICF)

... and 5 more (see full listing online)

Exclusion (17)

- Patient planned for a device upgrade, or a device or a lead replacement
- Patient with a congenital heart disease
- Patient with significant hypertrophic cardiomyopathy, cardiac amyloidosis or obstructive hypertrophic cardiomyopathy
- Patient with a Left Ventricular Ejection Fraction (LVEF) \leq 35%
- Patient already enrolled in another clinical investigation that could confound the results of this clinical investigation (e.g., clinical investigations involving intra-cardiac device)

... and 12 more (see full listing online)

Locations (3 total)

ULS de Coimbra, Coimbra, Portugal
Hospital Universitario Virgen de las Nieves, Granada, Spain
Hospital Universitari i Politècnic La Fe, Valencia, Spain

<https://clinicaltrials.gov/study/NCT06453850>

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