POLARIS

Safety and Performance evaluatiOn of a new catheter range for Lead implAntation at inteRventrIcular Septum

Results from phase I
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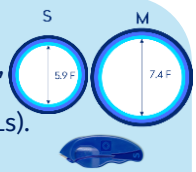
Background & Objectives

Background: Right ventricular pacing (RVp) has been a standard treatment for symptomatic bradycardia for decades. However, in a proportion of patients, conventional RVp can lead to dyssynchronous Left Ventricular (LV) contraction and Heart Failure (HF) over time. Recently "Conduction System Pacing" (CSP) has emerged via technological advancements to directly target the conduction system. Achieving ventricular lead placement at the interventricular septum for CSP requires a dedicated sheath or delivery system.

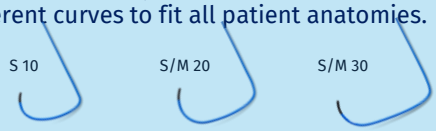
Objective: POLARIS is an interventional, pivotal, prospective, acute, single arm, open label, multicenter and international clinical investigation, and aimed at evaluating the safety and the implant performances of the new FLEXIGO™ 3D Delivery catheter range for transvenous ventricular pacing lead placement at the interventricular septum.

Materials and Method

FLEXIGO™ 3D Delivery catheters have several lengths and diameters (S and M), compatible with both Lumen Less Leads (LLLs) and Stylet Driven Leads (SDLs). Each catheter is compatible with a dedicated slitter (packaged separately).



FLEXIGO™ 3D Delivery catheter is available in three (3) different curves to fit all patient anatomies.



12

European centers

75

Patients included
AVB (58.7%),
Syncope (9.3%)
SND (8%)

*similar to usual practices of operators with commercially available devices

- S/M 20: 87%
- S/M 30: 9%
- S 10: 4%

- SelectSecure: 52%
- Solia S: 24%
- Tendril: 12%
- VEGA R58: 9%

- Mean procedural time: 55.89 min*
- Mean fluoroscopic time: 7.9 min*

Phase II is planned to start after the phase I completion. A total of 216 patients is planned to be included in Europe across the 2 phases, including CRT patients.

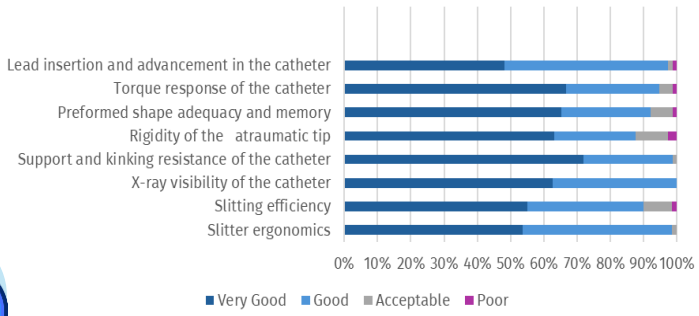
Results

SUCCESS RATE

94.7% of patients with ventricular pacing lead successfully implanted at the interventricular septum with use of the FLEXIGO™ 3D delivery catheter

92.0% of patients with ventricular pacing lead successfully implanted at the interventricular septum and meeting LBBAP criteria with use of the FLEXIGO™ 3D delivery catheter

Implantation Usability



0 delivery catheter other than FLEXIGO™ 3D were required as backup or for procedural support

SAFETY

0 unanticipated events nor deaths reported

0 serious adverse events as per Sponsor Assessment

Conclusion

The FLEXIGO™ 3D delivery catheter and slitter demonstrated good overall safety performance, with no abnormal safety trends observed, and exhibited acceptable implant performance for brady pacing.
Vast majority of operators were satisfied with procedural performance of catheter and slitter.

Therefore, the POLARIS clinical investigation demonstrated the FLEXIGO™ 3D delivery catheter and the FLEXIGO™ 3D slitter are safe and effective for their intended purpose.

POLARIS study (EU Identification Number: CIV-FR-25-01-050957): CLINICAL INVESTIGATION REPORT PRIMARY ENDPOINT RESULTS PHASE I – internal file. For more information about the clinical trial, please look at https://clinicaltrials.gov/study/NCT06453850?term=polaris%20septum&rank=1