Cera™ ASD Occluder Post-Market Clinical Follow-Up Study

NCT06849635

Status	RECRUITING
Sponsor	Lifetech Scientific (Shenzhen) Co., Ltd.
Enrollment	139 participants

Key Eligibility Criteria

Inclusion (3)

- Patients with a confirmed diagnosis of secundum Atrial Septal Defect (ASD).
- Patients was implanted with the study device from 01 Jan 2020 to 31 Dec 2023 as per IFU instructions.
- Patients or legally authorized representative are willing to the collection and processing of his/her data or sign the Informed Consent.

Exclusion (7)

- Patients who have extensive congenital cardiac anomaly which can only be adequately repaired by cardiac surgery.
- Patients who have sepsis within one month prior to implantation, or any systemic infection that can't be successfully treated prior to device placement.
- Patients known to have a bleeding disorder, untreated ulcer or any other contraindications to aspirin therapy, unless another anti-platelet agent can be administered for 6 months.
- Patients who have demonstrated intra-cardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Patients whose size (i.e., too small to tolerate TEE probe, catheter size, etc.) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.

... and 2 more (see full listing online)

Locations (6 total)

G.V.M.Carint Hospital, Myszków, Poland
Centre for Invasive Cardiology, Electrotherapy and Angiology G.V.M.Carint-Oswiecim, O[wi cim, Poland
Subcarpathian Centre for Cardiovascular Intervention G.V.M.Carint -Sanok, Sanok, Poland
... and 3 more locations