Abbott Cephea Mitral Valve Disease Registry

NCT07069673

Status	RECRUITING
Sponsor	Abbott Medical Devices
Enrollment	1,000 participants

Key Eligibility Criteria

Inclusion (5)

- Symptomatic mitral valve disease resulting in mitral regurgitation and/or severe mitral valve stenosis.
- New York Heart Association (NYHA) Functional Class II, III, or ambulatory IV.
- In the judgement of the Site Heart Team, transcatheter therapy is deemed to be more appropriate than conventional mitral valve surgery, TMVR is more likely to provide an optimal result than TEER, and the subject has been adequately treated per applicable standards, including for coronary artery disease, left ventricular dysfunction, and heart failure.
- Age 18 years or older at time of consent.
- The subject agrees to the study requirements, permits all follow-up data entry, and has provided written informed consent.

Exclusion (5)

- Prior surgical or interventional treatment that interferes with the Cephea valve delivery or function.
- Subject is undergoing dialysis or experiencing chronic renal failure
- Subject has chronic lung disease requiring continuous home oxygen therapy or chronic outpatient oral steroid use
- Subjects with comorbidities that are likely to result in a life expectancy of less than 12 months.
- Pregnant or nursing subjects and those who plan pregnancy during the follow-up period.

Locations (19 total)

Phoenix Cardiovascular Research Group, Phoenix, Arizona, United States
Los Robles Regional Medical Center, Thousand Oaks, California, United States
Piedmont Heart Institute, Atlanta, Georgia, United States
... and 16 more locations