

EFS of the CardioMech MVRS

NCT04820764

Status	RECRUITING
Phase	Not Applicable
Sponsor	CardioMech AS
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (3)

- Eighteen (18) years of age or greater
- Moderate to severe (e3+) or severe (e4+) mitral valve regurgitation (per American Society of Echocardiography (ASE) guidelines) due to mitral valve prolapse or flail
- Intermediate or high surgical risk for mitral valve repair

Exclusion (5)

- History of rheumatic heart disease
- History of prior endocarditis
- History of prior repair or replacement of the mitral valve, or annuloplasty
- Severely calcified mitral leaflet or has evidence of calcification in the grasping area of the leaflets that would prevent leaflet anchor positioning and deployment
- Complex mechanism of MR (leaflet perforation, severe leaflet calcifications, commissural extension, commissural prolapse, multiple flail or prolapsing segments, cleft) present on required imaging

Locations (12 total)

Cardiovascular Institute of Los Robles Health System, Thousand Oaks, California, United States
Northwestern University, Evanston, Illinois, United States
Ascension St. Francis via Christi, Wichita, Kansas, United States
... and 9 more locations