

ALLIANCE AVIV: Safety and Effectiveness of the SAPIEN X4 Transcatheter Heart Valve in Failing Aortic Bioprosthetic Valves

NCT05172973

Status	RECRUITING
Phase	Not Applicable
Sponsor	Edwards Lifesciences
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (5)

- Failing aortic bioprosthetic valve demonstrating e moderate stenosis and/or e moderate insufficiency
- Bioprosthetic valve size suitable for SAPIEN X4 THV
- NYHA functional class e II
- Heart Team agrees the subject is at high or greater surgical risk
- The subject has been informed of the nature of the study, agrees to its provisions and has provided written informed consent.

Exclusion (32)

- Anatomical characteristics that would preclude safe femoral placement of the introducer sheath or safe passage of the delivery system
- Failing valve has moderate or severe paravalvular regurgitation
- Failing valve is unstable, rocking, or not structurally intact
- Known severe patient-prosthesis mismatch or bioprosthetic valve with residual mean gradient \gt 20 mmHg at the end of the index procedure for implantation of the original valve
- Increased risk of THV embolization
- ... and 27 more (see full listing online)

Locations (35 total)

Hoag Memorial Hospital Presbyterian, Newport Beach, California, United States
Bay Area Structural Heart at Sutter Health, San Francisco, California, United States
Kaiser San Francisco, San Francisco, California, United States
... and 32 more locations