

Clinical Safety and Efficacy of the VDyne Transcatheter Tricuspid Valve Replacement System for the Treatment of Tricuspid Regurgitation (VISTA-US)

NCT05848284

Status	RECRUITING
Phase	Not Applicable
Sponsor	VDyne, Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (7)

- Symptomatic severe tricuspid valve regurgitation of primary or secondary etiology.
- NYHA class e II. If NYHA Class IV, patient must be ambulatory.
- Subject is adequately treated with medical therapy for heart failure e 30 days prior to
- index procedure, including a diuretic.
- Heart Team determines patient is a recommended candidate for the VDyne System.

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

Exclusion (39)

- Patient anatomy (cardiac and vascular) is not suitable for VDyne System as assessed by Imaging Core Labs, Sponsor or Clinical Screening Committee (CSC)
- Intolerance to procedural anticoagulation or post-procedural antiplatelet/ anticoagulation regimen that cannot be medically managed
- Hypersensitivity to nickel or titanium
- Left Ventricular Ejection Fraction (LVEF) \<30%.
- Severe RV dysfunction.

... and 34 more (see full listing online)

Locations (11 total)

Cedars-Sinai Medical Center, Los Angeles, California, United States
Henry Ford Hospital, Detroit, Michigan, United States
Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, United States
... and 8 more locations

<https://clinicaltrials.gov/study/NCT05848284>

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