

Clinical Safety and Efficacy of the VDyne Transcatheter Tricuspid Valve Replacement System for the Treatment of Tricuspid Regurgitation

NCT05797519

Status	RECRUITING
Phase	Not Applicable
Sponsor	VDyne, Inc.
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (6)

- Severe or greater 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 ≥ 30 days prior to index procedure, including a diuretic.
- Heart Team determines patient is a recommended candidate for the VDyne System.
- Age 18 years or older at time of the index procedure.

... and 1 more (see full listing online)

Exclusion (41)

- VDYNE SYSTEM SUITABILITY
- Patient anatomy (cardiac and vascular) is not suitable for the VDyne System as assessed by Imaging Core Labs, Sponsor and/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) $\leq 30\%$

... and 36 more (see full listing online)

Locations (21 total)

St. Vincent Hospital, Sydney, New South Wales, Australia
Flinders Medical Centre, Adelaide, Australia
Princess Alexandra Hospital, Brisbane, Australia

... and 18 more locations