Early Feasibility Study of the Cardiac Implants Percutaneous Ring Annuloplasty System

NCT04890821

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cardiac Implants LLC
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (10)

- Moderate to severe functional tricuspid regurgitation (TR) defined by ASE guidelines and the European Association of Echocardiography guidelines.
- Tricuspid valve annular diameter e 40mm or \> 21 mm/m2 as measured by baseline TTE in a 4-chamber view within 90 days prior to index implant procedure.
- Age e 18 years old at the time of enrollment.
- New York Heart Associate Classification e II.
- Symptoms of right heart failure despite optimized medical therapy.

... and 5 more (see full listing online)

Exclusion (31)

- Acute decompensated heart failure requiring hospital admission with 4 weeks of enrollment.
- Severe RV dysfunction as assessed by echocardiography.
- Primary (organic) tricuspid pathology (e.g. rheumatic, congenital, infective, etc.).
- Currently participating in another investigational drug or device study.
- Systolic pulmonary arterial pressure (sPAP) \> 70 mmHg as measured by Transthoracic Echocardiography (TTE).

... and 26 more (see full listing online)

Locations (2 total)

Hackensack University Medical Center, Hackensack, New Jersey, United States
Weill Cornell Medicine-New York Presbyterian Hospital, New York, New York, United States