

# SynCardia 70cc TAH-t for Destination Therapy (DT)

**Status:** Recruiting

## Eligibility Criteria

**Age:** 19 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

Primary Arm

### Inclusion Criteria:

1. Patients with ife-threatening, irreversible biventricular heart failure (Intermacs Patient Profile Classifications 1
- 4) 2. Ineligible for cardiac transplantation (e.g., contraindication to immunosuppression, cancer, elevated panel reactive antibodies [PRAs]) as determined by the implanting center at time of implant screening assessment. 3. On optimal medical management and failing to respond or failing DT VAD therapy (continuing to decline) 4. Ambulatory without assistance 5. Patients between 19 and 75 years of age 6. Patients with Body Surface Area (BSA) of ? 1.7m<sup>2</sup> 7. Sternum to T10 distance > 10cm OR adequate room in chest as determined by 3-D imaging assessment or by other standard clinical assessments

### Exclusion Criteria:

1. Cardiac transplant-eligible patients 2. Patients who cannot be adequately anticoagulated on the TAH-t 3. Patients with insufficient space in the chest 4. Patients on ECMO support 5. Patients with Cirrhosis (evidenced by ultrasound, CT scan, or positive biopsy) 6. Patients with Acute or Chronic Renal dysfunction (per Intermacs AE Definitions) 7. Patients with cardiac cachexia (e.g., pre-albumin <17, fragility, and catabolic/anabolic imbalance) 8. Patients with a comorbidity that has a poor prognosis of survival beyond six months 9. Patients with insufficient social support or who have demonstrated non-compliance with medical instructions (as determined by the Principal Investigator) Secondary Arm

### Inclusion Criteria:

1. Patients who are NOT eligible to participate in the Primary Arm 2. Patients with life-threatening, irreversible biventricular heart failure (Intermacs Patient Profile Classifications 1
- 7) 3. Ineligible for cardiac transplantation (as determined by the implanting center at time of implant screening assessment). 4. On optimal medical management and failing to respond or failing DT VAD therapy (continuing to decline) 5. Patients 19 years of age or older 6. Sternum to T10 distance > 10cm OR adequate room in chest as determined by 3-D imaging assessment or by other standard clinical assessments

### Exclusion Criteria:

1. Patients who are less than 19 years old 2. Cardiac transplant-eligible patients 3. Patients with Cirrhosis (evidenced by ultrasound, CT scan, or positive biopsy) 4. Patients with Chronic Renal dysfunction (per Intermacs AE Definitions) 5. Patients with insufficient space in the chest 6. Patients who cannot be adequately anticoagulated on the TAH-t 7. Patients with insufficient social support or who have demonstrated non-compliance with medical instructions (as determined by the Principal Investigator)

## Conditions & Interventions

### Interventions:

Device: 70cc TAH-t for Destination Therapy

### Conditions:

Life-threatening, Biventricular Heart Failure, Ineligible for Cardiac Transplant

### Keywords:

SynCardia, Total Artificial Heart, Biventricular heart failure, Ineligible for cardiac transplant

## More Information

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**Phase:** N/A

**IRB**

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