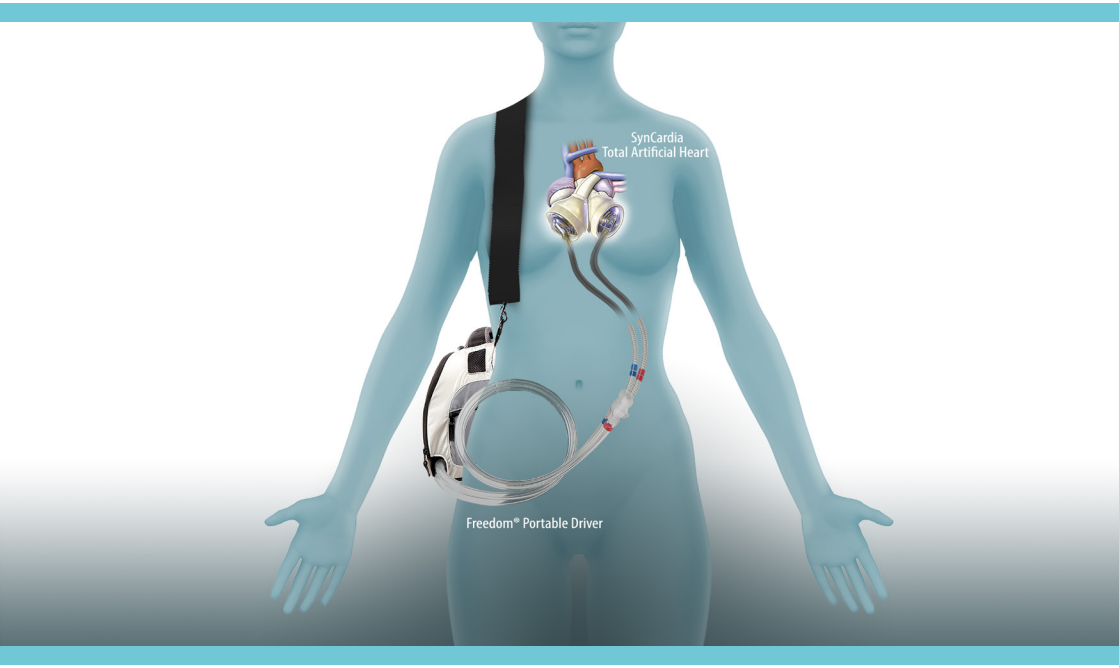
Consultation Guide for the SynCardia temporary Total Artificial Heart

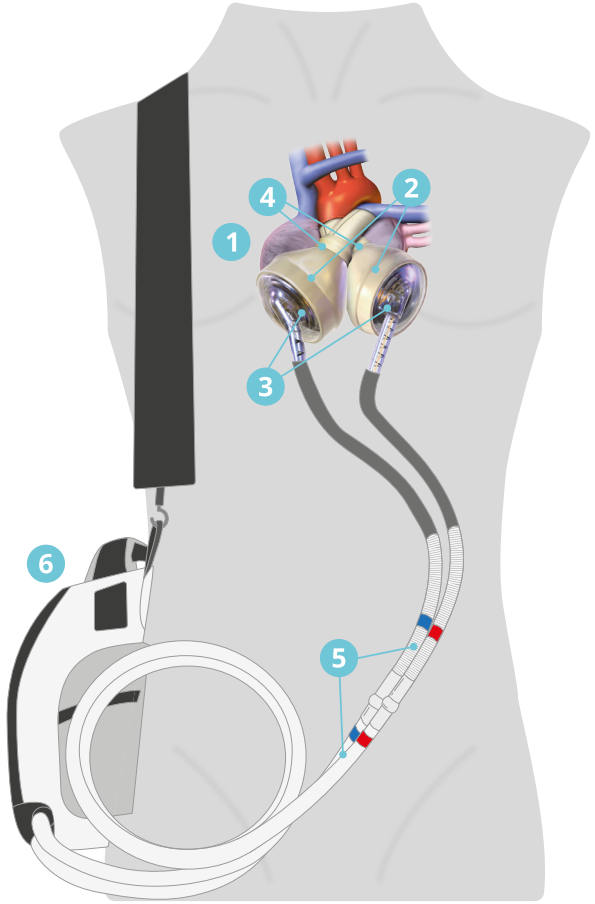
Help Your Patients Live Longer, Live Better



The SynCardia temporary Total Artificial Heart (TAH) is a clinically proven life-saving treatment option for cardiac transplant-eligible patients at risk of imminent death from biventricular failure. The TAH increases their chances of survival, allows them to enjoy a good quality of life at home and prepares them for transplant by increasing cardiac output and optimizing organ function.

What is the SynCardia TAH?

The SynCardia TAH is a pneumatically driven pulsatile system used for orthotopic replacement of the native ventricles and four valves in cases of end-stage biventricular heart failure.



1 Materials	The housings, diaphragms and connectors in the TAH are made from a highly specialized segmented polyurethane solution. The compound offers a high degree of biocompatibility, fatigue resistance and strength.
2 Ventricles	The TAH consists of two independent artificial ventricles and is produced in two sizes — 70cc and 50cc. The 70cc ventricle has a maximum stroke volume of 70 mL and is capable of generating a cardiac output of up to 9.5 L/min. The 50cc ventricle has a maximum stroke volume of 50 mL and is capable of generating a flow rate of up to 7.5 L/min.
3 Diaphragms	Each ventricle is divided by a multi-layer flexible polyurethane diaphragm that separates the blood chamber from the air chamber.
4 Valves	The direction of blood flow is controlled by four SynHall tilting disc valves that are mounted in the inflow and outflow ports of each artificial ventricle. These high-performing valves have proven to be extremely durable and dependable for long-term support.
5 Cannulae & Drivelines	The cannula of each artificial ventricle acts as a conduit for air from the driver to the ventricles. Each cannula is partially covered with velour fabric to promote tissue ingrowth, is tunneled through the chest wall and attaches to a driveline that connects to the external pneumatic driver.
6 External Driver	The Companion 2 (C2) Hospital Driver (for use in the hospital) and the Freedom® Portable Driver (for use in-hospital and at home) produce pulses of air that travel through the drivelines to inflate and deflate the TAH diaphragms to provide pulsatile blood flow. The drivers run on batteries as well as A/C power.



Jack, 62 - Dilated cardiomyopathy
Transplanted after 178 days of support



Tiernee, 19 - Anthracycline induced cardiomyopathy
Transplanted after 414 days of support



Steve, 53 - Non-ischemic cardiomyopathy
Transplanted after 358 days of support

Two Sizes to Fit Most Patients



70cc TAH

Device Selection Criteria

Patients with a T10 measurement* ≥ 10 cm. Patients supported by the 70cc TAH typically have a body surface area (BSA) ≥ 1.7m^2.

Approvals

Bridge to Transplant

- Approved in the U.S. (2004), Canada (2005)



50cc TAH

Device Selection Criteria

Patients with adequate T10 measurement* or adequate room in the chest as determined by 3D imaging assessment or by other standard clinical assessments. The 50cc TAH is intended to support patients with a BSA ≤ 1.85m^2.

Approvals

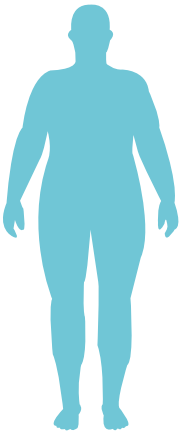
Bridge to Transplant

- Approved in the U.S. (March 2020) and Canada (2016)

*posterior sternum to anterior spine measurement at T10



TAH Patient Demographics



70cc TAH

- **89%** male
- **11%** female
- Age range: **9 to 80** years old
- Largest BSA: **2.96m²**



50cc TAH

- **61%** female
- **39%** male
- Age range: **11 to 72** years old
- Smallest BSA: **1.16m²**

Source: As reported on SynCardia Implant Forms as of 9 Oct 2017. Not all Implant Forms have complete information.

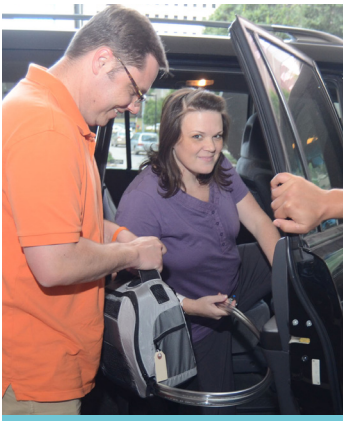
Patients with These Conditions Should Be Considered Promptly for TAH Consultation:[1,2,3,4]

- Irreversible biventricular failure (RVEF <20% or CVP >18 mmHg)
- Allograft failure, rejection or heart transplant vasculopathy
- Decompensated right heart failure on LVAD support
- Failure to wean from ECMO
- Massive myocardial infarction or direct myocardial injury that affects technical insertion of a VAD
- Recurrent ventricular tachycardia/fibrillation
- Intracardiac thrombus
- Small/non-dilated ventricles (hypertrophic, infiltrative and other restrictive cardiomyopathies)
- Post-infarction VSD or Type A aortic dissection with coronary artery dissection
- End-stage congenital heart disease
- Aortic regurgitation, stenosis, prosthesis or other valve issues with left and/or right ventricular failure
- Cardiac tumor



Jaheim, 11 - Graft failure/rejection
Transplanted after 280 days of support

Photo Credit: Jan Terry, Lurie Children's Hospital

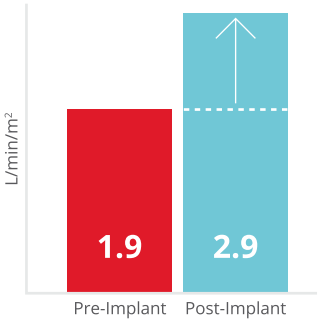


Shawn, 38 - Post-partum cardiomyopathy
Transplanted after 60 days of support

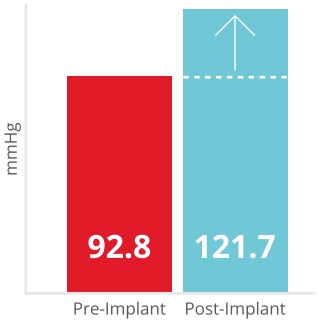
[1] FDA Summary of Safety and Effectiveness
[2] Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: executive summary. J Heart Lung Transplant. 2013;32:157-87.
[3] Shah KB, Thanavaro KL, Tang DG, et al. Impact of INTERMACS profile on clinical outcomes for patients supported with the total artificial heart. J Card Fail 2016;22(11):913-919.
[4] Cook JA, Shah KB, Quader MA, et al. The total artificial heart. J Thorac Dis. 2015;7(12):2172–80.

Immediate Improvement in Hemodynamic Status[1]

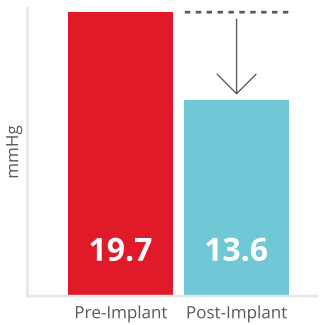
Cardiac Index



Systolic Arterial Pressure



Central Venous Pressure



[1] Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med 2004;351:859–67.



Marcela, 20 - Non-ischemic cardiomyopathy
Transplanted after 245 days of support



Randy, 39 - Non-ischemic cardiomyopathy
Transplanted after 451 days of support



Thomas, 52 - Acute MI with VSD
1,100+ days of ongoing support

Improved Quality of Life

The Freedom® Portable Driver was first used in 2010 during a clinical trial in the United States (FDA approval was granted in 2014). As of December 2019, it has supported over 450 patients worldwide (representing more than 450 years of patient support) and allowed many to await their transplants from the comfort of their homes. The TAH gives patients a second chance at life, and the Freedom Driver gives them the power to live it to the fullest. Discharged patients can exercise, sleep in their own beds, spend time with family and friends, enjoy recreational activities like hiking and dancing, and in some cases, even go back to work.





Meet Chris, SynCardia TAH Recipient

An avid hiker and outdoorsman, Chris isn't your average heart failure patient. Despite being diagnosed with cardiomyopathy, Chris continued hiking the wilds of Alaska with his family for more than a decade, determined to not let his condition get in the way of his passions. But after he experienced shortness of breath while hiking on level ground, doctors urged Chris and his wife, Kathy, to travel to University of Washington Medical Center in Seattle to be evaluated for a heart transplant. After doctors there discovered his ejection fraction was less than 10%, immediate action was needed. Because his RHF was so severe, Chris was not a candidate for an LVAD. The SynCardia TAH was his only option for survival.



Chris, 51 - Dilated cardiomyopathy with VT
Transplanted after 219 days of support

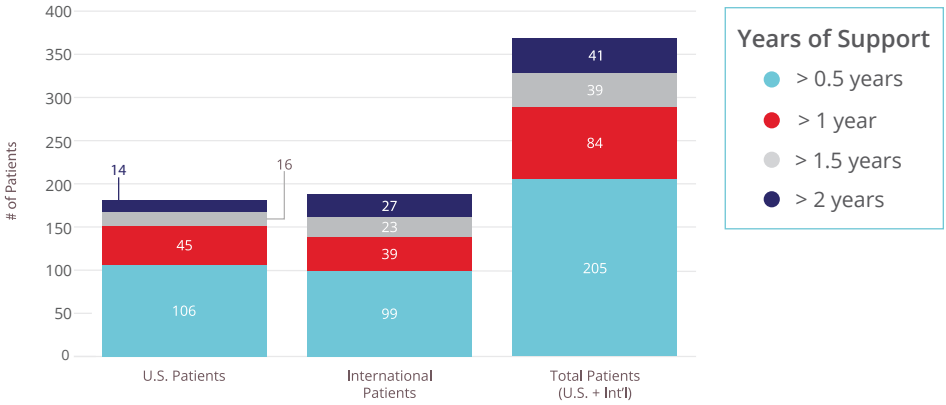
One month after receiving the SynCardia TAH, Chris was discharged from the hospital. The Freedom® Portable Driver, which powers the TAH, enabled him to await his transplant at home with Kathy and their beloved dog, Gracie.

Using the Freedom Driver, Chris was able to live life to the fullest while awaiting transplant. "I thought, 'I'm not just going to sit on the couch,'" says Chris. "I refuse not to live." Over the course of the seven months leading up to his transplant, Chris hiked a total of 607 miles with Kathy and their 25-year-old son, Patrick, wearing the driver in the Backpack.

Today, Chris is back at home in Alaska, working and enjoying his active lifestyle once again with his donor heart. "The SynCardia Total Artificial Heart was really a blessing," Kathy says. "With the Freedom Portable Driver, it enabled Chris to do so much."

> **"I walked 607 miles with the Total Artificial Heart, so I was really fit going into that surgery. That's very different from a lot of people who go into the transplant really sick."**

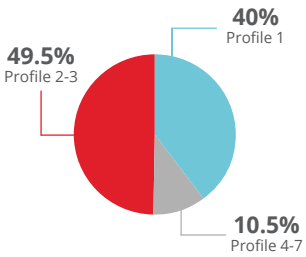
Reliable, Long-Term Support[1]



Several patients have been supported by the TAH for more than 4.5 years.

Providing Hope to the Sickest Patients

Patient INTERMACS Profile at Time of TAH Implant[2]



INTERMACS Profile Definitions

Profile 1: Critical cardiogenic shock
Profile 2: Progressive decline
Profile 3: Stable but inotrope dependent
Profile 4: Resting symptoms
Profile 5: Exertion intolerant
Profile 6: Exertion limited
Profile 7: Advanced NYHA Class 3

TAH Outcomes at 12 Months[2]

Overall Success Rate: **67.6%**

- Transplanted: **53.5%**
- Alive on Device: **14.1%**

[1] As reported on SynCardia Implant and Explant Forms as of 9 Oct 2017. Not all Implant and Explant Forms have complete information.
[2] INTERMACS Quarterly Statistical Report for SynCardia Systems, Inc. 2017 Q3



Jordan, 17 - Congenital heart failure
Transplanted after 160 days of support



John, 62 - Dilated cardiomyopathy with VT/VF
Transplanted after 147 days of support



Lexi, 16 - Severe cardiac allograft vasculopathy
Transplanted after 383 days of support

Time Is of the Essence

If you have a patient you think may benefit from the TAH, consider them as a TAH candidate promptly. Give your patients the best chance at an optimal outcome: to live a longer, healthier and happier life.

Contact Us

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SynCardia



"The Total Artificial Heart is definitely a lifesaver. I felt 100 percent. I could've refereed soccer I felt so good. If you need it, do it, no hesitation. With hospice, you know the end is coming; with the Total Artificial Heart, you know the future is coming."

Johnny, 55
Ischemic cardiomyopathy
Transplanted after 203 days of support

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