Selecting Patients for the SynCardia temporary Total Artificial Heart

Help Your Patients Live Longer, Live Better



The SynCardia 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.

Two Sizes to Fit Most Patients



70cc TAH

Fit Criteria

Patients with a BSA ≥ 1.7m^2 or with T10 measurement ≥ 10 cm

Approvals & Clinical Studies

Bridge to Transplant

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

Reimbursement

- Covered by Medicare (2008) and most large private payers and state Medicaid programs



50cc TAH

Fit Criteria

Patients with a BSA ≤ 1.85m^2 with adequate room in the chest

Approvals

Bridge to Transplant

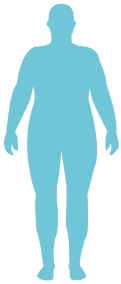
- Approved in U.S. (March 2020) and Canada (2016)

Reimbursement

- Covered by Medicare (2008) and most large private payers and state Medicaid programs



TAH Patient Demographics[1]



70cc TAH

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

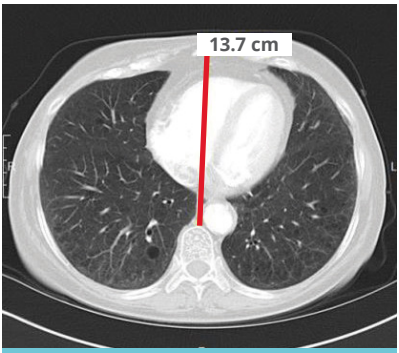


50cc TAH

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

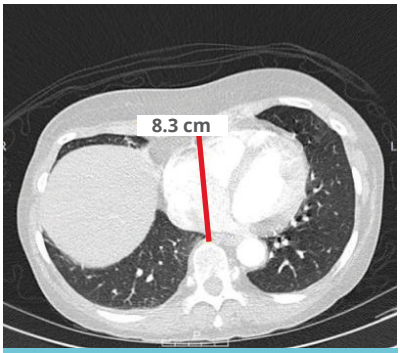
Fit Assessment

The most valuable determinant of whether the 70cc or 50cc TAH will fit in a patient's chest is their T10 measurement. Commonly assessed via CT scan, the T10 measurement is the anteroposterior distance between the sternum and the 10th thoracic vertebra (T10). Patients with a T10 measurement ≥ 10 cm should be considered for the 70cc TAH.



Example A

- T10: 13.7 cm
- BSA: 1.36m²



Example B

- T10: 8.3 cm
- BSA: 1.47m²

[1] 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 for the TAH[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 tumors

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.

Current TAH Use & Experience[1]

2,000+ Implants Worldwide

No. of Cases*	Most Common Pre-Implant Etiologies
560+	Idiopathic Dilated Cardiomyopathy
470+	Ischemic Cardiomyopathy
125+	Congenital & Genetic Conditions
110+	Post-Heart Transplant Graft Failure
85+	Valvular Cardiomyopathy
85+	Restrictive Cardiomyopathy
75+	LVAD Failures (Device Malfunction or RV Failure)

*Note: Some patients have multiple pre-implant etiologies and are counted as a case under more than one category. Call us to discuss these etiologies further or to discuss other etiologies not listed here.

Time Is of the Essence

- Since 2016, more than 1,400 patients[2,3] in the U.S. and Europe have been removed from the heart transplant waiting list because of death or deterioration.
- Optimal patient outcomes with the TAH depend on timely decision-making.



"When patients have been on ECMO for less than 4 days, the chance of a good outcome with the TAH as BTT can be as high as 80% or better. However, once patients surpass 7 days, their chances can drop to 50%."

Dr. Francisco Arabia
TAH surgical leader and proctor involved in more than 200 TAH cases

[1] SynCardia Implant Forms and published scientific papers as of 15 Dec 2017. Not all Implant Forms have complete information.
[2] Removal Reasons by Year, Organ Procurement and Transplantation Network National Data
[3] Heart waiting list removals, by year, by country, by reason, Eurotransplant

A New Approach in the OR: Dual Consents

With the exception of several conditions that can only be treated with the TAH, the best time to determine whether a patient requires an LVAD or a TAH is in the operating room. Only when the chest is open can you accurately assess the degree of stress on the right ventricle.

If possible, consider obtaining patient consent in advance for both options and have both devices ready for use in the OR.

In addition, having the TAH on hand for all major cardiac surgeries provides a critical safety net for unexpected emergencies or complications.



Danielle, 22 — Emergency in the OR



Danielle and her husband Chris became engaged shortly after she was bridged to transplant with the TAH.

Two years after surgery for an aortic graft and pacemaker because of an enlarged aorta caused by Marfan syndrome, Danielle developed severe endocarditis. After a heavy regimen of antibiotics, surgeons hoped to repair the damage to her heart in the OR. But while Danielle was lying sedated waiting for her surgery to begin, her heart suddenly stopped.

Because she was already in the OR, surgeons were able to quickly put her on bypass. From there, her only option for survival was the SynCardia TAH.

After 23 days of TAH support, Danielle received a heart transplant.

Give Your LVAD Patients a Safety Net



Right heart failure (RHF) is a frequent complication following left ventricular assist device (LVAD) implantation, occurring in 10% to 40% of patients.[1] However, adding an RVAD before orthotopic heart transplantation is associated with worse post-transplant outcomes and increased mortality.[2]

LVAD patients with RHF may benefit from having their devices replaced by the TAH and should be considered for implantation as soon as there is evidence of right heart decompensation. LVAD patients experiencing other common issues, such as pump thrombosis, should be evaluated for the TAH as well.

Danny, 37 — Dilated Cardiomyopathy & LVAD Thrombosis

Six weeks after Danny was implanted with an LVAD, a blood clot formed in the pump and he was rushed back to the hospital. "You could hear it," Danny says. "The LVAD sounded like a pump stuck in the mud. The doctors came in and told me, 'Your heart is so bad you're going to die unless you're willing to try the Total Artificial Heart.'"

After Danny received the TAH, he immediately started feeling better. "The LVAD didn't do anything for me because I was too sick, but I felt better with the Total Artificial Heart," he says. "I could breathe again, I could walk again."

Danny was transplanted after 316 days of TAH support.



Danny post-transplant with his family at his daughter's wedding.

[1] Lampert B.C., Teuteberg J.J. (2015) Right ventricular failure after left ventricular assist devices. J Heart Lung Transplant 34:1123–1130

[2] Taghavi S, Jayarajan SN, Komaroff E, Mangi AA. Right ventricular assist device results in worse post-transplant survival. The Journal of Heart and Lung Transplantation. 2016;35(2):236-241. doi:10.1016/j.healun.2015.10.018.

Bridge Your Graft Failure Patients to Their Next Transplant

As of 2015, there were approximately 30,000 living heart transplant patients in the U.S.[1] For each of these patients, the question is not if they will develop graft failure, but when. In the first year post-transplant, nearly one-quarter of heart recipients experience acute rejection.[1] In addition, graft failure is one of the most common documented causes of death in the first year post-transplant.[1] However, re-transplants are uncommon, accounting for only 2.9% of transplants in 2016.[1]

Most MCS devices are not effective options for bridging these patients to a second transplant. Because graft failure is often a biventricular issue, outcomes from LVAD support alone have been poor.[2,3] Although BiVADs provide biventricular support, they require graft ventricles to be in place. As a result, BiVAD patients need ongoing immunosuppression, which can adversely affect wound healing, increase susceptibility to sepsis and heighten the risk of MSOF.[2]

The TAH is the only device that allows for removal of the transplanted graft and discontinuation of all immunosuppression while the patient waits for a second donor heart.[3] With cardiac output of up to 9.5 L/min (70cc) or 7.5 L/min (50cc), the TAH can help reverse the MSOF often encountered in patients with advanced graft failure.[2]



1 OPTN/SRTR 2015 Annual Data Report: Heart
2 Quader MA, Tang D, Katlaps G, Shah KB, Kasirajan V. Total artificial heart for patients with allograft failure. J Thorac Cardiovasc Surg. 2013;145:e21–e23
3 Kalya A, Jaroszewski D, Pajaro O, et al. Role of total artificial heart in the management of heart transplant rejection and retransplantation: case report and review. Clin Transplant 2013;27:E348-50

Jaheim, 11 — Graft Failure/Rejection

Jaheim is the world's youngest and smallest person to receive the 50cc Total Artificial Heart. Born with hypoplastic left heart syndrome, Jaheim received his first heart transplant in 2012. However, four years later, tests revealed his heart was failing due to graft failure.



Jaheim is the youngest, smallest 50cc TAH recipient

Photos by Jan Terry, Lurie Children's Hospital

Jaheim was immediately admitted to the hospital and treated intensively for rejection, but within several weeks, his other organ systems began to fail. To save his life, the team at Lurie Children's removed his failing donor heart and implanted the 50cc Total Artificial Heart.

"We had no other options but to implant Jaheim with the artificial heart," said Carl Backer, MD, Division Head, Cardiovascular Surgery at Lurie Children's, during a news conference. "Since the artificial heart implant on December 1, 2016, Jaheim's other organs have recovered nicely. He keeps getting stronger and has now been listed for a heart transplant."

Cachectic prior to implant, Jaheim gained more than 10 pounds over the next few months, and after 280 days of support with the 50cc TAH, Jaheim received his second heart transplant.



Jaheim was discharged from the hospital with his new donor heart in November 2017.

Improved Quality of Life

The TAH gives patients a second chance at life, and since 2010, the Freedom® Portable Driver has given 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.

Freedom Discharge Planning

Discharge planning should begin prior to TAH implant when possible, including identifying the patient's caregiver(s).

- **Clinically stable TAH patients should be euvolemic and normotensive before being switched to the Freedom Driver.**
- **The patient and his or her caregiver(s) should be educated about the operation and care of the Freedom Driver early.**
- **Although discharge criteria are determined by the hospital, assessments of the caregivers' needs and the availability of community resources should be conducted.**
- **To ensure continuity of care, this information should be documented and shared with all relevant members of the patient's healthcare team both inside and outside the hospital, including first responders.**





Ready to Act?

Five Questions to Consider on a Weekly Basis

1. Who came in on ECMO in the past 24 hours?
2. Who crashed and burned over the weekend?
3. Which of your transplant patients is deteriorating?
4. Who was admitted with acute conditions?
5. Which of your VAD patients are under duress or experiencing mechanical issues?

We're Ready to Help

The sooner you contact us about potential patients, the better prepared we can be to assist you. In addition, if you have a new team member or your personnel need a refresher on TAH implantation and patient management best practices, our Clinical Support Team is ready to provide the necessary training to ensure that your team is confident and prepared to meet every patient's needs. Contact your SynCardia Clinical Support or Sales representative today.

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"When I came out of surgery, my family instantly noticed a difference. They told me my cheeks and lips were pink and rosy. When I woke up I noticed that it was much easier to breathe."

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