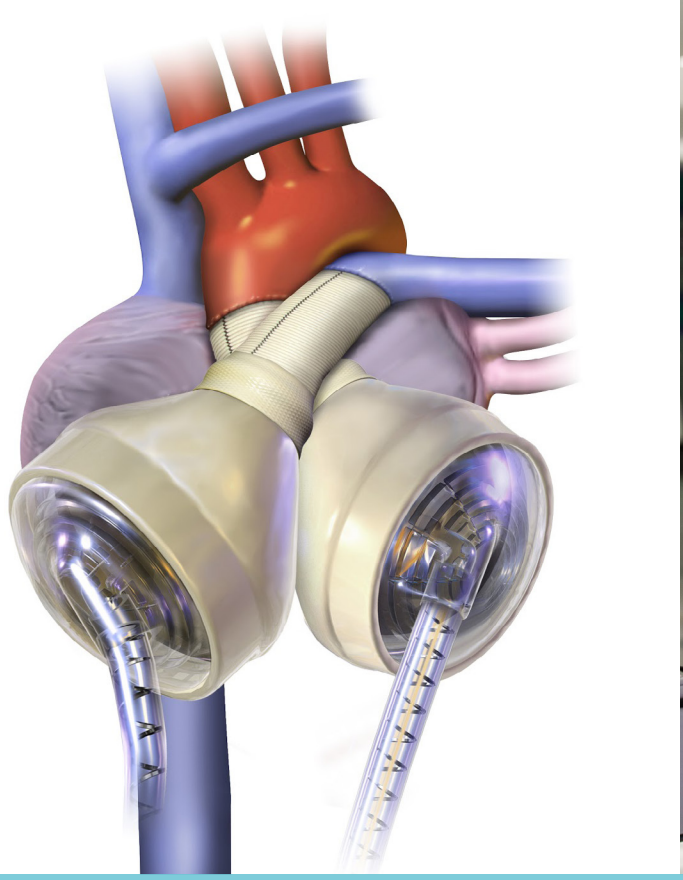








A New Heart Without the Wait:

SynCardia temporary Total Artificial Heart

SynCardia

A Guide for Patients and Their Families



Taking the “End” Out of End-Stage Heart Failure

Jaheim, 11
Transplanted after 280 days of TAH support



If you or a loved one has been diagnosed with end-stage heart failure, it can be a scary and overwhelming experience. However, it’s important to remember that you’re not alone or out of options. Not only are there expert healthcare professionals ready to help — there are also advanced, clinically-proven treatment options available, including the SynCardia temporary Total Artificial Heart (TAH).

If this is the first time you’re hearing about a total artificial heart, it might sound like something out of science fiction. The reality is that the SynCardia TAH has been in clinical use for more than 35 years. It’s the only approved device of its kind in the world and has been used more than 1,950 times to help save the lives of people facing end-stage biventricular failure. Nearly four decades of clinical use have shown that with the SynCardia TAH, it’s not just possible to survive, but also, *to thrive*.

What's In This Guide:

When faced with uncertainty, knowledge is power. With that in mind, we created this guide as an introduction to the TAH, including answers to common questions like:

- What is the TAH?
- How does the TAH work?
- Who is a candidate for the TAH?
- What can I expect during surgery and recovery?
- What is life like at home with the Freedom® Portable Driver?

We hope you find this resource helpful. If you have additional questions not answered here, your healthcare team will be happy to provide more information.



Randy, 39
Transplanted after 451 days of TAH support



What is the SynCardia TAH?

Fast Facts

- **2000+ TAH implants have been performed worldwide, accounting for more than 739+ patient-years of support**
- **140+ hospitals in more than 20 countries have implanted the SynCardia TAH**
- **Several patients have been supported by the TAH for more than 4.5 years**
- **Many patients are able to enjoy active lives at home while waiting for their transplants**
- **The TAH is covered by Medicare and most large private payers and state Medicaid programs**

The SynCardia TAH is the world's only commercially available total artificial heart. It is approved for use as a bridge to transplant in patients with end-stage heart failure affecting both sides of the heart (biventricular failure) and is undergoing a U.S. clinical trial for use as destination therapy in patients not eligible for transplant. Just like a heart transplant, the TAH replaces both lower chambers of the heart (the left and right ventricles) and the four heart valves, to restore blood flow to the body and eliminate the symptoms and source of heart failure.

In addition, the TAH offers some advantages that a donor heart does not:

- **The TAH is readily available when needed (no wait list)**
- **It's not restricted by blood type or antibody level (no matching required)**
- **It is biocompatible with the body (no anti-rejection medications needed)**

Two Sizes to Fit Most Patients

The SynCardia TAH is manufactured in two sizes: 70cc and 50cc. Your healthcare team will recommend which TAH is right for you based on your size, fit measurements, blood flow needs and treatment plan.



70cc TAH

50cc TAH

70cc TAH

The 70cc TAH has been in clinical use for more than 35 years and is the first and only TAH to receive regulatory approval in the U.S. (2004) and Canada (2005) as a bridge to transplant. The 70cc TAH received FDA approval following a 10-year pivotal clinical trial to demonstrate its safety and effectiveness. During the trial, 79% of patients who received the TAH were bridged to transplant.



70cc Fast Facts

- Fits a majority of men and some women
- Can generate blood flow of up to 9.5 liters per minute depending on patient need
- Oldest patient: 80 years old
- Youngest patient: 9 years old

50cc TAH



The 50cc TAH is a smaller version of the 70cc TAH, designed to fit people of smaller stature, including more women and adolescents. The 50cc TAH is approved for use as a bridge to transplant in the U.S. (2020) and Canada (2016).

50cc Fast Facts

- Fits most women and some adolescents
- The 50cc TAH is approved for use as a bridge to transplant in the U.S. (2020) and Canada (2016).
- Oldest patient: 72 years old
- Youngest patient: 11 years old

What Causes End-Stage Biventricular Failure?

The 70cc and 50cc TAHs have been used in patients with the following conditions that have caused or contributed to irreversible biventricular failure:

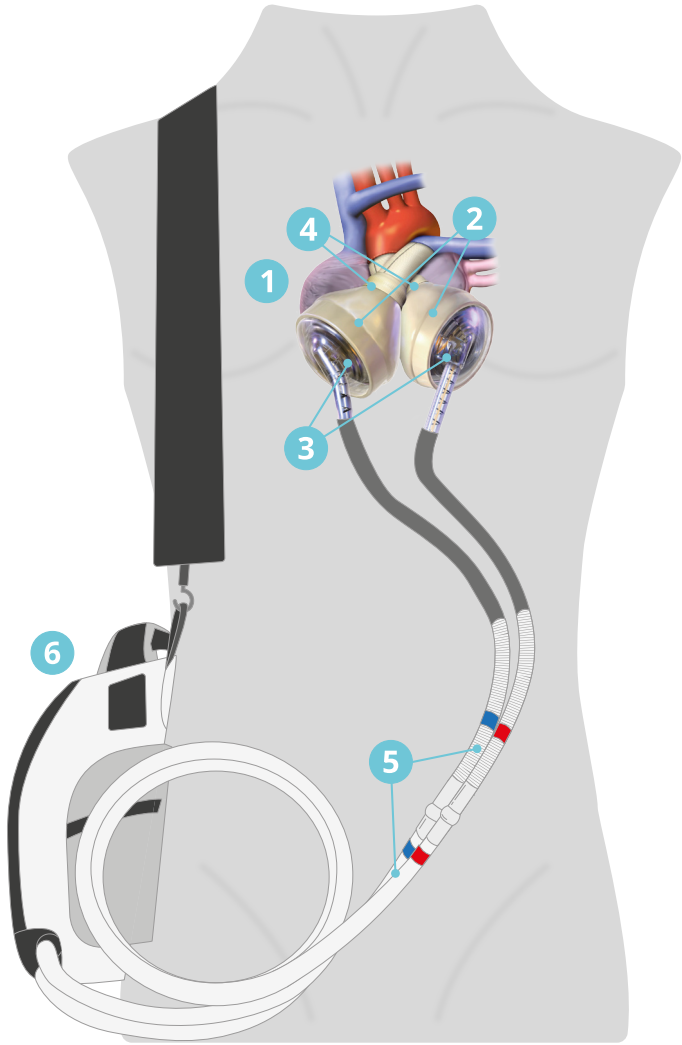
- Acute myocardial infarction
- Aortic root dissection
- Arrhythmogenic right ventricular dysplasia (ARVD)
- Cardiac tumor
- Chagas disease
- Dilated cardiomyopathy
- Donor heart rejection/failure
- Endocarditis
- End-stage congenital heart disease
- Ethylic cardiomyopathy
- Familial cardiomyopathy
- Hypertrophic cardiomyopathy
- Ischemic cardiomyopathy
- LVAD failure
- Marfan syndrome
- Mixed cardiomyopathy
- Myocarditis
- Post/peripartum cardiomyopathy
- Recurrent ventricular tachycardia/fibrillation
- Restrictive cardiomyopathy (including amyloid, sarcoidosis, scleroderma and radiation/chemo-induced cardiomyopathy)
- Valvular cardiomyopathy
- Ventricular septal defect
- Viral cardiomyopathy
- and more...



Stan, 23

Transplanted after 555 days of TAH support

How Does the SynCardia TAH Work?



1 Materials	The TAH is made of a special biocompatible plastic, which offers a high degree of fatigue resistance and strength for long-term durability and prevents the TAH from being rejected by the body.
2 Ventricles	The TAH consists of two independent ventricles that are connected by Velcro, allowing the surgeon to position the ventricles in the chest based on the patient's anatomy.
3 Diaphragms	Inside each ventricle is a flexible, balloon-like membrane known as a diaphragm. The diaphragm divides the ventricle into two chambers: a blood chamber, which holds the blood when it enters the ventricle, and an air chamber.
4 Valves	Each ventricle has two mechanical valves: an inflow valve and an outflow valve. These valves control the direction of blood flow in and out of the ventricle just like natural heart valves.
5 Cannulae & Drivelines	Two tubes called cannulae connect to the air chambers of the ventricles. The cannulae exit the body through the abdominal wall and attach to two tubes called drivelines. These drivelines are connected to an external air pump known as a driver.
6 External Driver	The external driver provides pulsatile blood flow by producing pulses of air and vacuum that travel through the drivelines to inflate and deflate the TAH diaphragms, pushing blood in and out of the ventricles.



How is the SynCardia TAH Powered?



Freedom® Portable Driver

The SynCardia TAH is pumped and monitored by an external machine called a driver, which produces pulses of air and vacuum that help pump blood in and out of the ventricles.

There are two drivers for the SynCardia TAH: the Companion 2 (C2) Hospital Driver (pictured on page 13) and the Freedom® Portable Driver (pictured left).

Companion 2 (C2) Hospital Driver

The C2 Hospital Driver is intended to pump the SynCardia TAH from implant through patient recovery in the hospital. In the operating room and during the initial stages of patient recovery, the C2 Driver is docked in the Hospital Cart, which features a large touch screen display, sturdy support handles and locking casters. It provides robust, reliable support for patients regaining their strength and mobility following the implant surgery.

Freedom® Portable Driver

After recovery from the initial surgery, stable patients can be switched to the smaller, lighter Freedom Driver, which offers increased mobility and can be carried in the provided Backpack or Shoulder Bag. The Freedom Driver (pictured on page 12) has supported patients as young as 11 years old.

Patients on the Freedom Driver who meet discharge criteria can leave the hospital to enjoy active and independent lives at home with their families and friends while they wait for a matching donor heart.

The Freedom Driver is powered by two lithium-ion batteries that can be recharged through either a standard electrical outlet or a car charger. This allows patients to recharge their batteries while traveling, during the day while stationary and at night while they are sleeping.

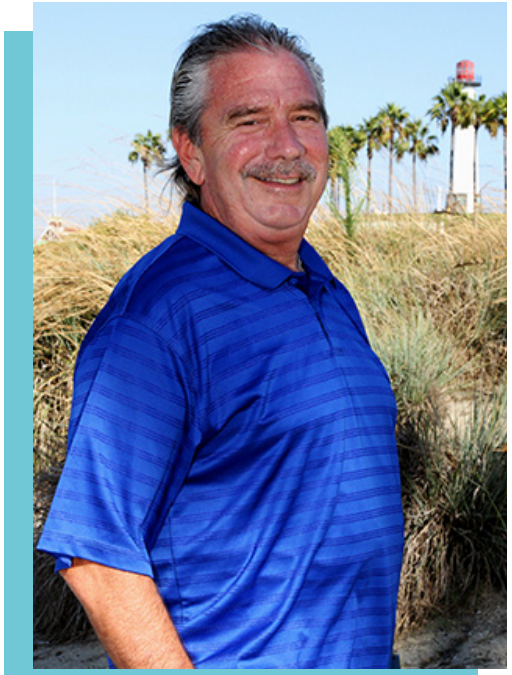


C2 Hospital Driver



What to Expect with the SynCardia TAH

In order to ensure the best outcomes with the SynCardia TAH, it's important that patients undergo implant surgery promptly so that prolonged low blood flow doesn't cause permanent damage to vital organs. The day your failing heart is replaced by the TAH is the day your recovery from heart failure can begin.



The SynCardia Total Artificial Heart is definitely a lifesaver. If you need it, do it, no hesitation. With hospice, you know the end is coming; with the TAH, you know the future is coming.

Johnny, 55

Transplanted after 203 days of TAH support

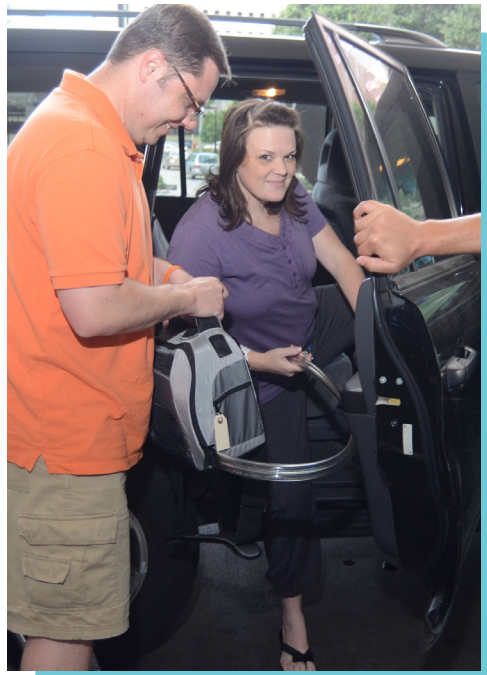
From Gray to Pink

Many doctors and families have described watching patients and loved ones turn from a sickly gray to a healthier pink as the SynCardia TAH restores blood flow to their bodies and vital organs. Typically, the 70cc TAH provides blood flow of around 7 liters per minute (up to 9.5 liters per minute) and the 50cc TAH provides blood flow of around 5 liters per minute (up to 7.5 liters per minute). In comparison, a typical human heart pumps an average of 5 liters of blood per minute.

"The first thing my family said after the surgery was they could not believe how pink my skin was and how deep the color of my lips was because I was getting oxygen for the first time in months. I could breathe when I walked and I didn't feel like I was going to suffocate. It was like an elephant had been sitting on my chest and then suddenly that elephant got off.

Shawn, 38

Transplanted after 60 days of TAH support



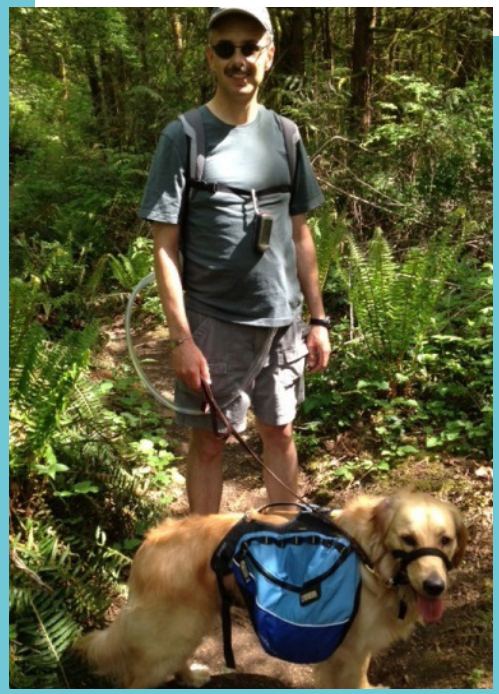
I walked 607 miles with the Total Artificial Heart, so I was really fit going into that surgery. That's very different from a lot of people who go into the transplant really sick. After the surgery, they not only have to recover from the transplant, but also from being sick for so long leading up to it.

Chris, 51
Transplanted after 219 days of TAH support

Exercise and Nutrition

Your physical and emotional well-being have a significant impact on your recovery. It's important that you maintain a positive attitude and have a strong support system to keep you motivated.

Key components of your recovery will include a healthy diet and exercise. Your medical team will design a nutrition and exercise plan tailored to your individual needs. Following this plan is critical for building up your strength and improving your health for your future heart transplant.



It's also important to start moving as soon as possible under the supervision of your medical team. Usually patients begin by sitting in a chair, standing and then walking around the hospital room. Eventually, you'll walk laps around the hospital floor.

Most patients progress to regular workouts as part of their cardiac rehabilitation supervised by hospital staff. Maintaining a healthy diet during this time provides the body with the energy and nutrients it needs to recover.

Discharge and Life At Home

Once stable, TAH patients can be switched to the Freedom Driver. Those who meet discharge criteria, as determined by their care team, are able to leave the hospital and enjoy active lives at home with their loved ones while they wait for their transplant. This greatly improves the patient's physical, mental and emotional health while eliminating most in-hospital costs for this portion of patient care.

Some examples of activities SynCardia TAH patients have been able to enjoy with the Freedom Driver include:

- **Going to the mall, athletic events, the zoo and county fairs with their families**
- **Cycling, basketball, hiking, golfing and other sports**
- **Tiling floors, painting walls and installing crown molding**
- **Trapshooting, fishing and hunting**
- **Taking interstate road trips**
- **Attending graduations and weddings**
- **Attending dances, concerts and other cultural events**



"

[After being switched to the Freedom Driver,] I came home and I continued my life. I played golf, did yard work and lifted weights. I walked 2 to 3 miles per day. The Freedom Driver wasn't an inconvenience to me because I knew what it meant. Without this machine, I wouldn't be here. I was proud of it. It was part of my life.

Johnny, 55
Transplanted after 203 days of TAH support

Training and Resources

Patients who are discharged home will need a trained caregiver with them 24 hours a day. Prior to being discharged, hospital staff will provide extensive training to you and your caregiver(s) on how to operate and take care of the Freedom Driver, including:

- **Cleaning the driveline exit sites and changing the bandages to prevent infection**
- **Changing and charging batteries**
- **Recognizing and responding to alarms**
- **Switching to the backup Freedom Driver if necessary**

Next Steps

Interested in talking to someone who's already been through this experience? Ask your hospital if you can talk to a current or former TAH patient.



"You can't give up. There is a light at the end of the tunnel. You just have to go with it. What is most important is to not let anything stop you — do what you enjoy.

Marcela, 20
Transplanted after 245 days of TAH support



Jaheim, 11
Transplanted after 280 days of TAH support
Photo by Jan Terry, Lurie Children's Hospital







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