



The Freedom driver is the first US portable driver designed to power the SynCardia Total Artificial Heart. It is undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the United States.

# Pneumatic Driver System Provides Bridge to Life

SynCardia's portable Freedom driver offers mobility and reliability for Total Artificial Heart recipients.

BY AL PRESHER, CONTRIBUTING WRITER

**T**he innovative Freedom pneumatic driver from SynCardia Systems is the first US portable driver, weighing just 13.5 lb, designed to power the company's Total Artificial Heart both inside and outside the hospital.

CE-approved for commercial use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the US, the new driver is allowing stable Total Artificial Heart

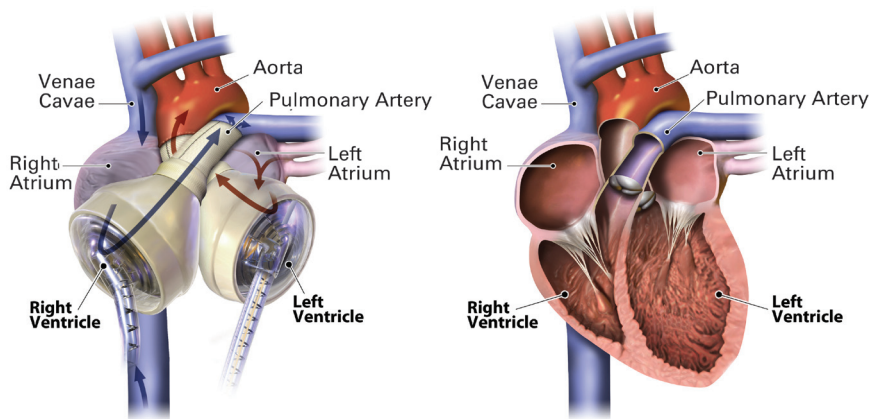
patients to wait for a matching donor heart at home and in their communities. Currently, the only FDA-approved driver is a 418-lb hospital driver nicknamed "Big Blue." Stable patients supported by this driver are confined to the hospital while they wait for a matching donor heart. The average wait was 144 days in 2009.

The SynCardia temporary Total Artificial Heart has six moving parts inside the body. Each ventricle has an inflow valve, an outflow valve, and a diaphragm. The unique

design doesn't require sensors, motors, or electronics of any type inside the body, so there is never a need to re-operate to repair faulty electronics. The only electronics needed are in the pneumatic driver which powers the heart and monitors blood flow. It is located outside the body.

## HOW IT WORKS

"Bimba's cylinders are used as a driver and are actually actuating the diaphragm inside the artificial ventricles surgically



**Total Artificial Heart**

**Human Heart**

The Total Artificial Heart from SynCardia eliminates the symptoms and source of end-stage biventricular failure. The system does not use motors or electronics of any type inside the body. All electronics are in a pneumatic driver, which powers the artificial heart and monitors the patient's blood flow.

implanted inside of a patient," says Tom Carlson, manager of Bimba Manufacturing's Service Excellence team. "Basically with a patient who has biventricular heart failure, the bottom half of their heart is cut out and is replaced with essentially today's version of the Jarvik heart."

Carlson says that two rubber diaphragms are "wetted components" provided as a part of the SynCardia package. These diaphragms sit inside the plastic ventricles which form the artificial heart, but are actually just static components until they are connected to the external driver.

The driver is connected to the heart using two small air tubes, called drivelines, that exit just below the patient's rib cage through the upper abdomen. The drivelines are then connected to the cylinder which effectively is pumping the artificial heart by actuating. The cylinder pumps the diaphragms of the artificial heart, circulating blood through a patient's entire body much like a natural heart.

## RHYTHM OF THE HEARTBEAT

"We worked very closely with SynCardia to try to perfect what I call the rhythm of the heartbeat," says Carlson. "Their goal is to have this product give a heart patient quality of life, not just provide a bridge to a transplantation." So they have a challenge of a 100 million cycles for the actuator, because 100 million cycles is approximately the number the typical human heart beats in one year. The Freedom driver is serviced by replacement every 120 days.

To replicate the rhythm of the heartbeat,

## THE CONCEPT FOR SYNCARDIA IS TO PROVIDE A BRIDGE TO LIFE.

SynCardia has developed specific requirements in terms of output pressures that ultimately relate to the performance of the actuator. Consistency of the cylinder's performance is a major reason why the SynCardia Freedom driver system works.

"Bimba's solution lies with the ability to maintain consistent output pressures, but our product itself is only one part of the entire system that SynCardia uses to make the Freedom driver," says Carlson. "Software, monitors, and simple position sensing on the cylinders all provide an ability to monitor the performance of the Freedom driver. Pressure sensors are also used to be able to identify what is going on, and how the actuators are actually performing."

These challenges are not like a typical pneumatic system where you have ready access to be able to do maintenance or provide lubrication. Basically everything is built and has to be truly available, ready, and usable from the factory for long life.

"The SynCardia Total Artificial Heart is what is implanted in the patient," says Carlson. "The actuator is part of the Freedom driver, the component that the person is basically going to have to carry around with them, and makes being light-

weight important. Providing a lightweight actuator that offers consistent actuation to replicate a heartbeat with a long life were the challenges we faced."

SynCardia says the Total Artificial Heart is the only device that pumps up to 9.5ℓ/minute through both ventricles, and offers a physiologically responsive design where blood flow is based on activity level. The uniqueness of its partial fill/full eject design is that it accepts blood based on the needs of the patient's body at rest. The two artificial ventricles partially fill and then fully eject the amount of blood returned to the heart by the body.

During exercise, increased muscle and body movement causes more blood to enter the ventricles. The ventricles can fill with up to 30 percent more blood but there is no need to adjust the heart rate because the body determines the amount of blood the artificial heart pumps.

Inside each ventricle is the diaphragm that is responsible for pumping blood. Vacuum supplied by the pneumatic driver pulls the diaphragm down to allow blood to enter the ventricle. To eject blood, a precisely calibrated pulse of air then pushes the diaphragm to the top of the ventricle.

## BRIDGE TO LIFE

Carlson says that every year there are approximately 100,000 people who could benefit from a heart transplant, but only about 2,000 hearts are donated annually. That leaves a wide gap that is never going to change and is only going to grow as the baby boomer generation gets older.

The concept for SynCardia is to provide a bridge to life. The SynCardia Freedom driver system allows a patient to continue to live and regain their health while they are waiting for a donor heart. By understanding that the donation gap is always going to be there, the longer term goal of the project is that it allows the potential for a patient to not only check out of the hospital, but then enjoy a long-term, improved quality of life. It can conceivably keep them alive indefinitely while they are waiting for a new heart.

The Freedom driver has approvals in Europe and has been used in dozens of patients worldwide. In 2010, a CBS news story showed the first patient walking out of a hospital using the Freedom driver after being hospitalized for two years. He was able to walk out of the hospital without a human heart, instead, using an artificial heart to walk around and sleep in

his own bed for the first time.

Over 25 years of use, the valves in the SynCardia Total Artificial Heart have never failed. The diaphragm has a failure rate of less than 1 percent over more than 950 implants (1,900-plus diaphragms).

In working on the project, the SynCardia and Bimba engineering groups collaborated to develop advances to the driver technology.

“We have a great partnership with SynCardia, and our chief engineer is basically an extension of their engineering staff,” says Carlson. “What we learned is that they are medical people and that is their forte but, when you get into issues that are more fluid power related, they relied on us as a resource to help them develop the system.”

In addition to fine-tuning the final design and dialing in the functionality

of the actuators, Bimba was also a consultative resource for the overall system, and provided recommendations on how things work within the entire Freedom driver concept. Carlson says the collaboration has actually been very fruitful and Bimba is extremely proud to be part of this because it is a life-saving project.

“When you see someone walk out of a hospital without a human heart and know that we have been part of helping to keep that person alive, that is a huge uplifting thing for our entire company,” Carlson says.

To achieve high reliability, the key is tried-and-true cylinder manufacturing and a combination of lubrication, seal materials, seal geometry, and selection of other bearing materials.

“As with any specialty actuator design, the seals, pistons, bearings, and lubrication

all play a role in its dynamic functionality, so we make sure that the selections provide optimal performance. From a pneumatic standpoint, the goal is not just about optimal life, but also to provide leak-free operation as well,” Carlson says.

Bimba used a combination of empirical testing combined with experience, as well as modeling and simulation, to assist in developing its part of the Freedom driver technology. Carlson says that modeling can only take the process so far, but then the proof is in actually trying it out. FMEA analysis can take you so far, but it doesn't replicate the nuance of an application, so performance validation in the application itself is a must.

*For more information, go to [www.syncardia.com](http://www.syncardia.com) and [www.bimba.com](http://www.bimba.com).*

