

Fact Sheet:

Freedom® Portable Driver

Background:

Prior to the development of the Freedom® portable driver, the only FDA-approved driver for powering the SynCardia temporary Total Artificial Heart was the “Big Blue” hospital driver, which weighs 418 pounds and is the size of washing machine. Due to the shortage of donor hearts, Total Artificial Heart patients supported by Big Blue were confined to the hospital for months, sometimes years, while they waited for a matching donor heart.

Weighing 13.5 pounds, the Freedom® portable driver is the world’s first wearable power supply for the SynCardia Total Artificial Heart. The Freedom® portable driver allows stable Total Artificial Heart patients who meet discharge criteria to wait for a matching donor heart at home and in their communities instead of in the hospital.

Regulatory Approvals:

- CE approved for commercial use in Europe
- FDA approved in the U.S.

Benefits of Discharge:

- Frees stable Total Artificial Heart patients from the hospital
- Improves patient quality of life/helps speed patient recovery
- Eliminates most in-hospital costs for this portion of patient care
- Frees up in-hospital resources to serve additional critically ill patients

Features:

- The Freedom® portable driver weighs 13.5 pounds, including two onboard batteries and a power adaptor.
- The batteries can be charged using a standard electrical outlet or the cigarette lighter adaptor in a car.
- The Freedom® portable driver can be carried by the patient in the Backpack or Shoulder Bag.
- The Freedom® portable driver uses a “dark cockpit” design, meaning the driver only flashes a light and sounds an alarm when something requires the user’s attention.

Milestones:

May 3, 2010: The first Total Artificial Heart patient in the world was discharged from the hospital using the Freedom® portable driver as part of the FDA clinical study in the U.S.

April 24, 2012: SynCardia completed the minimum enrollment required by the FDA clinical study of the Freedom® portable driver when the 30th Total Artificial Heart patient was discharged home.

October 2012: The number of patients supported by the Freedom® portable driver worldwide surpassed 100.

June 26, 2014: The Freedom® portable driver received FDA approval for use with the SynCardia temporary Total Artificial Heart as a bridge to transplantation in cardiac transplant candidates who are clinically stable.



The 13.5 lb Freedom® portable driver and the 418-lb “Big Blue” hospital driver



SynCardia Product Manager Karen Stamm holds the SynCardia temporary Total Artificial Heart while wearing the Freedom® portable driver.



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