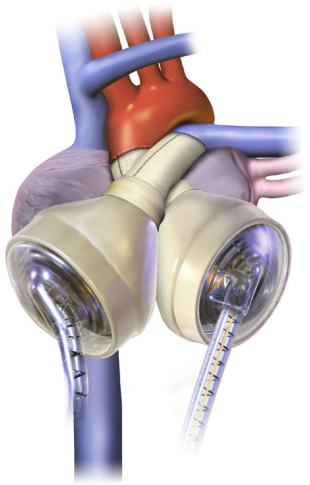
Fact Sheet:

About SynCardia



SynCardia Total Artificial Heart
- Weight: 160 grams
- Stroke volume: 70 ml

SynCardia Systems, LLC (Tucson, AZ) is the privately-held manufacturer of the world's first and only FDA, Health Canada and CE (Europe) approved Total Artificial Heart. The company was formed in 2001 by world-renowned heart surgeon Jack G. Copeland, MD, interventional cardiologist Marvin J. Slepian, MD, and biomedical engineer Richard G. Smith, MSEE, CCE, to commercialize the SynCardia temporary Total Artificial Heart.

Regulatory Approvals:
CE Mark (Europe): Sept. 10, 1999
FDA: Oct. 15, 2004
Health Canada: Oct. 27, 2005

SynCardia temporary Total Artificial Heart
Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart is currently approved as a bridge to transplant for patients suffering from end-stage heart failure affecting both sides of their heart (biventricular failure).

Similar to a heart transplant, the SynCardia Total Artificial Heart replaces both failing heart ventricles and the four heart valves, eliminating the symptoms and source of end-stage biventricular failure. Unlike a donor heart, the Total Artificial Heart is immediately available at SynCardia Certified Centers.

During the 10-year pivotal clinical study which resulted in FDA approval, 79% of near-death patients who received the Total Artificial Heart were bridged to transplant. This is the highest bridge-to-transplant rate of any approved device in the world.

Freedom from the Hospital
The Freedom® portable driver is FDA, Health Canada and CE approved for use in Europe. In 2010, SynCardia introduced the Freedom portable driver, the world's first wearable power supply for the Total Artificial Heart. Weighing 13.5 pounds (~6 kg), 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.

Destination Therapy Study
On December 18, 2014, the United States Food and Drug Administration (FDA) approved the SynCardia Investigational Device Exemption (IDE) application to conduct the study in 19 patients who do not qualify for a donor heart transplant, and the effectiveness of the SynCardia temporary Total Artificial Heart for permanent use, also called destination therapy. Once approved, the HDE will allow up to 4,000 U.S. patients annually who are not transplant-eligible to receive the Total Artificial Heart on a permanent basis. Currently, these patients have no other options for long-term survival and are often referred to hospice. *Caution: The 70cc SynCardia Total Artificial Heart, when used for destination therapy, is an investigational device, limited by United States law to investigational use.*

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