

# SynCardia Nearly Doubles Sales for Second Straight Year in 2011

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## **Manufacturer of World's Only Approved Total Artificial Heart Profitable for 1st Time in Company's 10-Year History**

TUCSON, Ariz., Jan. 4, 2012

TUCSON, Ariz., Jan. 4, 2012 /PRNewswire/ -- SynCardia Systems, Inc. (www.syncardia.com), manufacturer of the world's only FDA, Health Canada and CE (Europe) approved Total Artificial Heart, announced today that in 2011, the company nearly doubled sales for the second straight year, representing a four-fold increase since 2009.

"This is the first full year that SynCardia has been profitable during the company's 10-year history," said Michael Garippa, SynCardia CEO/President. "Acceptance of the SynCardia temporary Total Artificial Heart as the new standard of care for end-stage biventricular failure is accelerating and as a result, demand is growing rapidly."

There are currently 50 SynCardia Certified Centers worldwide. An additional 39 hospitals are currently in the process of completing SynCardia's Certification Program. In 2011, 29 new centers signed up to undergo certification. In addition, several world-renowned transplant programs performed their first implants of the Total Artificial Heart, including NewYork Presbyterian/Columbia, Texas Heart Institute, Keck Hospital of the University of Southern California, Florence Nightingale Hospital in Istanbul, Turkey and Papworth Hospital in the United Kingdom.

In 2012, SynCardia expects to complete the FDA-approved Investigational Device Exemption (IDE) clinical study of the Freedom® portable driver. Weighing 13.5 pounds, the Freedom driver is the world's first wearable power supply for SynCardia's Total Artificial Heart. To date, 35 patients have been enrolled in the U.S. study, and 23 of these patients have been discharged from the hospital using the Freedom driver. The study requires that 30 patients be discharged.

In November, the company formed SynCardia Systems Europe GmbH in Bad Oeynhausen, Germany to meet growing demand for the Total Artificial Heart in Europe. In the U.S., SynCardia recently expanded its sales and clinical support staff, hiring four regional sales managers and four additional clinical support specialists.

In 2011, SynCardia was honored with multiple awards:

- #20 in Fast Company's annual list of the "World's 50 Most Innovative Companies"
- #77 in Forbes' list of "America's Most Promising Companies"
- "2011 Arizona Bioscience Company of the Year" by the Arizona BioIndustry Association
- 1 of 6 finalists for the "2011 World Technology Award in Health and Medicine" by the World Technology Network in association with TIME, Fortune, CNN, Science/AAAS and Technology Review

*CAUTION – The Freedom portable driver is an investigational device, limited by United States law to investigational use.*

### **About the SynCardia temporary Total Artificial Heart**

SynCardia Systems, Inc. (Tucson, AZ) is the privately-held manufacturer of the world's first and only FDA, Health Canada and CE approved Total Artificial Heart. Originally used as a permanent replacement heart, SynCardia's Total Artificial Heart is currently approved as a bridge to transplant for people dying from end-stage biventricular heart failure. There have been more than 950 implants of the Total Artificial Heart, accounting for more than 230 patient years of life.

Similar to a heart transplant, SynCardia's 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 and does not require expensive anti-rejection medication, which can cause subsequent complications. It is the only device that provides immediate, safe blood flow of up to 9.5 liters per minute through both ventricles. This high volume of safe blood flow helps speed the recovery of vital organs, helping make the patient a better transplant candidate.

### **SynCardia Ranked #20 Among World's 50 Most Innovative Companies**

In March 2011, *Fast Company* magazine ranked SynCardia #20 in its annual list of the "World's 50 Most Innovative Companies" for "giving mobility to artificial heart recipients." Weighing 13.5 pounds, SynCardia's Freedom® portable driver is the world's first wearable driver designed to power the Total Artificial Heart both inside and outside the hospital. The Freedom driver is CE approved for use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the U.S.