Pittsburgh Surgeons Implant New Total Artificial Heart

The Associated Press

Cardiothoracic surgeons at Allegheny General Hospital (AGH) in Pittsburgh have become the first in western Pennsylvania and among an elite group in the world to replace a failing human heart with the latest generation total artificial heart implant, introducing a new, life-sustaining treatment option for the most critically ill patients with end-stage heart failure.

The SynCardia temporary Total Artificial Heart, developed by SynCardia Systems Inc., was implanted into a 62-year-old Pittsburgh man at AGH on Friday, February 17 by a team of cardiac surgeons and physicians from the hospital's Advanced Heart Failure, Transplant and Mechanical Circulatory Support Program.

"We are extremely proud to be the first cardiovascular team in Pittsburgh to offer this revolutionary technology to patients with advanced heart failure. AGH has a distinguished history of pioneering achievements in the treatment of complex cardiovascular diseases and the SynCardia Total Artificial Heart is another significant milestone in that legacy," said George J. Magovern, MD, Chair, Department of Thoracic and Cardiovascular Surgery at AGH and the West Penn Allegheny Health System (WPAHS).

The SynCardia Total Artificial Heart is currently approved by the Food and Drug Administration (FDA) as a bridge to transplant for patients who suffer from end-stage biventricular heart failure, a condition in which both sides of the heart become weakened and cannot pump blood adequately throughout the body. More than 950 have been used in patients worldwide to date.

To implant the SynCardia device, surgeons remove the left and right ventricles and the four natural valves of the heart, leaving the left and right atria, aorta and pulmonary artery intact.

Although transplantation is still the treatment of choice for those with end-stage heart failure who do not respond to other medical or surgical treatments, a shortage of donor organs limits the option of transplantation for many, according to Stephen Bailey, MD, director of AGH's Division of Cardiac Surgery and Surgical Director of Cardiac Transplantation and Mechanical Circulatory Support Program.

More than 3,100 patients are currently waiting for heart transplants in the United States, according to the United Network for Organ Sharing, and the average wait time is 168 days.

"This device can be a life-saving measure for patients whose only other option is an immediate heart transplant," said Dr. Bailey, who led the AGH surgical team that

performed the SynCardia implant procedure.

"The total artificial heart leads to recovery of end organ function in the most critically ill patients, allowing transplantation to be performed when the patient is more stable - which ultimately helps facilitate better outcomes following transplantation," Dr. Bailey said.

Dr. Bailey said AGH's first SynCardia recipient is progressing well and has been added to the heart transplant waiting list.

The SynCardia Total Artificial Heart is powered with air and vacuum provided by a pneumatic driver that weighs more than 400 pounds, requiring patients to remain in the hospital while on the device.

AGH, however, is one of 30 U.S. medical centers participating in the clinical trial of SynCardia's Freedom portable driver, which allows patients using the SynCardia Total Artificial Heart to leave the hospital while waiting for a donor heart. The Freedom driver weighs slightly more than 13 pounds and may be carried by the patient in a backpack or shoulder bag.

Twenty three people in the United States so far have gone home with the lightweight, portable device as participants in the study.

"Patients can live with artificial hearts for a significant period of time, but the goal is to get them a transplant as soon as they are medically ready," said Raymond Benza, MD, Medical Director of AGH's Advanced Heart Failure, Transplantation and Mechanical Circulatory Support Program. "We hope to enroll our patient in the trial of the portable driver so that he can fully recover and resume a reasonably normal lifestyle and activities for as long as it takes until a donor heart becomes available." The longest that a patient has been supported by the SynCardia technology as a bridge to successful heart transplantation was 46 months, according to the company.

About the SynCardia Systems Inc.

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. 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." 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. CAUTION - The Freedom@ portable driver is an investigational device, limited by United States law to investigational use.

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