

VCU leads study of first US portable driver for powering the total artificial heart

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The Virginia Commonwealth University Medical Center is the lead institution in a national clinical trial of technology that will allow artificial heart patients to recuperate, rehabilitate and wait in the comfort of their own homes until a donor heart becomes available for transplant.

The VCU Pauley Heart Center is one of up to 30 centers that will investigate a portable, mechanical driver that can power patients' artificial hearts and enable them to recover outside the hospital environment, including at home and at step-down facilities.

"This is the kind of technology that changes lives," said John Duval, CEO of MCV Hospitals at the VCU Medical Center. "VCU has long been a leader in heart-assist technology, pioneering the implantation of the first Total <u>Artificial Heart</u> on the East Coast in 2006.

"This portable driver, if successful, will allow patients who once had to spend months, and sometimes more than a year in the hospital waiting for a <u>donor heart</u>, to recuperate in the comfort of their own homes," Duval said.

The VCU Medical Center received institutional review board approval in early September to participate in an Investigational Device Exemption (IDE) clinical study of the Freedom driver, the first-ever U.S. portable driver designed to power SynCardia's Total Artificial Heart both inside and outside the hospital. The IDE clinical study is intended to demonstrate that the Freedom driver is a suitable pneumatic driver for



stable Total Artificial Heart patients and can be used safely at home.

"Prior to this, everyone who was placed on a Total Artificial Heart had to remain in the hospital until they underwent transplantation," said Michael Hess, M.D., director of the VCU Pauley Heart Center advanced heart failure transplantation program. "The reason for this is that the only FDA-approved driver system for powering the Total Artificial Heart is a 418-pound console.

"Now this driver - thanks to advances in engineering - is 13 and a half pounds and can be worn in a backpack, and we will be able to discharge stable patients away from the hospital to await their transplant," Hess said.

The SynCardia Total Artificial Heart currently used at the VCU Medical Center is approved as a bridge to human heart transplant for patients dying from end-stage biventricular failure.

The portable driver features two onboard lithium-ion batteries and a power adaptor. It is designed to be carried by the patient in a backpack or shoulder bag. Another participating medical center, Mayo Clinic Arizona, discharged a patient with the driver in May.

Vigneshwar Kasirajan, M.D., chair of cardiothoracic surgery and director of the Pauley Heart Center's heart transplantation program, said he anticipates a two-to-three week period from the time of implant to switchover to the driver and then two weeks to discharge.

"We have already talked with some of our patients about potentially being able to go home with a driver and a lot of the patients are excited by it ... the possibility they could actually go home while they're waiting for a transplant," Kasirajan said. "Right now the average waiting time for a transplant is about three months for patients with the artificial heart, so



I think for patients, it's a great opportunity to be able to go home."

The clinical trial is approved to enroll 60 patients. The VCU Medical Center has one of the best success rates in the country in artificial heart implants, with an approximate 85 percent survival rate among patients since 2006.

Provided by Virginia Commonwealth University

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