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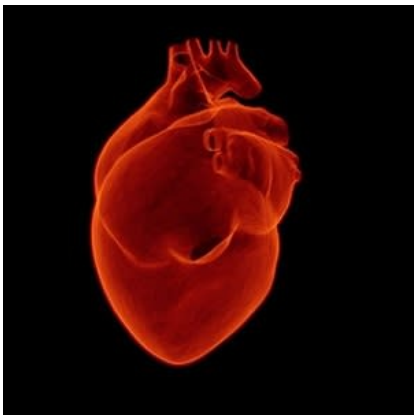
Optimizer® Smart device being tested in new cohort study



Thomas Jefferson University has announced implantation of the first Optimizer® Smart investigational device in a patient enrolled in a new study entitled Impulse Dynamics FIX-HF-5CA Continued Access Study. The device implantation was performed by interventional cardiologist Steven Roberts, MD, at Jefferson Torresdale Hospital's Heart Center.

Patients entered into this study will be representative of the patient population with stable, systolic left ventricular dysfunction and moderate-to-severe symptomatic heart failure despite appropriate medical therapy, according to researchers. The protocol is designed to collect adverse safety events, quality of life data and data needed for comparison with long-term mortality prediction models.

"The continued access study allows us to implant the device in a population of patients that we've never had a device for," explains Dr. Roberts, a Clinical Assistant Professor at Jefferson (Philadelphia University + Thomas Jefferson University). "It is particularly rewarding to offer academic level care in a community hospital setting – bringing the latest in cardiovascular interventions to patients close to home."

Unlike a traditional pacemaker, the Optimizer® Smart works by strengthening the heart's pump, which prevents backflow of blood into the lungs and reduces shortness of breath that heart-failure patients often experience. Although there are pacemakers in use today that also strengthen the pump, they can only be used in hearts with poor electrical conductance. The Optimizer® Smart serves a population of patient whose only current options are medicinal control of symptoms.

The device, manufactured by Impulse Dynamics, is limited to Investigational use only in the United States.

The Optimizer® Smart is designed to treat patients with moderate to severe heart failure generally characterized by NYHA Class III and IV symptoms and having a left ejection fraction measuring between 25 and 45 percent (inclusive). The device delivers cardiac contractility modulation therapy, a therapy that delivers non-excitatory CCM™ pulses that increase the pumping performance of the heart without influencing the heart rhythm. Research results suggest that CCM™ promotes increased expression and improved function of certain proteins in the heart muscle that play a key role in the contractility of the heart muscle cells. The CCM™ pulses are delivered during five 1-hour periods spaced equally throughout the day and generally go unnoticed by the patients.

The Optimizer® system has been implanted in over 3,500 patients and is currently available in Europe and several other countries around the world. The device maker has completed numerous

clinical studies, including several randomised controlled trials. The results have been published in over 70 publications in leading medical journals.

Source: Thomas Jefferson University
Image Credit: Pixabay

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