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UNIVERSITY OF PITTSBURGH MEDICAL CENTER SURGEONS IMPLANT HEARTMATE II HEART ASSIST DEVICE AS PART OF U.S. TRIAL

**Device's unique blood flow control system was developed at Pitt's McGowan Institute for
Regenerative Medicine**

PITTSBURGH, April 14, 2004 - Surgeons from the University of Pittsburgh Medical Center (UPMC) have implanted the HeartMate II, a new left ventricular assist system (LVAS), in a 22-year-old woman. The implant is the third in the United States as part of a pilot trial sponsored by Thoratec Corporation to test the safety and potential effectiveness of the HeartMate II.

The device is a miniature rotary pump with axial flow bearings and is intended for patients with end-stage heart failure. A key feature of the design is a sophisticated control system developed by researchers at the University of Pittsburgh's McGowan Institute for Regenerative Medicine that senses when to increase or decrease the rate of blood flow. Other approved and experimental devices require manual adjustments.

The operation took place on April 7 and was performed by a team led by Robert L. Kormos, M.D., professor of surgery at the University of Pittsburgh School of Medicine, director of UPMC's Artificial Heart Program and medical director of the McGowan Institute.

UPMC is one of four centers that will test the device in seven patients who are candidates for heart transplantation. The device will be evaluated initially for use as a bridge to heart transplantation, but its



developers see its eventual use for long-term support. Other centers that have implanted the device are the Texas Heart Institute in Houston and LDS Hospital in Salt Lake City.

The control system developed by University of Pittsburgh researchers involves a patented algorithm that permits the LVAS to respond to the needs of the patient based on the level of activity, generating up to 10 liters of blood flow per minute, a rate that would be required to climb stairs, for example. The controller was the brainchild of James Antaki, Ph.D., a member of the McGowan Institute who is associate professor of biomedical engineering and computer science at Carnegie Mellon University and associate professor of bioengineering and surgery at the University of Pittsburgh.

"This algorithm is essentially the intelligence of the system. Engineers don't need to stand at the patient's side in order to adjust the device to one of a few fixed settings, which is the case with other devices, even newer ones in trials. We are especially proud of this contribution to the design of HeartMate II," noted Dr. Kormos, who is principal investigator of the Pittsburgh site of the HeartMate II trial.

The University of Pittsburgh became involved in development of the device about eight years ago when it and Nimbus Inc. entered into a five-year contract with the National Institutes of Health to conduct studies of what was then called the Nimbus pump. The pump was among the first axial flow devices; instead of mimicking the heart's pumping mechanism, the Nimbus pump was designed as a much smaller rotary device that results in continuous flow of blood. In 1996, Thermo Cardiosystems Inc. acquired Nimbus, at which time the device became known as HeartMate II. In 2001, Thermo Cardiosystems merged with Thoratec Corp. The University of Pittsburgh has worked closely with the three companies, performing a large portion of the research and development.

As an axial flow device, HeartMate II produces no pulsatile action; patients being supported by the device have only minimal pulse. Weighing 12 ounces and approximately 1.5 inches in diameter and 2.5 inches long -- about the size of a D-cell battery -- it is significantly smaller than currently approved devices which weigh closer to 3



pounds. As such, it may be suitable for a wider range of patients, including small adults and children. The design also makes the device quieter and simpler to use.

It is implanted just below the diaphragm and attached between the apex of the left ventricle and the aorta, the main artery that feeds blood to the entire body. A system driver regulates pump speed. When implanted, HeartMate II takes over most of the function of the left ventricle, the heart's main pumping chamber, and helps generate the force necessary to propel oxygen-rich blood throughout the body. Without such circulatory support, patients are unable to produce blood flow adequate to meet their body's metabolic needs.

Heart failure accounts for more than 250,000 deaths in the United States each year. There are currently about 3,500 patients on the national heart transplant waiting list. According to the United Network for Organ Sharing, 506 patients died waiting for a heart transplant in 2003.

UPMC's Artificial Heart Program has supported more than 275 patients on assist devices for a period of time that equates to more than 60 years. The program often serves as both a proving ground for manufacturers and a training center for surgeons from around the world. Devices that UPMC has used over the years include the Jarvik/Cardiowest Total Artificial Heart, Novacor Left Ventricular Assist Device (LVAD), Thoratec VAD and HeartMate I, making it one of the most experienced and active programs in the United States.

Known also for its aggressive work to enable patients on devices to be discharged to the home setting, UPMC was the first center to discharge a patient still on a device to await a human donor outside the hospital. Based on UPMC's experience, the U.S. Food and Drug Administration later allowed patients implanted with the Novacor to be discharged to home to await heart transplant.

Established by the University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center, the McGowan Institute of Regenerative Medicine has a broad mission to develop a premier facility for clinical care, teaching and research in regenerative medicine, including organ and tissue engineering, artificial organs and cellular and other regenerative therapies. A collaborative relationship with the Bioengineering



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Program at the University of Pittsburgh School of Engineering provides the basis for unique partnerships between clinical and engineering specialties.