

The Stern Cardiovascular Center Seeks Heart Failure Patients For Investigational Study

The Stern Cardiovascular Center announced it is enrolling patients in



Dr. Frank A. McGrew

a clinical research study to investigate the safety and effectiveness of a new implantable pulse generator called the Optimizer™. The Optimizer™ System is designed to deliver electrical impulses to the heart for treatment of moderate to severe heart failure. This



Dr. Mark A. Coppess

study of the Optimizer System is sponsored by Impulse Dynamics (USA) Inc., a specialty medical device company located in New York and a



Dr. Eric E. Johnson

wholly-owned subsidiary of Impulse Dynamics N.V.

Heart failure is a disease that afflicts over 5 million Americans and an estimated 15 million patients worldwide. It is one of the most common causes of hospitalization and a growing and costly burden to the healthcare system. It is estimated that the U.S. healthcare system will spend a projected \$29.6 billion on caring for heart failure patients in 2006.

Heart failure is a disease caused by weak or damaged heart muscle that is unable to pump enough blood throughout the body. If proven safe

and effective, the Optimizer System has the potential to help treat heart failure in a large number of patients.

“In spite of the advances made over the last 15 years, heart failure remains a common cause of death or disability. This project tests one of the most exciting potential advances in the device therapy field,” said Dr. Frank McGrew, principle investigator of the Optimizer trial. “This novel therapy stimulates the heart as it is beating, which appears to make the heart beat more strongly. It could really make a positive impact in the quality of life for millions of people who suffer from heart failure.” Unlike a pacemaker, the Optimizer signals do not initiate a heartbeat; rather, its signals are intended to enhance the strength of the heart.

Dr. Frank McGrew is the Principal investigator for this project. Drs. Eric Johnson and Mark Coppess are sub-investigators. Dr. McGrew is the heart failure specialist whereas Drs. Johnson and Coppess are implanting physicians and implant the Optimizer devices.

Symptoms of heart failure result when the heart that is unable to pump enough blood to meet the energy needs of the body. A failing heart most often results from damage to the heart muscle due to injuries such as heart attack, untreated coronary artery disease or persistent high

blood pressure. It can also occur as a result of genetic and/or molecular abnormalities or infections. The most common forms of heart failure are treated with drugs and electrical devices such as pacemakers and implanted defibrillators, but if symptoms continue to worsen, other therapies are needed.

The Stern Cardiovascular Center provides state-of-the-art diagnostics and treatment of all aspects of cardiovascular disease; including hypertension, coronary artery disease, congestive heart failure, cardiac valve disorders (including mitral valve prolapse), myocardial infarction, cardiac hyperlipidemia, arteriosclerosis, and atherosclerosis. Stern Cardiovascular provides a team approach to preventative care, diagnosis, and treatment of Cardiovascular Disease which involves Physicians certified in Cardiovascular Medicine, Nurse Practitioners who hold advanced degrees in acute care nursing, Registered Nurses specially trained in cardiology, Medical Assistants specially trained to assist our Physicians, and Registered Diagnostic Technicians and Certified Laboratory Technicians to administer the sophisticated testing required to diagnose the complexities of Cardiovascular Disease. For more information about this important study, call 901-271-1000.

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