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News release on Transmyocardial Revascularization (TMR) procedures

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MILWAUKEE, Wis., November 19, 1992 -- St. Luke's Medical Center in Milwaukee announced today the use of a high-powered laser to create new blood flow channels in the beating heart of a 58-year-old Milwaukee man, suffering from heart disease so extensive that bypass surgery was not possible.

This intense carbon dioxide laser, named The Heart Laser, is manufactured by Laser Engineering Inc., a subsidiary of Massachusetts-based PLC Systems Inc. (AMEX: PLC, PLCE), following 20 years of research by St. Luke's heart surgeon Mahmood Mirhoseini, M.D. Mirhoseini's procedure creates channels that mimic the functioning of reptile hearts, which do not depend upon arteries to circulate blood. Instead, blood seeps through tiny spaces in the myocardium, or outer heart muscle to nourish the heart.

It was Mirhoseini's idea to use a laser to open channels in the human heart to restore oxygen-rich blood flow. This procedure, known as Transmyocardial Revascularization (TMR), creates new channels for blood to flow through the heart muscle.

"Many patients suffering from heart disease are not eligible or do not respond to bypass surgery, angioplasty and/or medication management," said Mirhoseini. "We anticipate this laser technique could offer new hope to approximately 300,000 Americans who currently have no avenue of treatment for their disease."
Mirhoseini began exploring the use of lasers to increase blood flow to the heart in the late 1960s, prior to the widespread use of heart bypass surgery. In addition to the experimental work, clinical studies were done to evaluate the safety and effectiveness of laser channels in the heart. Mirhoseini used a low-powered carbon dioxide laser in conjunction with bypass surgery. At the same time he guided the development of PLC Systems' high-powered laser that could open blood circulation channels while the heart was beating. The high-powered Heart Laser alleviates the necessity of placing a patient on a heart bypass machine, dramatically reducing time in surgery.

Surgeons access the heart through a left side chest incision, avoiding the need to cut through the sternum and open the rib cage. PLC Systems' computer-controlled laser fires between the patient's heartbeats. Each laser blast creates a permanent channel between the damaged area and the left ventricle. Oxygen-rich blood from the chamber now can reach, and constantly infuse, the damaged tissue, improving its function.

About 15 channels, each the size of a pencil lead, are created. The laser fires when the left ventricle is full of blood. This prevents the laser beam from continuing through the heart, because carbon dioxide laser energy is absorbed and dispersed by liquid. The laser's outer entry points into the myocardium close naturally, while the interior channels into the left ventricle remain open.

Mirhoseini's first patient underwent the two—hour surgery Tuesday, and a second surgery was performed today. The patients are expected to remain hospitalized for an average of five days following surgery.

From Mirhoseini's early TMR work that accompanied bypass surgery, 18 of the 20 patients with end-stage heart disease remain alive today, an average of six years after the laser surgery. Two of the patients subsequently died of unrelated causes. Autopsy results revealed the laser channels had remained open and formed vessel-like walls.

St. Luke's Medical Center is one of four U.S. hospitals approved for Phase II clinical trials of PLC Systems' Heart Laser System. The other three U.S. hospital locations for the 50 FDA approved TMR procedures, are: San Francisco Heart Institute, Texas Heart Institute, in Houston, Brigham & Women's Hospital in Boston.

PLC Systems Inc. develops, manufactures and markets medical laser systems, accessories and related surgical products.

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