



News Release

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Study demonstrates “therapeutic value of *Muscular CounterPulsation (MCP)* after coronary bypass grafting operation”, which is the basis of Cardiola’s *m.pulse®* system for treating chronic heart failure patients (CHF), non-surgically, at home

Data published in *Journal of Cardiac Surgery*

“Our study leads us to conclude that *Muscular CounterPulsation* represents a new, noninvasive, ECG-triggered circulation support system that is effective for achieving hemodynamic improvement and decreasing postoperative complications while significantly shortening the hospital stay of patients with chronic heart failure.”

Larry V. Lapanashvili, MD, PhD

WINTERTHUR, Switzerland, April 27, 2009—[Cardiola AG](#) announced today that a study (“Therapeutic Value of Muscular CounterPulsation After Coronary Bypass Grafting Operation”) published in the *Journal of Cardiac Surgery* (2009;24:134-140) demonstrates that “MCP (Muscular CounterPulsation) represents a new, noninvasive, ECG-triggered circulation support system, which is effective for achieving hemodynamic improvement via afterload reduction. The use of MCP decreases postoperative complications and significantly shortens the hospital stay.” The study’s principal investigator was **Larry V. Lapanashvili, MD**, a cardiac surgeon at Marji Medical Center, Tbilisi, Georgia.

Coronary artery bypass grafting (CABG) is the operation of choice in patients with severe multiple coronary artery disease. Nonetheless, there continue to be several unresolved issues with the CABG approach, such as treatment of postoperative heart failure following bypass surgery. Consequently, there is significant worldwide interest in evaluating new treatment methods for patients with ischemic heart disease (IHD) undergoing CABG surgery.

In the study by Dr. Lapanashvili (who is a recognized pioneer in MCP), 50 patients (mean age 54) undergoing CABG were randomized into two groups: A control group (20 patients) receiving standard postoperative treatment without counterpulsation, and a treatment group (30 patients) undergoing MCP treatment for 30 minutes daily for the eight initial postoperative days in addition to standard therapy. MCP treatment resulted in a 36 percent decrease of systemic vascular resistance compared to a 16 percent decrease in the control group. Postoperative complications occurred in just one patient of the MCP treatment group and in seven (39 percent) of the control group. In addition, compared to the control group, patients in the MCP treatment group had a 28 percent shorter postoperative hospital stay than in the control group.

“We are very pleased with the results of this study, which demonstrate that MCP—the proprietary technology platform of our patented *m.pulse®* device—facilitates timely and effective therapy, improving clinical outcomes of CHF patients,” said **Christof Lenz, Cardiola’s CEO and former**

Global Innovation Manager at Siemens Medical. “Our *m.pulse*® system offers patients a well-validated, affordable and *non-surgical* treatment alternative that they themselves can perform in their *own home*.”

Cardiola’s *m.pulse*® device, based on ***Muscular CounterPulsation (MCP)*** technology, is approved in Europe for treating chronic heart failure (CHF) as a nonsurgical, at-home therapy. Battery-powered *m.pulse*®, the size of a cell phone that the patient attaches to his belt for about 45 minutes per treatment, is synchronized to his cardiac cycle to stimulate the muscles of the calves and thighs to make them contract *counter* to the heart’s beating. This well-established *counterpulsation* action results in increased blood flow to the heart muscle while decreasing the heart’s workload. Counterpulsation was previously only available in a clinical setting. Now, ***m.pulse*® is the world’s first and only device enabling CHF patients to receive MCP therapy at home.**

CHF is among the world’s most prevalent diseases and the cause of numerous other serious clinical disorders. Approximately 17 million people currently suffer from CHF in Europe, the U.S. and Japan. Some six million of these patients are classified as NYHA (New York Heart Assn.) classes II and III with systolic dysfunction, the primary patient population for ***m.pulse*® with Muscular CounterPulsation** from Cardiola.

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