

# Conclusive EVIDENCE

HEARTFAILURE TYPICALLY DEVELOPS SLOWLY and is a chronic, long-term condition with signs and symptoms that persist: shortness of breath upon exertion or lying down; reduced ability to exercise; fatigue and weakness; and, rapid or irregular heartbeat, among others. Heart failure can involve the left side, right side, or both sides of the heart—although typically heart failure begins with the left side, specifically the left ventricle, the heart's main pumping chamber. But clinical research data indicate that even failing hearts retain the potential for normalization with the proper treatment. Medical devices that mechanically support blood circulation by unloading the heart are well-established at showing beneficial effects. These devices include (a) the invasive **intraaortic balloon pump (IABP)**; (b) the noninvasive **external counterpulsation (ECP)**; and, (c) the various types of surgically implanted **cardiac-assist devices**, in particular, the left ventricular assist devices (LVAD). Both IABP and LVAD require anticoagulation and bear significant interventional risks. And while ECP is noninvasive, it is bulky, must be utilized in a physician's office, and is very uncomfortable for the patient.

## **NEW MUSCULAR COUNTER-PULSATION DEVICE, m.pulse<sup>®</sup>, IMPROVES CARDIAC FUNCTION, CAN BE USED AT HOME**

Cardiola has recently launched its **m.pulse<sup>®</sup>** device in Europe to treat **chronic heart failure (CHF)** patients by improving their cardiac function. The noninvasive m.pulse<sup>®</sup> device consists of an ECG-triggered, portable, battery-powered pulse-generator that contracts muscles in a patient's calves and thighs during the early diastole phase of a heart beat. **A groundbreaking clinical study by Muscular CounterPulsation research pioneer Dr. Larry Lapanashvili demonstrated that CHF patients were able to increase their physical exercise duration by 56%, on average, and their walking distance by 72%, on average, after only eight consecutive days of 30-minute treatments with m.pulse<sup>®</sup>.**

## **BREAKTHROUGH: AT-HOME, NON-INVASIVE TREATMENT FOR CHF WITH ALMOST NON RISK, AT A LOW PRICE: m.pulse<sup>®</sup>**

"Essentially, Cardiola has transformed a highly invasive yet effective CHF treatment into a completely noninvasive and effective CHF treatment that can be performed in a patient's own home," says **Cardiola CEO Christof Lenz, previously an executive with Siemens Medical**. "In Europe the protocol is home treatment for 45 minutes daily for the first month, and then three or four times a week thereafter. Of course, individual adjustments will be made by the patient's physician, as well as regular parameter-monitoring by the physician. The potential for m.pulse<sup>®</sup> is quite staggering," adds Lenz, "particularly in light of the fact that the product is designed such that there is no risk of undesirable side effects."

### **INTERNATIONAL JOURNAL OF CARDIOLOGY**

2009, submitted

#### **Safety and Efficacy of ECG-Triggered Muscular CounterPulsation for Hemodynamic Improvement of Cardiac Function**

*MCP is safe and efficient for improving cardiac function in patients with ischemic heart disease (IHD). The technique is completely noninvasive and simple to use, with a battery-powered microprocessor-controlled portable pulse generator*

Beat H. Walpoth, M.D.  
Dept. of Cardiovascular Surgery,  
University Hospital, Geneva, Switzerland

### **JOURNAL OF CARDIAC SURGERY**

2009

#### **Therapeutic Value of Muscular CounterPulsation after Coronary Bypass Grafting Operation**

*MCP represents a new, noninvasive, ECG-triggered circulation support system. MCP significantly reduces systemic vascular resistance and, thus, is highly effective for hemodynamic improvement by reducing afterload.*

Leo A. Bockeria, M.D.  
Bakouley Scientific Center for  
Cardiovascular Surgery, Moscow, Russia

### **THE INTERNATIONAL JOURNAL OF ARTIFICIAL ORGANS**

2008

#### **ECG-Triggered Skeletal Muscle Stimulation Improves Hemodynamic Performance and Physical Performance of Heart Failure Patients**

*Earlier clinical data have indicated that even failing hearts retain a potential for normalization ... MCP represents a promising, noninvasive CHF treatment option that unloads the heart and improves exercise performance after just 8 days.*

Beat H. Walpoth, M.D.  
Dept. of Cardiovascular Surgery,  
University Hospital, Bern Switzerland

