MEDICAL DEVICE DAILY™
THE DAILY MEDICAL TECHNOLOGY NEWSPAPER
THURSDAY, DECEMBER 11, 2003 VOL. 7, NO. 239 PAGE 1 OF 9

Cook granted an IDE for thoracic endovascular graft

By HOLLAND JOHNSON
***Medical Device Daily* Senior Staff Writer**

The FDA has granted **Cook** (Bloomington, Indiana) an investigational device exemption for a pivotal clinical investigation of its endovascular graft for thoracic aortic aneurysms (TAA).

The company received conditional approval to begin a clinical trial of its Zenith TX2 Thoracic TAA Endovascular Graft involving 140 subjects at 20 U.S. medical institutions, and patient enrollment will begin soon, company officials said. A larger study may be permitted following FDA approval of modifications to the company's proposed clinical protocol.

"Coronary stents have been among the most dramatically successful medical device innovations in the last decade, and we believe the opportunity for vascular grafts is at least as exciting," Kem Hawkins, president and chief

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Study: Living, health costs will exceed retiree income by 2030

By KEVIN NEW
***Medical Device Daily* Washington Editor**

WASHINGTON – U.S. retirees probably won't be able to cover their basic living expenses and the cost of nursing home and home healthcare by the year 2030.

That assessment, which is from a recent study from the **Employee Benefit Research Institute** (EBRI; Washington) and the **Milbank Memorial Fund** (New York) foundation , gives credence to estimates earlier this week from economists at the Congressional Budget Office that rising healthcare costs will drastically affect the nation's seniors. Researchers concluded that by 2030, U.S. retirees will have a combined $45 billion shortfall in annual income than what's required to cover their expenses.

The $45 billion represents "what the federal and state governments will have to come up with to pay for care for retirees, unless there is some breakthrough in medical costs

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Report from Europe

NHS Care Records to bring a 'revolution' in healthcare

A *Medical Device Daily* Staff Report

Describing the effort as "a revolution in health and care information," the UK government this week announced a program intended to result in every **National Health Service** (NHS) patient in England having an electronic care record by the end of this decade.

British Telecom (BT) was awarded a 10-year contract earlier this week to set up and run the national NHS Care Records Service. Under that contract, valued at £620 million, BT will provide the infrastructure for a service that will provide 50 million persons served by the NHS with an individual electronic patient record.

Those records will outline treatments and care received under either England's health or social care programs, and for the first time, such information will be mobile, like the patients themselves.

The NHS Care Records Service will connect more than 30,000 general practitioners and 270 acute, community

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CardioLa MCP device improves efficiency of damaged hearts

By DON LONG
***Medical Device Daily* Managing Editor**

A firm in Switzerland has developed a new non-invasive, portable device that delivers, in a proprietary manner, low-voltage stimulation impulses to the patient's skeletal muscles through adhesive electrodes to improve the efficiency of even the most damaged hearts.

Development-stage firm **CardioLa** (Winterthur, Switzerland) calls its new technology Muscular CounterPulsation (MCP), a short form of "electrical stimulation of skeletal muscles in counterpulsation mode," with this stimulation performed in synchronization with the heartbeat. MCP has been shown to significantly unload the heart and improve the patient's hemodynamics by augmenting early diastolic pressure and reducing afterload, thus increasing overall cardiac efficiency, according to the company.

"Most importantly, a reduction in systemic vascular resistance has also been demonstrated with MCP," Christian Stuerzinger, president and chief executive officer of

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CardioLa

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CardioLa, told *Medical Device Daily*. "Reduction in systemic resistance reduces the heart's workload, as the left ventricle has less to push against and eventually leads to improved pumping function of the heart." MCP also helps give the heart more energy by increasing the blood flow to the heart muscle itself. "But that's just a small part of the story," Stuerzinger said, citing examples of patients able to walk who were previously unable to, as well as general improvements in the quality of life of cardiac patients treated with the system.

The device has received CE marking, and Stuerzinger reported more than 700 patients treated in Europe since 1990. The next step, he hopes, is to find strategic partners to pursue large-scale clinical trials and commercialization, notably in the U.S. "This is our objective," he acknowledged, but one that should prove realistic in light of the positive experience of other, more expensive and bulky counterpulsation systems on the market today.

Stuerzinger said that a key advantage of the CardioLa MCP system is its small size, ease of use and portability. The size of a laptop, it weighs just three pounds, which could be reduced further in large-scale production. Electrical pulses are generated through adhesive electrodes attached to the skin near areas "known for muscle stimulation, typically, the muscles of the lower belly, thigh or lower calf," Stuerzinger said. For synchronization with the patient's heartbeat, the device is connected to a standard ECG machine.

He emphasized the simplicity of CardioLa's MCP approach in two ways – besides its portability, the device "is using a normal part of the body's mechanism of muscle reaction to trigger these effects." In addition to the benefits of external counterpulsation, MCP also provides the advantages of conventional transcutaneous muscle stimulation, quite important since the treatment of cardiovascular diseases is increasingly seen as also involving skeletal muscle therapy. Because it unloads the heart, MCP can be performed without harming the patient.

Russian researchers recently have demonstrated the effectiveness of the device in an acute surgical setting, when they applied the method to 17 patients who were scheduled to undergo coronary bypass surgery. Ten of the patients received the MCP treatment for 15 minutes before being given general anesthesia.

"Within five minutes, peripheral resistance was significantly reduced in the patients who received the MCP treatment, which means that their heart pumped better," said study co-author Larry Lapanashvili, PhD, MD. When compared with a control group, patients who were treated with MCP had a 19% decrease in peripheral resistance, and their stroke index – the normalized volume of blood that goes out of the heart with each heartbeat – also improved. The study was presented at last month's annual meeting of the **American Heart Association** (Dallas, Texas) in Orlando, Florida.

The significance of the study, Lapanashvili said, is that cardiac patients "going into surgery are in better condition for the operation, and their surgical outcome could be much better. The improvement remained even after ending stimulation, and no side effects were observed. Most remarkably, even as a one-time, 15-minute treatment, the MCP method proved effective."

The CE mark was granted to the company this year based on two independent clinical investigations, one by the Swiss Cardiovascular Center at **University Hospital** (Bern, Switzerland), applying MCP to CAD patients in the cathlab, another by the **Bakoulev Scientific Center for Cardiovascular Surgery** (Moscow, Russia). Both studies confirmed the system's ability to bring positive hemodynamic changes, said Leo Bockeria, head of the Bakoulev Center. He also said that other studies are ongoing to understand in more detail the system's underlying mechanism of action, which is believed to combine what he called "mechanical-electrical and neuro-humoral factors."

"The harmless and portable nature of this easy-to-use device opens a whole range of possible applications, including peri-operative settings, in-hospital or outpatient treatment as a stand-alone or adjunctive therapy, or even at the patient's home under medical prescription," Stuerzinger said.

The MCP therapy is indicated mainly for cardiology patients with chronic or acute ischemic heart disease and congestive heart failure, as well as patients suffering from cardiomyopathy, valvular pathology or peripheral vascular disease. Because it immediately unloads the heart, MCP could also be used in emergency situations on acute MI or cardiogenic shock patients.

"The biggest opportunity will be when cardiologists start to prescribe MCP for home use, as they do with drugs," Bockeria said. "This is longer-term, but quite realistic in light of the comparatively low manufacturing costs of the device. MCP will be a true paradigm shift in the way of treating major heart diseases." ■

BRIEFLY NOTED

Nevada bill calls for public-site AEDs

Cardiac Science (Irvine, California), maker of Powerheart automated external defibrillators (AEDs) and provider of AED/CPR training and AED program management services, reported that that Nevada Gov. Kenny Guinn has signed into law State Assembly Bill 441, a homeland security-related legislation, which requires, among other things, the deployment of AEDs in Nevada high schools, colleges, county and state government offices, sporting arenas and airports.

Clark County, Nevada's largest school district, plans for each high school to have an AED coordinator and at least 10 employees trained in both cardiopulmonary resuscitation (CPR) and AED use. The bill requires the AED devices to be deployed by July 1.