Medtronic News

# Medtronic Announces FDA Approval of Consulta(R) and Syncra(TM) Cardiac Resynchronization Therapy-Pacemaker (CRT-P) Systems

*CRT Innovation is the First to Offer Exclusive OptiVol(R) Fluid Status Monitoring with Complete Remote Follow-Up for Proactive Heart Failure Management*

MINNEAPOLIS, Mar 24, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced that the U.S. Food & Drug Administration (FDA) has approved its Consulta(R) and Syncra(TM) cardiac resynchronization therapy-pacemaker (CRT-P) systems. Consulta is the first CRT-P that includes Medtronic's exclusive OptiVol(R) Fluid Status Monitoring, which identifies patients at risk for worsening heart failure before symptoms develop.3-9 Additionally, both Consulta and Syncra are the first CRT-Ps that include Leadless ECG Waveform, which together with the Medtronic CareLink(R) Network device data monitoring system, offer the possibility of remote follow-up in heart failure patients implanted with these devices. Shipments of Consulta and Syncra will begin immediately.

"Atrial arrhythmias are the number one cause of reduced cardiac resynchronization therapy; therefore, there is a real need for next-generation devices that can deliver lifesaving CRT in this patient population," said Robert Canby, M.D., Texas Cardiac Arrhythmia and Seton Medical Center, Austin, TX. "These new innovative technologies allow physicians to proactively manage their heart failure patients, and offer cutting-edge features that contribute to patient safety and physician ease-of-use."

Both next-generation systems are the most comprehensive cardiac resynchronization therapy-pacemaker systems offered by Medtronic, providing fully automatic capabilities and adaptive therapies that help to ensure CRT, even during atrial fibrillation, and enable physicians to monitor their heart failure patients in the office or remotely. Additionally, both systems include unique programming flexibility to avoid phrenic nerve stimulation, which helps prevent the need for more invasive surgical approaches.

While both Consulta and Syncra systems include the same technology, they have differentiating features. Consulta includes Medtronic's exclusive OptiVol Fluid Status Monitoring, as well as Complete Capture Management(TM), which monitors and adjusts to patient needs automatically and can positively impact device longevity and reduce in-office testing.

"We are pleased to offer two unique, next-generation CRT-P options, which provide top-of-the-line features that may benefit hundreds of thousands of heart failure patients and the physicians who treat them," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "These new innovations in the CRT space confirm our commitment to the development of novel, best-in-class cardiovascular technologies that are backed by industry-leading clinical research."

Cardiac resynchronization therapy (CRT), also known as bi-ventricular pacing, is a treatment for heart failure that uses an implantable device to improve the pumping efficiency of the heart. A cardiac resynchronization therapy-pacemaker is a stopwatch-sized device implanted in the upper chest to resynchronize the contractions of the ventricles by sending tiny electrical pacing impulses to the heart muscle via leads (thin wires) to help the heart pump blood throughout the body more efficiently, reduce symptoms and help decrease mortality. Cardiac resynchronization therapy is intended to complement standard drug treatment, and dietary and lifestyle modifications.

Heart failure, which is typically a late manifestation of one or more cardiovascular disease, affects more than 22 million people worldwide, and accounts for nearly $80 billion in cost each year worldwide.1 It is also a leading cause of hospitalization among people aged 65 years and older, and admissions for its symptoms have increased by 15 percent during the past 20 years.2

About OptiVol(R) Fluid Status Monitoring

OptiVol is an exclusive Medtronic technology that measures intrathoracic impedance in heart failure patients using very low electrical pulses that travel across the thoracic cavity (the chest area encompassing the heart and lungs). The system measures the level of resistance to the electrical pulses, which indicates the patient's fluid levels. Used in combination with the Medtronic Cardiac Compass(R) Report, the ability of OptiVol to monitor fluid status over time can provide physicians with important insights in conjunction with ongoing monitoring of other patient symptoms, which may lead to timely clinical intervention. Currently, there are more than 125,000 patients globally implanted with this exclusive technology.

About Complete Capture Management(TM)

Complete Capture Management helps improve patient safety and preserve the longevity of the device by continuously and automatically adjusting the pacing of the device to changing patient physiologic needs. Complete Capture Management also provides flexibility for clinicians so they may eliminate certain manual checks and devote more time to patients, procedures and complex cases.

About the Medtronic CareLink(R) Network and Remote Monitoring

The Medtronic CareLink Network enables clinicians to remotely monitor patients who are implanted with cardiac devices, to help further manage a patient's heart failure. It is the world's largest and most widely used remote monitoring system for implantable cardiac device patients, with more than 4,000 clinics and 500,000 patients enrolled in 30 countries. The CareLink Network has registered more than 2 million patient data transmissions since the service's inception in 2002.

Through this network, patient data are transmitted from their implanted devices using a portable monitor through cellular signals or a standard telephone line. Within minutes, the patient's physician and nurses can view the data on a secure Internet Web site. Available information includes, but is not limited to, OptiVol fluid status, arrhythmia episode reports and stored electrograms, along with device integrity information.

Remote monitoring of devices allows clinicians to quickly and thoroughly review a patient's device information, and facilitate a timely exchange of device information between various physicians involved in treating heart failure patients.

Because patients can transmit critical data from their heart device using a phone line from home, work or while on vacation, they may avoid potentially time-consuming travel to the physician's office for device monitoring. Remote monitoring also may provide peace of mind for the patient and family members, knowing that if a health concern arises between scheduled in-person appointments or remote data transmissions, patients have the option to transmit data for special clinician review, as directed by their physician.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1Medtronic data on file, Jan 2007 *statistics as indicated in the guidelines from the European Society of Cardiology
2 G Yao, N Freemantle, MJ Calvert, S Bryan, JC Daubert, JGF Cleland, "The long-term cost-effectiveness of cardiac resynchronization therapy with or without an ICD: European Heart Journal Advance Access published November 16, 2006
3Yu CM, Wang L, Chau E, et al. Intrathoracic impedance monitoring in patients with heart failure: correlation with fluid status and feasibility of early warning preceding hospitalization. *Circulation.* August 9, 2005;112(6):841-848.
4 Vollmann D, Nagele H, Schauerte P, et al. Clinical utility of intrathoracic impedance monitoring to alert patients with an

implanted device of deteriorating chronic heart failure.*Eur Heart J.* August 2007;28(15):1835-1840.
5 Catanzariti D, Lunati M, Landolina M, et al. Monitoring intrathoracic impedance with an implantable defibrillator reduces hospitalizations in patients with heart failure. *PACE*.March 2009;32(3):363-370.
6 Perego GB, Landolina M, Vergara G, et al. Implantable CRT device diagnostics identify patients with increased risk for heart failure hospitalization. *J Interv Card Electrophysiol*.December 2008;23(3):235-242.
7 Small RS, Wickemeyer W, Germany R, et al. Changes in intrathoracic impedance are associated with subsequent risk of hospitalizations for acute decompensated heart failure:clinical utility of implanted device monitoring without a patient alert. *J Card Fail.* August 2009;15(6):475-481.
8 Abraham WT, Compton S, Haas G, et al. Superior performance of intrathoracic impedance-derived fluid index versus daily weight monitoring in heart failure patients: results of the Fluid Accumulation Status Trial. (FAST). *J Card Fail.* November 2009;15(9):813.
9 Whellan DJ, Ousdigian KT, Al-Khatib SM, et al. Combined heart failure device diagnostics identify patients at higher risk of subsequent heart failure hospitalizations: results from PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients with Heart Failure) study. *JACC.* April 27, 2010;55(17):1803-1810.

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