

Cardica Applies CE Mark to Its MicroCutter XCHANGET 30 Surgical Cutting and Stapling Device

The Associated Press

Cardica, Inc.

(Nasdaq:CRDC), today announced it has applied Conformite Europeene, or CE Mark, to its proprietary MicroCutter XCHANGET 30 surgical cutting and stapling system, or XCHANGE 30, following the completion of design verification. The MicroCutter XCHANGE 30 is a cartridge-based system with a five-millimeter shaft diameter, substantially smaller than current surgical staplers. The MicroCutter XCHANGE 30 is designed for use in laparoscopic and open surgical procedures. Cardica expects to begin its commercial introduction of the XCHANGE 30 in Europe in the second calendar quarter of 2012.

"We have worked closely with leading laparoscopic surgeons to optimize the design, functionality and reliability of the XCHANGE 30, which we believe is a breakthrough in advanced stapling technology," said Bernard A. Hausen, M.D., Ph.D., president and chief executive officer of Cardica. "With a cross-sectional area nearly six times smaller than the smallest stapler on the market today, and almost twice the amount of articulation of currently available products, this product greatly reduces access port requirements, and improves access to internal organs in laparoscopic procedures. We believe the XCHANGE 30 has the potential to improve patient outcomes by reducing scarring and adhesions, inadvertent tissue damage, as well as improving patient recovery time." Cardica's MicroCutter XCHANGE 30 has a substantially smaller shaft diameter than any cutting and stapling device available today, and articulates up to 80 degrees. The device uses reloadable cartridges with a 30 millimeter staple line length. The cartridge comes with either blue staples, for medium tissue thicknesses, or white staples, for thin tissues such as vascular structures. Laparoscopic procedures today are primarily performed through 5 to 10 mm trocars ports. To accommodate conventional stapling technology, however, surgeons are forced to use 12 or 15 mm trocars, which can result in high post-operative pain, port site infection or ventral hernias. These complications can prolong surgical time, delay discharge, and result in unnecessary hospital readmissions. The smaller diameter and much higher articulation of the XCHANGE 30 platform are designed to allow easier access through smaller, less-invasive ports, and to enable faster and easier access to vital organs and tissue for key advanced laparoscopic procedures.

In addition to its European commercial introduction, Cardica expects to resume its European clinical trial with the XCHANGE 30 in the second calendar quarter of 2012 to support a regulatory filing in the United States. The MicroCutter XCHANGE 30 requires regulatory clearance through a 510(k) application process with the Food & Drug Administration and is not yet commercially available in the U.S.

About Cardica Cardica designs and manufactures proprietary stapling and anastomotic devices for cardiac and laparoscopic surgical procedures. Cardica's technology portfolio is intended to minimize operating time and enable minimally-invasive and robot-assisted surgeries. Cardica manufactures and markets its automated anastomosis systems, the C-Port® Distal Anastomosis Systems and PAS-Port® Proximal Anastomosis System for coronary artery bypass graft (CABG) surgery, and has shipped over 38,000 units throughout the world. In addition, Cardica is developing the Cardica MicroCutter XCHANGET 30, a cartridge-based microcutter device with a 5 millimeter shaft diameter, and the Cardica MicroCutter XPRESST 30, a true multi-fire laparoscopic stapling device designed to be used in a variety of procedures, including bariatric, colorectal, thoracic and general surgery. The Cardica MicroCutter XCHANGE 30 and XPRESS 30 products require 510(k) review and are not yet commercially available in the U.S.

Forward-Looking Statements This press release contains "forward-looking statements" including all statements regarding the future development, potential surgical uses, regulatory approval and commercialization of products in Cardica's proposed MicroCutter product line, including the MicroCutter XCHANGE 30, and the timing thereof. Any statements contained in this press release that are not historical facts may be deemed to be forward-looking statements. The words "expects," "believe," "potential" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Cardica's results to differ materially from those indicated by these forward-looking statements, including that the XCHANGE 30 may not ultimately provide the benefits Cardica anticipates; that Cardica may not be successful in its efforts to further develop or commercialize the XCHANGE 30; that Cardica's current and any future products may never gain any significant degree of market acceptance; that any future Cardica products face development, regulatory, reimbursement and manufacturing risks; that Cardica's intellectual property rights may not provide adequate protection; that Cardica's sales, marketing and distribution strategy and capabilities may not be sufficient or successful; and that general business and economic conditions may impair Cardica's ability to market and develop products, as well as other risks detailed from time to time in Cardica's reports filed with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended December 31, 2011. Cardica expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein. You are encouraged to read Cardica's reports filed with the U.S. Securities and Exchange Commission, available at www.sec.gov.

SOURCE Cardica, Inc.

-0- 03/29/2012 /CONTACT: Bob Newell, Vice President, Finance and Chief Financial Officer of Cardica, Inc., +1-650-331-7133, investors@cardica.com /Web Site: <http://www.cardica.com> (NASDAQ-NMS:CRDC) / CO: Cardica, Inc.

ST: California IN: MTC MEQ SU: PDT PRN -- SF78403 -- 0000 03/29/2012 12:00:00 EDT <http://www.prnewswire.c>

Cardica Applies CE Mark to Its MicroCutter XCHANGET 30 Surgical Cutting a

Published on Medical Design Technology (<http://www.mdtmag.com>)

Source URL (retrieved on 01/26/2015 - 10:28am):

http://www.mdtmag.com/news/2012/03/cardica-applies-ce-mark-its-microcutter-xchanget-30-surgical-cutting-and-stapling-device?qt-most_popular=0