Medtronic News

Medtronic Announces 510(k) Clearance for theAquamantys(R)3 System with Combined Hemostatic Sealing and Cutting Functionality

MINNEAPOLIS, Oct 17, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced today that it has received 510(k) clearance from the Food and Drug Administration (FDA) for its Aquamantys(R)3 System as well as the new 8.2L Bipolar Sealer with Cutting and 6.0 Bipolar Sealer hand pieces.

This new advanced energy platform provides the company's patented Transcollation(R) technology and radio frequency (RF) cutting functions to new and existing hand pieces. The new generator offers surgeons and operating room staff enhanced features to improve ease of use, including a graphic user interface and an integrated cassette for simplified setup. The addition of the 8.2L Bipolar Sealer with Cutting provides for the first time a combination of Transcollation technology and cutting capability, which can potentially reduce device exchanges during surgery.

"In the past, surgeons who used Transcollation technology had to use different devices for dissection during surgery," said Dr. Michael Huo, an orthopaedic surgeon at UT Southwestern Medical Center in Dallas, Texas. "With the new Aquamantys3 System and 8.2L Sealer, the need for such change is no longer necessary. The surgeon's needs are addressed with the new device as it provides Transcollation *and* dissection."

Transcollation technology is Medtronic's proprietary combination of radio frequency (RF) energy and saline designed to provide hemostatic sealing of soft tissue and bone during surgery. Intra-operative bleeding can present a number of challenges for surgeons, including impaired visibility and additional operating time. For patients, extensive bleeding often results in the need for blood transfusions.

"By giving doctors the ability to better control intra-operative bleeding through Transcollation, the Aquamantys System has always been a valuable addition in the operating room," said Mark Fletcher, President of Medtronic's Surgical Technologies division. "The new Aquamantys3 platform and the addition of 8.2L makes us even more valuable, and we look forward to the additional opportunities we can offer surgeons on this new product platform."

Transcollation technology has been used in more than 650,000 cases for patients undergoing a variety of surgical procedures, including orthopaedic reconstruction, spine surgery and surgical oncology.

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.

SOURCE: Medtronic, Inc.

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