Medtronic News

Medtronic Expands Pain Therapies Portfolio with the Launch of OsteoCool(TM) RF Ablation System

Minimally-Invasive Procedure Brings Relief to Patients Suffering from Painful Spine Tumors

DUBLIN - January 13, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance and U.S. launch of the OsteoCool(TM) RF Ablation System. For physicians who treat patients with painful spine metastases, the OsteoCool System is the only cooled radiofrequency (RF) ablation technology that offers simultaneous, dual-probe capabilities - providing procedural flexibility and predictable, customized treatment. Cooled RF ablation uses targeted high-frequency energy to destroy cancer cells.

"The most common complaint associated with spine metastases is pain - it's often progressive and significantly reduces the patient's quality of life," said Sandeep Bagla, MD, an interventional radiologist with the Vascular Institute of Virginia in Woodbridge, VA. "With the OsteoCool system, I can now ablate the patient's painful tumor with a reproducible procedure that's appropriate for their unique anatomy."

Metastatic bone disease has been reported to occur in 60-80% of cancer patients, most frequently among patients with primary malignancies of the breast, prostate, liver, and lung.i Seventy percent of metastatic bone cancer patients develop at least one lesion in the spine.ii

"The OsteoCool System expands our Pain Therapies portfolio," said Julie Foster, general manager and vice president of the Pain Therapies business in the Neuromodulation division, which is part of the Restorative Therapies Group at Medtronic. "Our customers treat patients with Kyphon® Balloon Kyphoplasty who also have painful spinal metastases. The OsteoCool system gives physicians a way to treat that pain in a single procedure with a familiar, minimally invasive technique."

In November, Medtronic received expanded indications for Kyphon Xpede® Bone Cement, which now includes clearance for the treatment of microfractures that can be caused by cancer cells breaking down bone (forming osteolytic lesions). Where indicated, the OsteoCool Bone Access Kit can be used for a subsequent, physician-directed procedure such as cementoplasty (i.e., vertebroplasty or kyphoplasty).

Medtronic acquired the OsteoCool technology and associated intellectual property from Baylis Medical on December 16, 2015 and partnered with the company to further innovate the system. Terms of the acquisition were not disclosed.

"We're pleased to be partnering with Medtronic to improve the treatment of patients suffering from spinal metastases," said Kris Shah, president of Baylis Medical. "Our company has a long, established track record of developing innovative clinical solutions. We are excited that this partnership with Medtronic will enhance patient access to our novel spinal tumor ablation technology."

The system is temperature controlled and uses internally water-cooled probes to prevent overheating of surrounding tissue during the procedure. The 17-gauge, bipolar probes are available in three lengths and may be used through a variety of cannula sizes. Because two OsteoCool RF ablation probes can be used simultaneously, the system supports a variety of ablation scenarios accommodating unique patient and procedural needs. The device is currently pending CE marking.

Multimemedia Release

A multimedia version of this release with animation can be found at: https://medtronicmediacap.gcs-web.com/medtronic-expands-pain-therapies-portfolio-launch-osteocooltm-rf-ablation-system

About Baylis Medical Company

Baylis Medical develops and markets high-technology medical devices used in the fields of interventional cardiology, interventional radiology, and spinal procedures. Our vision is to develop and market innovative medical therapies while *Improving the Lives of People Around the World* The company has offices in Montreal and Toronto (Canada), Boston (USA), and London (U.K.). For more information, visit www.baylismedical.com.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

i Schuleman et al. Economic Burden of Metastatic Bone Disease. American Cancer Society 2007.

ii Chow E, Finkelstein JA, Sahgal A, Coleman RE. Metastatic cancer to the bone. In:DeVita VT, Lawrence TS, Rosenberg SA, eds. DeVita, Hellman, and Rosenberg's Cancer: Principles & Practice of Oncology. 9th ed. Philadelphia, Pa: Lippincott Williams& Wilkins; 2011: 2192-2204.

Kyphon Balloon Kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

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