Medtronic News

Medtronic Introduces Signia(TM) Stapling System, Innovative Surgical Stapler for Minimally Invasive Surgery

New Single-Handed Powered Stapling System Provides Real-time Feedback During Surgery1

DUBLIN - Feb. 15, 2017 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) has cleared an expanded indication for the OsteoCool(TM) RF Ablation System. Originally cleared for use in the spine, the FDA now allows the marketing of the OsteoCool System for palliative treatment of metastases in all bony anatomy - such as ribs, sacrum, extremities, and hip - in patients who have failed or are not candidates for standard therapy. The system uses targeted radiofrequency energy to ablate malignant metastatic bone tumors.

"Patients with metastatic bone cancer may be treated with conventional therapies such as opioids, chemotherapy or radiation therapy for pain palliation," said Sandeep Bagla, M.D., an interventional radiologist with the Vascular Institute of Virginia in Woodbridge, Va. "With the expanded indication for the OsteoCool System, I now have the option to ablate these patients' painful bone tumors when conventional therapies are considered ineffective, too slow-acting or cause unacceptable side effects."1

Metastatic bone disease has been reported to occur in 60-80 percent of cancer patients, most frequently among patients with primary malignancies of the breast, prostate, liver, and lung.2 More than 80 percent of bone metastases are found in the axial skeleton, which includes the skull, spine, and ribs.3

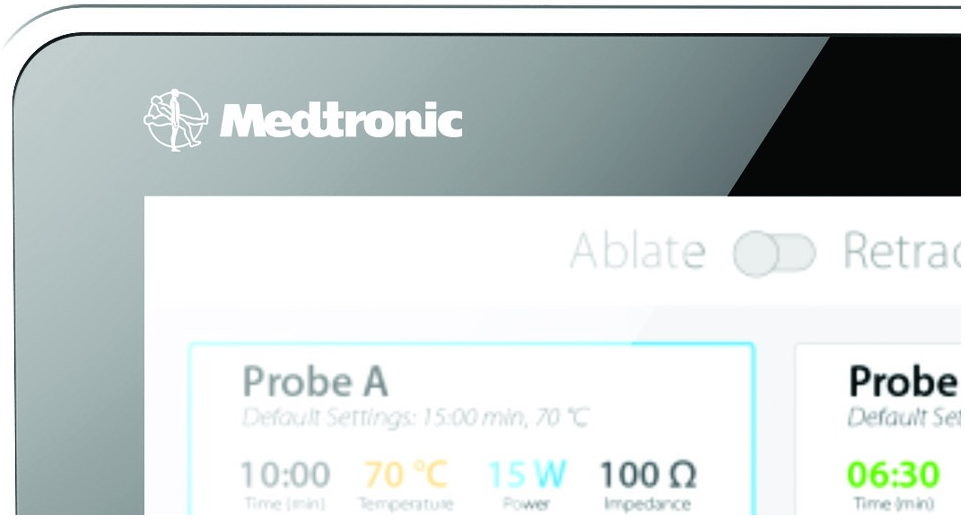
"Our Pain Therapies business is deeply rooted in the Medtronic Mission - which calls us to alleviate pain,"said Jeff Cambra, general manager of the Pain Therapies Interventional business, which is part of the Restorative Therapies Group at Medtronic. "With this expanded indication, we put an important treatment option into the hands of physicians so that they can help more patients suffering from debilitating pain."

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.

"We're pleased to broaden our partnership with Medtronic to improve the treatment of patients suffering from painful metastases," said Kris Shah, president of Baylis Medical. "The expansion of the OsteoCool System to include the ablation of malignant lesions in bone adds to our company's track record of offering innovative clinical solutions and further enhancing patient access and treatment options."

The OsteoCool system is the only cooled radiofrequency (RF) ablation technology that offers simultaneous, dual-probe capabilities - providing for procedural flexibility and predictable, customized treatment. The system is temperature controlled and uses internally water-cooled probes to prevent overheating of surrounding tissue during the procedure.

The device also has a CE mark for the ablation of benign bone tumors such as osteoid osteoma and palliative treatment of metastatic malignant lesions involving bone, including the vertebral body. This indication is not available in the United States.




°C
Active Tip: 20 mm
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50
25
0
40
30
20
10
0
min
0
3
6
9
12
15
Sensor A
Custom Warning: 50 °C
37 °C
Temperature
A





Medtronic's OsteoCool(TM) RF Ablation System
Click the thumbnail above for a larger image.

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), London (U.K.) and Munich (Germany). 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 88,000 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.

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1 Gangi et al. Image-Guided Ablation Therapy of Bone Tumors. Elsevier Inc., 2009.

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

3 Nielson et al. Bone Metastases: Pathophysiology and Management Policy. American Society of Clinical Oncology, 1991.

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