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Medtronic receives FDA clearance for OsteoCool™ 2.0 bone tumor ablation system

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Doubled probe count enables multi-level spine tumor ablations for increased flexibility and efficiency

Medtronic plc, a global leader in healthcare technology, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its OsteoCool™ 2.0 bone tumor ablation system for the treatment of painful bone metastases and benign bone tumors such as osteoid osteoma.

An upgraded design of the OsteoCool™ radiofrequency ablation system brings several new advantages over the previous system. It allows for the simultaneous use of 4 internally cooled probes, enabling physicians to ablate two vertebral bodies at once or create larger ablation zones in extra-spinal applications. OsteoCool 2.0 is the most powerful bone tumor ablation system on the market, delivering 20W per channel, more than twice the power of the Stryker OptaBlate™ bone tumor ablation system (7.5W per channel).[1,2,3,4,5] It also offers the widest selection of probe sizes in the U.S. market with 4 available options.

The OsteoCool platform remains the only bone tumor ablation platform with internally-cooled probes on the market, delivering predictable ablations, reduced risk of excess heating around the lesion site, and proven pain relief.[6,7,8,9,10] The clinically proven technology is backed by OPuS One, the largest study of RF ablation in bone metastases, which demonstrated swift (within 3 days), significant, and sustained (through 12 months) improvements in pain relief for cancer patients.[10]

“Patients with metastatic disease to the spine often experience severe pain that significantly decreases their quality of life,” said Dr. Jonathan Morris, neuroradiologist at Mayo Clinic in Rochester, MN. “OsteoCool 2.0 builds upon our years of experience with the previous generation, better enabling me to relieve pain in those suffering and return them to their normal activities.”

For patients with metastatic cancer, between 60-80% may develop bone tumors. These are found most frequently among patients with primary malignancies of the breast, prostate, and lung.[11,12]

Metastatic bone tumor ablation involves a minimally invasive procedure using probes to deliver radiofrequency

energy that heats and destroys the tumor while circulating water to cool the probes in close proximity to the active tip, to avoid excess heating.

"OsteoCool 2.0 is a welcome upgrade to our interventional portfolio and further cements our status as offering the most innovative and comprehensive pain management portfolio in the industry," said David Carr, vice president and general manager, Pain Interventions within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic.

Medtronic will initiate a limited market release of OsteoCool 2.0 immediately, with a broad U.S. market launch planned for later this calendar year.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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

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[1] IFU, OsteoCool Ablation Probe Kit, M708348B507E REV. D

[2] Stryker OptaBlate™ RF Generator System IFU 700001075365 Rev-AC

[3] Merit MetaSTAR™ RF Generator IFU 403321001_001

[4] IFU, OsteoCool 2.0 Generator, M333023W691E REV. A

[5] Clarivate Interventional Oncology Devices Market Insights United States report, December 2022.

[6] Based on internal data: ETR 31100966, OsteoCool Ablation Size Testing Report, 18 samples. 2015

[7] Based on internal data: ETR 31100961, RF-Ablation Bench Test, Armstrong Project, 12 samples. 2015.

[8] UC201605782fEN OsteoCool Surgical Technique Guide FY22

[9] IFU, OsteoCool Ablation Probe Kit, M708348B507E REV. D

[10] Levy J, David E, Hopkins T, et al. Radiofrequency Ablation Provides Rapid and Durable Pain Relief for the Palliative Treatment of Lytic Bone Metastases Independent of Radiation Therapy: Final Results from the OsteoCool Tumor Ablation Post-Market Study. Cardiovasc Intervent Radiol. 2023;46(5):600-609. doi:10.1007/s00270-023-03417-x

[11] Kurup and Callstrom. Ablation of Skeletal Metastases: Current Status. J Vasc Interv Radiol 2010; 21:S242-S250.

[12] Schulman KL, et al. Economic burden of metastatic bone disease in the U.S. Cancer. 2007;109(11):2334-2342.

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