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Proposed Infuse™ TLIF indication granted Breakthrough Device designation by FDA

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Medtronic, a global leader in medical technology, announced today that it has received U.S. FDA Breakthrough Device designation for Infuse™ bone graft with an intervertebral fusion device and a commercially available metallic screw and rod system. This designation pertains to the use of Infuse™ bone graft in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2 – S1 in the treatment of degenerative disease of the lumbosacral spine. The FDA Breakthrough Devices Program is intended to accelerate the development, assessment, and review of new technologies to treat irreversibly debilitating conditions more effectively.

"We appreciate the FDA's recognition that Infuse™ has the potential to raise the standard of care in TLIF. With this designation, our goal is to broaden the availability of this established technology, reaching more patients affected by debilitating spine conditions," said Michael Carter, vice president and general manager of Spine and Biologics within the Cranial and Spinal Technologies business, which is part of the Neuroscience Portfolio at Medtronic. *"By expanding access to Infuse™, we aim to empower healthcare providers with effective tools to address the challenges posed by degenerative spine conditions. Ultimately, our mission is to enhance the quality of life for individuals suffering from these conditions, fostering a future where patients can enjoy improved mobility and comfort."*

Medtronic is currently enrolling patients in a prospective, randomized clinical trial for the use of Infuse™ in a TLIF approach at one or two adjacent levels from L2-S1. The trial aims to provide clinical evidence to demonstrate safety and effectiveness sufficient for expanding indications in TLIF. *"Over the past two decades, Infuse™ has become an important and trusted technology in modern spine surgery and Medtronic's goal is to provide greater access for surgeons and patients. We are pleased to receive Breakthrough Device designation and look forward to continued collaboration with FDA as we broaden the clinical evidence regarding the safe and effective use of Infuse™ and pursue approval of new indications,"* said Dave Breiter, vice president of Regulatory Affairs, Clinical Research, Medical Science, and HEPR (Health Economics, Policy, and Reimbursement).

Infuse™ bone graft has received FDA approval for specific spine, oral-maxillofacial, and orthopedic trauma procedures. In spine surgery, it is utilized with select Medtronic interbody fusion devices for individuals with

degenerative disc disease alleviating donor site pain by negating the necessity of harvesting bone from the patient's body through a secondary surgical intervention [1].

The use of Infuse™ bone graft in TLIF procedures is investigational only.

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 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.

References

1. Burkus et al. J Spinal Disord Tech. 2002;15(5):337-349.

https://news.medtronic.com/2024-05-29-Proposed-Infuse-TM-TLIF-indication-granted-Breakthrough-Device-designation-by-FDA