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# Medtronic achieves major milestone in INFUSE™ Bone Graft for TLIF Study, paving the way for new spine procedure indication

Medtronic, a global leader in healthcare technology, has announced a significant milestone in its INFUSE™ Bone Graft for TLIF Investigational Device Exemption (IDE) Study, a randomized controlled trial of INFUSE™ Bone Graft in the Transforaminal Lumbar Interbody Fusion (TLIF) procedure used in spine surgery. Following the first interim analysis, the independent Data Monitoring Committee (DMC) determined that the study met the predefined criteria for early success. Based on this assessment, the DMC recommended stopping further enrollment. Medtronic is now in the process of preparing a Premarket Approval (PMA) submission to the U.S. Food and Drug Administration (FDA).

**Study overview and protocol amendment**

The INFUSE™ Bone Graft for TLIF study is a prospective, multicenter, randomized controlled trial conducted under an IDE. The study is designed to evaluate the safety and effectiveness of INFUSE™ Bone Graft in TLIF procedures for patients with degenerative lumbar spine conditions. In April 2025, FDA approved a protocol amendment which reduced the overall sample size and introduced a Bayesian adaptive design to enable interim analysis of study endpoints. The study design continued the evaluation of two dose levels of INFUSE™ Bone Graft and incorporated both PEEK and titanium cages to support broader clinical applicability.

**Breakthrough designation accelerates progress**

INFUSE™ Bone Graft for the TLIF indication received Breakthrough Device Designation from the FDA in April 2024. This designation is intended for devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions and that represent breakthrough technologies or offer significant advantages over existing alternatives. The designation supports prioritized review and enhanced interaction with the FDA throughout the development and regulatory process.

**Advancing spine care**

This potential new indication for INFUSE™ Bone Graft could expand treatment options for spine surgery patients if approved. TLIF is a spinal fusion procedure used to stabilize the lower back and alleviate pain caused by

degenerative disc disease or disc herniation. It involves removing a damaged disc, placing a spacer (cage) with bone graft material, and using screws and rods to fuse the adjacent vertebrae.

**What's Next**

While this milestone is a significant achievement, there is still work to be done to make INFUSE™ Bone Graft for TLIF commercially available. The FDA PMA process requires rigorous evaluation to ensure the safety and effectiveness of the product. Medtronic is fully committed to navigating this process with speed, efficiency, and accuracy. The study's innovative design, which includes a diverse dataset with contributions from international patients, represents a unique opportunity to demonstrate the broad applicability of INFUSE™ Bone Graft for TLIF.

"Our teams are deeply dedicated to seeing this process through to completion," said Dave Breiter, vice president of Clinical, Medical, Regulatory Affairs and Health Economics for the Cranial & Spinal Technologies business, which is part of the Neuroscience Portfolio at Medtronic. "We are prepared to work collaboratively with the FDA to address all aspects of the PMA submission and ensure we deliver a high-quality application that meets the highest standards."

Medtronic remains steadfast in its mission to bring this transformative technology to patients as quickly and responsibly as possible. The company is also preparing to file for New Technology Add-on Payment (NTAP) with the U.S. Centers for Medicare & Medicaid Services (CMS) shortly after submitting the PMA, further enhancing the economic value of this innovation for payers and providers.

**About the Cranial & Spinal Technologies Business at Medtronic**

As the global market leader, Medtronic Cranial and Spinal Technologies is transforming the standard of care in spine and cranial surgery by putting patients first and addressing the complex challenges faced by spine and neurosurgeons. With a portfolio of 150 products covering more than 20 pathologies, we serve over 4 million patients annually. Building on a legacy of innovation, our AiBLE™ ecosystem integrates advanced technologies, data and AI with a patient-centric approach, offering customizable solutions to enhance surgical precision, improve workflow efficiency, and achieve better outcomes, before, during and beyond surgery.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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, 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 Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

*The use of INFUSE™ Bone Graft for TLIF is investigational only and has not been approved or cleared by the U.S. Food and Drug Administration*

*The Infuse™ Bone Graft/Medtronic Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. Patients receiving the Infuse™ Bone Graft/Medtronic Interbody Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the Infuse™ Bone Graft/Medtronic Interbody Fusion Device.*

**Contacts**:

Christine Stewart
Public Relations
+1-269-377-2557

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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