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Medtronic Announces FDA approval of Infuse™ bone graft for one-and-two level Transforaminal Lumbar Interbody Fusion (TLIF) spine procedures

Infuse™ is the only PMA-approved growth factor bone graft indicated for ALIF, OLIF, and TLIF

February 17, 2026 – Medtronic, a global leader in healthcare technology, today announced U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for the use of INFUSE™ Bone Graft in Transforaminal Lumbar Interbody Fusion (TLIF) procedures at one or two levels from L2–S1, with both PEEK and titanium interbody cages. This approval expands the versatility of INFUSE™, making it the only PMA-approved growth factor bone graft for ALIF, OLIF, and now TLIF—and the only growth factor bone graft product approved for spine fusion, including 2-level constructs for TLIF.

Breakthrough Device Designation and Evidence-Driven Evaluation

The TLIF indication for INFUSE™ received FDA Breakthrough Device Designation in April 2024, recognizing its potential to offer more effective treatment options for patients with degenerative lumbar spine conditions. This designation supported enhanced FDA engagement and contributed to a prioritized review timeline. Medtronic submitted a panel-track PMA application on August 18, 2025. The FDA approved the application 180 days later on February 13, 2026—underscoring the strength and quality of the clinical evidence supporting INFUSE™ for TLIF.

"Every patient considering TLIF places tremendous trust in us during one of the most challenging moments of their lives, and they deserve the very best chance at healing and returning to the life they love," said **Joseph Smucker, M.D., Indiana Spine Group (Indianapolis, IN), and Global Investigator for the INFUSE™ TLIF Study**. *"Expanding INFUSE™ Bone Graft to this widely used procedure brings a biologic solution that reliably supports the body's natural healing process—an advancement grounded in years of rigorous study and a deep commitment to improving outcomes for patients and families everywhere."*

Strong Clinical Evidence and Early Stopping for Success

The PMA approval is supported by a prospective, multicenter, randomized controlled clinical study evaluating one- and two-level TLIF procedures. 493 patients were randomized 1:1:1 into three groups:

- INFUSE™ Bone Graft 2.1 mg/level
- INFUSE™ Bone Graft 4.2 mg/level

• Local Bone Autograft

A 2025 FDA-approved protocol amendment incorporated a Bayesian adaptive design. Following the first interim analysis at 480 treated patients, the Independent Data Monitoring Committee determined that the primary endpoints were met for both INFUSE™ dose groups and recommended stopping further enrollment. Patient follow-up continues to support comprehensive long-term data.

In the study, INFUSE™ achieved fusion rates exceeding 90 percent in single-level TLIF and demonstrated comparably strong results in two-level constructs. Patients also showed earlier radiographic evidence of radiographic fusion compared to autograft, which may help reduce hardware stress and postoperative complications.

"The FDA approval of INFUSE™ Bone Graft for TLIF is a major step forward for spine care," said **Christopher I. Shaffrey, M.D.**, neurosurgeon, Medtronic consultant, and independent expert in complex spine surgery who was not involved in the trial. "The strength of the clinical data, the versatility across levels and implant types, and the consistency of outcomes provide surgeons with a highly validated option for complex fusion cases. Having a PMA-approved biologic solution available for ALIF, OLIF, and now TLIF enhances our ability to tailor treatment to the individual needs of each patient."

Advancing Spine Care With a Proven, Flexible Solution

TLIF is one of the most commonly performed lumbar fusion procedures for patients with degenerative disc disease, disc herniation, or spinal instability. With this approval, INFUSE™ Bone Graft can now be used as an option in indicated TLIF procedures, including with titanium or PEEK cages—static or expandable—and in 2-level constructs. The approval also supports use in patients with up to Grade 2 spondylolisthesis or Grade 2 retrolisthesis and offers multiple dose options to match graft volume to case demands. INFUSE™'s radiolucent profile improves postoperative imaging, and its handling characteristics support consistent, efficient placement in the operating room.

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.

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