Medtronic News

Medtronic Announces New Clinical Trial to Study Infuse Bone Graft in TLIF Spine Procedures

Medtronic Continues to Invest in Scientific Evidence for Expansion of Indications and Greater Clinical Understanding of Infuse™ Bone Graft

DUBLIN and CHICAGO, Sept. 26, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced U.S. FDA approval of a prospective, randomized pivotal clinical trial for the use of Infuse™ Bone Graft in Transforaminal Lumbar Interbody Fusion (TLIF) spine procedures. A TLIF is a type of surgery that fuses – or joins – bones of the spine through a posterior approach. It is used to treat certain painful conditions of the lumbar – or low back – region of the spine.

"The potential to expand the indications for use of Infuse in posterior spine procedures may give a broader group of patients access to this novel biologic technology," said Dr. Joseph D. Smucker, an orthopedic spine surgeon with the Indiana Spine Group and principal investigator in the clinical trial. “When considering the patient, site, and procedure, Infuse can be a powerful option in a spine surgeon’s armamentarium. This study has the potential to add to the broader clinical and scientific evidence regarding use of Infuse, and may allow surgeons to better understand its safe and effective use in TLIF procedures.”

Medtronic has initiated site recruitment for the TLIF clinical trial with the potential to enroll up to 50 sites with over 1,000 patients. In 2017, Medtronic announced the FDA approval of a separate clinical trial to study Infuse Bone Graft in Posterolateral Fusion (PLF) procedures. The company is currently enrolling its prospective pilot PLF clinical trial and is working with the FDA to incorporate retrospective safety and effectiveness data sufficient for indication expansion in PLF.

"With 17 years of clinical use, Infuse Bone Graft has become one of the most extensively-researched biologic technologies commercially available today," said Jacob Paul, senior vice president and president of Medtronic's Spine division, which is part of the Restorative Therapies Group. "Medtronic continues to invest in scientific evidence on Infuse to continue adding to the growing body of clinical data, and we believe these trials will generate additional data to expand indications, increase access to surgeons, and alleviate pain and restore health for patients around the world."

Infuse Bone Graft has been on the market since 2002 and has been trusted clinically in over two million patients worldwide to date*. The product is FDA-approved for certain spine, oral-maxillofacial and orthopedic trauma surgeries. In spine surgery, Infuse is used with certain Medtronic interbody fusion devices at a single level for patients with degenerative disc disease (DDD) and eliminates the need to harvest bone from the patient's body in a secondary surgical procedure.

The use of Infuse Bone Graft in TLIF and PLF procedures is investigational only.

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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*Data on file.

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