Medtronic News

Medtronic Announces FDA Approval of Infuse® Bone Graft for Three New Spine Surgery Indications

Approval adds new implants and new surgical approaches to current spine labeling

DUBLIN - December 11, 2015 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of additional spine surgery indications for Infuse® Bone Graft. Upon receiving final labeling approval from the FDA, the company expects to begin marketing these expanded indications in early calendar year 2016. With this expanded approval, Medtronic will be able to market Infuse Bone Graft for use with certain spine implants made of polyetheretherketone (PEEK) in oblique lateral interbody fusion (OLIF) and anterior lumbar interbody fusion (ALIF) procedures.

The new indications for Infuse Bone Graft are:

- Use in OLIF51(TM) Procedures with certain sizes of the PEEK Perimeter® Implant at a single level from L5-S1.
- Use in OLIF25(TM) Procedures with certain sizes of the PEEK Clydesdale® Implant at a single level from L2-L5.
- Use in ALIF procedures with certain sizes of the PEEK Perimeter Implant at a single level from L2-S1.

"For my anterior and anterolateral lumbar spine fusion cases, the use of Infuse Bone Graft allows me to reliably obtain a solid arthrodesis without having to harvest bone from the patient's own hip which generally requires a second incision, results in significant pain, and increases the risk of complications such as bleeding or infection," said Peter Whang, MD, FACS, an Associate Professor in the Department of Orthopaedics at the Yale School of Medicine in New Haven, CT. "In particular, I believe that the proven osteoinductive properties of Infuse Bone Graft are particularly beneficial when used in conjunction with PEEK interbody spacers and the less invasive OLIF technique, which circumvents the psoas muscle and minimizes disruption of the surrounding soft tissues and neural structures."

Infuse Bone Graft is used with certain Medtronic interbody fusion devices to treat lumbar degenerative disc disease. This condition can cause back and/or leg pain, as well as functional problems, such as tingling or numbness in the legs or buttocks or difficulty walking.

"With these expanded indications, we can bring the benefits of this important technology to more patients to help ensure they achieve a solid fusion and the best potential for a positive clinical outcome," said Doug King, senior vice president and president of Medtronic's Spinal business, which is part of the Restorative Therapies Group at Medtronic. "We believe in the safety and effectiveness of Infuse Bone Graft and reiterate our continued commitment to the product."

Infuse Bone Graft is FDA-approved for certain spine, oral-maxillofacial and orthopedic trauma surgeries. For these surgeries, it can offer several benefits, including eliminating the need to harvest bone from the patient's body in a secondary procedure, shorter operating times, and proven rates of fusion or bone formation.i

The active ingredient in Infuse Bone Graft - rhBMP-2 - is a manufactured version of a protein already present in the body that promotes new bone growth. During surgery, it is applied to an absorbable collagen sponge (ACS). The ACS is a carrier to deliver the rhBMP-2 to the implant site and acts as a scaffold for the formation of new bone, and it will resorb, or disappear, over time. For more information about Infuse Bone Graft, visit www.bmp2.com.

The OLIF25 Procedure helps surgeons preserve the patient's psoas muscle when treating the L2-L5 levels of the spine. Additionally, it gives surgeons easier access around the patient's iliac crest - enabling placement of an implant into the disc space for anterior column support. The OLIF51 Procedure provides lateral access to the L5-S1 disc space and doesn't require surgeons to flip the patient from an anterior position during surgery. OLIF Procedures incorporate Medtronic's comprehensive surgical platform of access, interbody, navigation, fixation and biologic options.

Infuse Bone Graft is not indicated for use with a trans-psoas surgical approach. As with any surgery, a spinal fusion procedure with Infuse Bone Graft / Medtronic Interbody Fusion Device is not without risk. A variety of complications can occur. These may occur in isolation or in combination. Additional surgery may be needed to correct these complications.

A multimedia version of this release with downloadable media can be found here:https://medtronicmediacap.gcs-web.com/medtronic-announces-fda-approval-infuser-bone-graft-three-new-spine-surgery.

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 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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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i Data on file.

Clydesdale and Perimeter Implants incorporate technology developed by Gary K. Michelson, M.D.

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