Medtronic News

Medtronic Announces FDA Approval of Infuse(TM) Bone Graft in New Spine Surgery Indications Using PEEK Interbody Implants

Approval Adds Two Additional Implants to Current Spine Labeling

DUBLIN - April 30, 2018 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of Infuse(TM) Bone Graft in new spine surgery indications. InfuseBone Graft is now approved for use with additional spine implants made of polyetheretherketone (PEEK) in oblique lateral interbody fusion (OLIF 25(TM) and OLIF 51(TM)) and anterior lumbar interbody fusion (ALIF) procedures at a single level. This is the second expanded indication in just over two years.

The new approved indications for InfuseBone Graft are:

- Use in OLIF 51 procedures with Divergence-L®Interbody Fusion Device at a single level from L5-S1.
- Use in OLIF 25 procedures with Pivox(TM) Oblique Lateral Spine System at a single level from L2-L5.
- Use in ALIF procedures with Divergence-LInterbody Fusion Device at a single level from L2-S1.

"Different spine patients can have very different surgical needs, so the more options surgeons have to combine a clinically-proven bone grafting technology like Infuse with different procedures and implants, the greater the likelihood of successful outcomes," said Dr. Richard Hynes, president and spine surgeon at the B.A.C.K. Center in Melbourne, Florida. "This latest approval addresses some fairly common degenerative spine surgical correction needs."

InfuseBone 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.

"Infuse Bone Graft remains one of the most-extensively studied products in Spine that is commercially available today," said Doug King, senior vice president and president of Medtronic's Spine division, which is part of the Restorative Therapies Group at Medtronic. "The expanded approval with these PEEK devices for OLIF25, OLIF51, and ALIF procedures provide important options for surgeons and their patients."

InfuseBone Graft is approved for certain spine, oral-maxillofacial and orthopedic trauma surgeries. Infuse has been on the market since 2002 and has been used in more than one million patients worldwide.

The active ingredient in InfuseBone Graft is rhBMP-2 - 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.

The Divergence-LInterbody Fusion Device and the Pivox Oblique Lateral Spine System incorporate the technology of Gary K. Michelson, M.D.

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 84,000 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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