Medtronic News

Medtronic Announces New Bone Cement Indication for Treating Sacral Fractures

Minimally Invasive Procedure Provides More Options for Osteoporotic Fracture Patients Suffering from Pain

DUBLIN - March 14, 2017 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance of Kyphon(TM) Xpede Bone Cement for fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty - expanding the product's indications beyond treatment of vertebral fractures due to osteoporosis, cancer or benign lesions.

Sacral insufficiency fractures (SIFs) are a common cause of debilitating lower back pain in the elderly, with incidence ranging from 1 to 5 percent in at-risk populations.1,2 According to the National Osteoporosis Foundation, about 54 million Americans have osteoporosis and low bone mass, placing them at increased risk for a fracture. Breaking a bone is a serious complication of osteoporosis, especially with older patients. Osteoporotic bone breaks are most likely to occur in the hip, spine or wrist, but other bones can break, too - including the sacrum.3

"Sacral insufficiency fractures are associated with a tremendous amount of pain and debilitation for individuals who have them," said Dr. Douglas Beall, chief of Radiology Services at Clinical Radiology of Oklahoma. "Having this new indication with Kyphon Xpede Bone Cement to use in the treatment of sacral fractures will help to address this patient population."

A recent multi-center retrospective study of 243 patients with osteoporotic SIFs treated with sacroplasty reported significant pain relief for patients immediately following the procedure and after one-year follow-up; authors indicated that there were no major complications or procedure related deaths. The study reported a low procedure-related complication rate with 1 of 243 subjects (0.4 percent) having symptomatic leakage requiring decompression.2

"We are pleased to expand our therapies for interventional physicians treating osteoporotic patients to include those suffering from sacral insufficiency fractures," said Jeff Cambra, general manager of the Interventional Pain Therapies business, which is part of the Restorative Therapies Group at Medtronic. "As the pioneers in balloon kyphoplasty for treating vertebral compression fractures, this expanded indication for Kyphon Xpede Bone Cement demonstrates our long-term commitment to continuously innovate and empower physicians to deliver the best clinical solutions to their patients."

Kyphon Xpede Bone Cement is a quick-to-dough bone cement that provides ease of handling and allows sufficient time for careful, minimally invasive use. When paired with the Kyphon(TM) Cement Delivery System, clinicians can minimize their radiation exposure by standing up to four feet away from the radiation source during injection, which has been measured to reduce hand radiation exposure by 70 percent.4

About Sacral Insufficiency Fractures

Sacral insufficiency fractures (SIFs) are a common cause of debilitating back pain. SIFs mimic the symptoms of lumbar spine pathology and are commonly missed or underdiagnosed. Since the sacral ala is composed predominantly of cancellous bone - the first to be reduced in cases of osteoporosis and other metabolic conditions - it remains the most common region for SIFs.1,2

About Kyphon Xpede Bone Cement

Kyphon Xpede Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions

include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Risks of acrylic bone cements include cement leakage which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as:

- Cardiac arrest
- Cerebrovascular accident
- Myocardial infarction
- Pulmonary embolism
- Cardiac embolism

Payer coverage for sacroplasty may vary. Medtronic recommends providers review all payer coverage policies and/or call payers to determine coverage criteria and appropriate coding.

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 88,000 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.

Balloon kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

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1. Sudhir G., et al. Sacral Insufficiency Fractures Mimicking Lumbar Spine Pathology. Asian Spine J 2016;10(3):558-564
2. Kortman K, et al. Multicenter study to assess the efficacy and safety of sacroplasty in patients with osteoporotic sacral insufficiency fractures or pathologic sacral lesions. J Neurointerv Surg. 2013 Sep 1;5(5):461-6.
3. National Osteoporosis Foundation Website. www.nof.org
4. Medtronic data on file. The mean radiation reduction at the hands was 77.79 percent ($p<0.001$). Based on an internal testing of 24 total cadaveric procedures (n=12 using Kyphon(TM) CDS and n=12 using Kyphon(TM) Bone Filler Device). Dosimeters were placed on the wrist and fingers to measure radiation when delivering bone cement into the vertebral body. Radiation result reported is based on adherence to the Directions for Use.



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