Medtronic News

Medtronic Announces New Inflatable Bone Tamp for Treatment of Vertebral Compression Fractures

Kyphon Xpander(TM) II Inflatable Bone Tamp Is Latest Innovation in Minimally Invasive Treatment of Spinal Fractures

MINNEAPOLIS, Oct 21, 2010 (BUSINESS WIRE) --

Medtronic Inc. (NYSE:MDT) today announced Food and Drug Administration (FDA) clearance of the Kyphon Xpander II Inflatable Bone Tamp (IBT) for the treatment of vertebral compression fractures with minimally invasive Kyphon(R) Balloon Kyphoplasty.

Kyphon Xpander II is the latest innovation from the creator of balloon kyphoplasty and maker of the Kyphon Xpander(TM) IBT. The new IBT is designed to have an improved, pre-determined inflation pattern1 and exert greater lifting force than that of the Kyphon Xpander(TM) IBT*. It also gives physicians the ability to maintain inflation of one IBT while delivering polymethylmethacrylate (PMMA) bone cement on the contra-lateral side of the vertebrae2. Kyphon Xpander II will enter into limited market release in November in the U.S. The product is expected to be available internationally in 2011.

Xpander II is a significant addition to the industry-leading advancements Medtronic has made over the past 10 years in the treatment of vertebral compression fractures - the most common osteoporotic fractures with an estimated 900,0003 spinal fractures occurring in the U.S. every year. Vertebral compression fractures have shown to increase the likelihood of additional health problems as well as increase the risk of death.45 Since the Kyphon Products Division of Medtronic introduced balloon kyphoplasty in 2000, an estimated 800,000 fractures have been treated worldwide with Kyphon Balloon Kyphoplasty by approximately 14,500 trained spine specialists.

"Xpander II joins a host of innovative new products in what is the largest launch in our division's history," said Alex DiNello, vice president and general manager of the Kyphon Products Division. "Xpander II is the flagship product in our division's revitalized product platform, which also includes the Kyphon Express(TM) Curette, Kyphon ActivOs(TM) 10 Bone Cement with Hydroxyapatite, and the Kyphon(R) Cement Delivery System. These new products join the rest of our product family in providing our customers with performance they can count on in treating vertebral compression fractures."

For more information on these new product offerings, go to www.kyphon.com.

About Kyphon Balloon Kyphoplasty:

During the minimally invasive balloon kyphoplasty procedure, a needle and tube are used to create a small pathway into the fractured bone, generally on both sides of the vertebral body. Orthopedic balloons are inserted and then inflated inside the fractured bone in an attempt to return it to its correct position. Inflation of the balloons creates cavities in the vertebral body that are filled with bone cement, forming an "internal cast" to support the surrounding bone and stabilize the fracture.

Balloon kyphoplasty differs from other surgical therapies for VCFs such as vertebroplasty, which is designed to stabilize the fracture without correcting vertebral body deformity or providing a controlled fill for bone cement distribution. With balloon kyphoplasty, inflation of the balloons compacts the cancellous bone, which may fill fracture lines and reduce leak pathways. The presence of the space also allows a more viscous bone cement to

be injected under low manual pressure.

The complication rate with Kyphon Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement leakage), including serious complications, and though rare, some of which may be fatal. This procedure is not for everyone. A prescription is required. Patients should consult their physicians for a complete list of indications, contraindications, benefits, and risks. Only patients and their physicians can determine whether this procedure is right for a particular patient.

About the Spinal and Biologics Business at Medtronic
The Spinal and Biologics business is based in Memphis, Tenn. It is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. The Spinal and Biologics business works with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopedic, dental and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle-friendly surgical therapies. More information about the company and its treatment therapies can be found at www.medtronic.com and its patient-education Web sites, www.back.com, www.iscoliosis.com, www.maturespine.com and www.necksurgery.com.

About Medtronic
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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

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.

1 * While this data is supported with Medtronic performance bench testing, it has not been correlated to human clinical performance of the device. Predetermined inflation pattern is as designed by Medtronic.
2 Tested in a bone model with monomer for up to 5 minutes while the Kyphon Xpander(TM) II IBT was inflated to an inflation pressure of 100psi.
3 Medtronic, Inc. updated estimate from 700,000 spinal fractures estimated in 1985-89 study published by Riggs & Melton - Bone. 1995;17(5 Suppl):505S-511S] for demographics and incidence rate per Burge R, et al. J Bone Min Res. 2007;22:465-475.
4 Silverman SL, et al. The relationship of health-related quality of life to prevalent and incident vertebral fractures in postmenopausal women with osteoporosis: results from the Multiple Outcomes of Raloxifene Evaluation Study. Arthritis Rheum. 2001 Nov;44(11):2611-9.
5 Lau E, et al. Mortality following the diagnosis of a vertebral compression fracture in the Medicare population. J Bone Joint Surg Am. 2008 Jul;90(7):1479-86.

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