Medtronic News

Medtronic Launches New Balloon Kyphoplasty Products for Treating Spinal Fractures

Enhancements Give Physicians More Options for Treating Vertebral Compression Fractures

MEMPHIS, TN - September 17, 2014 - Medtronic, Inc. (NYSE: MDT), today announced the launch of the KYPHON Express(TM) II Balloon Kyphoplasty Platform, which includes the next generation KYPHON ® Cement Delivery System. This new platform is the latest advancement in the KYPHON® Balloon Kyphoplasty (BKP) technology for the treatment of vertebral compression fractures.



The KYPHON Express(TM) II Balloon Kyphoplasty Platform features a maximum pressure rating of 700 psi, providing the treating physician a more powerful option for reducing fractures. The new system also gives physicians the option of using the cement resistant technique, which allows one balloon to remain inflated during contralateral cement fill, helping to maintain the goal of fracture reduction.1. In addition, this system includes an expanded tools portfolio that is more versatile, allowing for the treatment of a variety of different levels of the spine1.

The next-generation KYPHON® Cement Delivery System (CDS) includes new features designed to increase the efficiency and precision of delivering bone cement into a vertebral body2. The re-designed cement cartridges can be filled simultaneously with a provided T-adapter, increasing procedure efficiency. In addition, KYPHON® CDS now has longer shelf life for enhanced usability. The CDS continues to allow the physician to deliver highly viscous bone cement to the patient from up to 4 feet away from the radiation source while maintaining tactile feel. It also still includes a Quick Release Button that provides the ability to halt the flow of bone cement on demand, giving the physician precise control over the amount of cement flow2.

"KYPHON® BKP is a proven therapy that provides numerous benefits to patients suffering from vertebral compression fractures, including long-term maintenance of height restoration 3,4,5,6" said Dr. Doug Beall, Chief of Radiology Services for Clinical Radiology of Oklahoma. "With the introduction of the KYPHON Express(TM) II platform and improved tools like the next-generation KYPHON® Cement Delivery System, physicians can now treat more spine levels by choosing the sizes, length and volume most appropriate for the individual patient's anatomy and fracture."

"Interventional physicians treating vertebral compression fractures now have more options with our BKP procedure," said Medtronic Spinal President Doug King. "KYPHON Express(TM) II and the next-generation CDS reinforce Medtronic's commitment to continuously innovating to empower physicians to deliver the best clinical outcomes to their patients."

About KYPHON® Balloon Kyphoplasty

KYPHON® Balloon Kyphoplasty (BKP) is a minimally invasive surgical procedure indicated for treatment of painful vertebral compression fractures (VCFs) caused by osteoporosis, cancer or benign lesions. The therapy aims to reduce and stabilize the fracture, thereby providing immediate and sustained pain relief, improved physical function and better quality of life 3,4,5,6

KYPHON® BKP is a percutaneous procedure that involves use of access tools with inflatable bone tamps placed inside the affected vertebral body. Balloon inflation compacts the cancellous bone and pushes the endplates apart. Once the balloons have been removed, the resulting void is filled with viscous bone cement to stabilize the vertebral body. By contrast, vertebroplasty involves insertion of a catheter and injection of liquid cement into the body without creating a cavity for the cement.4,5

The KYPHON Express II Inflatable Bone Tamp is the newest addition to the portfolio which already includes KYPHON Express(TM), KYPHON Xpander(TM) and KYPHON Xpander(TM) II.

The KYPHON Xpander(TM) II Inflatable Bone Tamps and KYPHON Express(TM) II Inflatable Bone Tamps are intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared

for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.



The complication rate for KYPHON® Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure, including serious complications, and though rare, some of which may be fatal. These include, but are not limited to heart attack, cardiac arrest (heart stops beating), stroke, and embolism (blood, fat or cement that migrates to the lungs, heart, or brain). Other complications include infection and leakage of bone cement into the muscle and tissue. Cement leakage into the blood vessels may result in damage to the blood vessels, lungs, heart, and/or brain. Cement leakage into the area surrounding the spinal cord may result in nerve injury that can, in rare instances, cause paralysis. A prescription is required. Please consult your physician for a complete list of indications, contraindications, benefits, and risks. Only you and your physician can determine whether this procedure is right for you.

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

MICHELSON TECHNOLOGY AT WORK

For more information on these new product offerings, go towww.StopSpinalFracturePain.com.

About Medtronic's Spinal Business

Medtronic's spinal business, based in Memphis, Tenn., is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. Medtronic's spinal business collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art therapies for spinal, neurological, orthopaedic and oral maxillofacial conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle friendly surgical therapies. More information about spinal treatments can be found at its patient-education Web site, www.back.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.

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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1. Medtronic Data on File - KYPHON Express (TM) II Inflatable Bone Tamps

2. Medtronic Data on File - KYPHON® Cement Delivery System

3. Van Meirhaeghe J, Bastian L, Boonen S, et al. A randomized trial of balloon kyphoplasty and non-surgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine. 2013 38(12), pp 971-983

4. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from randomized trial. J Bone Miner Res. 2011 Jul;26(7):1627-1637

5. Wardlaw D,Van Meirhaeghe J, Ranstam J, et al. Balloon kyphoplasty in patients with osteoporotic vertebral compression fractures. Expert Rev Med Dev 2012;9:423-36

6. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet. 2009 Mar 21;373(9668):1016-24

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