Medtronic News

New Directional Cannula Provides More Flexibility and Control to Balloon Kyphoplasty Procedures

DUBLIN, May 19, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the U.S. launch of Kyphon Assist™ Directional Cannula for use with its balloon kyphoplasty (BKP) products to treat vertebral compression fractures due to osteoporosis, cancer or benign lesions. This innovative new device allows physicians greater control when inflating the bone tamp while also increasing height restoration capability compared to a traditional balloon kyphoplasty cannula1.

The Kyphon Assist Directional Cannula is compatible across the Medtronic portfolio of balloon kyphoplasty products, including the Kyphon Xpander™ II Inflatable Bone Tamps. It provides the following benefits1:

- Allows for directional control of Inflatable Bone Tamps during a balloon kyphoplasty procedure
- Additional height restoration in a vertebral body
- Ability to inflate away from lateral wall and endplate defects
- Can be exchanged with existing access tools when needed

"Kyphon Assist allows me to directionally inflate my balloon tamp and decide the force and direction of pressure ," said Dr. Thomas G. Andreshak, orthopedic surgeon at St Luke’s Hospital in Maumee, Ohio. "This allows me to obtain the best reduction of the endplates, attempt to maximize height restoration , correction of kyphosis with caution while protecting the lateral, anterior and posterior walls of the vertebral body.”

Vertebral compression fractures (VCFs) are the most common osteoporotic fractures affecting 1.4 million people worldwide.2 According to the National Osteoporosis Foundation, about 54 million Americans have osteoporosis or low bone mass that puts 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.3

A recent study of patients with osteoporotic VCFs treated with a directional balloon technique(n=49) versus traditional nondirectional balloon technique(n=51) reported significantly early and immediate outcome improvement in Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and Roland Morris Disability Questionnaire (RMDQ) scores versus the nondirectional technique at 3 days.4 The study also reported immediate and sustained kyphotic angle correction post-surgery. A lower procedure-related extravasation rate was seen with the directional balloon group as 4 of 49 subjects (8.2%) having bone cement leakage versus 12 of 51 subjects (23.5%), p-value 0.036 with the traditional nondirectional balloon technique.4

"We are excited to offer a new option when it comes to treating osteoporotic patients that allows flexibility and more control with our existing balloon kyphoplasty products," said Anu Codaty, vice president and general manager of the Interventional Therapies business, which is part of the Restorative Therapies Group at Medtronic. "We are committed to continuously innovating in the vertebral augmentation space. Kyphon Assist will expand the capabilities of our existing Inflatable Bone Tamp Technology and empower physicians in their pursuit of delivering the best clinical solutions to their patients."

Faced with COVID-19 and recommended treatment and state guidelines related to elective procedures, we encourage clinicians to continue working with their national and local health departments for guidance applicable to their practice to help them make an informed treatment decision on what is appropriate and applicable to their state.

For more information visit: www.medtronic.com/kyphonassist

About Balloon Kyphoplasty

BKP is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. The complication rate with BKP has been demonstrated to be low. There are risks associated with the

procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal.

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, or cardiac embolism.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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. Medtronic Data on File. 2020.
2. Boonen S, et al. J Bone Miner Res. 2011;26(7):1627-1637.
3. National Osteoporosis Foundation Website. www.nof.org
4. Utilization of the directional balloon technique to improve the effectiveness of percutaneous kyphoplasty. Pu Wang, MD, Jin Li, MD, Zukun Song, MD, Zhan Peng, MD, Guangye Wang, MD, PhD. Medicine (Baltimore). 2019 May; 98(19): e15272

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Attachment

- Kyphon Assist™ Directional Cannula

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https://news.medtronic.com/2020-05-19-New-Directional-Cannula-Provides-More-Flexibility-and-Control-to-Balloon-Kyphoplasty-Procedures