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Benvenue Medical's Kiva(R) And Blazer(R) Highlighted As Advancements In Treating VCFs

Published in Techniques in Regional Anesthesia and Pain Management, Review Article Discusses Emerging VCF Treatments and Technologies

SANTA CLARA, Calif., April 22, 2013 /PRNewswire/ -- In a review of minimally invasive, state-of-the-art treatments for vertebral compression fractures (VCFs), the Kiva VCF Treatment System and the Blazer Vertebral Augmentation System, both by Benvenue Medical, Inc., were highlighted among the most innovative experimental and commercial technologies available today. The peer-reviewed article was published online and in the April edition of Techniques in Regional Anesthesia and Pain Management (Volume 16/Number 2).

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"While most studies have consistently shown percutaneous vertebroplasty and vertebral augmentation to be safe, effective, and cost-efficient, they do have some limitations, and emerging percutaneous technologies for VCF treatment are being developed to overcome some of them--namely to effectively increase vertebral height, control cement delivery, conserve the native cancellous bone structure, among others," said Sean M. Tutton, MD, FSIR, Professor of Radiology and Surgery at the Medical College of Wisconsin in Milwaukee and lead author of the review article. "One noteworthy and most widely published of these emerging VCF technologies is the Kiva VCF Treatment System." In the article, Dr. Tutton also called Blazer "perhaps the most novel cavity creation device in this review."

"Benvenue has developed a toolbox to treat painful VCFs as all fractures are not the same. Together, our products will be able to address the majority of patients suffering from VCFs," said Robert K. Weigle, CEO of Benvenue Medical.

The review article, entitled "Minimally invasive treatments for osteoporotic vertebral compression fractures: current concepts and state-of-the-art technologies," can be found on the Science Direct platform (www.journals.elsevier.com/techniques-in-regional-anesthesia-and-pain-ma nagement). The article is currently in press and the version available online is a corrected proof. Copies of this paper are available to credentialed journalists upon request; please contact Elsevier's Newsroom at newsroom@elsevier.com or +31-20-4853564.

About the Kiva VCF Treatment System

The Kiva VCF Treatment System provides a new approach to the treatment of painful VCFs.

The Kiva VCF Treatment System features a proprietary flexible implant made from PEEK-OPTIMA(R) , a biocompatible polymer that is widely used and well accepted as a spinal implant. The Kiva Implant is designed to function as a mechanical support structure and a reservoir to contain and direct the flow of bone cement.

The Implant is delivered percutaneously in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva Implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the Implant is designed to provide stabilization and structural support to the vertebral body and to directionally control and contain bone cement.

A randomized trial of Kiva and balloon vertebral augmentation was recently published in the February edition of Spine (2013;38:292-299). This Level I data demonstrated Kiva's superiority over balloons in many key areas:

-- Significant restoration of the Gardner angle in patients treated with Kiva (p=0.002) where as balloon kyphoplasty did not meet significance (p=0.067)

-- Lower extravasation rates (3% for Kiva and 9.8% for balloon kyphoplasty, p<0.05)

-- Lower cement volume (1.8 mL for Kiva and 2.8 mL for balloon kyphoplasty, p <0.001)

The Kiva VCF Treatment System is investigational in the United States and currently the subject of an approved IDE study - the KAST (Kiva System as a Vertebral Augmentation Treatment -- A Safety and Effectiveness Trial) clinical trial, sponsored by Benvenue Medical. The KAST trial completed enrollment of 300 patients in June 2012, more than 225 of whom completed their one-year follow-up. KAST is being conducted to support a 510(k) filing for market clearance from the U.S. Food and Drug Administration (FDA), which Benvenue Medical expects to submit in the third quarter of 2013. (ClinicalTrials.gov Identifier: NCT01123512)

About Blazer Vertebral Augmentation System

Blazer is a circular cavity creation device used in minimally invasive vertebral augmentation procedures that can be performed in a spine specialist's office or in a hospital setting. The device is indicated for the treatment of pathological compression fractures of the vertebral body that result from osteoporosis, benign lesions, or malignant lesions, by creating cavities via multiple channels in the existing spinal bone structure for the flow of bone cement. Blazer uses a nitinol wire that is percutaneously inserted and strong enough to penetrate bone to create cavities. Bone cement is then delivered into the fracture following the cavities created by Blazer providing controlled distribution of the cement fill.

The benefits of Blazer for spine specialists include:

-- Predictable cavity creation

-- Targeted delivery of cement

-- Minimally invasive, unilateral approach

About Benvenue Medical, Inc.

Founded in 2004, Benvenue Medical, Inc. is advancing spine repair through the development of proprietary, minimally invasive surgical and interventional solutions. The company is privately held and funded by Versant Ventures, DeNovo Ventures, Domain Associates and Technology Partners. Its first products are designed for the treatment of vertebral compression fractures and degenerative disc disease, which have combined revenues of $1.6 billion globally. For more information, visit www.benvenuemedical.com.

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