Small Implant, BIG IMPACT.
NOVEL TREATMENT FOR VERTEBRAL COMPRESSION FRACTURES

Kiva has been demonstrated to meet or exceed the performance of balloon kyphoplasty in 3 separate comparative studies. In one or more of these studies, as compared to balloon kyphoplasty, Kiva was shown to:

- Reduce rate of adjacent level fracture
- Improve kyphotic angle restoration
- Reduce rate of cement extravasation
- Reduce cement volume

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WHAT IS KIVA?

The Kiva System is a novel implant-based solution for vertebral augmentation and a departure from balloon kyphoplasty, making it the first new approach to the treatment of vertebral compression fractures (VCFs) in over a decade. In three Level I/II clinical studies, the Kiva System was shown to meet or exceed the performance of balloon kyphoplasty.

For the first time, Kiva allows a treating physician to deliver (through a transpedicular approach) an implant with a predictable structure. The implant also functions as a reservoir to contain and direct the flow of cement. It is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

How Does Kiva Work?

Kiva is a Unipedicular System. The Kiva Implant is delivered percutaneously over a removable guide-wire in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the implant delivered is physician-customized during the procedure to adjust to vertebral compression fracture morphologies. With Kiva, bone cement is delivered simultaneously through both the access cannula and the implant, reducing the added steps that other systems require.

Once the Kiva Implant is positioned in the center of the vertebra, bone cement is introduced through the implant to stabilize the fracture.

Biomechanical & Biomaterial Advantages of the Kiva Implant

The implant is made from PEEK-OPTIMA® and replaces bone cement as the primary structural support needed for the fractured vertebra. PEEK, a biocompatible polymer widely used and well-accepted in spinal implants, approximates bone characteristics.

A bench test material comparison demonstrated that the Kiva Implant with 1.25cc of PMMA is 63% less rigid than PMMA bone cement alone.¹

¹ Internal lab testing-data on file.
Supporting Data

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<th>CLINICAL STUDIES</th>
<th>KEY FINDINGS</th>
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<td><strong>1. KAST: The Kiva® System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial.</strong>&lt;br&gt;<strong>Design:</strong> Prospective, randomized clinical trial to evaluate the safety and effectiveness, and support non-inferiority of the Kiva VCF Treatment System versus balloon balloon kyphoplasty: 300 patient trial&lt;br&gt;<strong>Authors/Publication:</strong> Tutton, Garfin, et al.</td>
<td><strong>• Improvement in pain and function were similar to balloon kyphoplasty</strong>&lt;br&gt;<strong>• Similar safety to balloon kyphoplasty</strong>&lt;br&gt;<strong>• Reduced rate of adjacent level fractures as compared to balloon kyphoplasty - per protocol population*”&lt;br&gt;</strong>• Reduced rate of extravasation as compared to balloon kyphoplasty - as reported by Investigators*”&lt;br&gt;**• Significant reduction in cement volume over balloon kyphoplasty*”&lt;br&gt;*Posterior probability of superiority was ≥ 90%</td>
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<td><strong>2. Balloon kyphoplasty versus KIVA Vertebral Augmentation.</strong>&lt;br&gt;<strong>Comparison of two Techniques for Osteoporotic Vertebral Body Fractures. A prospective randomized study.</strong>&lt;br&gt;<strong>Design:</strong> Prospective, randomized study: 168 patients treated&lt;br&gt;<strong>Authors/Publication:</strong> Korovessis, et al. Spine, February 2013.</td>
<td><strong>• Significant restoration of the Gardner angle in patients treated with Kiva, whereas balloon kyphoplasty did not meet significance</strong>&lt;br&gt;<strong>• Lower extravasation rates with Kiva</strong>&lt;br&gt;<strong>• Lower cement volume with Kiva</strong>&lt;br&gt;<strong>• VAS, ODI, and SF-36 were similar</strong></td>
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<td><strong>3. Comparison of balloon kyphoplasty with the new Kiva VCF System for the treatment of vertebral compression fractures.</strong>&lt;br&gt;<strong>Design:</strong> Matched pairs study of Kiva vs. balloon kyphoplasty with Medtronic balloons: 52 patients&lt;br&gt;<strong>Authors/Publication:</strong> Otten, Pflugmacher, et al. Pain Physician Journal, October 2013.</td>
<td><strong>• New fractures following treatment with Kiva were significantly lower</strong>&lt;br&gt;<strong>• Mean cement used was less than half with Kiva</strong>&lt;br&gt;<strong>• Cement extravasation was significantly less with Kiva</strong>&lt;br&gt;<strong>• Pain improvement was significantly better with Kiva at 6 months</strong></td>
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Vertebral Compression Fracture Evolution
INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION

The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit. As with other vertebral augmentation devices and procedures, there are risks and considerations for use of the Kiva VCF Treatment System. The risks include serious complications up to and including death. Please see the product labeling for a more detailed discussion of risks, contraindications, warnings and precautions.

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Kiva Products

KIVA SYSTEM KITS
First Fracture Kits
KIV2100: Kiva VCF Treatment System, Right, First Fracture Kit
KIV2200: Kiva VCF Treatment System, Left, First Fracture Kit

Additional Fracture Kits
KIV2150: Kiva VCF Treatment System, Right, Additional Fracture Kit
KIV2250: Kiva VCF Treatment System, Left, Additional Fracture Kit

KIVA ACCESSORIES A LA CARTE
PLT1900: Kiva Pilot, Right
PLT1910: Kiva Pilot, Left

ACC5200: Kiva Access System, Right
ACC5205: Kiva Access System, Left

ACC5220: Bone Drill

ACC5230: Kiva Diamond Tip Bone Access Needle
ACC5240: Kiva Bevel Tip Access Needle
ACC5260: Kiv Trocar Tip Access Needle

ACC5250: Kiva Cement Needle Set, Right
ACC5255: Kiva Cement Needle Set, Left

ACC5270: Kiva Introducer Set

CEMENT AND MIXERS

VAK1800: Vertebral Augmentation Cement Kit
For Use With Kiva