



IZI Medical

Kiva[®]

VCF Treatment System

The Implant Solution for Restoration of Sagittal Alignment

2019 Product Catalog

Kiva[®] VCF Treatment System

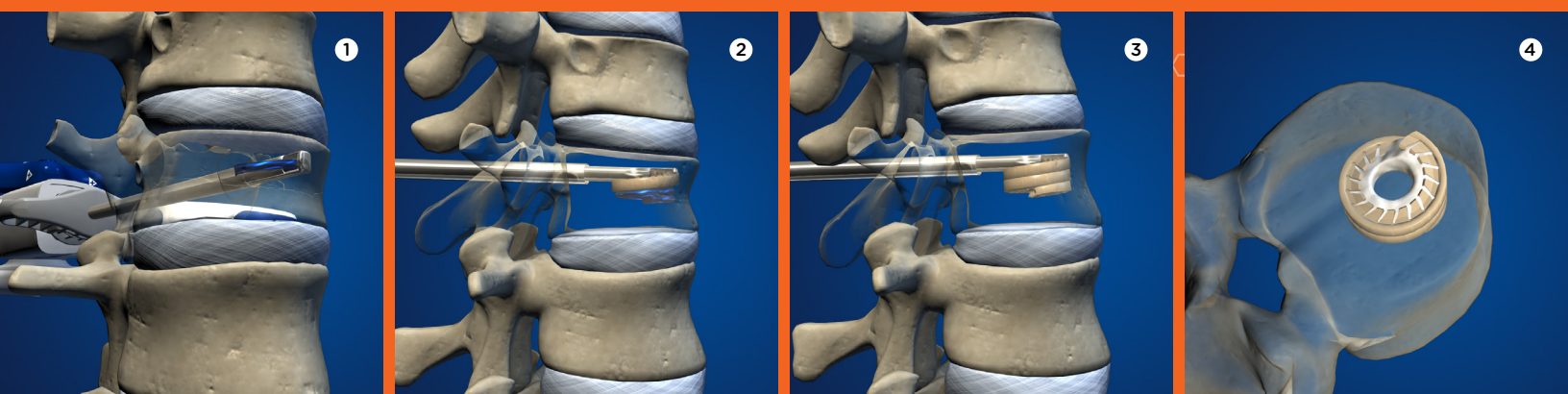
What is Kiva?

The Kiva[®] VCF Treatment System is an implant solution for treating vertebral compression fractures (VCFs). 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. In three Level I/II clinical studies, the Kiva[®] System was shown to meet or exceed the performance of balloon kyphoplasty (BKP).^{1,2}

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. Once the Kiva Implant is positioned in the center of the vertebra, bone cement is introduced through the implant to stabilize the fracture. Bone cement is delivered simultaneously through both the access cannula and the implant, reducing the added steps that other systems require.

Procedural Steps for Kiva[®] VCF Treatment System



- 1 A coil is advanced to create a path through the vertebral body bone and provide a pathway for the Kiva Implant.
- 2 As the loops of the Kiva Implant are delivered into the bone, they form a column structure.
- 3 The coil is removed and the Implant is left in place providing a path for the delivery of bone cement.
- 4 Once cured, the cement interlocks the Implant to the bone.

ORDER INFORMATION

Kiva System Kits

| SET ORDER NUMBER | DESCRIPTION |
|------------------|--------------------------------------|
| KIV2100 | Kiva VCF Treatment System Kit, Right |
| KIV2200 | Kiva VCF Treatment System Kit, Left |

Kiva Accessories A La Carte

| SET ORDER NUMBER | DESCRIPTION |
|------------------|---|
| PLT2100* | Pilot, Right |
| PLT2200* | Pilot, Left |
| ACC5350 | Ultraflex Cement Needle |
| ACC5270 | Working Cannula, 6G |
| ACC5225 | Bone Drill, 7G • 17 cm |
| G13018 | Access Needle, Diamond Tip, 11G • 10 cm |
| G13761 | Access Needle, Bevel Tip, 11G • 10 cm |
| G36211 | Access Needle with Coaxial Biopsy, Diamond Tip, 11G • 10 cm |

**Pilot is an accessory used in conjunction with Kiva if hard bone is encountered. Pilot contains a thicker Nitinol coil which cuts through bone to create space for the Kiva Nitinol coil.*

Cements & Mixers

| SET ORDER NUMBER | DESCRIPTION |
|------------------|--------------------------------------|
| G80000 | Osteo-site Mixing & Injection System |
| G90002 | Vertefix Plus Bone Cement |



PMMA Bolus



Kiva with cement

Biomechanical & Biomaterial Advantages of the Kiva Implant

A bench test material comparison demonstrated that the Kiva Implant is 63% less rigid than PMMA bone cement alone, which may reduce the risk of adjacent level fractures.^{1,2,3}

Compression testing at same rate to identical peak load (.5Hz, 300-3000N)

Kiva® Clinical Data

Clinical Studies

Key Findings

KAST: The Kiva® System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial.

Design: Prospective, randomized clinical trial to evaluate the safety and effectiveness, and support non-inferiority of the Kiva® VCF Treatment System versus balloon kyphoplasty: 300 patient trial

Authors: Tutton, Garfin, et al.

Publication: Spine, June 2015

Kiva® Compared to BKP:

- Similar pain reduction and function improvement
- Reduced rate of adjacent level fractures -per protocol population
- 50% less cement volume used
- Significantly reduced rate of extravasation as reported by investigators

Balloon Kyphoplasty Versus Kiva® Vertebral Augmentation. Comparison of two Techniques for Osteoporotic Vertebral Body Fractures. A Prospective Randomized Study.

Design: Prospective, randomized study: 168 patients treated

Authors: Korovessis, et al.

Publication: Spine, February 2013

Kiva® Compared to BKP:

- Similar pain reduction, function and QOL improvement
- Significantly reduced kyphosis (i.e. restoration of Gardner angle)
- Lower extravasation rates
- Lower cement volume used

Comparison of Balloon Kyphoplasty with the new Kiva® VCF System for the Treatment of Vertebral Compression Fractures.

Design: Matched pairs study of Kiva® vs. balloon kyphoplasty with Medtronic balloons: 52 patients

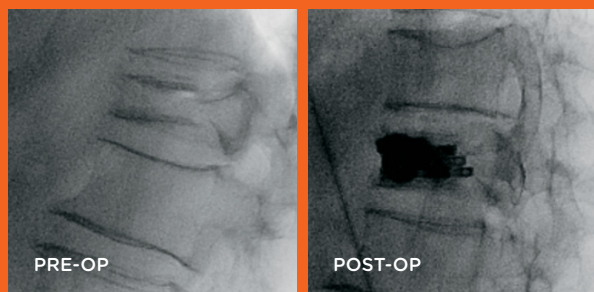
Authors: Otten, Pflugmacher, et al.

Publication: Pain Physician Journal, October 2013

Kiva Compared to BKP:

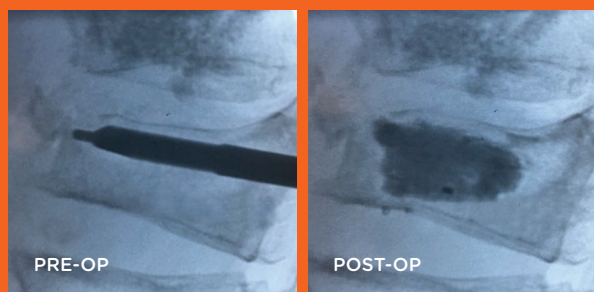
- Significantly fewer new fractures after treatment
- Mean cement used was less than half with Kiva®
- Significantly greater pain reduction at 6 months

The Implant Solution for Restoration of Sagittal Alignment



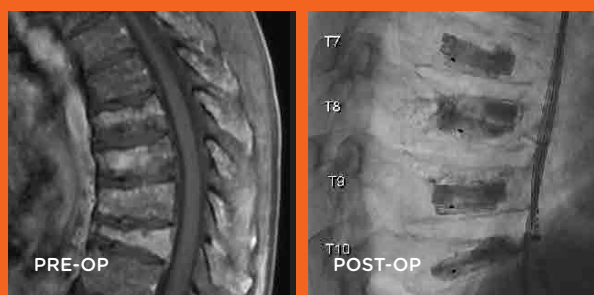
Structural Support

- Expandable implant preserves natural bone structure
- Predictable structure restores spinal alignment¹
- Controlled bone cement footprint for permanent spine restoration²



Predictable, Published Results

- Improved kyphotic angle restoration vs. BKP¹
- Reduced rate of adjacent level fractures vs. BKP²
- Proven economic savings vs. BKP⁴



¹ Balloon Kyphoplasty Versus Kiva Vertebral Augmentation Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures, Korovessis, Spine 2013

² KAST Study; The Kiva System As a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial. Tutton et al., Spine 2015.

³ Internal lab testing–data on file.

⁴ Economic Analysis of Kiva VCF Treatment System Compared to Balloon Kyphoplasty Using Randomized Kiva Safety and Effectiveness Trial (KAST) Data. Beall et al. Pain Physician 2015.

About IZI Medical Products

Based in Owings Mills, Maryland, just outside Baltimore, IZI is a leading innovator, manufacturer, and distributor of quality medical devices that provides the continuity our healthcare partners need to succeed. Over the last three decades, IZI has built a diverse portfolio of products backed by strong intellectual property and currently sells to more than 1,000 domestic customers as well as internationally across 25 countries. IZI's portfolio of high-quality medical consumable devices are used in interventional radiology and oncology, radiation therapy, neuro-spine, and image guided surgery procedures

Our mission is to improve each patient's quality of life by providing our healthcare professional partners a complete portfolio of clinically proven, high value, and innovative medical device solutions inspired by physicians, for physicians. With this mission in mind, our vision is to become a leader in diagnostic and therapeutic minimally invasive solutions to advance healthcare and improve patients' lives.

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