

WHAT ARE THE BENEFITS OF KIVA?

The Kiva VCF Treatment System has been shown to reduce pain and restore function for patients with VCFs. Kiva has also demonstrated to meet or exceed the performance of balloon kyphoplasty in three separate comparative studies. In one or more of these studies^{1,2,3}, as compared to balloon kyphoplasty, Kiva was shown to:

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

As with other vertebral augmentation devices and procedures, there are risks and considerations for use of Kiva. The risks include serious complications up to and including death. Please consult your physician for a more detailed discussion of risks, contraindications, warnings, precautions, and specific treatment options.

REFERENCES:

1. KAST: The Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial, Tutton, Garfin, et al. Spine, March 2015
2. Balloon Kyphoplasty versus Kiva Vertebral Augmentation. Comparison of Two Techniques for Osteoporotic Vertebral Body Fractures. A Prospective Randomized Study, Korovessis et al. Spine, February 2013
3. Comparison of Balloon Kyphoplasty with the New Kiva VCF System for the Treatment of Vertebral Compression Fractures, Otten, Pflugmacher, et al. Pain Physician Journal, October 2013

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 with the IZI Vertebral Augmentation Cement Kit.



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L122, Rev. B

Kiva[®]

VCF Treatment System



Minimally Invasive Treatment For
Vertebral Compression Fractures

VERTEBRAL COMPRESSION FRACTURES (VCFS)

Compression fractures of the spine occur when a vertebra - the bones of the spinal column - cracks, fractures, or collapses. These spinal fractures are unique because they frequently occur without apparent trauma and may cause no symptoms, often going undiagnosed until other complications arise. It is estimated that two-thirds of vertebral compression fractures are never diagnosed because many patients dismiss their back pain as a sign of aging or arthritis.

VCF TREATMENT OPTIONS

The following are traditional treatments for VCFs:

- Non-surgical care, such as back bracing, physical therapy, pain medication, etc.
- Vertebral Augmentation, including balloon kyphoplasty
- Vertebroplasty

Your doctor will discuss treatment options with you.



Kiva Implant

KIVA VCF TREATMENT SYSTEM

Your physician may recommend that you be treated with vertebral augmentation using the Kiva VCF Treatment System. Kiva features a flexible implant made from a polymer material widely used in spinal implants. The Kiva Implant is delivered into the vertebral body through a small, single incision in the back. The Kiva Implant is designed to function as an internal cast providing a mechanical support structure to the fracture.

Kiva is designed to:

- Utilize a single incision to access the broken bone in your back
- Require a small amount of bone cement to set the fracture
- Preserve as much of the natural bone in the vertebral body as possible
- Potentially reduce the rate of subsequent fractures in the back compared to other similar procedures

HOW KIVA WORKS

Vertebral augmentation with Kiva can be done under local or general anesthesia – your doctor will determine which option is best for you. The procedure usually takes less than an hour per fracture treated and you may be required to stay in the hospital overnight if your doctor determines it is necessary.

Your doctor will access your VCF via one small (1 cm) incision.

A COIL IS ADVANCED TO CREATE A PATH THROUGH THE VERTEBRAL BODY BONE AND PROVIDE A PATHWAY FOR THE KIVA IMPLANT.



AS THE LOOPS OF THE KIVA IMPLANT ARE DELIVERED INTO THE BONE, THEY FORM A COLUMN STRUCTURE.



THE COIL IS REMOVED AND THE IMPLANT IS LEFT IN PLACE PROVIDING A PATH FOR THE DELIVERY OF BONE CEMENT.



ONCE CURED, THE CEMENT INTERLOCKS THE IMPLANT TO THE BONE.

