

Do You Suffer from *Osteoporosis and Acute Back Pain?*



Discover the SHIELD™ VCF System

A minimally invasive treatment for vertebral
compression fractures



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SHIELD™

A minimally invasive treatment
for Vertebral Compression Fractures

Patient Information

This brochure will help you understand more about:

- General conditions of the spine
- Information about the surgical treatment
- What to expect from surgery

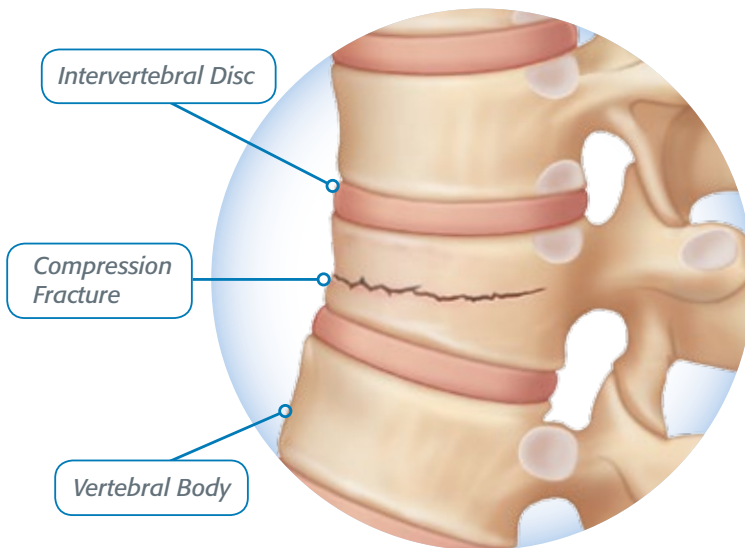
The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment or its outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, contraindications, precautions, warnings, clinical results and other important medical information that pertains to this procedure.

Understanding Vertebral Compression Fractures (VCF)

An estimated 54 million Americans age 50 and older are affected by osteoporosis and low bone mass.¹ Ten million of those Americans have osteoporosis, a disease more often found in women that causes an estimated two million broken bones each year.¹

Vertebral Compression Fractures (VCFs) are the most common fracture in patients with osteoporosis², affecting about 750,000 people annually.² VCFs are found in an estimated 25% of all postmenopausal women in the United States.³ The prevalence of this condition steadily increases as people age, with an estimated 40% of women age 80 and older affected.³ Although far more common in women, VCFs are also a major health concern for older men.³



1. *54 Million Americans Affected by Osteoporosis and Low Bone Mass.* (2014). Retrieved August 27, 2014, from the National Osteoporosis Foundation, www.nof.org.
2. Chen C, Wei H, Zhang W, Gu Y, Tang G, Dong R, Xu Y, Chen L. *Comparative Study of Kyphoplasty for Chronic Painful Osteoporotic Vertebral Compression Fractures via Unipedicular Versus Bipedicular Approach.* *Journal of Spinal Disorders and Technique.* 2011. 24(7):E62-65.
3. Ledlie J, Renfro M. *Kyphoplasty Treatment of Vertebral Fractures: 2-Year Outcomes Show Sustained Benefits.* *SPINE.* 2006. 31(7):57-64.

VCFs have a substantial and negative impact on the quality of life and day-to-day functioning of those afflicted. Short-term and long-term pain in the elderly is commonly attributed to vertebral compression fractures, which may lead to further health decline.

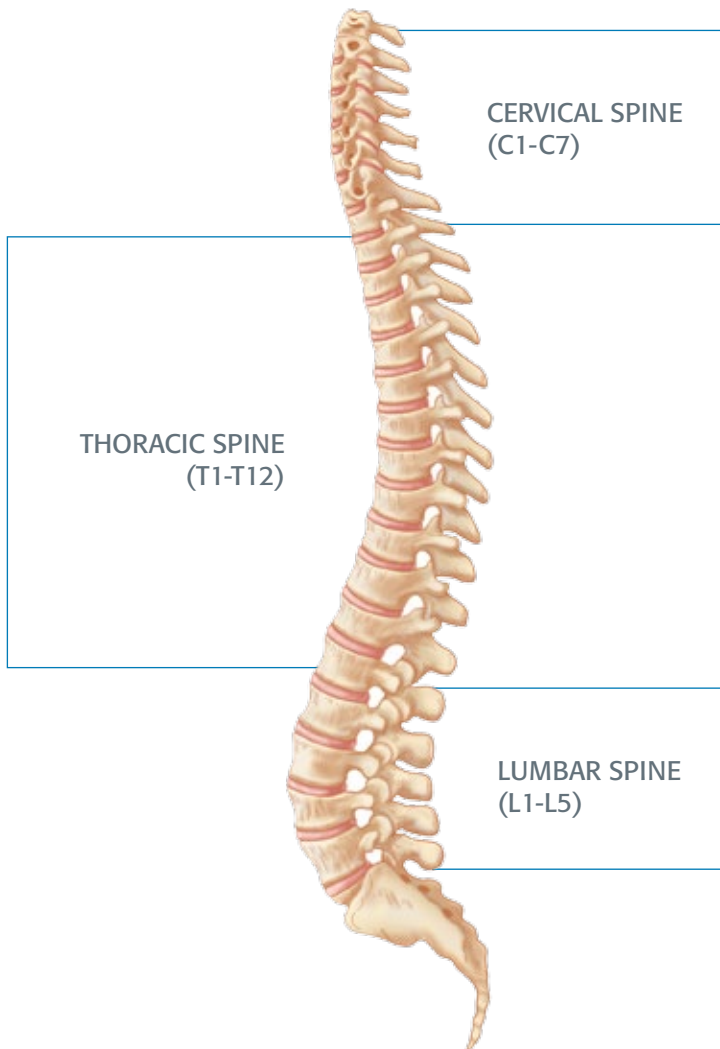
Because there is a substantial risk of subsequent fractures in all types of people who have had a vertebral compression fracture, it is important that VCFs are diagnosed and treated early.



Vertebral Compression Fractures are common, especially in older adults. VCFs are primarily caused by osteoporosis, and range from mild to severe. More severe fractures may cause significant pain, which may lead to an inability to perform activities of daily living, and decline in the elderly patient already suffering from other ailments.

What Causes a VCF?

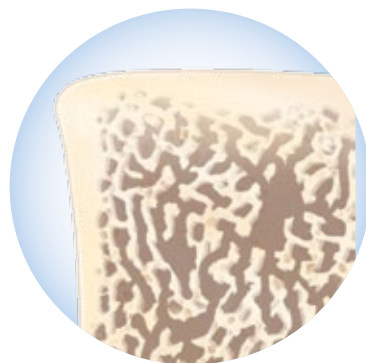
VCFs occur when the vertebral body in the spine collapses, which can lead to pain, deformity and loss of height. These fractures more commonly occur in the lower thoracic spine (the middle portion of the spine). While osteoporosis is the most common cause, these fractures may also be caused by trauma.



In people with severe osteoporosis, a VCF may be caused by simple daily activities, such as stepping out of the shower, sneezing vigorously or lifting a light object. In people with moderate osteoporosis, it usually takes increased force or trauma, such as falling down or attempting to lift a heavy object to cause a VCF. People with healthy spines may also suffer a VCF due to severe trauma, such as a car accident, sports injury or a hard fall.



HEALTHY BONE



OSTEOPOROTIC BONE



Osteoporosis, which means “porous bones”, causes bones to become weak and brittle – so brittle that a fall or even mild stresses like bending over or coughing can cause a fracture.



Symptoms

VCFs caused by osteoporosis and other pathologies may impact quality of life. The following effects of sustaining a VCF may occur:

- Sudden onset of back pain
- Increase of pain intensity while standing or walking
- Decrease in pain intensity while lying on the back
- Limited spinal mobility
- Eventual height loss
- Eventual deformity and disability
- Reduced mobility, loss of balance and increased risk of falls
- Reduced lung function
- Reduced physical activity and increased bed rest
- Chronic back pain and fatigue
- Decreased quality of life
- Increased risk of future fracture
- Increased risk of death

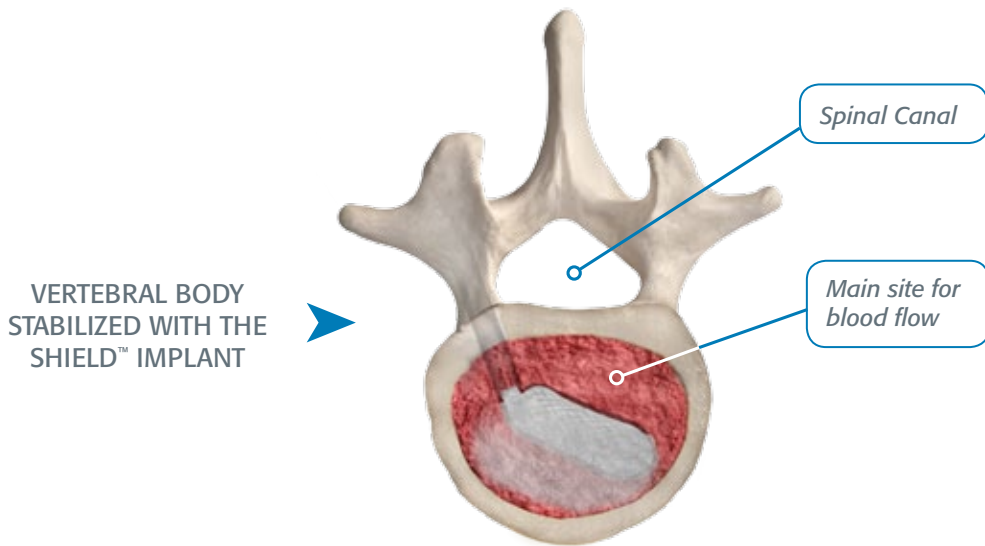
Treatment

VERTEBRAL AUGMENTATION (KYPHOPLASTY/VERTEBROPLASTY)

If you have been diagnosed with a VCF caused by osteoporosis, Vertebral Augmentation is a treatment option you may consider. Vertebral Augmentation is a minimally invasive procedure that may help reduce back pain and repair the vertebral compression fracture.

Vertebral Augmentation is a proven procedure, with a high success rate, however there can be complications. The most frequent complication is cement extravasation, or leakage. When cement leaks into the spinal canal or venous system, there may be other, related serious complications such as pulmonary embolism or even death.

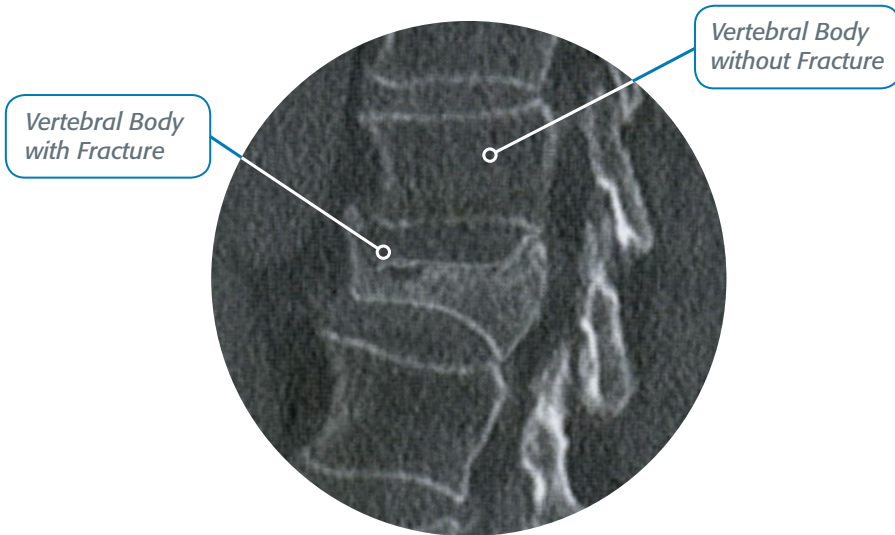
The SHIELD™ System is a vertebral compression fracture system that combines minimally invasive bone access, curved cavity creation and a cement directing implant with Barrier Technology™ to target cement flow.



About the Procedure

BEFORE YOUR PROCEDURE

Your doctor will perform a physical exam, ordering x-rays and other imaging tests such as MRI, CT or bone scan to determine the precise location of the fracture, how recently the fracture occurred and whether performing Vertebral Augmentation is the most appropriate treatment. The procedure can be performed under local or general anesthesia – you and your treating physician will decide which option is appropriate for you.



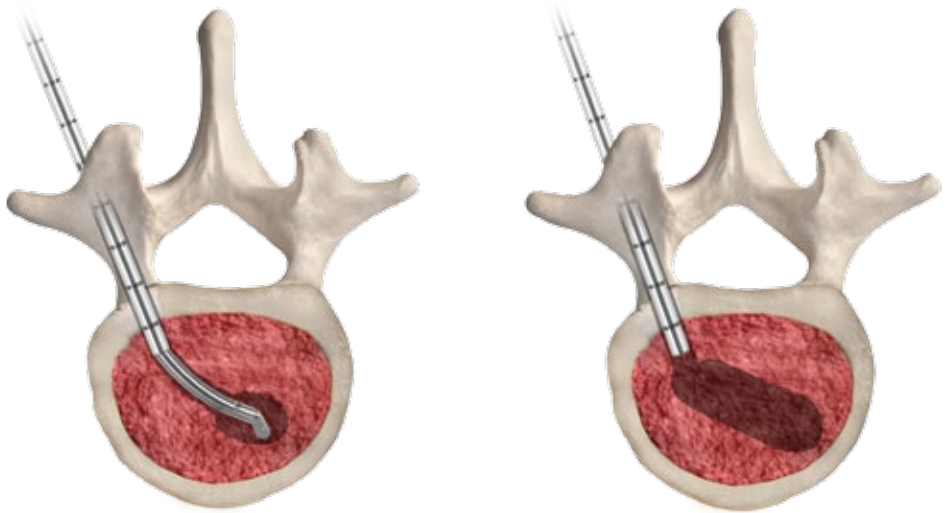
COMPRESSION FRACTURE
(CT SCAN)

DURING YOUR PROCEDURE

Vertebral Augmentation is generally performed through a small tube under local or mild sedation, eliminating many of the complications of open surgery. However, in some situations, general sedation is advised.

First, your back is numbed with a local anesthetic. Using x-ray guidance, the Curved Cavity Creation instrument is inserted into the fractured vertebra through a small incision.

The instrument creates a void, or cavity, on the inside of the vertebral body. Once the void is created, the instrument is removed.



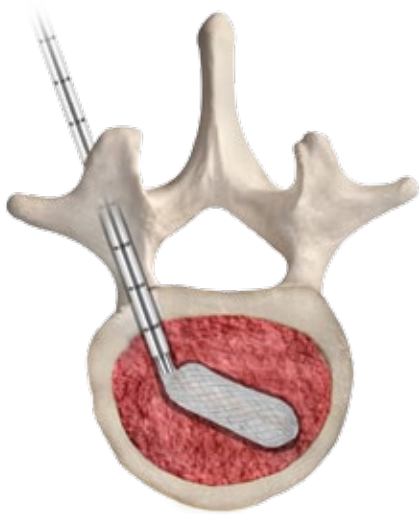
CAVITY CREATION

FRACTURE STABILIZATION

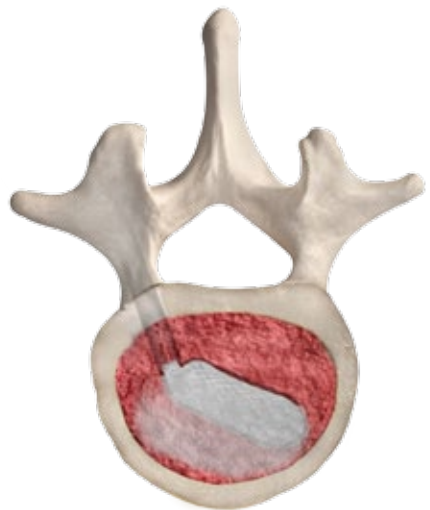
Next, the SHIELD™ Implant is inserted into the void and filled with bone cement to stabilize the compression fracture.

As the cement hardens on the inside of the vertebral body, it forms internal support for the fractured vertebra.

Vertebral Augmentation may be performed on an inpatient or outpatient basis, depending on medical necessity. After the procedure, you will most likely be transferred to the recovery room for observation.



IMPLANT INSERTION

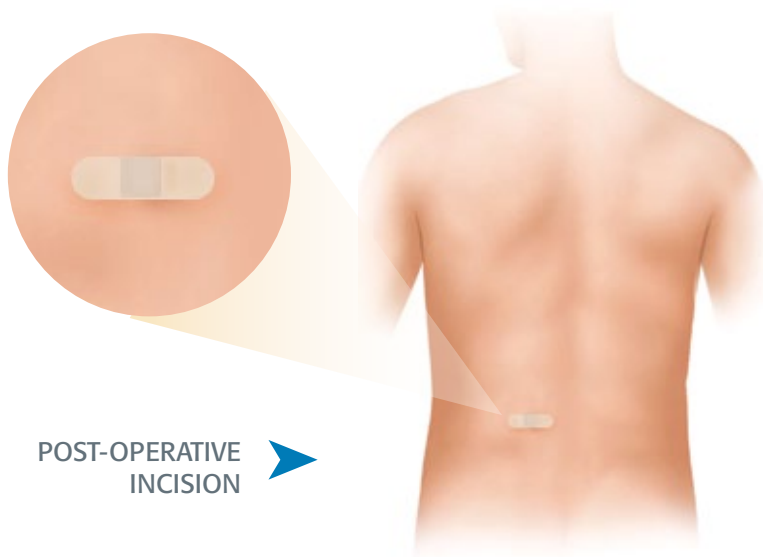


CURED CEMENT

AFTER YOUR PROCEDURE

After your VCF procedure, you will remain flat on your back for a period of time, in order for the cement to completely harden.

Typically, patients are able to be discharged within a few hours after treatment. The incision site is covered with a bandage.



What Should You Expect with Your Recovery?

Treatment with the SHIELD™ VCF System may help you return to normal activities. Many patients recover in 2–4 weeks; however, recovery time varies between patients.

A positive attitude, reasonable expectations and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

Benefits and Risks

POTENTIAL BENEFITS

Vertebral Augmentation with the SHIELD™ VCF System may help to reduce or eliminate your back pain, and is designed to reduce and stabilize compression fractures. Early and effective treatment may reduce the consequences of spinal fractures, especially those associated with other treatments such as prolonged bed rest and the use of analgesics.

Discuss this procedure with your physician to decide whether this treatment option is right for you. Vertebral Augmentation does not guarantee that your symptoms will improve following surgery.

Complications are rare, but all surgical procedures carry some degree of risk. Your doctor will review a complete list of possible complications which may include leakage of the cement into the spinal canal and adjacent veins, infection, bleeding, increased back pain, numbness, tingling or paralysis.



CONTRAINDICATIONS, COMPLICATIONS, WARNINGS AND PRECAUTIONS

You may be contraindicated (not suitable) for this device if you have an infection, multiple myeloma, paget's disease, spinal canal compromise, or are pregnant.

As with any surgical procedure, complications may occur following the placement of this device. These can include but are not limited to dural injury, embolism, cement extravasation, vascular injury, refracture, incomplete cement fill, hemorrhage and hematoma.

Other general complications associated with any spinal procedure include pain, second surgery, bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, respiratory problems, reactions to anesthesia, paralysis, and death.

This list does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.



Notes

PHYSICIAN'S NAME

PHYSICIAN'S PHONE

FACULTY NAME




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insert for description, indications, contraindications, warnings,
precautions and other important information.

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