

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



Discover the **AFFIRM™ VCF System**

A minimally invasive treatment for vertebral
compression fractures



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AFFIRM™

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

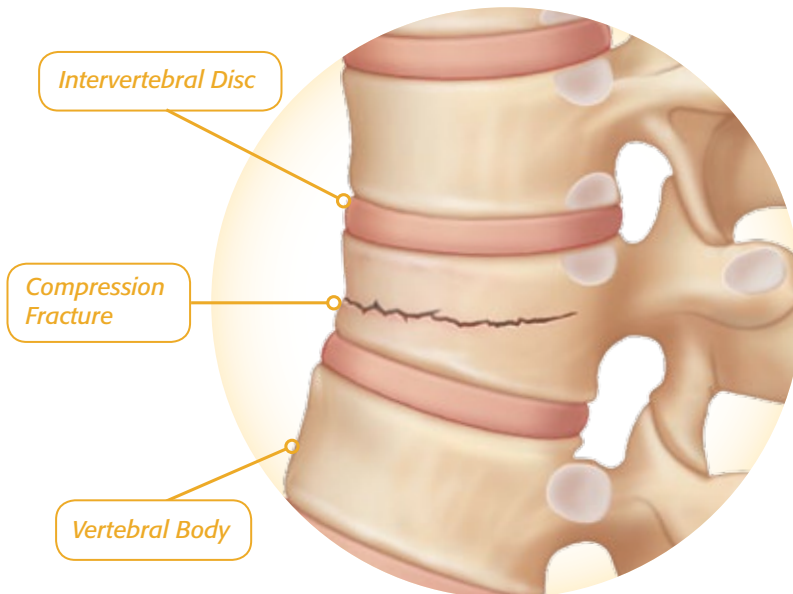
The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment or its outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability 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 10 million Americans have osteoporosis, and an additional 34 million are estimated to have low bone mass, placing them at increased risk for developing this condition. Of the 10 million Americans with osteoporosis, 8 million women and 2 million men have the condition.

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



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.

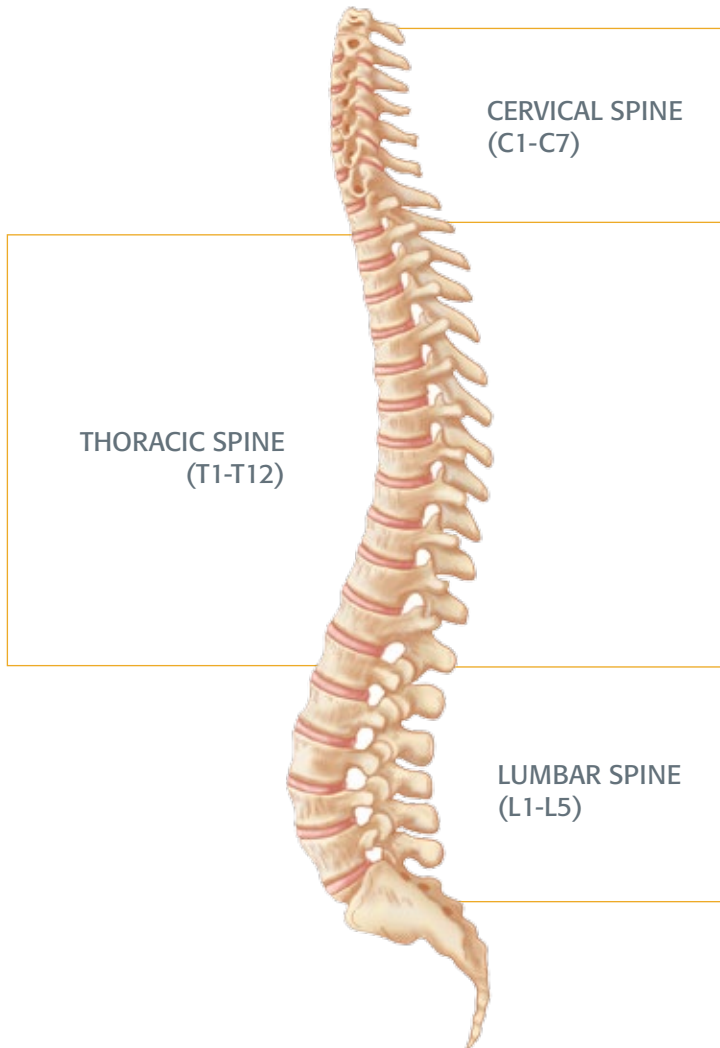
Because there is a substantial risk of subsequent fractures of all types in people who have had a vertebral compression fracture, it is important that VCFs are diagnosed and treated early.



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 or cancerous tumors.

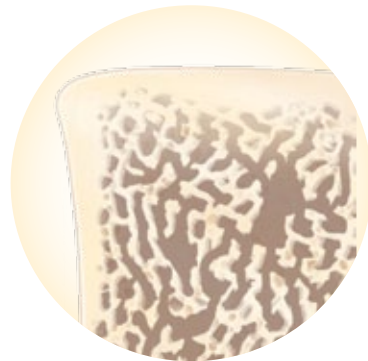


In people with severe osteoporosis, a VCF may be caused by simple daily activities, such as stepping out of the shower, sneezing vigorously or lifting a light object. In people with moderate osteoporosis, it usually takes increased force or trauma, such as falling down or attempting to lift a heavy object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

Cancerous tumors may be considered a potential cause of VCFs in patients younger than 55 with no history of trauma or only minimal trauma. The bones of the spine are a common place for many types of cancers to spread. The cancer may cause destruction of part of the vertebra, weakening the bone until it collapses.



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, tumors, malignancies, and other pathologies may impact the patient's 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

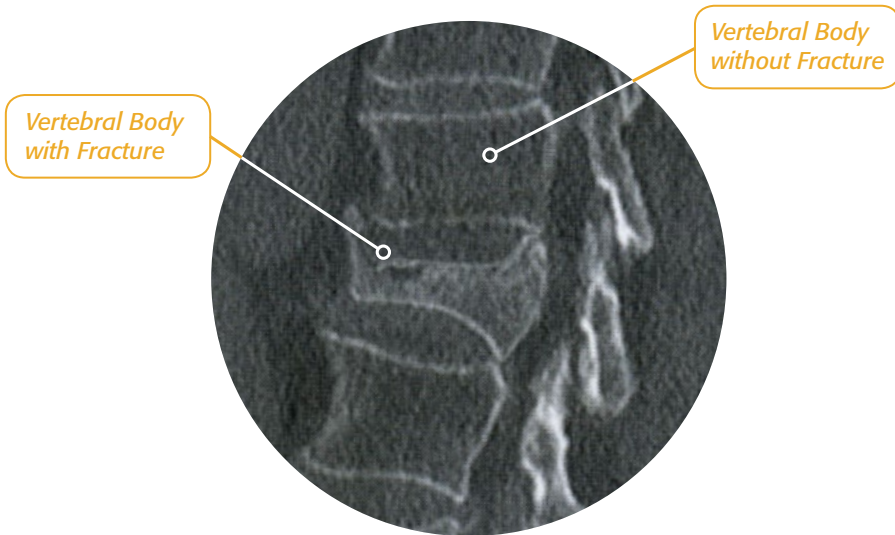
VERTEBRAL AUGMENTATION (KYPHOPLASTY/VERTEBROPLASTY)

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

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 – your treating physician will decide which option is appropriate for you.

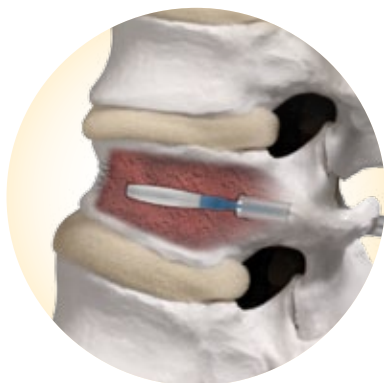


COMPRESSION FRACTURE
(CT SCAN)

DURING YOUR PROCEDURE

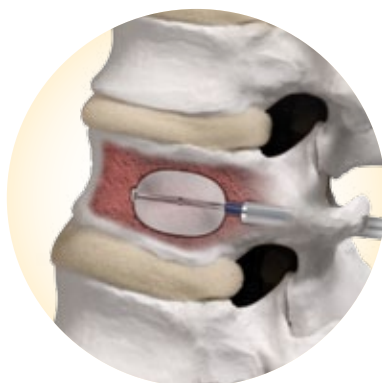
Vertebral Augmentation is generally performed through a small tube under local or mild sedation, eliminating many of the complications of open surgery. However, in some situations, general sedation is advised.

Your back is then numbed with a local anesthetic. Using x-ray guidance, a balloon is inserted into the fractured vertebra through a small incision.



← **BALLOON INSERTION**

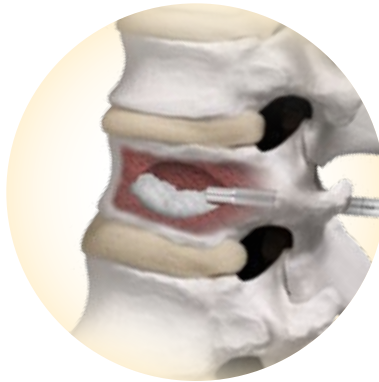
The balloon is then inflated, creating a void, or cavity, on the inside of the vertebral body. Once the void is created, the balloon is deflated and removed.



← **BALLOON INFLATION**

DURING YOUR PROCEDURE (cont'd)

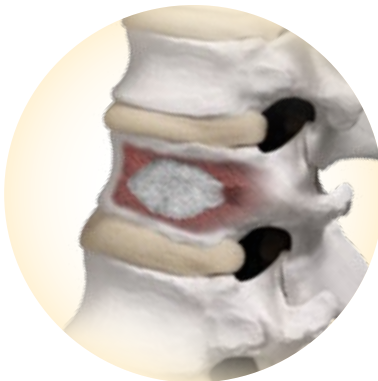
The void is then filled with bone cement to stabilize the compression fracture. As the cement hardens on the inside of the vertebral body, it will form internal support for the fractured vertebra.



◀ CEMENT DELIVERY

FRACTURE STABILIZATION

Vertebral Augmentation takes about one hour per fracture treated. It may be done 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.

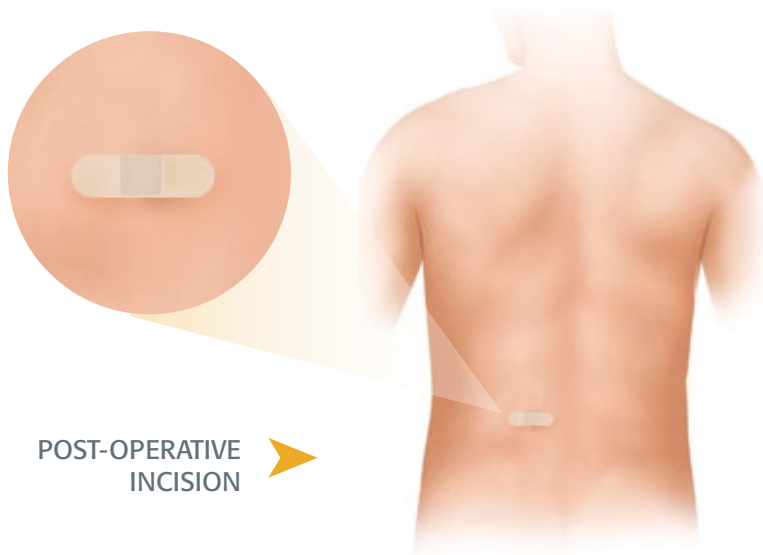


◀ CURED CEMENT

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 sight is covered with a bandage.



What should you expect with your recovery?

Treatment with the AFFIRM™ 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 AFFIRM™ 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.



WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

WARNINGS

One of the potential risks identified with this procedure is death. Other potential risks which may require additional surgery include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae;
- Rupture with fragmentation of the inflatable portion of the balloon resulting in retention of a fragment within the vertebral body;
- Rupture of the balloon causing contrast medium exposure, possibility resulting in an allergic reaction or anaphylaxis;
- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur;
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding;
- Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date;
- Deep or superficial wound infection;
- Retropathy, paresis or paralysis; and
- Bleeding or hematoma

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of spinal fracture.

PRECAUTIONS

Vertebral Augmentation procedures should be performed only by experienced spinal surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing Vertebral Augmentation.

PRECAUTIONS (cont'd)

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

CONTRAINDICATIONS

Use of the AFFIRM™ VCF System is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials;
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the Vertebral Augmentation procedure during healing and may be at a higher risk of failure;
- Bleeding disorder or treatment that increases the chance of excessive bleeding;
- Any known severe allergy to contrast material;
- Instability of posterior wall and/or pedicles;
- Pedicle fracture;
- Epidural abscess;
- Sepsis;
- Osteomyelitis;
- Active infection;
- Discitis;
- Uncorrectable coagulopathy;
- Symptomatic cord compression at the level of fracture;
- Severe cardiopulmonary disease; and
- Pregnancy

These instruments should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement.

Notes

PHYSICIAN'S NAME

PHYSICIAN'S PHONE

FACULTY NAME



Interventions for Life

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insert for description, indications, contraindications, warnings,
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