PATIENT INFORMATION

A MINIMALLY INVASIVE TREATMENT FOR VERTEBRAL COMPRESSION FRACTURES

VERTEBRAL AUGMENTATION

Life moves us

Outside the US Only

GLOBUS MEDICAL

Vertebral Augmentation

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 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.

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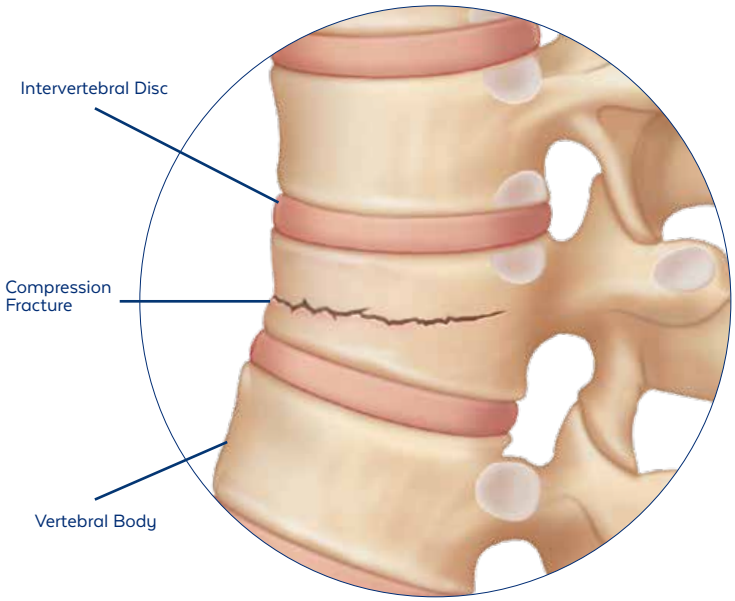
Understanding Vertebral Compression Fractures (VCF)

A large number of people have osteoporosis, and many more are estimated to have low bone mass, placing them at increased risk for developing this condition. The majority of individuals with this condition are women but it can also be present in men.

Vertebral compression fractures (VCFs) are the most common fracture type in patients with osteoporosis. Postmenopausal women have a higher risk of developing this condition. The prevalence of this condition steadily increases as people age, and it is quite common among women over 80 years old. Although far more common in women, VCFs are also a major health concern for older men.



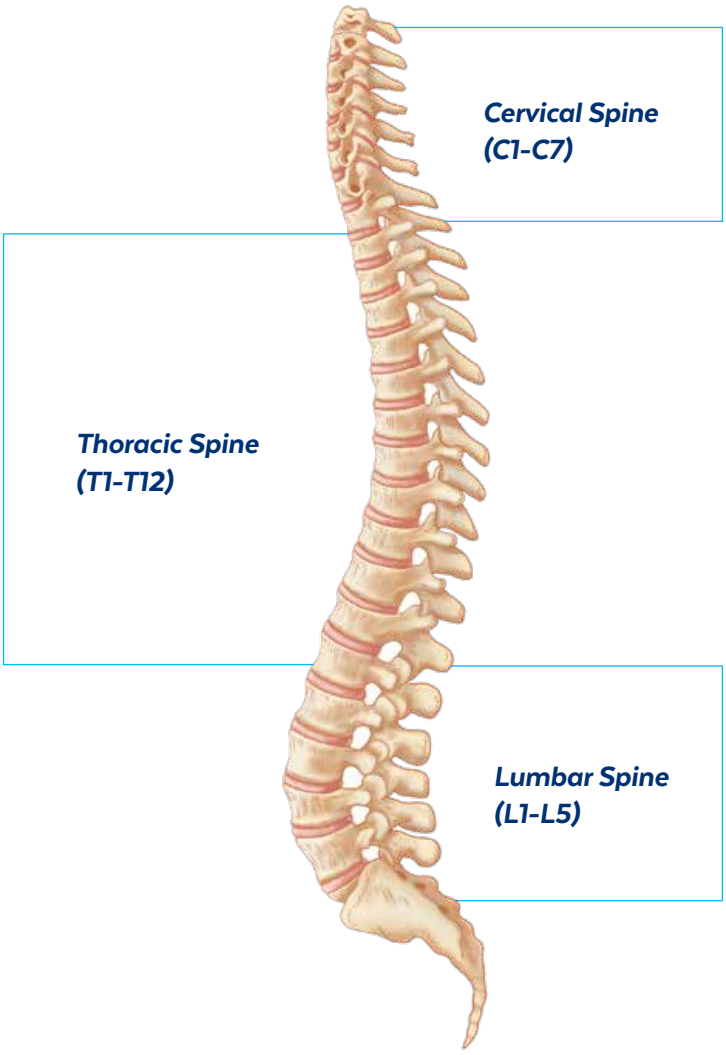
VCFs have a substantial impact on the quality of life and day-to- day functioning of those afflicted. Short-term and long-term pain in the elderly is commonly attributed to vertebral compression fractures, which may lead to further health decline.

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?

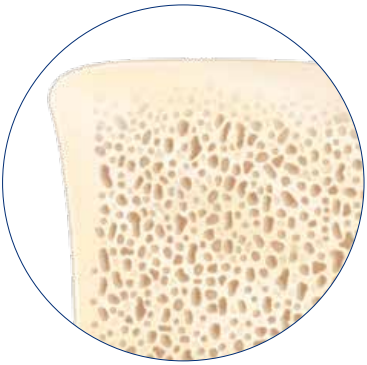
VCFs occur when the vertebral body (bone) in the spine collapses, which can lead to pain, deformity, and loss of height. These fractures more commonly occur in the lower thoracic spine (the middle portion of the spine). While osteoporosis is the most common cause, these fractures may also be caused by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



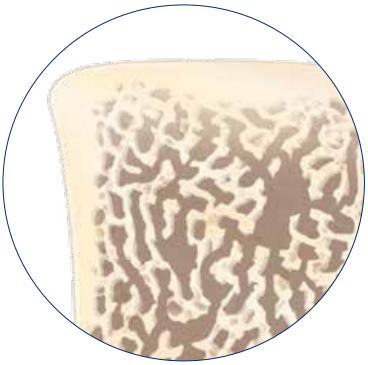
In people with severe osteoporosis, a VCF may be caused by simple daily activities, such as stepping out of the shower, sneezing vigorously, or lifting a light object.

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 and Risks

VCFs caused by osteoporosis, tumors, cancerous cells, and other diseases may impact the patient's quality of life. The following effects after 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

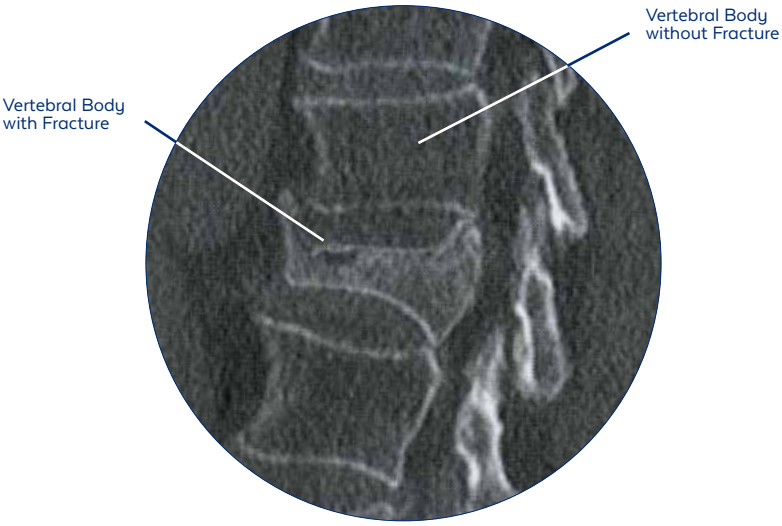
Vertebral Augmentation (Kyphoplasty/Vertebroplasty)

If you have been diagnosed with a VCF caused by osteoporosis, cancer, or benign tumors, vertebral augmentation (strengthening) is a treatment option for which you may be considered. Vertebral augmentation is a minimally invasive procedure that may reduce back pain and repair the vertebral compression fracture. Minimally invasive procedures use a small incision and may reduce trauma to surrounding tissue, as compared to a large open approach.

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 an appropriate treatment. The procedure can be performed under local or general anesthesia. Your treating physician will decide which option is most appropriate for you.

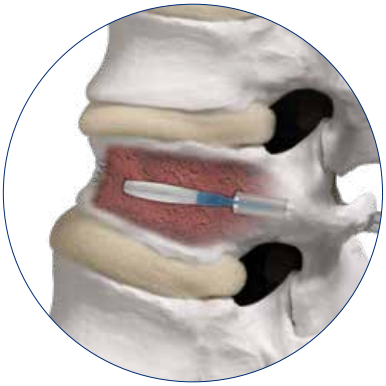


Compression Fracture (CT Scan)

During Your Procedure

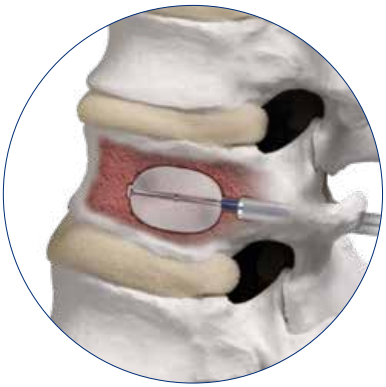
Vertebral augmentation is generally performed through a small tube under local or mild sedation, eliminating many of the complications of open surgery. However, in some situations, general sedation is advised.

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 (surgical cut).



Balloon insertion

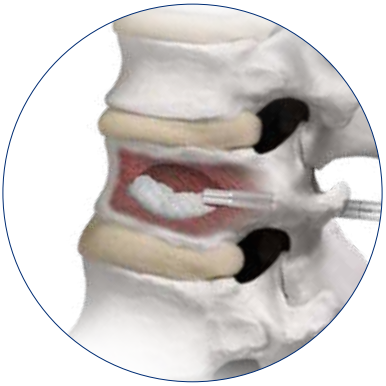
The balloon is then inflated, creating a void, or cavity, on the inside of the vertebral body. Once the void is created, the balloon is deflated and removed.



Balloon inflation

During Your Procedure (Cont'd)

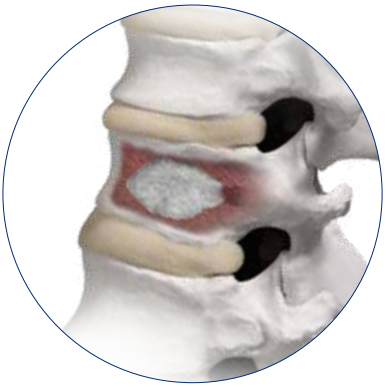
The void is then filled with bone cement to help stabilize the compression fracture. As the cement hardens on the inside of the vertebral body, it forms internal support for the fractured vertebra.



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.

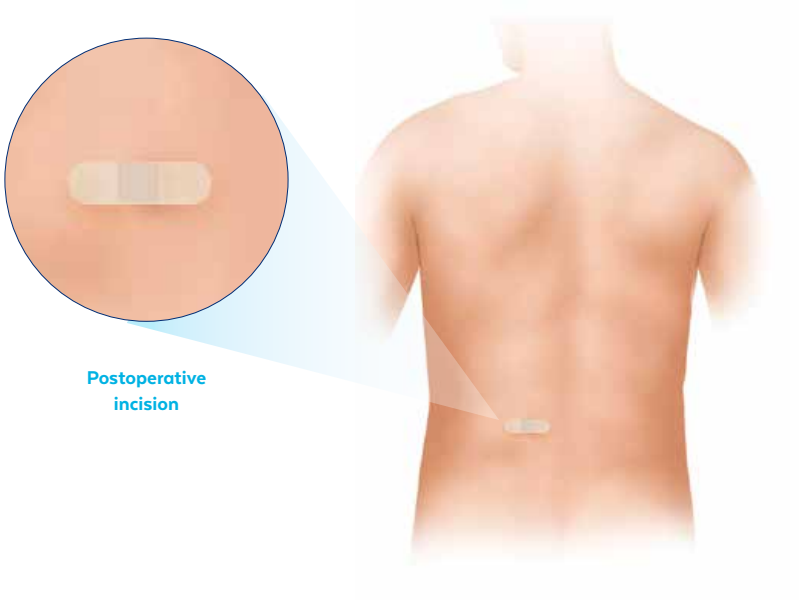


Cured (hardening) cement

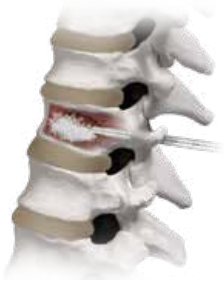
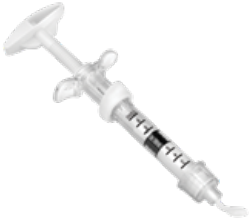
After Your Procedure

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.



Globus Medical offers a variety of VCF systems for vertebral augmentation.

Device Type	**Implant Name***
VCF Systems	AFFIRM® CONTAIN® SHIELD®
	
Bone Cement	**FORTRESS®
	

Visit Globus Medical's website at https://www.globusmedical.com/international/
**These products may not be available in your region.*
***FORTRESS is a bone cement composed of polymethyl methacrylate (PMMA) / methyl methacrylate-styrene copolymer, N:N Dimethyl-p-toluidine, hydroquinone, benzoyl peroxide, and barium sulfate. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult your physician.*

Frequently Asked Questions

What Should I Expect With My Recovery?

Vertebral augmentation may help you return to normal activities. Many patients recover in 2 to 4 weeks; however, recovery time varies among patients.

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

How Long Will the Bone Cement Last?

The lifetime of FORTRESS® is at least one year, in which it is expected that it will achieve its intended purpose (to solidify the bone) and maintain performance until the bone is completely solid. After this occurs, the bone cement is made to survive the life of the patient.

Can I Have an MRI After the Bone Cement in Implanted?

FORTRESS® can be safely scanned and does not require any special conditions for an MRI.

Benefits and Risks

Potential Benefits

Vertebral augmentation 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 pain killers.

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.

Your doctor will review a complete list of possible complications, which may include leakage of the cement into the spinal canal and neighboring veins, infection, pulmonary embolism, bleeding, increased back pain, numbness, tingling, or paralysis.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this procedure if you have an infection, a congenital abnormality, bleeding disorder, severe cardiac or pulmonary insufficiencies, thrombophilia, certain allergies, nonpathological fractured vertebrae or unstable pedicles, severe vertebral body collapse, rheumatoid arthritis, osteoporosis, osteomyelitis, diabetes, cancer, or are obese, pregnant, or mentally ill. In addition, a patient whose mental or physical impairment places undue stresses on the implant during healing may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of cement. These can include but are not limited to cement leakage, embolism or clots, bone separation, extra skeletal bone formation, decrease in bone density or bone fraction, abnormal sensations, and serious allergic reaction to the cement material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pseudarthrosis, pain, secondary surgery, bleeding, infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, urinary complications, tissue damage, joint inflammation, cardiovascular system compromise or cardiac event, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse effect with your implant, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

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