

Benefits and risks

The balloon kyphoplasty (BKP) procedure has been reported to provide patients with significant improvements in pain, mobility and the ability to perform daily tasks. Patients may be able to walk and return to their normal activities soon after surgery.⁵

Treatment with the BKP procedure may directly or indirectly cause side effects or complications. Discuss the risks and benefits of the BKP procedure with your doctor to decide if this treatment option is right for you.

Serious side effects have been known to occur with the use of bone cement in surgical procedures of the spine. These include, but are not limited to, heart attack, cardiac arrest (heart stops beating), stroke, embolism (blood clot or bone cement that moves to the heart or lungs) or death. Side effects may occur beyond a year or more after the procedure.

Other side effects related to use of an inflatable balloon device with bone cement include, but are not limited to, wound infection, bleeding, hematoma (collection of blood outside a blood vessel), allergic reaction and pneumothorax (collapsed lung). Please consult with your doctor for the full list of possible side effects related to the combined use of bone cement with an inflatable balloon device.

Understand what's causing your pain

Contact us to schedule a consultation:



Visit strykerivs.com or scan to find a doctor in your area.

Interventional Spine

Bibliographic information can be found online at: strykerivs.com/footnotes/vertebralaugmentationpatient

Only your doctor can make the medical judgment on which products and treatments are right for your own individual condition. Your physician will explain all the possible complications of the procedure, as well as side effects. Individual results vary and not all patients will receive the same post-procedure activity level.

Bone cement: Serious adverse events, some with fatal outcome, associated with the use of bone cements for vertebroplasty, kyphoplasty and sacroplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism and cardiac embolism. Although it is rare, some adverse events have been known to occur beyond a year or more post-operatively. Additional risks exist with the use of bone cement. Please see the IFU for a complete list of potential risks.

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Stryker Instruments
1941 Stryker Way
Portage, MI 49002

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Vertebral augmentation

Living with back pain

can be a daily challenge



Resume many of the physical activities you love.

Vertebral augmentation relieves pain in approximately 85-90% of patients.¹

Approach back pain with a surgical alternative

Understanding VCFs

Most people blame aging as the cause of back pain. However, the true cause may be a vertebral compression fracture (VCF) due to osteoporosis, which affects over 700,000 men and women in the United States each year.¹

Osteoporosis, meaning “porous bones,” is a gradual disease that slowly extracts calcium and minerals from your bones.² Over time, bones may become so weak that strains to the spine, such as tripping, falling off a chair or attempting to lift a heavy object, can cause a spinal fracture.³ VCFs are a hallmark of osteoporosis, which can adversely affect function and quality of life.⁴

Treating VCFs

Conservative therapy for VCFs includes bed rest, pain medication, external back braces and physical therapy.³ If there is little or no pain relief, your doctor may recommend vertebral augmentation.

This minimally invasive procedure is done on an outpatient basis and usually requires only local anesthetic. In some instances, general anesthesia is advised with a short hospital stay.⁵

Contact your doctor if you experience one or more of these symptoms:^{3,6}

- Sharp, sudden back pain
- Pain increases during standing or walking
- Lying on the back makes pain less intense
- Limited spinal mobility due to pain
- Do not respond to non-surgical treatment (bed rest, back brace and/or pain medications)

The procedure and what you can expect

Before

Your doctor will do a physical exam and order x-rays and/or other imaging tests, such as an MRI, CT or bone scan.⁷ These tests help to determine the location of the fractured vertebra, how recently the fracture occurred and whether or not vertebral augmentation with BKP is the most appropriate treatment.

During

Generally, vertebral augmentation with BKP is performed while you are awake but sedated. Your back is numbed by a local anesthetic. Using x-ray guidance, a balloon is inserted into the fractured vertebra through a small incision. The balloon is then inflated, creating a void or cavity. Once the void is established, the balloon is deflated and removed. The void is then filled with bone cement to stabilize the fracture. As it hardens, the cement forms an internal cast that holds the vertebra in place.⁸ The incision is covered with a bandage.

After

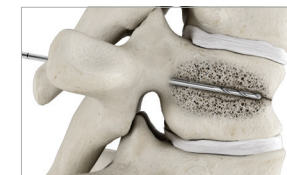
After the procedure, you’ll lie on your back for a short period of time while the cement continues to harden. Your vital signs will be monitored. Typically, patients are able to go home within a few hours of treatment.⁸ Please see the **Benefits and risks** section of the brochure for more information.

Procedure overview

Overview of BKP procedure⁹



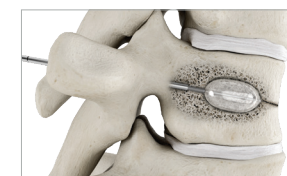
- 1 Needle is guided into fractured vertebra using x-ray guidance



- 2 Hand drill is inserted into the anterior third of the vertebral body to create a pathway¹⁰



- 3 Balloon catheter is inserted into the fractured vertebra



- 4 Balloon is inflated, creating a void in cancellous (spongy) bone



- 5 Once the balloon is deflated and withdrawn, the cavity is filled with bone cement



- 6 Vertebral body is stabilized