Benefits and risks

The SpineJack system has been shown to provide improved pain relief in patients up to 12 months following the procedure. Additional benefits for patients treated with the SpineJack system include restoring vertebral body height and reducing adjacent level fractures.[8]

The use of the SpineJack system may directly or indirectly cause side effects or complications. Discuss the risks and benefits of the SpineJack 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 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 up to one year after the procedure.

Side effects related to use of the SpineJack system with bone cement include infection, bleeding, allergic reaction, thrombosis (blood clot formation), numbness or tingling and changes in blood pressure. Please consult with your doctor for the full list of possible side effects related to the combined use of bone cement with the SpineJack implant.

SpineJack implants

Understand what's causing your discomfort and **treat more than just the pain**

Contact us to schedule a consultation:

Visit strykerIVS.com to find a practitioner in your area

Interventional Spine

Bibliographic information can be found online at: strykerIVS.com/footnotes/spinejackpatient

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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.

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SpineJack® system

Restore your spine

Pain doesn't have to be permanent

Approach back pain with a **restorative solution**

Understanding VCFs

Each year, more than 700,000 spinal fractures, also known as vertebral compression fractures (VCFs), occur in the United States due to osteoporosis.[1] Osteoporosis is a disease that causes bones to weaken and become more likely to break. Over time, bones may become so weak that mild strains, such as lifting a light object, coughing or sneezing, or turning in bed can lead to a spinal fracture.[2]

VCFs due to osteoporosis may initially be felt as severe back pain, which can affect mobility, activities of daily living and quality of life.[2-4] In many cases, painful osteoporotic VCFs may lead to loss of height, hunched posture (kyphosis) and disability.[2] Since having one or more VCFs increases the risk for developing another spinal fracture, it is important to get an early diagnosis and seek treatment as soon as possible.

Contact your doctor if you experience one or more of these symptoms[2,5]

- ☐ 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)

Treating VCFs

Conservative therapy for VCFs may include bed rest, pain medication, external back braces and physical therapy.[2] If there is little or no pain relief, your doctor may recommend vertebral augmentation with the SpineJack implant.

This minimally invasive procedure is done on an outpatient basis and usually requires only local anesthetic and mild sedation, helping to eliminate many of the complications that result from open surgery. In some instances, general anesthesia is advised with a short hospital stay.[6]

The procedure and **what you can expect**

Before

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

During

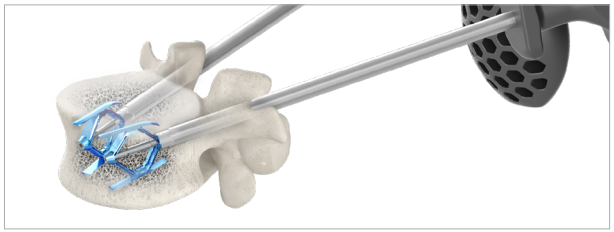
Generally, vertebral augmentation is performed while you are awake but sedated and your back is numbed with local anesthetic. Using X-ray guidance, two expandable implants are inserted into the fractured vertebra through small incisions. The implants are then expanded, restoring the vertebral anatomy and creating a cavity. The area surrounding the implants is then filled with bone cement to stabilize the fracture.[7] As it hardens, the bone cement forms an internal cast that holds the vertebra in place. Following the procedure, the incisions are covered with bandages.

After

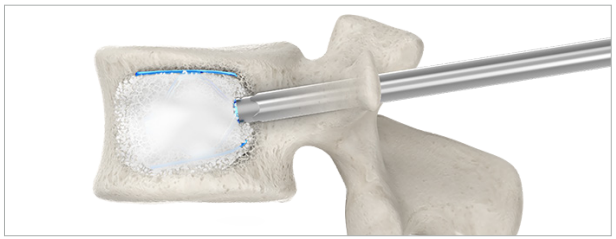
After the procedure, you'll lie on your back for a short period of time while the bone cement continues to harden. Your vital signs will be monitored. Typically, patients are able to go home within a few hours of treatment. Please see the **Benefits and risks** section of the brochure for more information.

Procedure **overview**

1 Two unexpanded implants are inserted into the fractured vertebral body.[7]



2 Implants are slowly expanded, allowing the SpineJack system to restore the height of the fractured vertebral body.[7]



3 Once spinal height is restored, bone cement is injected into the vertebral body to stabilize the fracture.[7]