

For more information or
to locate a physician trained to perform
KYPHON® Balloon Kyphoplasty,
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Vertebral Compression Fractures

A vertebral compression fracture (VCF) occurs when one of the bones of the spinal column weakens and collapses. Vertebral compression fractures tend to be painful and, if left untreated, can adversely affect overall health and well-being.

In cases of multiple VCFs, the spine shortens and angles forward, resulting in kyphosis, or a “hunchbacked” posture. Over time, this condition may compress the lungs and abdomen, causing medical complications seemingly unrelated to the spine, such as:

- Reduced activity and alteration in mobility^{1,2}
- Decreased appetite and sleep disorders^{1,2}
- Impaired pulmonary function (breathing problems)³
- Increased risk for future fracture⁴
- Decreased quality of life; feelings of isolation and sadness^{1,2}
- A 23% increase in mortality rate in women over age 65 with history of prior VCF⁵



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KYPHON® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KYPHON® HV-R™ Bone Cement), hand, tibia, radius and calcaneus. KYPHON® HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

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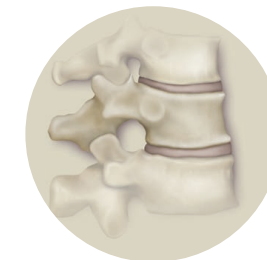
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Although the complication rate for KYPHON® Balloon Kyphoplasty is low, as with most surgical procedures, serious adverse events, some of which can be fatal, can occur, including heart attack, cardiac arrest (heart stops beating), stroke, and embolism (blood, fat or cement that migrates to the lungs or heart). Other risks include infection; leakage of bone cement into the muscle and tissue surrounding the spinal cord and nerve injury that can, in rare instances, cause paralysis; leakage of bone cement into the blood vessels resulting in damage to the blood vessels, lungs and/or heart. This procedure is not for everyone. A prescription is required. Please consult your physician for a discussion of these and other risks and whether this procedure is right for you.

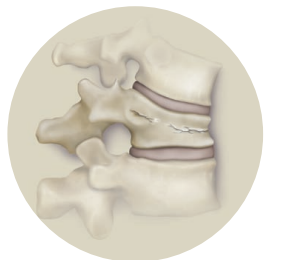
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KYPHON® Balloon Kyphoplasty

Treatment for vertebral compression fractures due to osteoporosis or cancer



Normal vertebra



Fractured vertebra



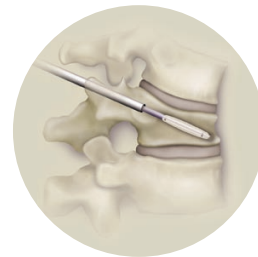
Long-term effect of spinal fractures

It is important that VCFs are diagnosed and treated by a physician. A physical exam, along with an x-ray, can help determine if a compression fracture has occurred.



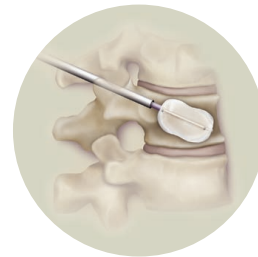
About KYPHON® Balloon Kyphoplasty

KYPHON® Balloon Kyphoplasty is a *minimally invasive treatment* that can repair VCFs caused by primary or secondary (e.g. steroid-induced) osteoporosis, cancer, or benign lesions. Orthopedic balloons are used in an attempt to elevate the bone fragments of the fractured vertebra and return them to the correct position. Performed under *local or general anesthesia*, the procedure typically takes less than an hour and may require an overnight hospital stay.



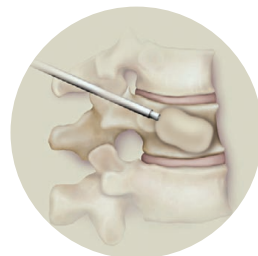
Balloon placement

With a hollow instrument, a narrow pathway is made into the fractured bone. A small orthopedic balloon is guided through the instrument into the vertebra. The incision site is approximately 1cm in length.



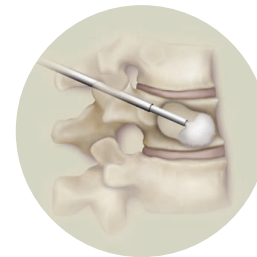
Full inflation

Next, the balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position.



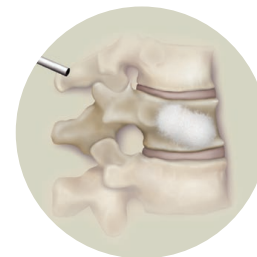
Void within the vertebra

Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (space) within the vertebral body. The void functions as a "container" for the bone cement.



Filling the void with cement

The void is then filled with bone cement to stabilize the fracture.



The internal cast

The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the vertebra.

Step back into life with KYPHON® Balloon Kyphoplasty

Balloon kyphoplasty can make it easier for patients to return to everyday activities such as walking, bending, or lifting with significantly less pain than they had prior to the procedure. Studies report favorable patient outcomes,⁶⁻¹⁵ including:

- Correction of vertebral body deformity
- Significant reduction in pain
- Improved ability to perform activities of daily living
- Improved quality of life
- Low complication rate

KYPHON® Balloon Kyphoplasty is performed worldwide and has been used to treat over 460,000 patients. For more information, please visit www.kyphon.com.

