

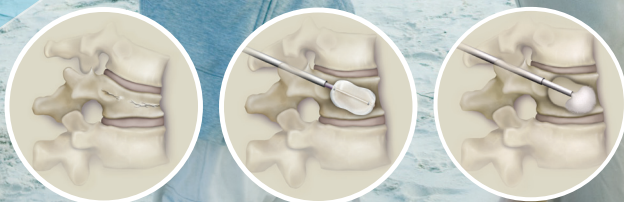


**Medtronic**

# KYPHON® Balloon Kyphoplasty

A Minimally Invasive Treatment For Spinal Fractures

Information for you  
and your family



**MICHELSON  
TECHNOLOGY  
AT WORK**





**Medtronic**

# KYPHON® Balloon Kyphoplasty

A Minimally Invasive Treatment For Spinal Fractures

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## Introduction

Your doctor has determined that you have a spinal fracture, also known as a vertebral compression fracture (VCF). This type of fracture can cause severe back pain. Left untreated, one compression fracture can lead to multiple fractures that, in turn, could alter the shape of your spine and adversely affect your overall health.

Traditional treatment for spinal fractures is limited to bedrest, bracing and management of pain, often with narcotics. Although appropriate in some cases, this type of treatment does not address the deformity caused by the fracture.

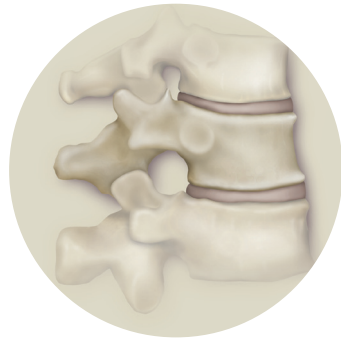
KYPHON® Balloon Kyphoplasty is a minimally invasive treatment that can stabilize the fracture and reduce back pain, as well as restore vertebral body height and spinal alignment.

This booklet explains how spinal fractures occur and why KYPHON® Balloon Kyphoplasty may be a viable treatment option for you.

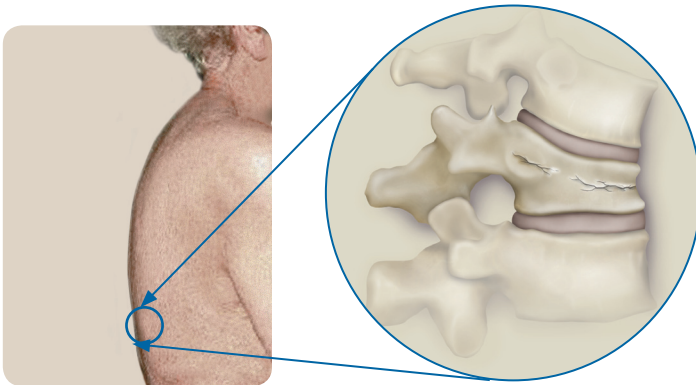


## What is a Spinal Fracture?

The bones in your spine are called vertebrae; the thick portion of bone at the front of each vertebra is referred to as the vertebral body (**Figure 1**). A spinal fracture, or vertebral compression fracture (VCF), occurs when the vertebral body fractures and collapses (**Figure 2**). Most spinal fractures are caused by osteoporosis, a disease that causes bones to become brittle and break easily. Because osteoporosis usually progresses without obvious symptoms, a person may not know that they have the disease until a fracture occurs. Spinal fractures can also occur as a result of certain types of cancer or tumors.



**Figure 1**  
Normal vertebral body  
(side view)



**Figure 2**  
Fractured vertebral body  
(side view)

Multiple spinal fractures can cause your spine to shorten and angle forward, resulting in a stooped posture or hunched back. This forward curvature of the spine (kyphosis) makes it difficult to walk, reach for things, or conduct activities of daily living.

Chronic back pain, height loss, diminished appetite, and difficulty sleeping have been associated with kyphosis. Over time, patients with multiple spinal fractures are at increased risk of suffering from serious, or even fatal, pulmonary complications.

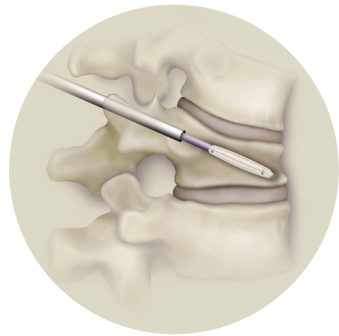
## How the Balloon Works

KYPHON® Balloon Kyphoplasty is a *minimally invasive treatment* in which orthopedic balloons are used to gently elevate the fractured vertebra in an attempt to return it to the correct position. Before the procedure, you will have diagnostic studies, such as x-rays and magnetic resonance imaging (MRI), to determine the exact location of the fracture.

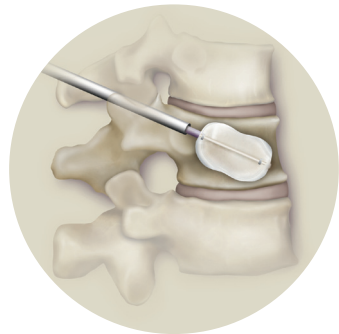
With a hollow instrument, the spine specialist creates a small pathway into the fractured bone. A small orthopedic balloon is guided through the instrument into the vertebra. The incision site is approximately 1 cm in length.

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

KYPHON® Balloon Kyphoplasty can be done under *local or general anesthesia*—your doctor will decide which option is appropriate for you. Typically, the procedure takes less than one hour per fracture level treated and may require an overnight hospital stay.



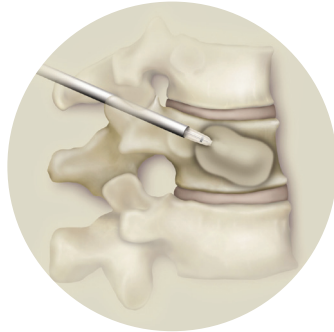
Balloon placement



Balloon inflation

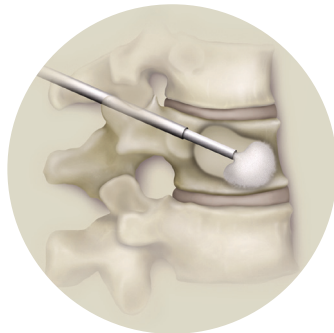
## How the Balloon Works *Continued*

Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a cavity within the vertebral body.



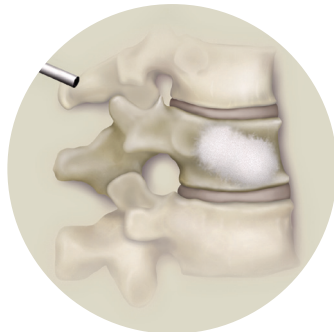
Cavity within vertebral body

The cavity is filled with a special cement to support the surrounding bone and prevent further collapse.



Filling the cavity with cement

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



The internal cast

## After KYPHON® Balloon Kyphoplasty Treatment

### Typical postoperative care involves the following:

After the procedure, you will most likely be transferred to the Recovery Room for about an hour. A specially trained nurse will monitor your condition and assess the degree to which your back pain has been alleviated.

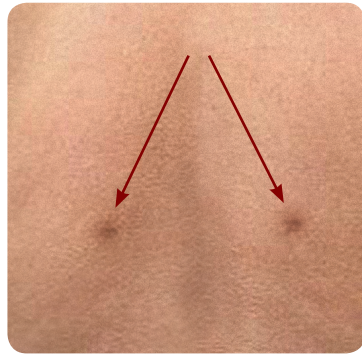
During your hospital stay, you will be encouraged to walk and move about. Generally, patients are discharged from the hospital within 24 hours.

Your doctor will have you schedule a follow-up visit and explain limitations, if any, on your physical activity. After treatment with KYPHON® Balloon Kyphoplasty, mobility is often quickly improved. Most patients are very satisfied with the procedure and are able to gradually resume activity once discharged from the hospital.

### Procedure Benefits:

- » Reduction in back pain
- » Improvement in quality of life
- » Improvement in mobility
- » Improvement in ability to perform activities of daily living

KYPHON® Balloon Kyphoplasty has been used to treat patients worldwide with spinal fractures since 1998.



Incision sites after KYPHON® Balloon Kyphoplasty

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.



## Frequently Asked Questions

### **Are spinal fractures difficult to diagnose?**

If a spinal fracture is suspected during a physical exam, diagnosis can be easily confirmed with radiographic studies. Spinal fractures, however, tend to be under-recognized by physicians and patients alike. The difficulty with diagnosis arises when the discomfort from a spinal fracture is mistaken as benign back pain or a “normal” part of aging. Sometimes, a person can have a spinal fracture and not have any symptoms at all; this too can be an obstacle to diagnosis.

If your back pain is caused by a spinal fracture, it is important to have it diagnosed. Only a complete physical exam, together with an x-ray and MRI, can help your physician determine whether your back pain is from a spinal fracture.

### **Why is it important to treat spinal fractures?**

After one spinal fracture, the risk for having another is increased five-fold. In addition, just one spinal fracture can affect the distribution of weight along the spinal column. Misalignment brought on by a fractured vertebra places more stress on adjacent vertebrae; the front of the spine has to withstand the same amount of stress with fewer functioning parts, resulting in a structure that is now weakened and vulnerable to additional fracture. Over time, a hunched back and chronic pain associated with multiple spinal fractures can contribute to an overall poor quality of life.

### **What are the symptoms of a spinal fracture?**

Spinal fractures can occur unrelated to specific injury or trauma. Fractures can occur as a result of normal activity; e.g., bending over to pick something up, reaching for an object, or carrying a bag of groceries. Patients can experience pain ranging from sudden and severe, to mild and persistent. The fact that symptoms of a spinal fracture can be easily confused with other back problems underscores the importance of paying attention to your back pain and seeing a physician for diagnosis.

## Frequently Asked Questions *Continued*

### **Can spinal fractures adversely affect my overall health?**

In cases of multiple fractures, kyphosis can become more pronounced, painful, and debilitating. Forward curvature of the spine has a compression effect on your organs, making it progressively difficult to breathe, walk, eat, or sleep properly. Patients with kyphosis have an increased risk for mortality compared to patients without fractures.

### **What are the psychosocial effects of spinal fractures?**

Clinical studies have shown that patients with multiple spinal fractures experience depression, anxiety, and lowered self-esteem, in addition to medical complications. The alteration in lifestyle that accompanies severe kyphosis can profoundly affect a patient's sense of well-being and cause feelings of isolation and sadness.

### **How common are spinal fractures?**

According to the National Osteoporosis Foundation, one-in-two women and one-in-four men over age 50 will have an osteoporosis-related fracture in their lifetime; many of these fractures are in the spine. Yet, with over 700,000 new spinal fractures occurring in the United States each year, as many as two-thirds of spinal fractures go undiagnosed and untreated – often because patients consider back pain a normal part of aging and fail to discuss fracture symptoms with their physician.

### **How long does the procedure take? What kind of anesthesia is used?**

Balloon kyphoplasty typically takes one hour per fracture level treated and may require an overnight hospital stay. The procedure can be done using either local or general anesthesia; the spine specialist will determine the most appropriate method, based on the patient's overall condition and medical necessity.

### **What are the benefits of the procedure?**

KYPHON® Balloon Kyphoplasty has been shown to restore vertebral body height and correct spinal deformity with a low complication rate.

Studies also report:

- » Reduction in back pain
- » Improvement in quality of life
- » Improvement in mobility
- » Improved ability to perform activities of daily living, such as walking, hobbies and work
- » Reduction in bedrest and the number of days where pain interfered with daily activities

## Frequently Asked Questions *Continued*

### **Are there risks associated with KYPHON® Balloon Kyphoplasty?**

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.

- » Overall frequency of patients with adverse and serious adverse events was similar between the BKP and NSM groups during the 24 months.
- » There was no statistically significant difference in the number of patients with subsequent fractures, including adjacent level fractures between the two groups.
- » Three patients with four BKP procedure/device-related serious adverse events were reported (spondylitis, an anterior cement migration, urinary tract infection, subcutaneous hematoma).

### **Is KYPHON® Balloon Kyphoplasty covered by insurance?**

In most cases, KYPHON® Balloon Kyphoplasty is covered by Medicare and private insurance carriers. If you have questions regarding your policy or coverage, please contact your insurance carrier.

### **Who performs KYPHON® Balloon Kyphoplasty?**

Balloon kyphoplasty is performed by spine specialists trained to perform the procedure. Physician specialties include orthopedic surgeons, neurosurgeons, interventional radiologists, and pain medicine. If you think you have a spinal fracture, you may need to see your primary care physician for diagnosis – and if necessary, get a referral to a spine specialist for treatment with balloon kyphoplasty.

### **Where can I obtain more information about the procedure?**

You can get more information on KYPHON® Balloon Kyphoplasty, as well as find a trained spine specialist in your area, by visiting [www.kyphon.com](http://www.kyphon.com).

## Patient Stories

*Early and effective treatment—fixing the fracture—can improve quality of life*



### Ron Luperine

Retired banker. Age: 62

Diagnosis: Steroid-induced fracture

Mr. Luperine suffered from a chronic lung ailment. Doctors prescribed corticosteroids; however, the drugs caused him to lose bone mass and he developed secondary osteoporosis. The resultant spinal fracture was so debilitating that he had an infusion pump implanted to manage the pain. Following treatment with KYPHON® Balloon Kyphoplasty, the pump was removed and Mr. Luperine is now happy to be “living and getting around again.”



### Chris Kern

Former x-ray technician. Age: 84

Diagnosis: Osteoporotic fracture

Ms. Kern lives with her wheelchair-bound roommate in a house in Northern California. One night, a few hours after helping her roommate to bed, she awoke with severe back pain. Over the next four months, Ms. Kern spent time in and out of the hospital, relying on narcotics to control the pain. She couldn't eat and lost over 30 pounds. Finally, she insisted that a back x-ray be taken and reviewed by an orthopedic surgeon. Four spinal fractures were found. After having KYPHON® Balloon Kyphoplasty, she says the difference in the way she feels is “like night and day.”



## Ellen Simpson, MD

Retired pediatric cardiologist. Age: 86

Diagnosis: Osteoporotic fracture

Dr. Simpson had already been diagnosed with osteopenia and was undergoing pharmacologic treatment for her condition. She recalls a Thanksgiving Day party in which she spent most of the day sitting hunched over because of back pain. The morning after the party, the pain made it difficult to get out of bed. Two spinal fractures were treated with KYPHON® Balloon Kyphoplasty. Now, Dr. Simpson takes delight in her renewed ability to bend and move. "My friends tell me I look 15 years younger!" she says.

## Glossary

### Balloon kyphoplasty

A minimally invasive treatment for spinal fractures. The procedure uses orthopedic balloons to repair and stabilize the fracture.

### Bone cement

A medical-grade material that can be used to fill a cavity or affix bone and/or orthopedic hardware to bone.

### Bone mineral density (BMD) test

An accurate, low-dose x-ray that measures the density and mineral content of bone.

### General anesthesia

The administration of anesthetic drugs during a surgical procedure to induce a state of total unconsciousness.

### Kyphosis

Excessive curvature of the upper spine resulting in a stooped posture or hunched back, often referred to as a “dowager’s hump”.

### Local anesthesia

The administration of anesthetic drugs to confine loss of sensation to a specific area; e.g., a “numbing shot” from the dentist. When local anesthesia is used, the patient is often awake and responsive.

### Minimally invasive

Any surgical technique in which a large incision is not required.

### MRI

Magnetic resonance imaging is a noninvasive test that produces two-dimensional images for viewing. MRIs do not involve the use of radiation.

## Osteoporosis

A disease that causes bones to become fragile and susceptible to fracture.

## Pulmonary

Having to do with the lungs and respiratory system.

## Vertebra

Any one of the 33 bones that form the spinal column. Humans have 7 cervical (neck), 12 thoracic (upper back), 5 lumbar (lower back), 5 sacral, and 4 coccygeal (“tailbone”) vertebrae.

## Vertebral body

The round, bony area of a vertebra.

## Vertebral compression fracture (VCF)

Osteoporosis and certain types of cancer can cause the bones of the spine to become weak or brittle, sometimes causing the vertebrae to fracture. This type of fracture is often called a “spinal fracture”.

## Cavity

An empty area, space or void.

## Web Resources

### Foundation for Osteoporosis Research and Education

[www.fore.org](http://www.fore.org)

### International Osteoporosis Foundation

[www.iofbonehealth.org](http://www.iofbonehealth.org)

### National Osteoporosis Foundation

[www.nof.org](http://www.nof.org)

### National Women's Health Resource Center

[www.healthywomen.org](http://www.healthywomen.org)

### Spine-health

[www.spine-health.com](http://www.spine-health.com)

### SpineUniverse

[www.spineuniverse.com](http://www.spineuniverse.com)

For more information about KYPHON® Balloon Kyphoplasty or to find a spine specialist trained to perform the procedure, please visit us at:

**[www.BalloonKyphoplasty.com](http://www.BalloonKyphoplasty.com)**

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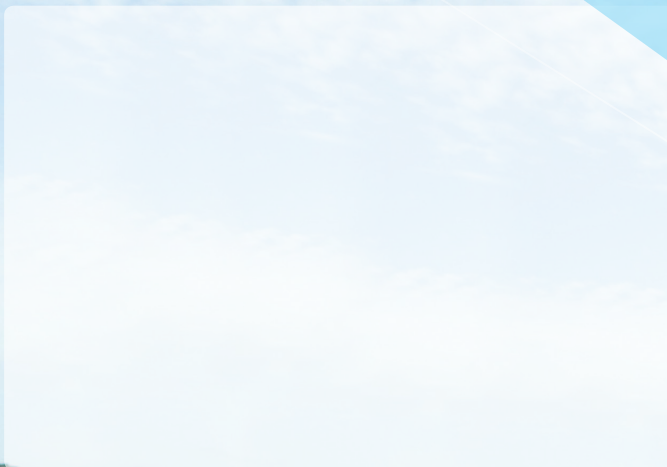








For more information or to locate a physician trained to perform  
KYPHON® Balloon Kyphoplasty, please visit [www.BalloonKyphoplasty.com](http://www.BalloonKyphoplasty.com)



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