

## For more information on balloon kyphoplasty, visit: [back.com/kyphoplasty](http://back.com/kyphoplasty)

1. Brunton S, Carmichael B, Gold D, et al. Vertebral compression fractures in primary care recommendations from a consensus panel. *J Fam Pract.* 2005;54(9):781-788.
2. Vedantam R. Management of osteoporotic vertebral compression fractures: a review. *Am J Clin Med.* 2009;6(4):14-18.
3. Ross PD. Clinical consequences of vertebral fractures. *Am J Med.* 1997;103(2A):30S-43S.
4. Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. *Bone.* 1996;18(3 Suppl):185S-189S. Review. (Historical information on epidemiology of spinal osteoporosis and QOL. MDT comment March 2013).
5. Silverman SL. The clinical consequences of vertebral compression fracture. *Bone.* 1992;13 Suppl 2:S27-S31. (Historical disease state information on vertebral compression fractures. MDT comment March 2013).
6. Lindsay R, Silverman SL, Cooper C, Hanley DA, et al. Risk of new vertebral fracture in the year following a fracture. *JAMA.* 2001;285(3):320-323.
7. Lau E, Ong K, Kurtz S, et al. Mortality following the diagnosis of a vertebral compression fracture in the Medicare population. *J Bone Joint Surg Am.* 2008;90(7):1479-1486. doi: 10.2106/JBJS.G.00675.
8. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol.* 2011;12(3):225-235.
9. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet.* 2009;373(9668):1016-1024.
10. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res.* 2011;26(7):1627-1637.
11. Van Meirhaeghe J, Bastian L, Boonen S, et al. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. *Spine.* 2013 38(12):971-983.
12. Klazen C, Lohle P, de Vries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. *Lancet.* 2010;376(9746):1085-1092.

## Medtronic

**Medtronic**  
Spinal and Biologics Business  
Worldwide Headquarters

2600 Sofamor Danek Drive  
Memphis, TN 38132



**Medtronic Sofamor Danek USA, Inc.**  
1800 Pyramid Place  
Memphis, TN 38132

(901) 396-3133  
(800) 876-3133  
Customer Service: (800) 933-2635

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

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website [www.medtronic.com/manuals](http://www.medtronic.com/manuals).

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

# YOUR SUDDEN BACK PAIN MAY BE A FRACTURE



Sudden-onset back pain could signal a spinal fracture. If left untreated, you could be at risk for more injury and even death.

**Medtronic**  
Further. Together



# TALK WITH YOUR DOCTOR

If you have tried treatments like rest and oral medication for your sore back **and still have sharp back pain**, you may have a spinal fracture, also known as a vertebral compression fracture (VCF). A VCF occurs when one of the bones of the spinal column weakens and collapses.

Normal  
Vertebra



Fractured  
Vertebra



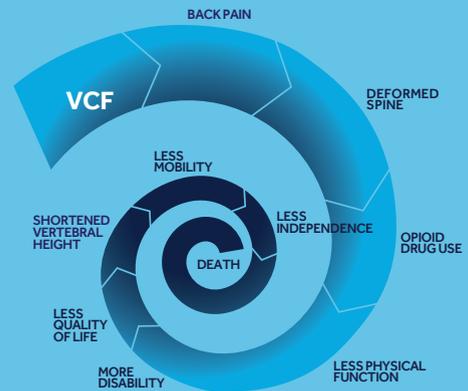
**You may have a vertebral compression fracture if you:**

- Have sudden onset of severe, sharp back pain that lasts longer than 3 days **AND**
- Are over 50 **OR**
- Have been told you have osteoporosis or low bone density

**It's important to talk to your doctor right away, and treat a fracture if you have one.**

# AVOID THE RISKS

**People with spinal fractures are at increased risk of complications and death compared with people who don't have spinal fractures.<sup>7</sup>**



Early diagnosis and treatment are important steps to avoid the downward spiral of complications associated with untreated VCFs.<sup>1-5</sup>

Over time, this condition may squeeze your internal organs and cause:

- reduced activity and mobility<sup>4,5</sup>
- sleep disorders and reduced appetite<sup>4,5</sup>
- feelings of isolation and sadness<sup>4,5</sup>
- greater risk of future fracture<sup>6</sup>
- risk of death<sup>1</sup>

# IMPROVE YOUR QUALITY OF LIFE

## UNTREATED SPINAL FRACTURES CAN STOOP YOUR BACK — AND MORE

When left untreated, spinal fractures can cause your spine to shorten and curve forward. This stooped or hunched back, called “kyphosis,” makes it difficult to walk, reach for things, and do other daily activities.



A spinal fracture can also lead to complications such as spine deformity, neurological complications, breathing problems, and death.<sup>1-5</sup>

People with spinal fractures treated with Kyphon Balloon Kyphoplasty experienced important benefits, compared to non-surgical treatments<sup>8-11</sup>:

- Less back pain
- Improved mobility
- Improved quality of life
- Satisfaction with the procedure

**Ask your doctor about if your pain could be a spinal fracture and if balloon kyphoplasty may be right for you.**

## COMMON TREATMENT OPTIONS MAY NOT BE EFFECTIVE

Treatments for back pain often include:

- Bed rest
- Special exercises
- Back bracing
- Pain medication

But if your back pain is from a vertebral compression fracture, these treatments will not repair the bone or restore the height of your vertebra (the bones that make up the spine). Therefore, they have limited effectiveness in reducing pain and improving function long term.<sup>8-12</sup>



# KYPHON<sup>®</sup> BALLOON KYPHOPLASTY TREATS SPINAL FRACTURES

Balloon kyphoplasty is a minimally invasive treatment that can repair spinal fractures caused by:

- Osteoporosis (low bone density)
- Cancer
- Non-cancerous tumors

**Kyphon Balloon Kyphoplasty uses orthopedic balloons to lift the fractured bone and return it to its correct position. The balloon is then deflated and removed** and the remaining cavity is filled with special cement that supports the surrounding bone and prevents further collapse. The procedure typically takes less than an hour.

Although the complication rate for Kyphon<sup>®</sup> Balloon Kyphoplasty is low, as with most surgical procedures, serious adverse events can occur. And though rare, some may be fatal including heart attack, cardiac arrest (heart stops beating), stroke, and embolism (blood, fat, or cement that migrates to the lungs, heart, or brain). Other risks include infection and leakage of bone cement into surrounding muscle and tissue. Cement leakage into the blood vessels may result in damage to the blood vessels, lungs, heart, and/or brain. Cement leakage into the area surrounding the spinal cord may result in nerve injury that can, in rare instances, cause paralysis. A prescription is required. Please consult your doctor to discuss the risks and benefits of this procedure and whether it's right for you.



Balloon  
Placement



Balloon  
Inflation



Special  
Cement