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KYPHON® BALLOON KYPHOPLASTY FACT SHEET

The Condition: Spinal Fractures

Osteoporosis causes more than 700,000 spinal fractures each year in the U.S. According to the National Osteoporosis Foundation, this is more than twice the annual number of hip fractures.

Spinal fractures can also be caused by cancer, the most common being multiple myeloma, breast, lung and prostate. According to the Multiple Myeloma Research Foundation, the majority of patients with multiple myeloma – some 70 to 95% -- have progressive metastatic bone disease particularly in the spine, which increases the risk of fractures.

Some spinal fractures may collapse immediately while others collapse over time. Left untreated, one fracture can lead to subsequent fractures, often resulting in a condition called kyphosis, or rounded back. Kyphosis, signified by the dowager's hump, compresses the chest and abdominal cavity, resulting in serious negative health consequences.

Balloon Kyphoplasty Outcomes

Balloon Kyphoplasty is a minimally invasive, orthopaedic treatment that stabilizes spinal fractures, thereby reducing pain and correcting vertebral deformity. Studies report the following benefits:

- Correction of vertebral body deformity
- Significant reduction in back pain
- Significant improvement in quality of life
- Significant improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work
- Significant reduction in the number of days per month that a patient remains in bed
- Low complication rate (<1%)

The Balloon Kyphoplasty Procedure

- Using a needle and tube, the spine specialist creates a small pathway into the fractured bone. A small, orthopaedic balloon is guided through the tube into the vertebra. The incision site is approximately 1 cm in length.
- The balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position. Inflation of the balloon creates a void (cavity) in the vertebral body.
- Once the vertebra is in the correct position, the balloon is deflated and removed.
- The cavity is filled with bone cement forming an "internal cast" to support the surrounding bone and prevent further collapse.
- Generally, the procedure is done on both sides of the vertebral body.



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

In most cases, Medicare provides coverage for Balloon Kyphoplasty. Other insurance plans often also cover the procedure.

Although the complication rate with KYPHON[®] Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with the procedure, including serious complications. This procedure is not for everyone. A prescription is required. Please consult your physician for a full discussion of risks and whether this procedure is right for you.

Since its founding in 1994, Kyphon has been dedicated to improving patient quality of life by revolutionizing the practice of medicine. A recognized global leader in restoring spinal function with minimally invasive therapies, Kyphon maintains its commitment to ongoing research, innovative product development and advanced professional and patient education. Kyphon was acquired by Medtronic, Inc. in November 2007 and is now part of Medtronic's Spinal and Biologics business.

For more information on Balloon Kyphoplasty, go to www.kyphon.com.

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