M06005-EN-01

www.kyphon-eu.com

Kyphon Europe

Cluster Center
Leuvensesteenweg 369/6
1932 Zaventem, Belgium

T +32 2 609 2222
F +32 2 731 7049
E-mail: info@kyphon-eu.com

KYPHON®
AHEAD OF THE CURVE™

Balloon Kyphoplasty Procedure

www.kyphon-eu.com

KYPHON®

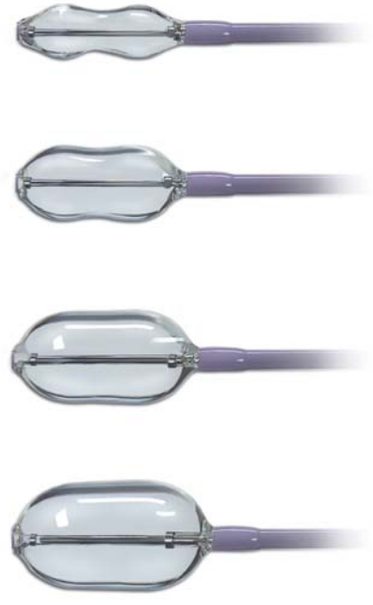
AHEAD OF THE CURVE™

Table of Contents

Introduction

The Kyphon KyphX® System is designed to reduce spinal compression fractures and restore sagittal alignment.

Intended to compact cancellous bone and move cortical bone, the KyphX® Inflatable Bone Tamp (IBT or Balloon) offers a revolutionary advancement. The KyphX® Inflatable Bone Tamp is positioned inside the bone, where it is inflated gradually. As the Balloon expands, the bone is moved with precision to restore anatomy.



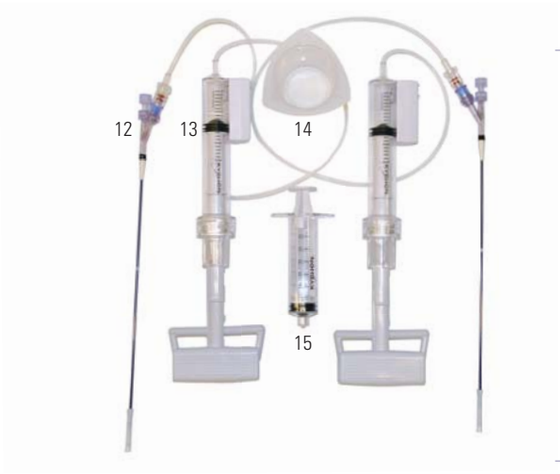
The KyphX® System also includes instruments for percutaneous access to bone. Depending on user preference and fracture type, physicians are able to select a fracture specific solution.

Pre-Operative Set-Up

Specific Instruments & Accessories

Bone Access

1 Surgical Marker Pen*
2 Scalpel*
3 Kyphon® 11 Gauge Bone Access Needle (**A02A**)
4 Guide Pin (Kirschner Wire) (included in **T05D**)
5 KyphX® Osteo Introducer® System (**T05D**)
6 KyphX® Osteo Introducer® Cannula (included in **T05D**)
7 KyphX® Bone Biopsy Device (**F05A**)
8 KyphX® Precision Drill (included in **T05D**)
9 KyphX® Bone Filler Device (**F04B**)
10 Surgical Mallet*
11 Surgical Forceps*



Fracture Reduction

12 KyphX Xpander® Inflatable Bone Tamp (**K08A-K09A-K13A**)
13 KyphX Xpander® Inflation Syringe (**A08A**)
14 Bowl with Contrast Liquid*
15 Luer Syringe (included in **A08A**)

Fracture Stabilisation

16 KyphX® Bone Filler Device (**F04B**)
17 KyphX® HV-R™ Bone Cement (**C01A**)
18 Kyphon® Mixer (**A07A**)
19 Funnel for Kyphon® Mixer (included in **A07A**)
20 Dispensing plunger for Kyphon® Mixer (included in **A07A**)
21 Luer adapter for Kyphon® Mixer (included in **A07A**)

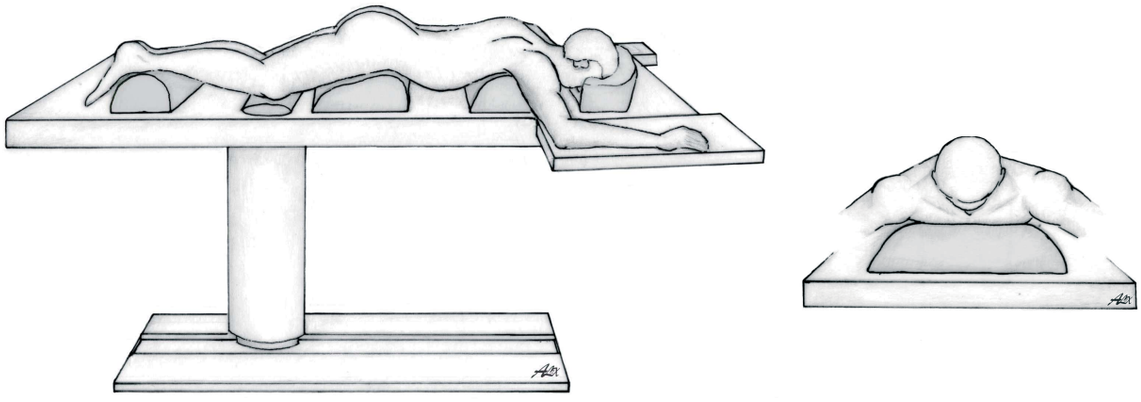
* not provided by Kyphon

The KyphX® Inflatable Bone Tamp (IBT) size and type will be determined by the fracture morphology.

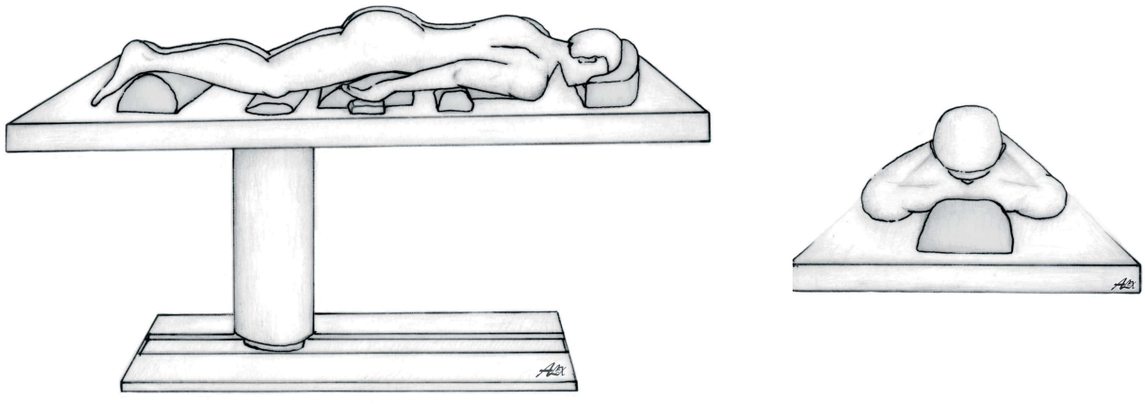
KYPHON AHEAD OF THE CURVE™

Patient Positioning

Position the patient to reduce any load on the fractured bone (if the fracture is located in the lumbar lordotic curvature, place the patient into hyper-lordosis).



Standard prone position with arms extended



Prone position with arms adducted for upper thoracic approaches.
A narrower cushion allows the shoulders to drop forward

Anæsthesia

The operation may either be performed under general or local anæsthesia.

Imaging Set-up

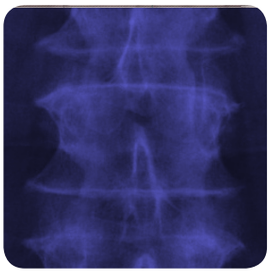
Positioning of the C-arms

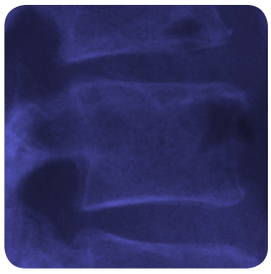
Use 1 or 2 C-arms for visualisation of the fracture. The use of 2 C-arms has been found to reduce the time of the procedure.

Tips: - With 1 C-arm, the position must be changed regularly from A-P to Lateral during the procedure.
- While draping, use long drapes to keep the C-arm under them in Lateral position.

Imaging: Lining up a proper view

Verify under A-P visualisation the correct position of the vertebral body, with the spinous process central in the image and endplates parallel. Verify that the image in the Lateral View is correct with the pedicles superimposed.



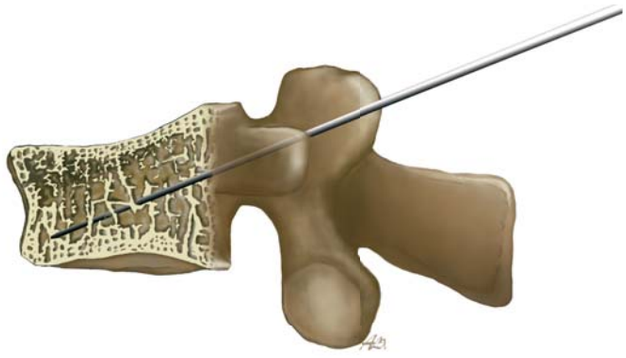


Correct position of C-arms gives these Lumbar level A-P & Lateral views.

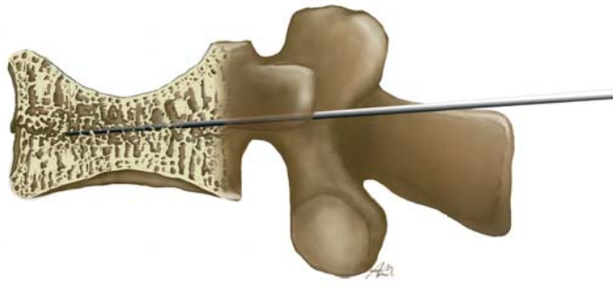
Determine the Trajectory

Before starting the procedure, determine the best inclination for bone access and placement for the KyphX® Inflatable Bone Tamp (IBT). Angle the guide pin inclination to the trajectory required for IBT placement.

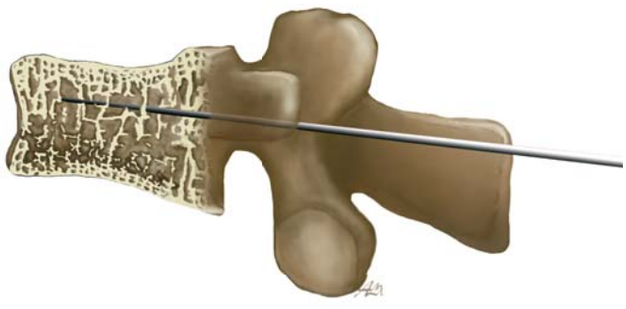
Superior Wedge Fracture



Central Compression Fracture



Inferior Wedge Fracture

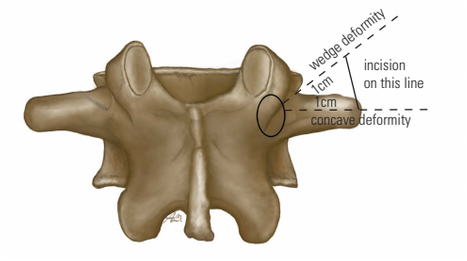


A wedge fracture will require a diagonal inclination while a central fracture will require a more horizontal inclination

Bone Access

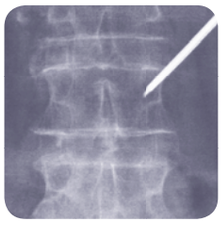
Here is a brief decription of the transpedicular approach:

- Mark the best incision locations with a surgical pen.
- Make a 1cm incision lateral to the entry point on the angle of inclination (2cm lateral when at level L5).

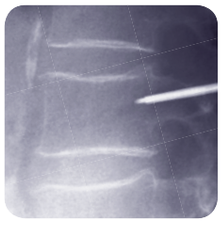


- Insert the 11 Gauge needle into the pedicle, verifying the angle of inclination and orientation in the two planes of imaging, alternating the two projections. The insertion should not exceed a few millimeters.

- Continue the insertion through the pedicle in the A-P View until you reach the medial edge of the pedicle ring. Before entering the vertebral body, verify the position of the needle in the lateral view.



- In the lateral view, advance the 11 Gauge needle to a point 2mm past the posterior wall of the vertebral body and remove the stylet.



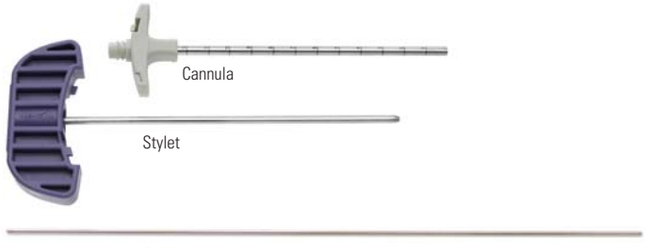
- Insert the guide wire in the stylus of the 11 Gauge needle to a point 2-3 mm beyond the tip of the stylus.
- Remove the stylus of the 11G needle leaving the wire in position.

KYPHON AHEAD OF THE CURVE™

- Position the KyphX® Osteo Introducer® over the guide wire and advance it forward until it is at least 4 mm past the posterior wall of the vertebral body.

KyphX® Osteo Introducer® System

- Remove the guide wire and the stylet of the KyphX® Osteo Introducer®.



- You may now take a bone biopsy to exclude the possibility of malignancy or to determine if the patient has osteomalacia.

KyphX® Bone Biopsy Device

- Use the Precision drill and/or a KyphX ®Bone Filler Device (with the stylet inside) to create a space in the vertebral body to facilitate the insertion of the IBT. Stop at 2-3mm before the cortical wall.

Precision Drill

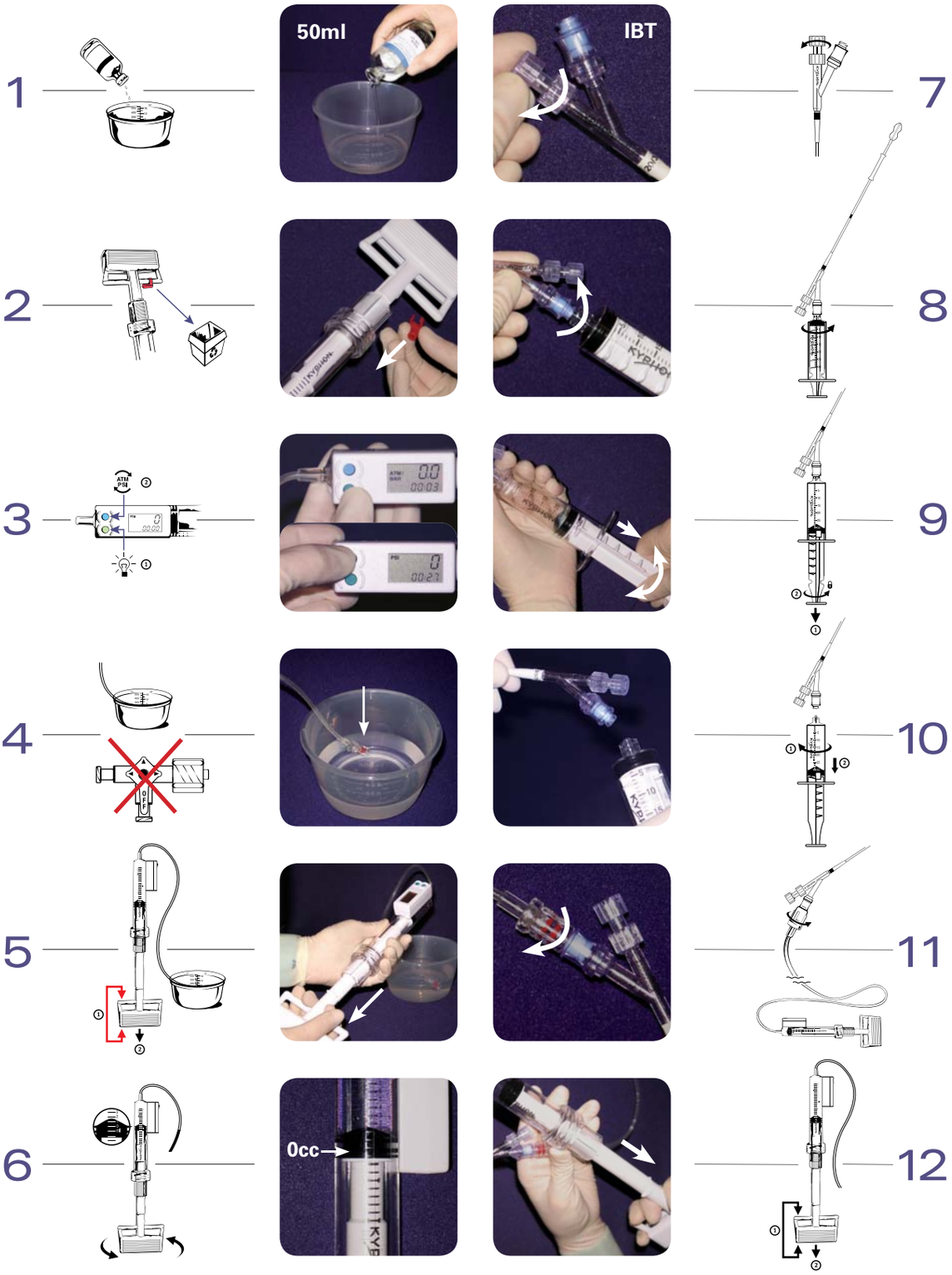
KyphX® Bone Filler Device

- Repeat on the contra-lateral side

Fracture Reduction

IBT Preparation

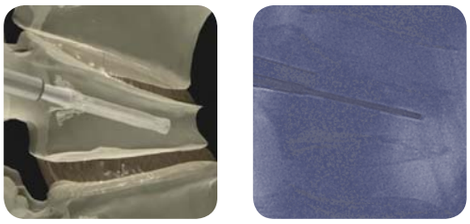
Prepare two KyphX Xpander® Inflation Syringes and two KyphX® Inflatable Bone Tamps for each treated level



KYPHON AHEAD OF THE CURVE™

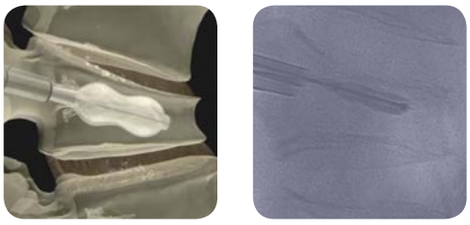
IBT Insertion

- Insert both IBT's and position them directly under the fracture zone.



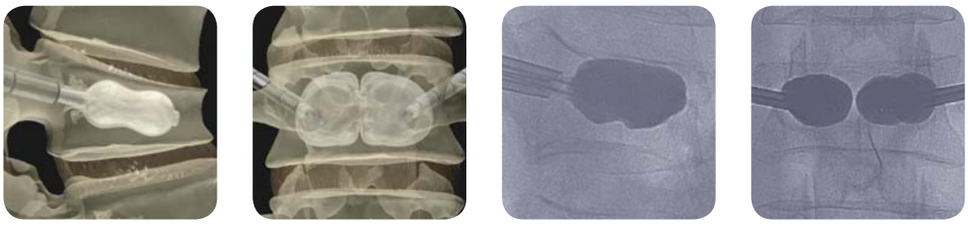
IBT Inflation

- Rotate the inflation syringe to 0 (releasing the vacuum).
- One 360° rotation will deliver 0.5 ml of fluid into the IBT.
- Take a lateral image to confirm the IBT is inflating.



- Remove the stylet from both Balloons.

- Inflate both IBT's together progressively in 0.25 ml (one-half turn) increments. Verify the inflation progress in the Lateral View.
- Inflate until the IBT fills approximately 25% of the vertebral body then switch to the A-P View to determine the position of the balloon in relation to the lateral walls.



- Return to the Lateral View and inflate progressively until reaching one of the following end points:
  - Realignment of the vertebral endplates.
  - Maximum pressure of the IBT (depends on the IBT type/size).
  - Maximum volume of the IBT (depends on the IBT type/size).
  - Contact with any of the cortical walls.

Fracture Fixation

- Open the required number of KyphX® Bone Filler Devices (BFD's) to fill the IBT void (1 BFD will hold 1.5 cc of cement). Your total IBT volume can be found on the inflation syringe volume gauge.

KyphX® Bone Filler Device

- Prepare a package of KyphX® HV-R™ cement using the Kyphon® Mixer.

KyphX® HV-R™ Bone Cement

Kyphon® Mixer

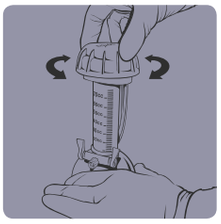
- Pour the polymer powder into the mixer followed by the liquid monomer.

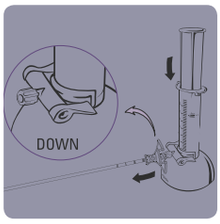
Polymer powder

Liquid monomer

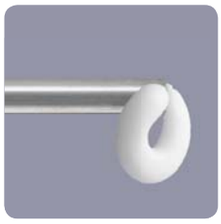
- Mix for 1 minute or until all of the powder is blended with the liquid and there are no lumps.

- Attach each BFD to the Mixer outlet and fill



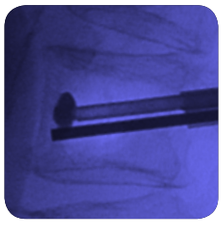


- Prepare a test syringe with at least 5 ml of the cement mixture. Attach the syringe to the end of one of the BFD's and test the consistency from time to time. Wait until the cement has reached the exact delivery consistency (toothpaste like).

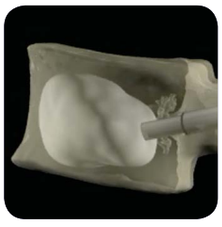
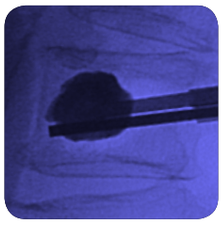


KYPHON AHEAD OF THE CURVE™

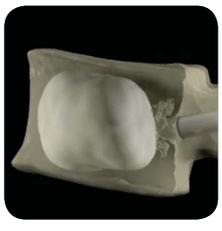
- Insert the BFD to the anterior portion of the balloon cavity.

- Leave the BFD anterior while slowly delivering the cement under a continuous lateral fluoroscopic image.

- Continue delivery of the cement until the cavity created by the balloon is filled. Take care NOT to overfill the vertebral body, particularly not in the posterior part of the vertebral body. Stop filling immediately if any cement exits the vertebral body.



- Repeat this procedure on the contra lateral side.

TIP: When delivering on the contra lateral side, it is a good idea to leave an already used BFD inserted in the opposing cannula. This prevents reflux of the cement into the cannula.

- After cement delivery is complete, remove the cannula and close the incisions according to your standards.

TIP: Before removing the cannulas, tamp the cement with the BFD to ensure the pedicle is clear of any cement.

Indications for Balloon Kyphoplasty

Balloon Kyphoplasty is designed for patients with Vertebral Compression Fractures caused by:

- Primary Osteoporosis
- Secondary Osteoporosis
- Multiple Myeloma
- Bone Metastases

Outcomes

The benefits of Balloon Kyphoplasty include: [1-5]

- Correction of spinal deformity
- Significant reduction in back pain
- Significant improvement in Quality Of Life
- Significant improvement in mobility
- Significant improvement in ability to perform Activities of Daily Living

Balloon Kyphoplasty is a safe procedure with a low complication rate.

1. Coumans et al., Kyphoplasty for vertebral compression fractures: 1-year clinical outcomes from a prospective study. J Neurosurg (Spine 1) 99:44-50, 2003.
2. Ledlie et al, Balloon Kyphoplasty: one- year outcome in Vertebral Body Height Restoration, Chronic Pain and Activity levels. J Neurosurg (Spine 1) 98:36-42, 2003.
3. Lieberman et al. Initial Outcome and Efficacy of Kyphoplasty in the Treatment of Osteoporotic VCFs Spine, Vol.26: No.2, 1631-1638, July 2001
4. Dudeney et al. Kyphoplasty in the Treatment of Osteolytic Vertebral Compression Fractures as a result of Multiple Myeloma. Journal of Clinical Oncology, Vol 20, Issue 96 (May), 2002:2382-2387
5. Fourney et al. Percutaneous Vertebroplasy and Kyphoplasty for Painful Vertebral Body Fractures in Cancer Patients. J Neurosurg (Spine1) 98:21-30, 2003

KYPHON AHEAD OF THE CURVE™

Notes