

GUARDIAN®

KYPHOPLASTY SYSTEM



bm KOREA

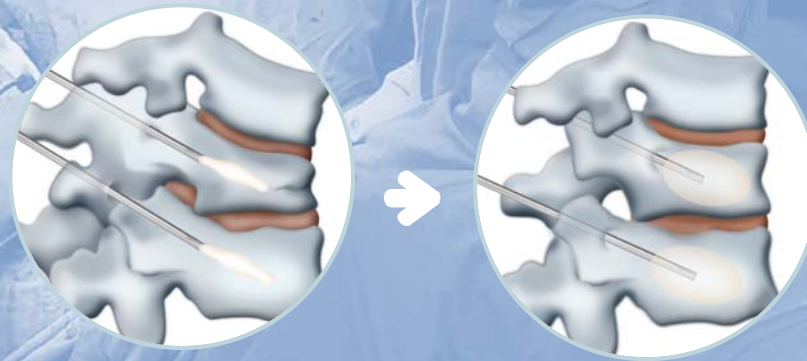
Importateur France : ITEM - 60100 CREIL
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+ Introduction

Balloon Kyphoplasty is a minimally invasive percutaneous method for stabilizing the spine.

It offers a good alternative for patients who fail to respond to the traditional approaches of bedrest, analgesics, and back braces.

Guardian helps to restore some of the height lost with fracture and reduce the angle of the deformity.



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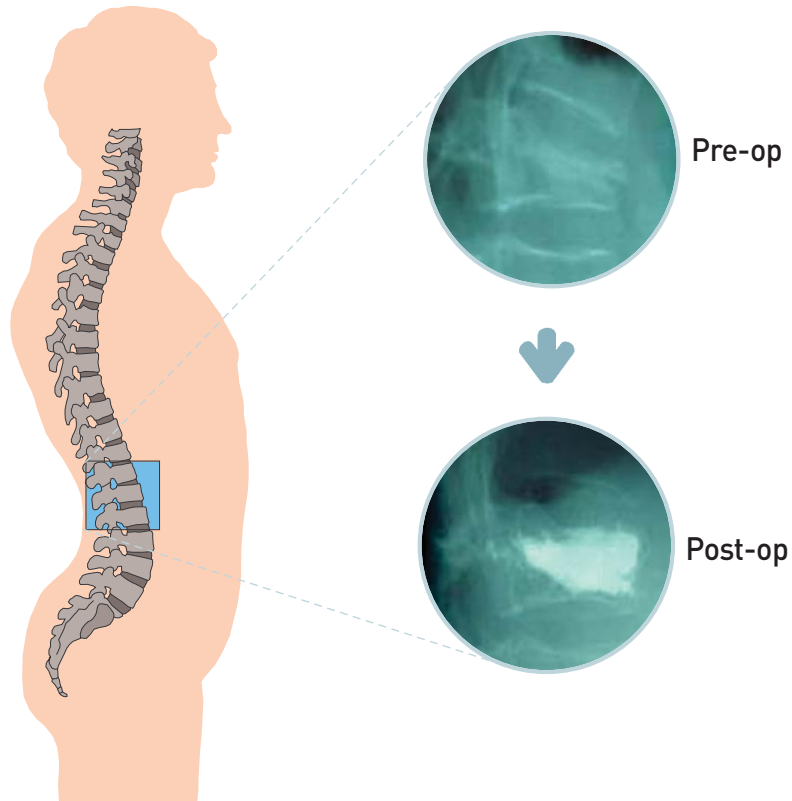
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+ Indications

- Vertebral Compression Fracture
- Osteoporosis
- Metastatic Bone Tumor



+ Contraindications

- Infection of the fractured vertebra
- Severe hemorrhagic diathesis
- Known allergies to the cement
- Pregnancy
- ASA score of 4

+ Features

- Minimally Invasive Spine Surgery
- Fast Pain Relief
- Safe Delivery of Bone Cement
- User Friendly Approach
- Local Anesthesia
- Fast Recovery

+ Preoperative Set Up

For Bone Access

- Surgical Marker Pen
- Scalpel
- Starting Needle
- Starting Needle Trocar
- Guide Wire
- Surgical Mallet
- Cannular
- Trocar
- Drill

For Fracture Restore

- Compressor
- Balloon Catheter
- 20cc Syringe
- Contrast liquid

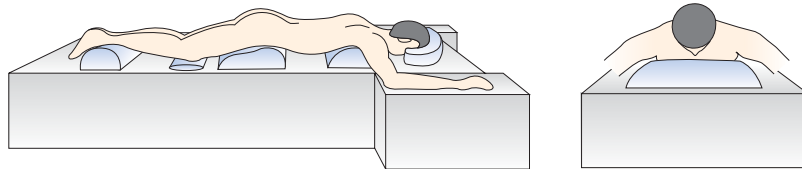
For Bone Stabilization

- Bowl
- Bone Cement
- Cement Bar & Infusion
- 10 cc Syringe

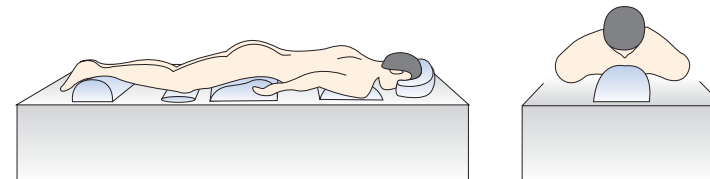


+ Patient Positioning

Prone position is recommended to reduce any load on the fracture bone.
If the fracture is located in the lumbar lordotic curvature, place the patient into hyper-lordosis.

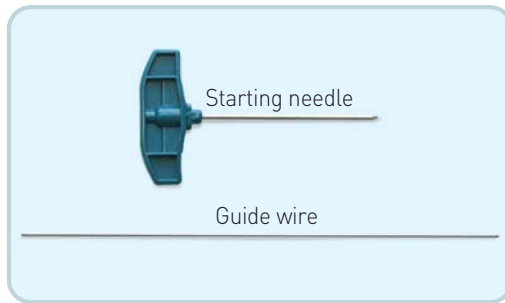


Standard prone position with arms extended.

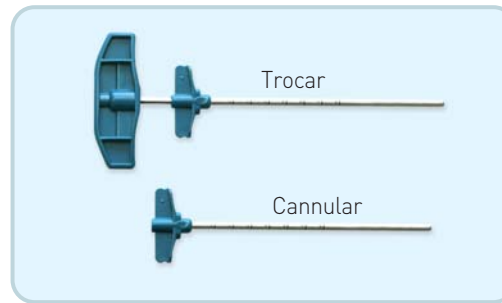


Prone position with arms adducted for upper thoracic approaches. A narrower cushion allows the shoulders to drop forward.

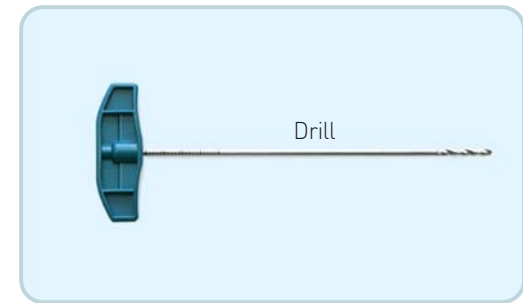
+ Pedicle Placement



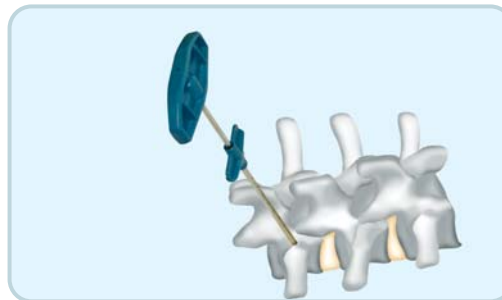
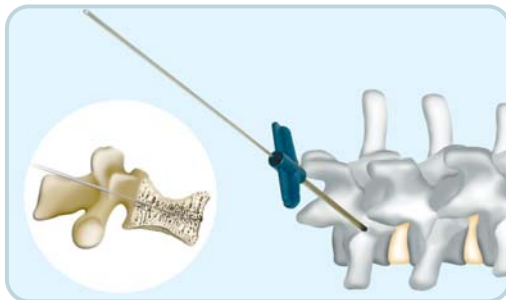
Insert the Starting needle and find a correct site using C-arm. Insert the guide wire into the starting needle canal then, remove the starting needle.



Insert the Trocar & Cannular along the guide wire. Leaving the Cannular only and remove the Trocar. It can be separated. So, the same procedure can be applied on the opposite pedicle.



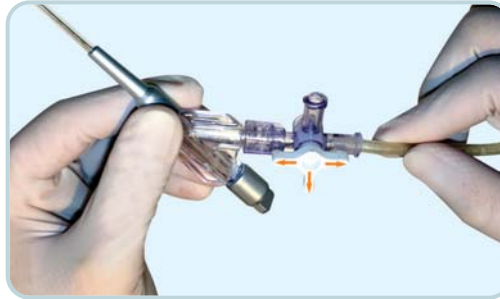
Using Drill, make a space smoothly.



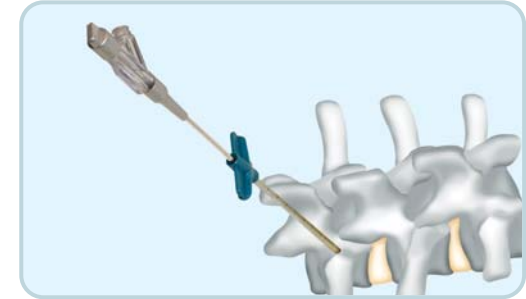
+ Prep Compressor & Balloon Catheter



If the right handle of compressor is pushed down, the compressor moves forward or backward gradually.



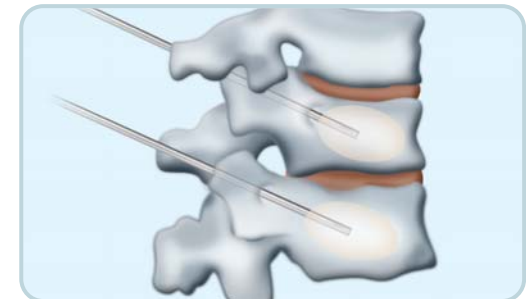
Connect 3-way with compressor to the balloon catheter. Then, remove an air inside of the balloon catheter.



Insert the balloon catheter to the injured vertebrobody. Then, inflate the balloon to fill the cavity.



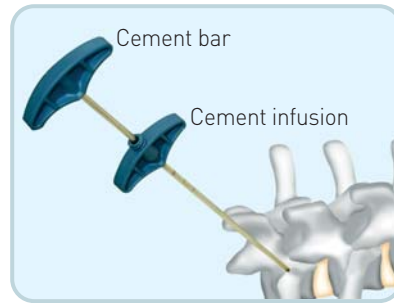
If the left handle of compressor is pushed down, the compressor moves forward or backward speedily.



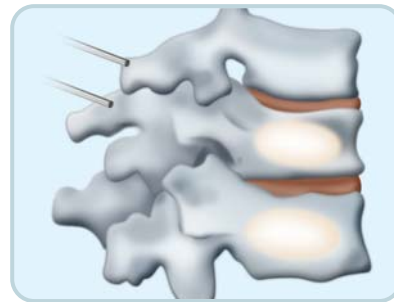
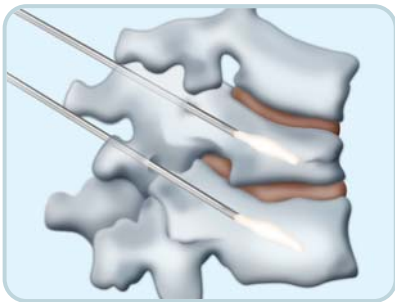
+ Cement Delivery



Mix the Polymer powder and Liquid monomer with the prepared bone cement. Then, wait until the cement gets proper consistency to go through the cement bar.



Put the mixed cement into the space using a cement bar. Then, remove the cement bar and cement infusion.



* All procedures are applied on both pedicles.

+ Picture of Guardian



+ Balloon Catheter Description

ARTICLE NO.	PSI RATING	MAXIMUM VOLUME(CC)
BM K 10	400	4
BM K 15	400	4
BM K 20	400	6

+ Components of Guardian

ARTICLE NO.	PRODUCT NAME	Q'TY
BM K - K 1	STARTING NEEDLE	1
BM K - K 2	STARTING NEEDLE TROCAR	1
BM K - K 3	GUIDEWIRE	2
BM K - K 4	CANNULA	2
BM K - K 5	TROCAR	1
BM K - K 6	CEMENT BAR	6
BM K - K 7	CEMENT INFUSION	6
BM K - K 8	DRILL	1
BM K 10	BALLOON CATHETER	2
BM K 15	BALLOON CATHETER	
BM K 20	BALLOON CATHETER	
BM P	COMPRESSOR	2

- Components Notice : This product is sterilized by EO gas and followed CE standard regulations.
- For more information, contact BM Korea Customer Service at (82) 31 451 9295

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