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Advancing BKP

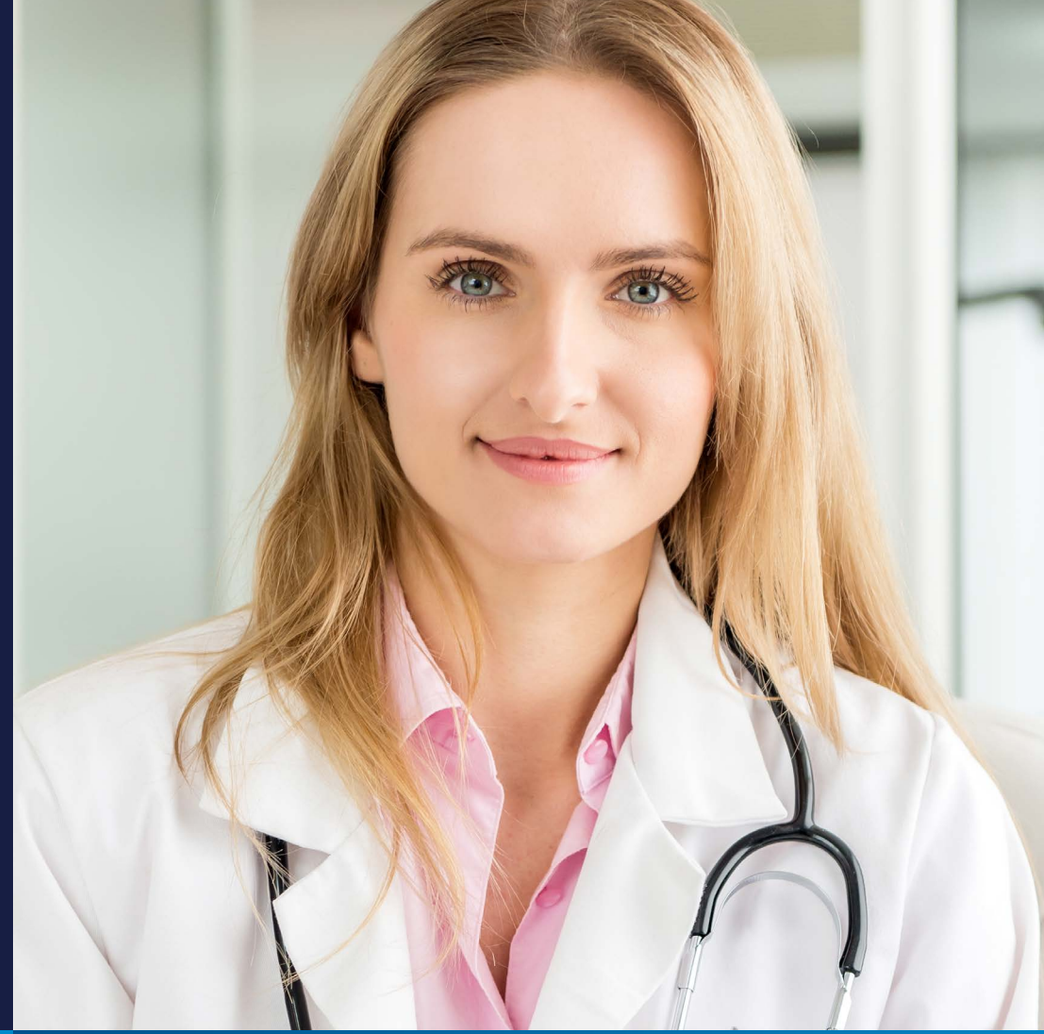
What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

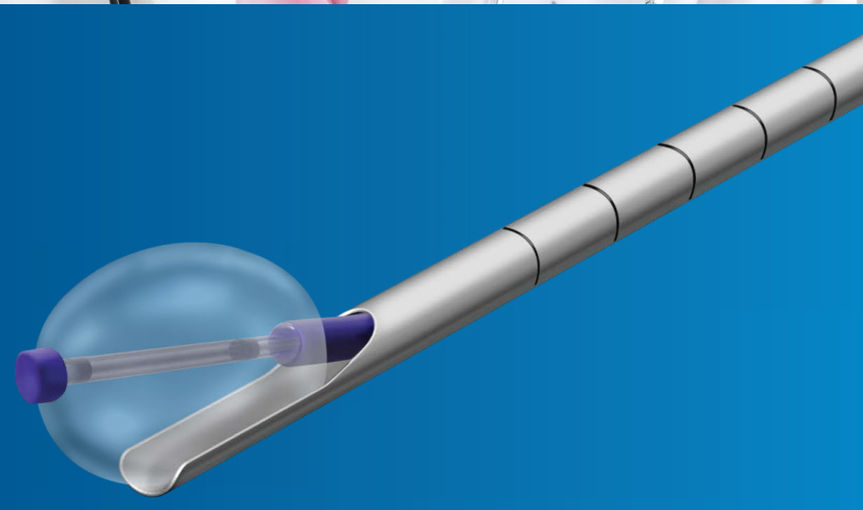
Clinical Benefits of Directional BKP

MORE CONTROL MORE HEIGHT MORE CONFIDENCE



Kyphon Assist™

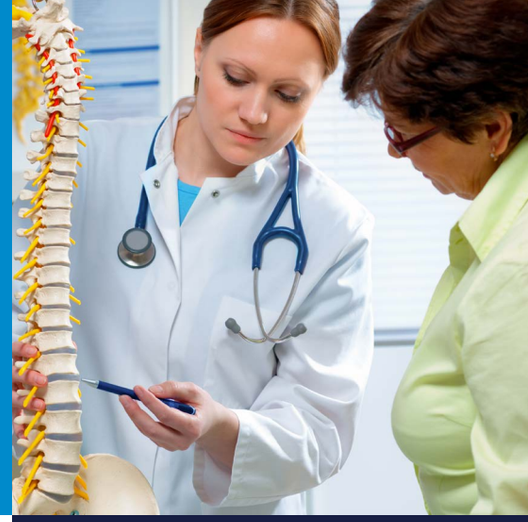
Directional cannula to provide precise balloon placement and inflation for balloon kyphoplasty procedures



MICHELSON TECHNOLOGY AT WORK

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INNOVATION THAT ADDS UP



Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

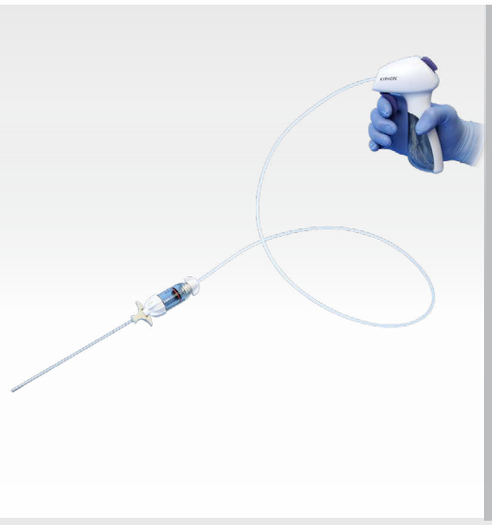
Clinical Benefits of Directional BKP

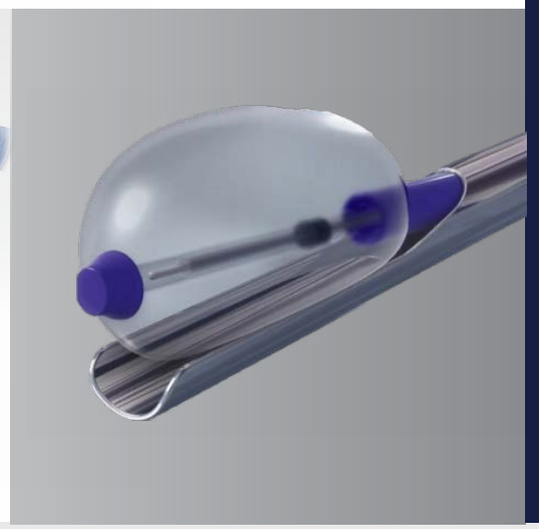
For over 20 years, Medtronic has been dedicated to the treatment of painful vertebral compression fractures (VCFs). That dedication has led to continued advances in the BKP procedure.

From more powerful inflatable bone tamps to the ability to reduce radiation exposure, Medtronic continues to advance the therapy by providing MORE control and MORE height with the Kyphon Assist™ directional cannula.

Physicians have used Kyphon™ BKP to treat more than **1.6 million vertebral fractures.**[1]







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KYPHON ASSIST DIRECTIONAL CANNULA

Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

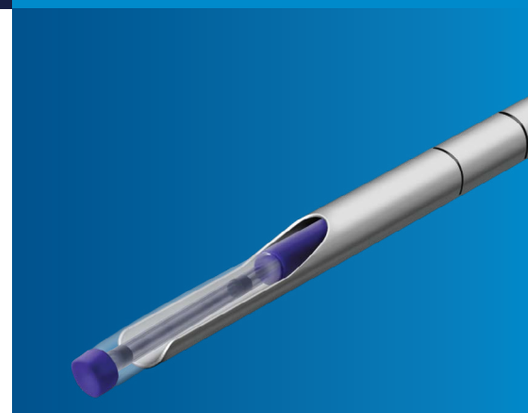
Kyphon Assist™ is a directional cannula that provides more predictable inflation and direction of cavity creation during BKP surgery for treating VCFs.

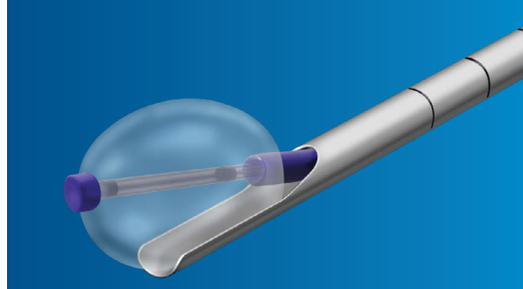
Features include[2]:

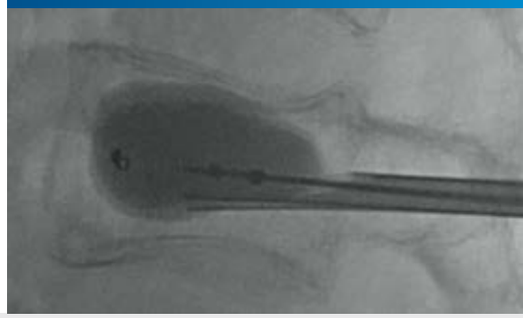
- Predictable placement of the balloon
- Additional height in a vertebral body
- Protection for vertebral body lateral walls and defects in the endplates

It provides:

- More user control
- Intra-operative versatility
- Optimal void creation for predictable fracture reduction
- Procedural confidence
- Improved patient outcomes[3]







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Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

KYPHON ASSIST DIRECTIONAL CANNULA

Kyphon Assist™ includes a trocar stylet for one-step access and a guide pin that can be used to exchange a standard cannula with the Kyphon Assist™ cannula if additional control or direction is needed during the procedure.





T15S - Kyphon Assist

Item Description	QTY
Direction Cannula	1
Trocar Stylet	1
Guide Pin	1

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MORE CONTROL + MORE HEIGHT = MORE CONFIDENCE

Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

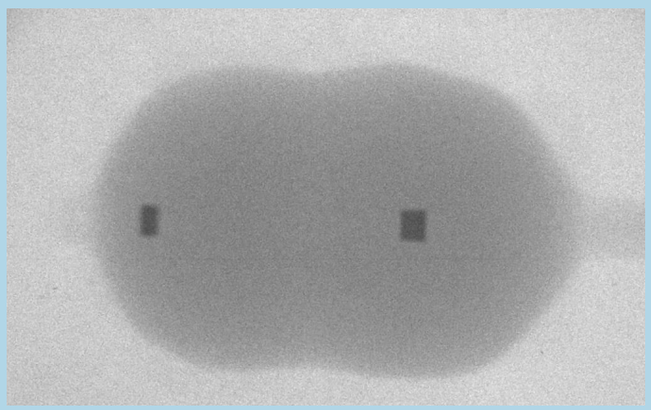
Clinical Benefits of Directional BKP

+37% MORE Height

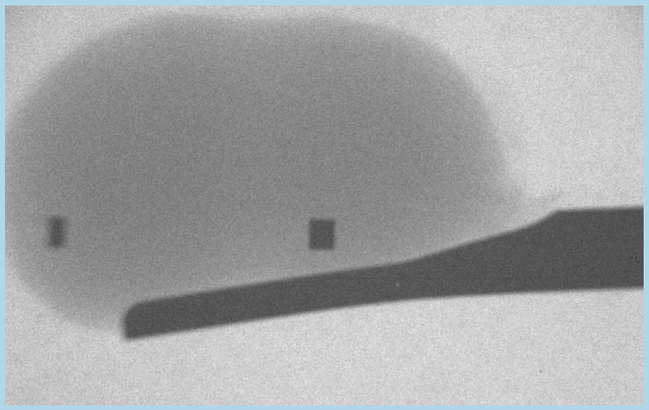
Kyphon Assist™ can increase the directional height of an inflatable bone tamp (IBT) by 37% when compared to IBTs used with standard access cannulas[2] for more height restoration potential.

+76% MORE Control

When compared to standard access cannulas,[2] the Kyphon Assist™ can redirect 76% of the IBT volume in the intended direction.



Kyphon Xpander™ II 15 mm IBT (5 cc)



Kyphon Assist™ with Kyphon Xpander™ II 15 mm IBT (5 cc)

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MORE CONFIDENCE

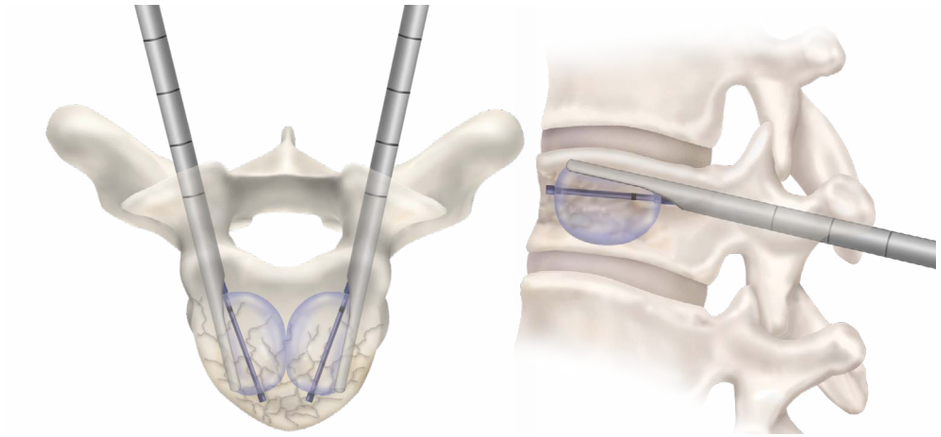
Advancing BKP

What is Kyphon Assist™

More Control More Height

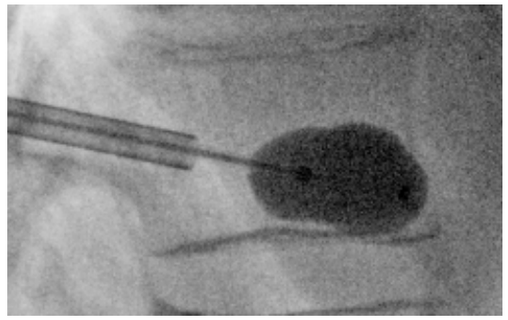
Performing BKP with Kyphon Assist™

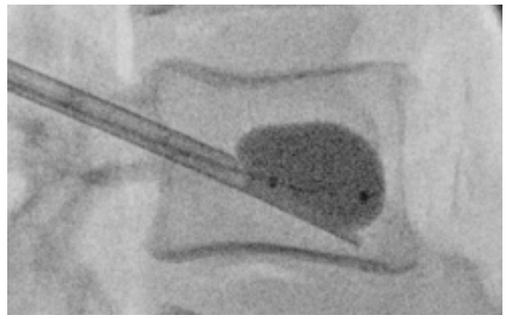
Clinical Benefits of Directional BKP



- The Kyphon Assist™ can be used with any IBT size, allowing flexibility for procedural goals and anatomic considerations. It comes in the familiar One-Step™ Xpander™ access and can be exchanged as needed for more accurate balloon placement. Kyphon Assist™ also can be used to correct access trajectory without retracting and repositioning your access needle.

- The Kyphon Assist™ also provides the ability to inflate away from the lateral walls and endplate defects, providing more control and confidence in balloon kyphoplasty procedures.





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ONE-STEP ACCESS TECHNIQUE

Advancing BKP

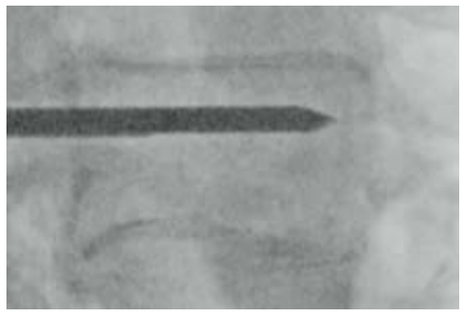
What is Kyphon Assist™

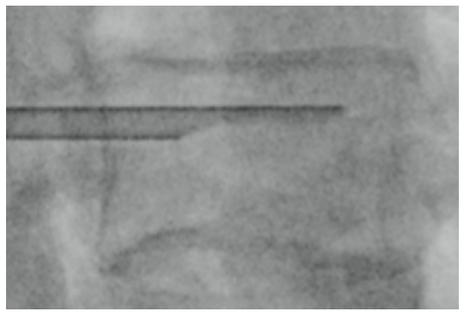
More Control More Height

Performing BKP with Kyphon Assist™

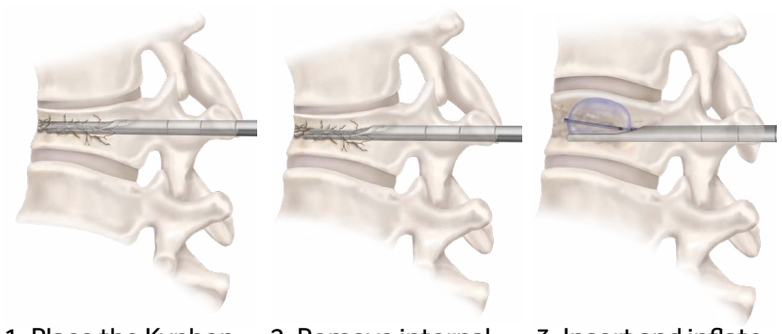
Clinical Benefits of Directional BKP

You have the option of more control and height for every BKP procedure when you use the Kyphon Assist™ directional cannula. Pedicle access can be gained using the familiar one-step method, providing immediate directionality for your inflatable bone tamps and reducing any need for a tool exchange.

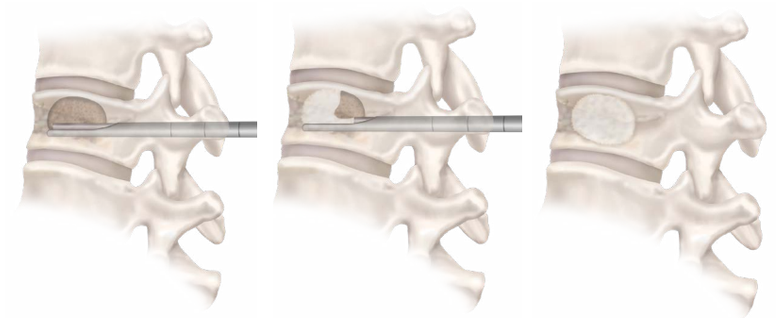




One-Step™ Access Technique



1. Place the Kyphon Assist™ into the fractured vertebrae
2. Remove internal stylet after placement
3. Insert and inflate balloon to reduce fracture



4. Remove balloon and place cement cannula into vertebrae
5. Inject bone cement into cavity
6. Technique results in stabilizing vertebrae with internal cast

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EXCHANGE TECHNIQUE

Advancing BKP

What is Kyphon Assist™

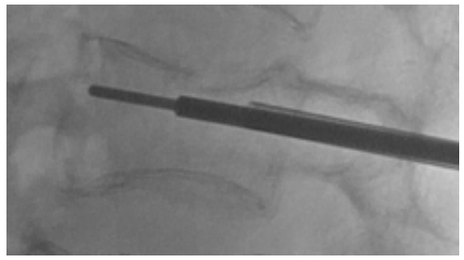
More Control More Height

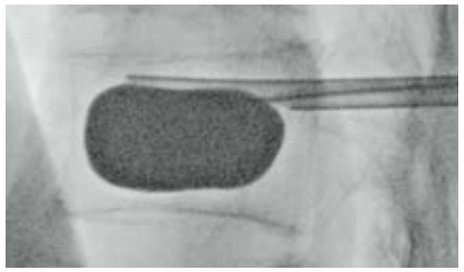
Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

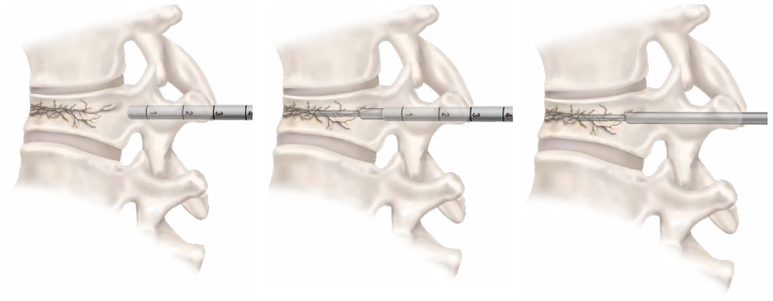
The exchange technique allows flexibility to incorporate the Kyphon Assist™ when additional control or protection is needed.

You can eliminate the need to re-adjust your trajectory by incorporating the directional cannula to control the inflation and protect against any defects or lateral walls when performing a BKP.

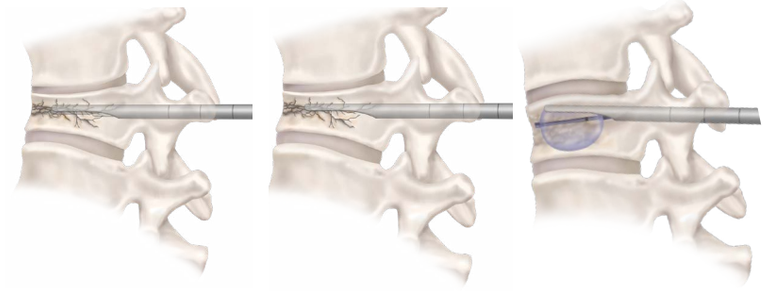




Exchange Technique



1. Gain access with a standard cannula
2. Place the guide pin into the vertebrae
3. Remove the standard cannula, leaving the guide pin



4. Place the Kyphon Assist™ over the guide pin
5. Once the Kyphon Assist™ is in place, remove the guide pin
6. Insert balloon and inflate to reduce fracture

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Advancing BKP

What is Kyphon Assist™

More Control More Height

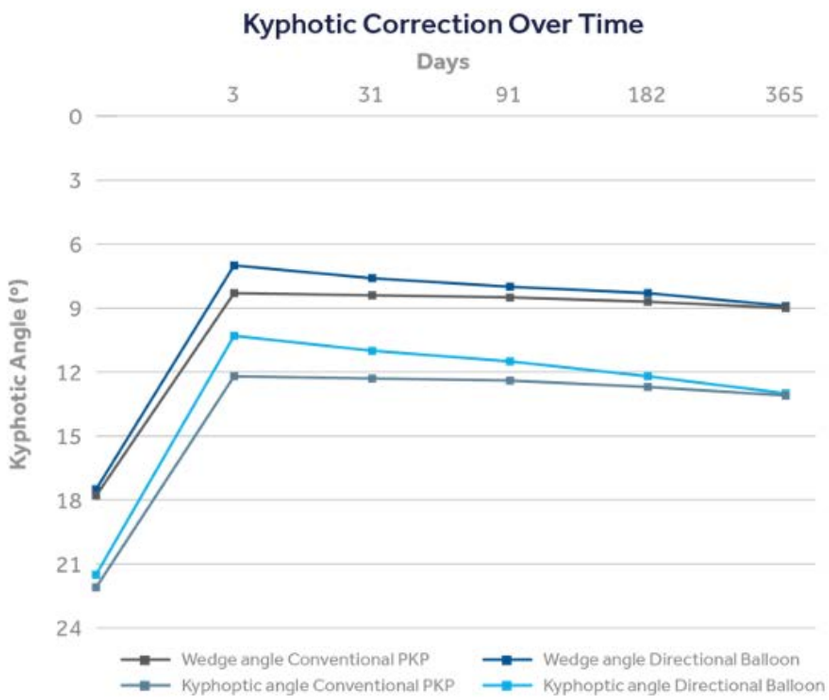
Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

STUDY RESULTS



- A recent study[3] of nondirectional balloon technique (n = 51) and VCF patients treated with directional balloon technique (n = 49) demonstrated significant immediate and sustained kyphotic angle correction post-surgery.



Study Limitations:

- In group 1, a conventional BKP technology was used (Percutaneous Kyphoplasty System, Shandong Dragon Crown Medical Co., Ltd) and in group 2, a new type of directional balloon dilation technology was used (Directional Percutaneous Kyphoplasty System, Suzhou and Science & Technology Development Co., Ltd).
- Data are presented as means ± standard deviation. KA = Kyphosis angle, WA = Wedge-shaped angle.
- Comparison between postoperative and preoperative in each group, $P < .05$.
- Group 1 compared with group 2 at different time points, $P < .05$.

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STUDY RESULTS

Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

Compared to nondirectional balloon technique, use of directional balloon technique reported:[3]

- Significantly early and immediate outcome improvement
- Improvement in VAS, ODI, and RMD scores that is significantly better than nondirectional technique at 3 days

Study Limitations:

- Significant kyphotic angle correction at 3 days could be attributed for early and immediate outcome improvement.
- Data were presented as mean ± standard deviation. ODI = Oswestry Disability Index, RMD = Roland Morris disability questionnaire, VAS = visual analogue scale.
- Comparison between postoperative and preoperative in each group, $P < .05$.
- Group 1 compared with group 2 at different time points, $P < .05$.

COMPARISON OF THE CLINICAL OUTCOMES RESULTS BETWEEN 2 GROUPS BEFORE AND AFTER OPERATION

		Preoperative	3 days	1 month	3 months	6 months	12 months
VAS	Group 1	8.1 ± 1.2	4.5 ± 1.3*†	2.4 ± 1.2*	2.1 ± 1.1*	1.9 ± 1.0*	2.3 ± 1.2*
	Group 2	8.0 ± 1.1	4.0 ± 1.1*	2.2 ± 1.0*	2.0 ± 1.0*	1.8 ± 0.9*	2.4 ± 1.3*
ODI	Group 1	48.1 ± 2.2	42.8 ± 3.2*†	32.5 ± 2.2*	25.4 ± 2.3*	20.3 ± 2.1*	18.8 ± 1.6*
	Group 2	48.4 ± 1.9	34.2 ± 2.4*	30.4 ± 1.99*	24.3 ± 2.1*	20.1 ± 1.9*	18.6 ± 1.3*
RMD	Group 1	21.5 ± 1.8	12.3 ± 1.3*†	7.2 ± 2.1*	6.9 ± 2.5*	5.7 ± 2.3*	7.1 ± 2.0*
	Group 2	12.0 ± 1.7	11.5 ± 1.2*	6.7 ± 2.2*	6.3 ± 2.3*	5.5 ± 2.1*	6.6 ± 1.9*

Group 1: Conventional BKP, Group 2: Directional BKP

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STUDY RESULTS

Advancing BKP

What is Kyphon Assist™

More Control More Height

Performing BKP with Kyphon Assist™

Clinical Benefits of Directional BKP

A recent study[3] of nondirectional balloon technique (n = 51) and VCF patients treated with directional balloon technique (n = 49) demonstrated:

- Significantly reduced cement extravasation rate
  - The directional balloon technique reduced cement extravasation by 65% compared to conventional BKP.
- Significantly shortened operative and exposure time
  - The directional balloon technique reduced operation time by 8% when compared to conventional BKP.
  - The directional balloon technique reduced X-ray exposure by 20% when compared to conventional BKP.

Bone cement leakage was classified into 3 types:

- Type B – cement leakage along the vertebrobasilar vein to the posterior border of the vertebral body
- Type C – cement leakage mainly along the cortical defect to the intervertebral disc
- Type S – cement leakage mainly around the vertebral body along the intervertebral vein

Limitation: Small sample size and short follow-up time. Further research recommended to determine strength comparison between the controllable directional device, bone, and balloon.

COMPARISON OF INTRAOPERATIVE DATA BETWEEN 2 GROUPS

	Group 1 Conventional BKP	Group 2 Directional BKP	*P*
Case (N)	51	49	
Operation time (min.)	47.8 ± 6.1‡	43.8 ± 5.7	.001
Times of x-ray exposure	10 ± 2.0‡	8 ± 1.9	<.01
Blood loss (mL)	2.4 ± 1.1	2.3 ± 1.0	.63
Inject cement volume (mL)	4.6 ± 1.4	4.8 ± 1.3	.46
Bone cement leakage rate (n/N)	12/51 (23.5%)‡	4/49 (8.2%)	.036
Leakage type			
B	1/51	1/49	.74
C	9/51‡	2/49	.03
S	3/51	1/49	.64

Quantitative data were presented as mean ± standard deviation.

REFERENCES AND IMPORTANT SAFETY INFORMATION

1. Medtronic data on file. Business Insights and Analytics. October 2017.

2. Medtronic data on file.

3. Wang P, Li J, Song Z, Peng Z, Wang G. Utilization of the directional balloon technique to improve the effectiveness of percutaneous kyphoplasty in the treatment of osteoporotic vertebral compression fractures and reduction of bone cement leakage. *Medicine (Baltimore).* 2019;98(19):e15272.

The Kyphon Assist™ Directional Cannula is intended for percutaneous access to bone.

Kyphon™ Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions. The complication rate with Kyphon™ Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

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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 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.

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