

**Release your pain
Stand like a pine**

Princeton Medical Scientific Co., Ltd

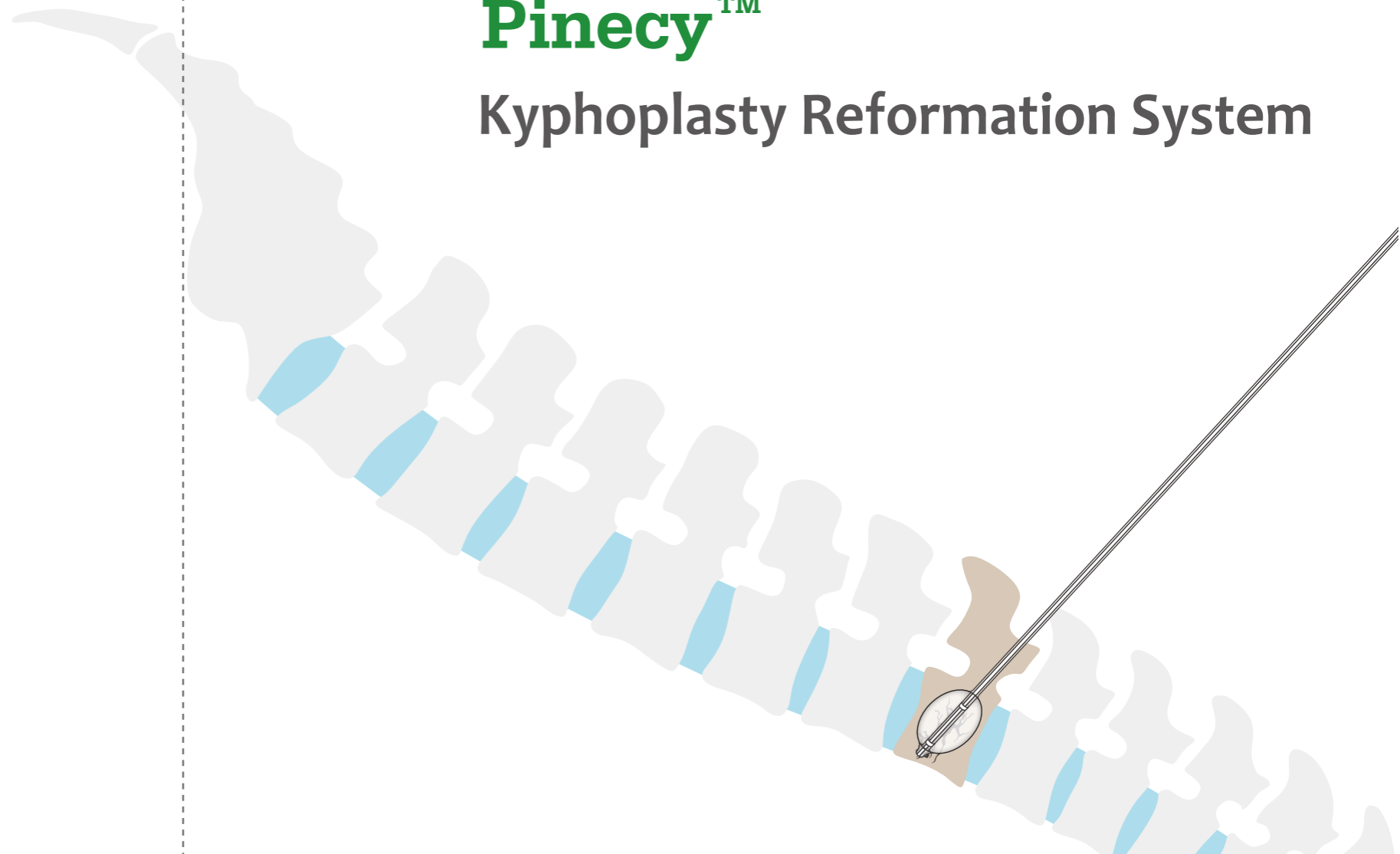
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Pinecy™

Kyphoplasty Reformation System



About Us

Established in September 2011, Princeton Medical Scientific Co., Ltd is specialized in manufacturing minimally invasive interventional medical devices in various categories.

Our main products focus on TAA stents, PTA and PTCA balloon catheters, interventional sheath and Kyphoplasty reformation tool kit which are certified by CE and CFDA. We also provide OEM manufacturing of balloon catheters, stents and braided/coiled tubes.



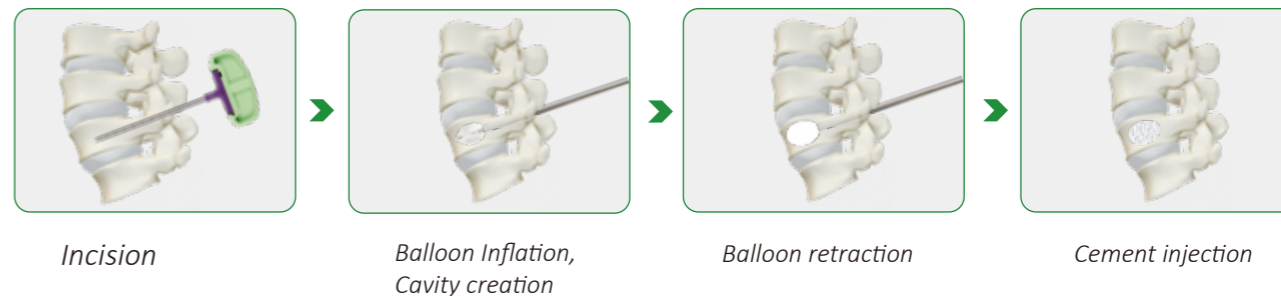
What is Percutaneous Vertebroplasty(PVP)?

Vertebroplasty is designed to stabilize the spine by the percutaneous transpedicular placement of bone cement into fractured vertebral bodies caused by osteoporosis, cancer or benign tumors.

What is Percutaneous Kyphoplasty(PKP)?

Kyphoplasty is a modification of the vertebroplasty. Balloon kyphoplasty creates a cavity in vertebral body before bone cement filled to reduce cement leakage, restore vertebral body height and also correct angular deformity. The main technique difference between PKP and PVP is the usage of balloon catheter.

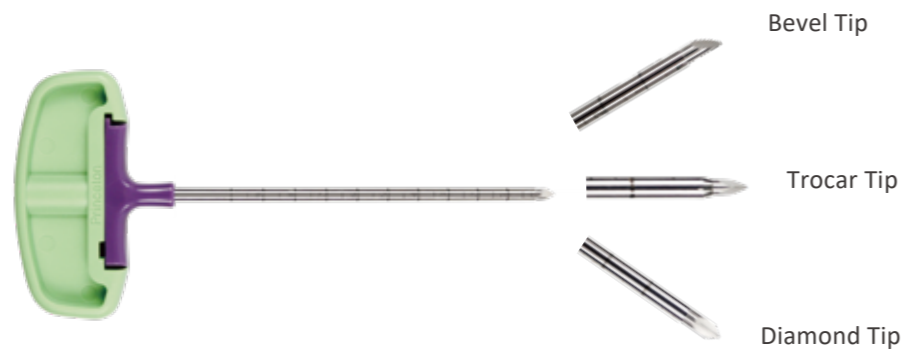
Procedure of Kyphoplasty(PKP)



Advantages of Kyphoplasty(PKP)

- More precise bone height restoration
- Effective reduction of spine deformity
- Less cement leakage / lower complication risk

Puncture Needle



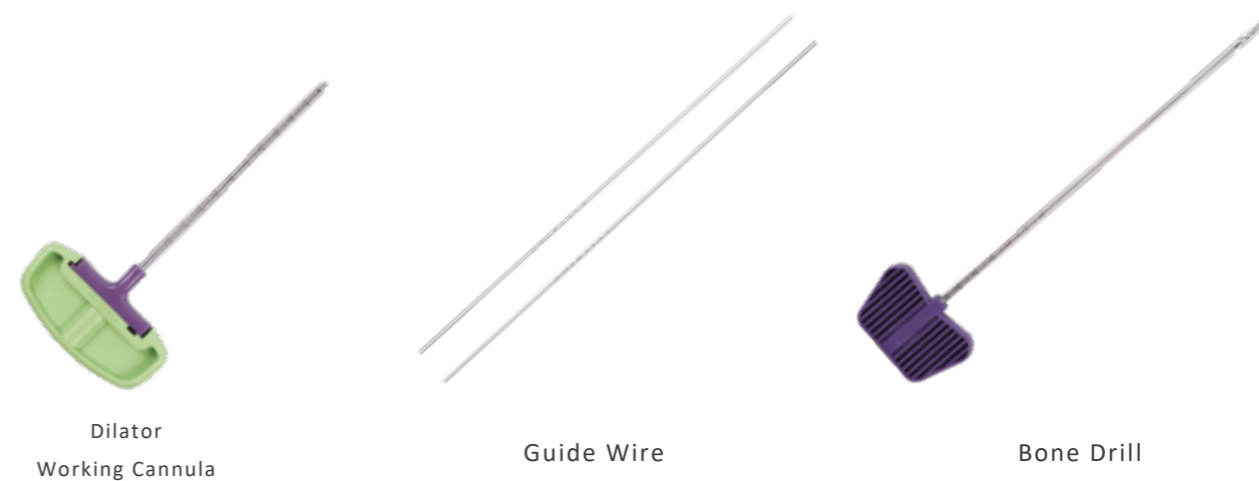
Features

- › Multiple size needles for lumbar/ thoracic vertebra
- › Different kinds of tips for different procedural needs

Specifications

Model	Name	OD (mm)	Length (mm)
FA0841	Puncture needle I (Trocar Tip) and cannula	3.00	146.00
FA0842	Puncture needle II (Trocar Tip) and cannula	4.20	146.00
FA0843	Puncture needle II (Diamond Tip) and cannula	4.20	146.00
FA0844	Puncture needle II (Bevel Tip) and cannula	4.20	146.00

Kyphoplasty Guide System



Description

- › Kyphoplasty Guide System consists of Working Cannula, Guide Wire and Bone Drill, designed for establishment of working channel in PVP/PKP procedure.

Specifications

Model	Description	OD (mm)	Length (mm)
FA0810	Guide wire	1.60	270.00
FA0811	Guide wire (round tip)	1.60	270.00
FA0821	Drill	3.60	239.00
FA0831	Dilator and working cannula	4.20	146.00
FA0832	Dilator and working cannula II	4.20	166.00

Kyphoplasty Balloon Catheter



Features

- Defined marker band on the shaft can help to identify the placement of the balloon tamp
- Bone marrow needle tip designed to establish accurate channel for balloon insertion
- Symmetrical balloon shape and atraumatic tip contribute to ideal balloon expansion and cavity formation to avoid damages of vertebra wall

Specifications

Model	Balloon Size	Max Pressure	Max Volume
FA03001-01	6.0mm*10mm	300 psi	4 ml
FA03001-02	6.0mm*15mm	300 psi	4 ml
FA03001-03	6.0mm*20mm	300 psi	6 ml

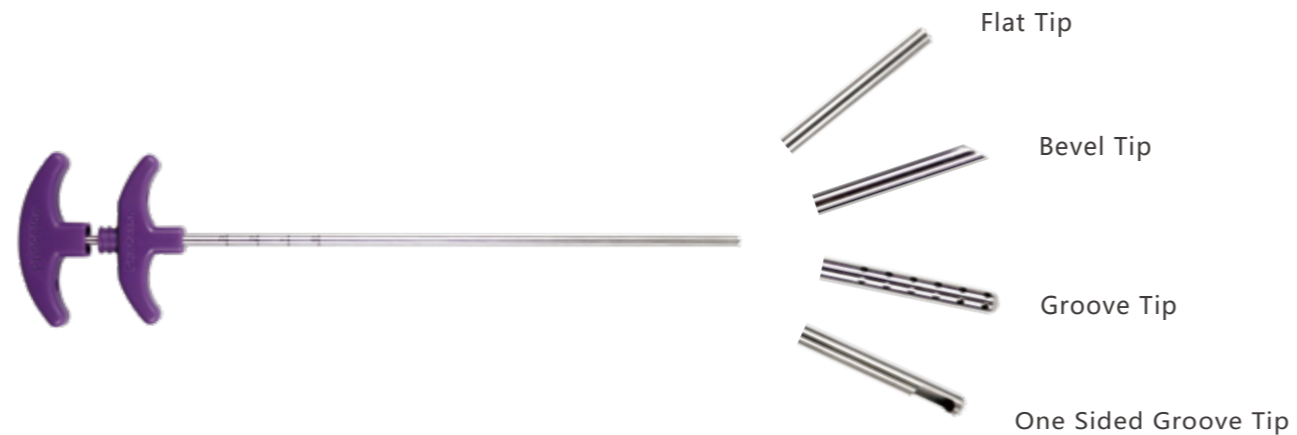
Inflation Device



Features

- 0.5ml/roll for stable & controlled expansion
- Lock mechanism for easy pressuring locking and 1-step release

Bone Cement Filler



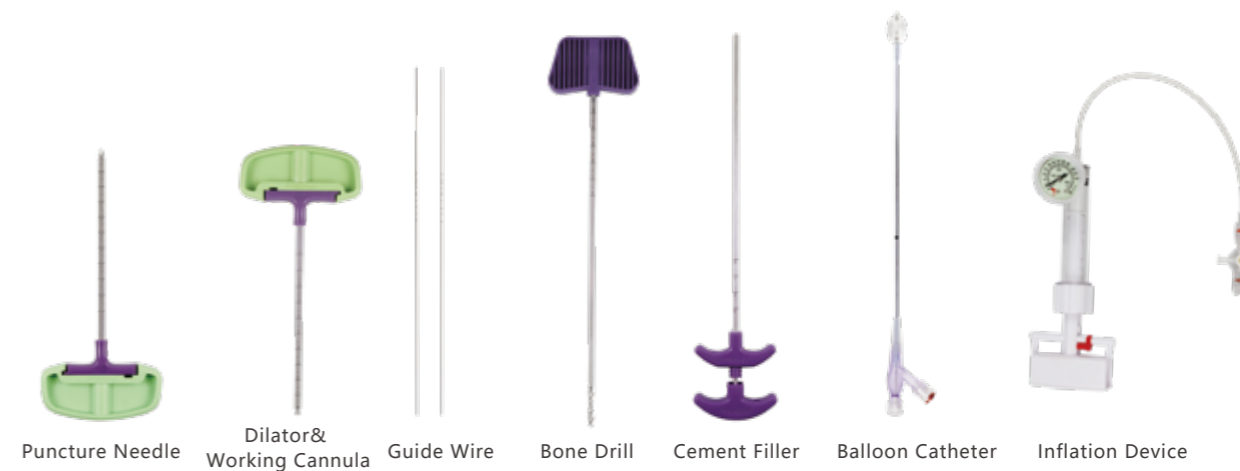
Features

- 4 kinds of tips to meet different procedural needs
- Volume mark on the pusher for 0.4ml, 0.8ml and 1.2ml

Specifications

Model	Description	ID (mm)	OD (mm)	Length (mm)
FA0851	Bone filler(Flat tip) and Bone filler pusher	2.9	3.50	216.00
FA0852	Bone filler(Bevel tip) and Bone filler pusher	2.9	3.50	216.00
FA0853	Bone filler(Groove tip) and Bone filler pusher	2.9	3.50	216.00
FA0854	Bone filler(One sided groove tip) and Bone filler pusher	2.9	3.50	216.00

Order Information



Puncture Needle

Dilator & Working Cannula

Guide Wire

Bone Drill

Cement Filler

Balloon Catheter

Inflation Device

Order Information

Model	Description		Quantity
FA08001-01	Two-Step Tool Kit	Puncture Needle (Trocar tip)	2 pcs
		Guidewire	1 pcs
		Dilator	1 pcs
		Working Cannula	2 pcs
		Bone Drill	1 pcs
		Bone Cement Filler (Flat tip)	6 pcs
FA08001-02	One-Step Tool Kit	Puncture Needle (Trocar tip)	1 pcs
		Bone Drill	1 pcs
		Bone Cement Filler (Flat tip)	4 pcs
FA03001-01	Kyphoplasty Balloon Catheter	6mm*10mm	Optional
FA03001-02		6mm*15mm	Optional
FA03001-03		6mm*20mm	Optional
Inflation Device	/	/	Optional

RCT of Pinecy™ & Kyphon balloon catheter

THE FIRST RCT OF KYPHOPLASTY BALLOON CATHETER IN CHINA

The clinical evaluation of Pinecy™ balloon catheter based on a randomized, controlled, single-blind and active control trail shows that there are no statistical differences in baseline cobb angles, heights of the compressed vertebral body, VAS and SF-36 scale with the Kyphon balloon catheter by Medtronic.

According to the clinical trial protocol, non-inferiority margin δ of cobb angles, heights of the compressed vertebral body and SF-36 scale were defined as 1/5 variation by Pre-operation minus post-operation of the control group. Herein, the non-inferiority margin δ should be $5.8258/5 = 1.1652$. We can draw a conclusion that the ability to correct the spinal deformity of the experimental group(Pinecy™ balloon catheter) is as good as that of the control group(Kyphon balloon catheter).

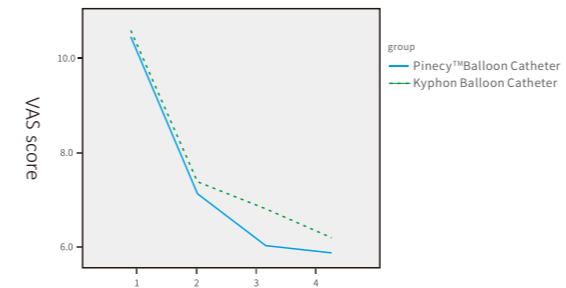


Figure 1. Trend-chart of VAS score

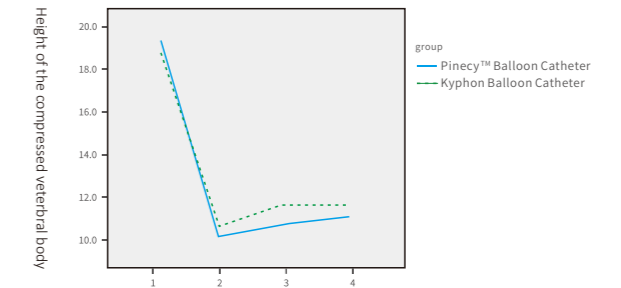


Figure 2. Trend-chart of height of the compressed vertebral body

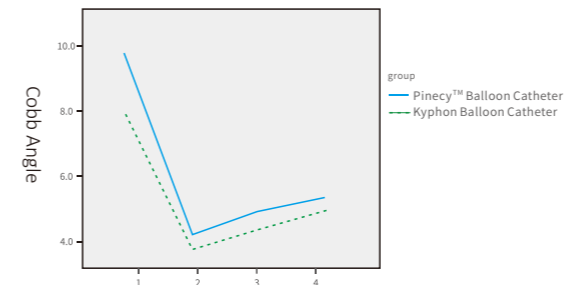


Figure 3. Trend-chart of Cobb angle

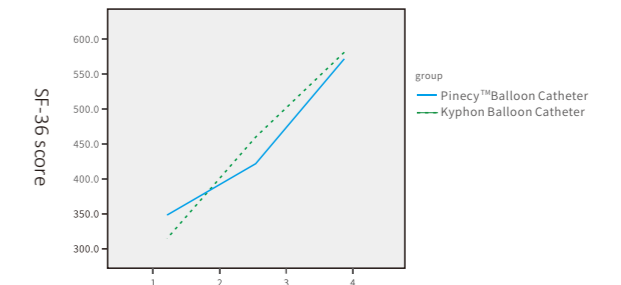


Figure 3. Trend-chart of SF-36 score