常美医疗
Changmei Medtech

Instruction for use of
Kyphoplasty Balloon Catheter

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【Product name】

Kyphoplasty Balloon Catheter

【Structure】

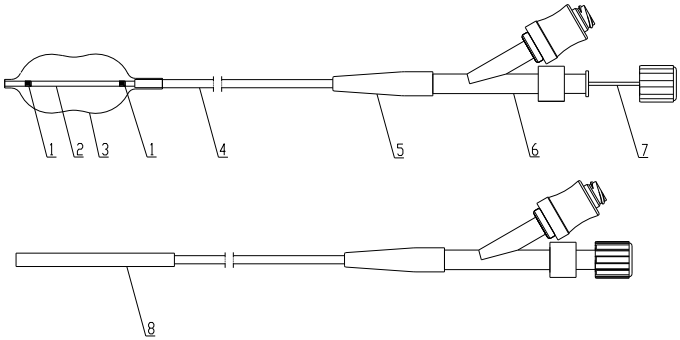

Figure 1 – Peanut type

1-Radiopaque maker, 2-Core tube, 3-Balloon, 4-Outer tube

5-Sheath, 6-Handle components, 7-Supporting wire components

8-balloon cover

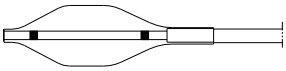

Figure 2 – Cylindrical Type top

【Models and Specification】

Balloon Type Code	Model	Overall Length (mm)	Maximum Volume (mm)	PSI Rating (psi)	Remark

01 Peanut Type	KB0110	315	3	400	No one-way valve
	KB0115	315	4	400	
	KB0120	315	6	400	
	KB0110S	280	3	400	
	KB0115S	280	4	400	
	KB01101	315	3	400	Having one-way valve
	KB01151	315	4	400	
	KB01201	315	6	400	
	KB0110S1	280	3	400	
	KB0115S1	280	4	400	
02 Cylindrical Type	KB0210	315	4	400	No one-way valve
	KB0215	315	4	400	
	KB0220	315	6	400	
	KB0210S	280	3	400	
	KB0215S	280	4	400	
	KB02101	315	4	400	Having one-way valve
	KB02151	315	4	400	
	KB02201	315	6	400	
	KB0210S1	280	3	400	
	KB0215S1	280	4	400	

【Packaging list】

Internal package: Paper-plastic bag, 1 pcs/bag

Middle package: Paper box, 1pcs/box

Outside package: Corrugated box

【Intended use】

This product is mainly used in a Percutaneous Kyphoplasty, PKP operation, to dilate vertebral body and form a vacuum which is for injecting bone cement to recover and stabilize vertebral body. Sterile, for single-use.

【Method of use】

(1)Preparation:

1. Take the product from the package, check if there is any bend or damage.

2. Used in combination with Balloon Kyphoplasty Kit. Connect the three-way valve with kyphoplasty balloon catheter, and inflate the balloon to see any leak before use. Don't use the instrument if any leak.

3. Prepare the instruments and kits demanded by the operation.

(2) Extract the balloon to vacuum：

1. Drain the inflator.

2. Draw about 20ml contrast medium by injector.

3. Connect the injector to the side joint of three-way valve at the inflator, and shut down the valve of open side.

4. Draw about 15ml contrast medium by inflator.

5. Shut down the side joint of three-way valve; then invert the inflator to drain the air in the soft tube.

6. Shut down the valve at the side of inflator; then drain the air in the upper three-way valve of the inflator by injector.

7. Screw the support wire, connect the three-way valve with kyphoplasty balloon catheter, then extract the balloon to vacuum by the injector.

8. Shut down the valve at the side of injector, and then remove the injector.

(3) Balloon Dilation：

1. Position pricking by puncture needle under the observation of double-surfaces fluoroscopic machine and single-arm or double-arms X-ray machine.

2. Remove the core of the puncture needle, and leave the sheath in the body; Put the guide wire to the located position through the sheath, then remove the sheath.

3. Rotate and insert the Dilator through the guide wire, rotation can reduce resistance.

4. Remove the dilator core; leave the sheath in the body as a work channel.

5. Dredge the sclerotic channel by bone drill through the work channel. If there is any bone chad or bone dirt during the dredging, bring it out by putting in and out of the bone drill for several times.

6. Insert the kyphoplasty balloon catheter which has been extracted to vacuum into the diseased vertebra, and turn on the valve to dilate the balloon. The balloon should be dilated slowly; it is suggested to inject 0.5ml or less contrast medium per time. Withdraw the core supporting wire when the pressure reaches 50psi, and focus on the balloon pressure to see if it drops or not (it will drop rapidly on patients with osteoporosis). Normally the balloon pressure is under220psi, stop dilating when the dilation reaches the required degree. Extract the kyphoplasty balloon catheter into vacuum and then remove it.

7. Inject the bone cement, pit the sheath of stuffing device to the front edge of the vacuum through work channel; Rotate and withdraw the

sheath of stuffing device while.

8. If two-side dilation will be operated, the method is similar.

(4) Dispose：

Dispose this device according to recognized hospital regulations.

【Notices】

1. Don’t use the instrument when the package is damaged..

2. Don’t use the instrument when the valid period is exceeded.

3. It’s a disposable product, thus please destroy it after using and repeat using is strictly forbidden.

4. Iodine allergy test is required before operation.

5. The quantity of contrast medium used during the operation should meet the demand requirements.

6. The balloon pressure in the operation should be within 220psi.

7. The instrument should be operated by trained and experienced physicians.

8. It is recommended to prepare another kyphoplasty balloon catheter before the operation.

【Contraindications】

1. Painless VCFs, or VCFs is not the major cause of pain.

2. There is osteomyelitis or whole-body infection.

3. There is a backward protruding bone, or a back tumor may imperil vertebral canal.

4. Perisporium of diseased vertebra, especially the paries posterior is destroyed or incomplete.

5. Fracture of vertebral pedicle.

6. Vertebral fracture with nerve injury.

7. Patients with osteogenic or metastatic tumor.

8. Patients who has bleeding trend or coagulation disorder.

9. Patients with serious cardiopulmonary disease, or with a very delicate health which can't bear the operation.

10. Patients with a fever above 38℃ or with inflammation at the puncture point;

11. Patients with vertebral compression fractures;

12. Patients not suitable for this operation.

【Storage and transportation】

1. The single package is paper-plastic bag, middle is the box, and outer is the carton. When in transport, it should be kept clean, dry and sealed. The transport condition should be of the temperature of -20℃～70℃, and the humidity of 10%～90%. It could not be transported together with sand, metal fragments, glasses, or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slinging of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.

2. This instrument is sterilized product, for single use only. Store the sterile package at the temperature of -20℃～60℃ and the humidity of 10%～90%. Store the instrument at the dry room of good ventilation. Do not store it in direct sunlight.

3. Do not store the sterile package containing the instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could cause risk of infection control or patient's affected part infection.

【Explanation for used symbols】

CE 0123	CE certified by TUV SUD	LOT	Lot number
	Single use		Date of manufacture

	Sterilized by EO		Manufacturer
	Read the IFU		European union representative
	Validity of device		

【Validity Period】3 years

【Manufacturer】Jiangsu Changmei Medtech Co., Ltd.

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