常美医疗
Changmei Medtech

Instruction for Use of Kyphoplasty Tool Kit

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【Product name】

Kyphoplasty Tool Kit

【Product structure and components】

Kyphoplasty Tool Kit consists of puncture device, puncture expandor device, expandor device, bone cement filling device, bone drill and guide wire. Metal parts of the products are made of 06Cr19Ni10 and 32Cr13Mo, which are in accordance with GB 1220 standard, and the handle is made of medical grade polymer materials.

【Specification】

Specification		Name	QTY	Unit	Purpose
Model	Specification				
KT-00-01	KT-01-01	Puncture device	2	Set	Approach
	KT-02-01	Puncture expandor Module	1	Set	Puncture and expansion
	KT-03-01	Expandor device	2	Set	Channel forming
	KT-05-01	Bone drill	1	Piece	
	KT-06-01	Guide wire	2	Branch	
	KT-04-01	Bone cement filling device	6	Set	Bone cement filling

【Intended use】

This product is mainly used for bone percutaneous intervention and establishing working channel by medical institutions. Sterile, for single-use.

【Indications】

Indications of PVP and PKP：

1. OVCF patients who have been treated with traditional non-operative therapy and but invalid, and the pain increased;
2. Vertebral compression fractures caused by osteoporosis, bone hemangioma, myeloma, and various vertebral metastatic tumors;
3. Long-term bed-ridden because of vertebral fractures may lead to bedsore and other complications;
4. Vertebral fractures with persistent and severe pain, the pain duration was more than 3 to 4 weeks;
5. Vertebra collapse after fracture, accompanied with kyphosis;
6. Vertebral metastasis of malignant tumor, vertebral hemangioma and multiple myeloma tumors have not affected the posterior wall of the vertebral body.

【Key technical indicators】

1. Connection strength: each joint of the tool should be able to bear at least 100N, without separation or falling off;
2. Performance: all the components are easy and flexible to cooperate with each other, without blocking phenomenon.
3. Cutting performance: bone drill should have good cutting

performance, without chipping, bending, cracks and other defects;

【Contraindication】

PVP and PKP have similar contraindications, there is no absolute contraindications. Any of the following conditions shall be deemed to be relative contraindications:

1. Vertebral body height is completely lost or lost more than 2/3 of normal vertebral body height;
2. Free bone enters into spinal canal;
3. Unable to bear emergency lamina decompression spinal canal probe
4. Pregnant woman
5. Pains which have nothing to do with vertebral collapse;
6. Bilateral pedicle fractures
7. Burst vertebral fractures and high energy fractures, which are in the acute phase;
8. Vertebral osseous tumor patients who are intolerance of operation;
9. Patients who have coagulation disorders;
10. Dying patients;
11. Local infection of skin;
12. Allergic to inflatable balloon materials, contrast medium or bone cement;
13. Patients whose vertebral body wall integrity is damaged because of pathological and (or) traumatic causes.

【Notice】

1. Do not use the instrument when the package is damaged.

2. Pay attention to the cutting edge of the tool. Check if there is curved blade, collapse edge, whether the moving parts is flexible and without blocking.
3. Users should be trained doctors.
4. Do not use the instrument when the valid period is exceeded.
5. Single use only, discards after use. Do not reuse.

【Usage】

a) Preparation:

① Kyphoplasty Tool Kit 1 pack;
② Balloon Inflator 1 piece;
③ Kyphoplasty Balloon Catheter 2 pieces;
④ Bone cement 1 box;
⑤ Syringe 1 piece

Remarks:

①open the package to check the product, the product should be in good condition. If there is scratch on the steel bar and the scale is vague, do not use.

②connect 3-way valve of balloon inflator with kyphoplasty balloon catheter, inflate the balloon to check for leakage before use. If there is leakage phenomenon, do not use.

③check carefully before use, make sure the packaging remains intact, if the packaging is damaged, please do not use.

b) Balloon vacuum:

1. Empty the balloon inflator;
2. Inject 20ml contrast medium with syringe;
3. Connect the syringe to the 3-way valve of the balloon inflator and then close the open end valve;
4. Pump 15ml contrast medium with balloon inflator;

5. Close the valve in the direction of syringe, place the balloon inflator upside down to empty the air in the hose;
6. Close the valve in the direction of balloon inflator, use the syringe to empty the air in 3-way valve of balloon inflator;
7. Tighten the supporting wire, connecting the 3-way valve of the kyphoplasty balloon catheter and the balloon inflator, then vacuum the balloon with a syringe;
8. Close the syringe valve, remove the syringe.

c) Surgical approach:

Possible surgical approach can be chosen by the clinician from transpedicular and posterolateral transpedicular according to actual situation.

1. The patients should be in prone position, the waist and back shall be disinfected and then spread a towel. Whether to adopt local anesthesia or general anesthesia, it depends on actual situation;
2. Under C arm X-ray positioning, find the projection point of injured vertebral pedicle in the skin, and then insert the needle through the skin to the injured vertebral pedicle screw to the vertebral body in the 1/3;
3. Remove the puncture needle, insert the guide wire, and then remove the cannula;
4. Insert the expandor device along with the guide wire, making sure the front end of the expandor cannula is situated at the posterior cortex of vertebra in front of 2 ~ 3mm;
5. Remove the expandor, left the expandor cannula in the human body as working channel;
6. Insert the bone drill via expandor cannula slowly, when drill tip reaches 1/2 anterior and posterior diameter of vertebra

in lateral projection, then the drill tip should not exceed 1/2 of pedicle and spinous process connection in frontal projection; when drill tip reaches anterior vertebra in lateral projection, then the drill tip should be close to the edge of spinous process.

7. Take out of the bone drill and put into the dilation balloon. Its ideal position can be in the front of the 3/4 of vertebral body in lateral projection, lean from posterosuperior to anterior inferior. Connect the injection device, through C arm X-ray machine to monitor the balloon dilatation and fracture reduction. Through the pressure of the syringe with contrast medium to gradually dilate the balloon. X-ray monitoring can clearly display the whole process of vertebral body support, height restoration and correction of kyphosis. Watch out for the pressure, compression or decompression at any time. After balloon dilatation and vertebra reduction, withdraw the deflated balloon.

   Warning:

   Index of stopping dilation:

   a) Balloon system pressure is at 16-18 atm;

   b) The volume of contrast medium shall be controlled within 4-6ml;

   c) Balloon contacts with vertebra cortex;

   d) Fractures have been recovered.

8. Take out the balloon, inject the bone cement which is in drawing stage into the vertebral body. Use C arm X-ray machine to monitor bone cement filling condition in the vertebral body. Stop filling when bone cement reaches at the posterior edge of the vertebral body. After completing

injection, remove the surgical device before bone cement become entirely coagulated.

Warning:

Mix bone cement according to the recommended proportion, then use pressure syringe to extract in gruel period. About 1 minute later, push out the bone cement a little from the syringe, observe it in the toothpaste period, thus can be injected into the vertebral body under fluoroscopy monitoring.

d) Postoperative disposal of the equipment

Dispose the device as dangerous biological medical goods in accordance with the requirements of the hospital.

【Sterilization】

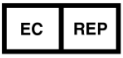
Kyphoplasty Tool Kit is sterilized by ethylene oxide.

【Storage & Transport】

1. The instrument should be placed in the environment with relative humidity of less than 80% and without corrosive gas. Store the device at cool, dry, clean room of good ventilation.
2. Do not store the sterile instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could pose a risk of infection control or cause infection in affected part of patients.
3. The inner package is paper-plastic bag, middle is the box, and outer is the corrugated carton. Transportation should maintain clean, dry and sealed.
4. Transportation conditions: It should prevent stress and 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.

【Signs & Symbols】

	Disposable		Sterilized by EO
	Date of manufacture		Expiration date
	Do not use when the package is damaged		Read instructions before use
	Lot number		Note that see instruction for use
	EU representative		Manufacturer
CE 0123	CE certified by TUV SUD		

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【**Validity Period**】3 years

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