1. Indications:

Vertebral tumors

Osteoporotic compression fracture

2. Intended Use:

Vertebral Forming Unitized Surgical Instruments and Vertebroplasty Toolkit is provided sterilized and for Transient single use, which is intended for Compressive Fracture lead by benign, malignant tumor and osteoporosis.

3. Contraindications:

PVP:

Osteomyelitis, Epidural Cyst;

Vertebral compression fractures with more than 70% height loss;

Severe spinal cord compression or secondary spinal stenosis at the level of fractured vertebral body;

Vertebral body’s posterior wall fracture or damage;

Severe cardiopulmonary dysfunction, coagulation disorders, sepsis and the other diseases that is not suitable for the operation.

PKP

Osteomyelitis or Presence of systemic infection ;

A prominent bone block to the rear vertebral body;

Tumor lumps in the rear side, which may involve the vertebral canal;

Severe cardiopulmonary dysfunction, coagulation disorders, sepsis and the other diseases that is not suitable for the operation.

4.Cautions and Warnings

Cautions:

1. Make the mix of cement according to a ratio of 1:1 , Pour the cement into the barrel when it is in the state ofgruel. Do injection when the cement has reached the exact delivery consistency, toothpaste like. (about 4 minutes after mixture , please refer to the bone cement’s instruction .)

2. Check whether the package is damaged before use. Do not use the product if the package is damaged.

3.The valid period of sterilization of the product is 24 months, please use it within the validity.

4. Do not reuse. Reuse may lead to infection, cross contamination or other illness/injury.

5. Do make a round with plunger handle anti-clockwise to release excess pressure, preventing the bone cement continuing injection.

6. Inflate the balloon progressively until reaching one of the following end points

1).The vertebral endplate has been lifted to achieve the treatment goal.

2). Contact with any of the cortical walls.

3).Maximum volume of the balloon (please refere to the following volume form)

4).It is recommended to expand the balloon to a working pressure of 20.5 atm

Balloon Specification(mm)	9×10	9×15	12×19	14×17	17×22
Volume(ml)	1.5	2	3	3.5	4

(approximately 300psi) before stopping the expansion. If necessary, the balloon expansion should not exceed the rated pressure of 27 atm (approximately 400psi).

7. Maximum volume of bone cement is 1.2ml for φ 3.4mm bone cement injector. Maximum volume of bone cement is 0.9ml forφ3.0mm bone cement injector. Choose the quantity of Bone Cement Injector according to the vertebral body and balloon's expanding.

8. When the Puncture Needle is knocked into the needle with a bone hammer, it can only be knocked directly behind the handle of the Puncture Needle, not on the side of the handle of the Puncture Needle.

9. The leaf of expander can not be rotated when it is in the expansion state, but can only be rotated when it is in the retracted state.

10. The parts of Vertebral Forming Unitized Surgical Instruments and Vertebroplasty Toolkit after clinical used shall be disposed in accordance with the relevant medical waste management regulations.

11. When disposing of medical waste, proper protection should be taken to avoid infection and microbial hazards, and attention should be paid to avoiding injury from sharp objects such as Puncture Needle, Solid Vertebral Drill, and Hollow Vertebral Drill.

12. Only the trained/experienced physicians should use this instrument.

13. The doctor evaluates the patient before surgery, and determines whether the patient is suitable for the

product according to his health condition, mental condition, allergy to foreign bodies, etc.: if applicable, choose the applicable models and specifications according to the patient's own situation, and different models and specifications of products should be prepared before the operation.

14. This instruction manual must be read carefully before use.

Suggestions for use:

It’s suggested to use these instruments with 10ml disposable injector with lock connector and acrylic resin bone cement .

The device can not cause death of any user or serious deterioration in health status.

Warnings

1. Incomplete posterior border of vertebral body caused by the vertebral body fracture line beyond the posterior border of vertebral body or bone destruction.

2. The vertebral body compression exceeding 75%.

3. Burst fracture of vertebral body caused by nervous system injury.

4. Dislocation of small joint or intervertebral joint caused by compressive fracture.

5. Infected punctured part.

6. Bleeding and coagulation dysfunction, and bleeding tendency.

7. Serious systemic diseases of heart, lung, etc., weak body inapplicable for operation, serious cardiovascular and respiratory diseases, very weak body unable to stand an operation.

8. Blood-fat high, and vessel embolization of lower limb or from head to foot.

5.Complications/Side Effects

Bone cement leakage causes circulatory embolism

Bone cement leakage causes increased or decreased venous pressure in the spinal canal

Pulmonary embolism

postoperative infection

Neurological injuries

Severe vascular injuries

Allergic to drugs or implants used during surgery.

6.Storage

The sterilized Vertebral Forming Unitized Surgical Instruments and Vertebroplasty Toolkit should be stored in an well-ventilated room with 0～30 ℃ , relative humidity not more than 80%, free of corrosive gas.

7.Labels and Symbols：

Medical device

Model number

Catalogue number

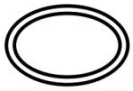

Manufacturer

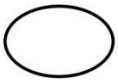

Date of Manufacture


Use-by date

Batch Code

Sterilized using ethylene oxide


Double sterile barrier system



Single sterile barrier system

Do not re-use

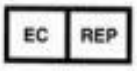
Do not use if package is damaged

Temperature limit

Caution

Humidity limitation

Do not resterilize



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