DRAGON CROWN 龙冠

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CE 2797

INSTRUCTION FOR USE

Bone Filling Container

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INSTRUCTION FOR USE

1. General Description

The bone filling container is intended for the treatment of osteoporosis vertebral compression fracture and is expected benefit patients by elevating the endplate, restore the vertebral height and relieve the pain. The mesh bag and the introducer are introduced through the working channel, and the bone filling materials are injected into the filling container by spiral injector to expand the container, so that to elevate the endplate, restore the vertebral height and relieve the pain. It can reduce the rate of bone cement leakage.

Bone filing container is composed of introducing instruments and a container. The introducing instruments include: introducing tube, a guide pin and a pushing rod. The introducing tube has two types: one is single tube and the other is double tubes. The double tubes type is with an outer cannula. The container has two types, one is single layer and the other is double layers.

The bone filling container is delivered in a sterile state and for single use.

The bone filling container kit is shown in Table 1. The model and specifications of the bone filling container are shown in Table 2.

Table 1: Model of Bone Filling Container Kit

组套型号 Kit model (Ref#)	器械名称 Instrument name	器械规格 specifications	产品特征 Products characteristic
BK-0120	骨填充网袋 Bone filling container	0120	单层注入管、单层网袋、螺纹连接 Single layer injection tube, single layer mesh bag, thread connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃 Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0125	骨填充网袋 Bone filling container	0125	单层注入管、单层网袋、螺纹连接 Single layer injection tube, single layer mesh bag, thread connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃 Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0130	骨填充网袋 Bone filling container	0130	单层注入管、单层网袋、螺纹连接Single layer injection tube, single layer mesh bag, thread connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/

	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0320	骨填充网袋 Bone filling container	0320	双层注入管、单层网袋、压紧连接Double layer injection tube, single layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0325	骨填充网袋 Bone filling container	0325	双层注入管、单层网袋、压紧连接Double layer injection tube, single layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0330	骨填充网袋 Bone filling container	GT-0330	双层注入管、单层网袋、压紧连接Double layer injection tube, single layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/
BK-0520	骨填充网袋 Bone filling container	GT-0520	双层注入管、双层网袋、压紧连接 Double layer injection tube, double layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器Expander	ϕ3.4×190	/
BK-0525	骨填充网袋 Bone filling container	0525	双层注入管、双层网袋、压紧连接 Double layer injection tube, double layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器Expander	ϕ3.4×190	/
BK-0530	骨填充网袋	0530	双层注入管、双层网袋、压紧连接

	Bone filling container		Double layer injection tube, double layer mesh bag, compact connection
	穿刺针 Puncture needle	ϕ4.0×126	三刃Three edges
	实芯椎体钻 Solid Vertebral Drill	ϕ3.4×190	/
	螺旋推进器 Spiral propeller	20ml	/
	骨扩张矫形器 Expander	ϕ3.4×190	/

Table 2: Model of bone filling container

型号规格 Model (Ref#)	规格 specification	结构型式 Structure type	连接方式 Connection method
GT-0120	20	单层注入管，单层网袋 Single layer injection tube, single layer	螺纹连接 Thread connection
GT-0125	25	单层注入管，单层网袋 Single layer injection tube, single layer	螺纹连接 Thread connection
GT-0130	30	单层注入管，单层网袋 Single layer injection tube, single layer	螺纹连接 Thread connection
GT-0320	20	双层注入管，单层网袋 Double injection tube, Single layer container	压紧连接 Compact connection
GT-0325	25	双层注入管，单层网袋 Double injection tube, Single layer container	压紧连接 Compact connection
GT-0330	30	双层注入管，单层网袋 Double injection tube, Single layer container	压紧连接 Compact connection
GT-0520	20	双层注入管，双层网袋 Double injection tube, double container	压紧连接 Compact connection
GT-0525	25	双层注入管，双层网袋 Double injection tube, double container	压紧连接 Compact connection
GT-0530	30	双层注入管，双层网袋 Double injection tube, double container	压紧连接 Compact connection

Indication:

Osteoporosis vertebral compression fracture

Contraindication:

1) osteomyelitis, epidural cyst;
2) vertebral compression, more than 70%
3) vertebra spinal cord severely depressed or secondary spinal steno-sis;
4) Severe cardiopulmonary dysfunction, blood coagulation disorders, sepsis and other surgery is not suitable.

2. Procedure

Matched with vertebroplasty instruments and (PMMA) bone cement.

(1) Establish the working channel : there are two ways for this step, and both should be made under the monitor of fluoroscopy

a) With puncture needle of Φ4.0×126, using transpedicular approach to access to the collapsed vertebral body, and remove the inner stylet, the working channel is established.

b) With puncture needle of Φ3.0×100, using transpedicular approach to access to the collapsed vertebral body, remove the inner stylet, and insert the guide pin, remove the puncture needle, and put dilating tube and working cannula along the guide pin, then remove the guide pin and dilating tube, the working channel is established.

(2) Introduce the bone drill (If specimen needed, use the hollow drill) through the working channel to the vertebral body to drill a channel for placing the container. It is performed under the monitor of fluoroscopy. When the drill arrived at the proper depth, take it out.

(3) Insert the bone expander into the channel and confirm through fluoroscopy that it has reached the site of vertebral compression fracture. Through repeated expansion, a space is formed inside the vertebral body.

(4) Insert the introducing tube and container into the working channel to introduce the container into the vertebral body. Confirm that the container has fully extended out from the working cannula by visualizing the anterior marker and titanium nozzle under the fluoroscopy. Remove the guide pin.

(5) Turn the handle of the spiral injector counterclockwise until the tip of the plunger back to the mark of 10ml, put the funnel onto the distal end of barrel.

(6) Open the package of bone cement, and make the mixture of bone cement. Pour the mixture to the barrel when it is in the state of gruel(Fig. 1).Attach the extension tube to the injector, and lock the connection tightly.

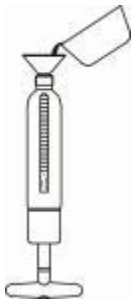


Fig. 1

(7) Hold the injector with the plunger handle pointing downwards; rotate the handle clockwise to purge the air from the barrel and extension tube.

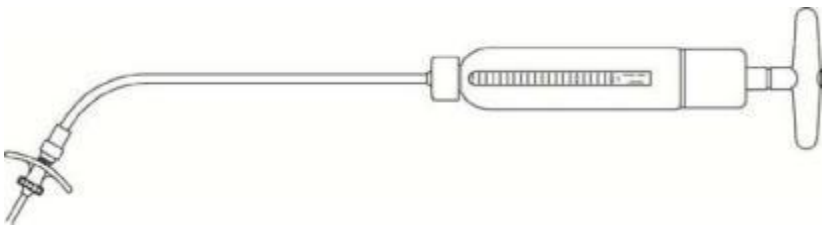


Fig. 2

(8) Slowly rotate the plunger handle clockwise, and observe the state of the cement emerge from the tube's tip. When the cement is of toothpaste-like consistency, connect the extension tube to the introducing tube (Fig. 2).

(9) Under the monitor of fluoroscopy, slowly inject the cement to expand the container and elevate the endplate.

(10) Detach the extension tube from introducer, and use pushing rod to inject the cement remained in the introducing tube to the container.

(11) Removal of introducing tube

a) Single introducing tube

Wait until the cement has completely set, slowly rotate the introducing tube and pushing rod counterclockwise until the introducing tube fully separate from the container, remove the introducing tube and pushing rod from the working cannula

b) Double introducing tubes

Wait until the cement has completely set, hold the outer cannula with left hand, and slowly rotate the inner cannula counterclockwise with right hand, until the fully separation between inner and outer cannula is made, take out the inner cannula from working cannula first, and then take out the outer cannula.

(12) Remove the working cannula; cover the incision with sterilized dressings, the procedure is finished.

3. Warnings and precautions

(1) Bone cement is generally in accordance with a bag of powder (10 g): 1 bottle of liquid (5ml) ratio deployment to constantly stir it evenly 30s ~ 60s after a while, and then poured into a syringe injection toothpaste-like (about 1 to 4 minutes after the deployment, see the bone cement manual).

(2) Pay attention to check the packages of the instruments before use. If the damage of packages is found, do not use.

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

(4) When the completion of the injection, immediately rotate counterclockwise the handle 1 turn to release residual pressure, preventing accidental injection of bone cement.

(5) Do not reuse, reusing may cause cross contamination.

(6) The parts of bone filling container after clinical used shall be disposed in accordance with the relevant medical waste management regulations

(7) Only the trained/experienced physicians should use this instrument.

(8) This device is a permanent implant. The avoidance of the usage of patient with highly allergy to metal or artificial vessel fabric should be noticed.

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

(10) This instruction manual must be read carefully before use;

(11) This procedure is strict in operational technology and poses a risk of serious injury to the patient, so the physician requiring the implant procedure using the product must be an experienced and necessary professionally trained surgeon. The surgeon should be familiar with the product implant technology and skilled in using the relevant surgical instruments.

(12) 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.

(13) During the process of use, the doctor should wear medical gloves for operation.

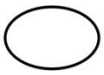
4. Complications/Side Effects

(1) Bone cement leakage causes circulatory embolism
(2) Bone cement leakage causes increased venous pressure in the spinal canal
(3) Pulmonary embolism
(4) postoperative infection
(5) Neurological injuries
(6) Severe vascular injuries
(7) Allergic to drugs or implants used during surgery.

5. Storage

The sterilized bone filling container should be stored in an well-ventilated room with 0-40℃ , relative humidity not more than 80%, free of corrosive gas.

6. Labels and symbols

	Medical device
	Model number
	Single sterile barrier system
	Date of manufacture
	Sterilized using ethylene oxide
	Batch Code
	Do not re-use
	Do not use ifpackage is damaged
	Temperature
	Caution
	Humidity limitation
	Do not resterilize
	Use by date
	Consult instructions for use
	Manufacturer
	MR conditional
	**Company Name : Lotus NL B.V.** **Company Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Nether**