CeraFix Bone Cement Instructions

1、Product Name

CeraFix Bone Cement

2、General Description

CeraFix bone cement, hereinafter referred to as bone cement, is a type of hydroxyapatite/polymethyl methacrylate bone cement used for filling, supporting, and stabilizing lesion sites. Adding 10% hydroxyapatite to the powder promotes interface fusion, reduces the temperature of bone cement polymerization reaction, and improves clinical safety.

Bone cement is a sterile disposable medical device, packaged with powder containers and liquid ampoules, both of which have been sterilized with ethylene oxide. The liquid is filtered for sterilization, and the powder is sterilized with ethylene oxide.

Product model and specifications

Bone cement is divided into eight models and specifications: GC10A, GC20A, GC30A, GC40A, GC10B, GC20B, GC30B, and GC40B, with A being medium viscosity; B is high viscosity.

The model specifications of bone cement products are shown in Table 1.

Table 1

Description \ Model / Spec		GC10A GC10B	GC20A GC20B	GC30A GC30B	GC40A GC40B
CeraFix Bone Cement	Powder	11g	22g	33g	44g
	Liquid	5ml	10ml	15ml	20ml

The packaging of bone cement products can be individually packaged according to the model specifications, or can be combined with the same model specifications.

3、Intended Purpose of the Products

Suitable for vertebral compression fractures caused by osteoporosis or vertebral fractures caused by trauma, with the expectation of filling and stabilizing the vertebral body during

percutaneous vertebroplasty or percutaneous kyphoplasty.

4、Contraindications

1.Active infection;

2.Hemorrhagic diseases;

3.Patients with symptoms of spinal cord compression caused by pathological tissue;

4.Individuals who are allergic to the ingredients in the product.

5、Cautions, Warnings and Reminders

1.The implantation process and conditions of the product should comply with the corresponding technical management standards of the Health and Family Planning Commission.

2. Surgical surgeons must receive training on the operating techniques of this product and carefully follow them. Operators must understand and follow the recommended time required for each stage of preparation. If the operating instructions are not followed, adverse reactions may occur.

3. The injection of bone cement must be slowly carried out under the control of continuous X-ray monitoring, observing the distribution at the lesion site and paying attention to any leakage outside the lesion site. In case of bone cement leakage, the operation should be stopped immediately.

4.Before the operation, the patient must undergo a thorough preoperative examination.

5. Please ensure the normal operation of the ventilation system in the operating room and try to eliminate the gas emitted by monomer fluids as much as possible. Monomer liquid is a volatile and flammable liquid.

6.If other objects are implanted near the surgical site after surgery, it may increase the risk of infection.

6、Complications/Side Effects

1. Bone cement leakage.

2. Sudden cardiac arrest, myocardial infarction, and sudden death.

3. Abnormal decrease or increase in arterial blood pressure, transient cardiac conduction disorder.

4. Cerebrovascular disease, cerebral infarction.

5. Pulmonary embolism, hepatorenal toxicity.

7、Method of Use

Place the powder container on a flat surface and open the container lid. Open the liquid ampoule bottle and pour all the liquid into the powder. After covering the container with a Ruhr joint, invert and vigorously shake the container until it is evenly mixed and reaches a fluid state. Pump the bone cement into the syringe and distribute it, or transfer the bone cement directly to the injection device.

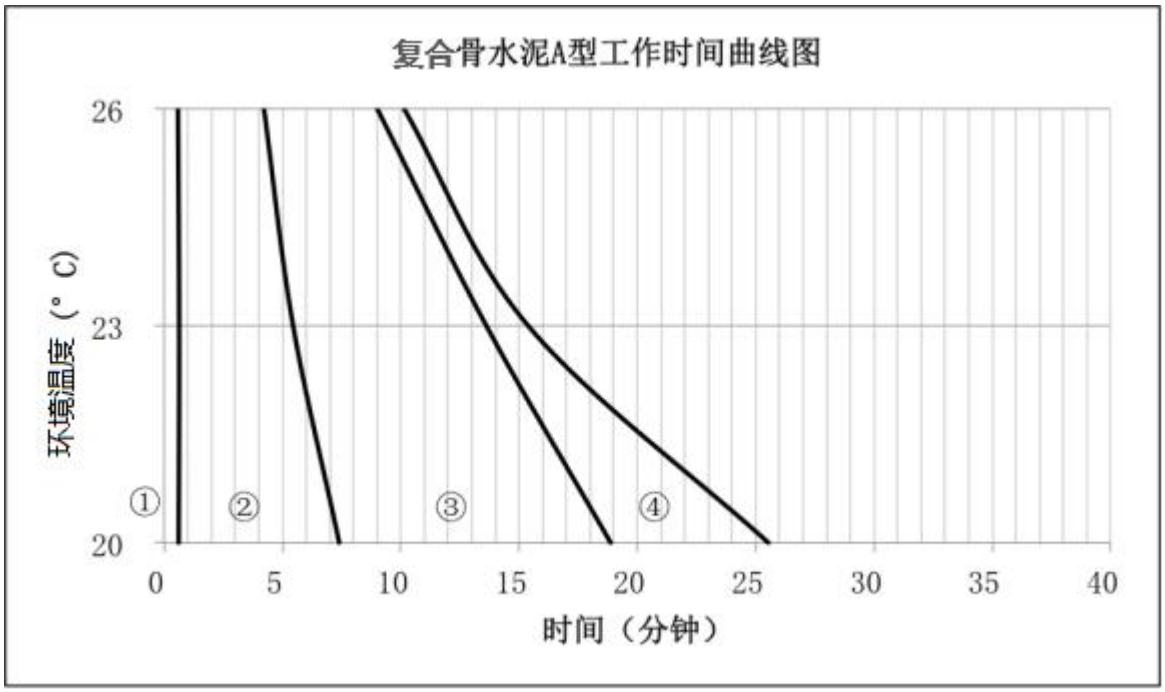
Preparation and use time:

Temperature has a significant impact on the preparation characteristics of this product. If

the temperature exceeds 23 ℃, the mixing equipment and environment will accelerate Various stages of the preparation process, and lower temperatures can delay the preparation process. Therefore, it is recommended to store the product in an environment of 23 ℃± 1 ℃ for 24 hours before using it.

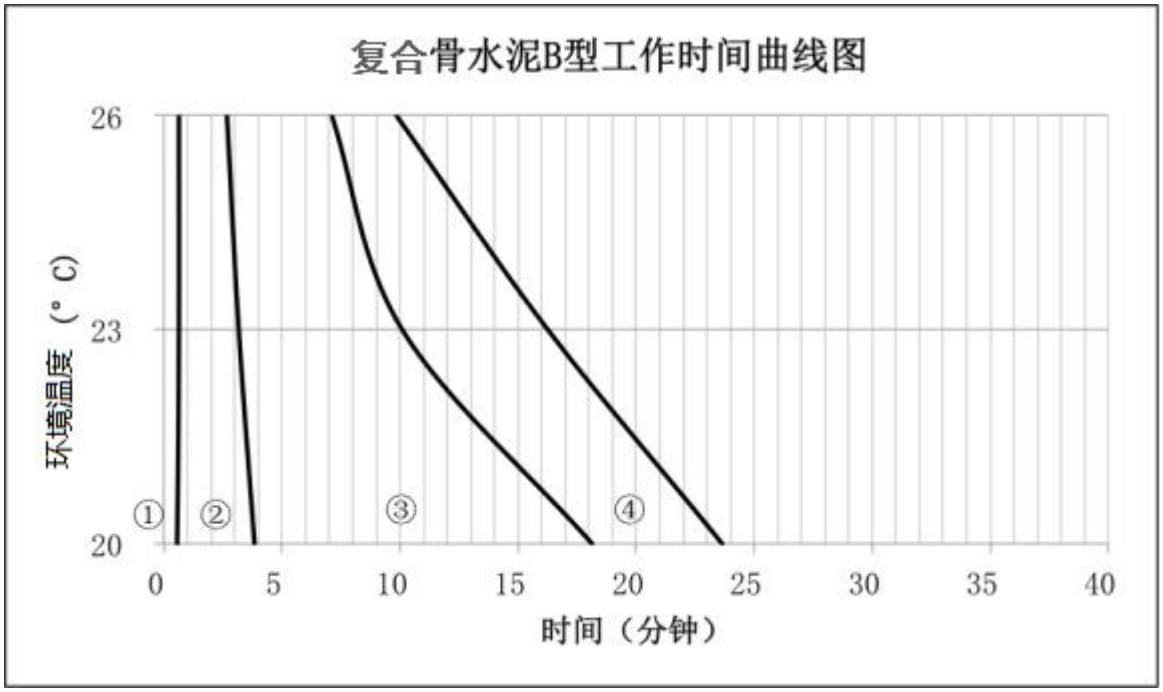
【Working characteristic curve of bone cement】

Model



① Mixing period ② Waiting period ③ Injection period (working period) ④ Curing period

Model B



①Mixing period ② Waiting period ③ Injection period (working period) ④ Curing period

The above operation time allows the operator enough time to continuously monitor by the radiation monitor. And pay attention to the filling situation to avoid any unnecessary leakage of bone cement.

8、Warnings

1.The length of time required for each stage of operation is not only related to the level of room temperature and the temperature of each material, but also to the humidity of the operating room. At high temperatures, the hardening time will be reduced, while at low temperatures, the required time will be extended.

2. Please carefully read the user manual before use.

3. Operators should receive specialized training and relevant experience to thoroughly familiarize themselves with the properties of the product, the characteristics of operation, the applicability of the product, and the implantation method of bone cement.

4. Our company does not recommend surgical techniques, and it is up to the operator to decide how to effectively use this product and the operating techniques for patients.

5. Strictly follow the instructions for the use, mixing, and preparation of bone cement.

6. It is strictly prohibited to sterilize the product again, and it is only for one-time use. Only when the original packaging is unopened and undamaged can complete sterilization be ensured.

7.If there is a hypotension reaction between 10 and 165 seconds. Some patients may even worsen to cardiac arrest. Therefore, it is important to carefully monitor changes in blood pressure during or after the placement of bone cement.

8. Methyl methacrylate may cause allergic reactions in certain high-risk groups of patients.

9.Due to insufficient clinical data, it is uncertain whether this product is harmless for pregnant, lactating women, and children.

10. The established surgical principles and techniques must be strictly followed. Deep wound infection is a serious complication after surgery and may result in the complete removal of implanted bone cement.

11. It is necessary to strictly prevent excessive exposure to harmful gases from monomer solutions, which may irritate the respiratory tract, eyes, and even the liver.

12. Before starting the operation, always check the status of the packaging contents. Do not use if there is turbidity or premature aggregation of the liquid, or if the powder color has turned yellow.

13. Do not let monomer solution come into contact with rubber or latex gloves. This solution is a powerful solvent, and in case of contact, the gloves may be dissolved, causing tissue damage. Wearing two pairs of gloves may reduce the likelihood of allergic reactions.

14. Do not allow personnel wearing contact lenses to approach or be responsible for mixing bone cement.

15. Use appropriate imaging techniques to confirm the correct position of the puncture needle, the absence of damage to surrounding tissues, and the accurate placement of injected bone cement. Use imaging techniques such as fluoroscopy to measure the volume of bone cement filled into the spine.

16. Avoid excessive compression of bone cement to prevent leakage to other areas that are not intended for treatment. The extravasation of bone cement can cause damage to surrounding tissues and problems with the nervous and circulatory systems.
17.During the injection period, if the puncture needle is inserted into the vein or there are undetected micro cracks, it can cause leakage.
18.During the operation, if any leakage of bone cement is found outside the spine or in the circulatory system, filling should be stopped immediately.
19. The final polymerization reaction stage occurs when filling the original site, which generates an exothermic reaction and releases a considerable amount of heat. Therefore, it is necessary to maintain the patient's position until the polymerization process is completed, so that the bone cement can be properly fixed. This may require an additional 1 to 2 hours or more, depending on the patient's health condition, and it is up to the operator to decide.
20. Monomer liquids have high volatility and flammability, therefore appropriate preventive measures should be taken in the operating room to maintain good ventilation.
21. The paper plastic bag of the powder container is additionally packaged with non sterile protective aluminum foil.

9、Storage

Store in a dry, dark, and unpolluted environment below 25 ° C.

10、Production date, expiration date

The sterilization validity period of the product is 3 years, and the production date and expiration date are detailed on the label.

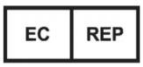
11、Important physician information

1.The surgical procedure for percutaneous vertebroplasty can only be performed in a medical environment where emergency decompression surgery can be performed.
2. Cardiovascular side effects may occur, mainly caused by bone cement containing acrylic acid. Recent studies have shown that monomer solutions rapidly hydrolyze into methacrylic acid, and most of the concentrated methacrylate salts are presented as free acids rather than methyl esters. The relationship between the cyclic concentration changes and blood pressure changes between methacrylate and methacrylic acid has not been determined.
3. If the physician causes any complications or harmful consequences due to the use of this product due to unauthorized indications, incorrect operating techniques, improper use of materials, or failure to follow the safety instructions in the user manual, the user shall bear all responsibilities.
4. Additives (such as antibiotics) cannot be mixed with bone cement, otherwise it will change the properties of this product.

12、Patient needs to know

The patient must be informed by the physician of the relevant contraindications, side effects, and any possible reasons and complications that may result in the surgery not achieving the expected results. Patients must also be informed of the measures to be taken to reduce the consequences of these factors.

13、Explanation of graphics, symbols, abbreviations, etc. used in medical device labels

symbols	Explanation of graphics	symbols	Explanation of graphics
	Model number		Upper limit of temperature
	Humidity limitation		Keep away from sunlight
	Manufacturer		Keep dry
	Sterilized using ethylene oxide		Date of manufacture
	Medical device		Batch Code
	Caution		Use-by dat
	Consult instructions for us		Serial number
	Authorized representative in the European Community		Do not use if package is damaged and consult instructions for use
	Do not resterilize		Do not re-use
	Double layer sterile barrier system		A single sterile barrier system with external protective packaging
	Single sterile barrier system		Sterilized using aseptic processing techniques
	Flammable liquid		

14、Compilation date of instruction manual

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