OPTIBONE®

INSTRUCTION FOR USE

Kyungwon Medical Co., Ltd.

OPTIBONE®
INSTRUCTION FOR USE

LABELING SYMBOLS

DO NOT REUSE (SINGLE USE ONLY)

CE CERTIFICATION

USE BY (EXPIRATION DATE)

METHOD OF STERILIZATION USING IRRADIATION

CATALOGUE NUMBER (REFERENCE NUMBER)

BATCH CODE (LOT NUMBER)

SEE INSTRUCTIONS FOR USE

FLAMMABLE

DATE OF MANUFACTURE

UPPER LIMIT OF TEMPERATURE

MANUFACTURER

AUTHORISED REPRESENTATIVE IN THE EUROPEAN UNION

DESCRIPTION

OPTIBONE® bone cements are a self-curing, two component system consisting of liquid and powder components. Bone cements are disposable and sterile medical device. The powder and liquid components are mixed prior to use. It is medium viscosity cement which is primarily for syringe and bone cement injection needle use.
The polymer powder consists of a PMMA copolymer(polymethyl methacrylate and methyl methacrylate-butyl methacrylate) with barium sulfate as the radio-pacifier, benzoyl peroxide as the initiator.
The liquid component consists of methyl methacrylate monomer, which includes hydroquinone as the stabilizer and n,n dimethyl-p-toluidine as the activator (promoter).
OPTIBONE® is available in 20g unit package only. Bone Cement powder together with peelable pouch are sterilized by Irradiation sterilization.
OPTIBONE® bone cements are supplied with the radiopague agent, barium sulphate, incorporated directly into the powder component.

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CHEMICAL COMPOSITION

OPTIBONE®			
Powder (Solid)		**Liquid**	
Poly [(methyl methacrylate)-co-(butyl methacrylate)]	68% w/w	Methyl methacryate	99.5 w/w
Benzoyl peroxide	2% w/w	N,N-Dimethyl-p-toluidine	0.5% w/w
Barium sulfate	30% w/w	Hydroquinone	70 ppm

INDICATION FOR USE

OPTIBONE® bone cement is indicated to pathological fractures of vertebral body due to osteoporosis, cancer, or benign lesions using vertebroplasty or kyphoplasty procedures. OPTIBONE® bone cement is indicated for use in children only in cases where no other procedure is likely to give a good chance of successful treatment.

CONTRAINDICATIONS

The use of OPTIBONE® bone cement is contraindicated in the presence of active infections and should not normally be used. The use of OPTIBONE® bone cement must be carefully considered in presence of Myasthenia Gravis or hypersensitivity to monomer or to any of the other components of the bone cement.

PRECAUTIONS

- Do not use this product after the expiration date printed on the package. This device may not be safe or effective beyond its expiration date.
- As OPTIBONE ® is a medium viscosity bone cement, the injection must be performed under continuous radioscopic control and must be done slowly, verifying the exit of the cement from the needle, its distribution inside the vertebral body, and checking for any possible extra-vertebral diffusion. If cement escapes from the vertebra, immediately discontinue the injection.
- Use Syringes and needles of proven chemical compatibility with the bone cement component. - Use *'Peverty® Needle'* & *'PNO'*, bone injection needles, for optimal results.
- Evidence from clinical investigation clearly indicates the necessity for strict compliance to good, aseptic surgical technique. It is important to note that deep wound infection will present a serious risk for the successful outcome of the surgical operation.

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INFORMATION FOR USE

Bone cements are temperature sensitive. Any increase or decrease in temperature of the working environment from the recommended temperature 25℃ will affect the handling characteristic and setting time of the cement. Humidity will affect the handling waiting and setting time.

EQUIPEMENT NEEDED

Sterilized scissors, mixing vessel, spatula, surgical glove, bone cement injection needle and syringe**.**

SPECIAL WARNINGS

- Do not re-sterilize any of the components OPTIBONE® bone cement are for single use only. Do not reuse, it might be infected or declined.
- For safe and effective use of OPTIBONE® bone cements the surgeon should have received specific training and experience to be thoroughly familiar with their handling characteristics, properties, limitations of use and proper application techniques.
- The liquid component is a powerful lipid solvent. Avoid monomer contact with the skin and mucous membranes. It has caused contact dermatitis in susceptible individuals. The liquid component should not be allowed to come into contact with rubber or latex gloves. Should contact occur, the gloves may dissolve and tissue damage may occur.
- Polymerization of the bon cement is an exothermic reaction, which occurs while the cement is hardening *in situ*. The released heat may damage bone or other tissue surrounding the implant.
- The wearing of a second pair of surgical gloves and strict adherence to mixing instructions may diminish the possible of hypersensitive reactions.
- The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. This usually occurs between one and two minutes after the liquid and powder components are mixed.
- Avoid over pressurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage to the surrounding tissues.
- OPTIBONE® bone cement's powder and liquid are pre-measured to give the best results. It is essential to add all liquid components when mixing the cements.
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation to the respiratory tract, eyes, and possibly the liver.

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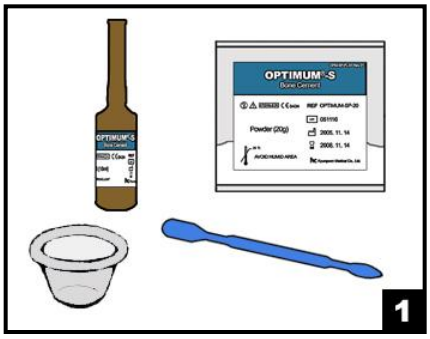
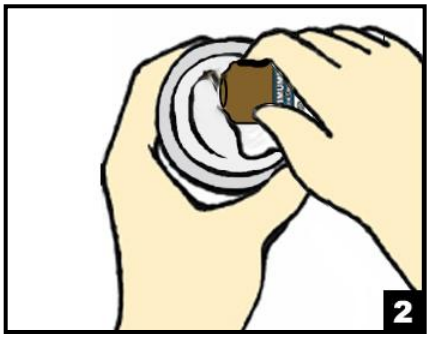
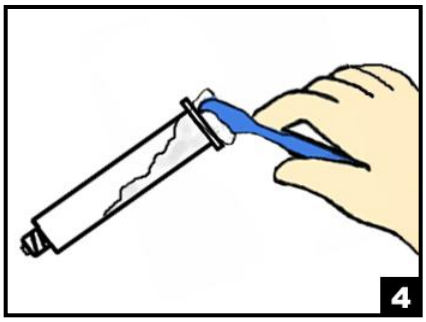
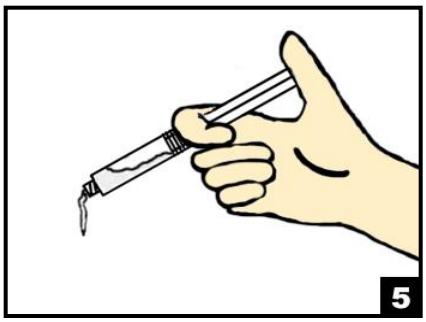
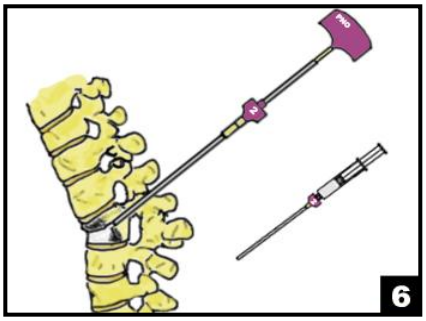
	The sterile powder bag and sterile ample are aseptically transferred into the sterile operative area. **WARNING:** Before using OPTIBONE® bone cements it is strongly advised to make sure that both powder and liquid are stored at a temperature of 25℃ for the previous 24 hours.
	The powder bag is opened with sterile scissors and the entire contents emptied into a suitable clean, dry, sterile mixing bowl made from an inert material. Snop open the ample of the liquid and the entire contents are emptied evenly onto the powder in the mixing bowl.
	Mix the powder and solution in a circular motion using a spatula, ensuring that all the solution has been distributed throughout the powder. (Mixing time : about 1 min. 30 sec.)
	Once the powder has been mixed with the liquid, transfer the mixture into the suitable bone cement gun cartridge or syringe.

INSTRUCTION



Wait for 3 minutes for the application.

The surgeon must use their clinical judgment to decide when the cement is of a suitable viscosity to allow the surgical procedure to continue.



The injection (Use '*Peverty® Needle'* & 'PNO bone cement injection needles', for optimal results) must be performed under continuous radioscopic control and must be done slowly, verifying the exit of the cement from the needle, its distribution inside the vertebral body, and checking for any possible extra-vertebral diffusion.

If bone cement escapes from the vertebra, immediately discontinue the injection.

The bone cement is mixed thoroughly but carefully to minimize the entrapment of air. When dough is formed the surgeon should wait until the cement no longer adheres to the glove. The cement can then be taken into gloved hands and kneaded thoroughly. The premature insertion of cement should be avoided as this may lead to a drop in the patient's blood pressure. To avoid this, the appearance of the cement must be observed to ensure the surface has become dull as opposed to shiny. Also cement should not adhere excessively to the surgeon's gloves. The time of bone cement application is at the discretion of the surgeon and will depend upon the surgical procedure used.

USE IN PREGNANCY AND LACTATION

The use of bone cement in pregnancy or lactation requires that the potential benefits be weighed against the possible hazards to the mother or fetus unless it is in life-threatening illnesses

PHARMACEUTICAL PRECAUTIONS

Store below 25℃ in a dry environment and protect from light. Sterility is only guaranteed if the container is undamaged. OPTIBONE® bone cements are for single use only. Do not re-sterilize any of the components.

ADVERSE EFFECTS

The below listed serious and frequent adverse may occur during or following the use of bone cement but are not necessarily directly related to the acrylic bone cement itself.

The surgeon should be aware of these reactions and be prepared to treat such reactions if they are encountered.

Some serious adverse events-myocardial infarction, cardiac arrest, cerebrovascular accident, and pulmonary embolism. Most frequent adverse reactions-transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis, and short-term cardiac conduction irregularities.

Other reported adverse reactions-heterotopic new bone formation and trochanteric separation, and pyrexia due to an allergy to the bone cement, hematuria, dysuria, bladder fistula, delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application, and adhesions and stricture of the ileum due to the heat released during polymerization**.**

Following surgery, if any form of infection should arise, patients must immediately consult their doctors to reduce the risk of infection.

PACKAGE QUANTITY

PACKAGE SIZE	POWDER (g)	LIQUID (ml)
20g	20	10
Cat. NO.	S302	

DISPOSAL

Bone Cement should be disposed of as clinical waste. Separate disposal of the liquid and powder components should be in accordance with local waste regulations.

DO NOT USE AFTER THE USE BY DATE PRINTED ON THE PACKAGE.

DO NOT USE IF THE PACKAGE IS DAMAGED OR OPENED.

DO NOT REUSE, IT MIGHT BE INFECTED OR DECLINED.

Further information on the use OPTIBONE® Bone Cements can be obtained from the manufacturer.

OPTIBONE® is a registered trademark of Kyungwon Medical Co., Ltd.

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