

RX ISOPLASTIC ISOPLASTIC1/2 pack XL







CEMEX®

INSTRUCTION BOOKLET

To the Medical Staff's attention

PRESENTATION

CEMEX is a radiopaque bone cement.

CEMEX cement has a low temperature polymerization since it uses a powder/liquid ratio that is higher than the traditional one of 2:1.

CEMEX bone cement is a sterile and disposable medical device.

CEMEX ISOPLASTIC is a high viscosity bone cement that can be prepared and handled rapidly and is ideal for manual application.

CEMEX RX is a low viscosity bone cement for both manual and syringe application.

CEMEX XL is an extra low viscosity bone cement, ideal for syringe application.

CÉMEX ISOPLASTIC, RX and XL are packed in a hermetically sealed blister pack whose contents, sachet and phial are sterilized by ethylene oxide. The liquid is sterilized by filtration and the powder by ethylene oxide.

CEMEX FAST bone cement has a high viscosity that is suitable for manual application in cases where reduced application times are required.

The package has 2 sachets (each containing 20g of sterile powder) and 2 hermetically sealed blister packs each containing 1 phial of 8.35g sterile liquid. The liquid is sterilized by filtration, the powder by Gamma-ray sterilization and the blister packs by ethylene oxide.

Composition of the CEMEX bone cements:

| | CEMEX ISOPLA- STIC | CEMEX ISOPLA- STIC 1/2 pack | CEMEX RX | CEMEX XL | CEMEX FAST |
|---------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|-----------------------------------|
| Liquid component | 13.30 g phial of sterile liquid | 6.65 g phial of sterile liquid | 13.30 g phial of sterile liquid | 18.33 g phial of sterile liquid | 8.35 g phial of sterile liquid |
| METHYL METHACRY- LATE | 99.10% w/w | 99.10% w/w | 99.10% w/w | 98.20%w/w | 98.20%w/w |
| N-N DIMETHYL-p- TOLUIDINE | 0.90% w/w | 0.90% w/w | 0.90% w/w | 1.80% w/w | 1.80% w/w |
| HYDROQUI- NONE | 75 ppm | 75 ppm | 75 ppm | 75 ppm | 75 ppm |
| Powder component | 40 g sachet of sterile powder | 20 g sachet of sterile powder | 40 g sachet of sterile powder | 50 g sachet of sterile powder | 20 g sachet of sterile powder |
| POLYMETHYL METHACRY- LATE | 84.30% w/w | 84.30% w/w | 88.27% w/w | 85.00% w/w | 85.00% w/w |
| BARIUM SULPHATE | 13.00% w/w | 13.00% w/w | 9.00% w/w | 12.00% w/w | 12.00% w/w |
| BENZOYL PEROXIDE | 2.70% w/w | 2.70% w/w | 2.73% w/w | 3.00% w/w | 3.00% w/w |



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INTENDED USE

CEMEX bone cement is intended to be used for the fixation of artificial joint prostheses to the host bone.

INDICATIONS FOR USE

CEMEX bone cement is indicated for the fixation of protheses to bone in orthopaedic musculoskeletal procedures for osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, traumatic arthritis, congenital deformities, avascular necrosis, post-traumatic degenerative problems of the joint, sickle cell anemia, osteoporosis, collagen disease and for the revision of previous arthroplasty procedures.

CONTRAINDICATIONS

CEMEX bone cement is contraindicated in the presence of active or incompletely treated infection which could involve the site where the cement is to be applied.

CEMEX bone cement is contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

CEMEX bone cement is contraindicated in patients who are allergic to the monomer or to any of its components.

GENERAL PRECAUTIONS

Read this instruction booklet very carefully.

The surgeon must ensure that the prosthesis and any plastic accessories and elastomers to be used are suitable for use with bone cement.

The product must be stored in a cool and dry place at a temperature not higher than 25° C and relative humidity not higher than 70% and away from direct light.

CEMENT PREPARATION PRECAUTIONS

- Sterility is assured only if the unit container is not damaged or opened.
- Do not re-sterilise any of the components.
- Do not use the product after the expiration date because the effectiveness of the device may be compromised.
- Make sure that the inner package is undamaged and that the components
 are undamaged. The powder should be uniform (no agglomerations) not
 present yellow or brown discoloring and the liquid in the ampoule should
 not appear syrupy. These conditions indicate that the product has not been
 stored correctly.
- · Do not add foreign substances to the cement components.
- Temperature has a major effect on the preparation characteristics of any bone cement. Temperatures of more than 23°C for the product, the preparation accessories and the environment accelerate the various stages in the preparation procedure. Lower temperatures retard the preparation stages. Before using CEMEX bone cements it is strongly advised to make sure that the package is stored at a temperature of 23°C ± 1°C for the previous 24 hours.
- An extended exposure to high conditions of humidity (>70%) can lead to an increase in the viscosity and therefore speed up the cement's preparation and application times.
- Make sure that the cement preparation accessories are specifically compatible with the product.
- Do not open the phial of liquid over the mixing bowl to avoid the risk of glass fragments entering the dough.
- Do not mix the cement in a flow of air since this will promote rapid evaporation of the liquid component and consequent variations in the performance of the cement.



CEMENT APPLICATION PRECAUTIONS

Clinical study data demonstrate the need to maintain strictly aseptic surgical techniques. It must be borne in mind that any deep infection of a surgical wound is a serious risk for the successful outcome of the implant. Such infection may begin in a latent manner without clinical evidence even some years after surgery.

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To minimise the risk of inclusion of blood and debris in the cement, and of marrow content in the vascular system, prior to the application of bone cement, the bone cavity should be thoroughly irrigated with Ringer or saline solutions and dried.

While the cement hardens, it is very important to maintain the position of the prosthesis by means of manual pressure until the end of the polymerisation process; this is essential to ensure optimal implantation results.

Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. A fibrous tissue layer may develop between the cement and bone, and loosening of the prosthesis may occur. Long-term follow-up is advised for all patients on a regularly scheduled basis.

USER PRECAUTIONS

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Caution should be exercised during the mixing of the liquid and powder components of the bone cement to prevent excessive exposure to the concentrated vapours of liquid monomer, which may produce irritation of the respiratory tract, eyes, and possibly the liver.

Avoid the monomer from coming into contact with the skin or the mucous membranes as the liquid component is irritant to the airways and the skin. It may cause sensitization when coming into contact with the skin. Cases of contact dermatitis have been observed in susceptible subjects. It is therefore advisable to wear a second pair of surgical gloves and scrupulously observe the instructions for mixing the components in order to reduce the possibility of reactions caused by hypersensitivity.

Personnel wearing contact lenses should not mix bone cement or be near its

Personnel wearing contact lenses should not mix bone cement or be near its mixing.

The liquid component of the bone cement is a powerful lipid solvent, therefore, avoid direct contact with the human body. Rubber or latex gloves do not always provide effective protection against the monomer. More suitable gloves made of different materials are however available on the market. Check that these materials are suitable for contact with bone cement (see the relative technical data sheets).

The bone cement should not contact the gloved hand until the cement has acquired the consistency of dough, about 1-2 minutes after mixing.

Once the two components are mixed, the consistency of the bone cement changes in just a few minutes: viscosity increases rapidly to form a marble-

like mass which securely anchors the prosthesis to the host site.

The attainment of this state is easily ascertained by the increase in temperature of the cement itself. After a few minutes, the cement cools spontaneously, indicating the end of the reaction and time when the prosthesis can be released.

SPECIAL PRECAUTIONS

Correctly cemented prostheses are stable and long-lasting; however, the cement or the prosthesis or both may become loose or fracture following desease trauma, incorrect cement insertion technique or latent infection: it is therefore advisable to follow-up all patients regularly and in the long-term following surgery.

Bone cement extrusion outside its application site may determine adverse effects for the patient (see Adverse Effects)

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

Caution: bone cements reach temperatures higher than physiological



temperatures during the exothermic polymerisation reaction.

Polymerisation of the bone cement is an exothermic reaction that occurs while the bone cement is hardening *in situ*. The released heat may damage bone or tissue adjacent to the implant.

The use of CEMEX should be carefully considered in patients with coagulation disorders and in patients with severe cardio-pulmonary insufficiency.

PRECAUTIONS DURING PREGNANCY, BREAST-FEEDING AND IN CHILDREN

There are no tests which demonstrate the utilisation safety of bone cement during pregnancy or breast-feeding and in children. Bone cement should not be used in the first three months of pregnancy; for the remaining gestation period, bone cement should only be used in life-endangering situations.

This cement is indicated for applications in children only when it is believed impossible to save the joint through other forms of intervention.

ADVERSE EVENTS

The blood pressure often drops temporarily immediately after implanting the bone cement and the prosthesis. The following serious and negative reactions may arise when using bone cement. However, they are not directly attributable to the bone cement as such. Surgeons must be aware of these complications and be ready to treat them if they occur.

Serious:

Myocardial infarct

Cerebrovascular incidents

Cardiac arrest

Sudden death

Pulmonary embolism

Other referred reactions:

Thrombophlebitis

Haematoma-haemorrhage

Infection of surface/deep surgical wound Trochanteric bursitis

Short-term cardiac irregularities

Pain and/or loss of function

Loosening or displacement of prosthesis

Elevated serum gamma-glutamyl-transpeptidase (GGTP) up to 10 days postoperation

Heterotopic new bone formation

Trochanteric separation

Breakage of the bone cement

Allergic pyrexia

Hematuria

Dysuria

Bladder fistula

Delayed trapping of the sciatic nerve due to cement extrusion beyond the region intended for its application

Local neuropathy

Local vascular erosion and occlusion

Intestinal obstruction due to adhesion and stenosis of the ileum because of the heat released during exothermic polymerisation

WARNINGS

The use of bone cement demands a high level of cooperation between the surgeon and the anaesthetist. During the operation, the surgeon must inform the anaesthetist that the cement is about to be introduced. In some cases events defined as "bone implantation syndrome" (BCIS) may occur which



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are characterized by a number of clinical features that include hypoxia, hypotension, cardiac arrhythmias, increased pulmonary vascular resistance

hypotension, cardiac arrhythmias, increased pulmonary vascular resistance (PVR), and cardiac arrest, which must be controlled with the methods in use in modern anaesthesiology. These phenomena are commonly associated with,

but is not restricted to, cemented hip arthroplasty which usually occurs at one of the five stages in the surgical procedure: femoral reaming, acetabular or femoral cement implantation, insertion of the prosthesis or joint reduction (Donaldson et al., 2009, Br J Anaesth). The blood pressure of patients should be monitored carefully during and immediately following the application of the bone cement. In addition, overpressurisation of the bone cement should be avoided during the insertion of the bone cement and implant in order to

The surgeon should be thoroughly familiar with the properties, handling characteristics and application of the CEMEX bone cements and of its restrictions on use. Because the handling and curing characteristics of bone cements vary with temperature and mixing technique, they are best determined by the surgeon's actual experience. It is strongly recommended that the surgical team carry out practical trials prior to use in patients under the

minimise the occurrence of pulmonary embolism.

same instrumental and environmental conditions.

The liquid component is flammable and volatile and for this reason the operating theatre must be correctly ventilated. The liquid component and/or its vapours must never be directly exposed to naked flames or heated materials. Ignition of monomer vapours caused by the use of electrocautery devices in surgical sites near freshly implanted bone cement has been reported.

Because of the volatility and flammability of the liquid monomer of the bone cement, the liquid monomer should be evaporated in a well-ventilated hood or absorbed by an inert material and transferred into a suitable container for disposal. The polymer component may be disposed in an authorized waste facility.

CAÚTION:Do not re-sterilize and/or re-use the device. It is designed for single-use on a single patient.

Avoid dividing the product into two or more portions, in order to use it other times. This would be a re-utilization and may lead to an error in the proportion of the powder and liquid components. It can also cause a sterility loss.

Re-sterilization should not be carried out since it can cause infection risks for the patient. Re-sterilization can also alter the device's morphology and the mechanical features, causing a malfunction of the same with serious risks for the patient's health.

All residues must be considered waste surgical material and therefore should be eliminated at the end of the operation.

DOSAGE AND ADMINISTRATION

A dose of bone cement is prepared by mixing the whole contents of a sachet and of a phial.

Differing lot numbers of CEMEX bone cement may be used together when mixed in accordance with the recommended instructions.

APPLICATION INSTRUCTIONS

To improve the use of CEMEX bone cements as far as possible:

- use cements and accessories at a temperature of 23°C ± 1°C;
- eliminate detritus and rinse the host bone site carefully with saline;
- avoid as far as possible the presence of liquid between the bone tissue and the cement; dry the bone surface with gauze and/or suction catheters before and during cementation;
- make every effort to apply an optimal thickness of bone cement. All the stem must be covered by bone cement.

PREPARATION:

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Bone cements are sensitive to temperature. Any increase in temperature of the working environment, the cement components or the mixing

instrumentation over 23 $^{\circ}$ C reduces the preparation times. Equally, lower temperatures increase such times.

Open the unit container/s and place the powder sachet and the liquid phial on a sterile shelf in the operating room.

Break open the phial and pour the liquid into the mixing bowl.

Open the powder sachet and pour the powder over the liquid.

To minimise the inclusion of air bubbles, it is advisable to mix the cement with a spatula from the outside of the bowl towards the centre. All the powder must be moistened by the liquid; inasmuch, use the spatula delicately to work any lumps of unmoistened powder into the overall mass of moist dough.

The necessary amount of cement for the particular clinical application is defined by the surgeon once the components have been mixed.

Caution: never arbitrarily modify the ratios between the liquid and solid components.

Mixing time is between 1-1.5 minutes, but the actual time depends on the temperature, the humidity and the mixing technique, and it is determined by the surgeon's experience.

For syringe application: after mixing, introduce the cement in an appropriate sterile device. The time taken to apply the cement is decided by the surgeon according to his experience, and to the temperature and humidity of storage, of the operating room and of the injection equipment.

For manual application: after mixing, continue moving the mass until it no longer sticks to the gloves. At this point, the mass is ready to be applied. The temperature and humidity of the operating room, of the product's storage, of the mixing accessories used and of the surgeon's hands can make a difference on the time taken to prepare and apply the cement. These are determined by the surgeon's experience.

APPLICATION:

During this phase, the cement must be inserted into the bone cavity. The cement must be well compressed inside the bone cavity. If a syringe is used to insert the cement, extrusion of the cement must begin in the distal area of the bone cavity and then flow into the proximal area. The cement flow must be kept as uniform as possible. This avoids the inclusion of air bubbles.

INSERTING THE PROSTHESIS:

Once the cement has been inserted, the prosthesis can be positioned; it must be held firmly until the cement has hardened. Remove excess cement before it hardens.

The final hardening time of the cement depends on the kind of cement, temperature, humidity and the degree of manipulation.

Caution! The temperature of the host bone cavity accelerates cement polymerisation. Inasmuch, the application of the prosthesis should be completed as quickly as possible.

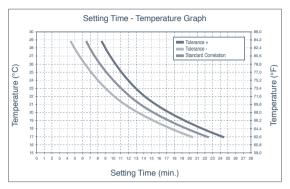
THE EFFECT OF TEMPERATURE ON PREPARATION AND APPLICATION TIMING OF CEMEX BONE CEMENTS

The timing for the cement's preparation and application is strongly influenced by the temperature in the operating room. The temperature's effect on cement setting time was evaluated with a laboratory test. A graph on setting time according to temperature is provided for ease of reference (data was obtained in controlled environmental and storage conditions subjected to standard deviation). In addition to temperature and humidity, different factors can influence the cement's setting time. These include the mixing technique (speed, use of mixer), the throughness of mixing, the utilization of the entire liquid and solid component, the inclusion of external substances inside the cement such as blood, saline solution, etc.



CEMEX ISOPLASTIC and ISOPLASTIC 1/2 PACK

Manual application is recommended for the application of CEMEX ISOPLASTIC Bone Cement.



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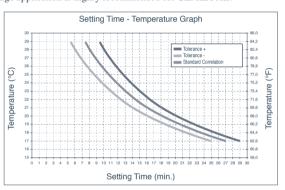
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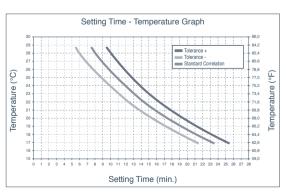
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Syringe application is highly recommended for CEMEX XL.



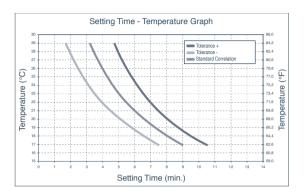
CEMEX RX

CEMEX RX Bone Cements can be inserted manually, bearing in mind that the syringe application is highly recommended.



Manual application is recommended for the application of CEMEX FAST Bone Cement.

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Caution: Federal law (USA) restricts to sale by or on the order of a physician.



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