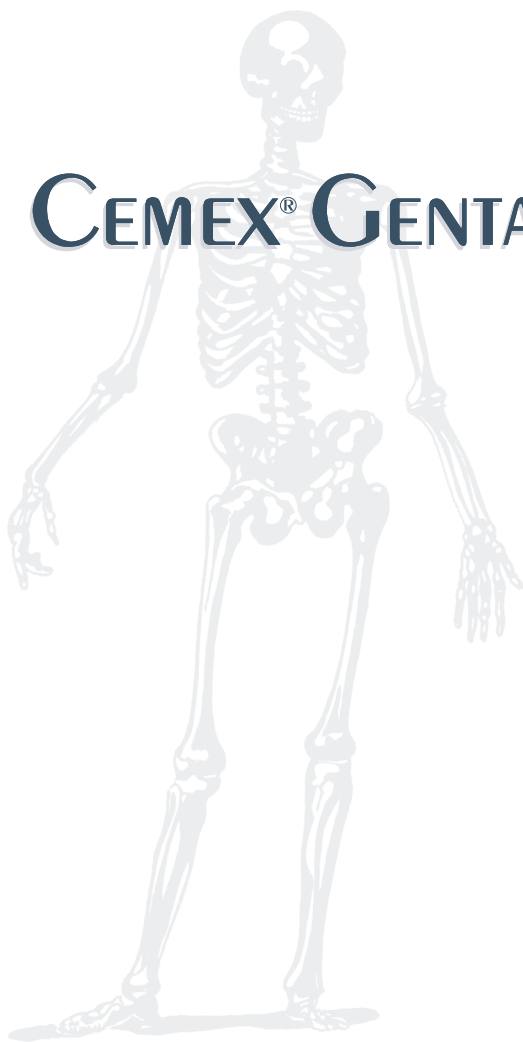
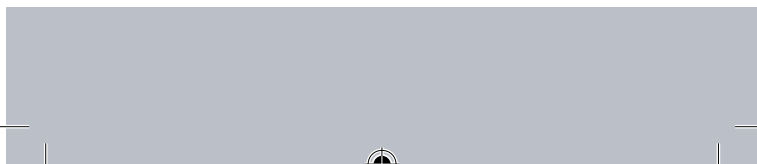




# CEMEX® GENTA



**TECRES®**  
ADVANCING HIGH TECHNOLOGY



# CEMEX® GENTA<sup>EN</sup>

## INSTRUCTION BOOKLET To the Medical Staff's attention

### Presentation:

- CEMEX GENTA is a bone cement with Gentamicin available in high viscosity (Cemex genta HV), low viscosity (Cemex Genta LV) and fast-set high viscosity (Cemex Genta Fast), indicated for the fixation of artificial joint prostheses to the host bone.
  - CEMEX GENTA bone cement is a low polymerisation temperature cement since it uses a powder/liquid ratio that is higher than the traditional one of 2:1.
  - CEMEX GENTA bone cement releases Gentamicin over time.
  - CEMEX GENTA bone cement is a STERILE, ONE-SHOT medical device.
- For codes 1400/AG and 1400/IG: the package consists of an aluminium wrapping containing a hermetically sealed blister pack whose contents (40 g sachet of powder and 14.7 g vial of liquid) are sterilized by ethylene oxide. The liquid is sterilized by filtration and the powder by ethylene oxide.
- For codes 1400/AG INT and 1400/IG INT: the package contains a 40g sachet of powder sterilized by gamma ray and a blister pack sterilized by ethylene oxide containing a 14.7g vial of sterile liquid. The liquid is sterilized by filtration.
- For code 12A3100: the package has 2 sachets (each containing 20g of sterile powder) and 2 phials (each containing 8.35g of sterile liquid). The liquid is sterilized by filtration and the powder by Gamma-ray sterilization.
- High viscosity CEMEX GENTA bone cement can be prepared and handled rapidly and is ideal for manual application.
  - Low viscosity CEMEX GENTA bone cement is ideal for application with injection device.
  - CEMEX GENTA FAST bone cement has a high viscosity that is suitable for manual application in cases where reduced application times are required.

CEMEX GENTA Bone Cement : Composition

	CEMEX GENTA Low Viscosity 1400/AG - 1400/AG INT	CEMEX GENTA High Viscosity 1400/IG - 1400/IG INT	CEMEX GENTA Fast 12A3100
Liquid component:	14.7g phial	14.7g phial	8.35g phial (x2)
METHYLMETHACRYLATE	98.20% w/w	98.20% w/w	98.20% w/w
N,N-DIMETHYL-p-TOLUDINE	1.80% w/w	1.80% w/w	1.80% w/w
HYDROQUINONE	75 ppm	75 ppm	75 ppm
Powder component:	40g sachet	40g sachet	20g sachet (x2)
POLYMETHYLMETHACRYLATE	82.78%w/w	82.78%w/w	82.78%w/w
BARIUM SULPHATE	10.00%w/w	10.00%w/w	10.00%w/w
BENZOYL PEROXIDE	3.00% w/w	3.00% w/w	3.00% w/w
GENTAMICIN SULPHATE	4.22%w/w*	4.22%w/w*	4.22%w/w*

\*Equivalent to 1.0 g (1.0 M.I.U.) 2.5% Gentamicin base in 40g unit and 0.5 g (0.5 M.I.U.) 2.5% Gentamicin base in 20g unit

### INDICATIONS

CEMEX GENTA bone cements are indicated for the fixation of joint prosthesis implants to the host bone.

In particular, these cements are indicated where there is the risk or presence of infections caused by organisms sensitive to Gentamicin.

### CONTRAINDICATIONS

The application of CEMEX GENTA bone cement must be considered carefully in the presence of serious myasthenia or hypersensitivity to Gentamicin or any of the other components in the bone cement. When the loss of musculature or neuromuscular compromise of the unhealthy limb would make the surgical procedure unjustifiable.

### PRECAUTIONS

Read this instruction booklet very carefully.

To ensure safe application of CEMEX GENTA bone cement, surgeons must be aware of the properties of the product, its preparation and handling characteristics,



applicational limitations and correct application technique. It is strongly recommended that the surgical team carry out practical trials prior to use in patients under the same instrumental and environmental conditions.

Surgeons must make sure that the prosthesis to be implanted is compatible with the use of bone cement.

#### CEMENT PREPARATION PRECAUTIONS

- Make sure that the package is in perfect condition and that the components are integral, i.e. the powder should not present yellow or brown discolouring and the liquid should not be syrupy.
- 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 GENTA 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 relative 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.

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 are characterized by a number of clinical features that include hypoxia, 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 minimise the occurrence of pulmonary embolism.

To minimise the risk of inclusion in venous circulation of medullary fat, bone fragments or other foreign bodies, it is advisable to irrigate the bone cavity carefully with Ringer or saline solutions prior to the insertion of the cement.

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.

#### USER PRECAUTIONS

Prolonged respiration of the vapours of liquid component may cause drowsiness: excessive exposure to monomer vapours may irritate the respiratory apparatus and the eyes.

Avoid monomer contact with the skin and mucous membranes. 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. 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).

Do not allow the liquid component to come into direct contact with accessories in rubber





or elastomers. The vapours of the liquid component may affect soft contact lenses. 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.

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.

#### INTER-REACTIONS

The use of cemex genta must be carefully evaluated in case it is used together with other nephrotoxic and ototoxic drugs.

#### SPECIAL CAUTIONS

In order to use CEMEX GENTA bone cement in the safest and most effective manner, surgeons must be trained in the use of bone cements and must be aware of the way they should be handled, their applicational limitations and the correct manner of insertion. Evidence from clinical studies clearly indicate the need for absolute observance of correct aseptic surgical techniques.

Correctly cemented prostheses are stable and long-lasting; however, the cement or the prosthesis or both may become loose or fracture following trauma, incorrect cement insertion technique, mechanical defects of the materials or latent infection: it is therefore advisable to follow-up all patients regularly and in the long-term following surgery. NEVER add other substances or foreign bodies to the bone cement. **Caution: CEMEX GENTA Bone Cement reaches temperatures higher than physiological temperatures during the exothermic polymerisation reaction.** Following surgery, if any form of infection should arise, patients must immediately consult their doctors to reduce the risk of infection.

The use of Cemex Genta as first option in the fixation of a prosthetic implant should be carefully considered as it may increase the risk of development of gentamicin resistant bacteria.

The use of CEMEX GENTA should be carefully considered in patients with coagulation disorders and in patients with severe cardio-pulmonary insufficiency. The application of CEMEX GENTA bone cement should be carefully considered in patients with pre-existing renal insufficiency.

CAUTION: 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, the efficiency of the antibiotic 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.

#### USE DURING PREGNANCY, BREAST-FEEDING AND IN CHILDREN

There are no tests which demonstrate the utilisation safety of bone cement during pregnancy or breast-feeding. 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.

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

#### APPLICATION INSTRUCTIONS

##### PREPARATION

Bone cements are sensitive to temperature. Any **increase in temperature** of the working environment, the cement components or the mixing instrumentation over 23°C **reduces the preparation times**. Equally, **lower temperatures increase such times**.

Open the unit container and place the powder sachet and the liquid phial on a sterile shelf in the operating room. Break open the phial and transfer all the liquid into a container suitable for mixing.





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 by moving a spatula from the outside of the container 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 polymerised. Remove excess cement before it hardens.

The polymerisation time of the cement depends on the kind of cement, manipulation, temperature and humidity of the storage and of the operating room.

**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 GENTA BONE CEMENTS

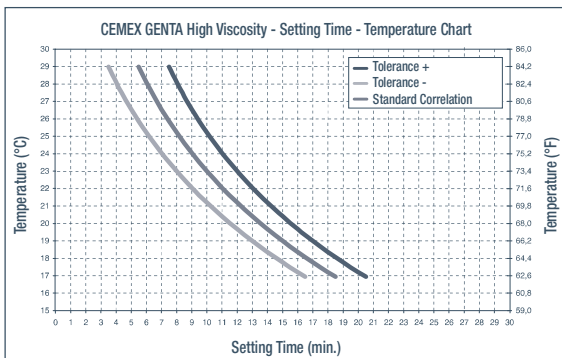
Preparation and application of the cement is highly influenced by the temperature of the storage and of the operating room. The temperature's effect on cement setting time was evaluated with a laboratory test. A graph on setting time according to temperature is provided for ease of reference (data was 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 thoroughness 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.), the pre-heating of the prosthesis component.





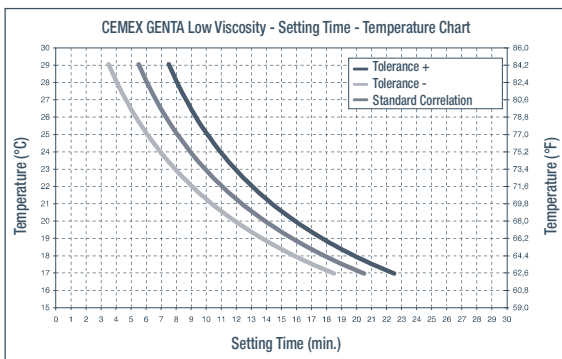
### CEMEX GENTA HIGH VISCOSITY

Manual application is recommended for the application of High Viscosity CEMEX GENTA bone cement.



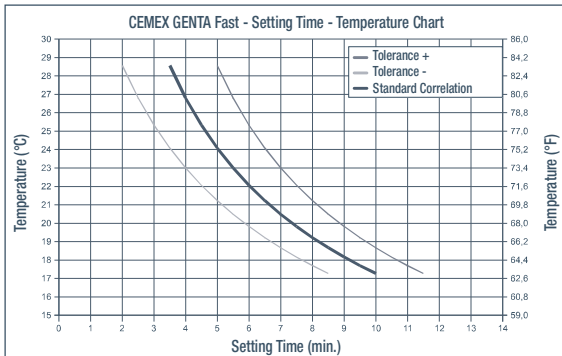
### CEMEX GENTA LOW VISCOSITY

All CEMEX GENTA bone cements can be inserted manually, bearing in mind that the syringe application is highly recommended for low viscosity cements.



### CEMEX GENTA FAST

Manual application is recommended for the application of CEMEX GENTA FAST bone cement.





### HINTS AND SUGGESTIONS

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

- Use cements and accessories at a temperature of  $23^{\circ}\text{C} \pm 1^{\circ}\text{C}$  and relative humidity of 60%
- 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.

### NEGATIVE EFFECTS

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 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

More frequent:

Thrombo-flebitis  
Haematoma-haemorrhage  
Infection of surface/deep surgical lesions  
Trochanteric borsitis  
Short-term cardiac irregularities

Other referred reactions:

Heterotopic new bone formation  
Trochanteric separation  
Loosening or detachment of the prosthesis  
breakage of the bone cement

### PHARMACEUTICAL PRECAUTIONS

Store at a temperature below  $25^{\circ}\text{C}$  away from all sources of light at a relative humidity no greater than 70%.

Sterility is assured ONLY if the unit packaging is intact.

NEVER attempt to re-sterilise ANY of the components.

Do not use the product if the powder has a yellowish or brownish colour or if the liquid is syrupy. These conditions indicate that the product has not been stored correctly.

### DISPOSAL

Disposal of the device or its components should be in accordance with local waste regulations. Prior to disposal the surplus bone cement should be allowed to set.

### Shelf-life

Shelf life of Cemex Genta is five years.





Z1G016 - REV. 22 del 03.02.2020



TECRES S.p.A.

Via A. Doria, 6 - 37066 Sommacampagna • Verona - ITALY

Telefono +39.045.9217311 - Fax +39.045.9217330

info@tecres.it • www.tecres.it

for Tecres  
internal use



CE  
2797