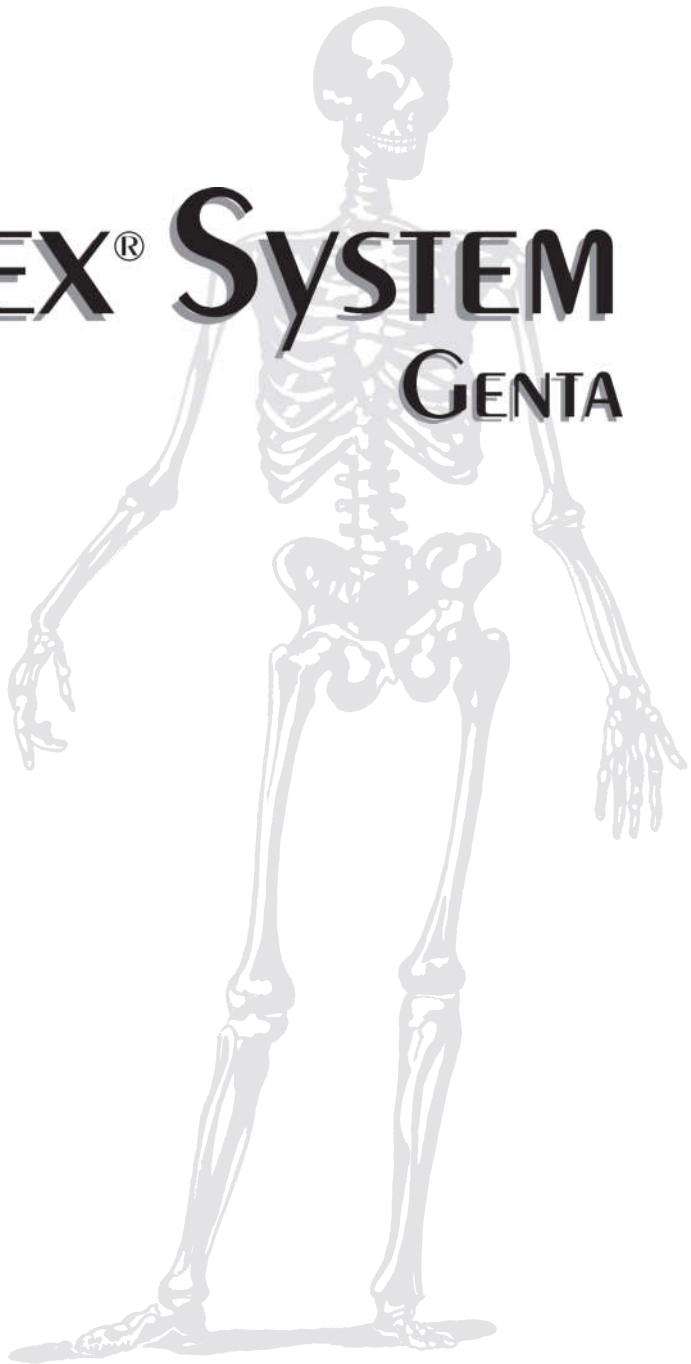




CEMEX[®] SYSTEM

GENTA



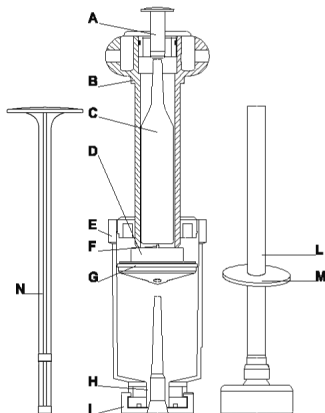
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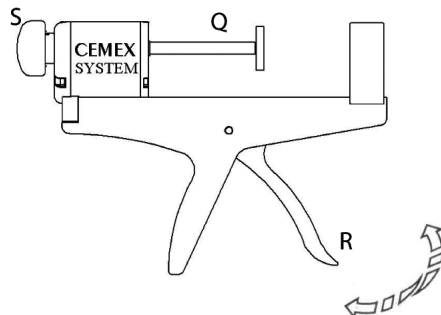




CEMEX SYSTEM



GUN APPLICATION DEVICE*



* La GUN è indispensabile per l'estrusione del cemento

* The GUN is essential for cement extrusion

* La pistola GUN es indispensable para la extrusión del cemento

* Le GUN est indispensable pour l'extrusion du ciment

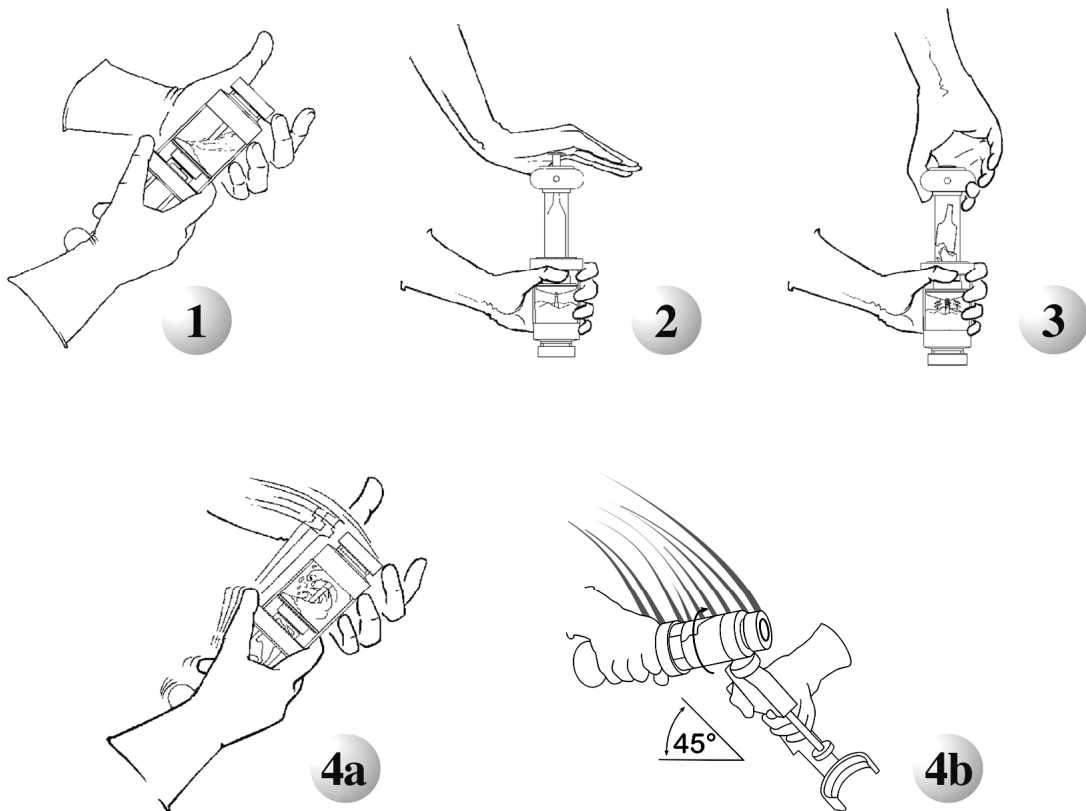
* Die Vorrichtung GUN ist zum Extrudieren des Zements unbedingt erforderlich

* A GUN é indispensável para a extrusão do cimento

* De GUN (pistool) is noodzakelijk voor de extrusie van het cement

* GUN çimentonun ekstrüzyonu için gereklidir

* Пістолет має важливе значення для екструзії цементу.





CEMEX® SYSTEM GENTA

INSTRUCTION BOOKLET

To the Medical Staff's attention

PRESENTATION

CEMEX SYSTEM GENTA is a sterile and disposable device for the preparation and application of bone cement pre-dosed with sterile powder dosed with Gentamicin antibiotic (sterilised by ethylene oxide) and sterile liquid (sterilised by filtration). The device is contained in a double sealed blister.

CEMEX SYSTEM GENTA allows surgeons to utilise a bone cement which, from preparation through to application, remains completely isolated inside the device, thereby eliminating any possibility of contamination. During the preparation phase, components are submitted to vacuum cycles (push-pull) (Fig. 3).

The preparation stage does not require any kind of accessory instrument, while final application is performed with the aid of the GUN APPLICATION DEVICE.

The clear device makes it easy to perform the preliminary verification of the components, as specifically required by ISO 5833 standards, and makes it possible for the user to see, and therefore to control the bone cement during the mixing, waiting and delivery stages.

Moreover CEMEX SYSTEM GENTA provides the following advantages:

- reduced possibilities of microbial contamination of the bone cement;
- reduced release of monomer vapours into the environment;
- optimal mixing of the cement;
- possibility of obtaining high and low viscosity cement.

CEMEX SYSTEM GENTA has the same features as CEMEX GENTA bone cements :

- low polymerisation temperature thanks to a powder/liquid ratio higher than the traditional 2:1;
- release of Gentamicin over time;
- low release of monomer residue;
- high mechanical performances.

CEMEX SYSTEM GENTA components:

- device containing powder and liquid components for the preparation and application of the bone cement;
- cannula for the extrusion;
- rod to extrude the cement from the cannula.

CEMEX SYSTEM GENTA

Formulation of components

Liquid component:

Methylmethacrylate	98.20 % w/w
N-N Dimethyl-p-Toluidine	1.80 % w/w
Hydroquinone	75 ppm

Powder component:

Polymethylmethacrylate	82.78 % w/w
Barium Sulphate	10.00 % w/w
Benzoyl Peroxide	3.00 % w/w
Gentamicin Sulphate	4.22 % w/w *

REF 1500/SG

29.3 g ampoule

98.20 % w/w
1.80 % w/w
75 ppm

80 g

82.78 % w/w
10.00 % w/w
3.00 % w/w
4.22 % w/w **

CEMEX SYSTEM GENTA FAST

REF 13A2100

29.3 g ampoule

98.20 % w/w
1.80 % w/w
75 ppm

70 g

82.78 % w/w
10.00 % w/w
3.00 % w/w
4.22 % w/w ***

REF 13A2110

16.7 g ampoule

98.20 % w/w
1.80 % w/w
75 ppm

40 g

82.78 % w/w
10.00 % w/w
3.00 % w/w
4.22 % w/w ****

*Equivalent to 1.5 g (1.5 M.I.U.), 2.5% Gentamicin base in 60 g unit.

**Equivalent to 2 g (2 M.I.U.), 2.5% Gentamicin base in 80 g unit.

***Equivalent to 1.75 g (1.75 M.I.U.) 2.5% gentamicin base in 70 g unit.

****Equivalent to 1 g (1 M.I.U.) 2.5% gentamicin base in 40 g unit.

INTENDED USE AND INDICATIONS FOR USE

CEMEX SYSTEM GENTA bone cement is intended for the fixation of joint prosthesis implants to the host bone.

In particular, this cement is indicated where there is the risk or presence of infections caused by organisms susceptible to Gentamicin.

CONTRAINDICATIONS

- When the loss of musculature or neuromuscular compromise of the unhealthy limb would make the surgical procedure unjustifiable.
- Hypersensitivity to the monomer or some of the other components of the bone cement.
- Presence of grave myasthenia or hypersensitivity to gentamicin.





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.

NB: Do not remove the product from the aluminium wrapping until the time of use of the device.

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. Do not use the product if the powder has agglomerations or a yellowish or brownish color or if the liquid is syrupy. These conditions indicate that the product has not been stored correctly.
- Do not add foreign substances to the cement components.

It is advisable to keep the CEMEX SYSTEM GENTA at a temperature of 23°C ± 1°C for 24 hours before use.

The product can be stored and used at different temperatures (see the graph at the end of the information leaflet) bearing in mind that bone cements are temperature-sensitive.

Temperatures of more than 23°C for the product, the prosthesis and the environment accelerate the various stages in the preparation procedure. Lower temperatures retard the preparation stages.

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.

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.

USER PRECAUTIONS

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 preparation 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). 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 disease, 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. Polymerization 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 SYSTEM GENTA should be carefully considered in patients with coagulation disorders and in patients with severe cardio-pulmonary insufficiency.

The application of CEMEX SYSTEM GENTA bone cement should be carefully considered in patients with pre-existing renal insufficiency.

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





INTER-REACTIONS

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

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 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.

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

NEGATIVE EFFECTS

The blood pressure often drops temporarily immediately after implanting the bone cement and the prosthesis. The following negative reactions may arise with use of bone cement, but they are not directly due to the bone cement.

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 cements 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.

The surgeon must be aware of the product's features, preparation characteristics as well as its handling, application and restrictions on use.

Because the handling and curing characteristics of this cement 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 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.

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.

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

Because of the volatility and flammability of the liquid monomer of the bone cement, the liquid monomer should be evaporated in a wellventilated 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.

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

Prepare a dose of CEMEX SYSTEM GENTA by mixing the entire powder and liquid content following the instructions given below. Packages of CEMEX SYSTEM GENTA having a different batch number can be used together, following the provided instructions.

INSTRUCTIONS FOR USE

- use at a temperature of $23^{\circ}\text{C} \pm 1^{\circ}\text{C}$;
- eliminate detritus and rinse the host bone site carefully with saline solution;
- Prevent liquid from coming between the bone tissue and the cement by drying the bone surface using gauze and/or suction cannulas before and during cementation;
- the whole stem of the prosthesis should be covered by a uniform coating of bone cement.

Bone cements are sensitive to temperature. Any increase in temperature of the working environment, the product and the prosthesis over 23°C reduces the waiting and hardening times of the bone cement. Equally, lower temperatures increase such times.

There follow detailed instructions for the preparation of CEMEX SYSTEM GENTA bone cement. Times indicated in the instructions were obtained by performing tests in laboratory under temperature controlled conditions of $23^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

The bone cement is extruded by GUN APPLICATION DEVICE.

KEY

CEMEX SYSTEM GENTA

A = PUSH-KNOB	G = GASKET
B = HANDLE	H = TIP OF THE DEVICE
C = AMPOULE	I = CAP
D = PLUNGER	L = CANNULA
E = BODY	M = PRESSURIZATION DISK
F = AMPOULE-BREAKER	N = PUSHER-ROD

GUN APPLICATION DEVICE (GUN)

Q = PERCUSSION UNIT
R = LEVER
S = SHOCK ABSORBER

STAGE 1: RELEASE OF THE POWDER

Hold the device by the handle (B) in one hand, turn it upwards and strike the device lightly against the palm of the other hand 5-6 times to release the powder (Fig.1).

STAGE 2: BREAKAGE OF THE AMPOULE

Position the device vertically with the cap (I) on a flat support surface. With one hand keep the device firmly and with the palm of the other hand firmly press the push-knob (A) in order to break the ampoule (C) (Fig. 2).

STAGE 3: TRANSFERRING OF THE LIQUID

Pull the handle (B) till it stops and keep it like that for about 3 seconds, push then the handle till it stops and keep it like that for 3 more seconds. **Repeat the cycle till the whole liquid is transferred (Fig. 3).**

CEMEX SYSTEM GENTA FAST

Duration of the stage: it is advised not exceed 30"

STAGE 4: MIXING

ATTENTION: FROM THIS MOMENT START MEASURING THE TIME

MANUAL MIXING

Hold the device and turn it upside-down to have it almost vertical. Immediately vigorously knock the device against the palm of the hand or the Shock Absorber (S) on the Gun Application Device with a frequency of about 1 knock a second and turning by a quarter turn with every knock.

Go on performing such action in order to have a homogeneous mass without lumps (Fig. 4).

CEMEX SYSTEM GENTA

Duration of the stage: about 90"

CEMEX SYSTEM GENTA FAST

Duration of the stage: about 60"

AUTOMATIC MIXING

See the IFU of the Cemex System Mixer

STAGE 5: PLACING OF THE CANNULA AND PREPARATION OF THE GUN

Holding the device vertically, unscrew the cap (I) and replace it with the cannula (L) (Fig. 5a). Delicately press the handle (B) upward so that some cement advances into the cannula for a few centimetres. Take the Gun Application Device (Gun). To fit the device on the body of the Gun, push the lever (R) forwards at the same time as pulling the percussion unit (Q) backwards, until it comes to a rest against the body of the Gun. (Fig. 5b)

Then take the device and fit it into the body of the Gun (Fig. 5c).

Use the lever (R) to advance the percussion unit until it comes into contact with the push-knob (A) (Fig. 5d).

Duration of the stage: about 30"





STAGE 6: WAITING

CEMEX SYSTEM GENTA

Now position the Gun with the device fitted in a vertical position (Fig. 6). With firm movements of the lever (R), make the bone cement advance into the cannula (L), till the middle of it.

Observe the meniscus of the cement. If, when stopping the advancing of the cement, the meniscus changes from convex to flat (detail X, fig. 6), **then the cement is NOT ready for the extrusion**. If, when stopping the advancing of the cement, the meniscus remains convex for 3-4 seconds (detail Y, fig. 6), **the cement is ready for the extrusion**.

The time needed to have the meniscus in the correct form depends on the temperature of the product and of the environment: temperatures higher than $23^{\circ}\text{C} \pm 1^{\circ}\text{C}$ reduce the waiting time, equally, lower temperatures increase such time.

Duration of the stage: from 60" to 120"

CEMEX SYSTEM GENTA FAST

Now position the Gun with the device fitted in a vertical position (Fig. 6). With firm movements of the lever (R), make the bone cement advance into the cannula (L), till the tip of it.

Duration of the stage: 30"

STAGE 7: APPLICATION

Bear in mind that the viscosity of the mass increases rapidly over time and the cement may not be expelled from the cannula. Insert the cannula (L) into the medullar cavity and begin to deliver the cement by firm movements of the lever (R). It is advisable to begin delivery from the deeper part of the cavity and work outwards proximally with the cannula leaving the cement behind it (Fig. 7).

Use the pusher-rod (N) to expel the cement left inside the cannula if necessary. Remove the cannula and then expel the cement from the cannula with the pusher-rod.

To remove the syringe from the body of the Gun, push the lever (R) forwards at the same time as pulling the percussion unit with rod (Q) backward, thereby releasing the contact with the push-knob (A); the syringe can now be removed.

CEMEX SYSTEM GENTA

The CEMEX SYSTEM GENTA can also be used to prepare a high viscosity cement. In this case, do not fit the cannula, wait until at least 5 minutes from the transferring of the liquid so that the dough becomes very viscous, unscrew the cap (I) and then make the cement come to the tip of the device (H) and touch it with the glove. When the bone cement does not adhere to the glove any longer, it is ready to be extruded without cannula directly into the final place.

CEMEX SYSTEM GENTA FAST

At a temperature higher than 23°C , deliver the cement without stopping. At a temperature lower than 23°C , wait 30 seconds or more.

STAGE 8: INSERTING THE PROSTHESIS

Once the cement has been inserted, the prosthesis can be positioned; it must be held firmly until the cement has hardened. The graphs at the end of these instructions indicate Setting Times for CEMEX SYSTEM GENTA and CEMEX SYSTEM GENTA FAST. Remove excess cement before it hardens. The final hardening time of the cement depends on viscosity of the cement, on the environmental temperature and on the temperature of the prosthesis.

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

Shelf-life

Shelf life of Cemex System Genta is five years.





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