AUSTRAL

AUSTRALIAN ORTHOPAEDIC RESEARCH AND LABS

SNUGFIX

Radiopaque Bone Cement 1x40

Standard Viscosity 40g

EN – INSTRUCTIONS FOR USE

SNUGFIX 1x40 Standard Viscosity Bone Cement

INSTRUCTIONS FOR USE

1. **Intended Use**

The Bone Cement has been designed for bone cementation and its use is recommended for orthopedy. This acrylic-based bone cements indicated for fixation and revision of articular prostheses of the hip, knee and shoulder and repair of bone defects.

Each bone cement consists of two component systems such as powder and liquid. The powder fraction is composed from a Methyl Methacrylate polymer with the Benzoyl Peroxide and Barium Sulphate and liquid fraction composed of a Methyl Methacrylate monomer stabilized with Hydroquinone and activated with N, N-dimethyl-p-toluidine. When the monomer and the polymer are mixed, the Benzoyl Peroxide is activated due to N, N-dimethyl-p-toluidine and the exothermic polymerization process is started.

Bone cement main features:

Appropriate viscosity to perform endoprostheses related arthroplasty Operations augmentation procedures, allowing application using a cannula, in the same time, enabling the operator to control cement distribution inside body in field of arthroplasty

Optimal application time

High mechanical performance and limited polymerization heat generation rate according to ISO 5833 standards

Characteristics:

Reduced mixing time

Working time suited to the type of application

Polymerization is completed after 10 minutes so as to reduce the risk of micro movements of the prosthesis once applied

Excellent mechanical properties

2. Composition

A pack of SNUGFIX 1x40 Standard viscosity Bone Cement contains one bag of cement powder and one glass ampoule monomer liquid.

Powder formula	40 g
Methyl Polimethacrylate	36. 16 g
Barium Sulfate	3.50 g
Benzoyl Peroxide	0.34 g
Liquid Formula	**20 ml**
Methyl Methacrylate	19.84 ml
N, N-dimethyl-p-toluidine	0.16 ml
Hydroquinone	20 ppm

3. Activation process

When the liquid component is added to the powder the N, N-dimethyl p-toluidine activates the catalyst benzoyl peroxide. This starts the polymerization process of methacrylic acid methyl ester.

The result is a homogeneous fluid and then dough. This dough introduced as stabilizing medium inside the operation area of the body to be replaced by arthroplasty, within the limit working time prescribed by the manufacturer, will become solid, obtaining the fixation and stabilization of the joint.

4. Clinical Indications

SNUGFIX 1x40 Standard Viscosity Bone Cement is used to for bone cementation and fixations. It is indicated for:

- Stable attachment of total or partial joint endoprostheses in bone
- Filling and stabilizing bone defects within the scope of internal fixation treatment or for endoprostheses revision surgery

5. Contraindications

SNUGFIX 1x40 Standard Viscosity Bone Cement should not be applied when it is known a patient's hypersensitivity to the components of bone cement or to the contrast medium (barium sulfate).

- During pregnancy or breast feeding
- Non controllable hemorrhagic disease
- Local or systemic infections not completely resolved

Other relative contraindications:

- Non collaborating patient, patient unable to follow operator's instructions
- Metabolic diseases which interfere with bone cement polymerization reaction
- Osteomalacia
- Non local infection foci potentially interesting implant
- Hypotension
- Congestive heart disease
- Renal failure

6. Side Effects

The pressure increase in the medullary canal may cause a temporary decrease in blood pressure after implantation of the direct cement and prosthesis or after preparation of the prosthetic bed. In addition to hypotension, cardiac embolism and cardiac arrest with potentially fatal consequences may be encountered. It can cause cardiovascular and respiratory side effects known as this implantation syndrome, and infiltration of bone marrow constructions in the vertebral vascular system. The site of the prothesis should therefore be rinsed thoroughly with an isotonic solution (e.g., physiological saline) before implantation. Adequate drainage is recommended in the presence of pulmo-vascular diseases to minimize the pressure increase in the medullary canal during implantation of cement and prosthesis. The blood loss should be monitored and anaesthesilogical measures may be required e.g. in the event of acute respiratory failure. When recasting the vertebral spines, necrosis of these spines including separation of the cement filling may occur. Components of bone cement can cause local irritations of hypersensitivity reactions in isolated cases.

7. Warnings

Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.

• Prior to implanting bone cement, as safeguard measure, it should be previewed the possibility of an immediate surgical action to correct percutaneous procedure complications.

• In case of treatment of hemangioma, a preliminary vascular sclerotization with percutaneous alcohol application may help in preventing bone cement penetration in blood vessels.

• Avoid direct operator's skin or eye contact of liquid component of dough and reduce as possible the exposition to monomer vapors, which may cause irritation of airways, of eyes and, in rare cases, affect liver.

• Ventilate the room to eliminate monomer vapors. Liquid component is volatile and flammable. In presence of monomers vapors do not use electrocautery instruments or other high temperature sources.

• Do not use latex gloves or other latex devices. Liquid component is a lipid solvent which can cause glove perforation and may damage exposed tissues. PVP gloves (three layers: polyethylene, vinyl copolymer, polyethylene) or Viton®-butile gloves give an adequate protection for a long period. In case surgical synthetic rubber gloves are going to be used, it is advisable to wear a second pair of gloves upon, adapted to bone cement handling.

• Operators wearing contact lenses shall not mix bone cement or be exposed to monomer vapors.

8. Preparation And Application

It is necessary while preparing bone cement:

• Sterile working area

• Sterile bowl made of ceramic, stainless steel, polypropylene or other material specifically approved to get in contact with bone cement dough.

• Sterile spoon or spatula made of ceramic, stainless steel, polypropylene or other material specifically approved to get in contact with bone cement dough

Only after a confirmation of the integrity of the packaging, an assistant will open the external blister and extract the internal blister containing the bag and the ampoule, maintaining sterile condition.

Internal blister can be laid on the sterile working surface. Bag and ampoule must be opened only in condition of absolute sterility, right before preparation of bone cement and subsequent application. A dose is prepared by pouring the entire content of the liquid component ampoule into a bowl containing the entire quantity of powder included in one bag.

Preparation:

• Before opening the non-sterile aluminium protective pouch (compare above) move the contents down (1 polyethylene-paper bag) by shaking or tapping in order to ensure that when the bag is cut open at the top the content is not damaged.

• The polyethylene-paper bag and the ampoule may only be opened under sterile conditions. For this purpose the sterile components (inner PE-paper bag and glass ampoule) are sterile when they are delivered.

Opening under sterile conditions:

• Open the outer PE-paper bag at the special point under sterile conditions so that the inner PE-paper bag remains sterile when it is removed. Also open the blister pack at the special point under sterile conditions so that the glass ampoule remains sterile when it is removed.

• Before opening the inner PE-paper bag, move the contents down by shaking or tapping in order to ensure that when the bag is cut open at the top no powder is lost. To make it easier to open the glass ampoule the latter is provided with a predetermined breaking point at the transition to the head of the ampoule.

• Do not open the ampoule over the mixing device to prevent contamination of the cement with glass fragments.

The preparation and application of bone cement is applied through four subsequent phases:

i. Mixing
ii. Waiting
iii. Application
iv. Setting

Mixing:

It is advisable to first measure out the liquid and then add the powder. If this order is reversed. powder nests are more likely to form as a result of polymerisation commencing immediately at the surface. Both components, i.e., the relative proportions of powder and monomer, are precisely matched. The pouch and ampoule must therefore be emptied completely if an optimal mix is to be achieved.

Bone cement can be mixed by these methods:

Preparation mixing by hand:

Cement components must be filled in the mixing bowl just before making. Filling and mixing should always be done under sterile conditions. The mixing time is 30 seconds. During this time, the two components are mixed together evenly. As a result, a homogeneous pulp compound is obtained if rubber gloves are no longer complied with. Always mix the powder polymer completely with a monomer liquid ampoule.

Mixing can be done a vacuum mixing:

The liquid and powder are mixed in a vacuum to provide a mixture of air intake minimized. For this, an airtight mixing system should be used, which ensures a sufficient vacuum in the mixing under sterile conditions. The mixing time is 30 seconds. For details on the mixing technique, see the instructions of the mixing system in use. The result is a homogeneous pulp compound that can now work when it is not sticking to rubber gloves. The entire contents of a bag are mixed with the entire contents of a monomer liquid ampoule.

Use in joint surgery

A suitable cementing technique should be used with bone cement to ensure stable and long-term fixation of the prosthesis. Thus, side effects are also limited. The primary application for this purpose is the careful preparation of the prosthesis area by rinsing before cement application (e.g. physiological saline).

Adequate drainage is recommended to prevent any pressure buildup in the medullary canal during implantation. Other prerequisites for better prosthetic anchoring include Filling the entire medullary canal

with cement (using femoral cement restriction), producing a cement cover that surrounds the implant (ideal thickness 2-5 mm), and biomechanically optimal placement of the implant.

• During preparation and application of bone cement higher temperature accelerates hardening, while lower temperatures slow it down.

• Apply a regular stirring action, not too fast, and continue for one minute. Do not exceed mixing time.

• Viscosity increases progressively as a consequence of polymerization reaction during the phases from II to IV.

• Keep waiting until completion of phase II (waiting phase) and then proceed with the application (phase III, the cement has become dough).

• Use cannula needles with mandrel, with internal diameter higher than 1.8 mm.

During applications it is mandatory to be supported by a real time XR monitoring. In case of arthroplasty related operations for bone cement, operator must interrupt immediately cement injection, wait, and continue only when the cement has reached a higher viscosity. If the filling of body related to arthroplasty operation and related field of operation to arthroplasty is insufficient and not correctly distributed, it is advisable to proceed with a contralateral access and complete filling of body related to arthroplasty operation. When cement injection is concluded, introduce the mandrel into the cannula needle, in such a way that, after taking out the needle and the mandrel, there will be no cements residuals in contact with the soft tissues of access canal. Patient must be remainq motion-less until bone cement is completely set.

9. Storage

SNUGFIX 1x40 Standard Viscosity Bone Cement must be stored:

• In its sealed original package

• Inside a dry and clean storage room

• Between 5°C and 25°C

10. Expiry Date, Disposal

• Expiry date is written on the external box and on the secondary outer blister labels.

• The Bone cement must be used before expiry date.

• The Bone cement is sterilized by ethylene oxide and cannot be re-sterilized.

• If the package is unsealed or the secondary blister is damaged, the bone cement cannot be used.

•Opened or damaged package of bone cement must be disposed with all their content.

•A yellowish color of the powder or of the liquid are not normal, in this case the cement. cannot be used and must be disposed.

• Dispose the remaining of bone cement and the content of partially utilized, expired, not usable or damaged packages, following rules and procedures applicable to this kind of hospital waste.

11. Packaging and sterility

Manufacturing and packaging process of bone cement is performed under strict quality procedures in controlled environment.

Liquid component is sterilized by filtration; powder component is sterilized by ethylene oxide. The sterile liquid is contained in an amber glass ampoule packed in a blister pack in sterile conditions and subsequently sterilized by ethylene oxide. The powder is packed in two bags in sterile conditions. The internal bag in medical-grade paper and polyethylene containing the powder component is inserted in

another bag in Tyvek and polyethylene and both are sterilized by ethylene oxide. The two bags are packed in a non-sterile protective aluminum wrapping.

Before using, it is necessary to control carefully the integrity of the packaging. If the packaging is uncompleted, damaged, unsealed, the cement cannot be used and must be discarded.

After the opening of the package on, it is mandatory, and responsibility of the operator, to use an aseptic handling technique. Any error in handling and during the transfer into the sterile field might affect bone cement sterility, the sterility of the surgical intervention and imply the risk of severe complications for the patient, such as infections and sepsis.

12. Shelf Life

The shelf life of the sterilized product is 3 (three) years when the products store at between 5°C and 25°C. The expiry date is printed on the outer box, on the protective aluminium packaging and on the inner sachet. SNUGFIX 1x40 Standard Viscosity Bone Cement must not be used after expiry date. The contents of opened or damaged aluminium sachets or ampoule blisters must not be resterilized and thus must be discarded. If the cement powder has turned to yellow do not use SNUGFIX 1x40 Standard Viscosity Bone Cement.

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