INSTRUCTION FOR USE

NTCem Spine™

PMMA Acrylic Resin Cement

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The PMMA acrylic resin cement for vertebroplasty

NTCem–Spine bone cement is self–curing, radiopaque, polymethyl methacrylate based cement and is a fast setting polymer for use in vertebroplasty.

NTCem–Spine bone cement is supplied as a two–component system, consisting of sterile liquid and powder components. The liquid component is sterilized by membrane filtration and filled into a sterile brown glass ampoule. The ampoule is packed in a blister pouch, which is sterilized using ethylene oxide. The powder component is contained in a Tyvek pouch and is sterilized using ethylene oxide too.

Liquid component

One component is an ampoule containing 8.5g, of a flammable liquid monomer that has a sweet slightly acrid odor and has the following composition.

- Methyl methacrylate(monomer) 8.415g
- N,N–dimethyl para toluidine 0.085g
- Hydroquinone 150ppm

Hydroquinone is added to prevent premature polymerization which may occur under certain conditions. N,N–dimethyl para toluidine is added to promote cold curing of the finished therapeutic compound.
The liquid component is sterilized by membrane filtration.

Powder component

The other component is a packet of 20g of finely divided powder of the following composition.

- Poly–methylmethacrylate 13.80g
- Zirconium dioxide 6.00g
- Benzoyl Peroxide 0.20g

The powder component is sterilized by EO gas. The zirconium dioxide incorporated in NTCem–Spine Bone cement–Radiopaque act as a contrast medium for X–ray examination.

Indications

NTCem–Spine bone cement is indicated for the filling of pathologic vertebral bodies

- painful vertebral body compression fractures in osteoporosis
- painful vertebral body tumors(metastasis or myeloma)
- symptomatic vertebral hemangioma

In all named indication is only a palliative treatment, a trerapy of the systemic illness is not achieved by the percutaneous vertebroplasty.

Preparation and administration

The liquid monomer, the ampoule itself and the ampoule package have been sterilized. If any packaging is damaged do not use this product.
Bone cement is heat sensitive. Any increase or decrease in temperature from the recommended temperature of 23℃ and variations in humidity will affect the handling characteristics and setting time of the cement.
It is recommended that the unopened product is stored at 23℃ for a minimum of 24 hours before use. And, manual handling and body temperature will reduce the final setting time.
Bone Cement. Variations in the expected setting time over the cement's shelf life can occur. This variation in setting time can be reduced to a minimum if the cement is stored under the recommended conditions throughout its shelf life.
Vacuum mixing of cement can noticeably accelerate the setting time of the product. The surgeon should read the manufacturer's instructions and be familiar with the mixing system together with the cement prior to use.

⚠ Contraindications

The use of NTCem–Spine bone cement is contraindicated in patients allergic to any of its components. It is contraindicated in the younger patient with a normal life expectancy because of lack of adequate information on the long–term effect.
NTCem–Spine must not be used during pregnancy or the nursing period.

⚠ Warnings, precautions and interactions

For safe and efficacious use of NTCem–Spine bone cement the surgeon should have specific training and experience to be thoroughly familiar with the properties, handling characteristics, and application of the product.
Avoid immoderate exercise for recovery period.

⚠ Caution

NTCem–Spine should be taken to avoid kneading of the product too long to avoid progression of the polymerization process to the point that the product is not adequately soft and pliable to obtain good filling of the bone cavities.
The completion of polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat.

The long–term effect of the heat produced along with the resulting tissue damage is not known.
As the liquid monomer is highly volatile and flammable, the operation room should be provided with adequate ventilation so as to eliminate the maximum amount of monomer vapour.

The premature insertion of bone cement may lead to a drop in blood pressure, which has been linked to the availability of methylmethacrylate at the surface of the product, although this has not been proven. This drop in blood pressure, on top of hypotension induced either accidentally or intentionally, can lead to cardiac arrhythmias or to an ischemic myocardium. To reduce this risk, the surgeon should avoid early insertion of the cement and it is recommended that the mixing and preparation instructions are followed closely. As a general guide, prior to insertion the cement surface should appear dull and should not stick to the surgeon's gloves. The hypotensive effects of methyl methacrylate are potentiated if the patient is suffering from hypovolemia.

The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or to be absorbed in the body.

If the liquid component comes into contact with eyes, wash with copious amounts of water. Concentrated vapours of the liquid component may have an adverse reaction with contact lenses. Personnel wearing contact lenses should be informed and limit their exposure. Guidance from contact lens manufacturers regarding exposure to irritating and noxious vapours should always be followed.

The safety and effectiveness of NTCem–Spine bone cements in pregnant women or in children has not yet been established. NTCem–Spine bone cement should not be used during the first third of pregnancy, and during the rest of the pregnancy period should only be used in life–threatening illnesses.

NTCem–Spine bone cement is supplied sterile for single use only. Do not re–use. Sterility is only guaranteed if the packaging is unopened or undamaged. Resterilization of any components of the cements must not be attempted.
As the monomer is volatile and flammable, any waste liquid component should be evaporated under a well–ventilated hood or absorbed by an inert material and transferred to a suitable container for disposal. Prior to disposal the surplus bone cement should be allowed to set. The polymer component and waste powder should be disposed of as clinical waste.

To prevent any possible contamination of the cement with glass fragments, do not break the ampoule containing the liquid component over the mixing device.

⚠ Side effects

– Serious side effects, some with fatal outcome, associated with the use of bone cements include:
Myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, anaphylaxis.
– The most frequent adverse reactions reported with bone cements are:
Transitory fall in blood pressure, leakage of the resin outside the vertebral body(in the perivertebral veins(pulmonary embolism), in the epidural plex(mielopathy, radicolopathy), in the intervertebral disc), elevated serum gamma–glutamyl–transpeptidase up to 10 days post–operation, thrombophlebitis, haemorrhage and haematoma, pain and/or loss of function, short–term cardiac conduction irregularities.
– Other potential adverse events reported for bone cements are:
Hypoxemia, cardiac arrhythmia, bronchospasm, adverse tissue reaction, pyrexia due to allergy to the bone cement, hematuria, dysuria, bladder fistula, local neuropathy, local vascular erosion and occlusion, transitory worsening of pain due to heat released during polymerization.

Important physician information

Adverse reactions affecting the cardiovascular system appear to be related to the liquid monomer rather than the powder polymer component of the final product. It appears the more monomer available on the surface of the final product for systemic absorption, the greater risk of hypotension and other cardiovascular reactions. The hypotension seen appears to be the result of peripheral vasodilatation. The reported fat, bone marrow and air emboli appear to be the result of the direct pressure from the forcing of the cement into the "raw" medullary cavity. The aetiology of cardiac arrest is unclear but may well be either a direct embolic effect or secondary to hypoxia produced by pulmonary embolic phenomenon.
The degree of hypotension seen appears to be more marked in patients with elevated or high normal blood pressures, in hypovolemic states, and in those patients with pre–existing cardiovascular abnormalities.

Directions for use

① To mix, empty the entire contents of the packet containg the powder component into an appropriate sterile, inert mixing device.
② Add the entire contents of the ampoule containing the liquid component.
③ Mix with a suitable inert device with a stirring action until the powder is completely saturated with the liquid.
④ Once the powder has been mixed with the liquid, transfer the mixture into the syringe(transferring time: approx. 30–40sec). At the end of the transfer, the mass can be injected.
⑤ It is distribution inside the vertebral body from the needle and checking for any possible extra–vertebral diffusion. If bone cement escapes from the vertebra, immediately discontinue the injection.
⑥ If the vertebral filling is not sufficient, additional contralateral access is viable. The patient must remain immobilized until the bone cement has fully set.

Storage

- Store in dark at a temperature below room temperature(15℃~25℃).
- Do not use this product after its expiry date.
- If the polymer shows a yellow discoloration, it must not be used.

Expiration Date

The expiration date for **NTCem spine** is two years from the date of manufacturing.

How supplied

- Powder component : 1 sterile packet containing 20g of sterile powder
- Liquid component : 1 sterile ampoule containing 8.5g of sterile liquid monomer.

Symbols

: Use By
LOT : Batch Code
: Consult operating instructions
: Caution
: Manufacturer
: Date of manufacture
CE 2195 : CE–mark and identification number of notified body Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
STERILE A : Sterile medical devices processed using aseptic technique
STERILE EO : Sterilization using ethylene oxide
EC REP : Authorized representative in the EC
: Do not reuse
: Do not resterilize
REF : Catalogue number
: Temperature limitation
: Do not use if package is damaged
: Keep away from sunlight

Made in Korea

Manufactured by
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