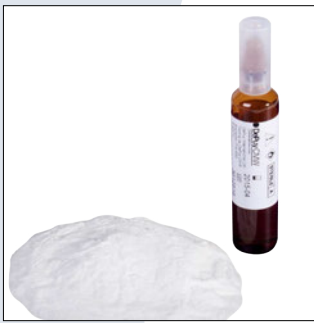


# DEPUY CMW ORTHOPAEDIC BONE CEMENTS



For internal use only.

**BIOMATERIALS**

SOLUTIONS BY DEPUY SYNTHES



This publication is not intended for distribution in the USA.

**FREQUENTLY ASKED  
QUESTIONS**



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 Image intensifier control

**Warning**

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

**Reprocessing, Care and Maintenance of  
DePuy Synthes Instruments**

CMW bone cements are for single use only, do not reuse. Resterilization of any of the components must not be attempted.

# ANTIBIOTICS IN BONE CEMENT

## Why are antibiotics used in bone cement?

Using antibiotics (most commonly the antibiotic gentamicin) in bone cement is one measure amongst many more to help prevent surgical-site infection – ie. prophylactic use of the antibiotic. National Registry data has shown that systemic (taken orally or given as injection) and local (e.g. gentamicin admixed in bone cement) antibiotic is more efficient for prophylaxis than one of these methods alone\*.

It is important to differentiate between prophylactic (reducing the risk of an infection) and therapeutic use (treating an existing infection) of antibiotics. All of our products contain gentamicin for prophylactic use only.

For more detailed information refer to:

Frommelt L, in Breusch SJ, Malchau H (2005). The well-cemented total hip arthroplasty. Springer Verlag. Page 313-319.

\*Havelin LI et al. (2000). Prospective studies of hip prosthesis and cements. Scientific Exhibition presented at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons, March 15-19, 2000, Orlando, Florida, USA. Page 6

Parvizi J et al. (2008). Efficacy of antibiotic-impregnated cement in total hip replacement. Acta Orthopaedica; 79.

## Which microorganisms does gentamicin cover?

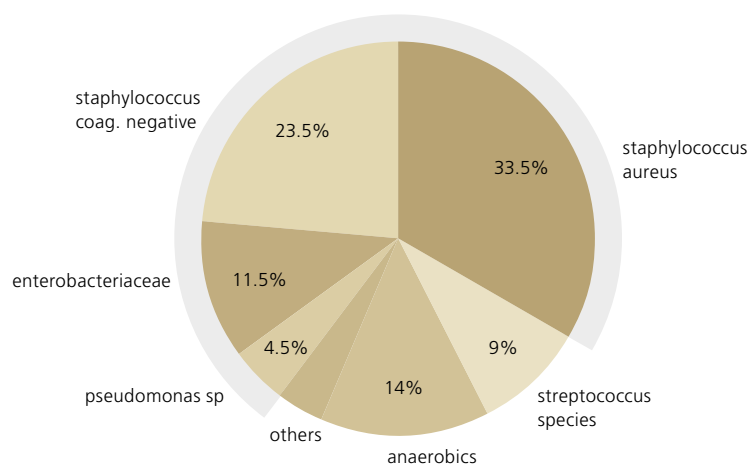
Most pathogens causing an infection originate from the human skin flora. Hence, in surgical procedures featuring endoprosthetics mainly gram-positive bacteria have been found to be relevant. These include *Staphylococcus aureus*, coagulase-negative *Staphylococcus*, *Streptococcus* and aerobic/anaerobic rod-bacilli, as well as the gram-negative bacteria *Escherichia coli*, *Enterobacter* and *Pseudomonas aeruginosa*. Hence, the antibiotic of choice needs to be active against most of these pathogens. Gentamicin belongs to the aminoglycoside family of antibiotics and covers this spectrum well\*\*. The graph 1 displays the most relevant micro-organisms associated with infected hip replacement.

For more detailed information refer to:

Kühn KD (2000). Bone cements. Springer Verlag. Page 254-255.

Frommelt L, in Breusch SJ, Malchau H (2005). The well-cemented total hip arthroplasty. Springer Verlag. Page 318.

\*\* Kühn KD (2000). Bone cements. Springer Verlag. Page 254-255.



Graph 1: Förster, G. et al.: Die infizierte Hüftendoprothese - Spätinfektion nach der 6. postoperativen Woche, In: Kühn, K.D. (2000). Bone cements. Springer Verlag. Page 254-255.

# BONE CEMENT COMPONENTS

## What do DePuy CMW bone cements contain?

	<b>SMARTSET™ HV / SMARTSET GHV GENTAMICIN</b>	<b>SMARTSET™ MV ENDURANCE / SMARTSET GMV ENDURANCE GENTAMICIN</b>	<b>DEPUY CMW™ 1 / DEPUY CMW 1 GENTAMICIN</b>	<b>DEPUY CMW™ 2 / DEPUY CMW 2 GENTAMICIN</b>	<b>DEPUY CMW™ 3 / DEPUY CMW 3 GENTAMICIN</b>
<b>Powder</b>					
Polymethyl Methacrylate		X	X	X	X
Methyl Methacrylate / Styrene Copolymer		X			
Methyl Methacrylate / Methyl Acrylate Copolymer	X				
Benzoyl Peroxide	X	X	X	X	X
Barium Sulphate		X	X	X	X
Zirconium Dioxide	X				
GENTAMICIN Sulphate	SMARTSET GHV GENTAMICIN	SMARTSET GMV ENDURANCE GENTAMICIN	DEPUY CMW 1 GENTAMICIN	DEPUY CMW 2 GENTAMICIN	DEPUY CMW 3 GENTAMICIN
<b>Liquid</b>					
Methyl Methacrylate	X	X	X	X	X
N,N-Dimethyl-p-toluidine	X	X	X	X	X
Hydroquinone	X	X	X	X	X

Please note that only the bone cements with antibiotic contain gentamicin. Hence, if a patient is allergic to aminoglycosides (e.g. gentamicin), plain cement should be used.

**What are the different ingredients of the bone cement for?**




Bone cement contains the following ingredients (please note that only the antibiotic- loaded bone cements contain gentamicin):





Powder	
PMMA powder	Polymethyl Methacrylate, Methyl Acrylate/Methyl Methacrylate Copolymer, Methyl Methacrylate / Styrene Copolymer
Initiator	Benzoyl Peroxide
Radiopaque agent	Zirconium dioxide, Barium Sulphate
Antibiotic	Gentamicin sulphate
Liquid	
MMA liquid	Methyl Methacrylate
Accelerator	N,N-Dimethyl-p-toluidine
Stabilizer	Hydroquinone

«When mixed together these two substances react with each other and initiate the polymerization (hardening) of the bone cement»

**Does bone cement contain the following ingredients?**

The following ingredients are **not** components of DePuy CMW bone cements

Component	Description
Ascorbic acid 	Ascorbic acid is a naturally occurring organic compound with antioxidant properties. It is a white solid, but impure samples can appear yellowish. The role of ascorbic acid has been replaced by added hydroquinone in bone cement liquids.
Chromate 	Chromate salts are moderately strong oxidizing agents. Chromates and dichromates are used in chrome plating to protect metals from corrosion and to improve paint adhesion. Chromate and dichromate salts of heavy metals, lanthanides and alkaline earth metals are only very slightly soluble in water and are thus used as pigments. Although certain dental or orthopaedic implants use chromates, they have never been used in DePuy CMW cements.
Colophony (also known as Rosin) 	The term "colophony" comes from colophonias resina or "resin from the pine trees of Colophon," an ancient Ionic city. Colophony is a solid form of resin obtained from pines and some other plants, mostly conifers, produced by heating fresh liquid resin to vapourize the volatile liquid terpene components. It is semi-transparent and varies in colour from yellow to black. At room temperature rosin is brittle, but it melts at stove-top temperatures. Rosin is an ingredient in printing inks, photocopying and laser printing paper, varnishes, adhesives (glues), soap, paper sizing, soda, soldering fluxes, and sealing wax. Although used in certain dental preparations, it has never been used in DePuy CMW cements.

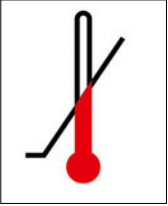


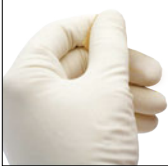
Component	Description
<p>Epoxy</p> 	<p>Epoxy is both the basic component and the cured end product of epoxy resins, as well as a colloquial name for the epoxide functional group. Epoxy resins, also known as polyepoxides, are a class of reactive prepolymers and polymers which contain epoxide groups. There have been misconceptions in the past that bone cement is a glue, similar to epoxy resins. However, this is not the case, bone cement is a grout, with little or no adhesive properties. Epoxy resins have never been used in DePuy CMW cements.</p>
<p>Formaldehyde</p> 	<p>Formaldehyde is a gas at room temperature; it is colourless and has a characteristic pungent, irritating odour. It is an important precursor to many other materials and chemical compounds. Commercial solutions of formaldehyde in water, commonly called formol, were formerly used as disinfectants and for preservation of biological specimens. In view of its widespread use, toxicity and volatility, exposure to formaldehyde is a significant consideration for human health. In 2011, the US National Toxicology Program described formaldehyde as "known to be a human carcinogen". Formaldehyde is not used in any of the DePuy CMW bone cements, they are sterilized by aseptic filtration, gamma radiation or ethylene oxide gas.</p>
<p>Latex</p> 	<p>Latex is a dispersion of polymers, originally from flowering plants, now also synthetic. There is no natural rubber latex or dry rubber latex included in the composition of any of our products. DePuy CMW seeks to prevent latex contact and inclusion at all stages of manufacture. However, all products (even those which do not contain latex in their construction) may come into contact with dry natural rubber or natural rubber latex through incidental contacts in the manufacturing process, e.g. employee protective clothing, gloved hands, conveyor belts etc. This will apply to all suppliers and limits any assurances that may be provided, of complete latex freedom.</p>
<p>Potassium dichromate</p> 	<p>Potassium dichromate is a common inorganic chemical reagent, most commonly used as an oxidizing agent in various laboratory and industrial applications. It is acutely and chronically harmful to health and must be handled and disposed of appropriately. It is a crystalline ionic solid with a very bright red-orange colour. Although certain dental or orthopaedic implants use chromates, they have never been used in DePuy CMW cements.</p>

This is just a listing of the most frequently asked questions of possible ingredients. The list is not complete. In case of doubt, please contact DePuy Synthes.

# HANDLING PROPERTIES

## What does affect the working properties of bone cement?

The following factors can have an impact on the working and hardening properties of bone cements

Factors	Effect
<p>Temperature</p> 	<p>Storage, theatre and mixing device temperatures can affect the working properties of orthopaedic bone cements.</p> <p>Low temperatures: Low temperatures lead to a lower initial viscosity of the bone cement. The consistency of the bone cement is more liquid and when applying the bone cement the surgeon needs to be careful that the cement has reached the right viscosity in order to withstand blood pressure when injected. In addition, both the working and setting times of the cement will be longer.</p> <p>High temperatures: High temperatures lead to an increased viscosity (more doughy consistency). In this case the surgeon should be aware that the bone cement has a shorter working and hardening time. Please refer to the instruction for use for guidance how the different bone cements behave at different temperatures. Please note that bone cement should be stored for 24 hours before use at the intended temperature of mixing in order to allow it to adapt. If storage temperature and OR temperature are different, it is important to take the bone cement out of the storage area just before mixing.</p>
<p>Humidity</p> 	<p>During testing at DePuy CMW, our laboratories are controlled between 40–60% humidity. Under these conditions cement properties remain relatively constant.</p> <p>High humidity: Under high humidity conditions (above 70% humidity) the cement may take up moisture leading to an increased viscosity. The mix can look gritty in appearance and the setting time may be slightly quicker.</p> <p>Low humidity: Under low humidity conditions (below 40% humidity) the cement may lose moisture, leading to a lower viscosity and hence the setting time may be slightly longer (the wetting of the polymer beads takes longer).</p> <p>In order to reduce the effects of humidity during storage, DePuy CMW cement powders are packed in an outer foil to keep the contents under constant conditions. Hence, the outer foil packaging should be left in place until immediately before use for protection against humidity.</p>
<p>Mixing technique</p> 	<p>Mixing technique also has an impact on the working properties of bone cement. The more energy that is put into bone cement while mixing the faster the bone cement cures. In addition, the application of reduced pressure (or 'vacuum') during mixing will also reduce cure times due to the removal of oxygen, which has a retarding effect on polymerization. These are reasons why bone cements mixed in vacuum mixing systems generally set quicker than those mixed manually.</p>
<p>Gloves</p> 	<p>Depending on which material is used for the glove, the adhesiveness of bone cement might change. Hence, the glove does not change the viscosity of bone cement, but might have an impact on its stickiness during manipulation.</p>



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**How should the bone cement be mixed (liquid first or powder first)?**

When mixing the powder and liquid in an open bowl it does not matter whether powder or liquid is placed in first. Historically DePuy CMW has always stated to add the powder first.

With regard to the CEMVAC mixing system, we recommend first adding powder. If liquid is added first the CEMVAC nozzle will become wet with monomer. Once wet it will then be difficult to add powder down the nozzle, since the powder will stick to the inner walls. Furthermore it can be more difficult to push the push-rod down into the nozzle, once powder is stuck to it. When mixing DePuy CMW bone cements in mixing systems provided by other suppliers, it is important to refer to their mixing instructions and guidance.

**Why is it so important to apply the bone cement at the right viscosity?**

Bone cement should be applied when it is no longer excessively sticky (doctor's finger test), particularly during total hip replacement surgery. This ensures that the bone cement is viscous enough to withstand the effects of bleeding pressure in the bone. Withstanding blood pressure is important as blood inclusions will weaken the cement structure. However, the bone cement should still be in a stage where it is easy to mould (when folded lines should be still easy to remove, before the bone cement becomes elastic). As long as the cement is well mouldable, positioning of the prosthesis is still possible and no pushing back of the prosthesis by the bone cement should occur.

**DePuy CMW mentioned that each batch of liquid is matched to the corresponding powder. Hence, what would happen to cement quality if for a bigger mix two cements of different batches had to be used? Is this allowed?**

The amount of activator (DMPT) in the liquid is matched to the initiator (BPO) in the powder for each batch of DePuy CMW bone cement. A blend of two liquids (which contain the two activators) should still be matched to the blended powders (containing the two

matched initiators). It is not recommended to use different bone cements and to blend them (e.g. mixing one package of DEPUY CMW 1 Bone Cement with one package of DEPUY CMW 2 Bone Cement). The mixing of two packs of bone cement which are of the same type, but are from different batches should not change the quality of the final cement.

# STORAGE

## How should the bone cement be stored?

Bone cement should be stored away from sunlight below 25°C in a dry space.

## What happens if the bone cement is stored above 25°C?

If the bone cement is stored above 25°C for a prolonged period there is an increased risk of the monomer liquid prematurely polymerizing and hardening. In addition, changes to the cement handling and setting properties may also occur.

## Is there any impact on the product properties of DePuy CMW bone cement if the bone cement is stored at temperatures lower than 0°C?

The liquid freezes at -40°C. Hence, storing bone cement at temperatures less than 0°C will not affect the stability of the product. However, storage below 0°C may affect the mixing characteristics of the cement. Studies have

been carried out where the bone cement has been stored at 4°C and testing has shown that mechanical strength is not affected by this low temperature storage. Storage and theatre temperatures can affect mixing, handling and setting characteristics of the cement. If the cement has been stored or transported at temperatures below 0°C, it is important to allow the cement to equilibrate to normal room temperature (for 24 hours) before use in the theatre, otherwise the cement may exhibit long dough times, lower viscosity and longer setting times than normal. If the cement is allowed sufficient time to equilibrate to room temperature, then it should mix and perform normally.

## What is the shelf life of the different products?

The DePuy CMW products have different shelf lives:

Product	Shelf life
VACUMIX PLUS Pre-packed with DEPUY CMW 1 Bone Cement	2 years
VACUMIX PLUS Pre-packed with DEPUY CMW 1 Gentamicin Bone Cement	2 years
VACUMIX PLUS Pre-packed with DEPUY CMW 3 Bone Cement	2 years
VACUMIX PLUS Pre-packed with DEPUY CMW 3 Gentamicin Bone Cement	2 years
DEPUY CMW 1 Bone Cement	3 years
DEPUY CMW 1 Gentamicin Bone Cement	3 years
DEPUY CMW 2 Bone Cement	3 years
DEPUY CMW 2 Gentamicin Bone Cement	3 years
DEPUY CMW 3 Bone Cement	3 years
DEPUY CMW 3 Gentamicin Bone Cement	3 years
SMARTSET HV Bone Cement	2 years
SMARTSET GHV Gentamicin Bone Cement	2 years
SMARTSET MV ENDURANCE Bone Cement	3 years
SMARTSET GMV ENDURANCE Gentamicin Bone Cement	3 years
SMARTMIX CEMVAC Pre-filled with SMARTSET HV Bone Cement	2 years
SMARTMIX CEMVAC Pre-filled with SMARTSET GHV Gentamicin Bone Cement	2 years

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## **Allergies: What are the implications if a patient is suspected of being allergic to PMMA bone cement?**

Allergies to bone cements are not very common. Nonetheless, in order to verify whether a patient is allergic, it is suggested to perform an allergy test for the different components of bone cement (please also see the section "Bone cement components"). In the past it has been requested to supply suitable cement samples for such work, but current regulations for medical device manufacturers do not allow the provision of materials for this purpose. When such requests are received it is advised that contact should be made with a centre carrying out hypersensitivity testing. If the patient should turn out to be allergic to one of the components in PMMA bone cement, it is recommended to look at alternative methods of fixation such as cementless prostheses.

The only exception is when a patient is allergic to the antibiotic gentamicin. In this case plain PMMA bone cement (without antibiotic) should be used. In some cases where the patient is allergic to the radiopaque agent, an alternative bone cement might be available (e.g. instead of using a bone cement with zirconium dioxide one with barium sulphate could be used).

## **Allergies: Some patients are allergic to Benzoyl Peroxide (BPO). Is there any bone cement that does not contain BPO?**

All DePuy CMW bone cements contain the activator Benzoyl Peroxide. As far as we know all competitor bone cements also contain BPO in their powder components as the curing initiator. Hence, it is suggested to perform an allergy test on the patient if sensitivity to BPO is suspected. If the patient is allergic to one of the components in bone cement, it is recommended to look at alternative methods of fixation such as cementless prostheses.

## **Does the monomer liquid harm the patient's body? What role does it play in the bone cement implantation syndrome?**

Although bone cement offers many benefits, as with all medical interventions, there are potential risks associated. These are concerns based on the known chemical effects of the monomer component, and include the following:

- General toxicity of MMA
- A role of MMA in promoting agglutination of lipids, producing anaphylactic reactions, or activating tissue thromboplastins
- In general, however, these have not been backed by experimental or clinical studies<sup>1,2,3</sup>. MMA is not generally considered to be a cause of severe cardiopulmonary complication, however there is evidence to suggest a risk due to:
  - Physical effects of introducing a mass of cement into the bone
  - Embolization of bone marrow and fat in the lungs has been observed following arthroplasty, and this can be life-threatening
  - Fat emboli, resulting from the forcible injection of cement into the medullary canal, have been suggested as being responsible for falls in blood pressure as opposed to the effect of monomer alone.

For more detailed information refer to:

1. Clarius M, Heisel C, Breusch SJ. Pulmonary Embolism in Cemented Total Hip Arthroplasty. In Breusch SJ, Malchau H. *The Well-Cemented Total Hip Arthroplasty*. Springer Verlag. 2005, p. 321 ff.
2. Pelling D, Butterworth KR (1973). Cardiovascular effects of acrylic bone cement in rabbits and cats. *The British Medical Journal*, Vol. 2, p. 638.
3. Orsini EC, Byrick RJ, Mullen JBM, Kay JC, Waddell JP (1987). Cardiopulmonary function and pulmonary microemboli during arthroplasty using cemented or non cemented components: the role of intramedullary pressure. *J Bone Joint Surg [Am]*; Vol. 69-A, pp. 822-32.

### How can the risk of embolism be reduced (mainly hip replacement)?

Embolism is a serious complication which is rare and mostly occurs during or following hip replacements. The risk of a fatal outcome in hip replacements has been stated in the literature as varying between 0.06% and 0.1%<sup>1</sup>. Entrapments of air, fat and bone marrow might lead to an embolism when intramedullary pressure is increased. In order to reduce the risk of an embolism, modern cementing technique should be used. Modern cementing technique includes the following points:

Method	Effect
Pulsatile lavage	Lavage is used to clean the cancellous bone to ensure a strong bone-cement interface. Additionally, by removing bone debris, fat and marrow, less material can be pressed into the veins. The quality of lavage is an essential factor in reducing the risk of embolism. A pulsatile lavage system is more effective in cleaning the bone than manual lavage (using syringes to clean the bone) as it ensures a deeper cement penetration into the bone.
Cement viscosity	Bone cement needs to be pressurized to achieve a good bone-cement interlock. If applied in a high viscosity state, there may be a risk of embolism and good bone cleaning is strongly recommended. However, if used in too low a viscosity state, with a considerable degree of flow or 'runniness' the cement may take the path of least resistance into the venous system before even penetrating the bone – leading to a cement embolization.
Pressure and Penetration	Pressurization is important as bone cement is not glue. Rather, it acts as a grout and as such it needs to be firmly anchored to the bone. To achieve good anchorage to the bone, the bone cement must penetrate into the cancellous bone and once penetrated it must set hard, giving good stability to the implant. The pressure that is created during this penetration is dependant upon several factors such as duration and magnitude of pressurization, cement viscosity, prosthesis design and relationship between the medullary cavity and the prosthesis size. The larger the prosthesis in relation to the medullary cavity, the higher the pressure and hence the potential amount of embolized material. Therefore, the medullary cavity should be thoroughly cleaned by pulsatile lavage and larger stems should be inserted slowly.
Cement restrictor	A cement restrictor should be used to occlude the intramedullary canal in the femur during cemented hip replacement surgery. This facilitates cement containment, cement pressurization and thereby improves the bone-cement interlock.
Filling technique / vacuum mixing	Bone cement should be applied to the femur using a retrograde filling technique. This usually means mixing the bone cement in a vacuum mixing system and then applying it through a nozzle with a cement gun, starting to fill the medullary canal at the cement restrictor. Mixing the bone cement in a vacuum mixing system also has the advantage that less air is entrapped in the bone cement which might lead to microfractures in the cement mantle.

In summary, one of the most important things to bear in mind to reduce fat embolism is the use of pulsatile lavage which will reduce the potential volume of the embolic load. Typically it is recommended to use 1 litre saline for pulsatile lavage to clean a femur.<sup>1</sup>

For more detailed information refer to:

1. Clarius M et al, in Breusch SJ, Malchau H (2005). The well-cemented total hip arthroplasty. Springer Verlag. Pages 321-329.

Draenert K, Draenert Y, Garde U, Ulrich C. Manual of Cementing Technique. 1999.

Christie J, Robinson CM, Singer B, Ray DC. Medullary lavage reduces embolic phenomena and cardiopulmonary changes during cemented hemiarthroplasty. J Bone Joint Surg 1995;77:456-459.

Heisel C, Clarius M, Schneider U, Breusch SJ (2001). Thromboembolische Komplikationen bei der Verwendung von Knochenzement in der Hüftendoprothetik – Pathogenese und Prophylaxe. Z Orthop; 139.

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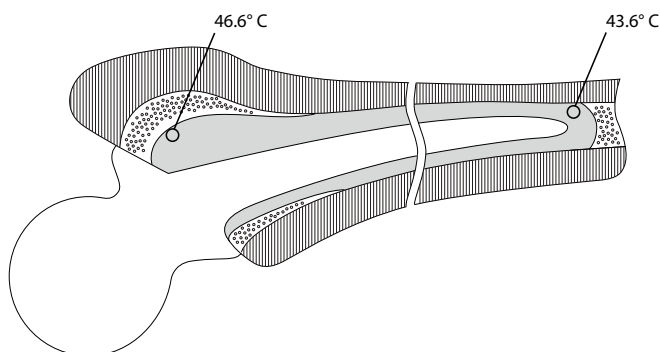
### How much does the bone cement shrink during polymerization?

During polymerization, pure monomer liquid (MMA) undergoes a shrinkage of 21% by volume. Since such shrinkage would not be tolerable for bone cements, they are mixed with a significant amount of powder in the form of polymerized monomer (PMMA). These small polymer particles are partially dissolved in the monomer liquid and shrinkage is reduced to 2% – 3%. It needs to be noted that this process of shrinkage starts when the two components are mixed together.

For more detailed information refer to:  
Kühn KD (2000). Bone cements. Springer Verlag. Page 21–22.

### Will the bone cement cause heat necrosis?

For a long time it was believed that the heat generated during the polymerization of PMMA bone cement might lead to thermal necrosis of adjacent tissues. The heat generated during polymerization originates from the monomer liquid and is dependent on the amount of liquid present in relation to the cement powder. Furthermore, the longer the cement polymerization process takes, the lower the temperature increase observed. Clinical tests have shown lower peak temperatures from curing bone cement compared to *in vitro* studies: the temperatures measured were below the protein coagulation point of 43°C – 46°C. This is due to a thin cement mantle (~ 3 – 5 mm), blood circulation and the presence of a prosthesis which dissipates heat.



For more detailed information refer to:  
Kühn KD (2000). Bone cements. Springer Verlag. Page 27–28

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## **Do monomer fumes have a health impact on users?**

Methyl methacrylate odour can be detected at very low levels (i.e. 2 parts per million). The occupational Short-term exposure limit (STEL) for methyl methacrylate is usually 100 ppm and long-term exposure limit (OEL) is 50 ppm. Levels can vary between countries and hence should be checked locally. The limited levels that personnel are in practice exposed to in operating theatres should be well within these limits and therefore long-term exposure to methyl methacrylate should not present a risk under standard conditions. It is advisable for the operating theatre to be monitored for exposure to methyl methacrylate vapour if there is a concern. Operating theatres in the UK are changing to mixing cement in vacuum mixing systems, in an attempt to further reduce the exposure to monomer fumes following concerns raised by nursing staff. It is advisable to mix cement in well-ventilated areas.

Potential risks from the use of MMA arise from repeated exposure (mixing bone cement all day long). Health issues include asthma, dermatitis, eye irritation including possible corneal ulceration, headache and neurological signs. Monomer fumes may be absorbed by contact lenses increasing eye irritation. Additionally, the IFU advises that pregnant women should minimize their exposure to monomer. The liquid component, methyl methacrylate as with any solvent, can in sufficient quantities be irritating, both to the respiratory system and the skin. The worst case short-term effect would be to mix the cement without gloves; over time the skin's natural oils will be removed resulting in dry, chapped skin. Hence, it is advised to wear 2 pairs of surgical gloves while handling PMMA bone cement. In the long term, the skin could develop sensitization to the methyl methacrylate resulting in dermatitis. This again would only occur if the cement was being handled without gloves. Given the small quantities of both liquid and powder component present in the cement, it is highly unlikely that any long-term respiratory effects will be realized, but that risk is further reduced if enclosed mixing systems are used.

## **What is the worst risk of being exposed to bone cement?**

Contact of monomer with the skin or mucous membranes should be avoided. The liquid component of bone cements has caused contact dermatitis in those handling and mixing them. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication.

The liquid component of bone cement is a powerful lipid solvent. The liquid component should not be allowed to come into contact with surgical gloves. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions.

For more detailed information refer to:  
Instruction for use

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## BIOMATERIALS

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