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Orthopaedics

OR Handbook
for Simplex P Bone Cement

Bone Cement

- Bone cement is used for fixation of prosthesis to living bone in orthopaedic musculoskeletal surgical procedures.
- Commonly referred to as PMMA (polymethylmethacrylate)

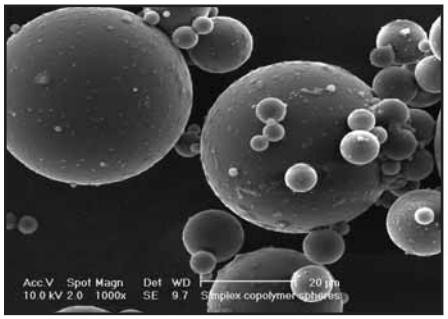
2 Main Components
- a Polymer (powder)
- a Monomer (liquid)

These two components are made up of a blend of ingredients which give each type of bone cement its unique characteristics.

Simplex P Bone Cement Polymer Ingredients
- 75% Methyl Methacrylate Styrene Copolymer
- 15% Polymethylmethacrylate
- 10% Barium Sulfate

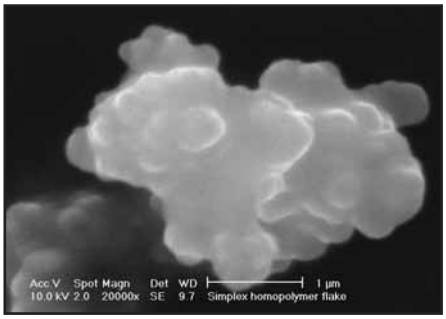
Unique Simplex™ P Formula

75% +
Methylmethacrylate-styrene-copolymer plus...



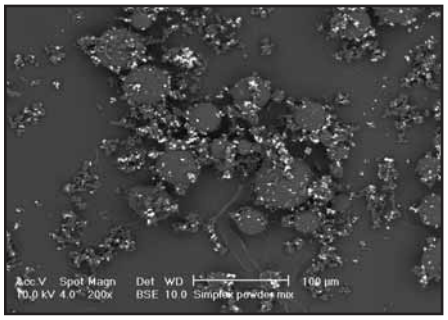
Styrene and methylmethacrylate are combined via a proprietary manufacturing process to form beads of varying size.

15% +
Polymethylmethacrylate (PMMA) plus...



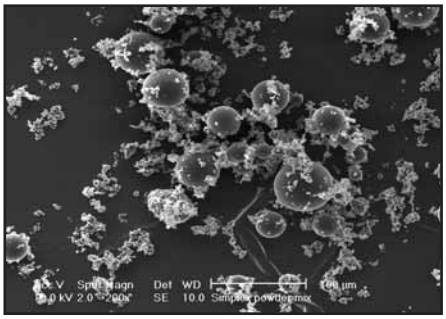
Methylmethacrylate is processed to form the PMMA 'flake' designed to increase wetability and improve handling characteristics.[1]

10% =
Barium equals...



Barium sulfate is blended under special controls to allow for uniform barium dispersion that is free of clumps.

The Orthopaedic Standard
Simplex P Powder Mixture – Complete



Indications
- Arthritis: rheumatoid, osteo-, or traumatic
- Avascular necrosis
- Sickle cell anemia
- Collagen disease
- Severe joint destruction secondary to trauma or other conditions
- Revision of previous arthroplasty
- Fixation of pathological fractures where loss of bone substance of recalcitrance of the fracture renders more conventional procedures ineffective
- Fixation of prosthesis to living bone in orthopaedic musculoskeletal surgical procedures

Contraindications
- Infectious arthritis
- Active infection of the joint or joints to be replaced
- History of such an infection
- Where loss of musculature or neuromuscular compromise in the affected limb would render the procedure unjustifiable
- Allergies to any component

Antibiotic Bone Cement

Antibiotic Bone Cement

- Bone cement pre-blended with antibiotics.
- Antibiotic Bone Cement is indicated for the fixation of prosthesis to living bone in the second stage of a two-stage revision arthroplasty procedure.*

Commonly used antibiotics in bone cement

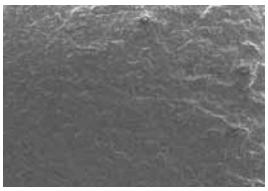
- Tobramycin
- Gentamicin

Simplex P with Tobramycin Bone Cement Polymer Ingredients

- 40g of Simplex P Bone cement powder
- 1g of Tobramycin

Simplex P Bone Cement with Tobramycin Pre-Blended Sample

Cross-section photos of cement showing antibiotic blending.



SEM Image
(20x Magnification)

Setting Process

- When the monomer (liquid) and polymer (powder) are mixed, the polymerization reaction occurs to form hardened bone cement.
- The liquid reacts with the polymer releasing the benzoyl peroxide, which reacts with N, N-dimethyl-p-toludine in the monomer, which accelerates the chemical reaction.
- Monomer molecules polymerize to one another and form a chain.
- Exothermic reaction occurs during this process and heat is generated and ends when polymerization is complete.
- The chain hardens into PMMA (bone cement) when the bone cement is cured.

Setting Process Times

(These times may vary with different cement types.)

Doughing Time: from the time that the monomer and polymer are mixed to the time when the mixture does not stick to the glove.

Working Time: the time between the start of kneading and when the cement becomes too stiff to be delivered into the bone.

Setting Time: the full time from when the components are mixed until polymerization is sufficient to maintain implant position. (80% of final properties are present at this time. Remaining 20% will be achieved over the next 48 hours.)

* U.S. indications only. Outside U.S. indications are not limited to the second stage of a two-stage revision.

Considerations for Bone Cement Selection

Chemical Composition
- Varies among the different brands of cement

Fatigue strength
- Durability over time

Compressive strength
- Ability to withstand compressive stress

Flexural strength
- Ability to withstand bending stresses

Shear strength
- Ability to withstand transverse loads

Viscosity (consistency)
- Low (runny) – Low viscosity cements remain in a runny state for a much longer period of time compared to medium or high viscosity cements. The true working time for when the cement can be picked up with a gloved hand is usually short, and the setting time can vary.
- Medium – Medium viscosity cements can offer versatility for all procedure types. Medium viscosity cements are both low and high viscosity depending on the time the cement is delivered. Considered dual phase cements, medium viscosity cements start out in a low viscosity state while being mixed. This provides for easy, homogenous mixing of the powder and liquid.
- High (thick) – High viscosity cements have no runny state at all. Immediately after mixing, the cement is doughy and ready to apply by hand to the implant surface. The working time for high viscosity cements needs to be closely monitored; it is not always easy to determine the end of the working time before it is too stiff to interdigitate with the bone.

Porosity
- Entrapped air in the bone cement (can be due to mixing technique and/or chemical composition of the cement)
- Reduction of porosity results in better mechanical properties[2]

Antibiotic Considerations
- **Thermo-stability**
- **Low toxicity**
- **Broad spectrum of coverage**
- **Good elution properties**
- **Easy to mix and homogenous blend**

Mixing Bone Cement

Common Methods

Hand Mixing

- The liquid and powder components are mixed in a plastic or stainless steel bowl using a spatula. Manufacturer's specific instructions should be followed.
- The fumes are introduced into the air with open bowl mixing (see Occupational Exposure section for more detail about monomer fumes.)
- Porosity may be increased and the cement strength may be decreased.

Vacuum Mixing

- Cement is mixed in an enclosed chamber connected to a vacuum source. Manufacturer's specific instructions for mixing should be followed.
- Vacuum mixing helps to eliminate most of the harmful fumes and to decrease porosity by removing entrapped air bubbles.
- Compressive strength is higher with vacuum mixing as opposed to hand mixing.[3]

Mixing Process

- Follow manufacturer's instructions.
- Both the monomer and polymer are supplied sterile.
- If any package is damaged, do not use or attempt to resterilize.

1. Empty the entire contents of the sterile packet into a cement mixer or other suitable, non-reactive container.

2. Break open sterile glass ampule containing the liquid component. Simplex P has a protective poly sleeve covering the monomer ampule tip. To protect yourself from glass fragments and reduce the likelihood of glass splinters falling into the cement, wrap the glass ampule and the polyethylene sleeve in sterile gauze before breaking it (if the ampule does not have the protective feature.)

3. Add all of the liquid monomer to the powder in the mixing container. Manufacturer's instructions for proper mixing of the liquid monomer may vary.

4. Stir in a slow, even manner with a sterile spatula or provided device until the powder is completely saturated.

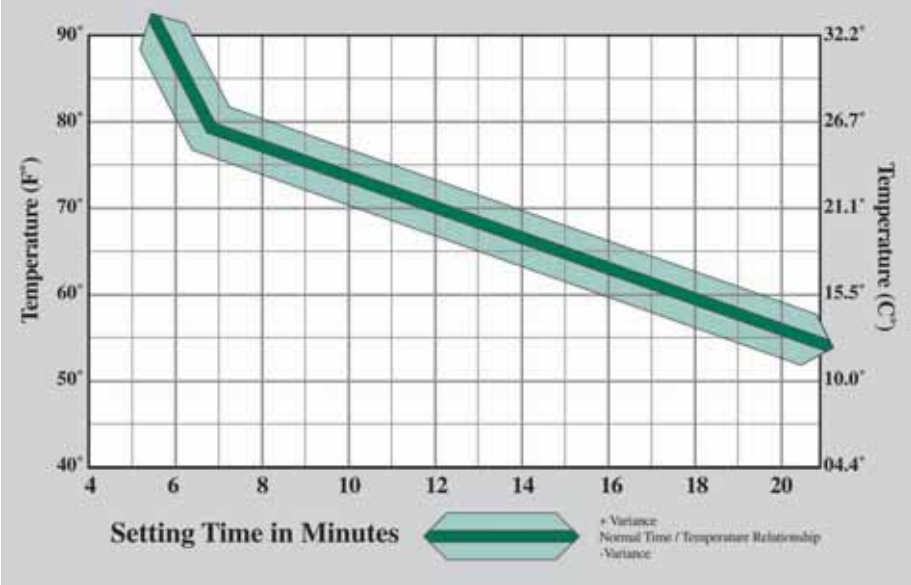
5. Follow manufacturer's instructions for the length of time to mix. When the mixture does not stick to the surgical gloves, the cement is ready for implantation. (Mixing too long can result in insufficient working time for the surgeon.)

6. To monitor progression of polymerization, place a small ball of cement on a non-porous surface and allow it to set or hold a small amount in your hand and the heat will be released until polymerization is complete.

Factors that may Influence Setting Time and/or Surgical Outcome

Temperature

- For the 12-24 hours prior to use in surgery, the product components should be kept at ambient OR temperature.
- Setting time is greatly affected by temperature; even a slight difference in temperature can mean a change in setting time.
- Recommended storage: store in a dark, dry place, and refer to packaging label.
- Implant and mixing equipment temperature can also affect the setting time of cement.



Mixing process/technique

- Vigorous mixing may accelerate the polymerization of the cement.
- Thoroughly mix both components until smooth consistency is achieved.

Powder-to-liquid ratio

- Be sure to use the entire contents of the packaged liquid and powder.
- If the entire contents are not used, the setting reaction may be affected.

Presence of intrusions

- Intrusions of water, saline, blood, fat, bone chips, or sterilizing solutions may affect the setting time and integrity of the cement.
- Intrusions may also cause laminations (faults or folds in the cement), which create areas of weakness or potential areas where a failure mode can occur.
- Various devices are available for thorough lavaging and drying to lower the potential for intrusion of foreign materials.

Viscosity

- Viscosity may affect the quality and longevity of the fixation achieved by cement.
- Viscosity also may affect the handling characteristics, handling time, and penetration into cancellous bone.
- Optimum viscosity is important for cement penetration into the bone (good attachment).

Surgical technique

- Strict adherence to good surgical principles and technique is important for the long-term survival of total joint arthroplasty.
- Use of modern cementing techniques may improve longevity.[6]

Factors that may Influence Cement Strength

Bone preparation

- Bone preparation is part of the surgical technique that is important for mechanical interlocking of the cement, bone, and prostheses.
- Exposed strong trabecular bone provides a sound mechanical anchor for the cement.
- Thoroughly washing, cleaning, and drying of the bony surface is important to obtain maximum strength at the cement-to-bone interface.

Medullary Plugs

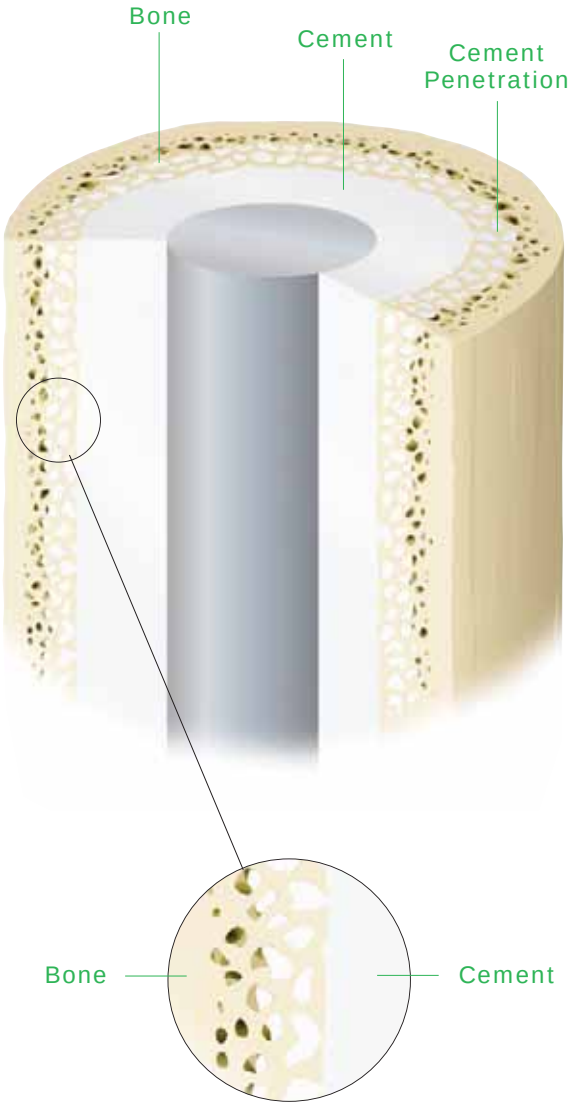
- May provide numerous advantages including:
    - Greater intrusion pressure
    - Improved cement-to-bone interface strength
    - Fewer voids in the cement mantle
    - Containment of cement in the proximal portion of the femoral canal
    - Improved fixation[7]

Porosity

- Reduce porosity by vacuum mixing.
- Reducing the porosity may improve fatigue life of the cement.[2]

Pressurization

- Increases penetration[13] into the cancellous bone (providing acceptable bone-cement interface)
- Minimizes laminations and porosity
- Over pressurization may have negative effects including:
    - Tissue damage
    - Nutrient obstruction
    - Increased monomer in the bloodstream



Safety Considerations

Flammability

- The liquid monomer is highly volatile and flammable (open cup flash point of 50°F).
- Never bring a flame, spark, or other ignition source near the surface of the liquid or uncured cement.
- Do not expose the product or materials to high temperatures.
- Cured bone cement is not a fire hazard.
- Proper ventilation is important for minimizing the danger of fire or explosion. (Typical well regulated OR ventilation is adequate.)
- Proper storage of electrosurgical devices is important to avoid potentially dangerous situations.
- Usual fire-fighting procedures are required in the unlikely event of a fire.
- Dry chemical foam or carbon dioxide extinguishers can extinguish the fire.
- Toxic gases and vapors, such as carbon monoxide, may be released in fires involving methylmethacrylate.

Spills and Disposal

- The EPA (Environmental Protection Agency) classifies the liquid (monomer) of bone cement as a volatile and flammable substance.[8]
- In the event that the liquid spills, remove all ignition sources and ventilate the area.
- Dispose of in accordance with local and federal regulations as hazardous waste.

Occupational Exposure

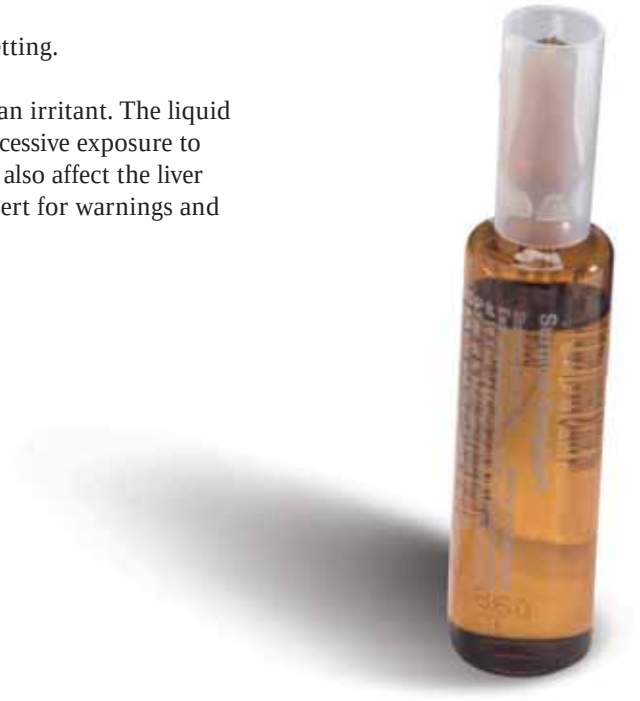
The surgical team is exposed to bone cement through skin contact and inhalation of its vapors. Team members should wear safety glasses and surgical gloves during the opening, pouring and mixing of bone cement.

AORN (Association of periOperative Registered Nurses) identifies methylmethacrylate as a potentially hazardous chemical. Safe practices should be established for its use. Personnel should read and follow all instructions provided by the manufacturer (Material Safety Data Sheets [MSDS], container label, Instructions For Use [IFU]). Material
Safety Data Sheets should be accessible within the practice setting.

Methylmethacrylate is a liquid solvent generally classified as an irritant. The liquid monomer and its vapors should be handled with caution. Excessive exposure to vapors can produce eye or respiratory tract irritation. It may also affect the liver and have systemic reactions. Please consult the packaging insert for warnings and proper handling.

Patient Considerations

Please consult the package insert for possible adverse effects.



Chronic Toxicity

- No chronic toxic effects have been found.[9]

OSHA Threshold Limit Values[10]

- Degree of hazard depends on the concentration level of the vapor in the OR.
- The threshold limit value (TLV) established by OSHA is based on the tolerance of industrial workers.
    - TLV for methylmethacrylate is a time-weighted average limit of 100 parts methylmethacrylate per million parts of air (ppm), or 410 milligrams per cubic meter of air during an 8-hour work shift in a 40-hour work week.
- Monomer vapor concentrations are generally measured well below the TLV.[11,12]
    - Distinctive acridly fruity odor of bone cement is detectable at levels far below the toxicity level, so the material's properties elicit warnings.

Exposure during pregnancy

- At concentrations far in excess of those recorded in operating rooms, methylmethacrylate vapor was not toxic or teratogenic in pregnant mice.[9]
- No studies to date have been conducted in pregnant women on the effects of mixing bone cement.
- It is strongly recommended that pregnant OR staff not be present during the mixing of bone cement.
- Use your judgement.

Use of contact lenses

- Manufacturers of contact lenses recommend that such lenses be removed "in the presence of noxious and irritating vapors."
- Contact lenses are subject to pitting and penetration by the vapors, therefore it is recommended that lenses of this type not be worn in the OR where methylmethacrylate is being mixed.

Skin Sensitivity

- Never allow direct skin or other soft tissue contact with bone cement because it can cause a local reaction or be absorbed.
- To reduce the risk of hypersensitivity reactions, you should double glove and discard the second pair of gloves after mixing.
- It is possible for fumes to penetrate some types of surgical gloves, therefore double gloving is recommended.
    - OR personnel who use non-latex gloves should change to natural latex gloves before handling bone cement to prevent exposure.

Emergency First Aid Procedures

Eye Exposure

- Wash eyes immediately with large amounts of water, lifting the upper and lower lids occasionally.
- Get medical attention as soon as possible.
- Do not wear contact lenses while mixing bone cement.
- As an added precaution, it is recommended that safety glasses be worn during opening, pouring, and mixing bone cement.

Skin Exposure

- Promptly flush the contaminated skin area with water.
- If it soaks through clothing, remove clothing and flush skin with water.
- Always seek medical attention for skin irritation.

Respiratory Exposure

- Use of vacuum mixing reduces any exposure to fumes.
- If a person has breathed a large amount of monomer vapor, move him or her to fresh air immediately.
- Perform artificial respiration if breathing has stopped.
- Keep the person warm and at rest.
- Seek prompt medical attention.

Swallowing

- Give immediate medical attention to any person who has swallowed methylmethacrylate.
- Do not induce vomiting unless directed by a medical professional, and ensure the airway is clear.
- If the person is conscious, wash out the mouth with water and give 200-300 mL of water to drink.
- Adsorbents such as activated charcoal may be of value.
- Gastric lavage may be effective if performed within 4 hours of ingestion.

Rescue

- Move the affected person away from the hazardous exposure area.
- Do not endanger yourself, but put emergency rescue procedures into effect.
- Be familiar with the hospital's emergency rescue procedures and know the location of rescue equipment.

* Please consult package insert for proper use and handling and the associated warnings.

References

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Suggested Reading

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