Cardinal Health™ Bone Cement and Mixing Systems

The perfect mix of quality and performance.
Cardinal Health™ Arthroplasty Bone Cements

The composition of Cardinal Health™ Arthroplasty Bone Cements is based on Charnley’s principle of using PMMA bone cement in artificial joint replacements, which was established as the gold standard 50 years ago. This formulation meets the ISO requirements for acrylic bone cements (ISO 5833:2002).\(^1\,^2\) It provides the mechanical and fatigue strength to meet surgeons’ needs.\(^1\,^4\) A short waiting time and a long working time offer surgeons flexibility during introduction and positioning of the implant.\(^5\,^6\)

- Available with Gentamicin
- Similar handling properties to Palacos® R and Palacos® R+G\(^5\,^6\)
- High viscosity, fast-setting\(^5\,^6\)
- Short waiting time and long working time\(^5\,^6\)
- Effective Gentamicin elution\(^7\)
- Can be mixed by hand or in vacuum mixing systems\(^5\,^6\)
- Can be pre-chilled when using vacuum mixing systems\(^5\,^6\)
- Includes zirconium dioxide for x-ray visualization\(^5\,^6\)
Delivering the confidence and performance clinicians expect at a significantly lower cost.

**Cardinal Health™ Vacuum Bowl Mixing System**

- Proven rotational axis design with over 20 years of clinical history
- Designed to operate at a vacuum level of 508mmHg–565mmHg
- Mixes up to 120g; all cement viscosities
- Closed system and charcoal disc filter reduce exposure to methylmethacrylate fumes to well below the U.S. Occupational Safety and Health Administration’s (OSHA) permissible exposure limit\(^8,9\)
- Includes a unique spatula designed to match the curvature of the mixing bowl
- No change needed in your clinical practice or technique

**Cardinal Health™ Vacuum Cartridge Mixing System**

- Proven design; over 19-year history
- Designed to operate at a vacuum level of 508mmHg–565mmHg
- Easy to assemble — Cartridge quickly connects to the injection gun with a simple twist — includes key components that surgeons rely on:
  - Extruder and Scraper — helps maximize the amount of cement used, reducing cement waste
  - Snap-Off Nozzle — converts to a shorter length, helping to reduce the number of nozzles needed for a procedure
- Closed system and charcoal disc filter reduce exposure to methylmethacrylate fumes to well below the U.S. Occupational Safety and Health Administration’s (OSHA) permissible exposure limit\(^8,9\)
- No change needed in your clinical practice or technique
# Ordering information

## Cardinal Health™ Arthroplasty Bone Cements

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Description</th>
<th>Qty.</th>
</tr>
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<tbody>
<tr>
<td>CMT-40-1</td>
<td>Cardinal Health™ Arthroplasty Bone Cement, High Viscosity</td>
<td>20 ea/cs</td>
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<tr>
<td>CMT-40-1G</td>
<td>Cardinal Health™ Arthroplasty Bone Cement with Gentamicin, High Viscosity</td>
<td>20 ea/cs</td>
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</tbody>
</table>

## Cardinal Health™ Bone Cement Mixing and Delivery Systems

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Description</th>
<th>Qty.</th>
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<tbody>
<tr>
<td>451-550-01</td>
<td>Cardinal Health™ Bone Cement Bowl Mixing System, High Vacuum</td>
<td>12 ea/cs</td>
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<tr>
<td>451-550-02</td>
<td>Cardinal Health™ Bone Cement Injection Gun</td>
<td>10 ea/cs</td>
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<tr>
<td>451-550-03</td>
<td>Bone Cement Injection Gun</td>
<td>1 ea/bx; 12 bx/cs</td>
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<tr>
<td>451-550-05</td>
<td>Cardinal Health™ Total Hip Kit</td>
<td>10 ea/cs</td>
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<tr>
<td>451-550-07</td>
<td>Cardinal Health™ Automatic Vacuum Pump</td>
<td>1 ea/bx; 4 bx/cs</td>
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<tr>
<td>451-550-08</td>
<td>Cardinal Health™ Femoral Canal Pressurizer</td>
<td>10 ea/bx; 4 bx/cs</td>
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Cardinal Health™ Arthroplasty Bone Cement

Indications
Cardinal Health™ Arthroplasty Bone Cement is intended for use in arthroplasty procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

Contraindications
- When active or incompletely treated infection is present at the site where the bone cement is to be applied.
- When it is known that the patient is hypersensitive to any of its constituents.
- If muscle wasting or neuromuscular compromise in the affected limb renders the procedure unjustifiable.

Warnings
- Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements.
- Hypotensive reactions have occurred between 10 and 165 seconds following application to bone; 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.
- Follow the handling, mixing and preparation instructions carefully.
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation of the respiratory tract, eyes and possibly the liver. In some cases, it has been reported that the monomer vapors produced during the mixing process may cause general malaise and headaches. Such symptoms can be reduced with adequate ventilation or by using closed mixing systems.
- Personnel wearing contact lenses should not be near or involved in mixing this bone cement.
- Polymerization of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. A fibrous tissue layer may develop between the cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.
- Do not allow the liquid component to contact rubber or latex gloves. The liquid component is a powerful lipid solvent. Direct skin contact with the liquid monomer should be avoided as much as possible, as allergic reactions (contact dermatitis) cannot be ruled out. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions.
- The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. This usually occurs between one and two minutes after the liquid and powder components are mixed.
- Avoid over-pressureurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage to the surrounding tissues.
- The safety of the bone cement in pregnant women or during lactation period or in children has not been established. Bone cement may adversely affect bone growth and fetal health.

Cardinal Health™ Arthroplasty Bone Cement with Gentamicin

Indications
Cardinal Health™ Arthroplasty Bone Cement with Gentamicin is intended for use in arthroplasty procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second stage of a two-stage revision after the initial infection has been cleared.

Contraindications
- When active or incompletely treated infection is present at the site where the bone cement is to be applied.
- When it is known that the patient is hypersensitive to any of its constituents or in a patient with severe renal failure.
- In patients with infectious arthritis.
- If muscle wasting or neuromuscular compromise in the affected limb renders the procedure unjustifiable.
- During pregnancy or the nursing period.

Relative contraindications include the following:
- Uncooperative patient or patient with neurologic disorder who is incapable of following directions.
- Metabolic disorders which may impair bone formation.
- Osteomalacia.
- Distant foci of infections which may spread to the implant site.
- Rapid joint destruction, marked bone loss or bone resorption, vascular insufficiency, neuromuscular disease.
- Congestive heart failure.
- Hypotension.

Warnings
- There may be an increased risk of ototoxicity from gentamicin if other ototoxic drugs such as cisplatin (antineoplastic agent) and vancomycin (antibiotic) are given at the same time. There also appears to be a synergistic effect of loop diuretics, such as furosemide or etacrynic acid, and also loud noise, when combined with gentamicin.
- Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements.
- Hypotensive reactions have occurred between 10 and 165 seconds following application to bone; 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.
- Follow the handling, mixing and preparation instructions carefully.
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation of the respiratory tract, eyes and possibly the liver. In some cases, it has been reported that the monomer vapors produced during the mixing process may cause general malaise and headaches. Such symptoms can be reduced with adequate ventilation or by using closed mixing systems.
- Personnel wearing contact lenses should not be near or involved in mixing this bone cement.
- Polymerization of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. A fibrous tissue layer may develop between the cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.
- Do not allow the liquid component to contact rubber or latex gloves. The liquid component is a powerful lipid solvent. Direct skin contact with the liquid monomer should be avoided as much as possible, as allergic reactions (contact dermatitis) cannot be ruled out. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions.
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- The safety of the bone cement in pregnant women or during lactation period or in children has not been established. Bone cement may adversely affect bone growth and fetal health.