PALACOS® R
Radiopaque bone cement

Instructions for use
**PALACOS® R**

Uses and properties

PALACOS® R bone cement is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone. It is a fast setting polymer, for use in bone surgery.

Mixing of the two component system, consisting of a powder and a liquid, initially produces a liquid and then a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced by movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X-ray contrast medium. The chlorophyll additive serves as optical marking of the bone cement at the site of the operation.

Contraindications

PMMA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied and if patients are allergic to any of its components.

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 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. Follow the handling, mixing and canal 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. 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, and loosening of the prosthesis may occur leading to implant failure. Long-term follow-up is advised for all patients on a regularly scheduled basis.
- When working with the monomer or the cement, gloves must be worn to ensure adequate protection against the penetration of the monomer (methyl methacrylate) into the skin. PVP (three-layer polyethylene, ethylene-vinyl alcohol copolymer, polyethylene) and Viton/Butyl gloves have proved to provide good protection over an extended period. Putting on two pairs of gloves – one pair of polyethylene surgical gloves over a pair of standard latex surgical gloves has also proved to offer adequate protection.

The use of latex or polystyrene-butadiene gloves, however, must be avoided. Please request the confirmation of your glove supplier whether the respective gloves are suitable for the use of this cement.

Avoid over pressurization 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 in children has not been established. Bone cement may adversely affect bone growth and fetal health.

Precautions

Do not use this product after the expiration date printed on the package. This device may not be safe or effective beyond its expiration date.

Follow the handling and mixing instructions to avoid contact dermatitis. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication. Adequately ventilate the operating room to eliminate as much monomer vapor as possible. The liquid monomer is highly volatile and flammable. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites.

<table>
<thead>
<tr>
<th>Composition</th>
<th>PALACOS® R 1x40</th>
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<tbody>
<tr>
<td>poly(methyl acrylate, methyl methacrylate)</td>
<td>33.8 g</td>
</tr>
<tr>
<td>zirconium dioxide</td>
<td>5.9 g</td>
</tr>
<tr>
<td>hydrous benzoyl peroxide</td>
<td>0.3 g</td>
</tr>
<tr>
<td>methyl methacrylate</td>
<td>18.4 g</td>
</tr>
<tr>
<td>N,N-dimethyl-p-toluidine</td>
<td>0.4 g</td>
</tr>
<tr>
<td>Other constituents:</td>
<td>In the powder: chlorophyll VIII</td>
</tr>
<tr>
<td></td>
<td>In the liquid: chlorophyll VIII in an oily solution, hydroquinone</td>
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near freshly implanted bone cements has been reported. It has been recommended by manufacturers of soft contact lenses that such lenses should be removed “in the presence of noxious and irritating vapors”. Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

Adverse Events
Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include myocardial infarction, cardiac arrest, cerebrovascular accident, and pulmonary embolism. The most frequent adverse reactions reported with acrylic bone cements are a transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis, and short-term cardiac conduction irregularities. Other reported adverse reactions include heterotopic new bone formation and trochanteric separation.

Other reported adverse events for acrylic bone cements include pyrexia due to an allergy to the bone cement, hematuria, dysuria, bladder fistula, delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application, and adhesions and stricture of the ileum due to the heat released during polymerization.

Dosage
The amount of bone cement required depends on the patient's anatomy and on the implant used. One or more complete units (the contents of one pouch and one ampoule) must always be mixed together. In practice, more than four dose units per implantation are only rarely used.

Notes on use
Before using PALACOS® R the surgeon must be thoroughly familiar with its properties, handling and use, and must have read the relevant literature. Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, they are best determined by the surgeon's actual experience. For special mixing and application techniques (e.g. vacuum mixing, vacuum application, use of a femoral cement restrictor), the relevant instructions of these mixing and application system must be consulted.

Before using PALACOS® R for the first time, a test mixing should be carried out to become familiar with the characteristics of PALACOS® R. To mix, the protective aluminum packaging and outer non sterile polyethylene pouch (“peel off” package) and the ampoule packaging should be opened, maintaining sterility, by the circulating nurse. The ampoule and powder pouch are then taken out under sterile conditions and placed on a sterile working surface. The ampoule is opened by breaking the neck and the inner pouch is cut open with sterile scissors. Do not open the ampoule over the mixing device to prevent contamination of the cement with glass fragments.

Opening under sterile conditions:
The opening flaps from the bag top assist to detach the foil from the paper. In order to grip as much of the opening flaps as possible, the side of the paper/foil should be kept between thumb, index and middle finger. Please use the whole thumb surface to grip foil and paper side and take off each side evenly.

Mixing
PALACOS® R can be mixed by two different methods:
– Mixing without vacuum
– Mixing under vacuum

Mixing without vacuum
First pour all the liquid from the ampoule into a sterile mixing device and add all the powder. Stir carefully with a sterile mixing rod until a homogeneous mass is obtained. The mixture should not be mixed longer than 30 sec, irrespective of the room temperature. The temperature/time diagrams must be consulted.

Vacuum mixing
To obtain a bone cement with lower porosity the components must be mixed under vacuum. However, mixing under vacuum usually shortens the working time and setting time, and it might increase the initial viscosity. It is recommended to mix under vacuum after pre-chilling the cement components (at least 24 h at 4–7 °C [39–45 °F]) as this prolongs the working time and setting time. Mixing under vacuum requires an airtight closed system and rapid generation of sufficient vacuum (approx. 200 mbar [150 mmHg] absolute pressure) in the mixing device. The mixing time for vacuum mixing is the same as for mixing without vacuum (30 sec). Method of mixing is given in the instructions for the system used and must be consulted.

Use in joint surgery
An appropriate up to date cementing technique should be used with PALACOS® R to limit side effects and to achieve a stable and long lasting anchorage of the prosthesis. A prerequisite for this is careful preparation of the prosthesis site by thorough rinsing (e.g. with physiological saline solution) before application of the cement. Suction drainage could be used to avoid any pressure build up in the medullary canal during implantation. Further prerequisites for better prosthesis anchoring include filling of the entire medullary canal with cement (using a femoral cement restrictor), the production of a cement mantle completely surrounding the implant (ideal thickness 3–5 mm), and biomechanically optimal siting of the implant in bone.

Working procedure
After careful preparation of the medullary canal, PALACOS® R can be applied manually or using a cement syringe or some alternative application system. Method of application is given in the instructions for the system used and must be consulted. The working time and the rate of polymerization are strongly dependent on ambient temperature and on temperature of the components. The hardening
time is shorter at high temperatures and longer at low temperatures. Viscosity increases as polymerization progresses, i.e. as the cement hardens.

**Manual application**
The working phase starts when the doughy paste no longer adheres to the instruments or surgical gloves and ends when the paste becomes rubbery/elastic with visible separation lines while kneading. The cement and the prosthesis must be applied within the working phase. Applying the cement after the end of the working phase may cause an uneven and inadequate filling of the medullary canal, thereby resulting in possible early loosening of the implant (see graphs). The cement and the prosthesis must be applied within the working phase. After positioning of the implant any movement must be avoided, to ensure the anchoring of the prosthesis.

**Application with a cement syringe**
After mixing, the cement is poured directly into a cement syringe. The working time depends on the ambient temperature and the temperature of the components (see graphs). The times may vary depending on the syringe system used.

**Application of pre-chilled vacuum-mixed cement**
Pre-chilled vacuum-mixed cement is usually applied with a syringe. Consider the graphs. The instructions of the mixing system used must be consulted.

**Storage**
Do not store above 25°C (77°F).

**Shelf life/sterility**
The expiration date is printed on the outer carton, the protective aluminum packaging and the inner pouch. **PALACOS® R** must not be used after the expiration date. The contents of unused but opened or damaged packs must not be resterilized and are therefore to be discarded. **PALACOS® R** is sterilized with ethylene oxide gas and must not be resterilized. If the polymer powder shows a yellow discoloration, it must not be used.

**Disposal**
Single components of the bone cement, cured solid material as well as (uncleaned) packaging material must be disposed by following the regulations of the local authorities. Dispose of the polymer component in an authorized waste facility. The liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred in a suitable container for disposal.

**Information status 2019-03**

**PALACOS®** is a trademark of Heraeus Medical GmbH, Germany.
Working times for vacuum mixing (not pre-chilled bone cement)

Working times for vacuum mixing (pre-chilled bone cement)

Working times for manual mixing (not pre-chilled bone cement)

Test conditions: Not pre-chilled vacuum mixing system PALAMIX®, 55% humidity.
Symbols

- 🏞️ Manufacturer
- 🏞️ Sterilized using aseptic processing techniques
- 🏞️ Sterilized using ethylene oxide
- 📚 Consult instructions for use
- ☀️ Keep away from sunlight
- ☂️ Keep dry
- 🌡️ Do not store above 25 °C (77 °F)
- ⏳️ Do not re-use
- ⚠️ Do not resterilize
- 🔔 Do not use if the product sterile barrier system or its packaging is compromised
- 📜 Catalogue number
- ⏰ Use by date
- 💰 Batch code
- 🔥 Flammable liquid – Flashpoint 10 °C
- ⚠️ Causes skin irritation
- 🔒 Federal law restricts this device to sale, distribution, and use by or on the order of a physician