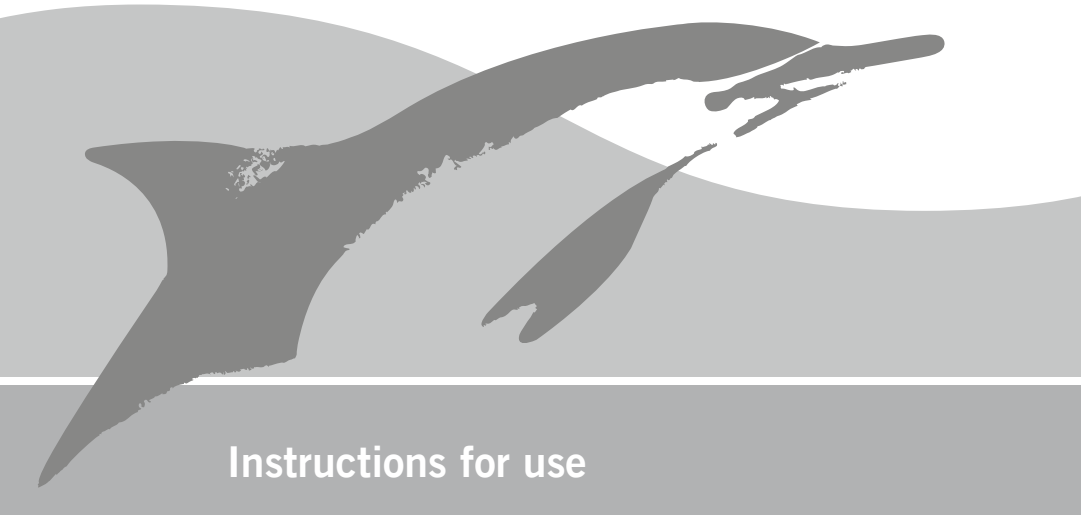
Heraeus

Medical

OSTEOPAL® V

Low-viscosity, radiopaque bone cement



Instructions for use

℞ Only

OSTEOPAL® V

1 General information

1.1 Device description

OSTEOPAL®V is a standard-setting, low-viscosity, radiopaque, poly(methyl methacrylate)-based (PMMA) bone cement. It contains the X-ray contrast medium zirconium dioxide. To improve visibility in the surgical field, it has been colored with chlorophyll-copper-complex (E141). The bone cement consists of two components and is prepared immediately before use by mixing the polymer powder (= powder) with the monomer liquid (= liquid). The low viscosity increases with progressing polymerization. A paste forms that is inserted into the vertebral body using an application system and sets within a few minutes.

OSTEOPAL®V is intended for single use and is supplied sterile.

1.2 Device sizes and packaging

Device sizes
OSTEOPAL®V is available in the size 20.

Package content
- 1 pouch filled with powder
- 1 brown glass ampule filled with liquid
- 1 set of product stickers for documentation
- 1 instructions for use

Packaging design
The powder is triple packaged: it is packed first in an inner polyethylene (PE) paper pouch and secondly in an outer PE-paper pouch (peel-off). Both PE-pouches are sterilized using ethylene oxide. The peel-off pouch contains the sterile inner PE-paper pouch with powder and is sterile on the inside and non-sterile on the outside. Afterwards the sterilized pouches are packed in a protective aluminum pouch.

The liquid is single packaged. The ampule blister is sterilized using ethylene oxide and contains a brown glass ampule with sterile-filtered liquid.

1.3 Composition

Composition	
Powder:	
PMMA copolymer	54 %
zirconium dioxide	45 %
benzoyl peroxide	1 %
Liquid:	
methyl methacrylate	98 %
N, N-dimethyl-p-toluidine	2 %

The data is rounded

Other constituents:
- Powder: chlorophyll-copper-complex (E141)
- Liquid: chlorophyll-copper-complex (E141), hydroquinone

OSTEOPAL®V does not contain a radiation source.

Device size	20
Powder:	26.3 g
Liquid:	10 ml

The data is rounded

The mass ratio is about 27 % liquid to 73 % powder.

1.4 Supporting equipment

Mixing equipment is required to mix the two components of **OSTEOPAL®V**. The mixing bowl with spatula distributed by Heraeus Medical GmbH is suitable.

OSTEOPAL®V can be introduced into the vertebral body using an application system that has been approved for vertebroplasty or kyphoplasty and enables steady and controlled injection. The user must ensure that the application system is compatible with the ingredients of the **OSTEOPAL®V** composition. For the correct usage and surgical technique, refer to the instructions of the manufacturer. The handling of the system is described in the manufacturer's instructions for use.

Cannulae with an inner diameter of less than 1.8 mm (13G) should not be used.

The instructions for use of the supporting equipment must be followed.

Note: Heraeus Medical GmbH has not tested the compatibility of **OSTEOPAL®V** with devices of other manufacturers and does not assume any liability for this. The use of mixing equipment of other manufacturers is done in the sole discretion and responsibility of the user.

1.5 MRI safety information
OSTEOPAL®V is MR safe.

2 Directions for use

2.1 Intended use
OSTEOPAL®V bone cement is intended for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

2.2 Intended patient population
Adult population.

2.3 Intended user
Healthcare professionals in a clinical context and experienced in the handling of the product. The surgeon and nurse must be thoroughly familiar with the properties and handling characteristics of **OSTEOPAL®V**. As the handling of **OSTEOPAL®V** varies with temperature, humidity and mixing technique, a test mix should be performed to ensure familiarity with its characteristics.

2.4 Indications
OSTEOPAL®V bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

2.5 Contraindications
OSTEOPAL®V must not be used
- in patients with hemorrhagic diathesis and infections
- in patients with lesions of the vertebral body with epidural extension due to the risk of spinal cord compression
- in patients with suspected or known hypersensitivity to constituents of the bone cement
- spinal stenosis (> 20 % by retropulsed fragments)
- compromised of the vertebral fractures due to posterior involvement
- patient clearly improving on medical therapy
- prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- non-pathological, acute traumatic fractures of the vertebra
- vertebral plana (collapse > 90 %)
- compromise of the vertebral body or the walls of the pedicles
- unstable vertebral fractures due to posterior involvement

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.

2.6 Adverse events and residual risks
Adverse Events
- Pneumonia
- Pneumothorax
- Fracture of a pedicle
- Rib fracture in patients with diffuse osteopenia, especially during thoracic vertebroplasty procedures, due to the significant downward force exerted during needle insertion

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the postoperative period, there have been some reports of diagnoses beyond a year or more after the procedure.

Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include: Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.

The most frequent adverse reactions reported with acrylic bone cements are a transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, superficial or deep wound infection and short-term cardiac conduction irregularities. Other reported adverse reactions include heterotopic new bone formation.

Other reported adverse events for acrylic bone cements include pyrexia due to an allergy to the bone cement, hematuria, dysuria, bladder fistula and 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.

Cement leakage between intervertebral discs.

Furthermore, application of **OSTEOPAL®V** can result in temporary neurological deficits.

Residual risk

Residual risks listed below are procedure related risks which are beyond the control of the manufacturer because they are procedure or user related.

Vascular System, Heart, Respiratory System, Blood and Lymphatic System

Bone Cement Implantation Syndrome (BCIS):
Insertion of bone cement may produce a high intravertebral pressure that forces bone marrow constituents into the venous vascular system, resulting in fat and marrow emboli.

In case of pulmonary or cardiovascular events it is necessary to monitor blood volume and possibly increase it. In the case of acute respiratory failure, anesthesiologic measures should be taken. In general, adverse reactions of BCIS might include low blood pressure/hypotension, hypoxia, bradycardia, tachycardia, pulmonary hypertension, thrombosis, embolism, pulmonary embolism, myocardial infarction, cerebrovascular accident, respiratory arrest, and cardiac arrest.

- BCIS grade 1
  moderate hypoxia (SpO_2 < 94 %) or hypotension [fall in systolic blood pressure > 20 %]
- BCIS grade 2
  severe hypoxia (SpO_2 < 88 %) or hypotension [fall in systolic blood pressure > 40 %] or unexpected loss of consciousness.
- BCIS grade 3
  cardiovascular collapse, requiring CPR
- Asymptomatic cement leakage
- Cement leakage, which can cause myocardial infarction, cardiac arrest, and cerebrovascular accident
- Symptomatic pulmonary embolism
- Symptomatic cardiac embolism

Nervous System

- Permanent neurological deficit

Musculoskeletal System

- Loss of range of motion
- Ambulation difficulties
- Re-collapse of treated or adjacent vertebrae/ secondary fractures

Infection

- Bacterial infection including cellulitis, and/ or osteomyelitis

Generalized Disorders

- Inflammation
- Swelling/edema
- Fibrosis
- Pain

2.7 Warnings

Regarding intended users

Caution should be exercised during the mixing of the two components of **OSTEOPAL®V** 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. Manufacturers of soft contact lenses recommend removing the lenses in the presence of damaging or irritant vapors. Since soft contact lenses are permeable to liquids and gases, they should not be worn in the operating room if methyl methacrylate is being used.

Eye protection is recommended when opening the ampoule during the sterile preparation steps of the bone cement to protect the eye from any glass fragments or monomer liquid.

The monomer is a powerful lipid solvent and should not come into direct contact with the body. When handling **OSTEOPAL®V** it is essential to wear gloves that provide the necessary protection against penetration of the monomer into the skin. Three-layered PVP gloves (polyethylene, ethylene vinyl alcohol copolymer, and polyethylene) and Viton®/butyl gloves have proved to provide good protection over an extended period. It is recommended that two pairs of gloves be worn over one another, e.g., a polyethylene surgical glove over an inner pair of standard latex surgical gloves. Do not allow the monomer to contact latex or polystyrene-butadiene gloves. Request confirmation from your glove supplier that the respective gloves are suitable for use with this bone cement.

The monomer is not for injection.

Polymerization of the bone cement is an exothermic reaction, which occurs while the bone cement is hardening in situ. The released heat may damage bone or other tissues.

Avoid over-pressurizing 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 tissue. Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events. If bone cement is seen outside the vertebral body or in the circulatory system during the procedure, immediately stop the injection.

Unanticipated postoperative events may affect the cement-bone interface and lead to micro motion of bone cement against bone surface. A fibrous tissue layer may develop between the bone cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.

Note: OSTEOPAL®V is a single-use device and must never be re-used! Re-use may result in diminished safety, performance, and compliance with relevant specifications.

Regarding the intended patient population
There is very little evidence with pregnant and lactating women, children and adolescents. Therefore, it is not recommended to use **OSTEOPAL®V**. If no other option is available, the decision whether to use **OSTEOPAL®V** lies with the attending physician. The benefits for the mother should be weighed against the potential risk to the child before using **OSTEOPAL®V** during pregnancy and lactation.

Monitor patients carefully for any change in blood pressure during and immediately after the application of bone cement. Adverse patient reactions involving the cardiovascular system are in particular linked to the pressurization of bone cement. Hypotensive reactions have occurred shortly after application of bone cement. However, consequences such as cardiac arrest are only reported in very few cases.

Few publications reported gradual deterioration of baseline cardiovascular parameters during consecutive augmentation of several vertebral bodies with PMMA. To avoid this, not more than 3 augmentations in a single operation are recommended.

In addition, paravertebral structures may be damaged by cement escaping. Complications such as spinal cord compression, intercostal neuralgia, cement escaping into the intervertebral space, peri-vertebral filling of veins and arteries (danger of embolism), infections and post-procedural pain are possible. To prevent cement escape and in order to detect unwanted occurrences in good time, application must be performed using imaging techniques (real-time display). In order to detect a vertebral extension, a phlebography must be performed before applying the cement. Immediate surgical intervention may also be necessary to counteract the described complications. Prior to surgery, a careful radiological investigation must be performed to assess possible risks (e.g. existing vertebral-body lesions, vascular supply of the vertebral body or edema).

2.8 Precautions
Regarding intended users
Do not use **OSTEOPAL®V** after the expiration date printed on the folding box. 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 is highly volatile and flammable. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.

Do not use the bone cement after the application phase.

Do not use the bone cement if its consistency is inhomogeneous.

Regarding the intended patient population
Blood pressure, pulse, and breathing must be monitored carefully during and immediately after introduction of the bone cement. Any significant change in these vital signs must be resolved without delay by taking appropriate action.

Incomplete filling of the vertebral body with bone cement may result in an insufficient reduction in acute pain and reduced long-term stability of the treated vertebral body.

3 Handling
Perform mixing and application of **OSTEOPAL®V** under sterile conditions. **OSTEOPAL®V** is mixed in a mixing bowl (see 1.4 Supporting equipment).

Prior to using **OSTEOPAL®V**, consult the instructions for use of the selected supporting equipment. Make sure that the handling steps of the supporting equipment are followed adequately (see 1.4 Supporting equipment).

If **OSTEOPAL®V** is used pre-chilled, it is recommended that the bone cement components be pre-chilled at 4 °C – 7 °C for at least 24 hours. It should be removed from cooling and filled into the mixing bowl just before mixing.

The mixing, waiting, application, and setting times of **OSTEOPAL®V** are shown in the diagrams at the end of the instructions for use (see 7.1 Working times). The values are valid for application using a 3 ml single-use syringe and a cannula with a diameter of 3.0 mm and a length of 10 cm. The processing may be different for other application systems, syringe diameter, cannula length and cannula diameter.

Note: These are stated for guidance only because the application and setting times depend not only on temperature but also on mixing method used and the humidity in the operating room. The storage temperature also influences the application time. In general, higher temperatures during storage and in the operating room, higher humidity, and vigorous mixing of the bone cement lead to shorter application times and vice versa.

Apart from the handling procedure described below, **OSTEOPAL®V** must not be modified in any way. Any admixing of substances, especially aqueous (e.g., antibiotic containing) solutions, has a considerable detrimental effect on the mechanical properties of the bone cement.

OSTEOPAL®V contains the following non-sterile/sterile packaging components:

Packaging component	Condition
Powder:	
aluminum pouch	non-sterile
outer PE-paper pouch	outside: non-sterile inside: sterile
inner PE-paper pouch	sterile
Liquid:	
ampoule blister	outside: non-sterile inside: sterile
ampoule(s)	sterile

3.1 Amount required

The amount of bone cement required depends on the specific surgical intervention, on the particular anatomical conditions, on the technique being used as well as the size of the particular vertebral body and the defect.

To avoid gradual deterioration of baseline cardiovascular parameters, not more than 3 augmentations in a single operation are recommended.

At least one additional pack of **OSTEOPAL®V** should be available before commencing the operation.

3.2 Non-sterile preparation steps

Non-sterile user

- Open the folding box, take out the aluminum pouch, the ampoule blister, the instructions for use, and the set of product stickers.
- Before opening the aluminum pouch, move the content down by shaking or tapping to ensure that when the aluminum pouch is torn open at the top, the content is not damaged.
- Open the aluminum pouch and take out the outer PE-paper pouch.
- Visually inspect the outer PE-paper pouch immediately prior to use in order to determine if breaches in sterile barrier system integrity are evident. Do not use if outer PE-paper pouch is damaged.
- Break the orange sterility seal, then open the outer PE-paper pouch as shown in Figure 1, and present the sterile inner PE-paper pouch to the sterile user for sterile removal.
- Open the ampoule blister using its flap and present the sterile ampoule to the sterile user for sterile removal.

Open the outer PE-paper pouch

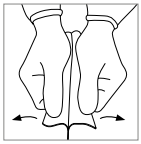


Figure 1

The opening flaps of the pouch top help to detach the foil from the paper. To maximize the area of the opening flaps that can be grasped, the side of the paper/foil should be kept between thumb, index, and middle finger. Use the whole thumb surface to grasp the foil and paper side and peel off each side evenly.

3.3 Sterile preparation steps

It is advisable to first add the liquid and then the powder. If this order is reversed, nests of unpolymerized powder are more likely to form due to polymerization commencing immediately at the surface.

Sterile user

- Remove the ampoule and open it under sterile conditions: the liquid is ready to fill into the mixing system.
- Remove the inner PE-paper pouch.
- Before opening the inner PE-paper pouch, move the content down by shaking or tapping to ensure that when the inner PE-paper pouch is cut open at the top, no powder is lost.
- Open the inner PE-paper pouch under sterile conditions: the powder is ready to fill into the mixing system.

Note: Do not open the ampoule over the mixing device to prevent contamination of the bone cement with glass fragments. To make it easier to open the ampoule, it is provided with a predetermined breaking point at the transition to the head of the ampoule.

The ampoules are provided with a snap-off device (tube) to facilitate the opening procedure. To do so, grasp the fitted snap-off device instead of the ampoule head and break off the ampoule head using the device. When the ampoule head has snapped off, it remains inside the tube.

3.4 Mixing and application

For mixing of **OSTEOPAL®V**, the instructions for use of the suitable system must be followed (see 1.4 Supporting equipment).

Mixing the powder and liquid together produces a paste that is used to fill and stabilize vertebral bodies.

Powder and liquid should only be added to the mixing system just before mixing. During the mixing time of 30 seconds, the two components are mixed with one another while stirring evenly. Always mix the entire contents of a pouch with the entire contents of an ampule of liquid.

If powder or liquid is spilled, a new package must be used.

Processing
The viscosity increases with progressing polymerization. The bone cement paste should be placed in an application system immediately after mixing because its viscosity is still low and it is easy to aspirate at this point. To prevent vascular leakage of bone cement, the bone cement should be applied when it is a paste-like consistency.

During intravertebral application, systematic real-time fluoroscopy (latero-lateral) is necessary. In the event of paravertebral cement leakage, cement injection must be immediately stopped and can be continued after the cement's viscosity has been increased. If the vertebral filling is not sufficient, additional contralateral access is viable. After augmentation, a mandrel should be inserted into the hypodermic needle so that no traces of bone cement remain in the soft tissue after removal of the hypodermic needle.

The patient must remain immobilized until the bone cement has fully set.

4 Storage, expected lifetime, transport, shelf life, sterilization

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

OSTEOPAL®V must be stored in dry conditions and must not be exposed to direct sunlight, ionizing radiation, extremes of temperature, or particulate contamination.

Expected lifetime
There is no general factor influencing the expected lifetime of **OSTEOPAL®V**. The actual lifetime of **OSTEOPAL®V** can be influenced by factors such as the medical situation and lifestyle of the patient.

Removal of the implant is not necessary unless it is clinically required. Implant removal is in the sole discretion of the responsible surgeon based on the medical condition of the patient.

Transport
Care shall be exercised during transport and handling of the **OSTEOPAL®V** to avoid any damage or alteration to the performance characteristics of the **OSTEOPAL®V** and its packaging as received. Do not remove the **OSTEOPAL®V** from the sterile packaging until immediately before use. Do not use if packaging is damaged.

Shelf life
The shelf life of **OSTEOPAL®V** is printed on the folding box. Do not use **OSTEOPAL®V** if the date indicated has expired.

Sterilization
Powder and packaging have been sterilized using ethylene oxide and the liquid by sterile filtration. The product must not be re-sterilized. Non-sterility may cause an infection in the patient. If the powder has turned yellow, do not use **OSTEOPAL®V**.

5 Disposal

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.

6 Safety and performance information

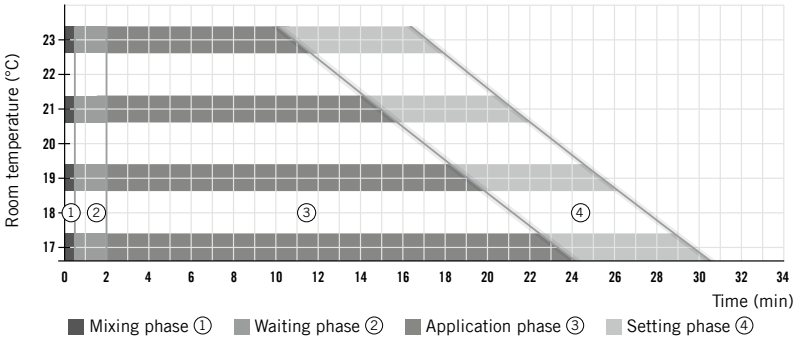
In the event of adverse events or malfunctions, contact the manufacturer via
hm.vigilance.medical@heraeus.com.

Follow the national reporting regulations in your country and also report serious events to the responsible authorities, if required.

7 Appendix

7.1 Working times

Working times for mixing without vacuum (not pre-chilled bone cement)



Test conditions: Not pre-chilled mixing bowl, 55 % humidity

Note: The working times are stated for guidance only because the application and setting times depend not only on temperature but also on mixing method used and the humidity in the operating room.

Symbols


Manufacturer

Country and date of manufacture (DE = Germany)


Use-by date

Batch code

Catalogue number

Sterilized using aseptic processing techniques

Do not resterilize


Do not use if package is damaged and consult instructions for use

Sterilized using ethylene oxide


Single sterile barrier system


Single sterile barrier system with protective packaging outside


Keep away from sunlight


Keep dry

Upper limit of temperature 25 °C (77 ° F)


Do not re-use


Consult instructions for use


Caution

Medical Device

Unique Device Identifier


Causes skin irritation


Flammable liquid

Federal law restricts this device to sale, distribution, and use by or on the order of a physician

MR safe

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