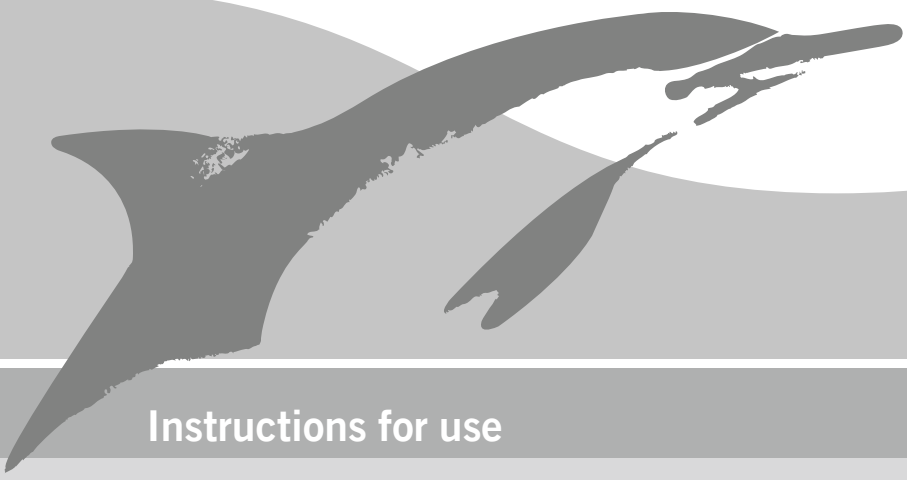
Heraeus

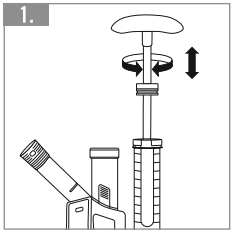
PALACOS® MV pro

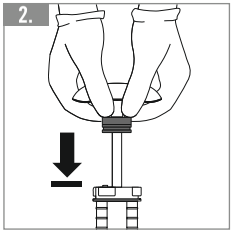
Medium-viscosity, radiopaque ready to mix bone cement

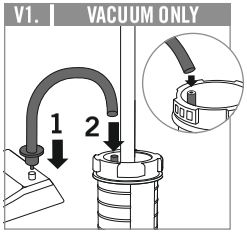


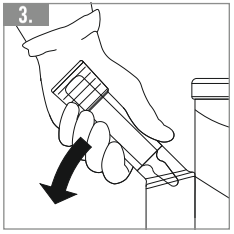
Instructions for use

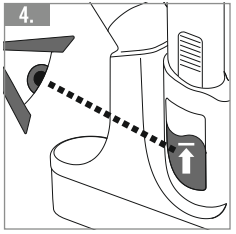
DESCRIPTION OF HANDLING STEPS STARTING ON PAGE 7

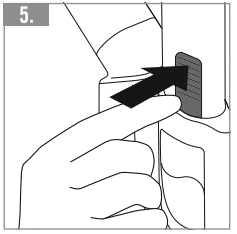


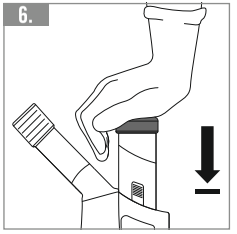


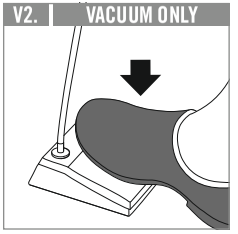


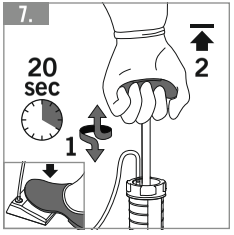


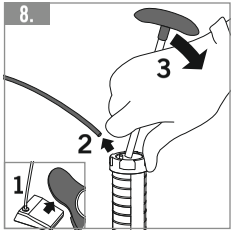


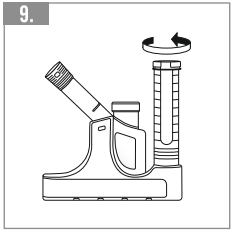


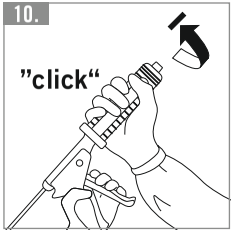


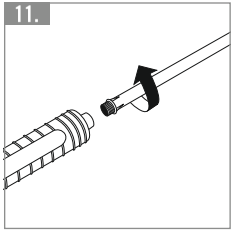


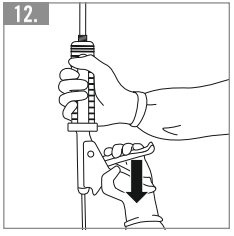


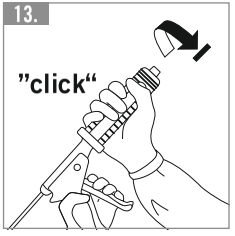


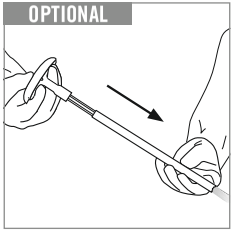


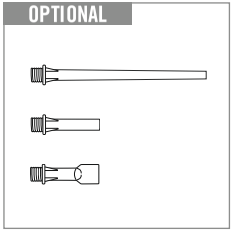


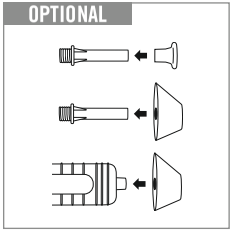












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PALACOS® MV pro

General information
Device description

PALACOS® MV pro is a standard-setting, medium-viscosity, radiopaque, poly(methyl methacrylate)-based (PMMA) bone cement, pre-filled into a mixing and application system, suitable for use with or without vacuum (ready to mix).
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). A ductile dough forms that sets within a few minutes.

Device sizes and packaging
Device sizes
PALACOS® MV pro is available in the sizes 40 and 80.

Package content
- 1 mixing and application system including 1 small or large cartridge filled with cement powder and 1 or 2 brown glass ampoule(s) filled with liquid
- 1 nozzle, long
- 1 nozzle, short
- 1 knee nozzle with spatula
- 1 femoral pressurizer
- 1 knee pressurizer
- 1 vacuum hose set with activated charcoal/sterile filter
- 1 set of patient stickers for documentation (attached to outer Tyvek)
- 1 instructions for use

Packaging design
The bone cement is triple packaged and sterilized using ethylene oxide. The protective outer blister is non-sterile on the outside and sterile on the inside and contains an inner blister with the mixing and application system. The powder is located inside the cartridge and the sterile-filtered liquid in (a) brown glass ampoule(s) within the ampoule casing of the **PALACOS® MV pro** system.

Composition

Composition	
Powder:	
PMMA copolymer	87 %
zirconium dioxide	12 %
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

PALACOS® MV pro does not contain a radiation source.

Device size	40	80
Powder	37.7 g	79.3 g
Liquid	20 ml	40 ml
Net amount of bone cement for application	44.8 g	104.2 g

The data is rounded

The mass ratio is about 32 % liquid to 68 % powder depending on the device size.

Supporting equipment
For mixing and application with **PALACOS® MV pro**, the following products from Heraeus Medical GmbH are suitable:

Article	Description	Qty	REF
Required			
PALAGUN® *if locally available*	Single-use cement gun	1	5082371
or			
PALAMIX® cement gun	Reusable cement gun	1	66036163
Optional			
PALAMIX® vacuum pump	Reusable vacuum pump with one-way valve	1	66036748
pro nozzle medium	Single-use, flexible, conical nozzle	10	66054436

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

MRI safety information
PALACOS® MV pro is MR safe.

Directions for use
Intended use
PALACOS® MV pro is a PMMA bone cement 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.

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

Indications
PALACOS® MV pro is indicated for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

Contraindications
PALACOS® MV pro must not be used in the following cases:
- suspected or proven hypersensitivity to components of the bone cement
- patients with renal impairment
- during pregnancy or breast-feeding
- children
- spinal surgery

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.
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.

Adverse events
General
Serious adverse events, some with fatal outcome, that are associated with the use of acrylic bone cements include bone cement implantation syndrome (BCIS): hypotension, hypoxia, embolism; resuscitation may be required. Rarely there is a temporary drop in blood pressure after preparation of the prosthesis bed or immediately after the implantation of bone cements and the endoprosthesis.
To avoid pulmonary or cardiovascular complications such as pulmonary embolism and cardiac arrest, it is recommended that the implantation site be irrigated thoroughly with an isotonic solution (pulse lavage application) before the bone cement is introduced. In the event 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.
The following adverse events have been observed when using PMMA bone cements: thrombophlebitis, hemorrhage, trochanteric bursitis, trochanteric separation, osteolysis due to bone cement fragments, heterotopic bone formation.
In individual cases severe complications can occur such as severe allergic reactions that are associated with pyrexia, anaphylactic shock, or even sudden death.
Other reported adverse events are myocardial infarction, brief cardiac arrhythmia, short-term cardiac conduction irregularities, cerebrovascular accident, hemorrhagic encephalitis, pain and/or loss of function of affected joint, infection, superficial or deep wound infection, hematoma, hematuria, dysuria, bladder fistula, delayed sciatic nerve entrapment, adhesions and strictures of the ileum, numbness, skin tingling, muscle twitching, convulsions.

Warnings
Regarding intended users
Caution should be exercised during the mixing of the two components of **PALACOS® MV pro** 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. However, **PALACOS® MV pro** minimizes the amount of free monomer in the operating room.
The monomer is a powerful lipid solvent and should not come into direct contact with the body. When handling **PALACOS® MV pro** 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.
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 surrounding the implant.
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. Inadequate fixation or 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 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.

Note: PALACOS® MV pro 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
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 have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds after application of bone cement. They have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest.

Precautions
Regarding intended users
Do not use **PALACOS® MV pro** after the expiration date printed on the product label that is applied to the outer Tyvek. 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.

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.
When using **PALACOS® MV pro**, the prepared bone should be carefully cleaned, aspirated, and dried just before the bone cement is placed.

Handling
A visualization of the handling is depicted on the first page of these instructions for use. Perform mixing and application of **PALACOS® MV pro** under sterile conditions. It can be mixed with or without vacuum (see Supporting equipment). Prior to using **PALACOS® MV pro**, consult the instructions for use of the selected supporting equipment. Make sure that the handling steps of the supporting equipment are followed adequately (see Supporting equipment).

Note: PALACOS® MV pro must not be pre-chilled.

The mixing, waiting, application, and setting times of **PALACOS® MV pro** are shown in the diagram at the end of the instructions for use (see Working times).

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, the **PALACOS® MV pro** system 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 (Frommelt L., 2007).

PALACOS® MV pro contains the following non sterile/sterile packaging components:

Packaging component	Condition
Powder and liquid:	
Outer blister	Outside: non-sterile Inside: sterile
Inner blister	Sterile
Cartridge	Sterile
Ampoule casing	Sterile
Ampoule/s	Sterile

Amount required
The amount of bone cement dough required depends on the specific surgical intervention and on the technique being used. At least one additional pack of **PALACOS® MV pro** should be available before commencing the operation.

Non-sterile preparation steps
Non-sterile user
- Prepare the vacuum pump for mixing “with vacuum” only (see Supporting equipment).
- Prepare the outer blister and the instructions for use.
- Open the outer blister and keep the outer Tyvek including the patient stickers.
- Present the sterile inner blister to the sterile user for sterile removal.

Sterile preparation steps

Sterile user

– Prepare a sterile cement gun and place it on a sterile, flat surface (see Supporting equipment).
– Remove the inner blister at the free corner of the outer blister under sterile conditions and keep the inner Tyvek including the pictograms if applicable.
– Remove the **PALACOS® MV pro** system and the selected accessories from the inner blister and place it on a sterile, flat surface.

The **PALACOS® MV pro** system is ready to use.

Mixing and application

Mixing the powder and liquid together in the **PALACOS® MV pro** system produces a paste that is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses generated in a movement to the bone via the large interface.
If powder or liquid is spilled, a new package must be used.
The bone cement can be applied as soon as the doughy bone cement no longer adheres to the gloves (doctor finger test). The application time depends on the temperature of the material and the room temperature. To ensure adequate fixation, the prosthesis should be introduced and held in position within the time window allowed for application until the bone cement has set completely. Remove any surplus bone cement while it is still soft.

With vacuum
Sterile user: Pictograms 1–13, V1–V2
Non-sterile user: Pictogram V1

Note: Pictograms indicated by "V" (V1, V2) are for mixing "with vacuum" only

1	– Move the mixing rod up + down once to loosen the powder and bring the mixing rod back to its initial position in the lower third of the cartridge
2	– Loosen the orange sealing ring on the mixing rod and press the sealing ring firmly into the cartridge
V1	– Take the vacuum hose and remove the paper banderole completely – Pass the end of the vacuum hose with charcoal filter to the non-sterile user and hold the other end of the vacuum hose – Non-sterile user: attach the end of the vacuum hose with charcoal filter to the vacuum pump (1) – Sterile user: connect the other end of the vacuum hose to the orange sealing ring (2)
3	– Press the ampoule casing down quickly and firmly once to break the ampoules and release the ampoule casing afterwards **Note:** Liquid flows into the middle chamber
4	– Check the liquid transfer to the middle chamber using the transparent inspection window **Note:** Transfer is completed when liquid level remains constant
5	– Push the green plunger button (above the inspection window) once and release afterwards **Note:** Button remains in this position
6	– Press the plunger down evenly until the stop edge of the plunger rests completely on the casing **Note:** Make sure that the liquid is transferred completely
V2	– Place the foot on the vacuum pump and keep the pump activated until the end of the mixing procedure. Start the vacuum pump 10 sec before mixing
7	– Move the mixing rod for at least 20 sec with rotating up and down movements (1) along the entire length of the cartridge until the liquid and powder form a homogeneous paste (approx. 1 stroke per sec) – At the end of the mixing procedure, pull up the mixing rod completely (2) and wipe off cement residues on the mixing paddle by turning it to the right and left
8	– Release the foot from the vacuum pump (1) – Remove the vacuum hose from the cartridge (2) – Pull the mixing rod up again and break it off quickly at the predetermined breaking point (3) – Keep the mixing rod for subsequent extrusion of any cement residue from the long nozzle (see Option 1)
9	– Unscrew the cartridge counterclockwise from the **PALACOS®MV pro** system
10	– Insert the cartridge into the prepared cement gun and screw it tight using a short clockwise rotation **Note:** An audible "click" confirms that the cartridge has been successfully connected to the cement gun
11	– Screw the selected nozzle onto the cartridge (see Option 2) – Combine the nozzle with a pressurizer if selected (see Option 3)
12	– Hold the cement gun in an upright position while advancing the cement – Advance the cement to the tip of the nozzle. – Doctor finger test: the cement can be applied as soon as it no longer adheres to the gloves **Note:** Comply with the processing times for the application phase
13	– Turn the cartridge counterclockwise and remove it from the cement gun **Note:** An audible "click" confirms that the cartridge has been successfully removed from the cement gun

Without vacuum
Sterile user: Pictograms 1–13

1	– Move the mixing rod up + down once to loosen the powder and bring the mixing rod back to its initial position in the lower third of the cartridge
2	– Loosen the orange sealing ring on the mixing rod and press it firmly into the cartridge
3	– Press the ampoule casing down quickly and firmly once to break the ampoule(s) and release the ampoule casing afterwards **Note:** Liquid flows into the middle chamber
4	– Check the liquid transfer to the middle chamber using the transparent inspection window **Note:** Transfer is completed when liquid level remains constant
5	– Push the green plunger button (above the inspection window) once and release afterwards **Note:** Button remains in this position
6	– Press the plunger down evenly until the stop edge of the plunger rests completely on the casing **Note:** Make sure that the liquid is transferred completely
7	– Move the mixing rod for at least 20 sec with rotating up and down movements (1) along the entire length of the cartridge until the liquid and powder form a homogeneous paste (approx. 1 stroke per sec) – At the end of the mixing procedure, pull up the mixing rod completely (2) and wipe off cement residue on the mixing paddle by turning it to the right and left
8	– Pull the mixing rod up again and break it off quickly at the predetermined breaking point (3) – Keep the mixing rod for subsequent extrusion of cement residues from the long nozzle (see Option 1)
9	– Unscrew the cartridge counterclockwise from the **PALACOS® MV pro** system
10	– Insert the cartridge into the prepared cement gun and screw it tight with a short clockwise rotation **Note:** An audible “click” confirms that the cartridge has been successfully connected to the cement gun
11	– Screw the selected nozzle onto the cartridge (see Option 2) – Combine the nozzle with a pressurizer if selected (see Option 3)
12	– Hold the cement gun in an upright position while advancing the cement – Advance the cement to the tip of the nozzle – Doctor finger test: the cement can be applied as soon as it no longer adheres to the gloves **Note:** Comply with the processing times of the application phase
13	– Turn the cartridge counterclockwise and remove it from the cement gun **Note:** An audible “click” confirms that the cartridge has been successfully removed from the cement gun

Optional
Option 1: Cement residue in the long nozzle
– Unscrew the long nozzle from the cartridge and extrude the cement residue using the sterile mixing rod

Option 2: Nozzle selection within the set
– Long nozzle, e.g., femur
– Short nozzle, e.g., knee or acetabulum
– Knee nozzle with spatula, e.g., knee

Note: The medium nozzle (flexible, conical) can be ordered separately (see Supporting equipment)

Option 3: Potential accessory combinations
– Short nozzle + knee pressurizer, e.g., knee
– Short nozzle + femoral pressurizer, e.g., femur
– Cartridge + femoral pressurizer, e.g., femur

Storage, transport, shelf life, sterilization

Storage

Storage between 4 °C (39 °F) and 25 °C (77 °F).

PALACOS® MV pro must be stored in dry conditions and must not be exposed to direct sunlight, ionizing radiation, extremes of temperature, or particulate contamination. **PALACOS® MV pro** must be brought to the temperature of the operating room at least 2 hours before use to achieve the depicted working times.

Transport

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

Shelf life

The shelf life of **PALACOS® MV pro** is printed on the product label that is applied to the outer Tyvek. Do not use **PALACOS® MV pro** 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 **PALACOS® MV pro**.

Disposal

Single components of the **PALACOS® MV pro**, set solid material as well as packaging material must be disposed of as clinical waste in compliance with local regulations. Mixed bone cement should be allowed to set before disposal with other clinical waste.

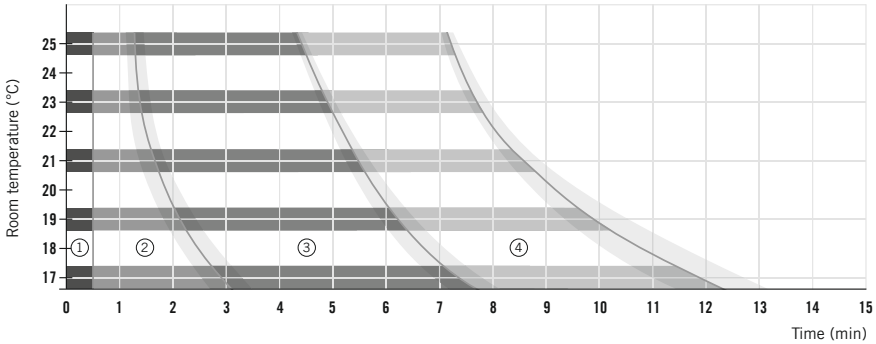
Disclaimer of liability

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

Information status: 2021-09

PALACOS® is a trademark of Heraeus Medical GmbH, Germany

Working times of PALACOS® MV pro (not pre-chilled)



Mixing phase ① Waiting phase ② Application phase ③ Setting phase ④

Test conditions: 55 % humidity.

Symbols


Manufacturer


Date of manufacture


Use-by date

Batch code

Catalogue number

Sterilized using aseptic processing techniques

Sterilized using ethylene oxide

Do not resterilize


Do not use if package is damaged


Fragile, handle with care


Keep away from sunlight


Keep dry

Storage between 4 °C (39 °F) and 25 °C (77 °F).


Do not re-use


Consult instructions for use


Caution


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

Medical Device


Single sterile barrier system with protective packaging inside

Heraeus

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PALACOS® MV pro complies with ISO 5833.