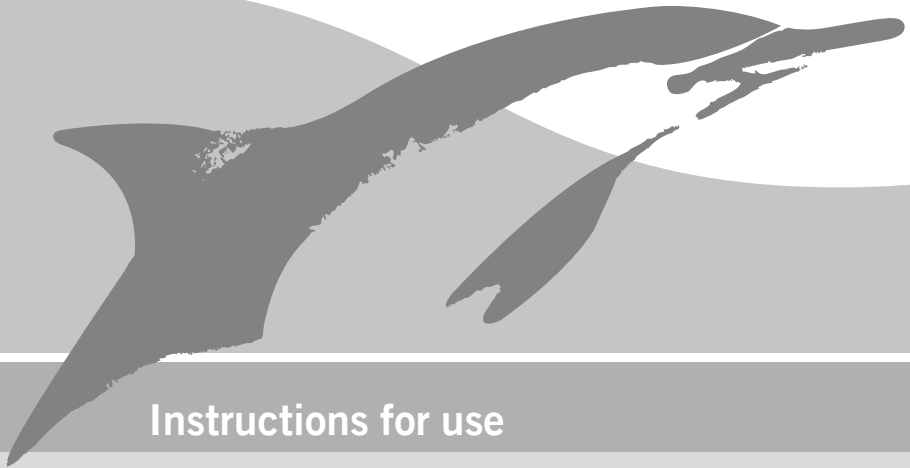


Heraeus

PALACOS® R pro

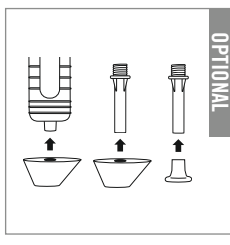
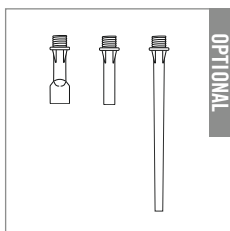
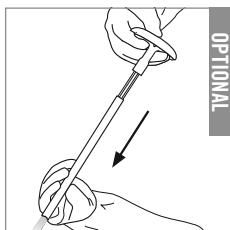
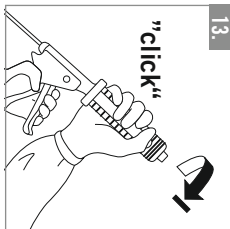
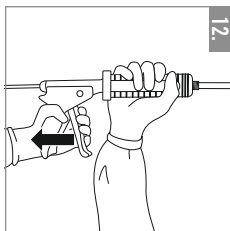
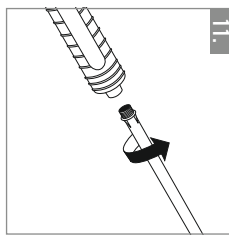
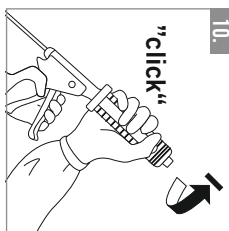
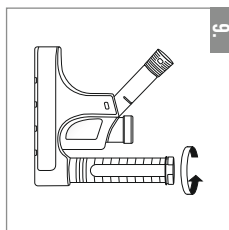
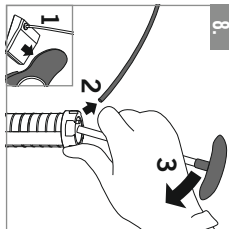
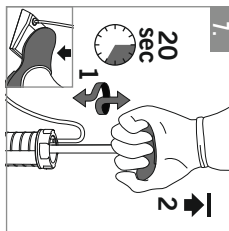
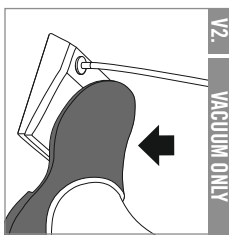
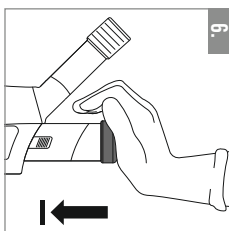
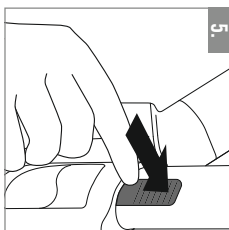
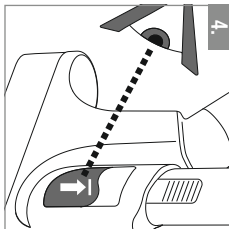
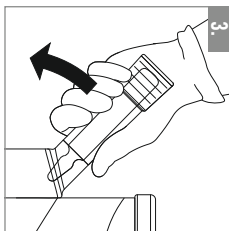
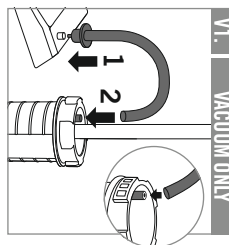
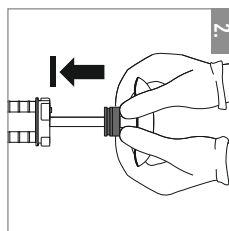
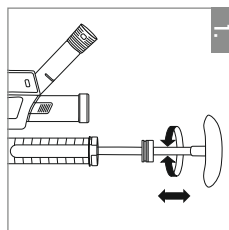
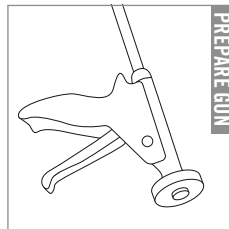
High-viscosity, radiopaque ready to mix bone cement



Instructions for use



DESCRIPTION OF
HANDLING STEPS
STARTING ON
PAGE 6



PALACOS® R pro

General information

Device description

PALACOS® R pro is a standard-setting, high-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® R 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® R pro** system.

Composition

Composition	
Powder:	
PMMA copolymer	84 %
zirconium dioxide	15 %
benzoyl peroxide	1 %
Liquid:	
methyl methacrylate	98 %
N, N-dimethyl-p-toluidine	2 %

The percentages are rounded off

Other constituents:

- Powder: Chlorophyll-copper-complex (E141)
- Liquid: Chlorophyll-copper-complex (E141), hydroquinone

PALACOS® R pro does not contain a radiation source.

Device size	40	80
Powder	34.3 g	72.2 g
Liquid	20 ml	40 ml
Net amount of bone cement for application	41.4 g	97.1 g

The data is rounded to one decimal place

The mass ratio is about 36 % liquid to 64 % powder.

Supporting equipment

For mixing and application with **PALACOS® R pro**, the following Heraeus Medical GmbH products are suitable:

Article	Description	Qty	REF
Required			
PALAGUN® <i>if locally available</i>	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® R pro is MR safe.

Directions for use

Intended use

PALACOS® R 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® R pro**. As the handling of **PALACOS® R pro** varies with temperature, humidity, and mixing technique, a test mix should be performed to ensure familiarity with its characteristics.

Indications

PALACOS® R 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® R 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, 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® R 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® R 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® R 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® R 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® R pro** 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 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® R 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® R pro** under sterile conditions. It can be mixed with or without vacuum (see Supporting equipment). Prior to using **PALACOS® R 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® R pro** must not be pre-chilled.

The mixing, waiting, application, and setting times of **PALACOS® R 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® R 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® R 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® R pro** should be available before commencing the operation.

Non-sterile preparation steps

Non-sterile user

- Prepare 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® R pro** system and the selected accessories from the inner blister and place it on a sterile, flat surface

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

Mixing and application

Mixing the powder and liquid together in the **PALACOS® R 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	<ul style="list-style-type: none">– 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	8	<ul style="list-style-type: none">– 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)
2	<ul style="list-style-type: none">– Loosen the orange sealing ring on the mixing rod and press the sealing ring firmly into the cartridge	9	<ul style="list-style-type: none">– Unscrew the cartridge counterclockwise from the PALACOS®R pro system
V1	<ul style="list-style-type: none">– 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)	10	<ul style="list-style-type: none">– Insert the cartridge into the prepared cement gun and screw it tight using a short clockwise rotation <p>Note: An audible “click” confirms that the cartridge has been successfully connected to the cement gun</p>
3	<ul style="list-style-type: none">– Press the ampoule casing down quickly and firmly once to break the ampoules and release the ampoule casing afterwards <p>Note: Liquid flows into the middle chamber</p>	11	<ul style="list-style-type: none">– Screw the selected nozzle onto the cartridge (see Option 2)– Combine the nozzle with a pressurizer if selected (see Option 3)
4	<ul style="list-style-type: none">– Check the liquid transfer to the middle chamber using the transparent inspection window <p>Note: Transfer is completed when liquid level remains constant</p>	12	<ul style="list-style-type: none">– 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 <p>Note: Comply with the processing times for the application phase</p>
5	<ul style="list-style-type: none">– Push the green plunger button (above the inspection window) once and release afterwards <p>Note: Button remains in this position</p>	13	<ul style="list-style-type: none">– Turn the cartridge counterclockwise and remove it from the cement gun <p>Note: An audible “click” confirms that the cartridge has been successfully removed from the cement gun</p>
6	<ul style="list-style-type: none">– Press the plunger down evenly until the <u>stop edge</u> of the plunger rests completely on the casing <p>Note: Make sure that the liquid is transferred completely</p>		
V2	<ul style="list-style-type: none">– 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 <u>before</u> mixing		
7	<ul style="list-style-type: none">– 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		

Without vacuum

Sterile user: Pictograms 1–13

1	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – Loosen the orange sealing ring on the mixing rod and press it firmly into the cartridge
3	<ul style="list-style-type: none"> – Press the ampoule casing down quickly and firmly once to break the ampoule(s) and release the ampoule casing afterwards <p>Note: Liquid flows into the middle chamber</p>
4	<ul style="list-style-type: none"> – Check the liquid transfer to the middle chamber using the transparent inspection window <p>Note: Transfer is completed when liquid level remains constant</p>
5	<ul style="list-style-type: none"> – Push the green plunger button (above the inspection window) once and release afterwards <p>Note: Button remains in this position</p>
6	<ul style="list-style-type: none"> – Press the plunger down evenly until the <u>stop edge</u> of the plunger rests completely on the casing <p>Note: Make sure that the liquid is transferred completely</p>
7	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – Unscrew the cartridge counterclockwise from the PALACOS® R pro system

10	<ul style="list-style-type: none"> – Insert the cartridge into the prepared cement gun and screw it tight with a short clockwise rotation <p>Note: An audible “click” confirms that the cartridge has been successfully connected to the cement gun</p>
11	<ul style="list-style-type: none"> – Screw the selected nozzle onto the cartridge (see Option 2) – Combine the nozzle with a pressurizer if selected (see Option 3)
12	<ul style="list-style-type: none"> – 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 <p>Note: Comply with the processing times of the application phase</p>
13	<ul style="list-style-type: none"> – Turn the cartridge counterclockwise and remove it from the cement gun <p>Note: An audible “click” confirms that the cartridge has been successfully removed from the cement gun</p>

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

PALACOS® R 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® R pro** to avoid any damage or alteration to the performance characteristics of the **PALACOS® R pro** and its packaging as received. Do not remove the **PALACOS® R pro** from the sterile packaging until immediately before use. Do not use if packaging is damaged.

Shelf life

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

Disposal

Single components of the **PALACOS® R 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.

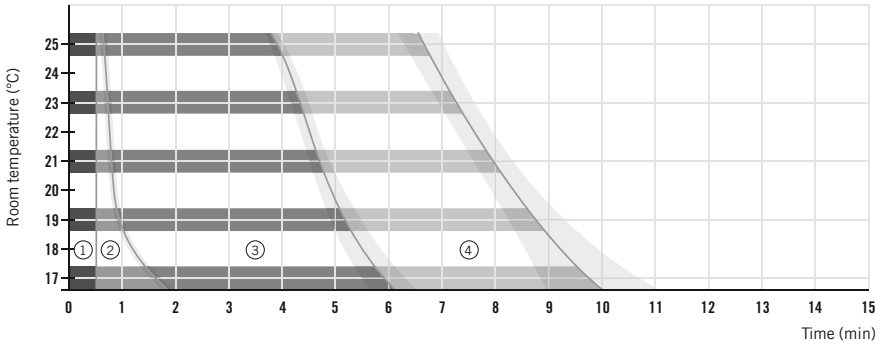
Disclaimer of liability

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

Information status: 2020-08

PALACOS® is a trademark of Heraeus Medical GmbH, Germany.























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



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

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

Symbols

	Manufacturer		Keep dry
	Date of manufacture		Storage between 4 °C (39 °F) and 25 °C (77 °F).
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		Caution
	Sterilized using aseptic processing techniques		Causes skin irritation
	Sterilized using ethylene oxide		Flammable liquid
	Do not re-sterilize		Federal law restricts this device to sale, distribution, and use by or on the order of a physician
	Do not use if package is damaged		MR safe
	Fragile, handle with care		Medical Device
	Keep away from sunlight		Single sterile barrier system with protective packaging inside

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PALACOS® is a trademark of Heraeus Medical GmbH. Made in Germany.
PALACOS®R pro complies with ISO 5833.