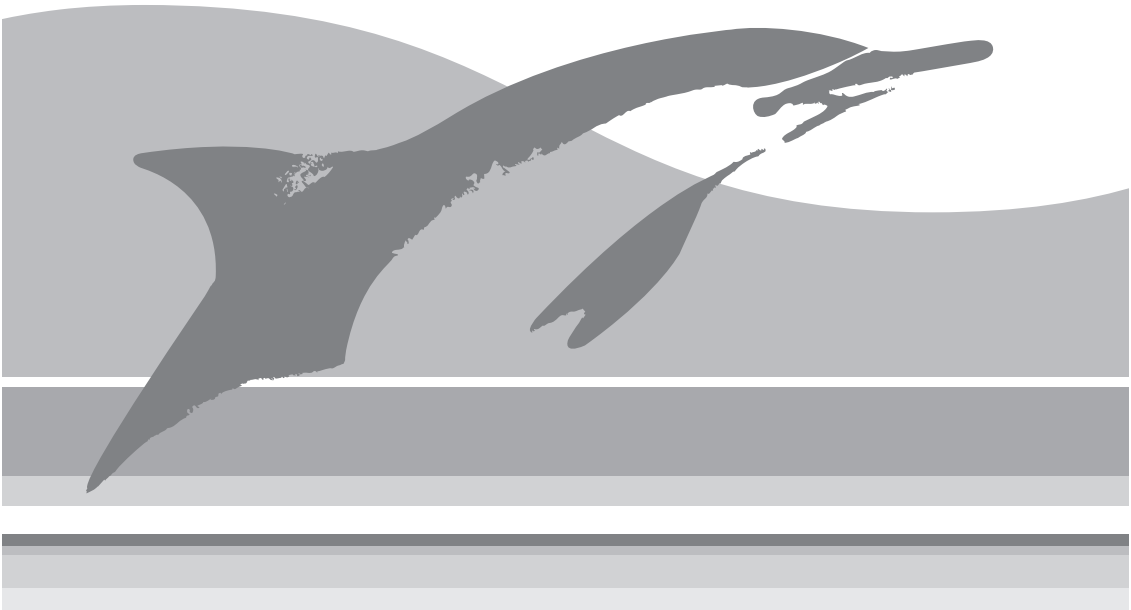
Heraeus

PALACOS®R+G

High viscosity, radiopaque bone cement with addition of gentamicin sulphate



PALACOS® R+G

66057812/06046

EN PALACOS® R+G

Properties – Composition
PALACOS® R+G is a radiopaque, quick-setting bone cement with the addition of **gentamicin sulphate** as an antibiotic. It is obtained by mixing a polymer powder component with a liquid monomer component. Zirconium oxide has been added to the cement powder as a X-ray contrast medium. The sterile-filtrated monomer component is supplied in an amber glass ampoule and comes in a sterile blister pack.
The polymer powder component is supplied in a double sterile packaging. The inner polyethylene sachet which contains the powder component is wrapped in an additional polyethylene sachet; both sachets were sterilized with ethylene oxide. The polyethylene sachets are contained in a non-sterile protective aluminium packaging.
Chlorophyll (Type E141) has been used to obtain the green colour of **PALACOS® R+G** in order to ensure clear visibility of the cement at the operating site.
After mixing, a plastic dough is obtained which is filled into the bone as an anchoring medium. The cement which then hardens in the bone allows stable fixation of the endoprostheses. The stress forces resulting from motions are transferred via the cement coating widely onto the bone.

Intended use
PALACOS® R+G is a radiopaque cement-like substance which allows the implantation and fixation of prostheses in the bone.

Indications
PALACOS® R+G is indicated for the fixation of prostheses in the bone in partial and total arthroplastic surgery of the hip, knee or other joints if an infection with gentamicin-sensitive germs is present or suspected. **PALACOS® R+G** offers protection against accumulation of gentamicin-sensitive germs on the graft and the adjacent tissue.

Contraindications
PALACOS® R+G must not be used during pregnancy or nursing. In cases of known hypersensitivity to the constituents of the bone cement **PALACOS® R+G** must not be used.
PALACOS® R+G must not be used in cases of serious renal insufficiency.

Warning information – Side effects
PALACOS® R+G has not been evaluated with regard to spinal surgery. In some cases, the use of this cement beyond the listed indications in spine surgery resulted in serious, life-threatening complications. Cases of pulmonary embolism, respiratory and cardiac insufficiency and death have been reported.
Prior to using **PALACOS® R+G** the surgeon should be familiar with its properties, handling and application during arthroplastic surgery. It is also recommended for surgeons to practice mixing, handling and application of **PALACOS® R+G** prior to use. Precise knowledge is also required, if mixing systems and syringes are used for the application of the cement. The monomer liquid is highly volatile and flammable; accordingly, suitable precautionary measures should be taken for use in the operating room. The monomer is also a powerful lipid solvent and should not come into direct contact with the body. 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-

Composition	PALACOS® R+G 1x40
	1 sachet of 40.8 g powder contains:
Poly (methyl acrylate, methyl methacrylate)	33.6 g
Zirconium dioxide	6.1 g
Benzoyl peroxide	0.3 g
Gentamicin base (as sulphate)	0.5 g
	1 ampoule with 20 ml liquid contains:
Methyl methacrylate	18.4 g
N,N-Dimethyl-p-toluidine	0.4 g
Other constituents	In the powder: colourant E141 In the liquid: colourant E141, hydroquinone

layer polyethylene, ethylene-vinyl alcohol-copolymer, polyethylene) and Viton/Butyl gloves have proven to provide good protection over an extended period. Wearing two pairs of 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 use with **PALACOS® R+G**.
The monomer vapors may irritate the respiratory tract and the eyes and possibly damage the liver. Skin irritations have been reported, which must be attributed to the contact with the monomer.
Manufacturers of soft contact lenses recommend the removal of the lenses in the presence of harmful or irritating vapors. Since contact lenses are permeable to liquids and gases, they should not be worn in the operating room if methyl methacrylate is used.

Precautionary measures
Blood pressure, pulse and breathing must be carefully monitored during and immediately after implanting the bone cement. Any significant change of these vital signs must be immediately responded to with adequate measures.
If **PALACOS® R+G** is used for a total hip endoprosthesis, the proximal part of the medullary (bone marrow) canal of the femur and the acetabulum need to be thoroughly cleaned, aspirated and dried.
To reduce the considerable increase in pressure in the intraosseous area during the implantation of the prosthesis, it is recommended to use suction drainage. If pulmonary, cardiovascular complications arise, monitoring and – in some cases – even increasing the blood volume may be required. In case of acute respiratory insufficiency, anaesthesiological measures should be taken.

Undesired effects
Frequently, a temporary drop in blood pressure immediately after the implantation of the bone cement and the endoprosthesis has been observed. Rare cases of hypotension, including anaphylactic shock, followed by cardiac arrest and sudden death have been reported.
The following, additional undesired effects of the use of methyl methacrylate bone cement have been observed: Thrombophlebitis, superficial wound infection, deep wound infection, pulmonary embolism, haemorrhage and haematoma, trochanter bursitis, loosening or displacement of the prosthesis, trochanter detachment.
Other side effects observed: heterotopic bone regeneration, myocardial infarction, temporary cardiac arrhythmia, cerebrovascular accident. When using gentamicin, the typical side effect of this antibiotic may occur, in particular damage to hearing and renal damage. The occurrence of this side effect, however, is unlikely due to the very low serum level.

Interactions
When administering muscle relaxants and ether, the neuromuscular blocking properties of the gentamicin may be reinforced; the occurrence of this side effect, however, is unlikely due to the very low serum level.

Incompatibilities
Aqueous solutions (e.g containing antibiotics) must not be added to the bone cement since they considerably impair the mechanical properties of the cement.

Dosing and preparation
A single dose is prepared by mixing the entire content of a powder sachet with one ampoule. The quantity to be used depends on the respective surgical operation and the technique employed. Before the beginning of the operation, at least one additional dose of **PALACOS® R+G** should be readily available. Each dose is prepared separately.
The following is required to prepare the bone cement:
Sterile working surface, porcelain or stainless steel bowls, sterile mixing spoons or porcelain or stainless steel spatulas or a sterile vacuum mixing system.
The protective aluminium packaging, the outer non-sterile polyethylene sachet and the blister pack of the ampoules should be opened by an assistant in a way to maintain sterility. The sterile polyethylene sachet and the ampoule are placed under aseptic conditions on a sterile table. Sterile conditions must be ensured when opening the polyethylene sachet and the ampoule.

Application
Two different methods can be used for mixing:
Manual mixing
Mixing under vacuum

Manual mixing
The liquid is poured into a bowl and the powder is added. Do not open the ampoule over the mixing device to prevent contamination of the cement with glass fragments. Then the mixture is stirred carefully for 30 sec.
If the dough-like mass no longer sticks to the rubber gloves, it can be processed. The application time depends on the material and room temperature. If the required consistency is obtained, the cement can be applied. To ensure adequate fixation, the prosthesis should be implanted and stabilized within the given time until the bone cement has hardened completely. Surplus cement must be removed as long as it is still soft.
If additional cement is needed during the operation, another sachet of powder can be mixed with one ampoule of liquid as described above. The kneadable mass which is obtained must be applied to the previously applied cement before it hardens. It is always required to mix the entire content of a sachet with the entire content of an ampoule.

Mixing under vacuum
To obtain a bone cement with reduced porosity, the components are mixed under vacuum after pre-chilling (at least 24 h at 4–7 °C). For this purpose an airtight closed system and rapid build-up of sufficient vacuum in the mixing equipment are required (absolute pressure: approx. 200 mbar). The stirring times for mixing under vacuum and mixing without vacuum are identical (30 sec). Processing and hardening times are extended due to pre-chilling. For details of the mixing method refer to the instructions of the mixing system used.

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

Shelf life/Sterility
The shelf life is 3 years. The expiration date is printed on the folded box, the protective aluminium packaging and the inner sachet. **PALACOS® R+G** must not be used after the expiration date. The contents of unused but opened or damaged packs must be discarded and must not be resterilized. **PALACOS® R+G** has been sterilized with ethylene oxide gas and must not be resterilized. The polymer powder must not be used if it exhibits yellow discoloration.

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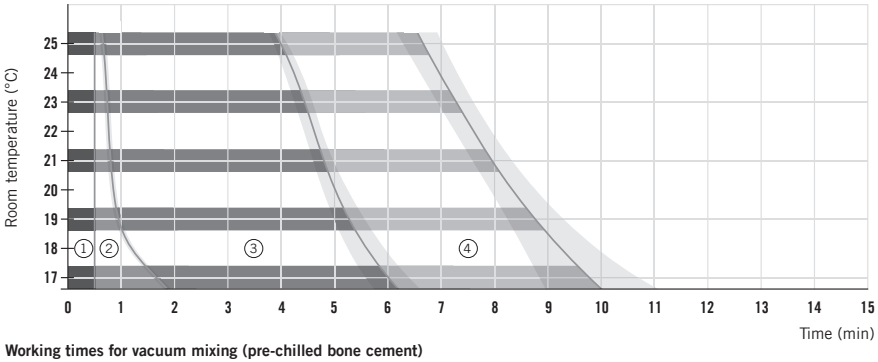
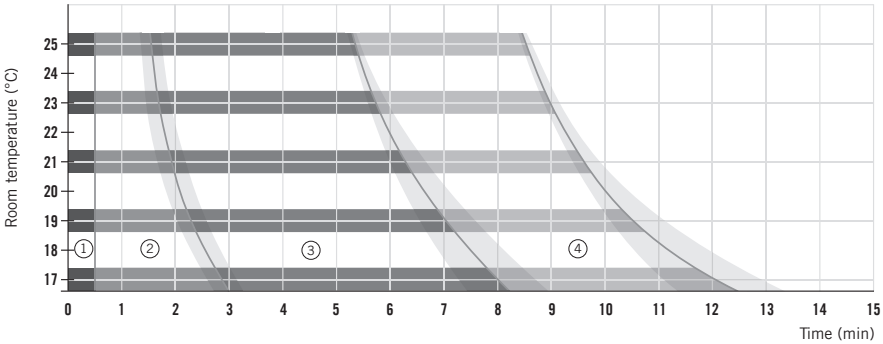
License number: CFDA (I)20113651064（更）
Product Standard: YZB/GER 3880-2010

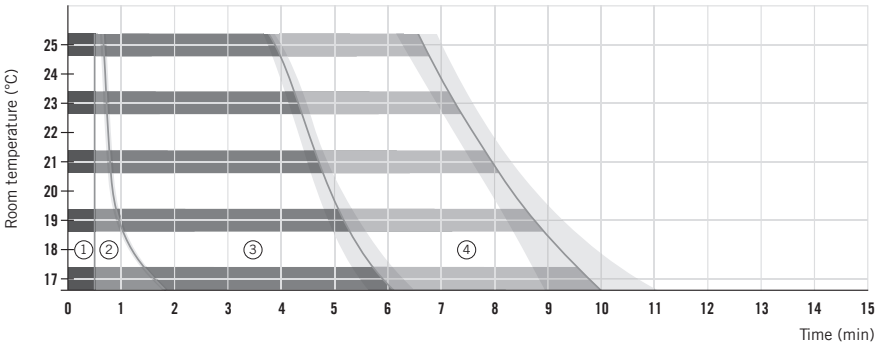
Working times for manual mixing (not pre-chilled bone cement)



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



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



Mixing ① Waiting ② Application ③ Setting ④

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

ZH PALACOS® R+G

性质-成分

PALACOS® R+G为一种不透辐射的快凝骨水泥，其中加有作为抗生素的硫酸庆大霉素。其制备方法为将一聚合体粉末状成分与一液状单体成分相混合。氧化锆已被作为X线造影剂加入该骨粉。该经无菌过滤的单体成分供货时以琥珀玻璃安瓿瓶装，外加有无菌泡罩包装，其经环氧乙烷灭菌。即在一个内层聚乙烯小袋中装粉末状成分，在其外再包一个聚乙烯小袋，这两个小袋均已用环氧乙烷灭菌。在这两个小袋外加有非无菌保护性铝包装。

叶绿素(索引号:E141)被用来使**PALACOS® R+G**变成绿色，以使该水泥在手术区域上清晰可见。

混合后，形成了一种面团状可塑物质，其被作为锚固剂注入骨。该水泥然后在骨内固化，从而使内假体被稳定地固定住。在活动时产生的压应力通过水泥层被大面积地施加于骨上。

使用意图

PALACOS® R+G为一种不透辐射的水泥状物质，其有助于将假体植入并固定于骨内。

适应症

PALACOS® R+G适用于有庆大霉素敏感性微生物感染存在或疑似存在的情况下，在进行部分或全部的髋、膝或其它关节的造形术时对骨中的假体起固定作用。 **PALACOS® R+G**可防止移植物或相邻组织上感染庆大霉素敏感性微生物。

禁忌症

在怀孕期或哺乳期禁用**PALACOS® R+G**。并在已知对骨水泥**PALACOS® R+G**的成分过敏的病例中禁用。严重肾功能不全者禁用**PALACOS® R+G**。

警示信息—副作用

未在脊椎手术方面对**PALACOS® R+G**做过评价。在针对上述适应症之外的病症的脊椎手术中使用该水泥可导致严重的危及生命的并发症，已有肺栓塞、呼吸功能不全、心功能不全乃致死亡的报道。

在使用**PALACOS® R+G**之前，外科医生应熟悉其在关节造形术中的性质、处理方法和应用。建议外科医生在使用**PALACOS® R+G**之前，练习混合、处理和施用。如果在施用

成分	PALACOS® R+G 1x40
	每小袋中的40.8 g粉中含有:
聚（丙烯酸甲酯、甲基丙烯酸甲酯）	33.6 g
二氧化锆	6.1 g
过氧苯甲酰	0.3 g
庆大霉素碱（以硫酸盐）	0.5 g
	每安瓿瓶中的20 ml 液体中含有:
甲基丙烯酸甲酯	18.4 g
N,N-二甲基-对甲苯胺	0.4 g
其它成分:	在粉中：着色剂 E141； 在液体中：着色剂 E141、对苯二酚。

水泥时使用混合系统和注射器，需要了解详尽的有关知识。单体液体具有高度的挥发性和易燃性，因此在手术室内应采用适当的预防措施。该单体液也是强脂溶剂，不应与身体直接接触。当用处理单体液或水泥时，应戴上手套以充分地防止单体（甲基丙烯酸甲酯）渗入皮肤。由三层聚乙烯、乙烯-乙烯醇共聚物、聚乙烯和氟橡胶(Viton®)/丁基制成的手套经长时间的检验，已被证明可提供充分的保护。戴两副手套也已被证明可提供充分的保护。但必须避免仅戴乳胶或聚苯乙烯-丁二烯手套。请要求您的手套供应商确认有关手套是否适用于**PALACOS® R+G**。

单体汽可刺激呼吸道和眼，可能对肝造成损害。已有因与单体接触而引起的皮肤炎症的报道。

软性隐形眼镜的生产厂家建议在有害或刺激性汽体存在的情况下去除镜片。因为液体和气体可渗透过隐形眼镜的镜片，如使用甲基丙烯酸甲酯，不得在手术室内戴隐形眼镜。

预防措施

应在植入骨水泥时或紧接植入水泥后仔细监测血压、脉搏和呼吸。如果这些生命标志有任何显著的变化，必须立刻采取适当的措施。

如果将**PALACOS® R+G**用于全髋内假体，需要将大腿骨和髋臼的髓管的近端部分彻底清洗，并吸出液体然后将其干燥。在植入假体时，为了降低骨内相当大的压力增加，建议使用抽吸引流。如果发生肺、心血管并发症，需要监测血量，在一些病例中甚至可能需要增加血量。在急性呼吸功能不全的情况中，应采取麻醉措施。

不良反应

经常在植入骨水泥和内假体后立即观察到暂时的血压降低。据报道在一些少见的病例中有伴随过敏性反应的血压过低，这些过敏性反应包括过敏性休克、心跳骤停和骤死等。

下列使用甲基丙烯酸甲酯骨水泥后产生的其它不良反应已被观察到：

血栓性静脉炎、表面伤口感染、深度伤口感染、肺栓塞、出血和血肿、转子粘液囊炎、假体松动与移位和转子脱离。观察到的其它副作用：异位成骨、心肌梗塞、短暂性心律不齐和脑血管事件。在使用庆大霉素时，可能会发生该抗生素的典型副作用，特别的损害为听力和肾损害。但该副作用的发生不是因为过低的血清水平。

相互作用

服用肌肉弛缓药和乙醚后，庆大霉素的神经肌肉阻滞作用可被加强；但该副作用的发生不可能是因为过低的血清水平。

不亲和性

勿将水溶液（例如含抗生素的）加入骨水泥，因为这些水溶液会相当大地损害水泥的力学性质。

剂量和制备

将一装粉的小袋中全部内容物与一个安瓿内的液体相混合以制备一剂。使用剂量取决于相应手术和所采用的技术。在手术开始前，必须准备至少一剂备用的**PALACOS® R+G**。每一剂应单独制备。

下列为制备骨粉所需要的条件：

无菌工作台面、瓷或不锈钢碗、无菌搅拌勺、瓷或不锈钢调药刀或一无菌真空混合系统。

应由助手以保持无菌的方法打开保护性铝包装、外层非无菌聚乙烯小袋和安瓿的泡罩包装。无菌聚乙烯小袋和安瓿应在无菌条件下放置地无菌工作台上。并应保证在无菌状况下打开聚乙烯小袋和安瓿。

施用

两个不同的方法可用于混合，

手动混合；

真空下混合。

手动混合

将液体倾倒入碗中，再加入粉。请勿在混合设备上方打开安瓿，以防骨水泥被玻璃碎片污染。然后仔细地搅拌混合物30秒。

当面团状物质不再粘在橡胶手套上，可对其进行加工。施用持续时间取决于材料和室温。当达到需要的稠度后，可以施用该水泥。为了保证充分地固定假体，必须在一定的时间内将其植入并使其保持固定，直到骨水泥彻底固化。必须将溢出的骨水泥在其未凝固前清除。如果在操作中需要额外的水泥，将另一小袋中的粉与一安瓿中的液体如上述混合。将得到的可揉性物质在其变硬前加入已施用的水泥中。必须总是将一个小袋中的全部内容物与一个安瓿中的全部内容物混合。

真空下混合

为了得到多孔性较低的骨水泥，将骨水泥成分在真空下混合。为了这个目的，必须有一个气密性系统，并在混合系统中快速建立足够的真空（绝对压力：约200 mbar）。在真空下混合的搅拌时间(30 s)与非真空下混合的相同。混合方法详见所采用的混合系统的使用说明。

储存

勿储存在高于25 °C (77 °F)的温度下。

储存期/无菌状态

该产品有效期三年。过期日期被印在折叠的盒、保护性铝包装和内层小袋上。过期后，**PALACOS® R+G**不能使用。未使用过的、但已打开或损坏的包装必须丢弃，不能再对其灭菌。聚合体粉如已呈黄色，不能再使用。

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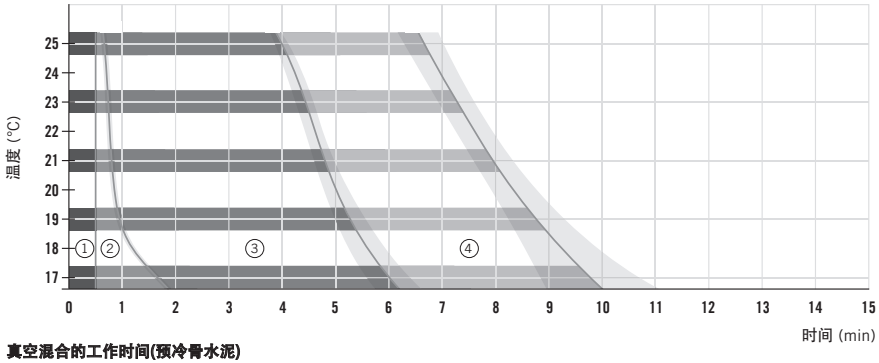
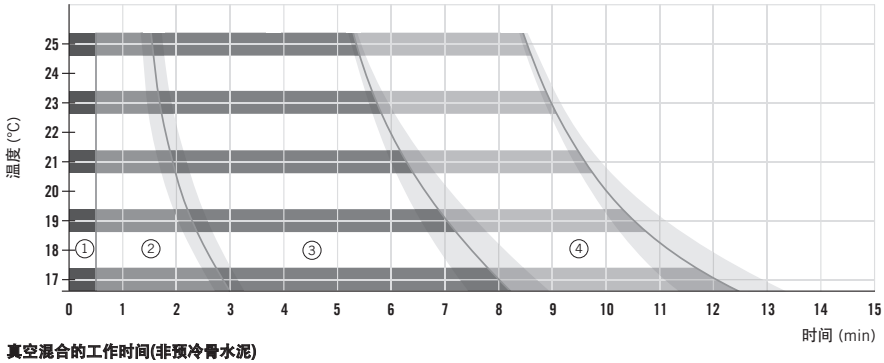
售后服务机构：雷德睦华医药科技（北京）有限公司
地址：北京市丰台区马家堡东路106号2号楼6层606室
电话：010-58031636
传真：010-58031636转804
医疗注册号：国食药监械（进）字2011第3651064号（更）
注册产品标准编号：YZB/GER 0761-2011

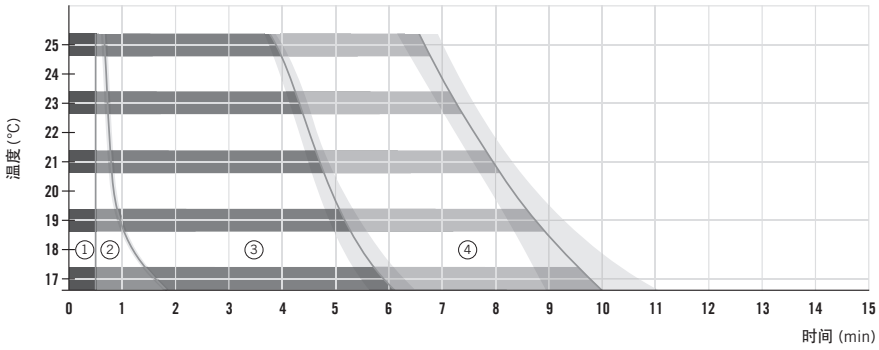
手动混合的工作时间(非预冷骨水泥)



真空混合的工作时间(预冷骨水泥)



真空混合的工作时间(非预冷骨水泥)



搅拌期 ① 粘丝期 ② 面团期 ③ 固化期 ④

测试条件：未预冷，使用PALAMIX真空混合 55% 湿度

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

Catalogue number


Use by date

Batch code


Flammable liquid – Flashpoint 10 °C


Causes skin irritation

Heraeus

EN Do not use if the product sterilization barrier or its packaging is compromised.
ZH 若发现无菌环境遭破坏或包转破损，则禁止使用。

REF 66055102

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