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Caution: Federal law restricts this device  
to sale by or on the order of a dental professional.

**CE 0197**



**MD**  
Medizinprodukt  
Medical device  
Dispositif médical  
Producto sanitario  
Dispositivo medico  
Medisch hulpmiddel  
Iatropotéchnický průstředek  
Zdravotnický prostředek  
Medicinski proizvod

## **GB Instructions for use Paladon® 65**

Medical Device – for use by dental health care professionals only.

### Intended purpose

This dental material is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.

Kulzer medical devices ensure the rehabilitation of oral functions such as chewing, speaking and aesthetics. They stabilize the remaining dentition and/or the alveolar ridge restoratively or prosthetically.

### Product description

Denture acrylic for full dentures, heat-curing acrylic.

Paladon 65 consists of a powder component in a range of colours (pink, pink veined, R50 veined, clear) and liquid.

For use in pack and press technique, and also injection technique for fixed and removable dentures.

### Composition

**Main powder component:**  
Poly(methyl methacrylate)

**Main liquid components:**  
Methyl methacrylate, dimethacrylate

Paladon 65 is cadmium-free.

Contains benzoyl peroxide.

### Process and indications

**Pack and press technique:**

- partial dentures

- full dentures

### Contraindications

Direct lining with Paladon 65 is contraindicated. The use of this product is contraindicated in case of known or suspected allergies against components of this product. Do not use in case of known or suspected allergy against (meth) acrylate compounds or benzoyl peroxide.

### Side effects

This product or one of its components may in particular cause hypersensitivity reactions. If suspected, information on the ingredients can be obtained from the manufacturer. Hypersensitivity reactions (allergies), local sensory disturbances, taste disturbances and irritation of the oral mucosa have been described in isolated cases. After processing, all MMA/PMMA-based denture materials always contain a permitted, small proportion of residual monomer (< 4.5 %). For further risk reduction of intolerance reactions, the denture has to be stored in tepid water for at least 12 hours before placement.

**Handling**

A hard stone (type 3) is sufficient for investment of the prosthesis set up in wax. After wax elimination with boiling water, the plaster is thinly isolated with Aislar® twice (see Aislar Instructions for Use). To improve the bond between Paladon 65 and the prefabricated teeth, the basal surfaces are roughened with a coarse diamond bur (remove grinding dust) and wetted with Palabond®. Apply Palabond® twice using a brush (without metal ferrule) and allow to set for 30 seconds each time. After the second application; the adhesive remains active for 10 minutes.

**Pack and press technique**

The recommended ratio of powder to liquid is 10 g : 4 ml or a multiple thereof. Place the required volume of liquid in the stirring beaker and, holding at an angle and simultaneously rotating and tapping the stirring beaker, rapidly sprinkle powder into the liquid. Mix thoroughly for about 30 seconds and leave to set for about 15 minutes in the covered stirring beaker. The material has reached its optimum consistency when it can easily be removed from the wall of the stirring beaker and is no longer sticky. A setting time of about 15 minutes at about 23°C (73°F) and about 30 minutes for processing is standard.

Place the dough with excess in the cuvette, slowly close under a press at intervals and leave under pressure for about 10 minutes. If pieces are thick, add small amounts of dough. Cuvette temperature should be between room temperature and 45°C (131°F).

**Polimerización**

Paladon 65 can be processed by the short-term method, the Kulzer water bath method or the long-term polymerisation method. Kulzer water bath polymerisation is recommended.

Pressure is always required via the flask handle to keep the prosthesis free of bubbles. In addition, the pressure of the polymerisation device can be switched on.

**Rapid boiling method**

With this method it is a requirement to keep the flask for 15 minutes at 80°C (176°F).

First place the flask in 90°C (194°F) warm water and leave for at least 20 minutes at 90°C (194°F), then let the flask cool down slowly in the handle. Place thick dentures also in 90°C (194°F) warm water. Shut off heat source and wait for 20 minutes, then 20 minutes at 90°C (194°F) afterwards leave to cool slowly in the water bath.

**Long-term water bath**

Place flasks in cold water and polymerise at 90°C (194°F) for 10 hours. Cool down slowly in the water bath.

**Trimming and polishing**

After cooling and re-occlusion the prosthesis is carefully removed from the model and trimmed with cross-toothed cutters.

Before polishing with pumice, the prosthesis is smoothed with sandpaper of decreasing grit size.

**Reparación**

The heat-curing Palä prosthetic resins from Kulzer can be restored, added to and repaired with all cold-curing Palä prosthetic resins.

**Storage advice**

Do not store above 25°C (77°F). Do not use the material after expiry date. Avoid direct exposure to sun. Reseal carefully after removing product.

**Handling**

A hard stone (type 3) is sufficient for investment of the prosthesis set up in wax. After wax elimination with boiling water, the plaster is thinly isolated with Aislar® twice (see Aislar Instructions for Use). To improve the bond between Paladon 65 and the prefabricated teeth, the basal surfaces are roughened with a coarse diamond bur (remove grinding dust) and wetted with Palabond®. Apply Palabond® twice using a brush (without metal ferrule) and allow to set for 30 seconds each time. After the second application; the adhesive remains active for 10 minutes.

**Polymerización**

Paladon 65 puede prepararse en baño maría, en baño maría Kulzer o por polimerización a largo plazo. Se recomienda utilizar la polimerización en baño maría Kulzer. Se requiere presión constante a través de la prensa de la mufa para evitar la aparición de burbujas en la prótesis. Además, puede conectarse la presión de la unidad de polimerización.

**Polimerización rápida**

Este método consiste en mantener la mufa al menos durante 15 min a 80°C (176°F).

Se sumerge la mufa en agua caliente a 90°C (194°F) y se polimeriza durante 20 min a 90°C (194°F). Luego se deja enfriar lentamente la mufa cerrada en su prensa. Las prótesis de mayor espesor también se sumergen en agua caliente a 90°C (194°F), interrumpir el calentamiento y esperar 20 minutos, después se polimeriza durante 20 minutos a 90°C (194°F), posteriormente dejar enfriar lentamente en el agua maría.

**Polimerización en baño maría, según Kulzer**

Sumerger la cubeta en al menos 3 litros de agua caliente a 70°C (158°F), cubriendo completamente la cubeta en el agua. Mantener esa temperatura durante 90 minutos, luego llevar la baño maría a ebullición y mantener la temperatura de cocción durante al menos 30 minutos. Dejar enfriar lentamente en el baño maría!

**Polimerización en tiempo prolongado**

Colocar las mufas en la cuba de calefacción tibia de agua y polimerizar a 90°C (194°F) durante 10 horas. Dejar enfriar lentamente la cuba con la agua.

**Acabado y pulido**

Tras enfriarse y la reoclusión, la prótesis se extrae con cuidado del modelo y se trata con fresas dentadas en cruz.

Antes de proceder al pulido con piedra pómez, la prótesis se alisa con papel esmerilado de granulado fino.

**Procesamiento**

Para el revestimiento de prótesis moldeadas en cera es suficiente un yeso duro de tipo 3. Después de extraer la cera, el yeso se alisará con dos capas delgadas de Aislar® (véase las instrucciones de uso de Aislar®). Para mejorar la unión entre Paladon 65 y los dientes artificiales, las superficies basales se han de raspar con una fresa de diamante gruesa (retirar los restos de polvo de metal) y humedecer con Palabond®. Aplicar Palabond® das veces con un pincel (sin borde de metal) y

después con una fresa de grano fino.

**Gebrauchsanweisung**

Recomendación: Eliminación de hiper sensibilidad a las normativas vigentes. No desechar el contenido ni los envases con restos de producto en la basura doméstica ni el alcantarillado. Lista europea de residuos: 180106 Productos químicos que consisten en, o contienen, sustancias peligrosas.

**Hojas de datos de seguridad y más información**

Están disponibles en nuestro sitio web [www.kulzer.com](http://www.kulzer.com)

**Revisione: 2021-05**

### General information

Please, carefully observe the following safety instructions and all processing notes in other sections.

This product is intended to be used only in accordance with this Instructions for Use. Any use of this product inconsistent with these instructions is at the discretion and sole responsibility of the dental health care professional.

### Warnings and safety instructions

May cause skin and eye irritation. Avoid contact with skin. Skin contact may cause sensitization. Wear suitable protective gloves. In case of contact with skin, immediately wash with plenty of water and soap. Avoid contact with eyes. In case of contact with eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms persist, consult an eye specialist. Highly flammable liquid and vapour. Flash point: 10°C. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources - no smoking. May cause respiratory irritation. Avoid breathing dust/fume/gas/mist/vapours/spray. Toxic to aquatic life with long lasting effects.

### Application notes

Examine the integrity of the primary packaging before first use. Damaged products must not be used. When positioning teeth in wax, do not use alcohol based separating agents (separation of gypsum and wax), as this may cause white discolouration on the basal surface of the prosthesis.

**Disposal information**

Recommendation: Dispose of in accordance with official regulations. Do not dispose of contents or partially emptied packaging in the household waste or allow them to enter the sewage system. European Waste Catalogue: 180106 Chemicals consisting of or containing hazardous substances.

### General information

Place the cuvette in at least three liters of hot water at 70°C (158°F) with the cuvette completely covered with water. Maintain this temperature for 90 minutes, then bring the water bath to the boil and maintain at boiling point for at least 30 minutes. Allow to cool down slowly in the water bath.

### General information

Place the cuvette in cold water and polymerise at 90°C (194°F) for 10 hours. Cool down slowly in the water bath.

### General information

After cooling and re-occlusion the prosthesis is carefully removed from the model and trimmed with cross-toothed cutters.

Before polishing with pumice, the prosthesis is smoothed with sandpaper of decreasing grit size.

### General information

The heat-curing Palä prosthetic resins from Kulzer can be restored, added to and repaired with all cold-curing Palä prosthetic resins.

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