# Instructions for use
# & technical data
# product group CopraTemp

CE 0483

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|---|---|
| **Manufacturer** | Whitepeaks Dental Solutions GmbH & Co. KG<br>Langeheide 9 - 45239 Essen – Germany |
| **Product/ Product type** | PMMA blanks for temporary or permanent restorations and splints |
| **Product form** | Discs or blocks in different sizes and colours |
| **Material type** | Polymethylmethacrylate (PMMA)<br>– polymer-based crown and veneering material (type II, class 1)<br>– medical device class IIa |
| **Circle of users** | Instructed users, who produce individual dental restorations/ splints |

**Indication/ intended use**
CopraTemp is exclusively suitable for the production of dental products.

CopraTemp is intended for use in the oral cavity for short or long terms.
The tooth coloured products CopraTemp A1 – D4 and CopraTemp Symphony A1 – D4 are suitable for the production of temporary crowns, bridges, inlays, onlays, etc., which are later replaced by permanent prostheses. A permanent application in the oral cavity is also possible.
CopraTemp Base is pink and is used for the production of denture bases.
CopraTemp Clear is colourless and is used for splints.

**Contraindication**
Do not use in case of proven hypersensitivity against one of the components.

**Material properties/ technical data**

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| composition | PMMA (polymethylmethacrylate) / pigments |
| flexural strength (Weibull) | ~ 113 MPa |
| water absorption | ~ 20 bis 23 µg/mm$^3$ |
| solubility | < 1 µg/mm$^3$ |
| Vickers hardness | ~ 26,6 HV |
| e-module | ~ 2771 MPa |

**Instructions for use**
Burs for acrylic materials are recommended. Polishing is possible with polishing paste and soft hair brushes. Pay attention not to overheat the material.

In the occlusal region the minimum wall thickness must be 1,0 mm and 0,6 mm in the cervical region. The connector profile has to be minimum 10mm$^2$ in anterior region and minimum 15mm$^2$ in the posterior region. In the posterior region max. two pontics are allowed.

**Veneering:**
All standard veneering materials, that are suitable for PMMA

**Safety instructions**
Warning: The dust produced during processing of this product may cause irritation to skin/ eyes/ respiratory system. Avoid inhalation/ contact with skin/ contact with eyes. Always wear respiratory protection (filter class FFP2), tightly fitting safety goggles, protective gloves and protective clothing and switch on suction device.

**Storage**
Protect from heat and direct sunlight. Store in the original packaging.

 
as of: 25.11.2020

**Disposal**
Dispose of product and packaging in accordance with local/ regional/ national/ international regulations.

**Notice**
Any serious incident, that has occurred in relation to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

**Explanation of the markings on the packaging**

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|---|---|
| REF | Symbol for „article number“ |
| LOT | Symbol for „LOT number“ |
| CE 0483 | Confirmation: The product complies with the applicable European directives. |
|  | Symbol for „number of products in package“ |
|  | Symbol for „follow the instructions for use“ |
| MD | Symbol for „is a medical device“ |
|  | Symbol for “production date” |
| **Rx only** | Symbol for “Caution: US Federal law ristricts this device to sale by or on the order of a licensed physician or dentist.” |