

|                              |   |
|------------------------------|---|
| <b>Manufacturer</b>          | Whitepeaks Dental Solutions GmbH<br>Alfredstr. 81 - 45130 Essen - Germany |
| <b>Product/ Product type</b> | Presintered co/cr blanks to produce individual dental restorations        |
| <b>Product form</b>          | Discs in different sizes with frames                                      |
| <b>Material type</b>         | Cobalt/ chrome alloy (type 4) – medical device class IIa                  |
| <b>Circle of users</b>       | Instructed users who produce individual dental restorations               |

**Indication/ intended use**

CopraSintec Evo K is exclusively suitable to produce dental products.

CopraSintec Evo K is a medical device intended for the fabrication of dental prostheses for temporary or long-term use, which are partially introduced into the human body by means of a clinical intervention, but in this case are inserted into the teeth or attached to the tooth structure with suitable luting material and are thus classified as class IIa.

**Indication**

- anatomical reduced copings and pontics in anterior and posterior area
- bridges up to 14 units or bridges with small diameters
- primary and secondary telescopic crowns
- clasps, bars, and retention constructions
- full anatomical crowns and bridges in anterior and posterior area
- restorations with small diameters which are exposed to high forces
- free end bridge constructions with maximum 1 pontic
- supra constructions for implant cases
- removable prosthesis

CopraSintec Evo K is a type 4 co/cr alloy. Therefore, it has no indication restriction compared to hard milled or cast type 4 co/cr alloys.

**Contraindication**

Do not use in case of proven hypersensitivity against the alloy or one of its components.

**Veneer ceramics**

Co/cr veneering porcelain

**Material properties/ technical data**

|                     |            |  |                             |
|---------------------|------------|--|-----------------------------|
| <b>Composition:</b> |            | <b>Technical data (after final sintering):</b> |                             |
| <b>Co</b>           | Balance    | <b>yield strength 0,2%</b>                     | 480 MPa                     |
| <b>Cr</b>           | 26,5 – 30% | <b>elongation at break in percent</b>          | 22%                         |
| <b>Mo</b>           | 4,5 – 7%   | <b>contraction at break in percent</b>         | 16%                         |
| <b>Mn</b>           | 0 – 1%     | <b>elasticity modulus</b>                      | 178 GPa                     |
| <b>Fe</b>           | 0 – 1%     | <b>tensile strength</b>                        | 864 MPa                     |
| <b>Si</b>           | 0 – 1%     | <b>density</b>                                 | 7,59 g/cm <sup>3</sup>      |
| <b>C</b>            | 0 – 0,35%  | <b>corrosion resistance</b>                    | < 200 µg/cm <sup>2</sup>    |
| <b>others</b>       | < 1%       | <b>tarnish resistance</b>                      | ja                          |
|                     |            | <b>Vickers hardness</b>                        | 224 HV1                     |
|                     |            | <b>coefficient of thermal expansion</b>        | 14,26 x 10 <sup>-6</sup> /K |

### **Specification**

CopraSintec Evo K blanks are isostatically pressed and presintered blanks made from biocompatible co/cr alloy for dental restorations. They are made of an extremely fine powder, first axially pressed, then each blank is isostatically repressed and goes through a debinding and presintering process. So, the debinding process in the argon sintering furnace is not needed any more and the sintering cycle can be shortened. Another advantage is the higher stability of the material, the wall thickness can be reduced, and the handling is much easier as the hardness is nearly equal to zirconia. To protect the material, the frame is a little wider than the material thickness of the blank.

Due to the manufacturing process of powder alloys, all disadvantages of cast alloy blanks can be eliminated. Cast blanks often tend to be inhomogeneous and have crystalline structures and hard dendrites within their microstructure. This is caused by the large amount of molten alloy cooling down, forming these imperfections.

CopraSintec Evo K blanks have an absolute homogeneous microstructure. They are easy to mill, and the wear of the burs is minimal. CopraSintec Evo K Blanks can be milled wet or dry.

### **Instructions for use**

#### **Processing of frameworks**

CopraSintec Evo K blanks can be milled with all dental CAD/CAM milling machines.

The dust from the milled material is extremely fine. Please check with your machine manufacturer if your machine is suitable for this material. Please follow the safety rules.

As the material is of firm and milling stable consistency, the burs for non-precious metal or zirconia can be used together with the corresponding milling strategy. The sintering shrinkage factor is printed onto the label on the side of the blank and your milling system must be adjusted accordingly.

#### **Milling**

Restorations of 5 units or more only require a sintering support if they are very curved. From 6 units on, a sintering support is necessary. Please connect every unit or at least every second unit with the sintering support.

The thickness of the sintering support should be 1,5mm, the diameter of the connectors 1,4mm. Units at the end of the restoration should always be connected to the sintering support (please see illustrations).



## Instructions for use & technical data CopraSintec Evo K



|                                 |        |
|---------------------------------|--------|
| minimum thickness:              |        |
| wall thickness single copings   | 0,4 mm |
| margin thickness single copings | 0,2 mm |
| wall thickness bridges          | 0,5 mm |
| margin thickness bridges        | 0,2 mm |

|                                       |                    |
|---------------------------------------|--------------------|
| bridges posterior region:             |                    |
| diameter connections                  | 9 mm <sup>2</sup>  |
| extension at bridges                  | maximum 1          |
| diameter connection extension pontics | 12 mm <sup>2</sup> |

|                          |                   |
|--------------------------|-------------------|
| bridges anterior region: |                   |
| diameter connections     | 6 mm <sup>2</sup> |

### Removal of frameworks

After the milling process has finished, the restoration must be removed from the blank.

If you cut one connector after the other, it might happen, that a crown or coping breaks because of the connector size of 1,4mm, as the connector is thicker as the wall thickness of the crown. To avoid that, please cut first all connectors 50% to create a predetermined braking point. So, when you come to the last connector it will break instead of the wall of your restoration.

### Sintering

The restoration is cleaned of dust and milling residues by carefully brushing it clean. Then place the objects in your sintering tray. They must not touch each other or the wall of the sintering tray, as they would melt into each other or the wall during sintering. Place the objects inside the sintering beads so that only the margins show out. There must be no sintering beads inside the crowns or in interdental areas as they would hinder the shrinking. Pontics or bar constructions should not be submerged in the sintering beads but show at the surface to avoid a heat spot.

The heating, sintering and cooling process should run on full automatic. Please follow the instructions and manual of your sintering furnace. After cooling down of the furnace to 50°C the restoration can be removed from the furnace.

- ▶ heating speed 15°C/ min
- ▶ final temperature approx. 1280°C
- ▶ holding time at final temperature 60 min
- ▶ cooling unregulated to 800°C, then with compressed air in closed furnace

Please note that the CopraSintec Evo K restoration will develop a brownish grey oxide surface. Please clean it by sand blasting with aluminium oxide (grain size 110 µm) at a pressure of 2-3 bar.

Make sure before sintering that your argon bottle contains enough gas, that all tubes are free from leaks and if your sintering crucible, tray, and bowls are clean and their surfaces residue free. ZrO<sub>2</sub> sintering beads will colour grey under argon gas. This is a normal and wanted effect.

In case of a faulty sintering cycle without or with not enough argon gas, the sintering beads will turn white again. Your restoration will look burned and have a very dark blue or green oxide. The restoration also might not fit well on your model. The restoration cannot be resintered as the oxide is inside all particles. It must be milled and sintered again.

After a cycle with no or insufficient argon gas, a full sintering cycle with argon gas must be run without a restoration.

If the sintering beads are again grey after sintering, you can use the furnace again like normal. If your sintering beads stay white, check the argon bottle, all connections and all connection surfaces of sintering trays, lids, bowls, plate etc.

Maybe also you exchanged the sintering beads to  $Al_2O_3$  instead of  $ZrO_2$  by mistake. If the problem persists, please contact the furnace manufacturer.

### **Veneering with ceramic**

Basically, all commercial veneering porcelains can be used. Please follow the instructions for use of your chosen veneering porcelain manufacturer and the coefficient of thermal expansion specified therein for compatibility.

The minimum thickness of the prepared coping should not be less than 0.3 mm. It's recommended to sandblast the frames with minimum 110  $\mu m$  of aluminium oxide with 3-4 bar and clean with steam cleaner. Oxide firing is not mandatory but can be done as an option for 5 minutes at 980 °C with vacuum (cleaning firing). The frame needs to be sandblasted with aluminium oxide with about 110  $\mu m$  and 3-4 bar to remove the present oxide layer thoroughly. In the end the cleaning by steam cleaner is mandatory. If you use a ceramic bonder, please consider the instructions for use of the manufacturer.

### **Soldering**

We recommend a chrome cobalt soldering metal for soldering. CopraSintec Evo K frames should not be soldered with gold or palladium solders. CopraSintec Evo K is easy to weld with a dental laser.

### **Safety instructions**

Warning: Contains cobalt (Co). The dust produced during processing of this product may cause cancer if inhaled, may damage fertility and is suspected of causing genetic defects. Always observe the following safety precautions.

Always wear respiratory protection (filter class FFP3), tight-fitting safety goggles, protective gloves and protective clothing and always switch on extraction equipment with filter class Hepa H. Do not inhale dust. Avoid contact with skin, mouth, eyes and clothing. Do not eat or drink while working. Keep away from food and beverages. Wash hands after use. Remove contaminated clothing and protective equipment before entering areas where food will be eaten. Keep away from sources of ignition. Do not smoke.

### **Storage**

No special storage conditions. Store in the original packaging.

### **Disposal**

Dispose of product and packaging in accordance with local/ regional/ national/ international regulations. Do not dispose of together with household waste. Do not allow to enter water, ground water or sewage system.

### **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**



Symbol for „article number“



Symbol for „LOT number“



Confirmation: The product complies with the applicable European directives.



Symbol for „number of products in package“



Symbol for „follow the instructions for use“



Symbol for „is a medical device“



Symbol for “production date”

**Instructions for use  
& technical data  
CopraSintec Evo K**



**RX only**

Symbol for "Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist."