Instructions for use & technical data CopraSintec K

CE 0483

Manufacturer	Whitepeaks Dental Solutions GmbH & Co. KG Langeheide 9 - 45239 Essen - Germany
Product/ Product type	Presintered co/cr blanks for the production of individual dental restorations
Product form	Discs and blocks in different sizes, partly with frames or holders
Material type	Cobalt/ chrome alloy (type 4) – medical device class IIa
Circle of users	Instructed users who produce individual dental restorations

Indication/ intended use

CopraSintec K is exclusively suitable for the production of dental products.

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 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

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

Specification

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

Instructions for use

Processing of frameworks
CopraSintec 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 instructions.

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 has to 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).

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^2
extension at bridges	maximum 1
diameter connection extension pontics	12 mm^2
bridges anterior region:	
diameter connections	6 mm^2

Removal of frameworks
After the milling process has finished, the restoration has to 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 K restoration will develop a brownish grey oxide surface. Please clean it by sand blasting with aluminium oxide (grain size110 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_2 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 has to be milled and sintered again.

After a cycle with no or insufficient argon gas, a full sintering cycle with argon gas has to 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 µm 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 µm 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 K frames should not be soldered with gold or palladium solders. CopraSintec 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, may reduce fertility and may probably cause genetic defects. Inhalation may cause allergies, asthma-like symptoms or breathing difficulties. Avoid inhalation/ contact with skin/ contact with eyes. Always wear respiratory protection (filter class FFP3), tightly fitting safety goggles, protective gloves and protective clothing and always switch on suction equipment with filter class Hepa H.

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”
RX only	Symbol for “Caution: Federal law ristricts this device to sale by or on the order of a licensed physician or dentist.”