Instructions for use & technical data CopraEasyMill NP

CE 0483

Manufacturer	Whitepeaks Dental Solutions GmbH Alfredstr. 81 - 45130 Essen – Germany
Product/ Product type	Sintered, hard Co/Cr blanks for the production of individual dental restorations
Product form	Discs in different sizes
Material type	Cobalt/ chrome alloy (type 4) - medical device class IIa
Circle of users	Instructed users who produce individual dental restorations

Indication/ intended use

CopraEasyMill NP is exclusively suitable for the production of dental products.

CopraEasyMill NP 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

CopraEasyMill NP is a type 4 co/cr alloy.

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:	
Co	balance
Cr	26,5 – 30%
Mo	4,5 – 7%
Si	0 – 1%
Mn	0 – 1%
Fe	0 – 1%
C	0 – 0,35%
others	< 1%

Technical data:	
yield strength 0,2%	475 MPa
tensile strength	731 MPa
elongation at break %	11%
contraction at break %	14%
elasticity modulus	186 GPa
densitiy	7,8 g/cm^3
corrosion resistance	< 200 µg/cm^2
coefficient of thermal expansion	13,74 x 10^{-6}/K
Vickers hardness	220 HV1
tarnish resistance	yes

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Specification

CopraEasyMill NP blanks are isostatically pressed and hard sintered 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. After that they go through a debinding process before being sintered to their final hardness.
No sintering process has to be done by the user.

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.

CopraEasyMill NP blanks have an absolute homogeneous microstructure. They are easy to mill and polish. After milling they are adjusted and polished normally and can be veneered or over pressed with porcelain or ceramics.
CopraEasyMill NP Blanks can be milled wet or dry.

Instructions for use

Processing of frameworks

CopraEasyMill NP blanks can be milled with all dental CAD/CAM milling machines suitable for co/cr milling.
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Removal of frameworks

Cut out and smoothen the surfaces of milled frameworks with carbide burs or separating discs. Please use the same rotating instrument only for one alloy to avoid contamination.

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. CopraEasyMill NP frames should not be soldered with gold or palladium solders. CopraEasyMill NP 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.

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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

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 restricts this device to sale by or on the order of a licensed physician or dentist.”