Instructions for use & technical data product group CopraTi



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Manufacturer Whitepeaks Dental Solutions GmbH

Alfredstr. 81 - 45130 Essen - Germany

Product/ Product type CopraTi-4 pure titanium blanks

CopraTi-5 titanium alloy grade 5 ELI blanks for the production of individual dental restorations

Product form Discs in different sizes

Material type Pure titanium grade 4 – medical device class lla

Titanium alloy grade 5 ELI – medical device class IIa

Circle of users Instructed users who produce individual dental restorations

Indication/ intended use

CopraTi is exclusively suitable for the production of dental products.

CopraTi is a medical device intended for the fabrication of dental prostheses intended for 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 by means of cement and are therefore classified as class IIa.

Indication

CopraTi-4

Single crowns, medium bridges and bar constructions in anterior and posterior region and superstructures

CopraTi-5

Single crowns up to big bridges and bar constructions in anterior and posterior region and superstructures

CopraTi is a type 4 material in accordance with DIN EN ISO 22674.

CopraTi is in accordance with DIN EN ISO 22674 free of nickel, cadmium, beryllium and lead.

Contraindication

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

Veneer ceramics/ composites

Veneering porcelains/ composites, that are suitable for titanium

Material properties/ technical data

composition	CopraTi-4	CopraTi-5
titanium (Ti)	≥ 99%	≥ 90%
iron (Fe)	max. 0,50%	max. 0,25%
aluminium (Al)	-	5,5 – 6,5%
vanadium (V)	-	3,5 – 4,5%
carbon (C)	max. 0,08%	max. 0,08%
nitrogen (N)	max. 0,05%	max. 0,05%
oxygen (O)	max. 0,40%	max. 0,13%
hydrogen (H)	max. 0,0125%	max. 0,012%

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mechanical properties	CopraTi-4	CopraTi-5
density	~ 4,51 g/cm ³	~ 4,43 g/cm ³
Vickers hardness	~ 180 - 210 HV10	~ 341 HV10
coefficient of thermal expansion	~ 8,7 * 10 ⁻⁶ /K	~ 9,7 * 10 ⁻⁶ /K
yield strength	min. 483 MPa	min. 780 MPa
tensile strength	min. 550 MPa	min. 860 MPa
elongation at break	min. 15%	min. 10%
reduction of area	min. 30%	min. 15%

Specification

CopraTi is a biocompatible nickel-, cadmium-, bryllium- and lead-free titanium milling blank, which has been especially configurated for the requirements of the CAD/CAM technique. The material is characterized by its good machinability and homogeneity as well as unrestricted laserability.

Instructions for use

Milling

The desired restoration is milled from the selected blank.

Removal of frameworks

Cut out and smoothen frameworks and single elements with cross-toothed hard metal milling burs or cutting discs. Please always use the same rotating instruments for one metal to avoid contamination.

Cleaning

Finalize frameworks with a hard metal milling bur suitable for titanium. Work only in one direction to avoid blistering during the firing of the veneering porcelain due to overlapping metal.

Then sandblast the surfaces clean aluminum oxide (110μ) with 2-3 bar pressure and steam clean or dip in methylalcohol. Never use hydrofluoric acid.

Veneering with ceramic

Basically all commercial veneering porcelains suitable for titanium 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.

Safety instructions

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

The titanium chips produced can easily ignite during dry machining. Keep ignition sources away. Do not smoke. Avoid accumulation of chips.

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.

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Explanation of the markings on the packaging

REF	Symbol for "article number"
LOT	Symbol for "LOT number"
C € ₀₄₈₃	Confirmation: The product complies with the applicable European directives.
	Symbol for "number of products in package"
<u> </u>	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."