Instructions for use & technical data product group Copran

(CopranZri, CopraSupreme, CopraSmile, CopraSupreme Hyperion)

CE 0483

Manufacturer	Whitepeaks Dental Solutions GmbH & Co. KG Langeheide 9 - 45239 Essen – Germany
Product/ Product type	Presintered zirconium dioxide blanks for the production of individual dental restorations
Product form	Discs and blocks of different sizes, colors and translucencies, partly with holder/ frame
Material type	ZrO_2 (yttrium oxide-stabilized, tetragonal zirconium dioxide) / Ceramic type 2, class 5 (exception: CopraSmile products ceramic type 2, class 4) medical device class IIa
Circle of users	Instructed users who produce individual dental restorations

Indication/ intended use

Copran Zri, CopraSupreme:
Crowns and bridges up to 16 units with max. 2 pontics between 2 crowns in the posterior region, with max. 4 pontics between 2 crowns in the anterior region, veneers, inlays, onlays, primary telescopes, bar constructions

CopraSupreme Hyperion:
Crowns and bridges up to 16 units with max. 2 pontics, veneers, inlays, onlays, primary telescopes, bar constructions

CopraSmile:
Crowns and bridges up to 3 units in the anterior or posterior region, veneers, inlays, onlays, primary telescopes, bar constructions

From Copran materials full anatomic restorations as well as copings and pontics are manufactured, that can be layered with porcelain after sintering.

Contraindication
Do not use in case of proven hypersensitivity against one or several contents.
Do not use in case of insufficient space.

Veneer ceramics
All ZrO_2 ceramics

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Material properties/ technical data (standard after final sintering)

	Copran Zri **Copran Zri Ultra Bleach**	**Copran Zri A1 – D4** **Copran Zri Light, Medium, Intense**	**Copra Supreme** **Copra Supreme Ultra Bleach**	**CopraSupreme A1 – D4** **CopraSupreme Joy Five - Nine** **CopraSupreme A Group - D Group** **CopraSupreme Bleach 0M1 – 0M3** **CopraSupreme Symphony A1 – D4** **CopraSupreme Symphony Bleach 0M1 – 0M3** **CopraSupreme Symphony Joy Five - Nine**	**CopraSupreme Hyperion A1 – D4** **CopraSupreme Hyperion Bleach 0M1 – 0M3** **CopraSupreme Hyperion Joy Five - Nine**	**CopraSmile** (up to 3 links in the anterior or posterior region)	**CopraSmile A1 – D4** **CopraSmile Joy Five - Nine** **CopraSmile A Group – D Group** **CopraSmile Bleach 0M1 – 0M3** **CopraSmile Symphony A1 – D4** **CopraSmile Symphony Joy Five - Nine** (up to 3 links in the anterior or posterior region)
ZrO_2	Balance	Balance	Balance	Balance	Balance	Balance	Balance
Y_2O_3	4,95 – 5,35 %	4,95 – 5,35 %	6,93 – 6,97 %	6,413 – 6,914 %	6,413 – 9,155 %	9,32 %	8,358 % – 9,155 %
Al_2O_3	0,15 – 0,35 %	0,15 – 0,35 %	0,04 – 0,06 %	0,038 – 0,062 %	0,038 – 0,062 %	0,049 %	0,046 % – 0,054 %
Fe_2O_3	0 – 0,01 %	0,04 – 0,25 %	0 – 0,01 %	0,010 – 0,151 %	0,010 – 0,151 %	0 – 0,002 %	0,015% – 0,142 %
ER_3O_3	0 %	0 %	—	0 – 0,564 %	0 – 0,626 %	0 %	0 – 0,626 %
CO_3O_4	0 %	0 %	—	0 – 0,008 %	0 – 0,009 %	0 %	0 – 0,009 %
other oxides	0 – 0,06 %	0 – 0,06 %	0 – 0,02 %	0 – 0,020 %	0 – 0,020 %	0 – 0,002 %	0 – 0,004 %
density g/cm³	6,05	6,05	6,07	6,07 – 6,33	6,046 – 6,33	6,046	6,046 – 6,33
flexural strength	≈ 1400 MPa	≈ 1250 - 1400 MPa	≈ 1100 MPa	≈ 1008 – 1100 MPa	≈ 1008 – 1100 MPa	≈ 600 MPa	≈ 600 – 641 MPa
coeffi-cient of thermal expansion (25°C-500°C)	10,5 +/- 0,5 x 10^{-6}/K	10,5 +/- 0,5 x 10^{-6}/K	10,5 +/- 0,5 x 10^{-6}/K	10,5 +/- 0,5 x 10^{-6}/K	10,5 +/- 0,5 x 10-6/K	10,5 +/- 0,5 x 10^{-6}/K	10,5 +/- 0,5 x 10^{-6}/K

Instructions for use
The desired restoration is milled from the selected blank:

Copran Zri, CopraSupreme, CopraSmile:
The wall thickness must not be less than 0.5mm for anterior teeth and 0.6mm for posterior teeth. The connection between two interconnected anterior crowns must not be less than 8mm^2. The connection between an anterior crown and a bridge element, two interconnected posterior crowns or two anterior bridge elements must not be less than 9mm^2. The connection between a posterior crown and a pontic or two posterior pontics must not be less than 12mm^2. The cross-section of a bar construction must not be less than 15mm^2.

CopraSupreme Hyperion:
The wall thickness must not be less than 0.8mm for anterior teeth and 1.0mm for posterior teeth. The connection between two interconnected anterior crowns, the connection between an anterior crown and a bridge element, two interconnected posterior crowns or two anterior bridge elements must not be less than 9mm^2. The connection between a posterior crown and a pontic or two posterior pontics must not be less than 12mm^2. The cross-section of a bar construction must not be less than 15mm^2. The margin/ dentin part of the blank is always 50% of the total blank height. The connection therefore must always be placed in the lower half of the blank to insure sufficient bending strength.

These specifications always refer to the dimensions to all zirconia after the final sintering process.

The enlargement or shrinkage factor is indicated on the blank, depending on the milling system used.

The unsintered restorations may still be adjusted. To achieve a perfect surface and maximum translucency, we recommend cleaning the restoration in the "White-Sonic" ultrasonic cleaning device and distilled water. Please use only our recommended ultrasonic cleaning device. Equipment from other companies could be too "strong" and damage the restoration. Swivel the restoration with plastic tweezers in the distilled water of the ultrasound device for 5 to 10 seconds until no "dust cloud" separates from the restoration. Remove excess water from the restoration by blowing off with oil-free air or by dry-dabbing with cellulose or cotton swabs. Dry the restoration under an infrared lamp or using an oven. Make sure it is completely dry. Insure, that the water never reaches boiling temperature during the drying process, as that could cause cracks.

If colouring is desired, this can be done with the corresponding liquids from the Copran Color Group. Please also refer to the instructions for use.

The finished, completely dry restoration, can be sintered now.

Sintering
To achieve maximum transparency of the material, please do not use a speed program.

	Normal Program	**Slow Program**	**Translucency Program**	**Speed Program**
Heating rate	10° per minute to 950°C	5°C per minute to 950°C	5°C per minute to 950°C	50°C per minute to 1100°C
Holding time	none	none	none	none
Heating rate	6°C per minute to 1500°C	2°C per minute to 1500°C	2°C per minute to final temperature	20°C per minute to 1500°C
Holding time	at final temperature 90 minutes	at final temperature 120 minutes	at final temperature 120 minutes	at final temperature 30 minutes
Final temperature	1500°C	1500°C	1500°C - 1630°C	1500°C
Cooling	unregulated in the closed furnace	unregulated in the closed furnace	unregulated in the closed furnace	unregulated in the closed furnace

Post-processing
After final sintering the restoration is adapted to the working model using a wet grinding process with diamond-coated grinding media, if necessary. Sintered diamonds, corundum stones or carbide cutters must not be used. Overheating must be avoided.

Firing the ceramic
All commercially available layering ceramics for zirconium dioxide frameworks can be used. Please observe the working instructions of the respective ceramic manufacturer.
Firing and cooling according to the firing table of the manufacturer of the layering ceramic material used.

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
Dry Storage. Protect from moisture / humidity. 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: US Federal law ristricts this device to sale by or on the order of a licensed physician or dentist.”