

<b>Manufacturer</b>	Whitepeaks Dental Solutions GmbH & Co. KG Langeheide 9 - 45239 Essen - Germany
<b>Product/ Product type</b>	PEEK blanks for the production of individual dental restorations
<b>Product form</b>	Discs and blocks in different diameters and colours
<b>Material type</b>	Polyetheretherketone (PEEK) - medical device class IIa
<b>Circle of users</b>	Instructed users, who produce individual dental restorations

#### **Indication/ intended use**

CopraPEEK is exclusively suitable for the production of dental products.

CopraPeek is suitable for the production of permanent, removable, respectively partly removable (screw-retained) dental prosthesis. This means, that with the described material crowns, bridges, partials, abutments, secondary structures for combined dental prostheses, implant-supported full crowns in the posterior region and partly removable, screw-retained bridges can be realised.

#### **Contraindication**

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

#### **Material properties/ technical data**

##### composition

PEEK (polyetheretherketone), modified

##### Technical data

flexural strength (Weibull)	186,6 MPa
water absorption	4,66 µg/mm <sup>3</sup>
solubility	-0,1 µg/mm <sup>3</sup>

#### **Instructions for use**

CopraPeek has to be processed with carbide burs. The milled restoration has to be cut out of the milling blank with a coarse toothed carbide bur. The retaining bars have to be cut without applying pressure. The restorations can be polished with suitable silicone polishers, goat hair brushes and suitable polishing paste (diamond particle).

Minimum wall thickness:	0,6mm
Connector cross-section in the anterior region:	10 mm <sup>2</sup>
Connector cross-section in the posterior region:	16 mm <sup>2</sup>

The posterior region is limited to 2 pontics.

#### **Cementation**

A composite primer (Ambarino P60 Creamed, Visio.link Bredent, Z-Prime Plus Bisco) is applied to the inner surface of the crown, which has been sandblasted with 220 µm. The primer establishes a safe compound between CopraPeek and the adhesive composite.

#### **Veneering**

All standard veneering materials, that are suitable for PEEK

**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**

Store cool and dry. Store in the original packaging.

**Disposal**

Dispose of product and packaging in accordance with local/ regional/ national/ international regulations.

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