

<b>Manufacturer</b>	Whitepeaks Dental Solutions GmbH Alfredstr. 81 - 45130 Essen - Germany
<b>Product/ Product type</b>	PA blanks for the production of splints
<b>Product form</b>	Discs in different diameters
<b>Material type</b>	Polyamide (PA) - medical device class IIa
<b>Circle of users</b>	Instructed users, who produce individual dental splints

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

CopraDur is exclusively suitable for the production of dental products.

Indication:

CopraDur is certified for use in the oral cavity and can remain in the mouth temporarily or permanently.

CopraDur Splint is clear and is suitable for the production of splints.

#### **Contraindication**

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

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

<b>composition CopraDur Splint (transparent)</b>		<b>technical data</b>	
polyamide (PA)	100%	flexural strength (Weibull)	72,8 MPa
		water absorption	31,7 µg/mm <sup>3</sup>
		solubility	-3,5 µg/mm <sup>3</sup>

#### **Instructions for use**

For milling CopraDur, uncoated, single edged PMMA milling burs should be used.

The milling strategy of your CAD/CAM equipment should be modified, as the material has a different impact strength for example from PMMA. Polishing paste should only be used with a soft polishing brush. Please make sure not to overheat the material during polishing. Work only with low rotation speed.

For an optimal milling result with our material we recommend the following parameters:

PMMA milling bur single edged: 2mm milling bur – feed rate: 25mm/s spindle speed: 16.000 rpm

PMMA milling bur single edged: 1mm milling bur – feed rate: 19mm/s spindle speed: 22.000 u/m

PMMA milling bur double edged: 2mm milling bur – feed rate: 25mm/s spindle speed: 8.000 u/m

PMMA milling bur double edged: 1mm milling bur – feed rate: 19mm/s spindle speed: 11.000 rpm

Air- or water cooling is advantageous during milling. It is recommended to cool the material with water while polishing.

Occlusal und cervical wall thickness should not be less than 0.3 mm.

#### **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

**Instruction for use  
& technical data  
product group CopraDur  
(CopraDur Splint)**



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.

**Storage**

Protect from heat and direct sunlight. 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 restricts this device to sale by or on the order of a licensed physician or dentist.”