

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



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

composition CopraDur Splint (transparent)		technical data	
polyamide (PA)	100%	flexural strength (Weibull)	72,8 MPa
		water absorption	31,7 $\mu\text{g}/\text{mm}^3$
		solubility	-3,5 $\mu\text{g}/\text{mm}^3$

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

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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.”