CE 0483

SRN: DE-MF-000021120

Basis UDI-DI: ++EWPDCKPOEK

CopraPoly FLEX

Whitepeaks Dental Solutions GmbH • Weikenrott 17 • 46499 Hamminkeln • Germany • +49 281 2064580

Instructions for use

Product/ Product type
PCT-G blanks for the fabrication of flexible occlusal splints

Material type
Copolyester (PCT-G), colourless/ clear
Class IIa medical device
Thermoplastic material type 3 according to DIN EN ISO 20795-2

Users
Professional users who produce customised dental occlusal splints, therapeutic splints, bite regulators and drilling templates.

Target group
Patients of all ages and genders who require customised dental splints/bite regulators.

Indication / Intended use
CopraPoly FLEX is a class IIa medical device intended for the manufacture of an invasive product, namely occlusal splints, therapeutic splints, bite regulators and drilling templates, which is intended for long-term use in the oral cavity up to the pharynx and cannot be absorbed by the mucous membrane.

Contraindication
Do do not use in case of proven hypersensitivity to one or more ingredients.

Material properties/ Technical data

Material composition: CopraPoly FLEX	PCT-G
Flexural strength	> 58 MPa
Bending modulus	~ 1500Mpa
Fracture toughness	≥ 2,7 MPa/ $m^{1/2}$
Solubility	< 0,6 µg/mm^3
Water absorption	~ 6 µg/mm^3

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Processing

We recommend single-edged PMMA milling cutters for machining.

For optimum milling results with our material, we recommend the following specifications:

PMMA milling cutter Single flute:	2mm Milling cutter - Feed rate: 25mm/s	Spindle speed: 16.000 u/m
PMMA milling cutter Single flute:	1mm Milling cutter - Feed rate: 19mm/s	Spindle speed: 22.000 u/m
PMMA milling cutter, double-edged:	2mm Milling cutter - Feed rate: 25mm/s	Spindle speed: 8.000 u/m
PMMA milling cutter, double-edged:	1mm Milling cutter - Feed rate: 19mm/s	Spindle speed: 11.000 u/m

Air or water cooling is an advantage when milling.

Polishing is carried out using suitable silicone polishers and polishing brushes. High-gloss polishing is carried out with conventional polishing pastes. The polishing paste should only be used with soft polishing brushes. Care must be taken not to overheat the material.

A minimum wall thickness of 1.2 mm must be maintained in the occlusal area and 0.6 mm in the cervical area.

Veneering

All commercially available veneering materials that are suitable for PCT-G. The respective instructions for use of the manufacturer of the primer, bonder, veneering or luting material used must be observed.

Cleaning

The restoration can then be cleaned with conventional soapy water or detergent. The restoration can be cleaned with an ultrasonic device (max. 40°C) or gently with a hand brush. Disinfection can be carried out with IPA or medical disinfectants. Gamma and ETO sterilisation is possible.

Safety instructions

Warning: Always wear respiratory protection (filter class FFP2), tight-fitting safety goggles, protective gloves and protective clothing and switch on extraction equipment. The dust generated during processing of this product can cause irritation to the skin/eyes/respiratory tract. Avoid inhalation/contact with skin, mouth and eyes. Do not eat or drink while working. Keep away from food and drink. Wash hands after handling. Remove contaminated clothing and protective equipment before entering eating areas. Keep away from sources of ignition. Do not smoke.

Storage

Store in a dry place. Protect from moisture. Store in the original packaging.

Waste disposal

Dispose of the product and packaging in accordance with local/ regional/ national/ international regulations.
Remains of the blank can be disposed of with the recycling waste.

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Note
All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The summary of safety and clinical performance according to (EU) MDR 2017 / 745 Article 32 (SSCP) is available in the European database for medical devices (Eudamed) under the associated base UDI-DI as soon as the corresponding database module exists.

https://ec.europa.eu/tools/eudamed

Explanation of the labelling on the packaging

CE 0483	Confirmation: The product complies with the applicable European directives
REF	Catalogue number/ item number
LOT	Batch designation
UDI	Unique product identification
	Number of products in the packaging
	Observe the warning in the operating instructions and instructions for use
www.wp-ifu.de/poly	Path to the electronic instructions for use
7d.	Instructions for use in paper form available within 7 days
MD	Medical device
	Date of manufacture
	Manufacturer
CH REP	Swiss authorised representative
Rx only	Caution: Federal law restricts this product to sale by or on the order of a licensed physician or dentist.