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Instruction For Use

Planmeca Surgical Guide

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CE

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Preface

The following instructions for use are for dental technicians, dentists and oral surgeons who use Planmeca Surgical Guide as a dental surgical guide material. Planmeca Surgical Guide is intended exclusively for professional dental work. This instruction for use provides also information about safety and environmental aspects. In case more information is needed about the processing of Planmeca Surgical Guide material contact the Planmeca office. Also see information at the end of this document.

1. Introduction

Planmeca Surgical Guide is a monomer based on Acrylic esters for manufacturing of 3D-printed surgical guides. Suitable for printing all types of surgical guides. Planmeca Surgical Guide is a class I material and CE-certified.

2. Description and effects

Planmeca Surgical Guide 3D printing material shall only be used with Planmeca Creo 3D printer.

3. Contra-indication

Planmeca Surgical Guide should not be used for any other purpose than dental surgical guides only. Any deviation from this instruction for use may have negative effect on the chemical and physical quality of Planmeca Surgical Guide. In case of an allergic reaction, please contact a medical physician.

4. Hazard & Precaution (H & P phrases)

Inhalation:

Irritating to respiratory system. High atmospheric concentrations may lead to irritation of the respiratory tract, dizziness, headache and anesthetic effects.

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Skin contact:

May cause sensitization by skin contact. Irritating to skin, repeated and/or prolonged contact may cause dermatitis.

Eye contact:

High vapor concentration may cause irritation.

Ingestion:

Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.

Protection:

Wear protection when handling Planmeca Surgical Guide. Protective glasses and nitrile gloves are advised.

Hazard Phrases:	H317	May cause an allergic skin reaction
	H413	May cause long lasting harmful effect to aquatic life

5. Storage conditions, expiry date and transport

Store the product in the original packaging at room temperature in a dry and dark area, preferably not exceeding 25°C. Close the packaging after each use. The expiry date of the product is mentioned on the product label. In case of exceeding the expiry date, the product is no longer guaranteed in terms of treatment.

6. Processing Planmeca Surgical Guide

We advise to use nitrille gloves when using Planmeca Surgical Guide until post-curing. Before using Planmeca Surgical Guide, make sure to shake the product in the original packaging for approximately 5 minutes. Color deviations may occur when shaken insufficiently.

Make sure that you work as clean as possible, dirty reservoirs or machines can cause deformation and therefore failure of the printed objects!

Pour the liquid material in the reservoir of the Planmeca Creo 3D printer. Start the machine. Follow the instructions for use for the printer. These are delivered together with the pinter. When the machine has finished its program remove the building platform from machine. Place the platform on some paper or cloth with the builded jobs facing upwards. The printed jobs can know be removed from the platform using a putty knife. Rinse the printed jobs twice in an alcohol solution (96%) to get rid of any excess material, making use of an ultrasonic bath. Rinse the first time for three minutes, second time for two minutes The second rinse must be carried out with a clean alcohol solution (96%). Rinsing in alcohol solution should not take longer than 5 minutes, as this will cause defects in the printed parts.

After cleaning make sure the printed part is dry and free of alcohol residu. Than place the printed jobs in a UV- light curing box for final polymerization. Time of curing depends strongly on type of lamps/ lightbox used. The final properties and also final color depend on the post curing process. Post-curing is an UV-light treatment to ensure that Planmeca materials obtain full polymer conversion, through this the residual monomer is reduced to a minimum and the highest mechanical properties are obtained. This procedure is a necessary step to produce a biocompatible end-product. We advice to make use of the Vertex[™] LC-3*D*Print Box or a curing unit with similar properties (for detailed description of required properties see the following table).



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Specific curing time with Planmeca Surgical Guide

Planmeca Material	Time min.	Wavelength nm	Total output Light Watt	UV lightbox output W*sec=J kJ
Planmeca	10	Blue UV-A + UV-Blue	UV-A 108	129,6
Surgical Guide		315-400 + 400-550 nm	UV-Blue 108	

The specifications of the Planmeca materials are determined on the basis of test plates, produced on a DLP 405nm 3D printer with the corresponding settings which are registered in the software.

The unit used at the manufacturer has 4x 18W/71 lamps (Dulux L Blue) and 4x 18W/78 lamps (Dulux blue UV-A). The calculated output is based on the UV light UVA lamp Blue. Please notice that the light sources and the Planmeca Creo 3D printer require routine maintenance following the manufacturer instructions.

7. Finishing

Remove any support structures and finish jobs if necessary, using conventional dental methods and instruments. Differences in color nuance may occur due to production in batches of the raw material and product or inadequate shacking of the original packaging before use.

8. Plastic and packaging waste

The product Planmeca Surgical Guide in its polymerized form is not environmentally harmful. Residual waste material in its liquid state should be delivered to a collection point for waste material.

9. Instructions for cleaning and disinfecting

Planmeca 3D-printing material should be cleaned with non chemical products. If disinfecting before intended use is required, an ethanol solution can be used. Planmeca Surgical Guide can be sterilized by making use of an autoclave or using gamma-ray sterilisation. Please make sure that the Surgical Guide is fully post-cured before sterilisation! This is important with regard to form stability. For post-curing procedure please see § 6 Processing Planmeca Surgical Guide.

10. Delivery units

The product Planmeca Surgical Guide is available in the following packaging size: 1000 gr.

Explanation of symbols on labelling



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