

Light-curing resin based on (meth)acrylate, biocompatible, for the generative fabrication of temporary restorations of anterior and posterior teeth for DLP printers with UV-LED 385 nm

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1. Introduction

The following instructions for use are for dentists and dental technicians who use FREEPRINT® temp as a temporary dental restorations.

2. Indications for use

Indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.

3. Special manufacturing requirements

Printing machine and post-curing unit should be set-up, validated and maintained according to their labelling and instructions for use.

3.1 File format

STL (see geometric presettings for CAD)

3.2. DLP printer and its operation software

Printer Manufacturer, Model	Rapidshape D30 II	Asiga Pro75	Asiga Max	Asiga Pico2
				
Light source	385 nm	385 nm	385 nm	385 nm
Pixel size x, y	±34 µm	±75 µm	±62 µm	±39 µm
Light intensity	2 mW/cm ²	5,7 mW/cm ²	6,1 mW/cm ²	20 mW/cm ²
Operation Software	Netfabb 2020	Composer 1.2.11	Composer 1.2.11	Composer 1.2.11

3.3. Printing Parameters

Printer Model	Rapidshape D30 II	Asiga Pro75	Asiga Max	Asiga Pico2
Parameter data set*	DETAX freeprint temp UV	Detax_Freeprint temp UV_3.3	Detax_Freeprint temp UV_3.3	Detax_Freeprint temp UV_3.3
Curing time	2.8 s	2 s	1.8 s	0.6 s
Support point size: Support density: Spacing:	0.3 mm 1.0 mm 1.5 mm	0.5 mm 3.5 mm 1.8 mm	0.5 mm 3.5 mm 1.8 mm	0.5 mm 3.5 mm 1.8 mm
Slicing	50 µm	50 µm	50 µm	50 µm
Build speed	1.5 cm/hr	1.5 cm/hr	1.5 cm/hr	1.5 cm/hr
Build path	surface layer drawing path	surface layer drawing path	surface layer drawing path	surface layer drawing path
Recommended orientation angle (degree)	0-90	0-90	0-90	0-90

*The set of parameters includes all relevant material- and printer specific information

3.4 Environmental Conditions

Processing temperature 23 °C ± 2 °C.

3.5 Cleaning Kit

Rinse bath tubs, flush cutter, paper towel, squeeze bottle for isopropyl alcohol, Scraper

3.6 Curing light equipment

Model: Otoflash G171

Manufacture: NK Optik

Technical Data:
ISO 10477-Type 2, Class 2

Processing:
at 23 °C ± 2 °C

Storage:



Ordering information:

FREEPRINT® temp 385

500 g bottle

A1 02014
A2 02108
A3 02119

1.000 g bottle

A1 02120
A2 02130
A3 02131

FREEPRINT® tray 385

1.000 g bottle, green 04086

FREEPRINT® ortho 385

1.000 g bottle, clear 04095

FREEPRINT® splint 2.0 385

500 g bottle, clear 02080
1.000 g bottle, clear 02076

 ▶ Consult Instructions for Use

 ▶ Catalogue Number

 ▶ Batch Code

 ▶ Use by Date

Rx only ▶ Caution: Federal U.S. law restricts this device to sale by or on the order of a licensed healthcare practitioner (or trained specialist personnel).

 ▶ Warning

 ▶ Temperature limitation

 ▶ Keep away from sunlight

 ▶ Manufacturer

FREEPRINT® temp

4. Contraindications

Contains (meth)acrylics and phosphine oxides.

Some ingredients of FREEPRINT® temp may cause allergic reactions in predisposed persons. In such cases refrain from using the product.

FREEPRINT® temp only insert intraorally in completely polymerised state.

5. Safety information

- ▶ Avoid direct contact with the liquid material and the components before post-curing, in particular in pregnant / breastfeeding women. Irritating to eyes and skin (sensitization possible). Wear personal protective equipment (protective gloves, goggles) when handling the uncured material.
 - ▶ Wear suitable personal protective equipment (protective gloves, goggles, face mask) when finishing the cured material.
 - ▶ After contact with eyes rinse thoroughly with water immediately and consult a doctor.
 - ▶ After contact with skin wash immediately with water and soap.
 - ▶ Biocompatibility is only guaranteed with complete polymerisation.
- Refer to the relevant safety data sheet for hazard and safety information.

6. Storage conditions, expiry date and transport

FREEPRINT® temp is to be stored dry (at 15 °C - 28 °C) and protected from light. Minimal influence of light can already induce polymerisation.

7. Manufacturing process



Mixing

Before filling resin into the reservoir the material must be mixed. Use a bolted roller or mix/shake it by hand. Inadequate mixing could cause deviations of colour and print failures.



Filling of printer

Fill 3D printing resin in the reservoir of the printer. The 3D printing resin can remain in the vat for a maximum of two days (maximum 10 print cycles). It is not allowed to pour 3D printing resin from the reservoir of the printer back into the resin bottle. Visual inspection of 3D printing resin; in case the resin is visually contaminated, it may not be used and must be discarded.

Different batches of the same 3D printing resin may not be mixed.



Construction process

The print resin material must be stirred before use.

Visual inspection of print resin material: in case print resin material is visually contaminated, it may not be used and must be discarded.

Generate a print job complying with printer and material parameters.

For setting up the printer follow the instructions for use of the printer.

Data preparation and fabrication of the support structure according to the instructions of the CAD software manufacturer.

Remaining print resin material after printing is not allowed to be poured back into the resin bottle.

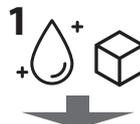


Post-processing / Removal of printed parts

If possible, post-processing should commence immediately following the construction process.

After raising the platform, a drip time of approx. 10 minutes is recommended.

Remove the platform from the printer and remove the construction components using appropriate device (e.g. knife).



Cleaning

Clean the construction components in a separate vessel with isopropyl alcohol (purity ≥ 98%) for 3 min. in an ultrasonic bath filled with water.

Then thoroughly clean the openings, cavities and gap areas, if necessary also with compressed air, and, if applicable, remove the construction components carefully from the support structure.



Further cleaning is performed in a separate vessel with fresh isopropyl alcohol (purity ≥ 98%) for 3 min. in an ultrasonic bath.

Prior to post-exposure, check the openings and additional bore holes for residues. Then blow off with compressed air.

After cleaning the surface of the construction components must no longer be sticky (dry) and not shiny (matt).



Post-exposure

Post-exposure is performed with a xenon photoflash unit (e.g. Otofash G171) with 2 x 2000 flashes under inert gas conditions (nitrogen), rotate components in between.

CAUTION: The use of FREEPRINT® temp is only approved when applied with the compatible devices mentioned in this instructions for use. Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specification

8. 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 of inadequate shaking of the original packaging before use or insufficient postcuring

9. Disposal

Disposal of the contents/container must be carried out in accordance with the local/regional/national and international regulations.

10. Notes

- ▶ Always keep container tightly sealed, immediately close the container carefully after each use.
- ▶ Please follow the instructions on the safety data sheet!

For users and/or patients:

Any serious incidents occurring in relation to this product should be reported immediately to incident@detax.de and to the competent authority in which the user and/or patient is established.



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