8. Hazards identification

Hazard and safety information can be found on the product label and/or in the corresponding safety data sheet.

9. Disposal

Disposal of contents/container in accordance with local/regional/national/international regulations and according to the safety data sheet.

Glossary

	Use-by date	Rx only	Use only by professionals
	Please note instructions for use		Protect from sunlight
	Temperature limitation	MD	Medical device
	Manufacturer	CE	CE marking of conformity according to the requirements for medical devices
LOT	Batch code		
REF	Item number		Made in Germany

20230803

Form of delivery

REF **D353002**

FotoDent® tray2 green transparent 1.0 kg bottle

18 °C 64 °F – 28 °C 82 °F

Rx only

MD

MADE IN GERMANY

Date of issue: 2023-06-22/Rev. 00

Dreve Dentamid GmbH
Max-Planck-Str. 31 • 59423 Unna/Germany
www.dentamid.dreve.de

FotoDent® tray2

Directions for use

For Carbon printers – Carbon® – For Carbon printers

CE

FotoDent® tray2 for Carbon printers

Intended use

Light curing material for production of dental impression tray.

Indications for use: Manufacturing dental impression trays. The dental impression tray will be filled with dental impression material to reproduce the structure of a patients teeth and gums.

Indication: Individual impression tray for taking dental impressions.

Contraindication: If an acrylic allergy exists, an allergic reaction may occur.

Patient target group: Patients who need dental care.

Intended users: The dental technician or specialist staff in the dental laboratory is responsible for the production of the impression tray in 3D printing. The dentist uses the finished impression tray on the patient.

1. Requirements / equipment

Printer: Carbon M2, M3, M3 Max

Software: Carbon Print Software

Cleaning: Isopropanol, orbital shaker, container

Post curing unit: PCU LED N_2

Basic Material Properties

Please refer to Technical Data Sheet (TDS). Available on request.

2. Process description

2.1 Preparation

- During processing of the liquid material, we recommend wearing personal protective equipment e. g. suitable gloves, safety goggles etc.
- Carefully pour the material into the pre-determined container of the production unit.
- Please see further steps within printer manual.
- Remove all bubbles with a cleaned object.

2.2 Printing Parameters

- Layer thickness: 300 µm
- Minimum wall thickness impression tray: 2.0 mm
- Minimum wall thickness impression handle: 5.5 mm
- Optimal Orientation: the handle faces the building platform and is built directly onto the building platform
- Supports: optional, to be added by the user

2.3 Printing process

- Processing temperature: 22 ± 3 °C
- Select the corresponding profile for FotoDent® tray2 in Carbon's software. Make sure the software used is up to date.
- Start the printing process.

2.4 Processing after the printing process

- It is recommended that the printing result be further processed directly after printing (see following steps).
- After the platform is taken up a dripping off time of approx. 10 minutes is recommended.

2.5 Cleaning

- Clean in isopropanol medium (purity ≥ 97 %) at an orbital shaker. Fill two suitable containers with isopropanol.
  1. Pre-clean with isopropanol for 6 minutes in the first suitable container.
  2. Blow off using compressed air.
  3. Perform the main cleaning step with isopropanol for 6 minutes in the second suitable container.
  4. Blow off using compressed air.

2.6 Post-curing

PCU LED N_2	8 minutes, 80 % light output using nitrogen

3. Important notes

- The specifications and biological safety have been qualified using the aforementioned printer, the associated software and the process parameters indicated.
- To avoid deterioration of the material quality, protect the liquid material from exposure to light. Variations from the described manufacturing process may impair biological safety, lead to modified mechanical characteristics and/or color variations of the material.
- Impurity due to the construction or a break of the material and impurity due to operation mistakes cannot be excluded. However, thanks to the low viscosity, it is possible to filter FotoDent® tray2. It is recommended to regularly take out the container of the production unit, to homogenize and filtrate the content. Upcoming entrained bubbles get eliminated through a holding time of approx. 1–2 hours with FotoDent® tray2.

4. Cleaning and disinfection

For cleaning and disinfection, we recommend the use of a 0.2 % chlorhexidine solution or 0.5 % sodium hypochlorite solution with an exposure time of 5 minutes for disinfection, and then allow to dry completely.

5. Sterilisation

FotoDent® tray2 cannot be sterilised.

6. Serious incidents

All serious incidents occuring in relation to the product shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is settled.

7. Lot number / Expiry date

The lot number and the expiry date are indicated on each FotoDent® tray2 packaging. In case of claims please always indicate the lot number of the product. Do not use the product after the expiry date