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E-DENTURE

Monomer based on acrylic esters for manufacturing of 3D-printed denture bases

CE 0120

Instruction For Use

E-Denture

E-Denture is a monomer based on acrylic esters for manufacturing of 3D-printed denture bases. E-Denture is a class IIa material and CE-certified.

The following instructions for use are for dental profesionals who use E-Denture as a denture base material for dentures. E-Denture is intended exclusively for professional dental work. This instruction for use provides also information about safety and environmental aspects, a safety data-sheet is available on http://envisiontec.com and at local dealers In case more information is needed about the processing of E-Denture material contact the EnvisionTEC Office. See also information at the end of this document.

E-Denture is a monomer based on acrylic esters for manufacturing of 3D-printed denture bases, normally intended for permanent use. E-Denture is a class IIa material and CE-certified.

IFU ID: IEDENTURE201702UK

Description and effects

E-Denture can be used in combination with DLP based 3D printers which support EnvisionTEC materials.

Contra-indication

E-Denture should not be used for any other purpose than denture base work only. Any deviation from this instruction for use may have an adverse on the chemical and physical quality of E-Denture. In case of an allergic reaction, please contact a medical physician.

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.

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 E-Denture. Protective glasses and gloves are advised. Information about the handling of the product can be found in the safety datasheet, which is available on http://envisiontec.com.

Hazard Phrases:
Pictogram

Signal word Warning

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

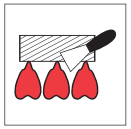
Processing / Post-curing

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

Thoroughly mix before using
Before using the material for the first time. Mix it for 2.5 hours in its original packaging. Each subsequent time you use this material. Mix for 1 hour. We advise to use a roller bench to thoroughly mix the material.
Color deviation and print failures may occur when mixed insufficiently.

Fill printerreservoir
Pour the liquid material in the reservoir of the 3D-printing machine.

For printer settings see IFU of 3D Printer
Follow the instructions for use of the printer. These are delivered together with the pinter.



Remove printed parts from platform
When the machine has finished its program remove the building platform from the machine. Place the platform on some paper or cloth with the built jobs facing upwards. The printed jobs can know be removed from the platform using a suitable knife.

Cleaning Pieces step 1
Rinse the printed jobs for three minutes in an alcohol solution (>90%) to eliminate any excess material, using of an ultrasonic bath.

Cleaning Pieces step 2
Rinse for two minutes in a clean alcohol solution (>90%).
Rinsing in a alcohol solution should not take longer than 5 minutes, as this may cause defects in the printed parts.

Post-Cure
After cleaning make sure the printed parts are dry and free of alcohol residual. Then place the printed jobs in a UV- light curing box for final polymerization.

Post-curing is an UV-light treatment to ensure that EnvisionTEC materials obtain full polymer conversion. Through this the residual monomer is reduced to a minimum and the required mechanical properties are obtained. This procedure is a necessary step to produce a biocompatible end-product. We strongly advice to make use of the Vertex-Dental™ LC-3DPrint Box.

Specific curing-time E-Denture

EnvisionTEC material	Time (min.)	Wavelength (nm.)	Total output Light (Watt)	UV lightbox output W*Sek=J (kJ)
E-Denture	10	Blue UV-A 315-400 UV-Blue 400-550	UV-A 108 UV-Blue 108	129,6

The unit used at Vertex-Dental has 6x 18W/71 lamps (Dulux L Blue) and 6, 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 printing machine need a routine maintenance following the manufacturer instructions.

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, inadequate shaking of the original packaging before use or insuficient post-curing.

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. Do not expose to UV-light and moisture.

Plastic and packaging waste

The product E-Denture in its polymerized form is not environmentally harmful. Residual waste material in its liquid state should be delivered to a collection point for chemical waste material.

Cleaning instructions

EnvisionTEC 3D-printing material should be cleaned with non-chemical products. If disinfecting before intended use is required, an ethanol solution can be used.

Delivery units

The product E-Denture is available in the following packaging size: 1000 gr.

Explanation of symbols on labelling

CE 0120 — CE mark with NB number

LOT — Batch number of product

Manufacturer

Keep away from sunlight

Consult instructions for use

Use-by date

5°C 30°C — Temperature limit; recommended storage temperature