



**RESINIFY
TECHNOLOGY**
THE ULTIMATE 3D PRINTING SOLUTION

Instructions for Use – MD-Temporary / Permanent Crown Light Curable Resin

1 - Introduction

MD-Temporary / Permanent Crown is a light-curing resin for the additive manufacturing of artificial teeth for dental prostheses, which are one of the main components in the fabrication of removable permanent full dentures. It has been optimized for use with all SLA, DLP, and LED printer types and may only be used together with these printers and the corresponding software systems. Dental applications from MD-Temporary / Permanent Crown may only be manufactured by dental technicians and dentists, and must be inspected by authorized practitioners, such as dentists, before they are released to the patients. Dentures including artificial teeth from MD-Temporary / Permanent Crown light curable resin are custom-made products for daytime use and intended exclusively for one patient. The target group is patients with a total loss of teeth on one or both jaws, whereby high-risk patients are excluded (see Section 3). The following Instruction for Use includes safety and environmental information, manufacturing instructions, and post-processing procedures of the product, which must be strictly adhered to.

2 - Indication

MD-Temporary / Permanent Crown is a light-curable resin indicated for the fabrication of artificial teeth for dental prostheses, which are used for removable permanent full dentures in dental laboratories. The material is an alternative to traditional heat-curable and auto polymerizing resins. MD-Temporary / Permanent Crown is intended exclusively for professional dental work. Fabrication of dental applications with MD-Temporary / Permanent Crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.

3 - Contraindications

MD-Temporary / Permanent Crown should not be used for purposes other than those identified herein. Any deviation from these instructions for use may have negative effects on the physical and/or chemical qualities of the resin and the biocompatibility of the end product. Dental applications from MD-Temporary / Permanent Crown should not be used in patients if there are known allergies to any of the ingredients (see Composition). Possible side effects may include shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions, or shocks,

itching and tearing (watery) eyes, headaches, or reactions of the skin or mucous membranes such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions.

4 - Composition

Acrylates, methylacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes, fillers and absorbers.

5 – Warnings

- Review the SDS prior to use.
- MD-Temporary / Permanent Crown may only be used for the production of artificial teeth for dental prostheses, which are one of the main components in the fabrication of removable permanent full dentures. Any deviation from the Instruction for Use can negatively affect the chemical and physical properties of the finished product. Consequently, the biocompatibility of the full denture cannot be guaranteed.
- MD-Temporary / Permanent Crown may not be used for the production of e.g. crowns, bridges, veneers, cover dentures, implant retained full or partial dentures or any other application which deviates from the indication.
- Do not substitute any of the components of the device system, i.e., device photopolymer materials, scanners, 3D printers, post-curing units, CAD/CAM software, templates, and tools. Use only those specifically identified in this labeling. Unauthorized changes may result in a device that is outside of specification. Contact the manufacturer for compatible components.
- Maintain and calibrate equipment according to manufacturer instructions.
- Products from MD-Temporary / Permanent Crown light curable resin cannot be sterilized. See section 12 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection when handling MD-Temporary / Permanent Crown light curable resin.
- In case of skin contact with the resin, wash with plenty of water.
- In case of eye contact, rinse cautiously with water for several minutes. Remove contact lenses, if necessary and easy to do. Continue rinsing. Consult a physician.
- If swallowed, immediately call the poison center.
- Any patients who come in contact with products from MD-Temporary / Permanent Crown light curable resin must be informed of potential side effects before use (see Section 3).

6 - Precautions

- Wear protective gloves, protective clothing, eye protection, face protection.
- Use in an appropriately ventilated area. Avoid breathing dust/fume/gas/mist/vapors/spray.
- MD-Temporary / Permanent Crown light curable resin must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- MD-Temporary / Permanent Crown light curable resin must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal. The resin must be used prior to the expiration date printed on the label.

- As described in chapter 7, when using an SLA, DLP, or LED printer, after 4 builds, mix the material remaining in the material tray thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Full denture bases with artificial teeth from MD-Temporary / Permanent Crown must be protected from exposure to light while not in use.

7 - Storage Conditions, Expiry Date and Re-use of Material

- MD-Temporary / Permanent Crown light curable resin must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- While removing the resin it must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal.
- An expiration date is displayed on the label of every material bottle. The use of expired material is not permitted.
- The resin inside the machine material tray can be re-used for several build jobs. If the level in the material tray is too low for subsequent jobs, resin from the bottle can be added as necessary. If the material is not in use, it must be filled back into the bottle. For further information on re-using and mixing material, please check the printer's User Manual.
- When using an SLA, DLP, or LED printer, after 4 builds, mix the material remaining in the material tray thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Artificial teeth from MD-Temporary / Permanent Crown need to be protected from exposure to light before the final use, while not in use and during storage.

8 - Notes on Disposal

Dispose of MD-Temporary / Permanent Crown light curable resin and material bottle in accordance with local regulation. Manufactured dentures which are used on patients must be disposed of in accordance with local regulation due to the risk of contamination by substances of human origin.

9 - Use of Software Systems and Products from Other Manufacturers

The use of certified software systems for generating the STL data, as well as the use of conventional denture bases materials and bonding agents depends on the user's assessments.

10 - Delivery Unit, Symbol Explanation

Delivery unit: MD-Temporary / Permanent Crown is available in containers of 1 kg.

Symbol explanation:

- Batch number
- Protect from sunlight
- Expiration date (YYYY-MM-DD)
- Follow Instruction for Use
- Manufacturer
- Temperature limit

- Catalogue number.
- Manufacturing date (YYYY-MM-DD)
- Prescription device labeling statement
- Unique device identification

11 - Manufacturing Instructions

A. SUPPLIES NEEDED FOR DENTURE FABRICATION

1. Released 3D Printer:
 - All SLA, DLP, and LED printer types
2. Material tray for use with MD-Temporary / Permanent Crown light curable resin only.
3. MD-Temporary / Permanent Crown light curable resin.
4. MD-Temporary / Permanent Crown material.
5. Up-to-date software.
6. Buildstyle for MD-Temporary / Permanent Crown. Contact Resinify Technology USA Technical Support if buildstyle is not supplied with the machine.
7. File in. STL format.
8. Starter Kit (included with the purchase of the 3D printer).
9. Paper towels.
10. Cone-shaped funnel.
11. Personal protective equipment, as per SDS.
12. Magnetic stirrer with bar, or lab shaker.
13. Isopropyl Alcohol min. >96%.
14. Post curing unit.
15. Pipette.
16. Standard dental polishing equipment.

B. DESIGN INFORMATION

The scanning and construction of the patient's STL data is the responsibility of the customer. Only trained dental personnel must perform the scanning and design. Further, certified software must be used, such as from e.g., 3Shape A/S.

C. PREPARING TO PRINT

Preparing the Material: MD-Temporary / Permanent Crown light curable resin must be properly mixed before use. Before using this material for the first time or after prolonged storage, it must be homogenized. Shake the material bottle vigorously for approximately 5 minutes. Be aware that vigorous shaking may cause air bubbles to form. Allow the material to rest in the bottle for an additional 5 minutes to allow any air bubbles to rise and dissipate before use.

Preparing the 3D Printer: Set up the 3D printer for MD-Temporary / Permanent Crown light curable resin (see the User Manual for the specific 3D printer used). Fill the material tray, resin tank, or the cassette. Use the spatula from the Starter Kit or a material mixing card if available to carefully mix the resin in the material tray, resin tank, or cassette. Mix until there is a uniform color. Take care not to damage the surface of the material tray, resin tank, or cassette. To avoid

contamination, a separate material tray dedicated to MD-Temporary / Permanent Crown material must be used.

Preparing the STL for 3D printing, Software Considerations: To prepare the .stl file for 3D printing and generate the support structures, use up-to-date software (see section 11-A-6). Connect the MD-Temporary / Permanent Crown buildstyle (Resinify Technology USA), Contact Resinify Technology USA Technical Support to receive a buildstyle for MD-Temporary / Permanent Crown, download the in file in the user section of the website. Transfer constructed STL files of artificial teeth to the printer. See the printer's User Manual / Software User Manual.

D. STARTING THE PRINT

Start the printing process as described in the printer's User Manual.

E. REMOVE MODELS FROM PRINTER

When the printing process is complete, carefully remove the models from the build platform.

NOTE: Always wear personal protective equipment when interacting with uncured material.

1. Open the printer's hood.
2. Remove the build platform from the printer.
3. Place the build platform on a sturdy surface. Use the provided scraper from the Starter Kit to carefully remove all models from the build platform. Place models on a clean paper towel and protect from ambient light.

F. CLEANING THE MODELS

Set up the magnetic stirrer with a bar or lab shaker in the Post Processing area and add Isopropyl Alcohol (min. >96 %) into an appropriately sized container. See the stirrer / shaker manual for setup instructions. Clean the models using the following procedure:

1. Clean in Isopropyl Alcohol (min. >96 %) for a maximum of 5 minutes in the stirrer or lab shaker (no ultrasonic bath). Clean and rinse gaps separately under pouring conditions.
2. Dry with compressed air.
3. Clean in Isopropyl Alcohol (min. >96 %) for a maximum of 2 minutes in the stirrer or lab shaker (no ultrasonic). Clean and rinse gaps separately under pouring conditions.
4. Dry with compressed air.
5. Parts must be completely dry before post-curing, e.g. air dry @ 15min.
6. Remove the supports with a scalpel or similar tool.

G. ASSEMBLING THE DENTURES

Artificial teeth printed with MD-Temporary / Permanent Crown may be bonded to denture bases printed with MD-Temporary / Permanent Crown light curable resin or conventional denture base materials. If using MD-Temporary / Permanent Crown (see MD-Temporary / Permanent Crown IFU for manufacturing instructions):

1. The 3D printed dentures and the printed artificial teeth must be uncured and unpolished prior to adding bonding agent (optional) and attaching to the denture.
2. Use the pipette to place drops of uncured MD-Temporary / Permanent Crown in the alveoli.
3. Immediately after place the teeth over the liquid photopolymer.
4. Follow with the step “Post-cure the part”

If using conventional denture base materials:

1. The artificial teeth need to be post-cured as described in step “Post-cure the part”.
2. The tooth neck may be sandblasted or ground with a dental milling machine prior to adding a bonding agent.
3. A bonding agent must be used to coat the tooth neck.
4. The Instruction for Use of the conventional denture base material has to be followed (Recommendation: Cold polymerization process).

Post-cure the part using the light curing units: Do not stack dentures or allow parts to touch in the light curing unit. Make sure that any excess resin that has been squeezed out of the alveolus is removed.

H. FINISHING THE DENTURES

1. Use a commercial dental handpiece to clean the remaining support structures and remove excess resin around the teeth.
2. Optional: Individualize with light-curing coloring materials for a better cosmetic effect, according to the Instruction for Use of the color material manufacturer.
3. High gloss polish the surface with a commercial dental handpiece or dental polishing machine.
4. Post-cure the product in the light curing units.
5. The product can now be used on the patient.

The post-curing process may cause minor temporary color deviation of artificial teeth built using MD-Temporary / Permanent Crown. The color will stabilize within 6 days.

12- Disinfection and Sterilization

Artificial teeth made of MD-Temporary / Permanent Crown light curable resin can be disinfected with any of the following disinfectants:

- 70% Ethanol solution in water
- Green&Clean AD
- MD 520
- PrintoSept-ID
- Dentavon

The disinfecting solutions must be used according to the manufacturer's instructions. Products from MD-Temporary / Permanent Crown light curable resin cannot be sterilized.

13- Cleaning Instructions for Dentures

The denture can be cleaned by the patient with clear water, a toothbrush, and toothpaste. Abrasive or whitening agents in toothpaste can damage the surface of the denture. After cleaning with clear water, the denture should be dried and not soaked in liquid.

Note: Care should be taken to ensure that the dentures are not shipped or stored soaking in water as this can adversely affect the mechanical properties.

14- Reporting Undesirable Effects

In the event of adverse effects, reactions, or similar occurrences arising from the use of these products, including those not listed in this Instruction for Use, these must be reported immediately by opening a support ticket via the website <https://resinify.com/> or by contacting your local distributor.

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15- Manufacturer

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16- Legal Disclaimer

The manufacturer does not accept any liability for damages or injury caused by improper use of the product.