Instructions for Use

Resinify CrownPro Light Curable Resin

Introduction

Resinify CrownPro is a light-curing resin developed for the additive manufacturing of:

- Artificial teeth for dental prostheses, integral to the fabrication of removable permanent full dentures.
- Individual permanent full single crowns and permanent partial crowns for both anterior and posterior regions, including inlays and onlays.
- Temporary bridges, including implant-supported bridges.
- Individual permanent veneers.
- Individual and removable monolithic full and partial dentures, later customizable with light-curing color composite pastes or liquids.

Optimized for use with various DLP and mSLA 3D printers, **Resinify CrownPro** is intended to be used exclusively with these printers and their associated software systems. Dental applications using **Resinify CrownPro** should be manufactured by dental technicians and dentists and must be inspected by authorized practitioners before being released to patients.

Temporary applications made with **Resinify CrownPro** are custom-made products that may be used for up to one year, considering their application and intended exclusively for one patient. Long-term dental applications made from this resin are also custom-made for individual patients. The target group includes patients needing restorations or teeth optimization, excluding high-risk patients. The use of this product is independent of the patient's age and sex, with the application decision at the discretion of the respective medical specialist.

The following instructions include safety and environmental information, manufacturing guidelines, and post-processing procedures that must be strictly adhered to.

Indication

Resinify CrownPro is an alternative to traditional heat-curable and auto-polymerizing resins, intended exclusively for professional dental use. Fabrication of dental applications with this resin requires a CAD/CAM system that includes digital dental files based on a digital impression or manufacturer's data for artificial teeth for dental prostheses, a DLP or mSLA printer, and curing light equipment.

Authorized applications:

- **Crowns, Veneers:**
    - Full anatomical single crown in anterior region
    - Full anatomical single crown in posterior region
    - Partial crown (Inlay/Onlay/Overlay)

  - Veneer
- **Artificial teeth, monolithic full and partial dentures:**
  - Artificial teeth for dental prostheses
  - Monolithic full and partial dentures (including implant-supported)
- **Bridges:**
  - Full anatomical monolithic bridge for anterior and/or posterior regions with no pontic (e.g., 6-unit bridge)
  - Full anatomical monolithic bridge for anterior and/or posterior regions with pontics and/or implant-supported (e.g., implant-supported full arch bridges or other implant-supported bridges)

Resinify CrownPro is available in the following colors:

- Bleach
- A1
- A2
- A3
- A3.5
- B1

Contraindications

Resinify CrownPro should not be used for purposes other than those specified herein. Deviating from these instructions may negatively affect the resin's physical and chemical qualities and the biocompatibility of the final product. This resin should not be used in patients with known allergies to any ingredients. Possible side effects include shortness of breath, gastrointestinal issues, dizziness, anaphylactic reactions, itching and watery eyes, headaches, or skin/mucous membrane reactions such as irritation, rash, swelling, redness, wheals, or blisters.

Composition

Resinify CrownPro contains acrylates, methylacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes, fillers, and absorbers.

Warnings

- **Review the SDS** prior to use.
- Use **Resinify CrownPro** only for the specified applications. Deviations can negatively impact the product's properties and biocompatibility.
- Do not substitute any components of the device system. Unauthorized changes may result in non-compliance. Contact the manufacturer for compatible components.
- Maintain and calibrate equipment according to manufacturer instructions.

- Products made from **Resinify CrownPro** cannot be sterilized. See section 12 for disinfection procedures.
- Wear protective gloves, clothing, eye protection, and face protection when handling the resin. In case of skin contact, wash with plenty of water. If eye contact occurs, rinse cautiously with water for several minutes and consult a physician.

Precautions

- Wear protective gloves, clothing, eye protection, and face protection.
- Use in a well-ventilated area. Avoid breathing dust, fumes, gas, mist, vapors, or spray.
- Store **Resinify CrownPro** in its original bottle between 41°F (5°C) and 86°F (30°C). Protect from light exposure to prevent spontaneous polymerization. Tightly close the bottle after each use. Use the resin before the expiration date.
- Mix the material remaining in the tray after 4 builds and return it to the bottle. Shake vigorously before use.
- Protect denture bases (full or partial) from light exposure when not in use.

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

- **Storage: Resinify CrownPro** light-curable resin must be stored in its original bottle between 41°F (5°C) and 86°F (30°C).
- **Light Exposure:** While removing the resin, it must be protected from light exposure to prevent spontaneous polymerization. Ensure the bottle is tightly closed after each use and material removal.
- **Expiration Date:** The expiration date is displayed on the label of each bottle. Do not use expired material.
- **Re-use:** The resin inside the material tray or resin tank can be re-used for several builds. If the level is too low for subsequent jobs, add resin from the bottle as needed. If not in use, return the resin to the bottle. For more information on re-using and mixing material, refer to the printer's User Manual.
- **Mixing:** When using a generic DLP or mSLA 3D printer, mix the remaining material in the tray thoroughly after no more than 4 builds and return it to the bottle. Shake the bottle vigorously before re-use.
- **Protection:** Protect dental applications made from **Resinify CrownPro** from light exposure before final use, when not in use, and during storage.

  Notes on Disposal

  Dispose of **Resinify CrownPro** light-curable resin and its bottle in accordance with local regulations. Manufactured dentures used on patients must be disposed of following local regulations due to the risk of contamination by substances of human origin.

  Use of Software Systems and Products from Other Manufacturers

  The use of certified software systems for generating the STL data, as well as any other additional medical or auxiliary products necessary for manufacturing crowns, veneers, artificial teeth for dental prostheses, and monolithic full and partial dentures (e.g., light-curing stains and composites for individualization, bonding

agents for fixing artificial teeth to the denture base, luting composite for bridge, crown or veneer fixing, materials for full denture bases, implants, and abutments), is subject to the user's discretion and assessment.

Delivery Unit and Symbol Explanation

Delivery Unit: Resinify CrownPro is available in containers of 0.5 kg and 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**

Manufacturing Instructions

A. Supplies Needed:

1. Generic DLP or mSLA 3D printer
2. Material tray or resin tank compatible with **Resinify CrownPro** light-curable resin
3. **Resinify CrownPro** light-curable resin
4. Resinify Base light-curable resin or conventional denture base materials for fabricating artificial teeth for dentures
5. Paper towels
6. Cone-shaped funnel
7. Personal protective equipment as per SDS
8. Magnetic stirrer with bar or lab shaker
9. Isopropyl alcohol (min. >96%)

10. Post-curing unit (e.g., Otoflash G171, Wicked Engineering CUREbox Plus, Dreve PCU LED N2, iLuxCure Pro, or iLuxCure Dental)
11. Pipette
12. Standard dental polishing equipment

B. Design Information:

The scanning and design of patient STL data are the customer's responsibility and must be performed by trained dental personnel using certified software (e.g., from 3Shape A/S).

Construction Rules:

Crowns and Veneers:

- Crowns must be adhesively fixed to a prepared natural tooth stump or an artificial tooth stump such as an implant abutment or post and core.
- Veneers must be adhesively fixed to a prepared natural tooth stump.
- Minimum wall thickness: 1.5 mm in central fissure, 1 mm circular.
- Parts must be built horizontally oriented to the platform, with supports connecting only to the occlusal or incisal surface to avoid manual post-processing of the sides in direct contact with the mating surface.

Monolithic Full Dentures:

- Design without additional fixtures to increase holding force. Use certified software based on digitalized data from the bite registration process.
- Minimum approved wall thickness: 2.5 mm.
- Parts must be built vertically oriented to the platform, with supports connecting only to the labial border to avoid manual post-processing of the sides in contact with oral mucosa.
- Add a connector to the lower denture base design to ensure stability during fabrication and accuracy of dimensions/fit once finished. Recommended connector designs should require minimal material while ensuring high accuracy.

Monolithic Partial Dentures

Monolithic partial dentures made of **Resinify CrownPro** should be designed without any additional fixtures to increase holding force, except for the clasps. The minimum approved wall thickness for the denture and the clasps is 2.5mm.

Bridges

Temporary bridges made of **Resinify CrownPro** must continuously consist of full anatomical crowns, need to be end pillar bridges, and need to be fixed to the bridge pillars (prepared natural tooth stump and/or an artificial tooth stump), such as "Toronto bridge" or other implant-supported bridges.

Minimum connector cross-section:

- **Anterior region:** 12 mm^2
- **Posterior region:** 14 mm^2

Minimum wall thickness:

- **Occlusal:** 1.5 mm in central fissure
- **Circular:** 1 mm

Parts must be built horizontally oriented to the platform, with supports connecting only to the occlusal or incisal surface to avoid manual post-processing of the sides in direct contact with the mating surface.

Preparing to Print

Preparing the Material: Resinify CrownPro light-curable resin must be properly mixed before use. Shake the material bottle vigorously for approximately 5 minutes. 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 **Resinify CrownPro** light-curable resin as per the User Manual. Fill the material tray or resin tank. Use a spatula or material mixing card to carefully mix the resin in the tray until a uniform color is achieved. Avoid damaging the surface of the tray or tank. To prevent contamination, use a dedicated material tray or resin tank for **Resinify CrownPro**.

Preparing the STL for 3D Printing, Software Considerations: To prepare the .stl file for 3D printing and generate the support structures, use appropriate software. Connect the **Resinify CrownPro** buildstyle or print parameters to the corresponding software. Transfer constructed STL files to the printer as instructed in the printer's User Manual.

Starting the Print

Start the printing process according to the printer's User Manual.

Removing Parts from Printer

Once printing is complete, carefully remove the parts from the build platform. Always wear personal protective equipment when handling uncured material.

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

Cleaning the Parts

Set up a magnetic stirrer or lab shaker with isopropyl alcohol (min. >96%) in an appropriately sized container. Clean the parts using the following procedure:

1. Clean in isopropyl alcohol for a maximum of 5 minutes in the stirrer or lab shaker. Rinse gaps separately under pouring conditions.
2. Dry with compressed air.
3. Clean again in isopropyl alcohol for a maximum of 2 minutes in the stirrer or lab shaker. Rinse gaps separately under pouring conditions.
4. Dry with compressed air.
5. Ensure parts are completely dry before post-curing (e.g., air dry for 15 minutes).
6. Remove supports with a scalpel or similar tool.

When Printing Artificial Teeth for Dentures

Assembling the Dentures: Artificial teeth printed with **Resinify CrownPro** can be bonded to denture bases printed with **Resinify BasePro** light-curable resin or conventional denture base materials.

Using Resinify BasePro:

1. Ensure 3D printed dentures and artificial teeth are uncured and unpolished.
2. Use a pipette to place drops of uncured **Resinify BasePro** in the alveoli.
3. Immediately place the teeth over the liquid photopolymer.
4. Follow the post-cure options.

Using Conventional Denture BasePro Materials:

1. Post-cure the artificial teeth with listed units.
2. Sandblast or grind the tooth neck prior to adding a bonding agent.
3. Apply a bonding agent to the tooth neck.
4. Follow the Instructions for Use of the conventional denture base material.

Post-cure Options

When bonding to Resinify BasePro, post-cure the part using: a) Otoflash G171: 2x3000 flashes (3000 flashes per side), recommended under inert gas (e.g., nitrogen) b) Wicked Engineering

CUREbox Plus: 2x25 minutes at 50°C (25 minutes per side) c) Dreve PCU LED N2: 90% Power for 18 minutes under vacuum

Finishing the Dentures

1. Use a commercial dental handpiece to clean remaining support structures and remove excess resin around the teeth.
2. Optionally, individualize with light-curing coloring materials for a better cosmetic effect as per the color material manufacturer's instructions.
3. High gloss polish the surface with a dental handpiece or dental polishing machine.
4. Post-cure the product using the following options:
    - Otoflash G171: 1000 flashes
    - Wicked Engineering CUREbox Plus: 5 minutes without temperature
    - Dreve PCU LED N2: 90% power for 3 minutes under vacuum
    - iLuxCure Pro or iLuxCure Dental: 1 minute at 50% power
5. The product is now ready for patient use. The post-curing process may cause minor temporary color deviation of artificial teeth built using **Resinify CrownPro**. The color will stabilize within 6 days.

When Printing Crowns, Veneers, Bridges, and Monolithic Dentures

1. **Post-curing:**
    - **Otoflash G171:** 2x3000 flashes (3000 flashes per side), recommended under inert gas (e.g., nitrogen).
    - **Wicked Engineering CUREbox Plus:** 2x25 minutes at 50°C.
    - **Dreve PCU LED N2:** 90% power for 18 minutes under vacuum.
    - **iLuxCure Pro:** 10 minutes at 100% power.
    - **iLuxCure Dental:** Program Setting P08 (12 minutes at 35% power).
2. **Lower Full Dentures Only:**
    - Remove the connector with a scalpel or similar tool.
3. **Optional Customization:**
    - Use light-curing coloring materials for a better cosmetic effect as per the manufacturer's instructions.
4. **Polishing:**
    - High gloss polish the surface with a commercial dental handpiece or dental polishing machine.

5. **Final Post-Cure:**
    - **Otoflash G171:** 1000 flashes.
    - **Wicked Engineering CUREbox Plus:** 5 minutes without temperature.
    - **Dreve PCU LED N2:** 90% power for 3 minutes under vacuum.
    - **iLuxCure Pro or iLuxCure Dental:** 1 minute at 50% power.
6. **Product Use:**
    - The product is now ready for patient use. Note: The post-curing process may cause minor temporary color deviation of printed dental parts. The color will stabilize within 6 days.

Disinfection and Sterilization

Printed dental parts made of **Resinify CrownPro** 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

Follow the manufacturer's instructions for the disinfecting solutions. Products made from **Resinify CrownPro** light-curable resin cannot be sterilized.

Cleaning Instructions for Dentures

Patients can clean dentures with clear water, a toothbrush, and toothpaste. Avoid abrasive or whitening agents in some toothpaste that can damage the denture surface. After cleaning with clear water, dentures should be dried and not soaked in liquid. Ensure dentures are not shipped or stored soaking in water, as this can adversely affect their mechanical properties.

Reporting Undesirable Effects

In the event of adverse effects, reactions, or similar occurrences from the use of these products, report immediately by contacting **Resinify Technology LLC** via the website or through your local distributor.

Manufacturer

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