

Instructions for Use

Resinify GuardPro Light Curable Resin

Introduction

Resinify GuardPro is a light-curable resin developed for the additive manufacturing of flexible, individual dental bite splints. This resin has been optimized for use with various DLP and mSLA 3D printers and their corresponding software systems. Bite splints made from **Resinify GuardPro** should be manufactured by dental technicians and dentists and must be inspected by authorized practitioners, such as dentists or orthodontists, before being released to patients.

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

Indication

Resinify GuardPro light-curable resin is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, and splints. Dental splints are used for various applications within splint therapy: to protect teeth or restorations (bite splints), to protect teeth from bruxism (night guard), to change the position and shape of the condyle (stabilization splint), and to address malposition of the temporomandibular joint (positioning splint). The fabrication of bite splints with **Resinify GuardPro** is intended exclusively for professional dental work and requires a CAD/CAM system that includes digital dental files based on a digital impression, a DLP or mSLA printer, and light-curing equipment.

Contraindications

Bite splints made from **Resinify GuardPro** should not be used in patients with known allergies to any of the ingredients. Possible side effects may 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 GuardPro contains acrylates, methylacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes, and absorbers.

Warnings

- **Review the SDS** prior to use.
- **Resinify GuardPro** should only be used for the production of dental bite splints. Any deviation from the instructions can negatively affect the chemical and physical properties of the finished product, impacting its biocompatibility.
- **Resinify GuardPro** is not suitable for the production of clear aligners, bleaching-splints, sports splints, or protrusion/snoring splints.

- 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 GuardPro** light-curable resin cannot be sterilized. See disinfection procedures section.
- 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, remove contact lenses if necessary, and consult a physician. If swallowed, call the poison center immediately.
- Inform patients of potential side effects before use.

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 GuardPro** 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 dental bite splints from light exposure when not in use.

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

- Store **Resinify GuardPro** in its original bottle between 41°F (5°C) and 86°F (30°C).
- While removing the resin, protect it from light exposure. Tightly close the bottle after each use.
- The expiration date is displayed on the label of each bottle. Do not use expired material.
- The resin inside the material tray can be re-used for several builds. Add resin from the bottle if the level is too low for subsequent jobs. 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.
- Mix the material remaining in the tray thoroughly after 4 builds and return it to the bottle. Shake the bottle vigorously before re-use.
- Protect dental bite splints from light exposure before final use, when not in use, and during storage.

Notes on Disposal

Dispose of **Resinify GuardPro** light-curable resin and its bottle in accordance with local regulations. Manufactured bite splints 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 additional medical or auxiliary products necessary for manufacturing bite splints, mouthguards, and nightguards, is subject to the user's discretion and assessment.

Delivery Unit, Symbol Explanation

Delivery Unit: Resinify GuardPro 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**

Manufacturing Instructions

A. Supplies for Dental Bite Splint Fabrication:

1. **Released 3D Printer:**
 - Generic DLP and mSLA 3D printers
2. **Material tray or cassette:** for use with **Resinify GuardPro** light-curable resin only.
3. **Resinify GuardPro** light-curable resin.
4. **Resinify GuardPro** material tag/RFID card (if applicable).
5. **Released Software:**
 - Software suitable for your 3D printer model

6. **Buildstyle or print parameters:** Contact **Resinify Technology LLC** for assistance if buildstyle is not supplied with the machine.
7. **File in .stl format**
8. **Starter Kit:** Includes a scraper, material mixing cards, and cone-shaped filters.
9. **Paper towels**
10. **Cone-shaped funnel**
11. **Personal protective equipment:** as per SDS.
12. **Lab shaker**
13. **Isopropyl Alcohol (min. >96%)**
14. **Post curing unit:**
 - Otofash G171
 - Wicked Engineering CUREbox Plus
 - Dreve PCU LED N2
15. **Standard dental polishing equipment**

B. Design Information:

The scanning and construction of the patient's STL data are the customer's responsibility. Only trained dental personnel must perform the scanning and design, using certified software (e.g., from 3Shape A/S). The minimum approved wall thickness is 2 mm, and the maximum approved wall thickness is 3 mm.

C. Preparing to Print:

Preparing the Resin: **Resinify GuardPro** light-curable resin does not require specific mixing instructions prior to printing.

Preparing the 3D Printer: Set up the 3D printer for **Resinify GuardPro** light-curable resin as per the Operations Guide for your specific 3D printer. Fill the material tray or cassette and use the spatula from the Starter Kit or a material mixing card to carefully mix the resin. Avoid damaging the surface of the tray or cassette. To prevent contamination, use a separate material tray or cassette dedicated to **Resinify GuardPro**.

Preparing the STL for 3D Printing, Software Considerations: Prepare the .stl file for 3D printing and generate the support structures using appropriate software. Connect the **Resinify GuardPro** buildstyle to the software. Transfer constructed STL files to the printer as per the printer's Operations Guide or Software User Manual.

Orientation and Supporting: Dental bite splints can be printed horizontally or vertically oriented. Vertically oriented splints need to be supported from the labial/vestibular surface, while

horizontally oriented splints need to be supported from the outer surface in contact with the opposite jaw.

D. Starting the Print:

Start the printing process as described in the printer's Operations Guide. Note that after several printing processes, the product may show slight color changes.

Post-Processing

A. Remove Printed Parts from 3D Printer:

When the printing process is complete, carefully remove the models from the build platform. Always wear personal protective equipment when handling 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 and use the provided scraper to carefully remove all models. Place models on a clean paper towel and protect them from ambient light.

B. Cleaning the Parts:

Set up the lab shaker in the Post-Processing area and add Isopropyl Alcohol (min. >96%) into an appropriately sized container. Clean the printed parts using the following procedure:

1. Clean in Isopropyl Alcohol for a maximum of 5 minutes in the lab shaker (no ultrasonic bath). Clean and 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 lab shaker (no ultrasonic). Clean and 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.

C. Post-Curing the Part:

Do not stack parts or allow parts to touch in the light-curing unit. Ensure that any excess resin squeezed out of the alveolus is removed. Parts will be hot immediately after post-curing, so handle with care.

Using the following light-curing units:

1. Otofash G171: 2x1000 flashes, flip parts between cycles (1000 flashes per side), recommended under inert gas (e.g., nitrogen).
2. Wicked Engineering CUREbox Plus: Parameters 2x5 minutes at 45°C (5 minutes per side).
3. Dreve PCU LED N2: 18 minutes with 90% power under vacuum.

Using an alternative light source may result in insufficient curing, affecting biological and mechanical properties.

D. Finishing the Parts:

1. Use a commercial dental handpiece to clean the remaining support structures.
2. Polish the surface with a commercial dental handpiece or dental polishing machine. Follow the manufacturer's instructions for the polishing device. Minimal differences in fit can occur due to the polishing process. Inspect the printed product on a dental model after processing.
3. Post-cure the product in the light-curing units:
 - Otofash G171: 1000 flashes
 - Wicked Engineering CUREbox Plus: 5 minutes at 30°C
 - Dreve PCU LED N2: 3 minutes with 90% power under vacuum

The product can now be used on the patient. Maintain and calibrate equipment according to manufacturer instructions. The post-curing process may cause minor temporary color deviation. The color will stabilize within 6 days.

Disinfection and Sterilization

If necessary, bite splints made of **Resinify GuardPro** can be disinfected before use with the following disinfectants:

- Cidex OPA
- Chlorhexidine Digluconate 2%
- 70% Ethanol solution

Follow the manufacturer's instructions for the disinfecting solutions. Bite splints made from **Resinify GuardPro** cannot be sterilized.

Cleaning Instructions for Patients

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

Reporting of 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 your local distributor.

Manufacturer

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