Resinify GuardPro™

Instructions for Use — Light-Curable Resin for Dental Bite Splints

1. 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.

2. Indication

Resinify GuardPro™ 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). 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.

3. 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.

4. Composition

Acrylates, methacrylates, methacrylated oligomers and monomers, photoinitiators, colorants/dyes, and absorbers.

5. 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™ cannot be sterilized (see Section 11).
- 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.

6. 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 between 41°F (5°C) and 86°F (30°C) in the original bottle. Protect from light exposure to prevent spontaneous polymerization. Tightly close the bottle after each use. Use 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.

7. Storage, Expiry & Re-Use

- Store in the original bottle between 41°F (5°C) and 86°F (30°C).
- Protect from light exposure while removing resin. Close the bottle tightly after each use.
- The expiration date is displayed on each bottle's label. Do not use expired material.
- Resin in the material tray can be re-used for several builds. Top up from the bottle if the level is too low; return unused resin to the bottle when not in use. See the printer's User Manual for details.
- Mix remaining tray material thoroughly after 4 builds and return it to the bottle. Shake vigorously before re-use.
- Protect dental bite splints from light exposure before final use, when not in use, and during storage.

Disposal

Dispose of Resinify GuardPro™ 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 & Third-Party Products

Use of certified software systems for generating STL data, as well as any additional medical or auxiliary products necessary for manufacturing bite splints, mouthguards, and nightguards, is at the user's discretion and assessment.

8. Delivery Unit & Symbol Explanation

Delivery Unit: Resinify GuardPro™ is available in containers of 1 kg.

Symbols used on the label: batch number · protect from sunlight · expiration date (YYYY-MM-DD) · follow Instructions for Use · manufacturer · temperature limit · catalogue number · manufacturing date (YYYY-MM-DD) · prescription device labeling statement · unique device identification.

9. Manufacturing Instructions

A. Supplies for Dental Bite Splint Fabrication

1. Released 3D printer — generic DLP and mSLA 3D printers
2. Material tray or cassette dedicated to Resinify GuardPro™ only
3. Resinify GuardPro™ light-curable resin
4. Resinify GuardPro™ material tag/RFID card (if applicable)
5. Released software suitable for your 3D printer model
6. Buildstyle or print parameters (contact Resinify Technology LLC if not supplied with the machine)
7. File in .stl format
8. Starter Kit — scraper, material mixing cards, 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 — Otoflash G171, Wicked Engineering CUREbox Plus, or Dreve PCU LED N_2
15. Standard dental polishing equipment

B. Design Information

Scanning and construction of the patient's STL data are the customer's responsibility and must be performed by trained dental personnel using certified software (e.g., from 3Shape A/S). Minimum approved wall thickness: 2 mm. Maximum approved wall thickness: 3 mm.

C. Preparing to Print

Preparing the resin: Resinify GuardPro™ does not require specific mixing instructions prior to printing.

Preparing the 3D printer: Set up the printer for Resinify GuardPro™ 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 tray or cassette surface. Use a dedicated tray or cassette for Resinify GuardPro™ to prevent contamination.

Preparing the STL / software considerations: Prepare the .stl file and generate support structures using appropriate software. Connect the Resinify GuardPro™ buildstyle to the software. Transfer constructed STL files to the printer per its 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; 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.

10. Post-Processing

A. Removing Printed Parts from the 3D Printer

> **NOTE:** 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.

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

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

Unit	Parameters
Otoflash G171	2×1000 flashes, flip parts between cycles (1000 per side); recommended under inert gas (e.g., nitrogen)
Wicked Engineering CUREbox Plus	2×5 minutes at 45°C (5 minutes per side)
Dreve PCU LED N_2	18 minutes at 90% power under vacuum

> **ATTENTION:** 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, per the polishing device manufacturer's instructions. Minimal differences in fit can occur due to polishing — inspect the printed product on a dental model afterward.
3. Post-cure the product:

Unit	Parameters
Otoflash G171	1000 flashes
Wicked Engineering CUREbox Plus	5 minutes at 30°C
Dreve PCU LED N_2	3 minutes at 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; color stabilizes within 6 days.

11. Disinfection and Sterilization

If necessary, bite splints made of Resinify GuardPro™ can be disinfected before use with any of the following: Cidex OPA, Chlorhexidine Digluconate 2%, or 70% ethanol solution. Follow the disinfectant manufacturer's instructions.

> **ATTENTION:** Bite splints made from Resinify GuardPro™ cannot be sterilized — disinfect only.

12. 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.

13. 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 your local distributor.

14. Manufacturer

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