Desktop Health™

Instructions for Use – **SmileGuard™**

Light Curable Resin

1 – Introduction

SmileGuard™ is a light-curable resin for the additive manufacturing of flexible, individual dental bite splints. ***SmileGuard*** has been optimized for use with Desktop Health's *Einstein* and *Einstein Pro XL* 3D printers and EnvisionTEC's *Perfactory® DDP* (*Digital Dental Printer*) *series, Perfactory® Vida* and *Vida cDLM*, *Perfactory® MicroPlusXL, Perfactory EnvisionOne cDLM, Perfactory® P4K Pro series and Perfactory® D4K* 3D printers and may only be used with these printers and the corresponding software systems. ***SmileGuard*** is a medical device classified per U.S. Food and Drug Administration (FDA) as Class 2 (21 CFR 872.3760) and classified in Canada as Class 2 according to Medical Device Regulations (SOR/98-282). Bite splints from ***SmileGuard*** may only be manufactured by dental technicians and dentists and must be inspected by authorized practitioners, such as dentists or orthodontists, before they are released to the patients.

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

SmileGuard light curable resin is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards and splints. Dental splints are used for different applications within splint therapy: to protect teeth or restauration (bite splints), to protect teeth for bruxism (night guard), positional and shape changing of the condyle (stabilization splint), malposition of the temporomandibular joint (positioning splint) etc. ***SmileGuard*** is intended exclusively for professional dental work. Fabrication of bite splints with ***SmileGuard*** requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital dental-files based on a digital impression, a digital light processing (DLP) printer, and light curing equipment.

3 – Contraindications

Bite splints fabricated from ***SmileGuard*** should not be used in patients if there are known allergies to any of the ingredients (see Section 4). 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 and absorbers.

5 – Warnings

- Review the SDS prior to use.
- ***SmileGuard*** may only be used for the production of dental bite splints. Any deviation from the Instruction for Use can negatively affect the chemical and physical properties of the finished product. Consequently, the biocompatibility of the bite splint cannot be guaranteed.
- ***SmileGuard*** may not be used for the production of clear aligners, bleaching-splints, sport splints or protrusion- / snoring-splints.
- 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 ***SmileGuard*** *light curable resin* cannot be sterilized. See section 13 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection when handling ***SmileGuard*** *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 ***SmileGuard*** *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 appropriately ventilated area. Avoid breathing dust/fume/gas/mist/vapors/spray.
- ***SmileGuard*** *light curable resin* must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- ***SmileGuard*** *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 *Einstein*, after 4 builds, mix the material remaining in the basement thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Dental bite splints must be protected from exposure to light while not in use.

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

- ***SmileGuard*** *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's 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 *Einstein*, after 4 builds, mix the material remaining in the basement thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Dental bite splints must be protected from exposure to light before the final use, while not in use, and during storage.

8 – Notes on Disposal

Dispose of ***SmileGuard*** light curable resin and material bottle in accordance with local regulation. Manufactured bite splints which are used on patients must be disposed of in accordance with local regulation due to the risk of contaminated 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 depends on user's assessments.

10 – Delivery Unit, Symbol Explanation

Delivery unit: ***SmileGuard***™ is available in containers of 1 kg.

Symbol explanation:

LOT	Batch number		Protect from sunlight
	Expiration date (YYYY-MM-DD)		Follow Instruction for Use
	Manufacturer		Temperature limit
REF	Catalogue number		Manufacturing date (YYYY-MM-DD)
Rx Only	Prescription device labeling statement	UDI	Unique device identification

11 – Manufacturing Instructions

A. SUPPLIES FOR DENTAL BITE SPLINT FABRICATION

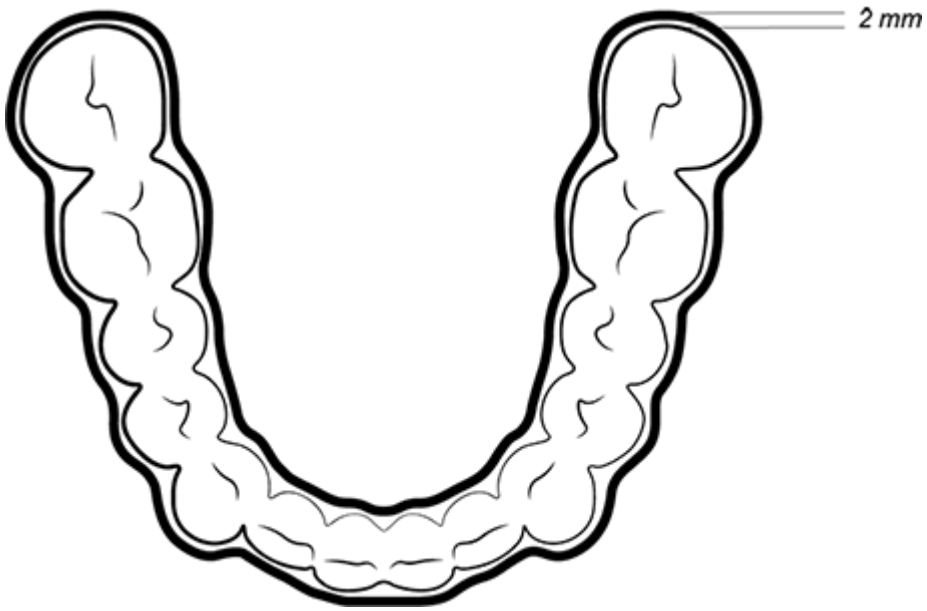
1. Desktop Health 3D printer: *Einstein* or *Einstein Pro XL*
   or
   EnvisionTEC 3D printer: *Perfactory® DDP* (*Digital Dental Printer*) *series, Perfactory® Vida* and *Vida cDLM*, *Perfactory® MicroPlusXL, Perfactory EnvisionOne cDLM, Perfactory® P4K Pro series and Perfactory® D4K.*
2. Material basement for use with ***SmileGuard*** *light curable resin* only. Order printer-specific parts from EnvisionTEC, Desktop Health, or authorized distributors.
3. ***SmileGuard*** *light curable resin*. Order from Desktop Health or authorized distributor.
4. ***SmileGuard*** material tag/RFID card (shipped with the material bottle).
5. Perfactory® RP Software (version 3.1540.1602 or later), Envision One RP (version 1.0.1165 or later) or the Cambridge Software from 3Shape A/S (version 2015 2650 or later).
6. Buildstyle for ***SmileGuard***™. Contact Desktop Health Technical Support if buildstyle is not supplied with the machine.
7. File in. stl format
8. Starter Kit (included with the purchase of printer): provided scraper (Einstein, Perfactory® Envision One cDLM®, Perfactory® D4K Pro) or material mixing cards (Einstein Pro XL, Perfactory® P4K series, Perfactory® P4K Advantage series, Perfactory® Vida® series), 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. Otoflash G171 curing unit. Order from Desktop Health or authorized distributor.
15. Standard dental polishing equipment.

B. DESIGN INFORMATION

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

The minimum approved wall thickness is 2 mm, and the maximum approved wall thickness is 3 mm, *Fig. 1.*

FIG. 1 BITE SPLINT 2 MM MINIMUM WALL THICKNESS



C. PREPARING TO PRINT

Preparing the Resin:

SmileGuard light curable resin does not require specific mixing instructions prior to printing.

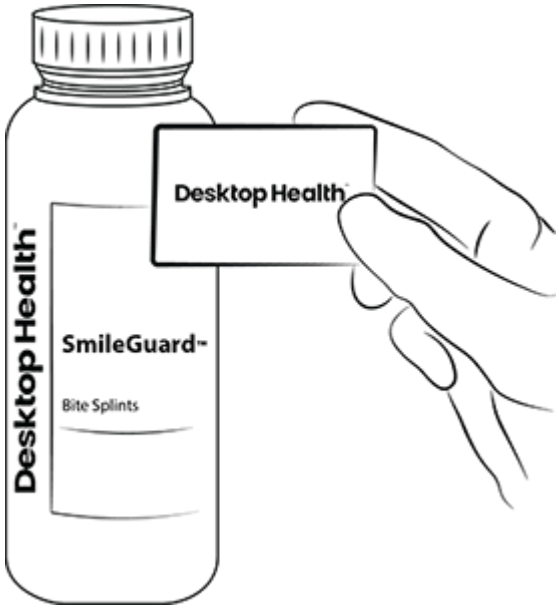
Preparing the 3D Printer:

Setup the 3D printer for ***SmileGuard*** *light curable resin* (*see the Operations Guide for the specific 3D printer used).*

Fill the material tray. Use the spatula from the Starter Kit *(Einstein, Envision One cDLM®, D4K Pro)* or a material mixing card *(Einstein Pro XL, Perfactory® P4K series, Perfactory® P4K Advantage series, Perfactory® Vida® series)* to carefully mix the resin in the material basement. Take care not to damage the surface of the material basement.
To avoid contamination, a separate material basement dedicated to ***SmileGuard*** must be used.

A material tag (RFID card) is shipped with the ***SmileGuard*** resin bottle, Fig. 2. Place the material tag on the RFID tag reader on the 3D printer. The card must remain on the reader for the duration of the print.

FIG. 2 MATERIAL BOTTLE AND MATERIAL TAG



Preparing the STL for 3D printing, Software Considerations:

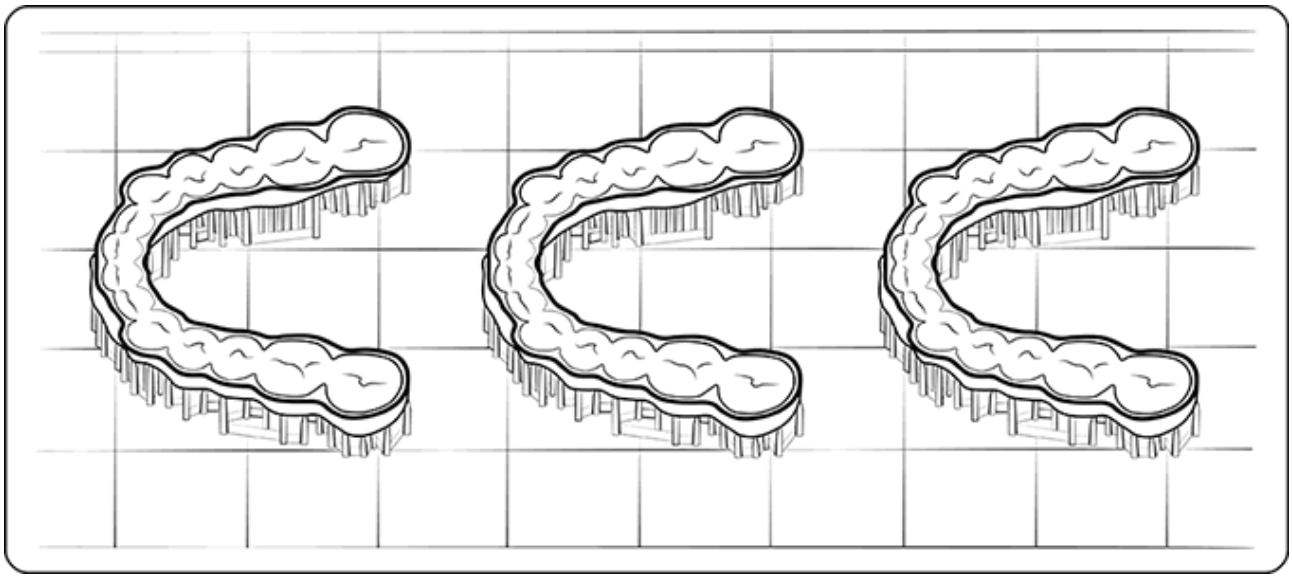
To prepare the .stl file for 3D printing and generate the support structures, use the Perfactory® RP Software (version 3.1540.1602 or later), EnvisionOne RP (version 1.0.1165 or later), or Cambridge Software from 3Shape A/S (version 2015 2650 or later).

Connect the ***SmileGuard*** buildstyle to the software. Contact Desktop Health Technical Support for assistance.

For accurate results, dental bite splints must be built flat (parallel with the build platform), with supports connecting only to the outer smooth surface, *Fig. 3.*

Transfer constructed STL files to the printer. See the printer's *Operations Guide/Software User Manual.*

FIG. 3 BITE SPLINTS RECOMMENDED ORIENTATION IN ENVISION ONE RP SOFTWARE



D. STARTING THE PRINT

Start the printing process as described in the printers *Operations Guide*.

Note: After several printing processes, the product may show slight color changes.

12 – Post-Processing

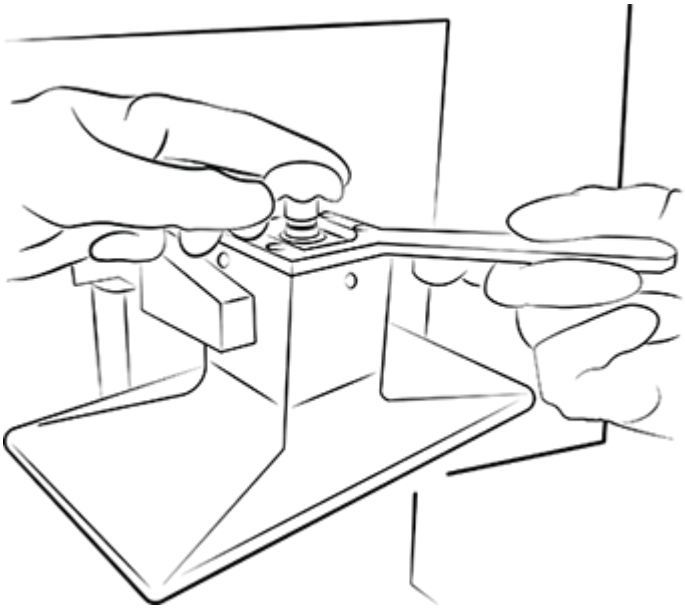
A. REMOVE PRINTED PARTS FROM 3D PRINTER

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

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

1. Open the printer's hood.
2. Remove the build platform from the printer, *Fig. 4*.
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.

FIG 4 ENVISION ONE CDLM – REMOVING BUILD PLATFORM



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. *See the shaker manual for setup instructions.*

Clean the printed parts using the following procedure:

1. Clean in Isopropyl Alcohol (min. >96 %) 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 in Isopropyl Alcohol (min. >96 %) 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. Parts must be completely dry before post-curing.
6. Remove the supports with a scalpel or similar tool.

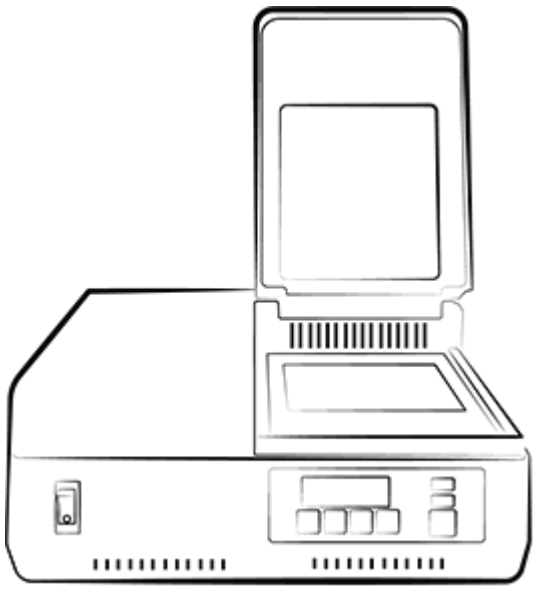
C. POST-CURING

Cure the parts using an **Otoflash G171:** 2 x 1000 flashes, flip parts between cycles (1000 flashes per side). Recommendation: under inert gas (e.g. nitrogen).

Important: Do not stack parts or allow parts to touch in the light curing unit.

Note: Parts will be hot immediately after post-curing, handle with care.

FIG. 4 OTOFLASH G171



Note: Using an alternative light source may result in an insufficient curing, which may adversely affect biological and mechanical properties.

D. FINISHING THE PARTS

1. Use a commercially dental hand piece to clean the remaining support structures.
2. Polish the surface with a commercially dental hand piece or dental polishing machine.

Important: Use the polishing device according to instruction for use of the manufacturer. Due to the polishing process, minimal differences in fit can occur. Therefore, the printed product should be inspected on a dental model after processing.

3. Post-cure the product in the Otoflash G171 with 1000 flashes.
4. The product can now be used on the patient.

Note: Maintain and calibrate equipment according to manufacturer instructions.

Important: Using an alternative light source can affect the properties of the final product.

13– Instructions, Disinfection and Sterilization

If necessary, the bite splint made of ***SmileGuard*** can be disinfected before use with the following disinfectants:

- Cidex OPA,
- Chlorhexidine Digluconate 2%, or
- 70% Ethanol-solution.

The disinfecting solutions must be used according to the manufacturer instructions.

Bite splints from ***SmileGuard*** cannot be sterilized.

14– Cleaning Instructions for Patients

Bite splint 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.

Important: Abrasive or whitening agents in some kinds of toothpaste can damage the surface of the splint.

15– Reporting of Undesirable Effects

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

16 – Manufacturer

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17 – Legal Disclaimer

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Rx Only

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