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 released 3D Printers (see section 11-A-1) and may only be used with these printers and the corresponding software systems. ***SmileGuard*™** is a medical device classified as class I according to Regulation (EU) 2017/745**.** 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 material tray 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 material tray (EnvisionTEC or Desktop Health™) or inside the cassette (Carbon®). If the level in these 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*™ 3D 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.
- 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)
CE	CE-Mark	UDI	Unique device identification
MD	Medical Device		

11– Manufacturing Instructions

A. SUPPLIES FOR DENTAL BITE SPLINT FABRICATION

1. Released 3d Printer:
    1. Desktop Health 3D printer
    2. EnvisionTEC 3D printer
    3. Carbon® M2, M3 and M3 Max printers.
2. Material tray (EnvisionTEC, Desktop Health™) or the cassette (Carbon®) for use with ***SmileGuard™*** *light curable resin* only.
3. ***SmileGuard™*** *light curable resin*.
4. ***SmileGuard™*** material tag/RFID card (shipped with the material bottle only for usage on Desktop Health™ or EnvisionTEC 3D Printer). Released Software:
5. Release Software:
    1. Perfactory® RP Software (version 3.1540.1602 or later)
    2. Envision One RP (version 1.0.1165 or later)
    3. Live Build DLP (version 2.0.102 or later)
    4. Carbon Printer UI
    5. Cambridge Software from 3Shape A/S (version 2015 2650 or later)

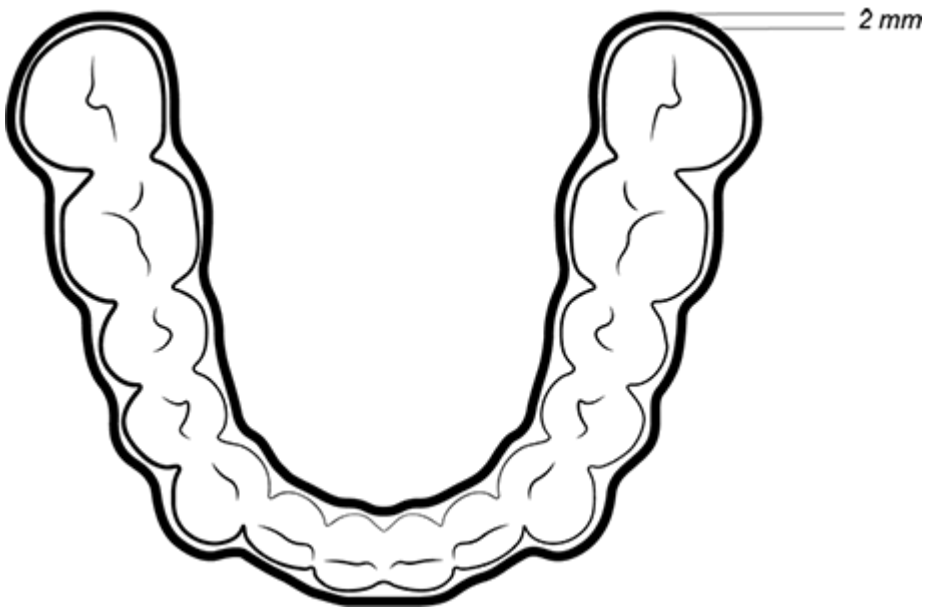
6. Buildstyle (EnvisionTEC or Desktop Health™) or for ***SmileGuard™***. Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine.
7. File in. stl format
8. Starter Kit (included with the purchase of printer): provided scraper (Einstein, Perfactory® Envision One cDLM®, Perfactory® 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. Post curing unit:
    1. Otoflash G171
    2. Wicked Engineering CUREbox Plus
    3. Dreve PCU LED N2
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 or the cassette. 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 tray or cassette. Take care not to damage the surface of the material tray or cassette.
To avoid contamination, a separate material tray or cassette dedicated to ***SmileGuard*™** must be used.

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

Preparing the STL for 3D printing, Software Considerations:

To prepare the .stl file for 3D printing and generate the support structures, use one of the released software (see section 11-A-5).

Connect the ***SmileGuard*™** buildstyle to the software. Contact Desktop Health or EnvisionTEC Technical Support for assistance or select ***SmileGuard*™** in the Carbon Printer UI.

Orientation and Supporting:
Dental bite splints can be printed horizontally and vertically orientated. The vertically (90° in relation to the build platform) orientated dental bite splints need to be supported from labial/vestibular surface (see Fig.2).
The horizontally orientated dental bite splints need to be supported from outer surface, which is in contact to the opposite jaw (see Fig. 3).

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

Fig.2 BITESPLINTS VERTICAL ORIENTATED AND SUPPORTED

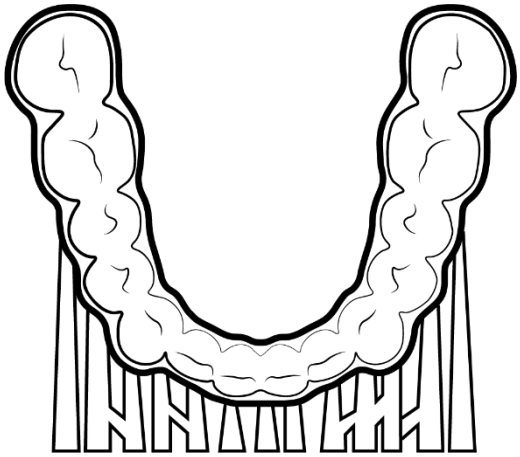
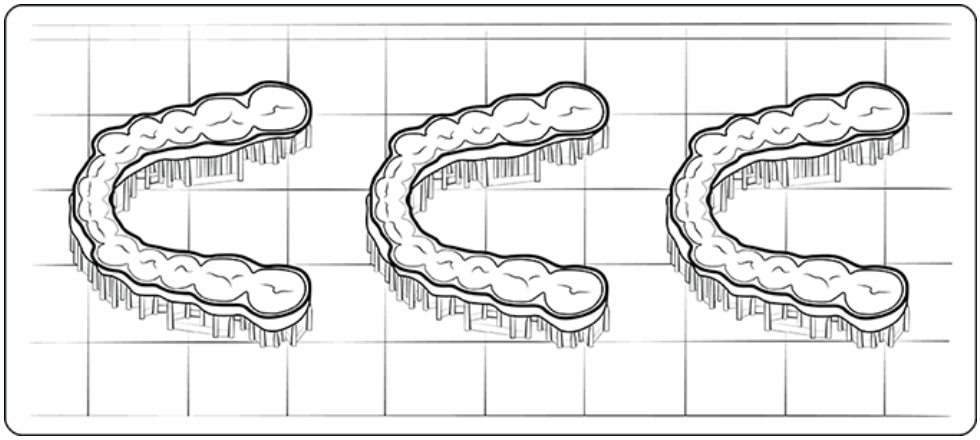


FIG. 3 BITE SPLINTS HORIZONTAL ORIENTATION IN ENVISION ONE RP SOFTWARE



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.

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.

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, e.g. airdry @ 15min.
6. Remove the supports with a scalpel or similar tool.

C. POST-CURE THE PART

Do not stack parts 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.

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

Using the following light curing units:

1. Otoflash G171: 2 x 1000 flashes, flip parts between cycles (1000 flashes per side). Recommendation: under inert gas (e.g. nitrogen)
2. Wicked Engineering CUREbox Plus: Parameters 2x 5min with 45° C (5min per side)
3. Dreve PCU LED N2 for 18min with 90% power under vacuum

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 light curing units:
    1. Otoflash G171 with 1000 flashes
    2. Wicked Engineering CUREbox Plus for 5 minutes at 30° C
    3. Dreve PCU LED N2 for 3min with 90% power under vacuum
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. The post-curing process may cause minor temporary color deviation The color will stabilize within 6 days.

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

EnvisionTEC® GmbH

Brüsseler Str. 51	Telephone:	+49-(0)2043-98750
45968 Gladbeck	E-Mail:	info@envisiontec.de
Germany	Website:	www.envisiontec.com

17– Legal Disclaimer

The manufacturer does not accept any liability for damages or injury caused by any other use of the material. Furthermore, before using the material, the user must independently check for its suitability and applicability for the intended use. EnvisionTEC, Perfactory, Envision One, cDLM, and Vida are registered trademarks of EnvisionTEC GmbH.

Dima is a registered trademark of Kulzer GmbH.
Wicked product names or logos are trademarks of the Wicked Engineering LLC.
Carbon® product names or logos are trademarks of Carbon, Inc.
Dreve product names or logos are trademarks of the Dreve ProDiMed GmbH
Desktop Health and Einstein are trademarks of Desktop Metal, Inc.

CE

Revision 4, 04.04.2024