1 Introduction

E-Guard, available as "E-Guard" and "E-Guard Blue", is a light-curing material for the additive manufacturing of individual dental bite splints. *E-Guard* has been optimized for use with EnvisionTECs *Perfactory® DDP* (*Digital Dental Printer*) *series, Perfactory® Vida* and *Perfactory® Vida cDLM*, *Perfactory® MicroPlusXL, Perfactory® EnvisionOne cDLM, Perfactory® P4K* series and *Perfactory® D4K* machines and may only be used with these machines and the corresponding software systems. *E-Guard* is a medical device classified as class I according to Schedule 2 of Therapeutic Goods (Medical Devices) Regulations 2002. Bite splints from *E-Guard* 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 and the instructions for the manufacturing and post-processing procedures of the product, which must be strictly adhered to.

2 Indication

E-Guard is intended for the fabrication of bite splints.
Bite 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. The minimum approved wall thickness is 3 mm and the maximum approved wall thickness is 10 mm. After several printing processes, the product may show slight color changes. However, this does not reduce the quality of the application of bite splints.

3 Contraindication

E-Guard 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. Consequently, the biocompatibility of the bite splint cannot be guaranteed.
E-Guard may not be used for the production of clear aligners, bleaching-splints, sport splints or protrusion- / snoring-splints.

For patient and users:
Patients, users or third parties who come in contact with products from *E-Guard* must be informed about any side effects before use. *E-Guard* products may not be used if there are known allergies to any of the ingredients, otherwise possible side effects such as shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions or shocks, itching and tearing (watery) eyes, headaches or reactions of the skin or mucous membrane such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions may occur.

4 Composition

Acrylate/Methylacrylates, methacrylated Oligomers and Monomers, photo initiators, colorants/dyes and absorbers.

5 Warning

Do not substitute any of the components of the device system, i.e., device resin materials, scanners, printers, post-curing units, CAD/CAM software, templates and tools. Use only those specifically identified in this labelling. Contact the manufacturer for compatible components.

6 Hazard and Precaution (H & P phrases) according SDS

Inhalation:	Avoid inhaling vapor of the material.
Skin contact:	If on skin: Wash with plenty of water.
Eye contact:	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Interaction:	No interactions are known.
Safeguards:	Wearing of protective glasses, protective clothes and protective gloves is advised. Information about the handling of the product can be found in the safety datasheet, which is available on www.envisiontec.com.

H-Phrases	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H412	Harmful to aquatic life with long lasting effects.
P-Phrases	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.

7 Storage conditions and und expiry date

The resin needs to be stored in the original packaging between 5 – 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. If the material is not used, it must be filled back into the bottle. An expiration date is given on the label of every product bottle. The use of expired material is not permitted. The bite splints need to be protected from exposure to light before the final use and during the not usage and storage.

8 Notes on disposal

Dispose of contents and container in accordance with local regulation.
Manufactured bite splints which were used on patients must be disposed properly due to the risk of infection (contaminated by substances of human origin).

9 Instruction disinfection and sterilization

If necessary, the bite splint made of *E-Guard* can be disinfected before use with the following disinfectants: Cidex OPA, Chlorhexidine Digluconate 2% or a 70% Ethanol-solution. The disinfecting solutions must be used according to the manufacturer instructions.
Bite splints from *E-Guard* cannot be sterilized.

10 Use of software systems and products from other Manufacturer

The use of certified software systems for generating the STL-data depends on user's assessments.

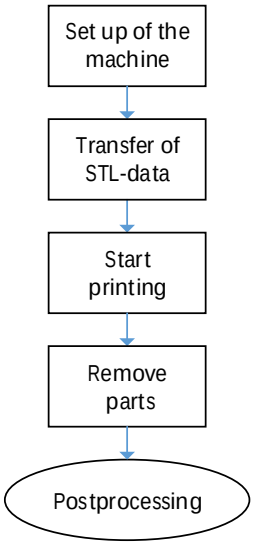
11 Delivery unit, symbol explanation and Manufacturer information

Delivery unit: *E-Guard* is available in containers of 1 kg.

Symbol explanation:

CE 0297	CE- Mark with ID-no. of the notified body		Protect from sunlight
LOT	Batch number		Follow Instruction for Use
	Expiration date		Temperature limit
	Manufacturer		Production date
REF	Purchase order number	UDI	Unique device identification
MD	Medical device		

12 Manufacturing process



Setup machine for the resin (Setting see machine manual) and fill the polymer tray / basement. To avoid impurities, resin mixes and contamination a separate polymer tray / basement must be used.

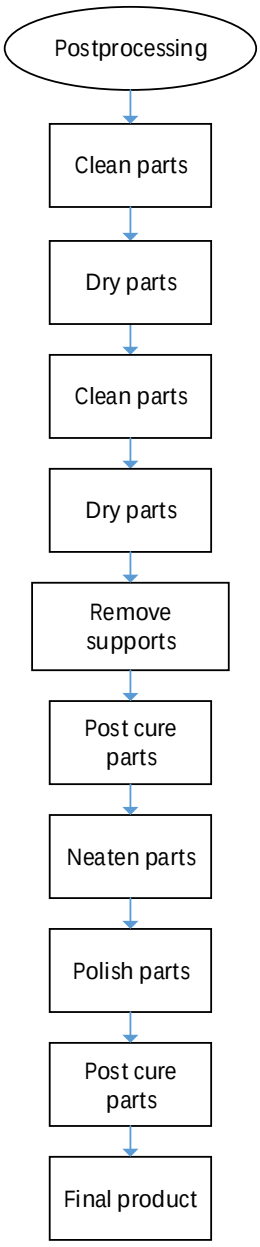
Transfer constructed STL-files for the bite splints to the machine (see machine / software manual) *.

Start the printing process as described in the machine manual.

When the printing is done, remove the parts carefully from the platform.

*The scanning and construction of patient's STL data is the responsibility of the customer. We recommend that only trained dental personnel perform the scanning and design. Further, a certified software such as, e.g. 3Shape is recommended. To generate the support structures, we recommend the Perfactory® RP Software (version 3.1540.1602 or later), EnvisionOne RP (version 1.0.1165 or later) or the Cambridge Software from 3Shape (version 2015 2650 or later).

13 Postprocessing



Cleaning in 2-propanol (min. >96 %) (max. 5 minutes); Cleaning under pouring conditions (no ultrasonic); Recommendation: Magnetic stirrer with bar or lab shaker. Clean and rinse gaps separately.

Dry with compressed air.

Cleaning in 2-propanol (min. >96 %) (max. 2 minutes); Cleaning under pouring conditions (no ultrasonic); Recommendation: Magnetic stirrer with bar or lab shaker. Clean and rinse gaps separately.

Dry with compressed air. Place the dried part in an incubator / oven at 37 °C for 30 minutes.

Remove the supports with a scalpel or similar tool.

Light curing unit: Otoflash G171; Parameters: 2x1000 flashes (= once each side); Recommendation: under inert gas (e.g. nitrogen)

Use a commercially dental hand piece to clean the remaining support structures.

Polishing the surface with a commercially dental hand piece or dental polishing machine.
Use the 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.

Post-cure the product in the Otoflash G171 with 1000 flashes.

The product can now be used on the patient.

Maintain and calibrate equipment according to manufacturer instructions. Using an alternative light source can affect the properties of the final product. If a manual removal of the material after the fitting on a patient is necessary, then the products needs to be post-cured again with 1000 flashes in Otoflash G171.

14 Patient cleaning instruction for bite splint

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

15 Reporting 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.

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