

1 Introduction

E-Splint Soft is a light-curing resin for the additive manufacturing of flexible, individual dental bite splints. *E-Splint Soft* has been optimized for use with Desktop Health's *Einstein* 3D printer and EnvisionTECs *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. *E-Splint Soft* is a medical device classified as class IIa according to 93/42/EWG. Bite splints from *E-Splint Soft* may only be manufactured by dental technicians and verify and permitted by authorized practitioners such as dentists or orthodontists before they are available for 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

E-Splint Soft is intended for the fabrication of flexible bite splints.

Bite splints are used for different applications within splint therapy: to protect teeth or restoration (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 2mm and the maximum approved wall thickness is 3mm. After several printing processes, the product may show slight color changes.

3 Contraindication

E-Splint Soft 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-Splint Soft* 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-Splint Soft* must be informed about any side effects before use. *E-Splint Soft* 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 to SDS

<u>Inhalation:</u>	Avoid inhaling vapor of the material.
<u>Skin contact:</u>	If on skin: Wash with plenty of water.
<u>Eye contact:</u>	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
<u>After ingestion:</u>	Do not induce vomiting. If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.
<u>Interaction:</u>	No interactions are known.
<u>Safeguards:</u>	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 .

<u>H-Phrases</u>	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H335	May cause respiratory irritation.
	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
	H411	Toxic to aquatic life with long lasting effects.
<u>P-Phrases</u>	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.
	P302 + IF ON SKIN:	Wash with plenty of water
	P352	
	P305 + IF IN EYES:	Rinse cautiously with water for several minutes. Remove
	P351 +	contact lenses, if present and easy to do. Continue rinsing.
	P338	
	P404	Store in closed container.
	P501	Dispose of contents/container to industrial incineration plant.

7 Storage Conditions and 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 E-Splint Soft and container in accordance with local regulation.

The manufactured bite splints, which are used on patients must be disposed of properly due to the risk of infection (contaminated by substances of human origin).

9 Instructions Disinfection and Sterilization

If necessary, the bite splint made of *E-Splint Soft* 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-Splint Soft* cannot be sterilized.












10 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.

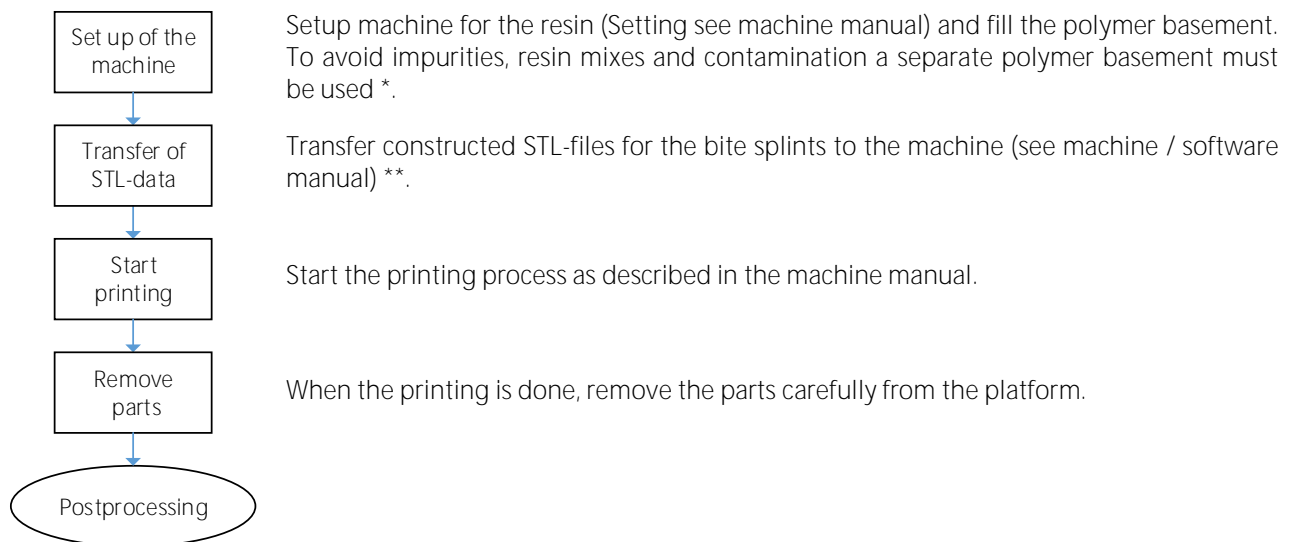
11 Delivery Unit, Symbol Explanation and Manufacturer Information

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

Symbol explanation:

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

12 Manufacturing Process

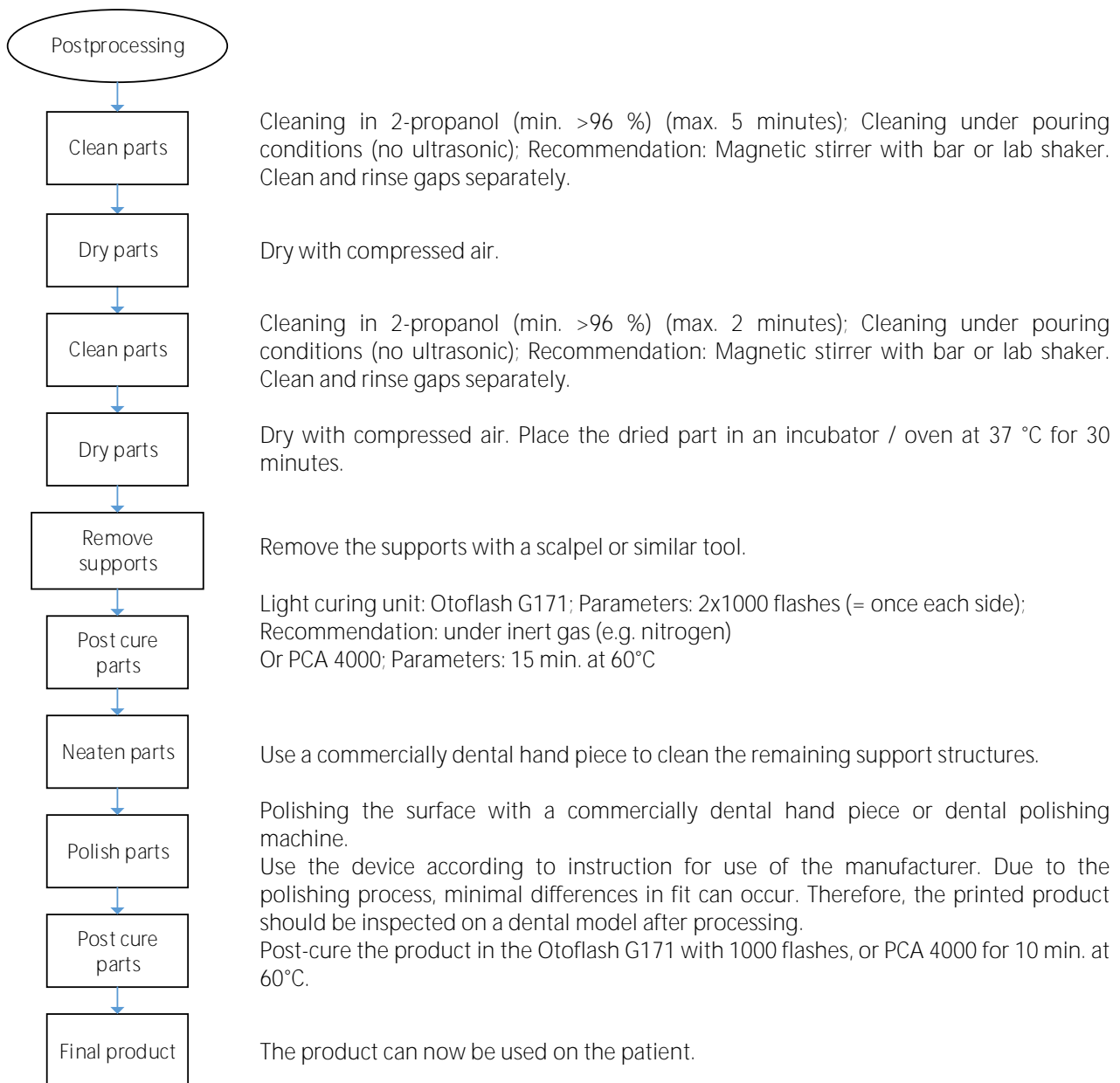


*When using Einstein Series printers, after 4 builds, mix the material remaining in the basement thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.

** 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).

For higher accuracy, parts must be oriented horizontal towards the platform, with support structures on the outer flat surface.

13 Postprocessing



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 need to be post-cured again with 1000 flashes in Otofash G171 or PCA 4000 for 10 min. at 60°C.

14 Patient Cleaning Instruction for Bite Splints

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 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 our website <https://envisiontec.com/> or by contacting your local distributor.

16 Manufacturer

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



Revision 03, 16.08.2022