1 Introduction

E-Guide is a light-curing material for the additive manufacturing of individual dental surgical drill guides. *E-Guide* 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-Guide* is a medical device classified as class I according to Regulation (EU) 2017/745. Surgical drill guides from *E-Guides* may only be manufactured by dental technicians and used on a patient by authorized users such as dentists or oral surgeons.
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-Guide is intended for the additive manufacturing of individual dental surgical drill guides, which serve as guiding aids for navigated-/ 3D-implantology of dental implants. These are intended as a precautionary protective measure to prevent injuries to nerves, blood vessels and jawbone. Surgical drill guides are used by dentists or oral surgeon prior to the surgical procedure in order to allow an exact drilling and thereby an exact placement of the dental implants in the patient's jawbone.
Surgical drill guides from *E-Guide* are custom-made products for single use during the surgical procedure, under consideration of their application and intended exclusively for one patient.
The target group are patients with missing teeth, whereby high-risk patients are excluded.
The minimum approved wall thickness is 3mm 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.

3 Contraindication

E-Guide may only be used for the production of dental surgical drill guides. Any deviation from the Instruction for Use can negatively affect the chemical and physical properties. Consequently, the biocompatibility of the surgical drill guides cannot be guaranteed.
E-Guide may not be used for the production of x-ray guides.

For patient and users:
Patients, users or third parties who come in contact with products from *E-Guide* must be informed about any side effects before use. *E-Guide* 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. Resin inside the machine tray can be re-used for several build jobs. If the level in the 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 machine manual. An expiration date is given on the label of every product bottle. The use of expired material is not permitted. The surgical drill guides 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.
The manufactured surgical drill guides, which are used on patients are surgical devices and must be disposed properly due to the risk of infection (contaminated by substances of human origin).

9 Instruction disinfection and sterilization

If necessary, the surgical drill guides made of *E-Guide* 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.
Surgical drill guides from *E-Guide* cannot be sterilized.

10 Use of software systems and products from other Manufacturer

The use of certified software systems for generating the STL-data and the use of sleeves for surgical drill guides and their additional products depends on user's assessments.

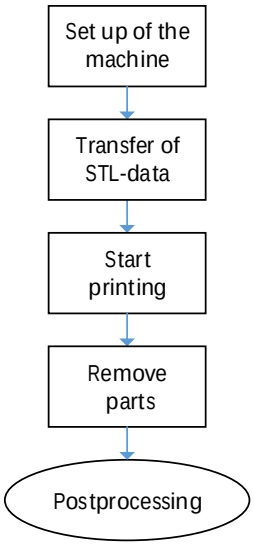
11 Delivery unit, symbol explanation and Manufacturer information

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

Symbol explanation:

CE	CE-Mark		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.

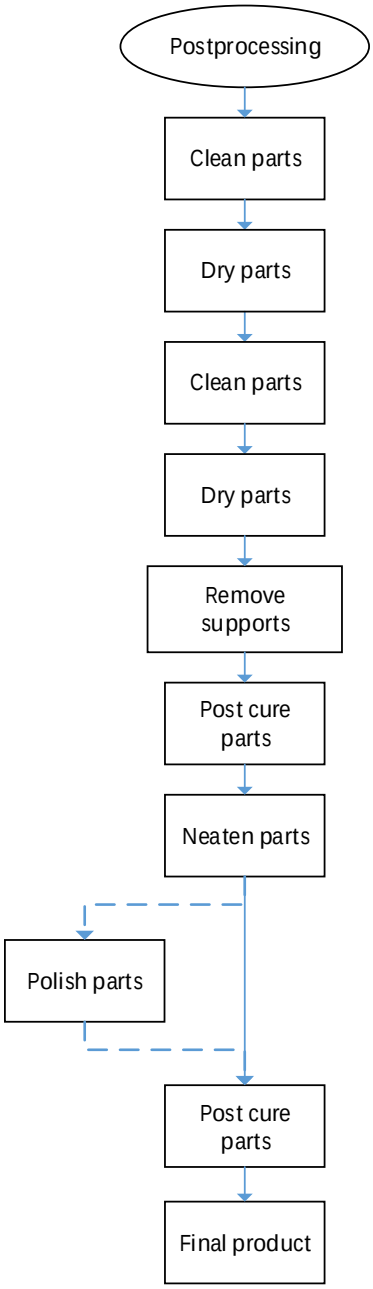
Transfer constructed STL-files for the surgical drill guides to the machine (see machine / software manual) *.

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.

Optional: 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 therefore be inspected on a dental model after processing.

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

The product as a basic framework is now ready for final assembly and can be combined with the sleeves.

Finally, the completed drill guide can 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. It is not allowed to do manual correction by material removal.

14 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 to the manufacturer (by opening a support ticket via the website https://envisiontec.com/) and to the competent authority of the Member State in which the user and/or patient is established.

15 Manufacturer

EnvisionTEC GmbH
Brüsseler Str. 51
45968 Gladbeck
Germany

Phone: +49-(0)2043-98750
E-Mail: info@envisiontec.com
Website: www.envisiontec.com

CE

Revision 07, 25.05.2021