Desktop Health™

Instructions for Use – **Flexcera**™ Smile

Light Curable Resin

1 - Introduction

Flexcera™ *Smile* is a light-curing resin for the additive manufacturing of artificial teeth for dental protheses, which are one of the main components in the fabrication of removable permanent full dentures. It has been optimized for use with Desktop Health's *Einstein*™ and *Einstein*™ *Pro XL* 3D printers and EnvisionTEC's *Perfactory® Envision One cDLM, Perfactory® Micro series Perfactory® Vida series, Perfactory® P4K series, Perfactory® P4K Advantage series,* and *Perfactory® D4K Pro* 3D printers and may only be used together with these printers and the corresponding software systems. ***Flexcera*** *Smile* is a medical device classified as class I according to Schedule 2 of Therapeutic Goods (Medical Devices) Regulations 2002. Dental applications from ***Flexcera*** *Smile* may only be manufactured by dental technicians and dentists, and must be inspected by authorized practitioners, such as dentists, before they are released to the patients.

Dentures including artificial teeth from ***Flexcera*** *Smile light curable resin* are custom-made products for daytime use and intended exclusively for one patient. The target group is patients with a total loss of teeth on one or both jaws, whereby high-risk patients are excluded (see Section 3).

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

Flexcera *Smile* is a light-curable resin indicated for the fabrication of artificial teeth for dental protheses, which are used for removable permanent full dentures in dental laboratories. The material is an alternative to traditional heat-curable and auto polymerizing resins. ***Flexcera*** *Smile* is intended exclusively for professional dental work. Fabrication of dental applications with ***Flexcera*** *Smile* requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.

Flexcera *Smile* is available in the following colors:

Bleach		
A1		***Flexcera*** *Smile A1* is comparable to VITA® classical, colors A1, C1, D2 Dentin
A2		***Flexcera*** *Smile A2* is comparable to VITA® classical colors A2, D4 Dentin
A3		***Flexcera*** *Smile A3* is comparable to VITA® classical colors A3, B3 Dentin
A3.5		***Flexcera*** *Smile A3.5* is comparable to VITA® classical colors A3.5, B4 Dentin
B1		***Flexcera*** *Smile B1* is comparable to VITA® classical color B1 Dentin

3 - Contraindications

Artificial teeth fabricated from ***Flexcera*** *Smile* 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, fillers and absorbers.

5 – Warnings

- Review the SDS prior to use.
- ***Flexcera*** *Smile* may only be used for the production of artificial teeth for dental protheses, which are one of the main components in the fabrication of removable permanent full dentures. Any deviation from the Instruction for Use can negatively affect the chemical and physical properties of the finished product. Consequently, the biocompatibility of the full denture cannot be guaranteed.
- ***Flexcera*** *Smile* may not be used for the production of e.g. crowns, bridges, veneers, cover dentures, implant retained full or partial dentures or any other application which deviates from the indication.
- 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 ***Flexcera*** *Smile light curable resin* cannot be sterilized. See section 12 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection while handling ***Flexcera*** *Smile 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 ***Flexcera*** *Smile light 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.
- ***Flexcera*** *Smile light curable resin* must be stored in the original material bottle between 5°C and 30°C.
- ***Flexcera*** *Smile 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*™ 3D printer, 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.
- Full denture bases with artificial teeth from ***Flexcera*** *Smile* must be protected from exposure to light while not in use.

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

- ***Flexcera*** *Smile light curable resin* must be stored in the original material bottle between 5°C and 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 basement can be re-used for several build jobs. If the level in the basement 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 basement thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Artificial teeth from ***Flexcera*** *Smile* need to be protected from exposure to light before the final use, while not in use and during storage.

8 - Notes on Disposal

Dispose of ***Flexcera*** *Smile light curable resin* and material bottle in accordance with local regulation. Manufactured dentures 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, as well as the use of conventional denture bases materials and bonding agents depends on the user's assessments.

10 - Delivery Unit, Symbol Explanation

Delivery unit: ***Flexcera*** *Smile* 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

11 - Manufacturing Instructions

A. SUPPLIES NEEDED FOR DENTURE FABRICATION

1. Desktop Health 3D printer: *Einstein*™, or *Einstein*™ *Pro XL*
   or
   EnvisionTEC 3D printer: *Perfactory® Envision One cDLM, Perfactory® Micro series, Perfactory® Vida series, Perfactory® P4K series, Perfactory® P4K Advantage series,* or *Perfactory® D4K Pro*.
2. Material basement for use with ***Flexcera*** *Smile light curable resin* only. Order printer-specific parts from EnvisionTEC or authorized distributors.
3. ***Flexcera*** *Smile light curable resin*. Order from Desktop Health™ or authorized distributor.
4. ***Flexcera*** *Base light curable resin*, or conventional denture base materials. Order ***Flexcera*** *Base* from Desktop Health™ or authorized distributor.
5. ***Flexcera*** *Smile* material tag/RFID card (shipped with the material bottle).
6. For the material mixing procedure: Ceramic balls, and bottle roller machine.
7. 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).
8. Buildstyle for ***Flexcera*** *Smile*. Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine.
9. File in .stl format
10. Starter Kit (included with the purchase of the 3D printer), provided scraper (Einstein™, Perfactory® Envision One cDLM, Perfactory® D4K Pro) or material mixing cards (Einstein™ Pro XL, Perfactory® P4K series, Perfactory® Micro series, Perfactory® P4K Advantage series, Perfactory® Vida series), and cone-shaped filters.
11. Paper towels.
12. Cone-shaped funnel.
13. Personal protective equipment, as per SDS.
14. Magnetic stirrer with bar, or lab shaker.
15. Isopropyl Alcohol min. >96%.
16. Otoflash G171 curing unit. Order from EnvisionTEC or authorized distributor.
17. Pipette.
18. 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, certified software must be used, such as from e.g., 3Shape A/S.

C. PREPARING TO PRINT

Preparing the Material:

Flexcera *Smile light curable resin* must be properly mixed before use.

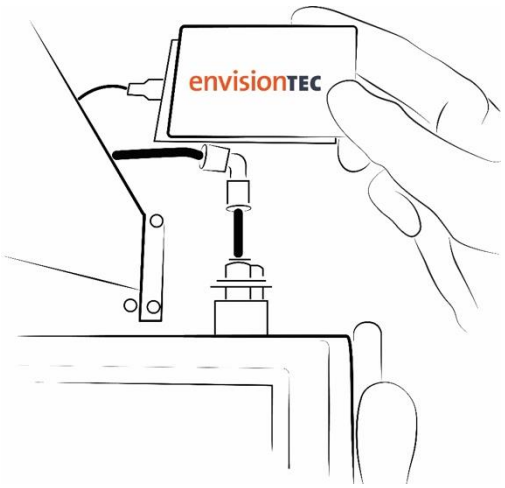
Prepare the material: Shake the resin bottle vigorously by hand. Add ceramic balls to the bottle and then place the resin bottle on a bottle roller for a minimum of 12 hours.

Preparing the 3D Printer:

Setup the 3D printer for ***Flexcera*** *Smile light curable resin* (*see the User Manual for the specific 3D printer used*). Fill the material basement. 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® Micro series, Perfactory® Vida series)* to carefully mix material in the material basement. Mix until there is a uniform color. Take care not to damage the surface of the material basement.

To avoid contamination, a separate material basement dedicated to ***Flexcera*** *Smile* material must be used.

FIG. 1 ENVISION ONE CDLM - PLACING MATERIAL



A material tag (RFID card) is shipped with the ***Flexcera*** *Smile* resin bottle. Place the material tag on the RFID tag reader on the 3D printer, *Fig. 1*. 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 the Perfactory® RP Software, Envision One RP (version 1.0.1165 or later) or the Cambridge Software from 3Shape A/S (version 2015 2650 or later).

Connect the ***Flexcera*** *Smile* buildstyle to the Software. Contact EnvisionTEC Technical Support to receive a buildstyle for ***Flexcera*** *Smile*.

Transfer constructed STL files of artificial teeth to the printer. *See the printer's User Manual / Software User Manual.*

D. STARTING THE PRINT

Start the printing process as described in the *printer's User Manual*.

FIG. 2 APPROVED 3D PRINTERS

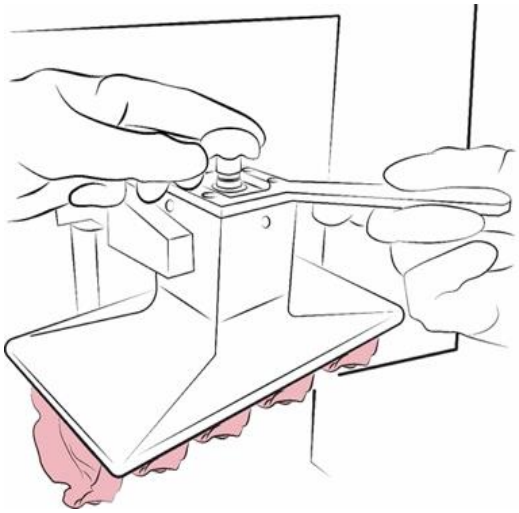
E. REMOVE MODELS FROM PRINTER

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

NOTE: 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. 3*.
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. 3 ENVISION ONE CDLM – REMOVING BUILD



F. CLEANING THE MODELS

Set up the magnetic stirrer with a bar or lab shaker in the Post Processing area and add Isopropyl Alcohol (min. >96 %) into an appropriately sized container. *See the stirrer / shaker manual for setup instructions.*

Clean the models using the following procedure:

1. Clean in Isopropyl Alcohol (min. >96 %) for a maximum of 5 minutes in the stirrer or 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 stirrer or 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.

G. ASSEMBLING THE DENTURES

Artificial denture teeth printed in ***Flexcera*** *Smile* may be bonded to denture bases printed in ***Flexcera*** *Base* or conventional denture base materials. If bonding to conventional denture base materials, the teeth must first be cured. Otherwise, the artificial teeth printed using ***Flexcera*** *Smile* must be uncured.

If using *Flexcera Base* : The 3D printed dentures must be uncured and unpolished prior to adding bonding agent (optional) and attaching to the denture. *See* ***Flexcera*** *Base IFU for manufacturing instructions.*

If using conventional denture base materials: The tooth neck may be sandblasted or ground with a dental milling machine prior to adding a bonding agent. A bonding agent must be used to coat the tooth neck.

Assembling the denture base and teeth:

1. When using conventional denture base materials, first post-cure the part as described in step 4. Optionally sandblast or grind the tooth neck. This step is not necessary when using 3D printed ***Flexcera*** *Base* dentures.

2. When using conventional denture base materials, coat the tooth neck with a bonding agent. This step is optional when using 3D printed ***Flexcera*** *Base* dentures.

3. When using 3D printed Flexcera Base dentures: Use the pipette to place drops of uncured ***Flexcera*** *Base* in the alveoli, *Fig. 4*. Immediately after place the teeth over the liquid photopolymer.

4. Post-cure the part using the light curing unit:

   Otoflash G171, *Fig. 5*; Parameters: 2x3000 flashes (i.e. 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen).

FIG. 4 USE PIPETTE TO PLACE DROPS OF UNCURED FLEXCERA BASE IN ALVEOLI

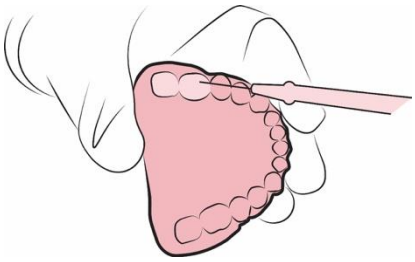
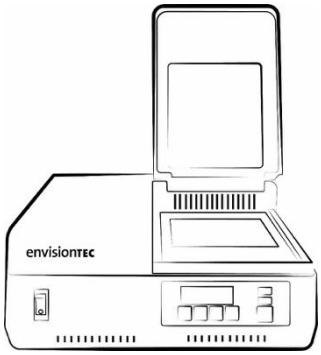


FIG. 5 OTOFLASH G171 CURING UNIT



H. FINISHING THE DENTURES

1. Use a commercial dental handpiece to clean the remaining support structures and remove excess resin around the teeth.

2. Optional: Individualize with light-curing coloring materials for a better cosmetic effect, according to the *Instruction for Use of the color material manufacturer*.

3. High gloss polish the surface with a commercially dental hand piece or dental polishing machine, *Fig 6*.

FIG. 6 POLISHING DENTURES

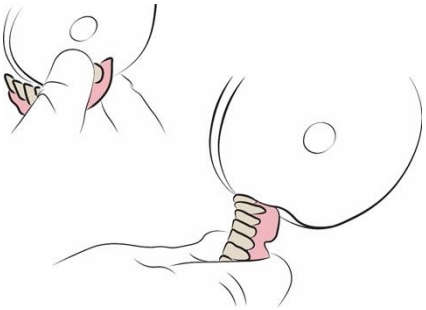


FIG. 7 FINISHED DENTURES

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

5. The product can now be used on the patient.

   The post-curing process may cause minor temporary color deviation of artificial teeth built using Flexcera Smile. The color will stabilize within 6 days.

12- Disinfection and Sterilization

Artificial teeth made of ***Flexcera*** *Smile light curable resin* can be disinfected with any of the following disinfectants:

- 70 % Ethanol solution in water
- Green&Clean AD
- MD 520
- PritoSept-ID
- Dentavon

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

Products from ***Flexcera*** *Smile light curable resin* cannot be sterilized.

13- Cleaning Instructions for Dentures

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

14- Reporting undesirable effects

In the event of adverse effects, reactions, or similar occurrences arising from the use of these products, including those not listed in this Instruction for Use, these must be reported immediately 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.

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17- Legal Disclaimer

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