

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 prostheses, which are one of the main components in the fabrication of removable permanent full dentures. It has been optimized for use with released 3D Printers (see section 11-A-1) and may only be used together with these printers and the corresponding software systems. **Flexcera™ Smile** is a medical device classified per U.S. Food and Drug Administration (FDA) as Class 2, 510(k) Exempt (21 CFR 872.3760) and classified in Canada as Class 2 according to Medical Device Regulations (SOR/98-282). 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 prostheses, 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

Flexcera™ Smile should not be used for purposes other than those identified herein. Any deviation from these instructions for use may have negative effects on the physical and/or chemical qualities of the resin and the biocompatibility of the end product. Dental applications from **Flexcera™ Smile** should not be used in patients if there are known allergies to any of the ingredients (see Composition). 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 prostheses, 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 when 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 41°F (5°C) and 86°F (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 material tray 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 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 machine material tray, cassette or resin tank can be re-used for several build jobs. If the level in the material 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 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.
- 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:

	Batch number		Protect from sunlight
	Expiration date (YYYY-MM-DD)		Follow Instruction for Use
	Manufacturer		Temperature limit
	Catalogue number		Manufacturing date (YYYY-MM-DD)
	Prescription device labeling statement		Unique device identification

11 - Manufacturing Instructions

A. SUPPLIES NEEDED FOR DENTURE FABRICATION

- Released 3D Printer:
 - Desktop Health 3D printer
 - EnvisionTEC 3D printer
 - Carbon® M2, M3 and M3 Max printers
 - Asiga Max-series, Ultra-series, and Pro 4K-series
 - LuxCreo iLux Pro Dental and LuxCreo fastprint.io printer
- Material tray (EnvisionTEC, Desktop Health™ or Asiga®), the cassette (Carbon®), or resin tank (LuxCreo) for use with **Flexcera™ Smile light curable resin** only.
- Flexcera™ Smile light curable resin.**
- Flexcera™ Base light curable resin**, or conventional denture base materials.
- Flexcera™ Smile** material tag/RFID card (shipped with the material bottle and only for usage on Desktop Health™ or EnvisionTEC 3D Printer).
- Released Software:
 - Perfactory® RP Software (version 3.1540.1602 or later)
 - Envision One RP (version 1.0.1165 or later)
 - Live Build DLP 2.0.102
 - Carbon Printer UI
 - Cambridge Software from 3Shape A/S (version 2015 2650 or later)
 - Asiga® Composer
 - LuxFlow Software
- Buildstyle (EnvisionTEC or Desktop Health™), .ini file (Asiga®) or Print Parameter (LuxCreo) for **Flexcera™ Smile Ultra+**. Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine or download the .ini file the user section of the Asiga® website (www.asiga.com).

8. File in .stl format
9. Starter Kit (included with the purchase of the 3D printer).
10. Paper towels.
11. Cone-shaped funnel.
12. Personal protective equipment, as per SDS.
13. Magnetic stirrer with bar, or lab shaker.
14. Isopropyl Alcohol min. >96%.
15. Post curing unit:
 1. Otoflash G171
 2. Wicked Engineering CUREbox Plus
 3. Dreve PCU LED N2
 4. iLuxCure Pro or iLuxCure Dental
16. Pipette.
17. 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: Before using this material for the first time or after prolonged storage, it must be homogenized. Shake the material bottle vigorously for approximately 5 minutes. Be aware that vigorous shaking may cause air bubbles to form. Allow the material to rest in the bottle for an additional 5 minutes to allow any air bubbles to rise and dissipate before use.

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 tray, resin tank or the cassette. Use the spatula from the Starter Kit or a material mixing card if available to carefully mix the resin in the material tray, resin tank or cassette. Mix until there is a uniform color. Take care not to damage the surface of the material tray, resin tank or cassette.

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

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 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 a released software (see section 11-A-6).

Connect the **Flexcera™ Smile** buildstyle (EnvisionTEC or Desktop Health™), .ini file (Asiga®) or Print Parameter (LuxCreo) to the corresponding software. Contact EnvisionTEC Technical Support to receive a buildstyle for **Flexcera™ Smile**, download the .ini file in the user section of the Asiga® website or select the appropriate resin shade in the Carbon Printer UI.

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*.

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.
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.

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

G. ASSEMBLING THE DENTURES

Artificial teeth printed with **Flexcera™ Smile** may be bonded to denture bases printed with **Flexcera™ Base light curable resin** or conventional denture base materials.

If using Flexcera™ Base (see **Flexcera™ Base IFU** for manufacturing instructions):

1. The 3D printed dentures and the printed artificial teeth must be uncured and unpolished prior to adding bonding agent (optional) and attaching to the denture.
2. Use the pipette to place drops of uncured **Flexcera™ Base** in the alveoli.
3. Immediately after place the teeth over the liquid photopolymer.
4. Follow with the step "Post-cure the part"

If using conventional denture base materials:

1. The artificial teeth need to be post cured as described in step "Post-cure the part".
2. The tooth neck may be sandblasted or ground with a dental milling machine prior to adding a bonding agent.
3. A bonding agent must be used to coat the tooth neck.
4. The Instruction for Use of the conventional denture base material has to be followed (Recommendation: Cold polymerization process).

Post-cure the part using the light curing units:

Do not stack dentures 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.

1. Otofash G171: Parameters: 2x3000 flashes (i.e., 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen)
2. Wicked Engineering CUREbox Plus: Parameters: 2x 25minutes with 50°C (25minutes per side).
3. Dreve PCU LED N2 for 18min with 90% power under vacuum (can be used alternatively when using conventional denture base materials, Parameters: 90% Power for 18 minutes under vacuum)
4. iLuxCure Pro for 10min with 100% power or iLuxCure Dental Program Setting P08 (12min with 35% power)

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.
4. Post-cure the product in the light curing units:
 1. Otofash 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. iLuxCure Pro or iLuxCure Dental for 1min with 50% power
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
- PrintoSept-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.

Note: Care should be taken to ensure that the dentures are not shipped or stored soaking in water as this can adversely affect the mechanical properties.

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/> or by contacting your local distributor.

15- Manufacturer

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16- Legal Disclaimer

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