

Instructions for Use – Flexcera™ Smile Ultra+ Light Curable Resin

1. – Introduction

Flexcera™ Smile Ultra+ 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,
- individual permanent full single crowns and permanent partial crowns in anterior and posterior region, including inlays and onlays,
- temporary bridges,
- individual permanent veneers,
- individual and removable monolithic full and partial dentures for later individualization by light curing color composite pastes or liquids.

It has been optimized for use with Desktop Health's *Einstein™* 3D printer 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 Ultra+* is an FDA 510(k)-cleared medical device, classified per U.S. Food and Drug Administration (FDA) as Class 2. Dental applications from *Flexcera Smile Ultra+* may only be manufactured by dental technicians and must be inspected by authorized practitioners, such as dentists, before they are released to the patients.

Temporary applications from *Flexcera Smile Ultra+* are custom-made products that may be used up to one year, under consideration of their application and intended exclusively for one patient. Dental applications from *Flexcera Smile Ultra+* are custom-made products for long-term use, under consideration of their application and intended exclusively for one patient.

The target group is patients which need restorations or optimization of the teeth, 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 Ultra+ is an alternative to traditional heat-curable and auto polymerizing resins. The resin is intended exclusively for professional dental work. Fabrication of dental applications with *Flexcera Smile Ultra+* requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression or, in case of artificial teeth for dental prostheses, digital dental files based on **manufacturer's** data, a digital light processing (DLP) printer, and curing light equipment.

Authorized applications:

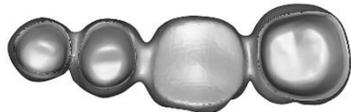
Crowns, Veneers:

			
Full anatomical single crown in anterior region	Full anatomical single crown in posterior region	Partial crown (Inlay/ onlay /overlay)	Veneer

Artificial teeth, monolithic full and partial dentures:

	
Artificial teeth for dental prostheses	Monolithic full and partial dentures

Bridges:

Full anatomical monolithic bridge for anterior and/or posterior region <u>with no pontic</u> (up to 6-unit bridge capability)	Full anatomical monolithic bridge for anterior and/or posterior region <u>with max. 1 pontic</u> (up to 6-unit bridge capability)	Full anatomical monolithic bridge for anterior and/or posterior region <u>with max. 2 not adjacent pontics</u> (up to 6-unit bridge capability)
		
		

Flexcera Smile Ultra+ is available in the following colors:

Bleach		
A1		<i>Flexcera Smile Ultra+</i> A1 is comparable to VITA® classical, colors A1, C1, D2 Dentin
A2		<i>Flexcera Smile Ultra+</i> A2 is comparable to VITA® classical colors A2, D4 Dentin
A3		<i>Flexcera Smile Ultra+</i> A3 is comparable to VITA® classical colors A3, B3 Dentin
A3.5		<i>Flexcera Smile Ultra+</i> A3.5 is comparable to VITA® classical colors A3.5, B4 Dentin
B1		<i>Flexcera Smile Ultra+</i> B1 is comparable to VITA® classical color B1 Dentin

3. – **Contraindications**

Flexcera Smile Ultra+ 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 Ultra+* 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 Ultra+* 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,
 - individual and fixed temporary or permanent full single crowns and temporary or permanent partial crowns in front and posterior area,
 - temporary bridges,
 - individual and fixed single veneers,
 - individual and removable monolithic full and partial dentures for later individualization by light curing color composite pastes or liquids.
- Any deviation from the Instruction for Use can negatively affect the chemical and physical properties and biocompatibility of the finished product.
- 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 Ultra+ light curable resin* cannot be sterilized. See section 12 for disinfection procedure.
- *Flexcera Smile Ultra+ light curable resin* contains materials which may cause skin irritation or allergic reaction. Wear protective gloves, protective clothing, eye protection, face protection.
- Suspected of damaging fertility or the unborn child.
- In case of skin contact with the resin, wash with plenty of water.
- The resin causes serious eye damage. 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 Ultra+ 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 Ultra+ light curable resin* must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- *Flexcera Smile Ultra+ 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 the *Einstein™*, mix the remaining material in the basement thoroughly after no more than 4 builds and return it to the bottle. Shake the bottle vigorously.
- Dental applications from *Flexcera Smile Ultra+* must be protected from exposure to light while not in use.

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

- *Flexcera Smile Ultra+ 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 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, the remaining material in the basement must be thoroughly mixed and filled back into the bottle. For further information on re-using and mixing material, please check the **printer's User Manual**.
- When using the *Einstein™*, mix the remaining material in the basement thoroughly after no more than 4 builds and return it to the bottle. Shake the bottle vigorously.
- Dental applications from *Flexcera Smile Ultra+* 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 Ultra+ 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 any other additional medical products or auxiliary products to manufacture crowns, veneers, artificial teeth for dental prostheses and monolithic full and partial dentures, such as e.g. light-curing stains and composites for individualization, bonding agents for fixing artificial teeth with denture base, luting composite for bridge, crown or veneer fixing, material for full denture bases or implants and abutments as retaining element inside patients mouth etc. depends on the user s assessments.

10. – Delivery Unit, Symbol Explanation

Delivery unit: *Flexcera Smile Ultra+* is available in containers of 0.5 kg and 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)
 Rx Only	Prescription device labeling statement	 UDI	Unique device identification

11. – Manufacturing Instructions

A. SUPPLIES NEEDED

1. Desktop Health 3D printer: *Einstein™*
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 Ultra+ light curable resin* only. Order printer-specific parts from EnvisionTEC or authorized distributors.
3. *Flexcera Smile Ultra+ light curable resin.* Order from Desktop Health or authorized distributor.
4. *Flexcera Base light curable resin*, or conventional denture base materials, if fabricating artificial teeth for dentures. Order *Flexcera Base* from Desktop Health or authorized distributor.
5. *Flexcera Smile Ultra+* 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 Ultra+*. 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 (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. Incubator/oven (optional).
17. Otofash G171 curing unit. Order from EnvisionTEC or authorized distributor.
18. Pipette.
19. 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.

Construction rules

Crowns and veneers:

Crowns made of *Flexcera Smile Ultra+* must be adhesively fixed to a prepared natural tooth stump or an artificial tooth stump such as an implant abutment or post and core.

Veneers made of *Flexcera Smile Ultra+* must be adhesively fixed to a prepared natural tooth stump.

Minimum wall thickness

Occlusal:	1.5 mm in central fissure
Circular:	1 mm

Parts must be built horizontally orientated to the platform, with supports connecting only to the occlusal or incisal surface e.g., to avoid manual post processing of the sides in direct contact with the mating surface.

Monolithic full dentures:

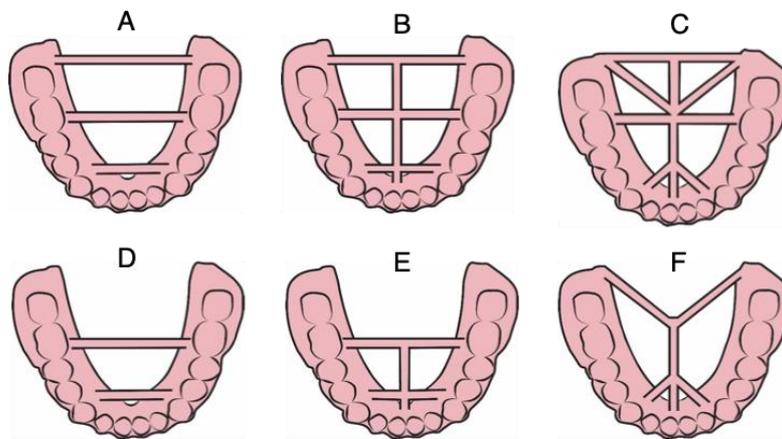
Monolithic full dentures made of *Flexcera Smile Ultra+* must be designed without any additional fixtures to increase holding force. Design the denture base using the certified software based on the digitalized data obtained from the bite registration process. The minimum approved wall thickness is 2.5mm.

Parts must be built vertically orientated to the platform, with supports connecting only to the labial border, to avoid manual post processing of the sides in direct contact with oral mucosa.

A connector must be added to the design of the lower denture base to ensure the stability of the part during fabrication and accuracy of the part's dimensions/fit once finished. The connector designs in *Fig. 1*

are permitted (Figure 1A is recommended, as it will require the least amount of material while ensuring high accuracy).

FIG. 1 VALIDATED CONNECTOR DESIGNS FOR LOWER DENTURE BASE



Monolithic partial dentures:

Monolithic partial dentures made of *Flexcera Smile Ultra+* must be designed without any additional fixtures to increase holding force, except for the clasps. The minimum approved wall thickness of the denture as well as for the clasps is 2.5mm.

Bridges:

The temporary bridges made of *Flexcera Smile Ultra+* must continuously consist of full anatomical crowns, need to be end pillar bridges and need to be adhesively fixed to the bridge pillars (prepared natural tooth stump and/or an artificial tooth stump). The maximum number of units in a bridge made of *Flexcera Smile Ultra+* are 6. Full anatomical end pillar bridge can have max. 2 not adjacent pontics within a 5- or 6-unit bridge.

Minimum connector cross-section

Anterior region:	12 mm ²
Posterior region:	14 mm ²

Minimum wall thickness

Occlusal:	1.5 mm in central fissure
Circular:	1 mm

Parts must be built horizontally orientated to the platform, with supports connecting only to the occlusal or incisal surface e.g., to avoid manual post processing of the sides in direct contact with the mating surface.

C. PREPARING TO PRINT

Preparing the Material:

Flexcera Smile Ultra+ 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 Ultra+* 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 (*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 Ultra+* material must be used.

A material tag (RFID card) is shipped with the *Flexcera Smile Ultra+* resin bottle. Place the material tag on the RFID tag reader on the 3D printer. 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 Ultra+* buildstyle to the Software. Contact EnvisionTEC Technical Support to receive a buildstyle for *Flexcera Smile Ultra+*.

Transfer constructed STL files of planned applications 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 PARTS FROM PRINTER

When the printing process is complete, carefully remove the parts 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 parts from the build platform. Place parts on a clean paper towel and protect from ambient light.

F. CLEANING THE PARTS

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 parts 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. Place the dried parts in an incubator/oven at 37 °C for 30 minutes (alternatively, the parts may be airdried for a minimum of 45 minutes at a temperature between 73°F and 85°F (23°C and 28°C) and a humidity level below 45%).
6. Remove the supports with a scalpel or similar tool.

G. WHEN PRINTING ARTIFICIAL TEETH FOR DENTURES: ASSEMBLING THE DENTURES

Artificial denture teeth printed in *Flexcera Smile Ultra+* may be bonded to denture bases printed in *Flexcera Base* or conventional denture base materials. In either case, the artificial teeth printed using *Flexcera Smile Ultra+* 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, 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. Immediately after place the teeth over the liquid photopolymer.
4. Post-cure the part using the light curing unit: Otoflash G171; Parameters: 2x3000 flashes (i.e., 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen).

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 Otoflash G171 with 1000 flashes.
5. The product can now be used on the patient. If any further polishing during patient fitting is necessary, then the products must subsequently be post-cured with 1000 flashes in Otoflash G171.

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

I. WHEN PRINTING CROWNS, VENEERS, BRIDGES AND MONOLITHIC DENTURES

1. Post-cure the part using the light curing unit:
2. Otoflash G171; Parameters: 2x3000 flashes (i.e., 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen).
3. For lower full dentures only: Remove the connector with a scalpel or similar tool.
4. Optional: Individualize with light-curing coloring materials for a better cosmetic effect, according to the Instruction for Use of the color material manufacturer.
5. High gloss polish the surface with a commercially dental hand piece or dental polishing machine.
6. Post-cure the product in the Otoflash G171 with 1000 flashes.
7. The product can now be used on the patient. If any further polishing during patient fitting is necessary, then the products must subsequently be post-cured with 1000 flashes in Otoflash G171.

The post-curing process may cause minor temporary color deviation of printed dental parts built using *Flexcera Smile Ultra+*. The color will stabilize within 6 days.

12. – Disinfection and Sterilization

Printed dental parts made of *Flexcera Smile Ultra+ 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 Ultra+ 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/> or by contacting your local distributor.

15. – **Manufacturer**

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16. – **Legal Disclaimer**

The manufacturer does not accept any liability for damages or injury caused by any other use of the material. Furthermore, before using the material, the user must independently check for its suitability and applicability for the intended use. EnvisionTEC, Perfactory, Envision One, cDLM, and Vida are registered trademarks of EnvisionTEC GmbH.

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Rx Only