Desktop Health™

Instructions for Use – **Flexcera™** Base

Light Curable Resin

1 - Introduction

Flexcera™ *Base* is a light-curable resin for the additive manufacturing of individual full denture bases. 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™*** *Base* is a medical device classified per U.S. Food and Drug Administration (FDA) as Class 2 (21 CFR 872.3760) and classified in Canada as Class 2 according to Medical Device Regulations (SOR/98-282). Full denture bases from ***Flexcera™*** *Base* 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 from ***Flexcera™*** *Base 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 minimum approved wall thickness is 3mm and the maximum approved wall thickness is 10mm. 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™ *Base* is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. ***Flexcera™*** *Base* is intended exclusively for professional dental work. Fabrication of denture bases with ***Flexcera™*** *Base* requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base-files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.

Flexcera™ *Base* is available in the following colors:

Light Pink		***Flexcera™*** *Base Light Pink* is comparable to Kulzer's dima® Print Denture Base Light Pink
Original Pink		***Flexcera™*** *Base Original Pink* is comparable to Dentsply Sirona's Lucitone® 199 Original and Lucitone® Digital Print 3D Denture Resin Original
Medium Pink		***Flexcera™*** *Base Medium Pink* is comparable to Ivoclar Vivadent's IvoBase® Pink
Dark Pink		***Flexcera™*** *Base Dark Pink* is comparable to Ivoclar Vivadent's IvoBase® 34-V
Dark Meharry		***Flexcera™*** *Base Dark Meharry* is comparable to Dentsply Sirona's Lucitone® 199 Dark Pink

3 - Contraindications

Full dentures fabricated from ***Flexcera™*** *Base* 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 and absorbers.

5 - Warnings

- Review the SDS prior to use.
- ***Flexcera™*** *Base* may only be used for the production of full denture bases. 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™*** *Base* may not be used for the production of partial dentures, cover dentures, and implant retained full dentures.
- 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™*** *Base light curable resin* cannot be sterilized. See section 12 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection when handling ***Flexcera™*** *Base 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™*** *Base 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™*** *Base light curable resin* must be stored in the original material bottle between 5°C and 30°C.
- ***Flexcera™*** *Base 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™*, 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 must be protected from exposure to light while not in use.

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

- ***Flexcera™*** *Base 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 material tray (EnvisionTEC, Desktop Health™ or Asiga®) or inside the cassette (Carbon®) can be re-used for several build jobs. If the level in these 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.
- Full denture bases must be protected from exposure to light before the final use, while not in use, and during storage.

8 - Notes on Disposal

Dispose of ***Flexcera™*** *Base 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 conventionally manufactured artificial teeth and bonding agents depends on the user's assessments.

10 - Delivery Unit, Symbol Explanation

Delivery unit: ***Flexcera™*** *Base* 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)
Rx Only	Prescription device labeling statement	UDI	Unique device identification

11 - Manufacturing Instructions

A. SUPPLIES NEEDED FOR DENTURE FABRICATION

1. Released 3d Printer:
    1. Desktop Health 3D printer
    2. EnvisionTEC 3D printer
    3. Carbon® M2, M3 and M3 Max printers.
    4. Asiga® Max-series, Ultra-series and Pro 4K-series
2. Material tray (EnvisionTEC, Desktop Health™ or Asiga®) or the Standard and AO-Polishing cassette (Carbon®) for use with ***Flexcera™*** *Base light curable resin* only.
3. ***Flexcera™*** *Base light curable resin*.
4. ***Flexcera™*** *Smile* or ***Flexcera™*** *Smile Ultra+ light curable resin*, or conventionally fabricated artificial teeth (PMMA).
5. ***Flexcera™*** *Base* material tag/RFID card (shipped with the material bottle and only for usage on Desktop Health™ or EnvisionTEC 3D Printer).
6. Released Software:
    1. Perfactory® RP Software (version 3.1540.1602 or later)
    2. Envision One RP (version 1.0.1165 or later)
    3. Live Build DLP (version 2.0.102 or later)
    4. Carbon Printer UI
    5. Cambridge Software from 3Shape A/S (version 2015 2650 or later)
    6. Asiga® Composer

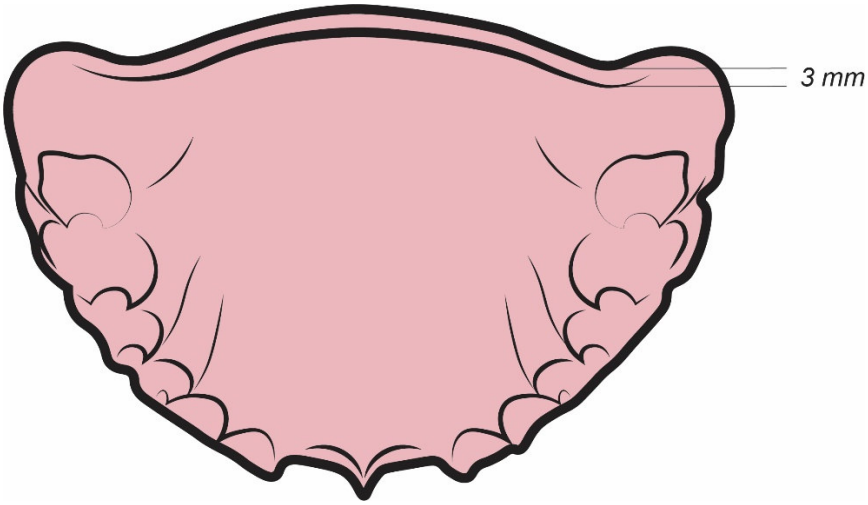
7. Buildstyle (EnvisionTEC or Desktop Health™) or .ini file (Asiga®) for ***Flexcera™*** *Smile Ultra+.* Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine or download the .ini file the user section of the Asiga® website (www.asiga.com).
8. File in. stl format
9. Starter Kit (included with the purchase of the Desktop Health™ or EnvisionTEC 3D printer), provided scraper (Einstein™, Perfactory® Envision One cDLM ®, Perfactory® D4K Pro) or material mixing cards (Perfactory® P4K series, Perfactory® P4K Advantage series, Perfactory® Vida ® series), and cone-shaped filters.
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.
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.

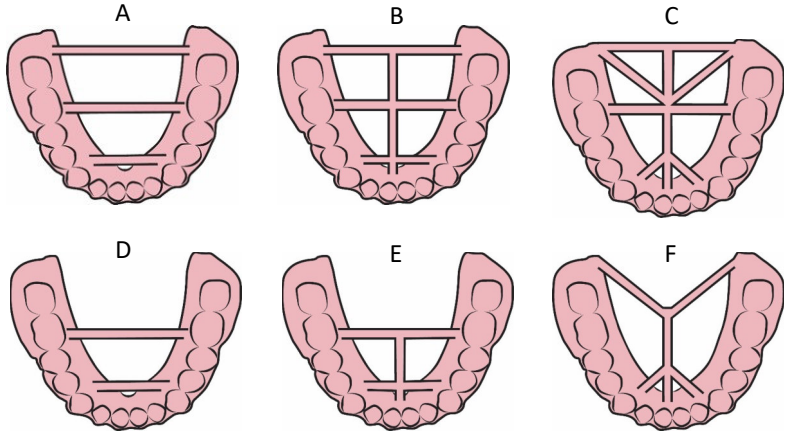
Design the denture base using the certified software based on the digitalized data obtained from the bite registration process. **The minimum approved wall thickness is 3mm and the maximum approved wall thickness is 10mm**, *Fig. 1.*

FIG. 1 MINIMUM WALL THICKNESS IS 3MM



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. 2* are permitted (Figure 2 Type A is recommended, as it will require the least amount of material while ensuring high accuracy).

FIG. 2 VALIDATED CONNECTOR DESIGNS FOR LOWER DENTURE BASE



C. PREPARING TO PRINT

Preparing the Resin:

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

Prepare the resin: 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™*** *Base light curable resin* (*see the User Manual for the specific 3D printer used).* Fill the material tray 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 or cassette. Mix until there is a uniform color. Take care not to damage the surface of the material tray or cassette.

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

A material tag (RFID card) is shipped with the ***Flexcera™*** Base 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™*** *Base* buildstyle (EnvisionTEC or Desktop Health™) or .ini file (Asiga®) to the corresponding software. Contact EnvisionTEC Technical Support to receive a buildstyle for **Flexcera™** Base, download the .ini file in the user section of the Asiga® website or select the appropriate resin shade in the Carbon Printer UI.

For accurate results, denture bases must be built vertically orientated to the build platform, with supports connecting only to the labial border. In this orientation, additionally, manual post-processing of the sides in direct contact with the oral mucosa will be avoided.

Transfer constructed STL files of full denture bases 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 PRINTED PARTS FROM 3D 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 printed 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. 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

Denture bases printed from ***Flexcera™*** *Base* may be bonded to denture teeth printed from ***Flexcera™*** *Smile or* ***Flexcera™*** *Smile Ultra+ light curable resin* or conventionally fabricated artificial teeth (PMMA). The denture bases printed using ***Flexcera™*** *Base* must be uncured.

If using printed artificial teeth with *Flexcera™ Smile or Flexcera™ Smile Ultra+* *(see the corresponding IFU for manufacturing instruction)*:

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

If using conventionally fabricated artificial teeth (PMMA):

1. The tooth neck must be sandblasted or ground with a dental milling machine prior to adding a bonding agent and attaching it to the denture.
2. A bonding agent must be used to coat the tooth neck. (see IFU of bonding agent)

   or

   Use the pipette to place drops of uncured ***Flexcera™*** *Base* in the alveoli.
3. Immediately after that place the teeth over the liquid photopolymer.
4. Follow with the step “Post-cure the part.”

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. Otoflash 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

H. FINISHING THE DENTURES

1. Remove connector(s) with a scalpel or similar tool,
2. Use a commercial dental handpiece to clean the remaining support structures and remove excess resin around the teeth.
3. Polish the surface with a commercial dental hand piece or dental polishing machine, *Use the device according to instructions for use by the manufacturer*. Due to the polishing process, minimal differences in fit can occur. Therefore, the printed product should be inspected on a dental model after processing.
4. Post-cure the product in the light curing units:
    1. Otoflash 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
5. The product can now be used on the patient.

12 - Disinfection and Sterilization

Full denture bases made of ***Flexcera™*** *Base 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™*** *Base light curable resin* cannot be sterilized.

13 - Cleaning Instructions for Patients

The denture can be cleaned by the patient with clear water, a toothbrush, and toothpaste. Avoid abrasive or whitening agents in some kinds of toothpaste which 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/ and to the competent authority of the Member State in which the user and/or patient is established.

15 - Manufacturer

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