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 EnvisionTEC's *Perfactory® Envision One cDLM ®, 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*** *Base* is a medical device classified per U.S. Food and Drug Administration (FDA) as Class 2 (21 CFR 872.3760). Full denture bases from ***Flexcera*** *Base* may only be manufactured by dental technicians and must be inspected by authorized practitioners, such as dentists, before they are released to the patients.

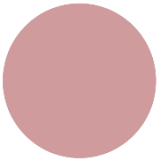
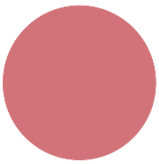
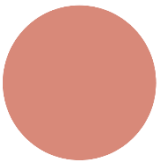
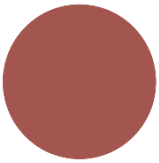
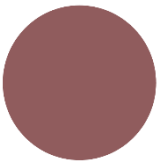
Dentures from ***Flexcera*** *Base light curable resin* are custom-made products for daytime use and intended exclusively for one patient. The target group is patients with a total loss of teeth on one or both jaws, whereby high-risk patients are excluded (see Section 3).

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.
- ***Flexcera*** *Base 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*** *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 41°F (5°C) and 86°F (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.
- 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 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, it must be filled back into the bottle. For further information on re-using and mixing material, please check the printer's *User Manual*.
- 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

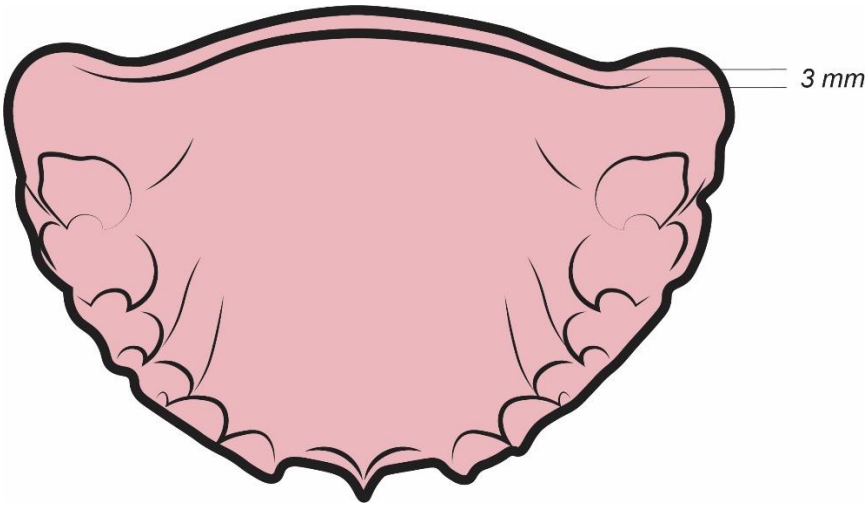
1. EnvisionTEC 3D printer: *Perfactory® Envision One cDLM®, Perfactory® Vida® series, Perfactory® P4K series, Perfactory® P4K Advantage series,* or *Perfactory® D4K Pro.*
2. Material basement for use with ***Flexcera*** *Base light curable resin* only. Order printer-specific parts from EnvisionTEC or authorized distributors.
3. ***Flexcera*** *Base light curable resin*. Order from Desktop Health™ or authorized distributor.
4. ***Flexcera***™ *Smile light curable resin*, or conventionally fabricated artificial teeth (PMMA). Order ***Flexcera*** *Smile* from Desktop Health™ or authorized distributor.
5. ***Flexcera*** *Base* 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*** *Base*. 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 EnvisionTEC printer), provided scraper (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.
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. Otoflash 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.

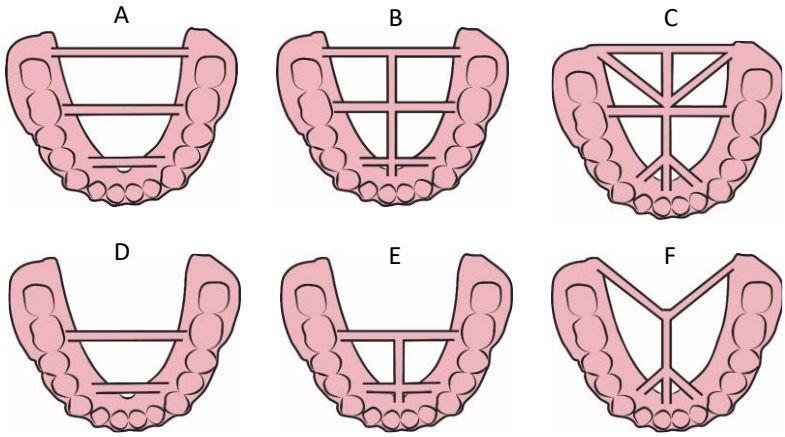
Design the denture base using the certified software based on the digitalized data obtained from the bite registration process. **The minimum approved wall thickness is 3mm and the maximum approved wall thickness is 10mm**, *Fig. 1.*

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 2A 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: 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:

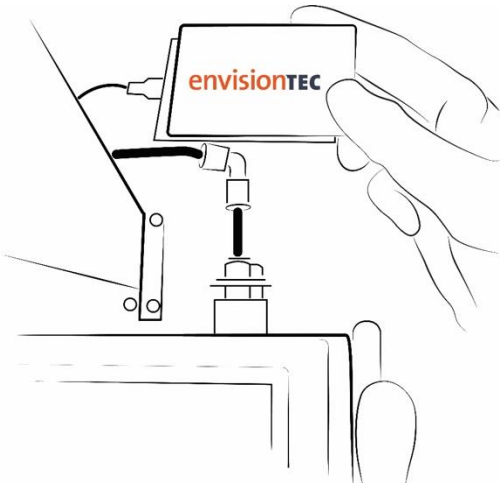
Setup the 3D printer for ***Flexcera*** *Base light curable resin (see the User Manual for the specific 3D printer used).* Fill the material basement. Use the spatula from the Starter Kit *(Envision One cDLM®, D4K Pro)* or a material

mixing card *(Perfactory® P4K series, Perfactory® P4K Advantage series, Perfactory® Vida® series)* to carefully mix the resin 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*** *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, *Fig. 3.* The card must remain on the reader for the duration of the print.

FIG. 3 ENVISION ONE CDLM - PLACING MATERIAL TAG



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*** *Base* buildstyle to the software. Contact EnvisionTEC Technical Support to receive a buildstyle for ***Flexcera*** *Base.*

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.*

FIG. 4 APPROVED 3D PRINTERS

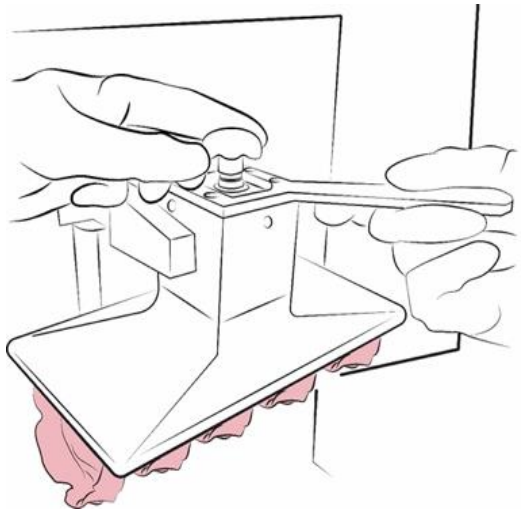
E. REMOVE PRINTED PARTS FROM 3D PRINTER

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, *Fig. 5.*
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. 5 ENVISION ONE CDLM – REMOVING BUILD PLATFORM



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. Place the dried models in an incubator/oven at 37 °C for 30 minutes (alternatively, the parts may be air-dried 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. ASSEMBLING THE DENTURES

Denture bases printed from ***Flexcera*** *Base* may be bonded to denture teeth printed from ***Flexcera*** *Smile light curable resin,* or conventionally fabricated artificial teeth (PMMA). In either case, the denture bases printed using ***Flexcera*** *Base* must be uncured.

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

If using conventionally fabricated artificial teeth (PMMA): 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.

Assembling the denture base and teeth:

1. When using conventionally fabricated artificial teeth (PMMA), coat the tooth neck with a bonding agent. For 3D-printed artificial teeth, see the material's IFU for the recommendation on bonding agent. This step is optional when using uncured 3D-printed artificial teeth (see manufacturer's IFU).

2. Use the pipette to place drops of ***Flexcera*** *Base resin* in the alveoli of the uncured denture base, *Fig. 6.* Immediately after, place the teeth over the resin and proceed to post-curing in step 3. Do not cure individual teeth to the denture base.

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

   Otoflash G171, *Fig. 7*; Parameters: 2x3000 flashes (i.e. 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen).

   Do not stack dentures or allow parts to touch in the light curing unit. Parts will be hot immediately after post-curing, handle with care.

   Note: Using an alternative light source may result in an insufficient curing, which may adversely affect biological and mechanical properties.

FIG. 6 USE PIPETTE TO PLACE DROPS OF UNCURED FLEXCERA BASE IN ALVEOLI

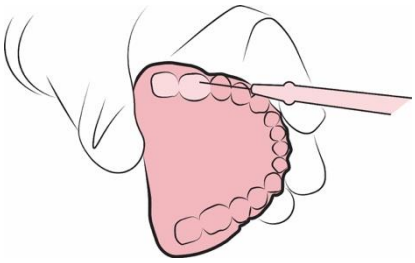
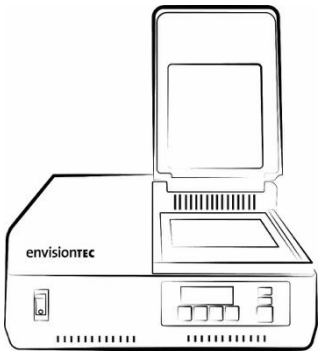


FIG. 7 OTOFLASH G171 CURING UNIT



H. FINISHING THE DENTURES

1. Remove connector(s) with a scalpel or similar tool, *Fig. 8.*

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, *Fig. 9*.
   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 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.

FIG. 8 REMOVE CONNECTOR WITH SCALPEL

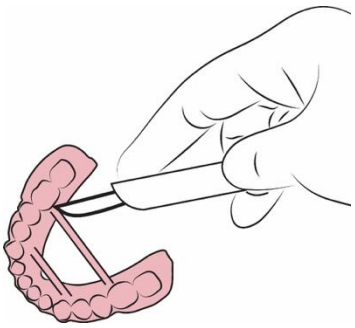


FIG. 9 POLISHING DENTURES

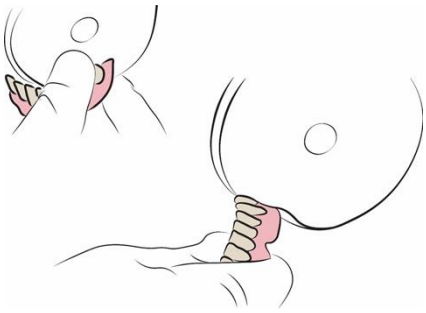
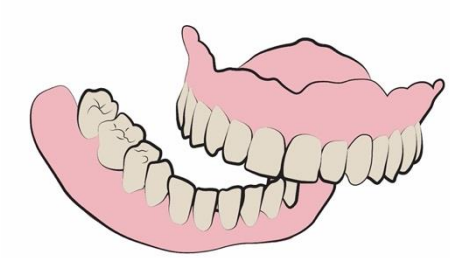


FIG. 10 FINISHED DENTURES



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
- PritoSept-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. 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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Rx Only

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