Product Name:
LuxCreo Flexible Partial Denture Resin

Model: Clear

Specifications
0.5kg/bottle; 1kg/bottle; 5kg/bottle.

Product Description
LuxCreo Flexible Partial Denture (FPD) Resin is a state of the art resin engineered specifically for the 3D Printing of digitally designed flexible partial denture bases. The FPD resin utilizes LuxCreo's Digital Polishing platform to deliver clear, accurate, and biocompatible partials in a single session with minimal need for finishing.

Indications Use
LuxCreo Flexible Partial Denture Resin is a liquid light-curing resin indicated for the fabrication and repair of partial denture bases. It is intended for use by dental professionals in dental and orthodontic laboratories and clinics.

Indications
LuxCreo Flexible Partial Denture Resin is intended for the additive manufacturing of removable partial denture bases, including denture bases for interim and transitional dentures, for the replacement of one or more missing teeth. The device is supported by remaining natural dentition and oral tissues. Partial dentures manufactured using this resin may be used permanently as a total removable replacement or temporarily while the patient is preparing for permanent implant.

Contraindication
- Not indicated for full-denture (completely edentulous) cases.
- LuxCreo Flexible Partial Denture Resin contains acrylate monomers and oligomers and should not be used in individuals with a history of acrylic sensitization.

Intended patient population
Partially edentulous adult patients that require replacement of one or more missing teeth.

Intended users
Dental professionals.

Intended use site
Dental/Orthodontic laboratories and clinics.

Clinical Benefits
- Restores masticatory function by replacing one or more missing teeth.
- Provides acceptable esthetic outcomes for patients with partial edentulism.
- Enables interim or transitional treatment during healing phases or prior to definitive prosthetic rehabilitation.
- Provides a removable and reversible prosthetic option when fixed restorations are not feasible.

Performance Characteristics
- Flexural Modulus ≥700 MPa
- Flexural Strength ≥25 MPa

Composition
Luxcreo Flexible Partial Resin is composed of polyurethane (meth)acrylate oligomer, (meth)acrylate monomer, photo-initiator, and additive.

Warnings
- Avoid direct skin and eye contact; skin contact may cause an allergic skin reaction.
- Inhalation: Irritating to respiratory system. Prolonged or repeated exposure may cause headache, drowsiness, nausea, weakness (severity of effects depends on the extent of exposure).
- Ingestion: Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract. Handle with care. Do not swallow and avoid breathing dust/fume/gas/mist/vapors/spray.

Precautions
- Wear protective gloves, protective clothing, eye protection, face protection when handling LuxCreo Flexible Partial Denture Resin. If resin contacts skin, wash thoroughly with soap and plenty of water. If dermatitis or other symptoms persist, seek medical assistance.
- If resin contacts eyes, immediately flush by plenty of water. After initial flushing, remove any contact lenses and continue flushing for 15 minutes. Have eyes examined and tested by medical personnel.
- Provide proper ventilation while using indoor.
- Keep out of reach of children and animals.
- LuxCreo Dental Clear Aligner Resin is light curable resin which 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.
- Use within 2-month after opening the original package and ensure that the product is still within its shelf life.

Storage & Transportation
- Store in dry place 5~30°C (41~86°F) and away from sunlight, ultraviolet rays and heat.
- Ensure the bottle is sealed while not in use.

Shelf Life
18 Months.

Compatible Equipment
- LuxCreo Printers (including iLux Pro Dental and fastprint. io)
- LuxFlow Slicing Software
- iLuxWash Dental Cleaning System
- LuxOven Series
- iLuxCure Series (including iLuxCure Pro and iLuxCure Dental)

Note: For alternative or additional compatible equipment, please contact LuxCreo's technical personnel.

Compatible cleaning reagent
>99 % isopropyl alcohol (IPA)

Direction for Use

1 Design Information
a. Patient's bite and dentition is digitally reproduced via intra-oral scan. The quality of the scan impacts the quality and fitment of the resulting device, and is the responsibility of an appropriately trained and qualified practitioner. A dental design service or dental CAD software (e.g. Exocad PartialCAD) can be used to design dental models in according to treatment plan.

b. The dental model files are imported into dental CAD software (e.g. Exocad PartialCAD) to generate flexible partial denture base model files compliant with the following design guidelines:

1. Minimum Body Thickness: 1.5mm
2. Maximum Body Thickness: 2.5mm
3. Recommended Body Thickness: 2.0mm
4. Other Body Thickness considerations:
5. <1.5mm of tapering distance to gingival margin.
6. Maximum taper thickness (at edge of margin) of 0.3mm.
7. Buccal/Lingual Side Coverage: minimum of 4.0mm past socket.
8. Thickness of Socket Area: >0.75mm
9. Socket Glue Gap: >100um
10. Length of Undercut Clasps: maximum of one tooth
11. Minimum Thickness of undercut clasps: 1.5mm
12. Other Undercut Clasp Thickness Considerations: <1mm of tapering distance. Maximum taper thickness (at edge of clasps) of 0.3mm.

2 Before Printing
a. Every bottle of FPD resin has a marked expiration date. Check expiration date prior to use. Expired resin may have adverse effects on material printability, safety, and clinical performance.

b. Shake resin for >10 seconds prior to use.

3 Printing
a. Software

1. Import the flexible partial denture base ".stl" files to LuxFlow.
2. After importing the flexible partial denture base ".stl" files into LuxFlow, users can efficiently orient, support, batch, slice, and send parts to printers. An automatic option is also provided, where the software will orient, support, and batch the parts for the user. Parts are automatically labeled on the support structure in accordance with the file name. File name is reflective of patient ID, allowing for track and trace throughout the manufacturing process.

b. Start print

LuxCreo printers will accept a job wirelessly via LuxFlow

or physically via USB flash drive. User can select job from machine or through LuxCreo' s fleet management system.

c. Remove printed parts from build platform

1. Remove the build platform from the machine.
2. Place the build platform face up on a tray or clean surface.
3. Remove printed parts from platform using a metal scraper angled at 15 degrees.

4 Post-processing

a. Cleaning Printed Parts: Place printed parts in the iLuxWash Dental cleaning chamber with >99% isopropyl alcohol (IPA) to remove excess liquid resin from the printed part. The washing step has two stages, with 15 minutes for each step. The washing step is performed under continuous agitation, at room temperature, without ultrasonic.

b. Thermal Curing: First place printed parts in LuxOven Pro using corresponding parameters.

c. UV Curing: After thermal curing, place the printed parts in iLuxCure Pro or iLuxCure Dental using corresponding parameters.

Post-Curing Parameter

Thermal Curing		UV Curing	
Device	Setting	Device	Setting
LuxOven Pro	20 minutes /130°C	iLuxCure Pro	30 minutes / "Flexible Partial Denture" program
		iLuxCure Dental	30 minutes /"P04" program

5 Finishing Parts

a. After post-curing, remove supports and finish parts with buffing/polishing wheel. Flush the parts under a running tap to remove the dust accumulated from buffing. Use a toothbrush to thoroughly cleanse the dust from the internal surfaces of the components.

b. If additional esthetic performance is desired, user may glaze the assembled denture using any commercial denture glazing kit such as Optiglaze or Rodin Palette 2.0.

6 Dental professionals may attach denture teeth to the finished flexible denture base using FDA-cleared dental materials, such as approved teeth and adhesive, to construct the partial denture.

Safe Disposal

- Dispose of the fully cured resin and containers as household waste.
- Do not pour liquid or partially cured liquid resin into drains.
- Disposal of liquid resin and its containers shall comply with local laws and regulations.

Manufacturer Information

LuxCreo Inc.

Suite 700, 350 W Ontario Street, Chicago, IL 60654

www.luxcreo.com

TEL: +1(650)336-0888

support@luxcreo.com

Reporting Adverse Events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1. Report Online at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
2. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at: www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
3. Call FDA at 1-800-FDA-1088 to report by telephone
4. Reporting Form FDA 3500 commonly used by health professionals. The form is available at: www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

Labels and Packing Logo Design:

Symbol	Introductions	Symbol	Introductions
LOT	Batch code	NON STERILE	Non-sterile
	Date of manufacture		Indicates the medical device manufacturer
	Use-by date		Read instructions
	Do not use if package is damaged		Temperature limit
UDI	Unique device identifier		Keep away from sunlight
MD	Medical device	Rx Only	Prescription use
	Harmful/Irritant		Health Hazards
	Fragile, handle with care		This end up
	Keep Dry		Recyclable

If assistance in setting up, using, or maintaining the device is needed or to report unexpected operation or events, please contact us.

LuxCreo
Simplify Digital Dentistry

FPD

Instruction for Use

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