Product Name:
LuxCreo Dental Surgical Guide Resin DSG

Model: DSG

Product Description

Surgical Guide Resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, endosseous dental implant accessories. It is for the manufacture of 3D printed parts used in the production of dental surgical guides. Users should independently verify the suitability of the material for their application and intended purpose.

Indications for Use

LuxCreo Dental Surgical Guide Resin

Model: DSG is a liquid curing resin product indicated for the three-dimensional fabrication of orthodontic and dental appliances retainers.

Specifications

1kg/bottle; 5kg/bottle.

Composition

It is composed of (methyl) acrylate monomer, (meth) acrylate resin, photon-initiator, and additive.

Property

1. Density: 1.10±0.5g/cm³

2. Liquid state

Contraindication

LuxCreo Dental Surgical Guide Resin contains acrylate monomers and oligomers, it should not be used in susceptible people. It may cause skin irritation or other allergic reactions.

Warnings

- Wear protective gloves, protective clothing, eye protection, face protection when handling LuxCreo Dental Surgical Guide Resin
- Do not swallow and avoid breathing dust/fume/gas/mist/vapors/spray; avoid direct skin and eye contact.
- 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.
- 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.

Precautions

- Wear PPE (Personal Protective Equipment) such as gloves and eye protections when handling.
- Provide proper ventilation while using indoor.
- Keep out of reach of children and animals.
- LuxCreo Dental Surgical Guide Resin 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.

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

12 Months.

Compatible Equipment

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

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

Direction for Use

1 Design Information

- The scanning and construction of patient's STL data is the responsibility of the customer. A dental design service or dental CAD software (e.g. 3Shape Splint Studio) must be used to design it. This STL file is delivered to the clinician for fabrication.

2 Before Printing

- Please check the expiration date on the resin bottle. A failed print is possible if an expired resin is used. In case of exceeding the expiration date, the product is no longer guaranteed in terms of performance.
- Shake resin for greater than 10 seconds prior to use for best results.

3 Printing

- Software: Bring the designed STL files to LuxFlow. After importing CAD files designed by a third-party software (e.g. 3Shape Splint Studio) into LuxFlow, users can efficiently orient, support, batch, slice, and send parts to printer. 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.
- 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.
- Remove printed parts from build platform.
  Remove the build platform from the machine. Place the build platform face up on a tray or clean surface. Remove printed parts from platform using a metal scraper angled at 15 degrees. Do not remove supports from 3d printed parts.

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 has two steps, with 4 minutes for each step.

B-Post-Curing

- Let the parts dry in ambient air or accelerate the drying with compressed air. After fully dried, the parts are ready for post-curing.
- Place the printed parts in a UV-cure box for an appropriate amount of time for final polymerization, 5 minutes in iLuxCure Pro with "Surgical Guide">"DSG" program, or 5 minutes in iLuxCure Dental with "P05" program.

C-Finishing Parts

- Non-sterile device.

Disposal Considerations

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

Manufacturer Information

Company: Ningbo Sezen Technology Co.,Ltd

Address: 2F, 13th Building, 518 Xinmei Road, Yinzhou District, Ningbo, China

| +1(650)336-0888 |info@luxcreo.com | LuxCreo

EU REP

Company: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands.

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:

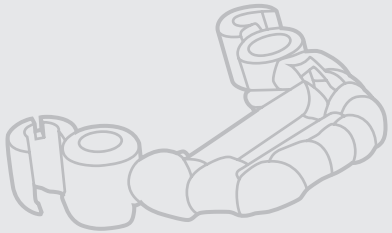
1. Report Online a: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
2. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at: www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
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
CE	CE marking	EU REP	Authorized representative in the European Union
	Use-by date		Read instructions
	Do not use if package is damaged		Temperature limit 5~30°C (41~86°F)
UDI	Unique device identifier		Keep away from sunlight
	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



DSG

Instruction for Use

Update Date:2025/6/4

Version: A/2

CE