



Instructions for Use

SURGICAL GUIDE RESIN

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The following instructions for use are for Formlabs biocompatible photopolymer Surgical Guide Resin. Basic information about safety and environmental concerns are also included. For more detailed safety and environment information please refer to the Safety Data Sheet, available at [Formlabs.com](https://www.formlabs.com). For further information regarding the use of the material, please contact Formlabs.

1. Introduction and Indications for Use

INDICATIONS FOR USE

Surgical Guide Resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, endosseous dental implant accessories. It is intended 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 particular application and intended purpose.

Surgical Guide Resin is a biocompatible photopolymer resin made of a mixture of methacrylic esters and photoinitiators.

2. Specific Manufacturing Considerations

NOTIFICATION

The device specifications have been validated using the printer process parameters indicated below.

REQUIREMENTS

Use dedicated accessories for Surgical Guide Resin. For biocompatibility, Surgical Guide Resin requires a dedicated resin tank, build platform, Form Wash, and finishing kit, which should not be mixed with any other resins.

RECOMMENDED 3D PRINTER AND PRINTING PARAMETERS

- a. Hardware: Formlabs SLA 3D Printer
 - Laser wavelength : 405 nm
- b. Software: Formlabs Preform
 - STL file import
 - Manual/Automatic rotation and placement
 - Manual/Automatic generation of supports
- c. Printing Parameters
 - Layer thickness: 50 µm and 100 µm
 - Optimal Orientation: horizontal orientation, dentition matching surface oriented upwards
 - Minimum thickness of 2 mm
- d. Recommended Post-Processing Equipment:
 - Formlabs Form Wash
 - Isopropyl alcohol (IPA) ≥ 99%
 - Formlabs Form Cure

3. Hazards and Precautions

HAZARDS

1. Surgical Guide Resin (uncured) contains polymerizable monomers which may cause skin irritation (allergic contact dermatitis) or other allergic reactions in susceptible persons. If resin contacts skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
2. **Eye contact:** High vapor concentration may cause irritation.
3. **Skin contact:** May cause sensitization by skin contact. Irritating to skin. Repeated and/or prolonged contact may cause dermatitis.
4. **Inhalation:** Irritating to respiratory system. Prolonged or repeated exposure may cause: headache, drowsiness, nausea, weakness (severity of effects depends on the extent of exposure).
5. **Ingestion:** Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.
6. **Protection:** Protective glasses and nitrile gloves should be worn while handling Surgical Guide Resin. Detailed information about the handling of Surgical Guide Resin can be found in the Safety Data Sheets at [Formlabs.com](https://www.formlabs.com).

PRECAUTIONS

1. When washing the printed part with solvent, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Expired or unused Surgical Guide Resin shall be disposed in accordance with local regulations.
3. IPA shall be disposed of in accordance with local regulations.

4. Procedure to Fabricate Surgical Guide Resin

A. PRINTING AND POST-PROCESSING

1. **Set up:** Insert resin cartridge into compatible Formlabs 3D printer.

2. **Printing:**

- a. Prepare a print job using PreForm software. Import a surgical guide STL file. Orient and generate supports. For recommendations on print orientation and support placement, see the detailed application guide at support.formlabs.com.
- b. Send print job to printer. Begin print by selecting print job from print menu. Follow any prompts or dialogs shown on printer screen. Printer will automatically complete print.

3. **Part removal:**

- a. Remove build platform from printer.
- b. Printed parts can be removed from build platform prior to- or post- cleaning in a Form Wash. To remove, wedge the part removal tool under the print raft, and rotate the tool. For detailed techniques see our online support material.

4. **Post-Processing:**

- a. See up-to-date manufacturer's recommendations for post-processing steps: Form Wash, drying, and Form Cure use in the online Surgical Guide Resin Application Guide [SKU: RS-F2-SGAM-01] dental.formlabs.com/indications/surgical-guides/guide/

5. **Support removal:**

- a. Remove supports using a cutting disk and a handpiece, or by using other part removal tools. Carefully smoothen the supported surfaces of the surgical guide using a bur and handpiece.

6. Attention: Inspect the surgical guide for cracks. Discard if any cracks are detected.

B. ASSEMBLY

1. Press the metal surgical drill guide sleeve(s) in the corresponding hole(s) of the surgical guide.
 - a. Ensure to use only compatible and validated metal sleeves

C. POLISHING

1. The surgical guide may be polished if desired using typical dental polishing methods.
2. If there are rough marks left on the surface of the surgical guide after support removal, polish/sand these down smooth to improve patient comfort.

D. DISINFECTION AND STERILIZATION

1. The surgical guide may be cleaned, disinfected, and sterilized according to facility protocols. Tested methods of disinfection include: soaking the finished surgical guide in fresh 70% IPA for 5 minutes. Note: Do not leave the part in alcohol solution for an extended period.
2. Surgical guides may be steam sterilized according to CDC recommended cycles (132 °C / 270 °F for 4 minutes in a pre-vacuum steam sterilizer or 30 minutes at 121 °C / 250 °F in a gravity displacement autoclave), or according to facility/autoclave manufacturer's protocols, as long as cycles do not exceed 20 minutes for 134 °C / 273 °F or 30 minutes at 121 °C / 250 °F.
 - a. Autoclave cycles should include a dry cycle to best maintain accuracy. For example, wrapped instruments sterilized in a prevacuum autoclave should be dried for 20-30 minutes according to CDC recommendations.¹ Longer or hotter autoclave cycles than those listed above may result in degradation of physical properties and accuracy. **Note:** A color shift will be observed after autoclaving, this is normal.
3. After disinfection and sterilization inspect the surgical guide for cracks to ensure the integrity of the surgical guide.

E. STORAGE


1. Store in a cool, dry place out of direct sunlight, in opaque or amber containers.
2. Store the containers at 10 – 25 °C (50 – 77 °F).
 - a. Do not exceed 25 °C (77 °F) when in storage.
3. Keep containers closed.
4. Avoid ignition sources.


F. DISPOSAL


1. Any cured resin is non-hazardous and may be disposed of in regular waste.
 - a. Follow clinic or facility protocols for waste that may be considered biohazardous.
2. Liquid resin should be disposed of in accordance with governmental regulations (community, national or regional).
 - a. Contact a licensed professional waste disposal service to dispose of liquid resin.
 - b. As with all foreign substances, do not allow to enter storm or sewer drainage systems.
 - c. Avoid release into the environment.
 - d. Contaminated Packaging: Dispose of as unused product.

¹ <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>

Symbols & Manufacturer Information

 : European Conformity


 : Keep away from sunlight

 : Consult instructions for use

LOT : Batch Code


 : Manufacturer

 : Use-by date

 : Caution

EC REP : Authorized representative
in the European Community

REF : Catalog Number

 : Temperature Limit



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