Resinify SurgiPro™

Resin Instructions for Use & Safety Guidelines — Material Best Practice Guide for Dental Surgical Guides

The following instructions for use are for Resinify Technology LLC's biocompatible photopolymer Resinify SurgiPro™ Resin. Basic safety and environmental information is included here. For more detailed safety and environmental information, refer to the Safety Data Sheet available at ResinifyTechnology.com. For further information regarding the use of the material, contact Resinify Technology LLC.

1. Introduction and Indications for Use

Resinify SurgiPro™ Resin is a light-curable polymerizable resin used for the additive manufacturing of 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.

Resinify SurgiPro™ Resin is a biocompatible photopolymer resin made of a mixture of methacrylic esters and photoinitiators.

Specific Manufacturing Considerations

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

> **NOTE:** Use dedicated accessories for Resinify SurgiPro™ Resin. For biocompatibility, it requires a dedicated resin tank, build platform, washing unit, and finishing kit, which should not be mixed with any other resins.

Recommended 3D printer and printing parameters:

Hardware: Generic DLP mSLA 3D printer; laser wavelength 405 nm.

Software: Suitable software for STL file import, with manual/automatic rotation and placement and manual/automatic support generation.

Printing parameters:

Parameter	Value
Layer thickness	50 µm
Optimal orientation	Horizontal, dentition-matching surface oriented upward
Minimum thickness	2 mm

Recommended post-processing equipment: washing unit, isopropyl alcohol (IPA) ≥99%, curing unit.

2. Hazards

1. Uncured Resinify SurgiPro™ Resin 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. Discontinue use if skin sensitization occurs; seek medical assistance if dermatitis or other symptoms persist.

2. Eye contact: high vapor concentration may cause irritation.
3. Skin contact: may cause sensitization. Irritating to skin. Repeated and/or prolonged contact may cause dermatitis.
4. Inhalation: irritating to the respiratory system. Prolonged or repeated exposure may cause headache, drowsiness, nausea, or weakness, depending on exposure.
5. Ingestion: low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.
6. Protection: wear protective glasses and nitrile gloves while handling Resinify SurgiPro™ Resin. Detailed handling information can be found in the Safety Data Sheet.

3. Precautions

- When washing the printed part with solvent, work in a properly ventilated environment with proper protective masks and gloves.
- Expired or unused Resinify SurgiPro™ Resin must be disposed of in accordance with local regulations.
- IPA must be disposed of in accordance with local regulations.

4. Step-by-Step Guide for Treatment Planning and Surgical Guide Design

The exact step-by-step process for treatment planning and surgical guide design varies by software package, but generally follows the same high-level flow. For detailed advice on designing surgical guides, contact your software manufacturer.

4.1 Import scans. Import intraoral or desktop 3D optical scans of the patient's dentition and the CBCT scan of the patient's hard tissue structures into your dental CAD software. The standard file format for 3D optical scans is .STL; the standard for CBCT is .DICOM. Confirm your software is compatible with your scanners when purchasing new solutions.

4.2 Review scans. Review the CBCT scans and identify the mandibular nerve, if applicable.

4.3 Align scans. Align the intraoral scan and the CBCT scan using both manual point-of-interest identification and automatic alignment tools, so detailed surface scan data and CBCT bone data can both be used in treatment design.

4.4 Design treatment. Select the desired implant and place it on the patient's anatomy — position, angulation, depth, desired clinical outcomes, and restoration design. Most dental CAD software offers implant libraries allowing you to design virtually with the implant system used for the specific case.

4.5 Design the surgical guide. Draw the desired area of the arch to cover. For best retention and accuracy, use full-arch guides. The dental CAD software should generate a model integrating the implant system with the guide design.

4.6 Export. Once the design is complete, export a digital model of the part in .STL format.

5. Print

5.1 Select material. Open your 3D printing software and select "SurgiPro" from the Material menu.

5.2 Import model files. Import the STL or OBJ file into the software.

> **NOTE:** If your dental CAD software integrates with the 3D printing software, steps 5.2–5.4 are automated: the software orients parts and generates supports automatically, and the ready-to-print file opens directly in the printing software. Just click print.

5.3 Orient models. Orient parts horizontally with the intaglio surface facing away from the build platform, so supports are not generated on these surfaces. If printing more than one surgical guide in a single print, arrange each model on the build platform for best fit.

Orientation for printers with overlap: If your printer has a laser overlap creating a seamline dividing the build volume into halves, position parts entirely in the rear or front half of the build area — not crossing the seamline. Avoid overlapping surgical guides on the seamline, as this may adversely affect fit. The raft or support structure can cross the seamline without affecting the part it supports.

5.4 Generate supports. Use the auto-generation feature in your software. Ensure there are no supports near the guide sleeve holes or on the intaglio surfaces. Use manual support editing to closely inspect support locations and add or remove supports as needed.

5.5 Upload the print. Send the print job to your 3D printer.

5.6 Prepare the printer and resin. Thoroughly agitate the Resinify SurgiPro™ Resin cartridge by shaking and rotating it several times. Insert the appropriate resin tank, resin cartridge, and build platform into the printer.

> **ATTENTION:** For full compliance and biocompatibility, Resinify SurgiPro™ Resin requires dedicated resin tanks, build platform, and finishing kits or wash units, which should only be used with other biocompatible resins.

5.7 Print. Begin printing by selecting the print job from the printer's print menu. Follow any prompts or dialogs shown on the printer screen; the printer will automatically complete the print.

6. Post-Process

Post-processing 3D printed surgical guides involves six steps: part removal, rinsing, drying, post-curing, support removal, and polishing.

6.1 Part removal. Remove the build platform from the printer, slide the removal tool under the base of the print, and rotate the tool to release the surgical guide. Parts can be removed before or after cleaning.

6.2a Wash parts with a washing unit (skip to 6.2b if you do not own one). Place the surgical guides, free-standing or still attached to the build platform, in a washing unit filled with 99% IPA. Wash for 20 minutes to clean parts and remove liquid resin before post-curing.

6.2b Wash parts with the Finish Kit (skip if using a washing unit). Remove parts from the build platform with the part removal tool as in Section 6.1. Rinse parts in two buckets of 99% IPA for 10 minutes each, to clean parts and remove liquid resin before post-curing.

6.3 Drying parts. Leave parts to air dry completely (at least 30 minutes), or use compressed air to blow IPA away from surgical guide surfaces. Inspect parts closely to confirm all guides are fully washed, with no particles or uncured resin present, before proceeding. Repeat the wash with fresh 99% IPA if needed. If printed parts are still on the build platform, remove them with the removal tool per Section 6.1.

6.4 Post-cure parts with a curing unit. Printed surgical guides must be exposed to light and heat to achieve biocompatibility and optimal mechanical properties. Post-curing is critical to fully cure the surgical guide for patient comfort and safety. Place printed guides inside a curing unit; the post-curing process depends on the printer used.

Printer	Temperature	Post-Cure Time
Printer	70°C	30 minutes

Allow the curing unit to cool to room temperature between post-cure cycles. During post-curing, a color change from translucent yellow to translucent orange will occur.

6.5 Remove supports. Use flush cutters or other part removal tools to carefully cut supports at their touch points on the surgical guide. Use caution — post-cured material may be brittle. Supports can also be removed with specialized appliances such as cutting disks or round cutting instruments like carbide burs.

CAUTION: Post-curing outside of the recommended settings can lead to suboptimal mechanical and biocompatibility properties. Post-cure only in accordance with official recommendations for best results.

6.6 Polish parts. Polish using typical dental polishing methods, such as high-grit sandpaper to smooth support marks for patient comfort. For higher part translucency, polish guides using pumice and a rag wheel or other specialized appliances.

ATTENTION: Inspect the surgical guides for cracks. Discard if any are detected.
NOTE: Remove supports only after post-curing, to ensure parts do not warp.

6.7 Assemble the surgical guide. Surgical guide sleeves are required to ensure drill bits do not cut into the printed guide itself. To ensure proper safety and use, assemble printed guides with the surgical guide sleeve selected during design. When using the recommended design parameters, metal tubes or surgical guide sleeves can be press-fit into the guide, held in place by friction. Only use compatible surgical guide sleeves.

7. Use

7.1 Sterilization, Cleaning & Disinfecting

Resinify SurgiPro™ printed guides can be sterilized according to CDC-recommended guidelines in industry-standard steam autoclaves, with or without sterilization pouches. Sterilize according to facility or autoclave manufacturer protocols, or one of the cycles below.

Autoclave Type	Temperature	Time
Pre-vacuum steam sterilizer	132°C / 270°F	4 minutes
Gravity displacement	121°C / 250°F	30 minutes

> **NOTE:** Do not exceed autoclave cycles of 20 minutes at 134°C / 273°F or 30 minutes at 121°C / 250°F — longer, hotter cycles may degrade surgical guide mechanical properties and accuracy. Autoclave cycles must include a dry cycle to maintain best accuracy (per CDC guidelines, wrapped instruments in a pre-vacuum autoclave must be dried for 20–30 minutes). After autoclaving, parts will change color from translucent orange to translucent light yellow.

If cleaning or disinfection methods are preferred or required, use facility protocols. A tested disinfection method is soaking the finished product in fresh 70% IPA for 5 minutes.

> **NOTE:** Do not leave surgical guides in alcohol solution for an extended period, as this may degrade mechanical properties and accuracy. After disinfection or sterilization, inspect the printed part for cracks to confirm the surgical guide's integrity before use in patients.

7.2 Perform Procedure

Execute the procedure with precision using the surgical guide.

8. Biocompatibility

Resinify SurgiPro™ Resin is non-cytotoxic, not a sensitizer, non-irritating, and complies with ISO 10993-1:2018 standards.

Reporting Undesirable Effects

In the event of adverse effects, reactions, or similar occurrences from the use of these products, report immediately by contacting Resinify Technology LLC via the website or through your local distributor.

Manufacturer

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