

SurgiPro Resin Instructions for Use and Safety Guidelines

Instructions for Use

The following instructions for use are for Resinify Technology LLC's biocompatible photopolymer SurgiPro Resin. Basic information about safety and environmental concerns is also included. For more detailed safety and environmental information, please refer to the Safety Data Sheet available at ResinifyTechnology.com.

For further information regarding the use of the material, please contact Resinify Technology LLC.

Introduction and Indications for Use

Indications for Use

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.

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

Specific Manufacturing Considerations

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

Requirements: Use dedicated accessories for **SurgiPro Resin**. For biocompatibility, **SurgiPro Resin** 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:

a. Hardware: Generic DLP mSLA 3D Printer

- Laser wavelength: 405 nm

b. Software: Suitable software for STL file import

- STL file import

- Manual/Automatic rotation and placement
- Manual/Automatic generation of supports

c. Printing Parameters:

- Layer thickness: 50 µm
- Optimal Orientation: horizontal orientation, dentition matching surface oriented upwards
- Minimum thickness of 2 mm

d. Recommended Post-Processing Equipment:

- Washing unit
- Isopropyl alcohol (IPA) ≥ 99%
- Curing unit

Hazards

1. **SurgiPro 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 **SurgiPro Resin**. Detailed information about the handling of **SurgiPro Resin** can be found in the Safety Data Sheets.

Precautions

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

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.

A few best practices and considerations for 3D printing surgical guides are:

2.1 Import Scans Import the 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**, while the standard for CBCT is **.DICOM**. Most scanners allow open export and most software allow for open import of these file types. Be sure to check that the software is compatible with scanners when purchasing new solutions.

2.2 Review Scans Review the CBCT scans and identify the mandibular nerve if applicable.

2.3 Align Scans Align the intraoral scan and the CBCT scan using both manual point-of-interest identification tools and automatic tools for detailed alignment. This allows both the detailed surface scan data and the CBCT bone data to be used in treatment designs.

2.4 Design Treatment Select your desired implant and place it on the patient's anatomy. Choose the position, angulation, depth, desired clinical outcomes, and restoration design. Most dental CAD software packages offer a range of implant libraries, allowing you to design virtually with the implant system being used for the specific case.

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

2.6 Export Once the design is created, export a digital model of the part in **.STL** format.

3. Print

3.1 Select Material Open your 3D printing software. Select "SurgiPro" from the Material menu.

3.2 Import Model Files Into Software Import the **STL** or **OBJ** file into the software.

Note: If you are using dental CAD software that integrates with the 3D printing software, steps 3.2-3.4 are automated. The software automatically orients parts and generates supports. Your ready-to-print file will open directly in the printing software. After it loads, just click print.

3.3 Orient Models Orient parts horizontally with the intaglio surface facing away from the build platform to ensure that supports will not be generated on these surfaces. If printing more than one surgical guide in a single print, manipulate the placement of each model on the build platform for the best fit.

3.3.1 Orientation for Printers with Overlap If your printer has a laser overlap that creates a seamline dividing the build volume into halves, parts should be positioned in the rear or front half of the build area, not crossing the seamline.

Incorrect Placement: Avoid overlapping surgical guides on the seamline, as this may adversely affect the fit of those parts.

Correct Placement: Ensure parts are completely in the rear and front half of the print area. Note: The raft or support structure can cross the seamline without affecting the part it supports.

3.4 Generate Supports Generate supports using the auto-generation feature in your software.

Ensure there are no supports near the guide sleeve holes or on the intaglio surfaces. Use the manual support editing feature to closely inspect support locations and add or remove supports as needed.

3.5 Upload the Print Send the print job to your 3D printer.

3.6 Prepare the Printer and Resin Thoroughly agitate the **SurgiPro Resin** cartridge by shaking and rotating it several times. Insert the appropriate resin tank, **SurgiPro Resin** cartridge, and a build platform into the printer.

ATTENTION: For full compliance and biocompatibility, **SurgiPro Resin** requires dedicated Resin Tanks, Build Platform, and Finish Kits or Wash Units, which should only be used with other biocompatible resins.

3.7 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.

4. Post-Process

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

4.1 Part Removal Printed parts can be removed from the build platform prior to or after cleaning. To remove parts from the build platform, remove the build platform from the printer, slide the removal tool under the base of your print, and rotate the tool to release the surgical guide.

4.2a Wash Parts with a Washing Unit If you do not own a washing unit, skip to 4.2b.

Place the surgical guides, free-standing or still attached to the build platform, in a washing unit filled with 99% isopropyl alcohol (IPA). Set to wash for 20 minutes to clean the parts and remove liquid resin before post-curing.

4.2b Wash Parts with the Finish Kit If you own a washing unit, skip 4.2b.

Remove parts from the build platform with the part removal tool as described in Section 4.1 Part Removal. Rinse the parts in two buckets of 99% isopropyl alcohol (IPA) for 10 minutes each to clean parts and remove liquid resin before post-curing.

4.3 Drying Parts Leave parts to air dry completely (at least 30 minutes) or use a compressed air hose to blow IPA away from surgical guide surfaces. Inspect parts closely to ensure all surgical guides are fully washed with no particles or uncured resin present on the surfaces before proceeding to subsequent steps. If needed, repeat the wash with fresh 99% IPA.

If printed parts are still on the build platform, remove the parts using the removal tool as instructed in Section 4.1 Part Removal.

4.4 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 to ensure patient comfort and safety. Place the printed guides inside a curing unit. The post-curing process depends on the printer used to print the surgical guides.

Printer | Temperature | Post Cure Time:

- **Printer** : 70°C for 30 minutes

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

4.5 Remove Supports Use flush cutters or other part removal tools to carefully cut the supports at touch points attached to the surgical guide. Use caution when cutting the supports, as the post-cured material may be brittle. Supports can also be removed using other 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 the best possible results.

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

ATTENTION: Inspect the surgical guides for cracks. Discard if cracks are detected.

NOTE: Remove supports only after post-curing to ensure that parts do not warp.

4.7 Assemble the Surgical Guide Surgical guide sleeves are required to ensure that 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. Friction holds the metal tube in place. Make sure to only use compatible surgical guide sleeves.

5. Use

5.1 Sterilization, Cleaning, and Disinfecting

SurgiPro Resin printed guides can be sterilized according to CDC recommended guidelines in industry-standard steam autoclaves, either with or without sterilization pouches. Sterilize according to facility or autoclave manufacturer protocols, or one of the autoclave cycles listed 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, as longer and hotter autoclave cycles may result in degradation of surgical guide mechanical properties and accuracy.
- Autoclave cycles must include a dry cycle to maintain best accuracy. For example, according to CDC guidelines, wrapped instruments sterilized in a pre-vacuum autoclave must be dried for 20-30 minutes. After autoclaving, parts will change in color from translucent orange to translucent light yellow.

If cleaning or disinfection methods are preferred or required, use facility protocols. Tested methods of disinfection include 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 it may lead to degradation of mechanical properties and accuracy.
- After disinfection or sterilization, inspect the printed part for cracks to ensure the integrity of the surgical guide is maintained prior to use in patients.

5.2 Perform Procedure

Execute the procedure with precision using the surgical guide.

6. Biocompatibility

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