

# SprintRay Gingiva Mask Resin

## Instructions For Use

### Indications for Use

The SprintRay Gingiva Mask resin is a light-curable polymerizable resin intended to be used for the fabrication of gingiva replication via additive manufacturing. This material is an alternative to traditional IBT material.

### Device Description

Fabrication of dental appliances with this device requires computer-aided design and CAD/CAM manufacturing system that includes the following components not part of the device: digital file created in an optical impression system, 3D printer, and curing light equipment. The material is intended exclusively for professional dental work.

### Requirements

#### **Additive Printer and its Operation Software:**

<b>Provider</b>	<b>Product Name</b>	<b>Model Number</b>	<b>OS</b>
SprintRay	Pro Printer	Pro 55	RayWare
SprintRay	Pro Printer	Pro 95	RayWare
SprintRay	Pro S Printer	Pro 55S	RayWare
SprintRay	Pro S Printer	Pro 95S	RayWare

#### **Curing Light Equipment:**

<b>Provider</b>	<b>Product Name</b>
SprintRay	ProCure
SprintRay	ProCure 2

#### **Notification:**

The device specifications have been validated using the software, printers, and process parameters specified in this document. Any other printers, operation software and post-printing processes will be outside of the device specifications and the FDA clearance. Users shall follow this document to use the device.

## Contraindication

The Gingiva Mask resin is contraindicated in case of the following:

- If a patient is known to be allergic to any of the ingredients.
- Direct intraoral contact of uncured or partially uncured material.
- For every application that is not part of the indication (see above).

## Warning

- The SprintRay Gingiva Mask resin is non-toxic in solid form, and it is classified as a biocompatible material. It is also classified as a sensitizer, which means that exposure over time can cause your body to have a mild allergic reaction. May cause skin irritation. May cause an allergic skin reaction. If contact with skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
- Avoid inhalation or ingestion. High vapor concentration can cause headache, irritation of eyes or respiratory system. Direct contact with eyes may cause possible corneal damage. Long-term excessive exposure to the material may cause more serious health effects. Monitor air quality per OSHA standards.
- Eye Contact: Immediately flush eyes with plenty of clean water for at least 20 minutes and consult a physician. Wash the contacted area thoroughly with soap and water.
- Inhalation: In case of exposure to a high concentration of vapor or mist, remove person to fresh air. Give oxygen or artificial respiration as required.
- Ingestion: Contact your regional poison control center immediately.

## Precautions

- When washing the printed gingiva mask with solvent or grinding the gingiva mask, it should be in a properly ventilated environment with proper protective masks and gloves.

- **Material Reuse:** The remaining resin in the Resin Tank can be reused. You may use a filter to ensure the resin is free from any cured particles to avoid print failures. The remaining material in the tank can be poured back into the resin bottle upon filtration. This process can be repeated until the material in the bottle is fully consumed. Please note that in the case of reuse, the resin must be filtered and poured back into the same bottle.
- Recommended storage conditions for *unprocessed* SprintRay Gingiva Mask are at 15 – 25° C (60 -77° F) and avoid direct sunlight.
- Keep container closed when it is not in use.
- Expired or unused SprintRay Gingiva Mask should be completely cured or polymerized prior to disposal.
- Product shall not be used after expiration date.
- For *activation and complete polymerization* of the SprintRay Gingiva Mask please follow the steps involved in "Fabrication of Gingiva Mask" and "Post-curing".



The use of expired resin will likely result in failed prints and/or not-meeting biocompatible properties, as the compounds required for curing break down and will not activate properly.

## Fabrication of Gingiva Mask

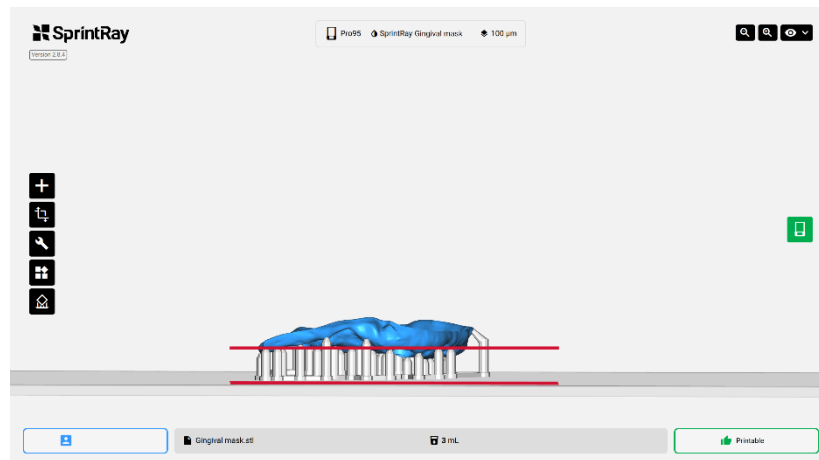
### 1. Design of the gingiva mask

Once the intraoral scans of the patient are submitted to a dental-design service/lab, the gingiva mask is designed and provided in STL file format by the dental-design service/lab.

### 2. Printing

- Bring the designed STL files to RayWare. Position the gingiva mask parallel to print platform, ensure the tissue side is towards print platform (facing down). (Fig. 1)
- Add full supports. Avoid having any support at the edges and any critical anatomy.
- Select "SprintRay Gingiva Mask" resin setting for print-setting and use 100-micron thickness.
- Ensure Resin Tank is fully secured and filled to the recommended Resin-Level.

- Ensure the Print Platform is clean, dry, securely placed, and locked on the platform-arm.



(Fig. 1)

### 3. Washing and Drying

- After your gingiva mask has been printed successfully, it must be washed using Isopropyl Alcohol (IPA) with a concentration of 91% or higher before being post-cured.
- Next step is to clean and wash the device from excess uncured-resin residue. Use >91% IPA to wash the device using any of the following methods:
  - Sonication
  - ProWash/Dry
- Ensure NOT to immerse the Gingiva Mask for more than 10 min in the IPA bath.
- Remember: IPA is highly flammable! Please keep it away from heat sources, sparks, and flames.
- Ensure that your gingiva mask is completely dry before the next step; if not, use compressed air to dry your gingiva mask rapidly.
- Remove the gingiva mask from the Print Platform.

### 4. Support Removal

Once the post-curing is completed, we need to remove all the supports by using a flush cutter. Try to cut as close as possible to the gingiva mask to minimize the smoothing and finishing procedure.

### 5. Post curing


- Next, the printed gingiva mask needs to be properly post-cured using a ProCure to maximize strength and accuracy and comply with required standards.
- All the post-curing settings are preset in ProCure 1 and ProCure 2 unites.

## Finishing and Polishing

- Use the Scotch-Brite™/Fuzzies™ Wheel for smoothing the gingiva mask surface.
- Wash and clean the device with a brush using soap and warm water.

## Additional Help & Support

We are here to support you throughout the implementation period of your new technology and throughout the life of your product. Our experienced support technicians are available M-F from 7 am – 5 pm PST at 800-914-8004 (EXT 2).

 <p><b>SprintRay Inc.</b> 2705 Media Center DriveSuite #100A Los Angeles, 90065 USA</p>	<p><b>Contact information</b> For product assistance, please review help information at <a href="https://sprintray.com/digital-dentistry/">https://sprintray.com/digital-dentistry/</a></p> <p>To report product issues, please contact SprintRay at: <a href="https://support.sprintray.com/hc/en-us/requests/new">https://support.sprintray.com/hc/en-us/requests/new</a></p> <p>Phone: 1-800-914-8004</p> <p>Rx (2)</p>
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