

# SprintRay Gingiva Mask

## Instructions For Use

### Indications for Use

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

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### Contraindications

SprintRay Gingiva Mask is contraindicated when:

- a patient is known to be allergic to any of the ingredients
  - there is direct intraoral contact with resin that is not fully cured
  - it is used for any purpose other than its indications for use
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### Device Description

Gingiva Mask is an alternative to traditional material for the fabrication of gingiva replication that is intended exclusively for professional dental work.

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### Printing and Hardware Parameters

These device specifications have been validated using the following manufacturing products. Any products or processes not specified in this document are outside of the device specifications.

- a. **CAD File:** CAD file of treatment device in STL file format
- b. **Printer:** SprintRay Pro or Pro S DLP 3D printer
  - i. 55 or 95 micron XY resolution
- c. **Software:** RayWare Desktop or RayWare Cloud
  - i. STL file import
  - ii. Manual/automatic orientation
- d. **Printing Parameters**
  - i. Intaglio surface facing away from build platform
  - ii. 100 micron layer thickness
  - iii. Default support structures
- e. **Wash Device:** SprintRay Pro Wash/Dry or hand spray & wipe
  - i. 91% or higher IPA
  - ii. Standard preprogrammed wash cycle
- f. **Cure Device:** SprintRay ProCure 2 or ProCure

- i. Use manufacturer recommended curing times
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## Warning and Precautions

SprintRay Gingiva Mask is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, Gingiva Mask is classified as a sensitizer. When washing with solvent or grinding the device, do so in a well-ventilated area with proper protective equipment.

- **Skin Contact:** May cause skin irritation. If unprocessed resin contacts skin, wash thoroughly with soap and water. May cause an allergic skin reaction. If skin sensitization occurs, stop using. If dermatitis or other symptoms persist, seek medical assistance.
  - **Inhalation:** High vapor concentration may cause headache, irritation of eyes and/or respiratory system. If exposed to a high concentration of vapor or mist, move to fresh air. Use oxygen or artificial respiration as required.
  - **Eye Contact:** Wash the contacted area thoroughly with soap and water.
  - **Ingestion:** Contact your regional poison control center immediately.
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## Storage

- **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.
- Store Gingiva Mask at 15-25°C (60-77°F) and avoid direct sunlight.
- Keep the bottle closed and/or the tank lid securely attached when not in use.
- Before disposal, completely polymerize.
- Do not use Gingiva Mask after the expiration date printed on the bottle.



Do not use expired resin; biocompatibility and print stability may be compromised if expired photoinitiators do not activate properly.

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## Fabrication of Device

### Designing

The device is designed in STL file format by a dental design service or dental CAD software using digital anatomical data from the patient. This STL file is delivered to the clinician for fabrication.

### **3D Printing**

Sign in to RayWare Cloud and select the appliance type; the algorithm will automatically orient and add supports. Select this material and use 100 micron layer thickness. Queue the job to your printer.

Shake the resin bottle thoroughly for one minute, then pour into the resin tank up to at least the min fill line. From the printer touchscreen, navigate to the printer queue. Start the print job.

### **Part and Support Removal**

After your device has been printed, remove it from the print platform using the provided Print Removal Tool. Remove all supports using a flush cutter or round diamond disc. Cut as close as possible to the device to minimize the smoothing and finishing procedure.

### **Washing and Drying**

Use  $\geq 91\%$  IPA to wash the device using SprintRay Pro Wash/Dry:

- Standard cleaning cycle

Dry the part completely before post curing.

### **Post Curing**

Use one of the following post-curing equipment from SprintRay to cure the device and select the preprogrammed profile for Gingiva Mask:

- ProCure 2 (preprogrammed material profile)
- ProCure (preprogrammed material profile)

### **Finishing**

Use A Scotch-Brite/Fuzzies Wheel with a lab handpiece to smoothen the surface. Wash and clean the device with a brush using soap and warm water.

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## **Additional Help & Support**

We are here to support you throughout the implementation period of your new technology. Our experienced support technicians are available M - F from 6 AM - 5 PM PT at 800-914-8004.

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## **Contact Information**

For product assistance, please review help information at:

<https://sprintray.com/digital-dentistry/>

To report product issues, please contact SprintRay at:

<https://support.sprintray.com/hc/en-us/requests/new>

Phone: 1-800-914-8004

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## **Manufacturer information**

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