

SprintRay NightGuard Firm Resin

Instructions For Use

Indications for Use

SprintRay NightGuard Firm resin is a light-curable polymerizable resin intended to be used for the fabrication of:

- Nightguards
- Occlusal guards
- Occlusal splints

This material is an alternative to traditional night guard 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

CAD File Format:

Ensure to meet the minimum of 1.5 mm wall thickness.

Additive Printer and its Operation Software:

Provider	Product Name	Model Number	OS
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:

Provider	Product Name
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 NightGuard Firm 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 NightGuard Firm resin is non-toxic in solid form, and it is classified as 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 NightGuard with solvent or grinding the NightGuard, 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 NightGuard Firm 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 NightGuard Firm 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 NightGuard Firm please follow the steps involved in "Fabrication of NightGuard" 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 NightGuard

1. Design of the NightGuard

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

2. Printing

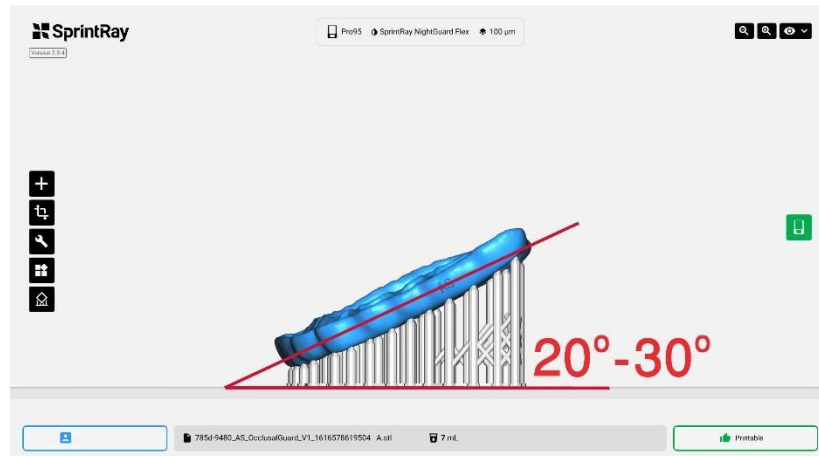
Bring the designed STL files to RayWare. Position the NightGuard on print platform so that the intaglio surface is facing up, and the occlusal plane makes an angulation of 20-30 degrees to the print platform. The anterior part of the design should be closer to print platform than the posterior. (Fig. 1)

Add full supports.

Select “SprintRay NightGuard Firm” 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 NightGuard 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 NightGuard 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 NightGuard is completely dry before the next step; if not, use compressed air to dry your NightGuard rapidly.
- Remove the NightGuard from the Print Platform.

4. Support Removal

Once removed from the Print Platform, we need to remove all the supports by using a flush cutter. Try to cut as close as possible to the NightGuard to minimize the smoothing and finishing procedure.

5. Post curing

- Next, the printed NightGuard 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

1. Finishing



Use the Scotch-Brite™/Fuzzies™ Wheel for smoothing the denture surface.

2. Polishing

- Use pumice and muslin wheel to remove the minor scratches from the surface.
- Use polishing compound and muslin wheel to further polish the 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>SprintRay Inc. 2705 Media Center Drive Suite #100A Los Angeles, 90065 USA</p>	<p>Contact information For product assistance, please review help information at https://sprinray.com/digital-dentistry/</p> <p>To report product issues, please contact SprintRay at: https://support.sprinray.com/hc/en-us/requests/new</p> <p>Phone: 1-800-914-8004</p> <p>R_x </p>
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