

SprintRay NightGuard Flex

Instructions For Use

Indications for Use

SprintRay NightGuard Flex is indicated for the fabrication of dental appliances such as mouthguards and nightguards.

Contraindications

SprintRay NightGuard Flex 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

Device Description

NightGuard Flex is an alternative to traditional hard occlusal guard material that is intended exclusively for professional dental work.

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
 - i. Minimum thickness 1.0 mm
- 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 S or SprintRay Pro Wash/Dry
 - i. 91% or higher IPA
 - ii. Standard preprogrammed wash cycle
- f. **Cure Device:** SprintRay ProCure 2 or ProCure

- i. Use manufacturer recommended curing times

Warning and Precautions

SprintRay NightGuard Flex is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, NightGuard Flex 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.

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 NightGuard Flex 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 NightGuard Flex 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.

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 SprintRay NightGuard Flex 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 the SprintRay Pro Wash S or 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 NightGuard Flex:

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

Finishing

Use A Scotch-Brite/Fuzzies Wheel with a lab handpiece to smoothen the surface.

Polishing and Disinfect

Use pumice and a muslin wheel to remove minor scratches from the surface of the appliance, then use a polishing compound and muslin wheel to polish. 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. Our experienced support technicians are available M - F from 6 AM - 5 PM PT at 800-914-8004.

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

Australian Sponsor

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