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

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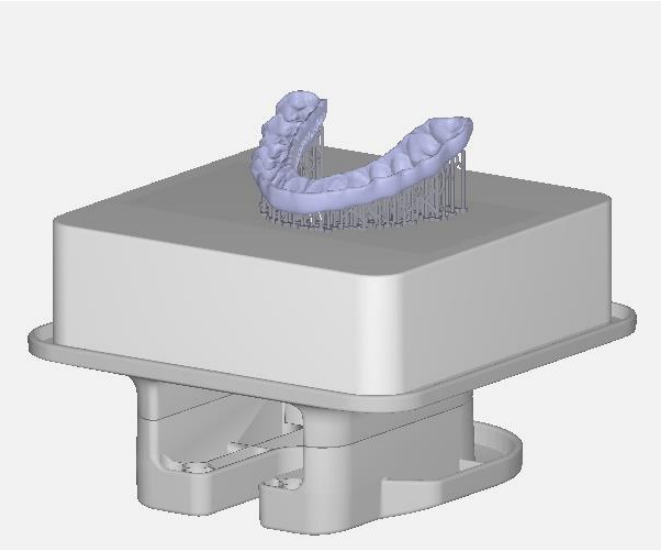
Device Description

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 or Pro 2 3D printer
    i. Pro and Pro S: 55 or 95 micron XY resolution
    ii. Pro 2: 35 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. 25^{o} from print platform
    iii. Anterior closer to platform
    iv. Select the desired layer thickness (RayWare will typically default to 100 microns)
    v. 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 NanoCure, ProCure 2 or ProCure
    i. Use SprintRay-recommended curing times that are built in the device

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. Wear protective gloves, clothing, eyewear, and face protection when handling.

- **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.
- **Use of Incompatible Components:** Do not substitute any of the components of the device system, i.e., device photopolymer materials, bonding systems, scanners, 3D printers, post-curing units, CAD/CAM software, templates, and tools. Use only those specifically identified in this labeling. Unauthorized changes may result in a device that is outside of specification. Contact the manufacturer for compatible components.

- Maintain and calibrate equipment according to manufacturer instructions.
- **Minor Color Differences:** Shade variance may occur due to inadequate shaking and mixing of the original packaging before use; inadequate stirring in the resin tank before use; insufficient post-curing

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 15-25ºC (60-77ºF) and avoid direct sunlight.
- Keep the bottle closed and/or the tank lid securely attached when not in use.
- Do not use NightGuard Flex after the expiration date printed on the bottle.
- Resin must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage.

Do not use expired resin as biocompatibility, performance, and print stability may be compromised.

Fabrication of Device

This resin was validated using the following workflow. Failure to follow the recommended practices may lead to undesired safety and performance implications.
Any deviation from these instructions for use may negatively affect the physical and/or chemical qualities of the resin and the biocompatibility of the final device.

If applicable, refer to the Workflow Guide for detailed best practices for producing specific appliance types with SprintRay resins.

Designing

The device is designed in STL file format by a dental design service, preferably SprintRay Cloud Design, 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 the desired 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, assign the resin tank to the proper material and shade, then 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 smoothening and finishing procedure.

Washing and Drying
Use ≥91% IPA to wash the device using the SprintRay Pro Wash S or SprintRay Pro Wash/Dry:

- Standard cleaning cycle

To ensure the proper function of the wash unit, always follow on-screen instructions for device cleanliness and maintenance. 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:

- NanoCure (preprogrammed material profile)
- 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.

Disposal Considerations
Always follow federal, state, and local regulations for hazardous waste disposal. To ensure proper classification, consult your local regulations. US guidelines can be found in 40 CFR part

261.3. Liquid resin must be cured completely before regular disposal. Simply pour it into a clear container and expose it to direct sunlight until hardened or in one of the post-cure boxes. SprintRay NightGuard Flex is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

Symbol Guide

The below table provides reference for symbols that may appear on the resin bottle label.

	Keep away from sunlight		Use-by date
	Consult instructions for use		European conformity
	Lot number		SKU number
	Manufacturer		Temperature limit
	Prescription only		Medical device
	Environmental hazard		Irritation
	Unique device identifier		Importer
	Indicates the authorized representative in Switzerland		Authorized representative in the European community
	Manufacturing date		Wear gloves
	Health hazard		UK Conformity Assessed (UKCA) Marking
	UK responsible person		

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

Any serious incident that has occurred in relation to the device due to a malfunction should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

Manufacturer information

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