

SprintRay OnX Tough resin Instructions For Use

Indications for Use

SprintRay OnX Tough is a tooth shade resin-ceramic hybrid material used for the fabrication of prosthetic devices by dental professionals.

Device Description

The material is an alternative to traditional dental prostheses material. SprintRay OnX Tough resin is intended exclusively for professional dental work.

OnX Tough resin is offered in the following shades: Hollywood Bleach, Bleach, A1, and B1.

Requirements

CAD File Format:

Device CAD file; STL format file with the following minimum thickness of equal to or greater than 0.5mm.

Additive Printer and its Operation Software:

Provider	Product Name	Model Number	OS
SprintRay	Pro Printer	Pro 55	RayWare
SprintRay	Pro S Printer	Pro 55S	RayWare

UV Curing Equipment:

Provider	Product Name
SprintRay	ProCure

SprintRay	ProCure 2
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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. Users shall follow this document to use the device.

Contra-indication

The SprintRay OnX Tough 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 for use.

Warning

- The SprintRay OnX Tough 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 device with solvent or grinding the device, it should be in a properly ventilated environment with proper protective masks and gloves.
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- 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 OnX Tough are at 15 – 25°C (60 -77°F) and avoid direct sunlight.
- Keep the container closed when it is not in use.
- Expired or unused SprintRay OnX Tough 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 OnX Tough please follow the steps involved in “Fabrication of device” 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.

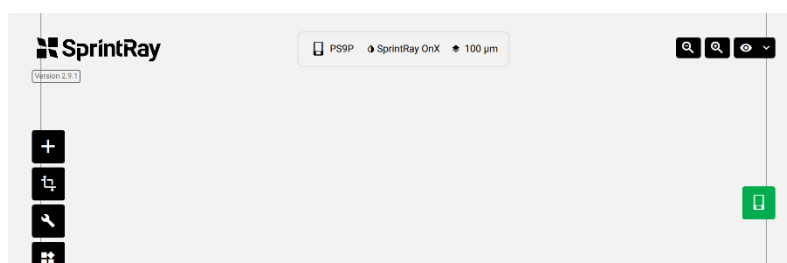
Fabrication of Device

1. Design of the Device

The Device is designed and provided in STL file format by the dental-design service/lab, using intraoral scans of the patient.

2. Printing

- Upload the STL file to RayWare. Position the device with the occlusal surface facing the print platform (intaglio facing away from the print platform) and the occlusal plane parallel to the print platform. (Fig. 1)
- Add supports.
- Select the “SprintRay OnX Tough” resin setting for print-setting and use 100-micron layer 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. Support Removal

After your device has been printed successfully, you need to remove it from the print platform using the Part-Removal-Tool, followed by removing all the supports using a flush cutter or round diamond disc. Try to cut as close as possible to the device to minimize the smoothing and finishing procedure.

4. Washing and Drying

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:

- Hand spray and wiping with dry towel
- Sonication
- ProWash/Dry

Remember: IPA is highly flammable! Please keep it away from heat sources, sparks, and flames.

Ensure that your prints are completely dry before the next step; if not, use compressed air to dry your parts rapidly.

5. Post Curing

Use below recommended post-curing equipment to maximize strength, accuracy, and complete polymerization to comply required standards:

- If using ProCure, you need to post-cure for 60 minutes at 60°C.
- If using ProCure 2, choose SprintRay OnX Tough setting for post-curing.

Finishing


Remove any excess support-nubs by using a lab carbide bur.

Polishing

Use medium and fine polishing wheels to polish and shine the device.
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 Dr. 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 (2)</p>
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