

OnX Tough 2

Instructions for Use

Indications for Use

SprintRay OnX Tough 2 is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth to be used in a denture.

Contraindications

SprintRay OnX Tough 2 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

OnX Tough 2 is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The product is offered in various shades such as: Bleach, A1, A2, B1, and Hollywood White.

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 0.5mm
- 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. Occlusal surface towards build platform
 - ii. Occlusal surface parallel to build platform
 - iii. 100 micron layer thickness
 - iv. Default support structures

- e. **Wash Device:** SprintRay Pro Wash/Dry, SprintRay ProWash S (recommended) or hand spray & wipe
 - i. 91% or higher IPA
 - ii. Standard preprogrammed wash cycle
- f. **Cure Device:** SprintRay NanoCure, ProCure 2 or ProCure
 - i. Use manufacturer recommended curing times

Warning and Precautions

SprintRay OnX Tough 2 is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, OnX Tough 2 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 OnX Tough 2 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 OnX Tough 2 after the expiration date printed on the bottle



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

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

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. Add supports. Select the “SprintRay OnX Tough 2” resin setting for print-setting and use 100-micron layer thickness. Queue the job to your printer.

Ensure the Print Platform is clean, dry, securely placed, and locked on the platform-arm. 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.



RayWare Cloud will automatically set the correct parameters for Hybrid Dentures. If you're using RayWare Desktop, set the *Fit and Adjustment* setting to *-100 microns*.

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 one of the following methods:

- Hand spray and wipe with a dry towel
- SprintRay Pro Wash/Dry (Custom wash cycle: 3 min wash, 0 min rinse, 3 min dry)
- SprintRay ProWash S (Material profile: 3 min wash, 0 min rinse, 3 min dry)

Dry the part completely before post curing.

Post Curing

Use one of the following post-curing equipment and processes. For both SprintRay devices, use the recommended settings

- NanoCure (preprogrammed material profile)
- ProCure 2 (preprogrammed material profile)
- ProCure (60 min at 60° C)

Dry the part completely before post curing.

Finishing

Use a fine lab carbide bur or an abrasive fiber wheel attachment to remove remaining stubs leftover by the support structures until the surface is smooth and uniform.

Characterization

We recommend characterization for the best patient experience and aesthetics.

We recommend Vita Akzent LC™ for the best cosmetic effect, which you can layer and light cure to your desired aesthetics.

Tack cure in between steps using a handheld curing light. Final cure the hybrid denture in the ProCure 2 for 5 minutes.

Disinfect

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. 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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