

# 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.

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### 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

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### 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.

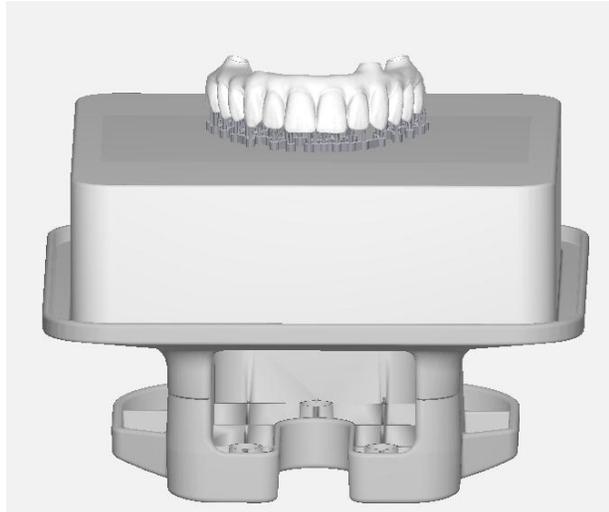
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### Printing and Hardware Parameters

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.

- CAD File:** CAD file of treatment device in STL file format
  - Minimum thickness 0.5mm
- Printer:** SprintRay Pro or Pro S DLP 3D printer; SprintRay Pro 2 3D printer
  - Pro or Pro S: 55 or 95 micron XY resolution
  - Pro 2: 35 micron XY resolution
  - Midas: 45 micron XY resolution
- Software:** RayWare Desktop or RayWare Cloud
  - STL file import
  - Manual/automatic orientation
- Printing Parameters**
  - Occlusal surface towards build platform
  - Occlusal surface parallel to build platform
  - Select the desired layer thickness (RayWare will typically default to 100 microns)

iv. Default support structures



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

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## 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. 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

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## 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
- Do not use OnX Tough 2 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.

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## 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.

### Designing

The device is designed in STL file format by a dental design service, preferably SprintRay Cloud Design, or other dental CAD software using digital anatomical data from the patient. This STL file is delivered to the clinician for fabrication.

### Capsule Priming

Follow the instructions for priming the capsule before scanning and placing it on the printer optical path. Failure to properly prime the capsule may lead to print failure.

1. Identify the capsule cylinders, then turn upside down.
2. Press the white cylinder halfway down.

3. Press the black cylinder all the way down.
4. Repeat 10 times to fully prime.

### 3D Printing

Sign in to RayWare Cloud and select the appliance type; the algorithm will automatically orient and add supports. Verify that the appliance is properly oriented (occlusal surface facing the print platform, intaglio facing away from the print platform, and the occlusal plane parallel to the print platform). Select this material and use the desired layer thickness. Queue the job to your printer.

Pro/ Pro S/ Pro 2: 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, assign the resin tank to the proper material and shade, navigate to the printer queue. Start the print job.

Midas: Navigate to the Queue and select your print job. Follow the on-screen props to start the print.



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:

- **(Preferred)** Hand spray and wipe with a dry towel for 15 sec. Blow dry samples for 30 sec. Hand spray and wipe again for 15 sec.
- SprintRay Pro Wash/Dry
  - o Custom Single Cycle Wash – Wash/Dry 1 (3 min wash, 0 min rinse, 3 min dry)
- SprintRay ProWash S
  - o Custom Cycle (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)

After post curing, hand spray with IPA and wipe with a dry towel for 30 sec.

### Finishing & Characterization

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.

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.

Wash and clean the device with a brush using soap and warm water.

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

### 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 OnX Tough 2 is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

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## 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                                  |   |   |

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## 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.

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## 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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## Manufacturer information

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