SprintRay Ceramic Crown

Instructions for Use

Indications for Use

SprintRay Ceramic Crown is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material.

Contraindications

SprintRay Ceramic Crown 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

Ceramic Crown is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The device is manufactured via additive manufacturing process using a 3D printer with 405 nm wavelength, 50µm print layer thickness, and light energy of 28.8 mW/cm2. It is available in the following shades: Bleach, A1, A2, A3, B1, C2, D2.

Physical Properties:

Property	Standard
Flexural Strength	Complies with ISO 4049
Flexural Modulus	Complies with ISO 4049
Inorganic Filler	>50% by weight
Water Absorption	Complies with ISO 10477
Solubility	Complies with ISO 10477

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 with the following thickness:
    i. Crown walls - ≥ 1.0 mm
    ii. Crown margins - ≥ 1.0 mm
    iii. Veneer thickness - ≥ 0.5 mm
b. **Printer**: SprintRay Pro S series DLP 3D printer
    i. 55 or 95 micron XY resolution
    ii. Light energy of 28.8 mW/cm^2
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. 50 micron layer thickness
    iii. Default support structures
e. **Wash Device**: Submerge in a small bowl of IPA and brush, 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 manufacturer recommended curing times

Warning and Precautions

SprintRay Ceramic Crown is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, Ceramic Crown 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 Ceramic Crown at 15-25ºC (60-77ºF) 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 Ceramic Crown 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 Restoration design with occlusal surface facing the print platform (intaglio facing away from print platform) and the occlusal plane parallel to the print platform. Add supports. Select “SprintRay Digital Crown” resin setting for print-setting and use 50-micron 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.

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 by submerging in small bowl of IPA and scrub with a brush. 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.

Washing and Drying

Use ≥91% IPA to wash the device using one of the following methods:

- Submerge in small bowl of IPA and scrub with a brush
- SprintRay ProWash/Dry

Finishing and Polishing

You may remove the supports before or after washing the printed restoration. Use a flush cutter, or a diamond disk to remove all the supports. Try to cut as close as possible to the Restoration to minimize the smoothening and polishing procedure.

Polishing

For best results, use the SprintRay Restorative Finishing Kit. Follow the instructions on the kit to obtain a polished, glossy finish.

Characterization (optional)

You may use an OptiGlaze™ kit by GC for a cosmetic effect. Apply and light cure the OptiGlaze colors and stains on the device. When finished, finalize with clear glaze.

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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