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 and 385 nm wavelength, and 50µm/100um print layer thicknesses. 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 or Pro 2 3D printer
   i. Pro or Pro S: 55 or 95 micron XY resolution
   ii. Pro 2: 35 micron XY resolution
   iii. Midas: 45 microns XY resolution
c. **Software**: RayWare Desktop or RayWare Cloud
   i. STL file import
   ii. Manual/automatic orientation
d. **Printing Parameters**
   i. Pro/ Pro S/ Pro 2: Intaglio surface facing away from build platform
   ii. Midas: Automatically oriented on RayWare Cloud
   iii. Select the desired layer thickness (50-micron layer thickness recommended)
   iv. Default support structures
e. **Wash Device**: Submerge in a small bowl of IPA and brush.
   i. 91% or higher IPA
   ii. Standard preprogrammed wash cycle
f. **Cure Device**:
   i. Printed on Pro/ Pro S: SprintRay NanoCure, ProCure 2 or ProCure
   ii. Printed on Midas: NanoCure

Use SprintRay-recommended curing times that are built in the device

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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. 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 Ceramic Crown 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 Ceramic Crown 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 end product.

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 this material and use the desired layer thickness. Queue the job to your printer.

If using RayWare Desktop (only Pro/ Pro S), 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 Ceramic Crown” resin setting for print-setting and use the desired layer thickness (50-micron thickness recommended). 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 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.

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

Printed on Pro/ Pro S and Pro 2: Use one of the following post-curing equipment and processes. For SprintRay devices, use the recommended settings

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

Printed on Midas: Use one of the following post-curing equipment and processes. For SprintRay devices, use the recommended settings

- NanoCure (preprogrammed material profile)

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.

Clean & Disinfect

Use a laboratory steamer to clean the denture of all debris and polishing compounds. Use dish soap and a brush with 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 Ceramic Crown is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

Capsule Disposal Procedure: Return capsules to SprintRay Inc. (Refer to the manufacturer address in this document).

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 REP

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

Australian Sponsor

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