SprintRay Crown HT

Instructions for Use

Indications for Use

SprintRay Crown HT 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 Crown HT 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

Crown HT 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 DLP 3D printer, and 100-µm print layer thickness. It is available in the following shades: Bleach, A1, A2, A3, unpigmented, and B1. Crown HT is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.

The expected duration of use is based on in vitro testing of the SprintRay Crown where abrasion volume up to 6 mm^3 and height loss up to 1.2 mm were observed under the test conditions (i.e. loading up to 2.4 MC that corresponds to an in-vivo time of ten years).

Physical and Mechanical Performance Testing:

Property	Standard
Flexural Properties	Complies with ISO 4049
Shear Bond Strength	Complies with ISO 10477

Biocompatibility	Complies with ISO 10993-1 and ISO 7405
Inorganic Filler	>60% by weight
Water Sorption/Solubility	Complies with ISO 10477
Radiopacity	Complies with ISO 4049

The flexural and compressive strengths are >124 MPa and >209 MPa, respectively.

Printing and Hardware Parameters

The device specifications have been only validated using the following hardware and software. Any products or processes not specified in this document have not been validated to meet the intended performance. Always refer to the SprintRay equipment user instructions for device setup, maintenance, and lifespan. Always refer to the SprintRay material IFU for recommended design limits and proper validated equipment parameters. SprintRay Crown HT is intended exclusively for use by trained dental professionals.

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 Midas 3D printer
   i. Midas: 45-micron XY resolution and energy of 29 mW/cm^2
c. **Software**: RayWare Cloud
   i. STL file import
   ii. Automatic or manual orientation
d. **Printing Parameters**
   i. Midas: Automatically oriented on RayWare Cloud
   ii. Default layer thickness (100 microns)
   iii. Default support structures
e. **Washing Process**:
   i. Wipe off the excess resin with an IPA-soaked towel*
   ii. Blow air onto the appliance until the surface is IPA free
   iii. With an IPA-soaked towel*, wipe the surface of the appliance until the surface is resin free
   iv. Blow the appliance with air to fully dry the surface
   *It is recommended to use the 91% or higher IPA

f. Cure Device:

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

Warning and Precautions

SprintRay Crown HT devices are non-toxic in fully cured form and are classified as a biocompatible material. In uncured form, Crown HT resin is classified as hazardous. When washing with solvent or grinding the device, do so in a "well-ventilated area" with proper "personal protective equipment", including protective gloves, clothing, eyewear, and face protection when handling. It is strongly recommended to review the Safety Data Sheet (SDS) prior to the usage of the Crown HT resin to understand the safety risks.

- **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 it. 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 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

- Store the Crown HT Capsule at 15-25 ºC (60-77 ºF) and avoid direct sunlight
- Do not use Crown HT after the expiration date printed on the packaging
- Remove protective film only prior to the usage. It ensures resin in capsule is protected from exposure to light, as spontaneous polymerization is possible.

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 product.

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.

Capsule Priming

Follow the instructions for priming the capsule before scanning and placing it on the Midas printer. 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 at least 10 times to fully prime.

3D Printing

For the validated devices' (including 3D printers and post-curing units) set-up, usage, on-site validation, Maintenance, and Troubleshooting, refer to the original equipment manufacturer (OEM) labeling for these compatible system components. It can be found online at:

- Printing devices: https://support.sprintray.com/s/printer
- PostCuring Devices: https://support.sprintray.com/s/cure

RayWare Cloud (Midas): 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.

Printing on 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

i. Wipe off the excess resin with an IPA-soaked towel*
ii. Blow air onto the appliance until the surface is IPA free
iii. With an IPA-soaked towel*, wipe the surface of the appliance until the surface is visually resin free,
iv. Blow the appliance with dry air for at least 30 seconds to “fully dry” the surface before postcuring. This step ensures all residual alcohol is removed from the appliances.
*It is recommended to use the 91% or higher IPA

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

- NanoCure (preprogrammed material profile)

Note: “dry the part completely” before post curing.

Finishing
After the post cure cycle is complete, you may use one of the following optional methods:

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

You may remove the supports before or after washing the 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.

Bonding

The recommended cement for bonding the Crown HT is the Adhese Universal by Ivoclar.

Clean & Disinfect

Use a laboratory steamer to clean the restoration of all debris. 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 Crown HT is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

Symbol Guide

The table below provides reference for symbols that may appear on the resin 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		

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

Manufacturer information

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