SprintRay Digital Temp

Instructions for Use

Indications for Use

SprintRay Digital Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns, and temporary bridges. The material is an alternative to traditional restorative dental material.

Contraindications

SprintRay Digital Temp 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

SprintRay Digital Temp is a photo-polymer methacrylate resin material used in conjunction with a 3D printer and a scanned 3D image in a dental office to build dental prosthetics by 3D printing layer upon layer of the composite material. SprintRay Digital Temp resin is offered in various shades such as Bleach, A1, A2 and B1. Digital Temp is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The expected duration of use is 29 days or less.

Physical and Mechanical Performance Testing:

Property	Standard
Flexural Properties	Complies with ISO 10477
Shear Bond Strength	Complies with ISO 10477
Biocompatibility	Complies with ISO 10993-1 and ISO 7405
Water Sorption/Solubility	Complies with ISO 10477

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 Digital temp 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 Pro S, Pro 2 or Midas 3D printer
   i. Pro S: 55 or 95 micron XY resolution and energy of 33 mW/cm^2
   ii. Pro 2: 35 micron XY resolution and energy of 25 mW/cm^2
   iii. Midas: 45 microns XY resolution and energy of 29 mW/cm^2
c. **Software**: RayWare Desktop or RayWare Cloud
   i. STL file import
   ii. Manual/automatic orientation
d. **Printing Parameters**
   i. Pro S: Intaglio surface facing away from build platform
   ii. Pro 2: Automatically oriented on RayWare Cloud
   iii. Midas: Automatically oriented on RayWare Cloud (Select the desired layer thickness: 50- micron layer thickness recommended)
   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. Standard Multi-Cycle Wash
f. **Cure Device**:
   i. Printed on Pro S: SprintRay NanoCure or ProCure 2
   ii. Printed on Pro 2/Midas: SprintRay NanoCure
   Use SprintRay-recommended curing times that are built in the device

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Warning and Precautions

SprintRay Digital Temp devices are non-toxic in fully post cured form and are classified as a biocompatible material. In uncured form, Digital Temp 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.

- **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 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 Digital Temp at 15-25ºC (60-77ºF) and avoid direct sunlight
- Keep the bottle closed and/or the tank lid securely attached when not in use
- Do not use Digital Temp after the expiration date printed on the packaging
- Remove protective film only prior to the usage. Resin must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage. The capsule must be kept sealed until the print is complete.

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.

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.

Capsule Priming

Follow the instructions for priming the capsule before scanning and placing it on the printer optical path. For detailed priming instructions refer to the Workflow Guide. 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

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 (Pro S/Pro 2 or 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.

RayWare Desktop (only 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 Digital Temp” resin setting for print-setting and use the desired layer thickness (100-micron thickness recommended). Queue the job to your printer.

Printing on Pro S or 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.

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
Use ≥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. Repeat until the surface of the appliance is visually free of liquid resin. Blow the appliance with air for 30 seconds to fully dry the surface before post curing.

- SprintRay Pro Wash/Dry and ProWash S

    - Standard Multi-Cycle Wash – Wash/Rinse/Dry (3 min wash, 3 min rinse, 3 min dry). To ensure proper function of the wash unit, always follow on-screen instructions for device cleanliness and maintenance. Blow the appliance with dry air for at least 30 seconds to “full dry” the surface before post curing.

Post Curing
Printed on Pro S: 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)

Printed on Pro 2/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.

Finishing
After the post cure cycle is complete, use IPA to wash the device using one of the following 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 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.

Characterization (optional)

You may use an IPS Empress Direct kit by Ivoclar for a cosmetic effect. Refer to SprintRay workflow guide for further details.

Bonding

The recommended cement for bonding the Digital Temp is the Telio Link by Ivoclar. Refer to SprintRay workflow guide for further details.

Polishing

Use a Scotch-BriteTM/FuzziesTM wheel to smoothen the restorative, then pumice and polishing compound and muslin wheel to polish the surface. You may use a pink compound bar and cotton buff to achieve a mirror finish.

Clean & Disinfect

Use a laboratory steamer to clean the restoration of all debris. Use 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 Digital Temp 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 bottle or capsule 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
	Health hazard		Irritation
	Unique device identifier		Importer
	Indicates the authorized representative in Switzerland		Authorized representative in the European community
	Manufacturing date		Wear gloves
	UK responsible person		UK Conformity Assessed (UKCA) Marking

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/

Phone: 1-800-914-8004

Australian Sponsor

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