

SprintRay Midas Restore

Instructions for Use

Indications for Use

Midas Restore is a light-curable polymerizable resin intended to be used for the fabrication of individual and fixed definitive full single crowns; definitive partial crowns (e.g., inlays, onlays) in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material.

Contraindications

SprintRay Midas Restore 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 Midas Restore 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 Midas Restore is offered in various shades. Midas Restore is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.

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
Inorganic Filler	>70% by weight

Water Sorption/Solubility	Complies with ISO 10477
Radiopacity	Complies with ISO 4049

SprintRay Midas Restore is composed of principal organic constituents including methacrylate oligomers and monomers, photoinitiators, pigments, and stabilizers. The inorganic filler is a mixture of silica and zirconia particles, comprising >70% by weight. The range of dimensions for inorganic filler particles is 0.01–10 µm.

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 Midas Restore is intended exclusively for use by trained dental professionals.

- a. **Printer:** SprintRay Validated 3D printers - <https://support.sprintray.com/resin-hardware-compatibility/sprintray-hardware-resin-compatibility>
- b. **Software:** Print Setup
 - i. STL file import
 - ii. Automatic or manual orientation
- c. **Printing Parameters**
 - i. Automatically oriented on Print Setup
 - ii. Default layer thickness (100 microns)
 - iii. Default support structures
- d. **Washing Process:**
 - i. Wipe off the excess resin with a dry towel*
 - ii. Continue wiping the surface of the appliance with a dry towel until the surface is visibly resin free.
 - iii. Use a micro-applicator to remove resin from grooves and screw channels before post curing. This step ensures all dimensions are maintained once the device is hardened during post curing.

*It is recommended to limit IPA exposure before post curing to maintain the surface aesthetics.

- iv. SprintRay Validated Wash Devices - Use SprintRay-recommended wash device <https://support.sprinray.com/resin-hardware-compatibility/sprinray-hardware-resin-compatibility>
- e. **Cure Device:** SprintRay Validated Post Cure Devices - Use SprintRay-recommended curing times that are built in the device <https://support.sprinray.com/resin-hardware-compatibility/sprinray-hardware-resin-compatibility>

Warning and Precautions

SprintRay Midas Restore devices are non-toxic in fully cured form and are classified as a biocompatible material. In uncured form, Midas Restore 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 Midas Restore resin in order 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. If dermatitis or other symptoms persist, seek medical assistance. Wear protective clothing. Contaminated work clothing must not be allowed out of the workplace. Take off contaminated clothing and wash it before reuse.
 - **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. Get medical advice/attention if you feel unwell. Do not breathe dust/fume/gas/mist/vapors/spray.
 - **Eye Contact:** Wash the contacted area thoroughly with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
 - **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.
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Storage

- Store the Midas Restore capsules at 15-25 °C (60-77 °F) and avoid direct sunlight
- Do not use Midas Restore 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.

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.sprinray.com/s/printer>
- Post Cure Devices: <https://support.sprinray.com/s/cure>

Print Setup: Sign in to Dashboard 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.

*On your printer display: Navigate to the Queue and select your print job. Follow the on-screen props to start the print.

* In case of Autoprint, skip the aforementioned printing sections.

Part and Support Removal

After your device has been printed, remove it from the print platform. 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

Follow validated cleaning processes and use the applicable equipment with the recommended settings.

- i. Wipe off the excess resin with a dry towel*
- ii. Continue wiping the surface of the appliance with a dry towel until the surface is visibly resin free.
- iii. Use a micro-applicator to remove resin from grooves and screw channels before post curing. This step ensures all dimensions are maintained once the device is hardened during post curing.

*It is recommended to limit IPA exposure before post curing to maintain the surface aesthetics.

Post Curing

Use validated post-curing equipment and processes. For SprintRay Post Cure Devices, use the recommended settings

Finishing

- After the post cure cycle is complete, you may use one of the following optional methods to remove any remaining uncured resin:
- Submerge in a small bowl of IPA and scrub with a brush
- SprintRay Validated Wash Device

You may remove the supports before or after cleaning 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

Use validated bonding materials and processes for cementing Midas Restore restorations – SprintRay Cemented Restoration Workflow (<https://sprintray-public.helpjuice.com/workflow-guide/cemented-restoration-workflows>).

Clean & Disinfect

Use a laboratory steamer to clean the restoration of all debris. Use dish soap and a brush with warm water.

Reuse and Disposal Considerations

Leftover resin material shall not be carried over to subsequent print runs, as the remaining volume may be insufficient to successfully print another dental appliance.

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. SprintRay Midas Restore resin is packaged in small, non-pourable capsules due to its high viscosity. To safely dispose of unused or excess resin, fully cure the entire contents of the capsule using a UV light source or by prolonged exposure to direct sunlight until the resin is completely hardened throughout. Once the resin is fully polymerized (in solid state), it is no longer classified as an environmental hazard and can be disposed of with regular household waste. Do not dispose of uncured resin (liquid or paste) in drains or general trash.

Symbol Guide

The below table 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

Authorized representative
in the United Kingdom

Irritation



Unique device identifier



Importer

Indicates the authorized
representative in SwitzerlandAuthorized representative
in the European community

Manufacturing date



Wear gloves



Health hazard

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 8 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/s/contactsupport>

Phone: 1-800-914-8004



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