SprintRay Precision Guide

Instructions for Use

Indications for Use

SprintRay Precision Guide is a light-curable polymerizable resin intended to be used for fabrication of surgical guides. This material is an alternative to traditional surgical guide material.

Contraindications

SprintRay Precision Guide 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 Precision Guide is a tinted photo-polymeric methacrylate/acrylate resin mixture used in conjunction with a 3D printer and a scanned 3D image in a dental office to fabricate surgical guides by 3D printing layer upon layer of the composite material. The product will be available in one shade.

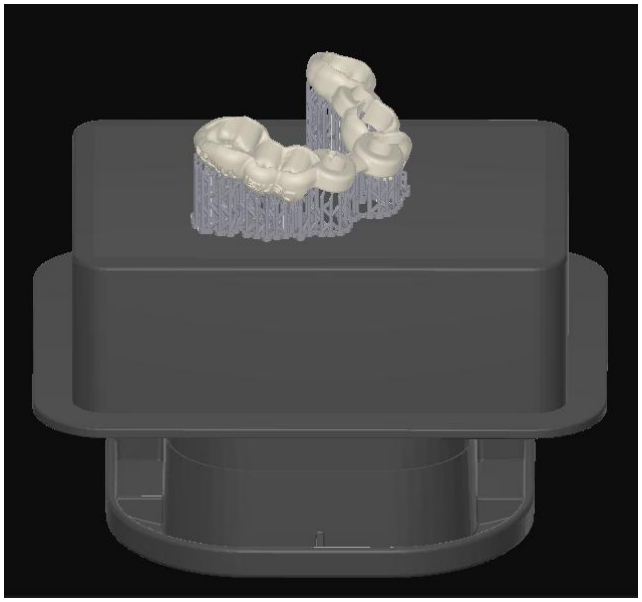
Workflow Guidelines

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 Instruction for Use (IFU) for recommended design limits and proper validated equipment parameters. SprintRay Precision Guide is intended exclusively for use by trained dental professionals.

a. **CAD File:** CAD file of treatment device in STL file format:
    i. Upload an STL or SPR file to Cloud Print Setup.
b. **Printer:** SprintRay Pro 2 3D printers

i. Pro 2: 35-micron XY resolution

c. **Software:** Dashboard Print Setup
   i. STL file import
   ii. Manual/automatic orientation
d. **Printing Parameters:**
   i. Pro 2: Automatically oriented on Print Setup



   ii. Default support structures
e. **Wash Device:** SprintRay ProWash S or SprintRay Pro Wash/Dry
   i. 91% or higher IPA
   ii. Standard Multicycle: 3 minutes wash, 3 minutes rinse, 3 minutes dry
f. **Cure Device:**
   i. Printed on Pro 2: SprintRay NanoCure
   ii. Use SprintRay-recommended curing times that are built in the device
g. **Autoclave:**
   i. Step one: Sterilize for 5 min at 134 °C
   ii. Step Two: Dry for 15 min at 134 °C

Warning and Precautions

SprintRay Precision Guide devices are non-toxic in fully post cured form and are classified as a biocompatible material. In uncured form, Precision Guide resin is classified as hazardous. When washing with solvent or grinding/polishing 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 SprintRay Precision Guide resin 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 SprintRay Precision Guide resin 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 product.

Where 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, 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' set-up (including 3D printers and post-processing units), 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
- Post Curing Devices: https://support.sprintray.com/s/cure

Nesting on Dashboard Print Setup (Pro 2): Sign in to Dashboard, and begin nesting by selecting print setup, and 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 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.

Part and Support Removal

After your device has been printed, remove it from the print platform using a 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:

- SprintRay ProWash S and Pro Wash/Dry
    - Standard Multi-Cycle Wash – Wash/Rinse/Dry (3 min wash chamber 1, 3 min rinse chamber 2, 3 min dry)

Post Curing

Printed on Pro 2: Use 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

You may remove the supports before or after washing the printed appliance. Use a flush cutter, or a diamond disk to remove all the supports. Try to cut as close as possible to the device to minimize the smoothening and polishing procedure. Use A Scotch-Brite/Fuzzies Wheel with a lab handpiece to smoothen the surface.

Ensure the device is completely dry of Isopropyl Alcohol before post curing. It is advisable to use an air dryer or leave the appliance away from the light at an ambient temperature for a short time.

Polishing (optional)

Use pumice and a muslin wheel to remove minor scratches from the surface of the appliance, then use a polishing compound and muslin wheel to polish.

Sterilization

Wash and clean the device with a brush using soap and warm water.
Insert the surgical guide sleeves into the drill holes and autoclave for 5 minutes at 134 °C. Then, Dry for 15 minutes at 134 °C.
Note that there will be a color change in the device after the curing and autoclaving steps are complete.

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 Precision Guide 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 product 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
	Unique device identifier		Irritation
	Indicates the authorized representative in Switzerland		Importer
	Manufacturing date		Authorized representative in the European community
	UK responsible person		Wear gloves

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/s/contactsupport

Phone: 1-800-914-8004

Manufacturer information

SprintRay Inc.
2710 Media Center Dr., Suite #100A
Los Angeles, CA 90065, USA