SprintRay IDB 3

Instructions for Use

Indications for Use

SprintRay IDB 3 is a light-curable polymerizable resin intended to be used for the fabrication of indirect bonding trays. This material is an alternative to traditional IBT material.

Contraindications

SprintRay IDB 3 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 IDB 3 is a photo-polymeric methacrylate/acrylate resin used in conjunction with a 3D printer in a dental office to fabricate indirect bonding trays. The product will be available in one shade: clear. It is intended exclusively for professional dental work.

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 Instruction for Use (IFU) for material handling and the properly validated equipment parameters. SprintRay IDB 3 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 https://dashboard.sprintray.com/print-setup.
b. **Printer:** SprintRay Pro S and Pro 2 3D printers
    i. Pro S 55: 55-micron XY resolution and energy of 33 mW/cm^2
    ii. Pro S 95: 95-micron XY resolution and energy of 33 mW/cm^2
    iii. Pro 2: 35-micron XY resolution and energy of 25 mW/cm^2
c. **Software:** Cloud Dashboard Print Setup
    i. https://dashboard.sprintray.com/print-setup
    ii. STL file import

iii. Manual/automatic orientation (automatic orientation is preferred given it is optimized for support placement and print efficiency)

d. Printing Parameters:

i. Pro S and Pro 2: Automatically oriented on RayWare Cloud

ii. 100-micron layer thickness

iii. Default support structures

e. Wash Device: SprintRay ProWash S or SprintRay Pro Wash/Dry

i. 91% or higher IPA

ii. For Pro Wash/Dry: Custom Multicycle: 3-minute wash from chamber 1, 5-minute rinse from chamber 2, 3-minute drying

iii. For Pro Wash S: Preprogrammed as “SprintRay IDB 3”.

f. Cure Device:

i. Printed on Pro S or Pro 2: SprintRay NanoCure or ProCure 2

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

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Warning and Precautions

SprintRay IDB 3 devices are non-toxic in fully post cured form and are classified as a biocompatible material. In uncured form, IDB 3 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 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.
- **Device Maintenance:** 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 IDB 3 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 IDB 3 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' (including 3D printers and post-processing units) setup, usage, onsite 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 S and Pro 2): Sign into https://dashboard.sprintray.com , navigate to print setup. Add your print files 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 Pro S and 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
    - For Pro Wash/Dry: Custom Multicycle: 3-minute wash from chamber 1, 5-minute rinse from chamber 2, 3-minute drying
    - For Pro Wash S: Preprogrammed as "SprintRay IDB 3".

Post Curing

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

- NanoCure (preprogrammed material profile)
- ProCure 2 (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-BriteTM/FuzziesTM wheel to smoothen any support nubs on the device.

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.

Clean & Disinfect

Use a laboratory steamer to clean the appliance of all debris. Finally, use dish soap and a brush with warm water to further clean the appliance.

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 IDB 3 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 product label.

	Keep away from sunlight		Use-by date
	Consult instructions for use	CE	European conformity

LOT	Lot number	REF	SKU number
	Manufacturer		Temperature limit
Rx	Prescription only	MD	Medical device
UK CA	UK Conformity Assessed (UKCA) Marking		Irritation
UDI	Unique device identifier		Importer
CH REP	Indicates the authorized representative in Switzerland	EC REP	Authorized representative in the European community
	Manufacturing date		Wear gloves
UK REP	UK responsible person	UK CA	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 1-800-914-8004.

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

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