

SprintRay IDB 2 Resin

Instructions For Use

Indication for Use

SprintRay IDB 2 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.

Device Description

Fabrication of dental appliances with this device requires computer-aided design and CAD/CAM manufacturing system that includes the following components not part of the device: digital file created in an optical impression system, 3D printer, and curing light equipment. The material is intended exclusively for professional dental work.

Requirements

Additive Printer and its Operation Software:

Provider	Product Name	Model Number	OS
SprintRay	Pro Printer	Pro 55	RayWare
SprintRay	Pro Printer	Pro 95	RayWare
SprintRay	Pro S Printer	Pro 55S	RayWare
SprintRay	Pro S Printer	Pro 95S	RayWare

Curing Light Equipment:

Provider	Product Name
SprintRay	ProCure
SprintRay	ProCure 2

Notification:

The device specifications have been validated using the software, printers, and process parameters specified in this document. Any other printers, operation software and post-printing processes will be outside of the device specifications and the FDA clearance. Users shall follow this document to use the device.

Contraindication

The IDB 2 resin is contraindicated in case of the following:

- If a patient is known to be allergic to any of the ingredients.
- Direct intraoral contact of uncured or partially uncured material.
- For every application that is not part of the indication (see above).

Warning

- The SprintRay IDB 2 resin is non-toxic in solid form, and it is classified as Biocompatible material. It is also classified as a sensitizer, which means that exposure over time can cause your body to have a mild allergic reaction. May cause skin irritation. May cause an allergic skin reaction. If contact with skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
- Avoid inhalation or ingestion. High vapor concentration can cause headache, irritation of eyes or respiratory system. Direct contact with eyes may cause possible corneal damage. Long-term excessive exposure to the material may cause more serious health effects. Monitor air quality per OSHA standards.
- Eye Contact: Immediately flush eyes with plenty of clean water for at least 20 minutes and consult a physician. Wash the contacted area thoroughly with soap and water.
- Inhalation: In case of exposure to a high concentration of vapor or mist, remove person to fresh air. Give oxygen or artificial respiration as required.
- Ingestion: Contact your regional poison control center immediately.

Precautions

- When washing the printed IBT with solvent or grinding the IBT, it should be in a properly ventilated environment with proper protective masks and gloves.
- 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.

- Recommended storage conditions for *unprocessed* SprintRay IDB 2 are at 15 – 25°C (60 -77°F) and avoid direct sunlight.
- Keep container closed when it is not in use.
- Expired or unused SprintRay IDB 2 should be completely cured or polymerized prior to disposal.
- Product shall not be used after expiration date.
- For *activation and complete polymerization* of the SprintRay IDB 2 please follow the steps involved in “Fabrication of Indirect Bonding Tray” and “Post-curing”.



The use of expired resin will likely result in failed prints and/or not-meeting biocompatible properties, as the compounds required for curing break down and will not activate properly.

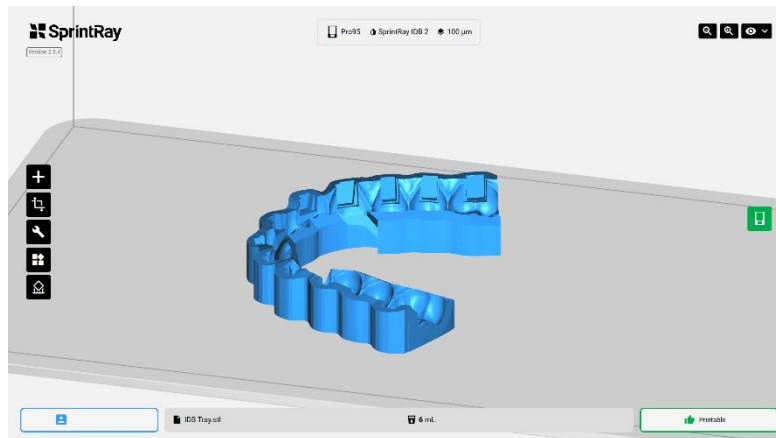
Fabrication of Indirect Bonding Tray

1. Design of the IBT

Once the intraoral scans of the patient are submitted to a dental-design service/lab, the IBT is designed and provided in STL file format by the dental-design service/lab.

2. Printing

- Bring the designed STL files to RayWare. Position the Intaglio surface of the IBT away from the print platform, with the occlusal surface/base of the design lying flat on the print platform. (Fig.1)
- Select “SprintRay IDB 2” resin setting for print-setting and use 100-micron thickness.
- Ensure Resin Tank is fully secured and filled to the recommended Resin-Level.
- Ensure the Print Platform is clean, dry, securely placed, and locked on the platform-arm.



(Fig. 1)

3. Washing and Drying



- After your IBT has been printed successfully, it must be washed using Isopropyl Alcohol (IPA) with a concentration of 91% or higher before being post-cured.
- Next step is to clean and wash the device from excess uncured-resin residue. Use >91% IPA to wash the device using any of the following methods:
 - Sonication
 - ProWash/Dry
- Ensure NOT to immerse the IBT for more than 10 min in the IPA bath.
- Remember: IPA is highly flammable! Please keep it away from heat sources, sparks, and flames.
- Ensure that your IBT is completely dry before the next step; if not, use compressed air to dry your IBT rapidly.
- Remove the IBT from the Print Platform.

4. Post-Curing

- Next, the printed IBT needs to be properly post-cured using a ProCure to maximize strength and accuracy, and to comply with the required standards.
- All the post-curing settings are preset in ProCure 1 and ProCure 2 unites.
- Wash and clean the device with a brush using soap and warm water.

Additional Help & Support

We are here to support you throughout the implementation period of your new technology and throughout the life of your product. Our experienced support technicians are available M-F from 7 am – 5 pm PST at 800-914-8004 (EXT 2).

 <p>SprintRay Inc. 2705 Media Center Drive Suite #100A Los Angeles, 90065 USA</p>	<p>Contact information For product assistance, please review help information at https://sprintray.com/digital-dentistry/</p> <p>To report product issues, please contact SprintRay at: https://support.sprintray.com/hc/en-us/requests/new</p> <p>Phone: 1-800-914-8004</p> <p>Rx </p>
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