

High Impact Denture Base Instructions for Use

Indications for Use

SprintRay High Impact Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.

Contraindications

SprintRay High Impact Denture Base 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 High Impact Denture Base is an alternative to traditional materials used to fabricate denture bases. It is intended exclusively for professional dental work. It is available in various shades: Original Pink, Dark Pink, Original Meharry, and Bubble Gum Pink.

Printing and Hardware Parameters

These device specifications have been validated using the following manufacturing products. Any products or processes not specified in this document are outside of the device specifications.

Area	Maxillary	Mandibular
Lingual ridge	≥ 2.5 mm	≥ 2.5 mm
Palatal/lingual	≥2 mm	≥ 2 mm
Facial/buccal	≥ 2 mm	≥ 2 mm
Implant Overdenture area	≥ 2.5 mm	≥ 2.5 mm

a. CAD File: CAD file of treatment device in STL file format with the following thickness:

b. Printer: SprintRay Pro or Pro S DLP 3D printer



- i. 55 or 95 micron XY resolution
- c. Software: RayWare Desktop or RayWare Cloud
 - i. STL file import
 - ii. Manual/automatic orientation
- d. Printing Parameters
 - i. Intaglio surface facing towards build platform
 - 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. Standard preprogrammed wash cycle
- f. Cure Device: SprintRay ProCure 2 or ProCure
 - i. Use manufacturer recommended curing times

Warning and Precautions

SprintRay High Impact Denture Base is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, High Impact Denture Base is classified as a sensitizer. When washing with solvent or grinding the device, do so in a well-ventilated area with proper protective equipment.

- **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 soap and water.
- Ingestion: Contact your regional poison control center immediately.

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 High Impact Denture Base 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
- Before disposal, completely polymerize
- Do not use High Impact Denture Base after the expiration date printed on the bottle





Do not use expired resin; biocompatibility and print stability may be compromised if expired photoinitiators do not activate properly.

Fabrication of Device

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

Upload the STL file to RayWare. Position the Intaglio surface of the denture toward the print platform (teeth facing up), with the posterior portion of the design angled toward the platform at 60°. Add supports. However, remove any supports that rest on the intaglio surface. Leave the supports only on the flanges' perimeter. Select "SprintRay High Impact Denture Base" resin setting for print-setting and use 100-micron thickness. Queue the job to your printer.

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, 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 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 the SprintRay ProWash S or SprintRay Pro Wash/Dry:

• Standard cleaning cycle

Denture Assembly

Use denture base resin to adhere the teeth to the base. To obtain the optimal bonding of artificial teeth to the dental object, it may be necessary to roughen the surface of the denture/teeth sockets before assembly.

- Place a drop of the denture base resin into each tooth socket
- Place the teeth in the sockets
- Press the teeth and base firmly together



• Use a curing light to tack cure the pieces together

Post Curing

Use one of the following post-curing equipment and process. For both SprintRay devices, select the preprogrammed material profile.

- ProCure 2 (preprogrammed material profile)
- ProCure (60 min at 60° C)

Polishing

Use a Scotch-Brite[™]/Fuzzies[™] wheel to smoothen the denture, 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 denture of all debris and polishing compounds. Use dish soap and a brush with warm water.

Repairing Dentures and Baseplates

This process is only applicable to temporary repair cases. The whole denture should be remade using an original design file. For temp repair cases:

- Prepare a cast made of putty using the broken denture
- Grind the fracture area to open it, and roughen the outer side of the fracture area
- Place the broken denture on the cast
- Apply High Impact Denture Base resin to cover the roughened and fracture areas
- Cure the areas by light curing until the resin solidified
- Place the denture, on the cast, in your post curing machine for half of the program time
- Carefully denture from the cast and cure the tissue side for half of the program time
- Grind, polish, and finish

Contact Information

For product assistance, please review help information at: <u>https://sprintray.com/digital-dentistry/</u>

To report product issues, please contact SprintRay at: <u>https://support.sprintray.com/hc/en-us/requests/new</u>

Phone: 1-800-914-8004



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Manufacturer information

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