# 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.

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### 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

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### 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, Dark Meharry, and Bubblegum Pink.

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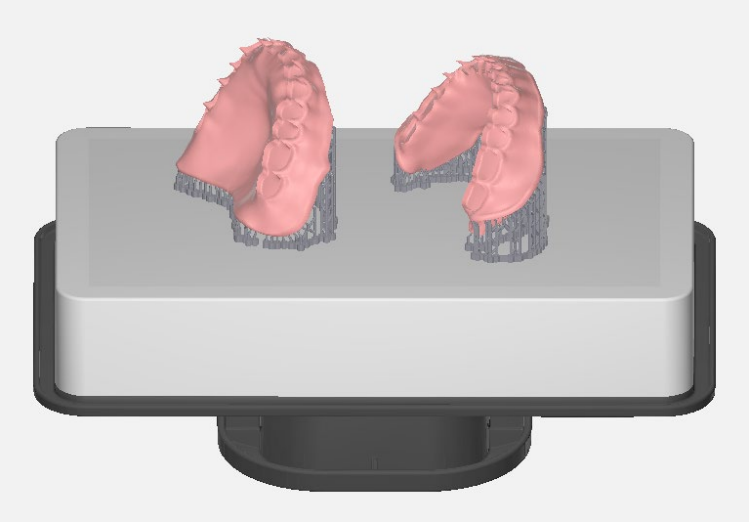
### Printing and Hardware Parameters

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.

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

| 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 |

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. 60-degree angulation, while the posterior is closer to build platform
    iii. Select the desired layer thickness (RayWare will typically default to 100 microns)
    iv. Default support structures



e. **Wash Device**: SprintRay ProWash S or SprintRay Pro Wash/Dry
    i. 91% or higher IPA
    ii. Standard preprogrammed multi-cycle wash
f. **Cure Device**: SprintRay NanoCure or ProCure 2
    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. Wear 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 soap and 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; and/or 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 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.
- Do not use High Impact Denture Base 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 end product.

If 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, 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
Sign in to RayWare Cloud 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.

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 multi-cycle

To ensure the proper function of the wash unit, always follow on-screen instructions for device cleanliness and maintenance. Dry the part completely before post-curing.

### 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.

- NanoCure (preprogrammed material profile)
- ProCure 2 (preprogrammed material profile)

## 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 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

## 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 postcure boxes. SprintRay High Impact Denture Base is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

## Symbol Guide

Keep away from sunlight

Use-by date

| | | | |
|---|---|---|---|
|  | Consult instructions for use |  | European conformity |
|  | Lot number |  | SKU number |
|  | Manufacturer |  | Temperature limit |
|  | Prescription only |  | Medical device |
|  | Environmental hazard |  | Irritation |
|  | Unique device identifier |  | Importer |
|  | Indicates the authorized representative in Switzerland |  | Authorized representative in the European community |
|  | Manufacturing date |  | Wear gloves |
|  | Health hazard |  | UK Conformity Assessed (UKCA) Marking |
|  | UK responsible person | | |

## 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/hc/en-us/requests/new

Phone: 1-800-914-8004

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## Manufacturer information

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