

SprintRay APEX FLEX

Instructions for Use

Indications for Use

SprintRay Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.

Contraindications

SprintRay Apex Flex 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 Apex Flex is a photo-polymeric methacrylate/acrylate resin material used in conjunction with a 3D printer and a scanned 3D image in a dental office to fabricate partial dentures by 3D printing layer upon layer of the composite material. The product is available in two shades: Light Pink and Standard Pink.

Printing and Hardware Parameters

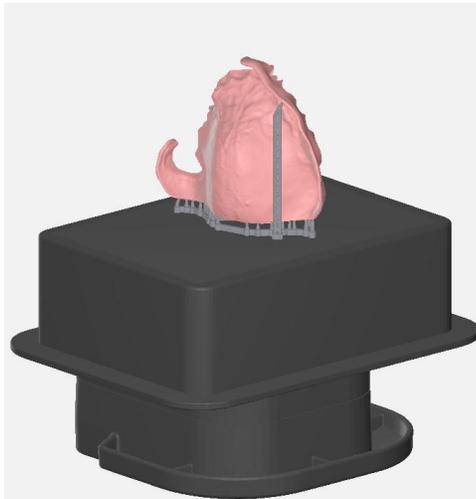
The device specifications have been only validated using the following hardware and software. Any products or processes not specified in this document have not been validated to meet the intended performance. Always refer to the SprintRay equipment user instructions for device setup, maintenance, and lifespan. Always refer to the SprintRay material Instruction for Use (IFU) for recommended design limits and proper validated equipment parameters. SprintRay Apex Flex is intended exclusively for the use by trained dental professionals.

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

Area	Maxillary	Mandibular
Palatal/lingual	≥1 mm	≥1 mm
Facial/buccal	≥1 mm	≥1 mm

Implant Overdenture area	≥1.5 mm	≥1.5 mm
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- b. **Printer:** SprintRay Pro 2 3D printer
 - i. Pro 2: 35-micron XY resolution and energy of 25 mW/cm²
- c. **Software:** RayWare Cloud
 - i. STL file import
 - ii. Manual/automatic orientation
- d. **Printing Parameters**
 - i. 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. Standard Multi-Cycle Wash
- f. **Cure Device:**
 - i. Printed on Pro 2: SprintRay NanoCure or ProCure 2
 Use SprintRay-recommended curing times that are built in the device

Warning and Precautions

SprintRay Apex Flex devices are non-toxic in fully post cured form and are classified as a biocompatible material. In uncured form, Partial Denture Base 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 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; 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 Apex Flex 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 Apex Flex 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. The capsule must be kept sealed until the print is complete.



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-curing units) set-up, 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.sprinray.com/s/printer>
- PostCuring Devices: <https://support.sprinray.com/s/cure>

RayWare Cloud (Pro 2): 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.

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 smoothing and finishing procedure.

Washing and Drying

Use $\geq 91\%$ IPA to wash the device using one of the following methods:

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

Denture Assembly

Use SprintRay Apex Flex 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

Printed on 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 denture base. 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 smoothing and polishing procedure.



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

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. Use dish soap and a brush with warm water.

By following the aforementioned workflow, the residual monomer content of the device is <0.8, where the minimum requirement according to ISO 20795-1 is 2.2%.

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 SprintRay Apex Flex 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 remove the 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 post cure boxes. SprintRay Apex Flex 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 bottle 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

	UK Conformity Assessed (UKCA) Marking		Irritation
	Unique device identifier		Importer
	Indicates the authorized representative in Switzerland		Authorized representative in the European community
	Manufacturing date		Wear gloves
	UK responsible person		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://sprinray.com/digital-dentistry/>

To report product issues, please contact SprintRay at: <https://support.sprinray.com/s/contactsupport>

Phone: 1-800-914-8004



Manufacturer information

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