SprintRay Retainer

Instructions For Use

Indications for Use

SprintRay Retainer is an alternative to traditional thermoplastic material used for the fabrication of retainers. It is intended exclusively for professional dental work.

Contraindications

SprintRay Retainer 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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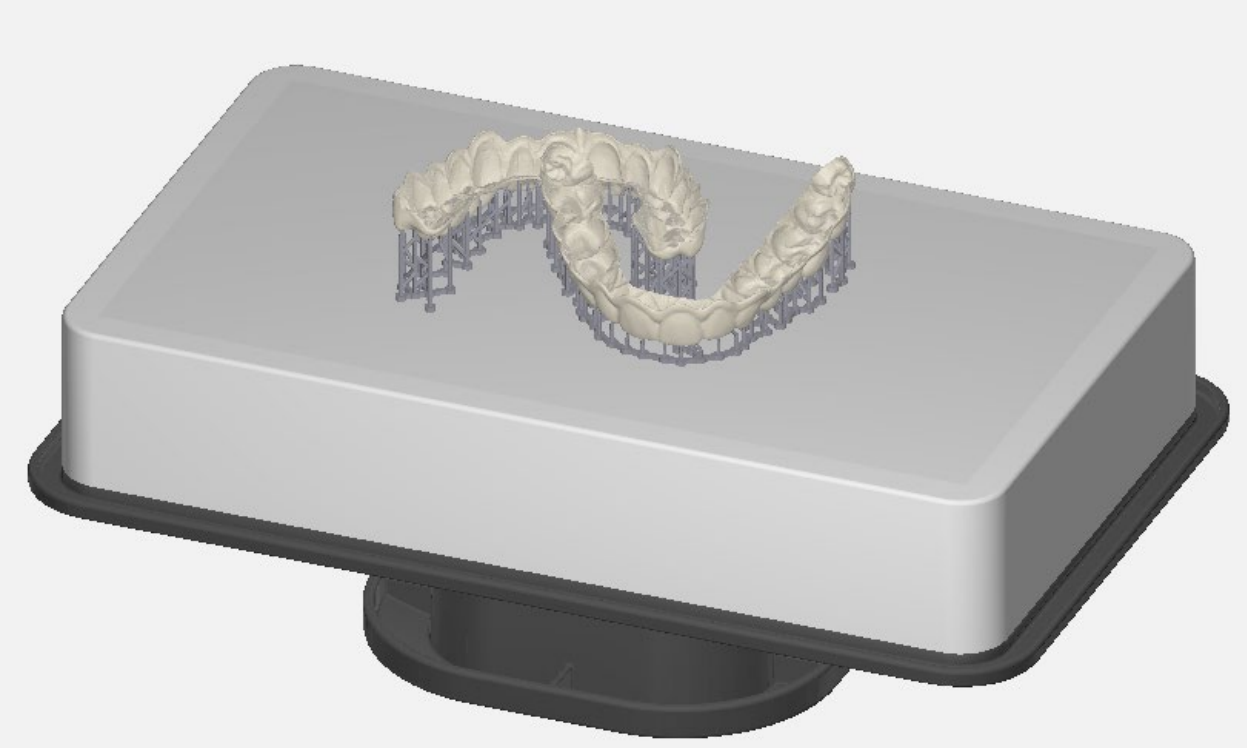
Device Description

SprintRay Retainer is a photo-polymeric methacrylate/acrylate resin material used in conjunction with a 3D printer and a scanned 3D image in a dental office or laboratory to fabricate retainers by 3D printing layer upon layer of the material.
SprintRay Retainer resin comes in one shade: clear.

Printing and Hardware Parameters

The 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
    i. Minimum thickness 0.6 mm
b. **Printer**: SprintRay Pro S or Pro 2 3D printer
    i. Pro S: 55 or 95 micron XY resolution with Optical Polish Tanks
    ii. Pro 2: 35 micron XY resolution
c. **Software**: RayWare Cloud
    i. STL file import
    ii. Manual/automatic orientation
d. **Printing Parameters**
    i. Intaglio surface facing away from build platform
    ii. Orient 10˚ from the anterior
    iii. Select the desired layer thickness (RayWare will typically default to 170 microns)
    iv. Default support structures



e. **Wash Device**: SprintRay Pro Wash S or SprintRay Pro Wash/Dry
   i. 91% or higher IPA
   ii. Standard preprogrammed wash cycle
      1. Platform Wash
      2. Basket wash with intaglio facing the propellor (preferred)

f. **Cure Device**: SprintRay NanoCure
   i. Use SprintRay-recommended curing times that are built in the device
   ii. Allow the retainers to cool before removing from the NanoCure

Warning and Precautions

SprintRay Retainer is non-toxic in processed, cured form, and is classified as a biocompatible material. In uncured form, Retainer resin 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; 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 Retainer 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 store the filled tank on the printer cradle when not in use.
- Do not use Retainer 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 final device.

If applicable, refer to the Workflow Guide for detailed best practices for producing specific appliance types with SprintRay resins.

Designing
Get a free AI Retainer Design by visiting dasboard.sprintray.com, then go to Cloud Design and choose the AI Retainer treatment. Upload the patient scans, then receive a design in minutes. The device is designed in STL file format by a dental design service, preferably SprintRay Cloud Design. Alternatively, you may print your own design imported as an STL from dental CAD software using digital anatomical data from the patient.

3D Printing
Sign in to RayWare Cloud and select the appliance type; the algorithm will automatically orient and add supports. Select SprintRay Retainer 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, assign the resin tank to the proper material and shade, 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. You may remove all supports before post curing using a flush cutter or round diamond disc. Cut as close as possible to the device to minimize the smoothening and finishing procedure. Pay close attention when handling the device before post curing to prevent roughening the surface or deforming the shape, otherwise leave the supports on the device until after post cure.

Washing and Drying
Use ≥91% IPA to wash the device using the SprintRay Pro Wash S or SprintRay Pro Wash/Dry:

- Standard cleaning 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.
Remove excess resin from the build platform before cleaning the parts on the build platform (optional). Washing the retainers in the wash basket with the intaglio facing the propellor is preferred. Remove the retainers from the wash chamber immediately after the cycle is complete and ensure they are dry. Use compressed air or a blow drier to ensure the surface is dry if needed.

Post Curing

Use the following post-curing equipment from SprintRay to cure the device and select the preprogrammed profile for Retainer:

- NanoCure (preprogrammed material profile)

For your safety, allow the retainers to cool before removing them from the NanoCure. Removing the hot retainers is unsafe without protective gloves and could deform the retainer's shape. Removing the supports from the cool, post cured retainers is preferrable and will ensure the surface and shape remain as designed.

Finishing

Use a silicone burr with a lab handpiece to smoothen the surface.

Polishing and Disinfect

Apply a thin coat of mineral oil to the occlusal surface and use a cotton buffing rotary hand tool piece to remove debris from finishing and improve the sheen of the support nubs (optional). If the deburred surfaces become cloudy, coat with mineral oil to improve clarity (optional). Wash and clean the device with a brush using soap and warm water.

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 Retainer is not an environmental hazard in its final, fully cured state. Once cured, it can be thrown away with regular trash.

Symbol Guide

The below table 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
	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		

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://sprintray.com/digital-dentistry/

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

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Australian Sponsor

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