



BITE TRAY



Instruction For Use

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Device Description

Rodin Bite Tray resin is for use in fabricating custom full and quadrant maxillary and mandibular arch impression bite trays in combination with CAD/CAM systems.

Composition

Rodin Bite Tray resin is comprised of a methacrylate-based resin, photo initiator, inhibitor, and pigments. It utilizes the same resin components found in injection mold acrylic impression tray compositions.

Intended Customer

Rodin Bite Tray resin is intended to be used only by trained professional dentists or dental lab technicians

Intended Use

Rodin Bite Tray resin is designed for the fabrication of custom full and quadrant maxillary and mandibular arch impression bite trays for use with Polyvinyl siloxane(PVS), Vinyl Polysiloxane (VPS), and Alginate impression material systems. Rodin bite tray resin requires a computer-aided design and manufacturing (CAD/CAM) system includes the following components not part of the device: oral casting impression, digital restorative file created from a scanned impression system, stereolithographic additive printer, and curing light equipment. For use in tandem with **validated** 3D printers and post-curing devices listed below while following manufacturer's suggested instructions.

Contraindications

- 5.1 Designing bite trays with a thickness below 2mm is not recommended for custom and stock tray designs. Breakage of tray and/or deformation of impression body may occur when removing tray from the patient's mouth.
- 5.2 Designing impression trays without retention holes may lead to set impression material separating from tray when removing from the patient's mouth

Orientation & Supporting

- 6.1 Orientate both upper lower bite tray designs with adaptive tissue area side down at a 45-degree angle. Place the supports on the parameter of the ridge. Avoid placing supports in the adaptive sensitive areas which may collide with teeth and prevent tray from seating when impression taking.
- 6.2 The recommended minimum support diameter is 0.3mm at the point of contact where the support meets the restoration.
- 6.3 The recommended minimum support height is 2mm for ease of tray removal.

Mixing

3D printing resins contain chemicals of different weights; therefore, it is essential to thoroughly mix the resin prior to starting a new print job.

- 7.1 For resin already in the resin vat, use a silicon blade or spatula to gently mix resin if it has been sitting for longer than a 12-hour period.
- 7.2 Before dispensing the resin from the bottle, agitate the bottle for 1 minute.

Post-processing Instructions

- 8.1 After completion of the print job, remove the build platform from the 3D printer.
- 8.2 Wash printed trays in IPA (99% recommended) in a vortex or ultrasonic bath for 3 minutes then move semi clean parts to a secondary vortex or ultrasonic bath with fresh IPA for an additional 3 minutes.

Note - Do not expose bite trays to IPA for longer than 10 minutes in total to prevent material strength loss.

- 8.3 Use compressed air to remove excess IPA and/or residual uncured resin.
- 8.4 Repeat steps 8.2 to 8.3 until the printed part is thoroughly clean leaving a shine-free, matte finish.
- 8.5 Post-cure trays in a **validated** light curing device following recommended time and temperature schedules if applicable.

Note - Post curing must be performed to be in compliance with FDA.

Validated 3D Printers

- 9.1 Asiga Max (385nm) and Pro4k (385nm) 3D printers

Validated Light Curing Devices

- 10.1 Otofash - Post cure at 5000 flash cycles (recommended for optimum mechanical properties).
- 10.2 Dreve PCU LED N2 - 30 minutes @ 80% Light intensity
- 10.3 Ackuretta Curie - 30min, P12, D10
- 10.4 Form labs Form Cure - 20 minutes @ 60C

Note - No inert or vacuum environment required when post curing these materials.

Chairside Adjustments and Impression Taking

- 11.1 If making chair side adjustments to the bite tray, remove undesired material with standard dental carbide burs. Smooth sharp edges and remove burs with dental polishing wheels.
- 11.2 Follow recommended manufacturer's impression kit instructions when dispensing impression material and allow impression material to fully set before tray removal from patient's mouth.

Environment Conditions

- 12.1 3D photopolymer resins are very light-sensitive, sensitive to ambient office lights and sun light from a window. Do not leave resin bottles open. Resin that has been poured into a resin tank should be covered if not used.
- 12.2 Best to store resin between 65F and 85F. Printing temp should be set to 30 degrees Celsius for optimum performance if applicable. If the bottle is stored in colder lab conditions as indicated above, it is recommended to place resin bottle with lid tightly sealed in a warm water bath.

Nightly/Long-term Storage

At the end of the day, it is best to pour unused resin from the printer back into the resin bottle for storage. When pouring resin from your tank or other vessel back into the bottle, always pour through a fine mesh filter. This will trap partially-cured debris and prevent contamination of the rest of your bottle, prolonging the life of your materials. The resin is best stored in its original container to maintain shelf-life.

Disposal

Dispose in accordance with all federal, state and local regulations. Consult state and local hazardous waste regulations to ensure complete and accurate classification of waste. US EPA guidelines for the classification of hazardous waste are found in 40 CFR part 261.3. Liquid resin should be cured before being disposed of. Pour liquid resin into a clear container and set it in direct sunlight. Once it has cured, it can be treated as waste and disposed of in the regular trash.

Legal Disclaimer

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