



RODIN[®]
3D Resin

DENTURE BASE 2.0

For Digital Dentures



Instruction For Use

Table of Contents

Material Description	1
Rodin Denture Base 2.0	
Composition	
Intended Customer	
Intended Use	
Contraindications	
Design Consideration	1-2
Orientation & Supporting	3
Mixing	
Post-Processing Information	
Validated 3D Printers	4
Chairside Adjustments	
Environment Conditions	
Night/Long-Term Storage	
Disposal	5
Legal Disclaimer	

Material Description

Rodin Denture Base 2.0 is a Biocompatible, Class II resin for use fabricating maxillary and mandibular denture bases in combination with CAD/CAM systems.

Composition

Rodin Denture Base 2.0 resin is comprised of a Methacrylate based resin, photo initiator, inhibitor, fumed silica, and pigments.

Intended Customer

Rodin Denture Base 2.0 resin is intended to be used only by trained professional dentists or dental lab technicians. All sales are restricted to dental supply dealers, teaching institutions and government dental facilities. This product is labeled for sales restricted to dentists (or licensed practitioner) unless state and local laws permit otherwise.

Intended Use

Rodin Denture Base 2.0 resin use is specific for fabrication of temporary and long term maxillary and mandibular arch denture bases for use with 3D or injected acrylic crown and bridge material systems. Rodin denture base 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 postcuring devices listed below while following manufacturer's suggested instructions.

Contraindications

- 5.1 Patients allergic to methacrylate material.
- 5.2 Flexible denture indications.

Design Consideration

- 6.1 If a denture base is designed as a split file, design sockets with a minimum thickness of 0.3mm to prevent possibility of holes from occurring during the printing process. This may alter the intaglio surfaces of the denture base when bonding teeth into the base.
- 6.2 Set cement gap of tooth sockets to 150Qm for snap-in assembly.

Orientation & Supporting

- 7.1 Orientate both maxillary and mandibular denture bases with adaptive tissue area side down at a 45-degree angle.
- 7.2 Place the supports on the parameter of the ridge. Avoid placing supports in the adaptive sensitive areas to prevent high spots that can lead to tissue irritation if not removed.
- 7.2 The recommended minimum support diameter at the point of contact is 0.3mm.
- 7.3 The recommended minimum support height is 2mm to prevent damage during part 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.

- 8.1 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.
- 8.2 Before dispensing the resin from the bottle, use a plastic spatula to stir the bottom of the bottle for 1 minute minutes before dispensing or mix using an automated bottle roller for 10 minutes.
- 8.3 If the bottle has been in storage for excess of a month, it is recommended to roll the bottle for 1 hour to allow the chemical components to mix thoroughly.

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 99% IPA in a vortex or ultrasonic bath for 5 minutes then move semi clean parts to a secondary vortex or ultrasonic bath with fresh 99% IPA for an additional 5 minutes.

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

- 8.5 Use compressed air to remove excess IPA and/or residual uncured resin.
- 8.6 Repeat steps 4 and 5 until the restoration is thoroughly clean leaving a shine-free, matte finish.
- 8.7 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 regulations.

Validated 3d Printers

- 9.1 Asiga Max (385nm), Asiga Pro4k (385nm), Asiga Pico 2 (385nm)
- 9.2 Ackuretta Sol
- 9.3 Phrozen Sonic Mini 4K, Phrozen Sonic 4K 2022, Phrozen Sonic XL 2022

Validated Light Curing Devices

- 10.1 Otofash – Post cure at 4500 flash cycles (recommended for optimum mechanical properties).
- 10.2 Dreve PCU LED N2 – 15 minutes @ 80% Light intensity
- 10.3 Ackuretta Curie – 20min, P12, D10
- 10.4 Form labs Form Cure – 15 minutes @ 60C

Note – No inert or vacuum environment required when post curing if not using light curable stain or glaze systems that requires inert atmosphere conditions.

Charside Adjustments

- 11.1 If making chair side adjustments to the denture base, remove undesired material with standard dental carbide burs. Smooth sharp edges and remove burs with dental polishing wheels.

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.
- 6) Immediately place relined denture into patient's mouth and instruct patient to close bite to maintain correct occlusion. Have patient continue resting bite for 5 minutes to allow VPS Reline to completely set.

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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