



RODIN[®]
3D Resin

A Pac-Dent Brand

DENTURE BASE 2.0

For Digital Dentures



Instruction For Use

Rodin Denture Base 2.0**Instructions for Use**

Revision 090226

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1. DEVICE DESCRIPTION

Rodin Denture Base 2.0 is a light-curable resin for the fabrication of 3D printed denture bases. It is meticulously engineered for crafting high-precision, long-term temporary or permanent denture hybrid prosthetics, providing dental professionals with a reliable and efficient solution for their practice.

2. MATERIAL COMPOSITION

Rodin Denture Base 2.0 resin is comprised of:

- Methyl methacrylate resin
- Photoinitiator
- Photoinhibitor
- Pigment

3. INTENDED CUSTOMER

The product is exclusively intended for use by trained professional dentists or dental lab technicians. Sales are restricted to:

- Dental supply dealers
- Teaching institutions
- Government dental facilities

4. 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 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.

5. INDICATIONS FOR USE

Rodin Denture Base 2.0 is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins.

6. CONTRAINDICATIONS

Methyl Methacrylate Allergy

Patients who have a known allergy to methyl methacrylate should not be prescribed products containing this compound. Methyl methacrylate is a common ingredient in dental resins and acrylics. Exposure to materials containing it can trigger allergic reactions in sensitized individuals. These reactions can range from mild (such as skin irritation or rash) to severe (such as anaphylaxis, which is a potentially life-threatening condition).

7. SAFETY INFORMATION

Recommended personal protective equipment includes:

- Gloves
- Eye protection
- Lab coat
- Closed-toed shoes

8. DESIGN GUIDELINES FOR DENTURE BASES

8.1. General Design Considerations

To ensure optimal performance, durability, and patient comfort for your denture, follow these design thickness guidelines.

8.2. General Surface Thickness

Maintain a minimum thickness of 2 mm for all gingiva mask and denture base surfaces, excluding the tooth arch sockets and locator recess areas. This ensures structural integrity and reliable performance.

8.3. Tooth Arch Sockets and Locator Recesses

Allow for a minimum thickness of 0.3 mm in these areas to prevent holes from forming during 3D printing or cleaning processes. Holes in these recessed areas can compromise the intaglio (tissue-contacting) surface when bonding teeth to the base, potentially causing patient irritation or discomfort. Socket cement gap of the denture base design should be preset to 150 microns to allow for tooth arch to passively fit.

8.4. Runner Bars

Add runner bars across the palate to stabilize maxillary and mandibular bases. This will help improve global accuracy, allowing for better adaptation with the tissue.

9. VALIDATED EQUIPMENT

9.1. Validated 3D Printers

For the most current list of validated equipment and their settings, please refer to the provided link:

<https://rodin-3d.com/validated-equipment-settings/>

9.2. Validated Light-Curing Parameters

For the most current list of validated equipment and their settings, please refer to the provided link:

<https://www.rodin-3d.com/3d-printers/light-curing-devices>

Special Note: For applications involving light-cured stains and/or glaze, post-curing under vacuum or in an inert gas environment is recommended. This practice enhances the polishability, high shine retention, durability, and wear resistance of the final restoration.

10. PRINTING PREPARATION

10.1. Mixing Recommendations

Importance of Mixing

Resins used for 3D printing contain chemicals of varying densities. Thorough mixing is therefore crucial to ensure a homogeneous mixture and consistent printing quality.

10.2. Mixing Resin Within a Printer's Vat:

- Use a silicon blade to gently mix the resin, particularly aiming to re-suspend any settled ceramic particles at the bottom of the tank.
- If a previous print has failed, strain the resin using a 50-micron mesh strainer to remove any debris.
- Avoid metal strainers, which may cause oxidation and discoloration.

10.3. Preparing Resin from the Bottle:

- Before using resin from a new bottle or one that has been sitting for a while, stir the bottom of the bottle thoroughly with a plastic spatula for several minutes.
- Alternatively, place the bottle on an automated roller for 30 minutes to ensure even mixing.

- If the resin has been stored for more than a month, roll the bottle for 1 hour. This helps reintegrate any ceramic fillers back into suspension, ensuring consistency in the printed object.

10.4. Caution with Aluminum Build Plates:

Certain 3D printer models use aluminum build plates that may oxidize when exposed to uncured resin. This oxidation can discolor the resin if it is returned to the vat or original bottle, potentially affecting the color

of subsequent printouts. To prevent this, exercise caution when handling aluminum build plates, ensuring uncured resin is properly managed and not reintroduced into the resin supply.

10.5. Nesting and Orientation

Proper nesting ensures accuracy, structural integrity, and patient comfort.

Orientation Positioning:

- Orient both maxillary and mandibular denture bases with the adaptive tissue-contacting (intaglio) surface facing downward at a 45-degree angle to optimize resin flow and reduce print failures. Ensure papilla structures and palatal areas are positioned to be self-supporting, avoiding overhangs that require additional support structures.
- Orient the gingiva mask with papilla structures facing away from the build plate surface.

10.6. Support Placement

- Place supports along the perimeter of the ridge every 2mm.
- Avoid placing supports on adaptive tissue-contacting areas to prevent high spots, which could cause tissue irritation if not fully removed during post-processing.

10.7. Support dimensions:

- Minimum Support Diameter: Ensure supports have a minimum diameter of 0.8 mm at the initial point of contact (island) with the denture base to provide adequate stability during printing. All other supports can have a contact width diameter of 0.35mm.
- Minimum Support Height: Use a minimum support height of 2 mm to ensure sufficient structural support and to prevent damage during removal from the build platform. Shorter supports (less than 2 mm) may lead to breakage or deformation during post-processing.

Adhering to these nesting guidelines enhances print accuracy, maintains structural integrity, and reduces the risk of complications during post-processing. This strategy ensures the tooth arch fits intimately with the denture base socket area, minimizing the need for extensive support removal and hand-finishing, thereby improving efficiency in back-end post-processing and ensuring high-quality denture bases that prioritize patient comfort.

11. POST-PROCESSING PROCEDURES

Maximizing the quality and longevity of 3D printed dental restorations necessitates strict adherence to the post-processing instructions. Below are the key steps to be followed:

11.1. Removal from Printer

- **Post-Printing Removal:** Gently detach the build platform from the 3D printer.
- **Restoration Removal:** Utilize a metal spatula, maintaining a perpendicular angle to the build plate, to carefully pry off the printed restoration. This technique is particularly crucial for bridges.

11.2. Removing Excess Resin

- **Resin Removal:** Employ low-pressure air to dispel any uncured resin from the model and build plate.
- **Aluminum Build Plate Caution:** Refrain from reusing resin if it has come into contact with an aluminum build plate due to potential contamination with grey metal oxide.
- **Spatula Guidance:** Glide a metal spatula under the print base, encircling the perimeter until the print detaches. Ensure the spatula is parallel to the build plate for bridge removal.

12. CLEANING RESTORATIONS

12.1. Cleaning Recommendations: Rodin® Universal Resin Cleaner

1. **Remove Excess Resin:** Wipe away or blow off excess residual resin from the printed object using compressed air or a paper towel.
2. **Run Prewash Cycle 3 Minutes:**

Place the object in an ultrasonic, vortex, or oscillating bath filled with Rodin® Universal Resin Cleaner. Run the prewash cycle for 3 minutes.
3. **Scrub Surface (Optional):**

After the prewash, dip a clean brush into a fresh batch of Rodin® Universal Resin Cleaner and thoroughly scrub the entire surface of the object.

4. Run Secondary Wash Cycle 3 Minutes:

Transfer the object to an ultrasonic, vortex, or oscillating bath filled with fresh Rodin® Universal Resin Cleaner. Run this secondary cycle for 3 minutes.

5. Dry the Object:

Blow off any remaining wash solution using compressed air until the object is completely dry.

6. Inspect for a Matte Finish: Crucial before post-curing. Examine the object closely for any shiny spots.

- If shiny areas are present: Residual resin remains. Repeat the secondary wash (Step 4) and drying process (Step 5).
- If the surface is completely matte: The object is clean and ready for characterization or post-curing procedures.

12.2. Cleaning Recommendations: Isopropyl Alcohol (IPA)

Recommended Workflow for 99%+ Isopropyl Alcohol

Never submerge printed objects in Isopropyl Alcohol for a combined total of more than 10 minutes. Prolonged exposure to IPA will break down the resin, causing degradation to the mechanical properties and structural integrity of the final printed part.

1. Remove Excess Resin:

Wipe away or blow off excess residual resin from the printed object using compressed air or a paper towel.

2. Run Prewash Cycle 3-4 Minutes:

Place the object in an ultrasonic, vortex, or oscillating bath filled with IPA. Run the prewash cycle for 3 to 4 minutes.

3. Scrub Surface (Optional):

After the prewash, dip a clean brush into fresh IPA and thoroughly scrub the entire surface of the object. Do not leave the part soaking in a bath during this step.

4. Run Secondary Wash Cycle 3-4 Minutes:

Transfer the object to an ultrasonic, vortex, or oscillating bath filled with fresh IPA. Run this secondary cycle for 3 to 4 minutes.

5. Dry the Object:

Immediately after removing the part from the secondary wash, blow off all remaining solvent using compressed air until the object is completely dry.

6. Inspect for a Matte Finish: Crucial before post-curing. Examine the object closely for any shiny spots.

- If shiny areas are present: Residual resin remains. Do not run another full wash cycle. Spot-clean the shiny areas manually with a brush dipped in fresh IPA, then dry immediately with compressed air.
- If the surface is completely matte: The object is clean and ready for characterization or post-curing procedures.

13. SUPPORT REMOVAL AND ADJUSTMENTS

- Remove supports using a low-speed handpiece with a dull carbide bur.
- Perform contour and occlusal adjustments using ceramic wheels, carbide burs, or diamond burs.

Green State Adjustment:

All adjustments should be performed before final curing to prevent micro-fracturing.

These steps are essential to ensure that the 3D printed restorations are safe, clean, and ready for use in dental applications. Proper post-processing not only affects the aesthetic quality but also the structural integrity and biocompatibility of the final product.

14. DENTURE ASSEMBLY AND CHARACTERIZATION

14.1. Denture Assembly Workflows

Workflow 1 (Recommended) – Using Rodin Glaze N2-Free

- Apply Rodin N₂-Free Glaze to the socket areas of the denture base.
- Firmly press the sectioned or full denture tooth arch into the sockets.
- Brush excess glaze onto the cameo surfaces of the base and teeth.
- Cure using the recommended cure cycle settings.

Note: If using Glaze N₂-Free solely as a bonding agent, cure under nitrogen for full surface polymerization, improved polishing efficiency, and long-term high-shine retention.

Workflow 2 – Using Rodin Denture Base 2.0 Resin

- Apply Rodin Denture Base 2.0 resin into the socket areas.
- Firmly press the sectioned or full denture tooth arch into the sockets.
- Carefully remove excess resin from sulcus, embrasures, and occlusal areas with a brush or paper towel for optimal esthetics.
- Cure under nitrogen for full surface polymerization, improving polishing efficiency, and long-term high-shine retention.

14.2. Characterization Workflow

Green State Application

Apply light-curable stains, glazes, and composite sheet products while the printed parts are in their green state, meaning before they have undergone final curing. This state allows for the best adhesion of the products to the restoration surface.

Product Selection

Use only products that are specifically designed for 3D printed materials. These products are formulated to bond effectively with the resin material and cure properly under light without compromising the integrity of the restoration.

Avoid Conventional Systems:

Do not use traditional stain and glaze systems that require firing in a furnace. The high temperatures involved in these processes are incompatible with 3D printed resin restorations and will lead to degradation of the polymer, resulting in damage or destruction of the restoration.

15. FINISHING AND POLISHING

15.1. Post-Curing in an Inert Environment

It is recommended to post-cure printed restorations or provisional prostheses in an inert environment, such as nitrogen. Post-curing in an oxygen-free environment improves polymerization and enhances polishability, helping the final restoration maintain a high-gloss surface.

Follow the validated curing parameters listed in Section 9.2 Validated Light-Curing Parameters

15.2. Conventional Polishing Workflow

Initial Polishing

- Use a lathe with a cotton or synthetic rag wheel and 50 µm pumice under heavy pressure to smooth the surface.
- Rinse off residual pumice using a steam gun.

Intermediate Polishing

- Apply an acrylic polishing compound with light pressure.
- Add water and lightly polish to begin developing a high-shine surface.

Steam Cleaning

After using the abrasive compound, steam clean the restoration to remove residual polishing materials and ensure a clean surface before final polishing.

Final High-Shine Polishing

For the final polish, use a rag wheel with fine-grit diamond paste to produce a smooth, high-gloss finish.

Following these recommendations ensures that 3D-printed dental restorations and provisional prostheses achieve a smooth, high-quality finish that resembles natural dentition. Always use tools and polishing compounds designed for dental materials to avoid damaging the restoration.

15.3. Characterization, Stains, And Glazes Manufacturer Recommendations:

After applying the topical products, follow the post-cure procedures as recommended by the manufacturer. This typically involves curing the restoration under specific light conditions to ensure that the stains and glazes are properly set and bonded.

Green State Application

Characterization materials should be applied while the printed part is in the green state (pre-final cure) to maximize bonding and surface integration.

Material Compatibility

Use only stains, glazes, or composite characterization products specifically designed for 3D-printed photopolymer resins. These materials are formulated to bond properly and cure without compromising structural integrity.

Avoid using traditional stain and glaze systems that require furnace firing, as high temperatures can degrade photopolymer resins.

Avoid Over-Curing

Be cautious not to over-cure the restoration, as excessive exposure to light and heat can alter the color and properties of both the resin and the applied products.

By following these recommendations, you can achieve aesthetically pleasing and durable finishes on 3D printed dental restorations without compromising their structural integrity. Always refer to the specific guidelines provided by the manufacturers of both the 3D printing materials and the topical stain and glaze products to ensure compatibility and optimal results.

16. ADJUSTMENTS AND REPAIRS**16.1. Chairside Modifications****Material Removal:**

Treat the 3D printed restoration similarly to a composite material.

- Utilize carbide burs to carefully remove material from areas requiring adjustment.
- Be gentle and precise to avoid unnecessary removal of material to maintain ideal adaptation at intaglio surfaces.

Regaining Luster:

After the adjustments, use acrylic polishing compounds to buff the adjusted areas. This helps to restore the shine and ensure that the restoration blends seamlessly with the surrounding natural teeth.

16.2. Reline and Repairs**Soft Reline**

Rodin Soft Reline system is recommended for immediate post-op denture relines. Follow manufacturer's instruction guidance for surface preparation and application workflow recommendations.

Cold Cure Repairs

If any repairs are necessary, use cold cure reline systems to make repairs. Follow manufacturer's instruction guidance for surface preparation and application workflow recommendations.

Note: Hot cure reline systems may mess with dimensional integrity causing the base to warp and affect adaptation to the tissue surface.

17. PATIENT CARE INSTRUCTIONS

Proper care of your Rodin dentures ensures their longevity, functionality, and esthetic appearance. Follow these instructions to maintain your dentures effectively.

17.1. Removal

Carefully remove the denture from mouth before brushing to ensure all surfaces can be cleaned effectively.

17.2. Cleaning

- Carefully brush the intaglio and cameo surface of the denture gently using a soft or medium-bristle toothbrush with non-abrasive toothpaste and water.
- Avoid abrasive toothpastes to prevent premature wear of topical stain and glaze characterization products.

If your denture has a Rodin Soft Reline applied to the intaglio surface, do not brush the beveled areas at the denture's border to prevent debonding of the reline material.

18. DRYING AND STORAGE

- Pat dry the denture with a paper towel after cleaning.
- Allow to air dry in a clamshell container overnight to maintain its shape and integrity.
- Do not submerge Rodin dentures in water or denture cleaning solutions, as this can weaken the material over time.

Additional Tips

- Brush dentures daily to minimize plaque buildup and prevent unpleasant odor.
- Handle your dentures with care to avoid dropping them.
- Schedule regular dental check-ups to ensure your dentures remain in optimal condition.

19. PRINTING ENVIRONMENT CONDITIONS

Maintaining optimal environmental conditions is essential for successful 3D printing with photopolymer resins, particularly in dental applications where precision and material properties are crucial. Here are the key considerations for creating and preserving an ideal printing environment:

19.1. Light Exposure

Ambient Light Sensitivity: Photopolymer resins are sensitive to UV and certain types of artificial light. Prolonged exposure can cause unintended curing or degradation of the resin's properties.

Sunlight Protection: Direct sunlight can rapidly cure photopolymer resins. It is important to store resin bottles and tanks away from windows or areas that receive direct sunlight.

Laboratory Lighting: If possible, use lighting that does not emit UV wavelengths, or keep the resin covered and shielded from ambient light when not in use.

19.2. Resin Handling

Bottle Sealing: Always keep resin bottles tightly sealed when not in use. This prevents contamination from dust or other particles and minimizes the risk of accidental light exposure.

Cleanliness: Ensure that the resin tank and tools used for stirring or handling the resin are clean to avoid introducing contaminants that can affect print quality.

19.3. Temperature Control

Optimal Printing Temperature: Most photopolymer resins have an optimal printing temperature range, typically around 70°F to 85°F (21°C to 29°C). Maintaining this temperature range ensures consistent viscosity and print performance.

Heated Environments: For printers with temperature regulation, setting the printing environment to around 35°C can optimize performance. This helps maintain the resin's ideal flow characteristics.

Cold Conditions Management: If the resin is stored or used in colder conditions, gently warming the resin to the optimal temperature is necessary. This can be done using a warm water bath or temperature-controlled heating mats, ensuring the resin is sealed to prevent water contamination.

By adhering to these guidelines, you can ensure that the resin maintains its intended properties and that the 3D printing process produces accurate and reliable dental restorations. Proper environmental control is a key factor in achieving the high-quality results expected in dental applications.

20. STORAGE RECOMMENDATIONS

Storing 3D printing resins correctly is crucial to maintain their quality and ensure consistent results in printing. Here are the detailed storage recommendations:

20.1. Resin Vat Management

Dedicated Vats: Assign a specific resin vat for each type of resin, especially different shades. This prevents cross-contamination and ensures that the resin's properties are preserved.

Residual IPA: After cleaning, ensure that vats are completely free from isopropyl alcohol (IPA) residues before refilling them with resin. IPA can react with the resin, potentially altering its properties.

20.2. Resin Handling and Transfer

Avoid Pouring Back: Do not transfer resin from the vat back into the original bottle. This can introduce contaminants into the bottle, compromising the quality of the remaining resin.

Use of Original Containers: Always store the resin in its original container. Manufacturers design these containers specifically to protect the resin from light and air exposure.

20.3. Storage Environment

Light Protection: Store resin containers in a dark place, away from direct sunlight and bright artificial light, to prevent inadvertent curing.

Dust-Free: Ensure the storage area is clean and free from dust. Dust particles can contaminate the resin, affecting the quality of the prints.

Temperature Control: Store resins at a consistent, moderate temperature, away from extremes of heat or cold. Extreme temperatures can affect the viscosity and curing properties of the resin.

21. SHELF LIFE

Unopened resin has a shelf life of 24 months from the date of manufacture when stored according to the recommended storage conditions. Do not use resin beyond its expiration date. Over time, even well-stored resins can degrade and lose their optimal printing properties.

22. DISPOSAL RECOMMENDATIONS

22.1. Classification of Waste

Regulatory Compliance: Familiarize yourself with and comply with all applicable federal, state, and local regulations concerning hazardous waste disposal.

Hazardous Waste Identification: Consult the US EPA guidelines and other relevant sources to accurately classify whether the waste you're disposing of is considered hazardous.

22.2. Disposal of Liquid Resin

Curing Before Disposal: Never dispose of liquid resin directly into the trash or down the drain. Uncured resin should be fully cured before disposal.

Sunlight Curing: Pour the liquid resin into a clear container and expose it to direct sunlight. UV light will cure the resin. Alternatively, use a UV lamp if sunlight is not sufficient.

Solidification: Once the resin is fully cured and solidified, it can generally be disposed of as regular trash. However, always verify with local regulations, as there may be specific guidelines for cured resins.

22.3. Solid Resin Waste

Printed Objects and Supports: Cured resin objects, failed prints, and supports should be considered for disposal as solid waste. Ensure they are fully cured before disposal.

Containment: Place the cured resin waste in a sealed bag or container to prevent any potential exposure or reaction.

23. PERSONAL PROTECTIVE EQUIPMENT (PPE) AND CLEANING MATERIALS

Gloves and Masks: Used gloves, masks, and any other PPE contaminated with resin should be disposed of in accordance with hazardous waste regulations.

Cleaning Materials: Materials used to clean resin spills or tools, such as paper towels or cloths, should also be cured if saturated with uncured resin before disposal.

24. LEGAL DISCLAIMER

Pac-Dent Inc. Release of Liability

Pac-Dent Inc. ("the Company") expressly disclaims any and all liability associated with the improper use of its products, including but not limited to its range of 3D printing resins, tools, and equipment intended for dental applications. The end user ("User") acknowledges and agrees that strict adherence to the instructional guidance provided by the Company is essential for the correct function and performance of the medical device ("Product").

The User understands that deviation from the provided instructional guidance, or the use of invalidated or unauthorized equipment in conjunction with the Product, may result in alterations to the function and performance of the Product. The Company shall not be held responsible or liable for any such alterations or any consequences thereof.

By using the Product, the User agrees to indemnify, defend, and hold harmless Pac-Dent Inc., its officers, directors, employees, agents, affiliates, successors, and assigns from and against any and all losses, claims, damages, expenses (including reasonable attorneys' fees), or liabilities of any kind arising out of, related to, or in connection with the User's deviation from the provided instructional guidance or use of invalidated equipment.

This release of liability is binding upon the User, and, as applicable, the User's heirs, executors, administrators, legal representatives, and assigns. It is the User's responsibility to ensure comprehension and observance of this disclaimer and all accompanying instructional materials provided by the Company.

THE COMPANY'S LIABILITY UNDER THIS DISCLAIMER, IF ANY, SHALL BE LIMITED TO THE PURCHASE PRICE PAID BY THE USER FOR THE PRODUCT. IN NO EVENT SHALL THE COMPANY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE PRODUCT.

The User's acceptance of the Product constitutes acceptance of these terms and an agreement to be bound hereby.

25. MANUFACTURER INFORMATION



Pac-Dent, Inc.

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