

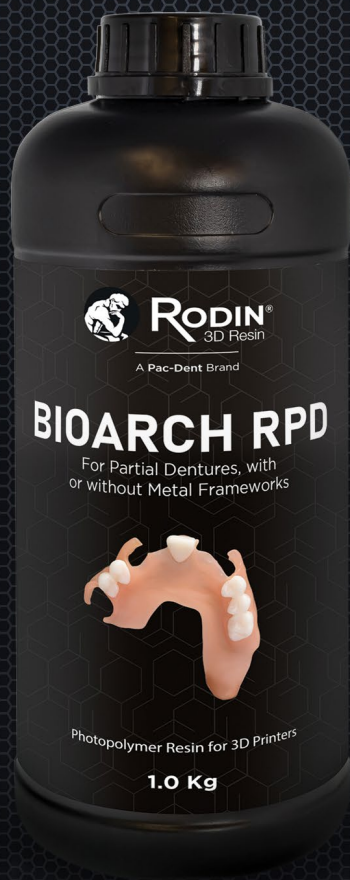


RODIN[®]
3D Resin

A Pac-Dent Brand

BioArch RPD

For Partial Dentures, with or without Metal Frameworks



Instruction For Use

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BIOARCH RPD

Device Description

BioArch RPD is Class II biocompatible, light-curable resin specifically developed for 3D printing for full maxillary and mandibular removable partial denture bases that may include metal frameworks. BioArch RPD produces strong yet flexible metal-free partials with precise fit, natural gingival esthetics, and outstanding long-term performance. Its advanced formulation delivers exceptional fatigue resistance, allowing the prosthesis to withstand millions of chewing cycles without cracking or fracturing — ideal for both temporary and permanent removable prosthetics.

Material Composition

RODIN BioArch RPD is a proprietary photopolymer resin comprised of:

- Methacrylate ester-based resins (proprietary)
- Photoinitiator
- Photoinhibitor
- Pigment

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

Intended Use

Partial maxillary and mandibular removable partial denture bases intended for load-bearing intraoral use.

Contraindications:

Methacrylate Sensitivity: Patients with known hypersensitivity or allergic reactions to methacrylate-based materials should not be prescribed this product. Exposure to uncured methacrylate resins may result in allergic reactions ranging from localized irritation to systemic hypersensitivity responses.

PPE Recommendations

Recommended personal protective equipment includes:

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

Use in a well-ventilated area. Respiratory protection is not normally required; however, if misting, heating, or aerosolization occurs, use approved respiratory protection in accordance with applicable regulations

Design Recommendations for Denture Bases

General Design Guidelines - To ensure optimal performance, durability, and patient comfort for your denture, follow these design thickness guidelines:

General Surfaces

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

Tooth Arch Sockets and Locator Recesses

Use a minimum thickness of 0.5 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.

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.

Clasp Dimensions:

For a wrap-around design, specify a clasp width of 4 mm and thickness of 3 mm to withstand fatigue from repeated insertion and removal.

Validated 3D Printers

Please click on link below for up-to-date information.

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

Nesting Tips

Proper nesting of denture bases during 3D printing ensures accuracy, structural integrity, and patient comfort while streamlining back-end post-processing. Follow these guidelines for optimal results:

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

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.

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 0.4mm.

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.

Mixing Recommendations

Importance of Mixing: Since 3D printing resins contain chemicals of varying densities, thorough mixing is crucial. This ensures a homogeneous mixture, which is essential for consistent printing quality.

Mixing Resin in the Vat: For resin that's already in the 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. Metal strainers should be avoided as they can cause oxidation and alter the resin's color.

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 pigments back into suspension, ensuring consistency in the printed object.

Caution with Aluminum Build Plates

Certain 3D printer models are equipped with 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 uncontaminated resin supply.

Post-processing Instructions

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

Cleaning with Rodin Universal Cleaner Solvent (Recommended)

- Step 1 - Remove Residual Resin:** Use compressed air to remove residual resin from the printed object.
- Step 2 - Prewash with Agitating Vortex or Ultrasonic Bath:** Use Rodin Cleaner solvent to remove uncured resin from denture bases for 3 minutes. Transfer to final rinse bath promptly.
- Step 3 - Final Agitating Vortex or Ultrasonic Bath Rinse:** Saturate a soft-bristle toothbrush with Isopropyl alcohol or Rodin Cleaner solvent and scrub the entire surface thoroughly. Place printed object in a vortex or ultrasonic bath with Rodin Cleaner for 3 minutes. Remove from bath promptly after time expires.
- Step 4 - Dry:** Blow off residual Rodin Cleaner or water from printed object with compressed air.
- Step 5 - Inspect:** Inspect the printed object for high sheen areas. If sheen is visible, repeat steps 3 and 4.
- Step 6 - Proceed:** To support removal once matte surface is achieved.

Cleaning with Isopropyl Alcohol Solvent

- Step 1 - Remove Residual Resin:** Use compressed air to remove residual resin from the printed object.
- Step 2 - Prewash with Agitating Vortex or Ultrasonic Bath:** use Isopropyl alcohol to remove uncured resin from denture bases for 3 minutes. Transfer to final rinse bath promptly.
- Step 3 - Final Agitating Vortex or Ultrasonic Bath Rinse:** Saturate a soft-bristle toothbrush with Isopropyl alcohol and scrub the entire surface thoroughly. Place printed object in a vortex or ultrasonic bath with Isopropyl alcohol for 3 minutes. Remove from bath promptly after time expires.
- Step 4 - Dry:** Blow off residual Isopropyl alcohol from printed object with compressed air.
- Step 5 - Inspect:** Inspect the printed object for high sheen areas. If sheen is visible, repeat steps 3 and 4.
- Step 6 - Proceed:** To support removal once matte surface is achieved.

Support Removal

- **Support Tip Removal:** Employ a low-speed handpiece fitted with a dull carbide bur to smooth support tips.
- **Adjustments:** Utilize ceramic wheels, carbide, or diamond burs for necessary to fully seat tooth arches.
- **Green State (uncured) Adjustments:** Execute all adjustments while the prosthetic base is in uncured state to prevent potential micro-fracturing.

Note: 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 esthetic quality but also the structural integrity and biocompatibility of the final product.

Denture Assembly Workflows:

Workflow

- **Workflow 1** (Recommended) – Liberally apply Rodin Glaze N2-Free 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.

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** – Apply Rodin BioArch Clear 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 inert atmosphere (nitrogen) for complete surface polymerization. Course polish with 50-micron pumice. Final polish with fine diamond polishing paste and cotton rag wheel for best high shine.

Characterizing

Applying Characterizing Light Curable Stain, Glaze, or Composite Sheet Products

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.

Careful 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.

Post-Cure Procedures

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.

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.

Conventional Polishing Recommendations

Post-Curing:

Inert Environment:

It's advised to post-cure the printed restorations or provisional prostheses in an inert environment, like nitrogen. This step enhances polish-ability and helps retain a high shine on the final product.

Polishing:

Layer Line Removal:

Begin the polishing process by removing the XY print layer lines, which are a common artifact in 3D printing. Use an abrasive dental polishing compound designed for this purpose.

Steam Cleaning:

After using the abrasive compound, steam off residual pumice to ensure a clean surface for further polishing.

High Shine:

For the final polish and to achieve a high shine, use a rag wheel with a fine grit diamond paste to provide a glossy finish.

Following these recommendations ensures that 3D printed dental prosthetics have a smooth, high-quality finish that resembles natural teeth. Always use the appropriate tools and compounds designed for dental materials to avoid damaging the restorations during the polishing process.

Validated Light Curing Parameters

For optimal post-curing of 3D printed dental restorations, use only validated light-curing devices and settings. The most current list of validated equipment and corresponding cure parameters is available at:

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

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 polish-ability, high shine retention, durability, and wear resistance of the final restoration.

Chairside Modifications



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Chairside Adjustments:

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.

Reline, Pickup, and Repair Guidance

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.

Hard Reline

Acrylic based systems ideal for best compatibility - Follow manufacturer's instructions for guidance.

Pick-up

Pick-up Material Systems - Acrylic based systems ideal for best compatibility - Follow manufacturer's instructions for guidance.

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.

Special Note: Hot cure reline systems may cause the base to warp and affect adaptation to the tissue surfaces and occlusal relationship with the antagonist arch.

Patient Care Instructions

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

Removal

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

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.

Drying and Storage

- Pat-dry 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.

By following these care instructions, you can help ensure the durability and performance of your Rodin dentures.

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:

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's 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.

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.

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.

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:

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.

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.

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.

Shelf Life:

- **Manufacturer Guidelines:** Adhere to the manufacturer's recommended shelf life for each resin. Over time, even well-stored resins can degrade and lose their optimal printing properties.
- **Regular Checks:** Periodically inspect stored resins for signs of separation or changes in consistency. Stir or shake them as recommended by the manufacturer to maintain uniformity.

By following these storage recommendations, you can extend the life of your resins and ensure that they perform as expected, producing high-quality dental restorations and models. Proper storage is an integral part of successful 3D printing operations in dental practices and laboratories.

Disposal Recommendations

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.

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.

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.

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.

Maintain Records:



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Keep records of your waste disposal practices, especially for any waste that may be classified as hazardous. This can help demonstrate compliance with regulations. Regular Review and Training:

Regular Review and Training:

- **Stay Informed:** Regularly review disposal practices and stay informed of any changes in regulations.
- **Staff Training:** Ensure all staff members are trained in proper disposal procedures to maintain a safe and compliant workplace.

By adhering to these disposal recommendations, dental practices and laboratories can minimize their environmental impact and ensure they are in full compliance with waste disposal regulations. Responsible disposal is an essential aspect of 3D printing operations in the dental industry.

Legal Disclaimer

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.



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