

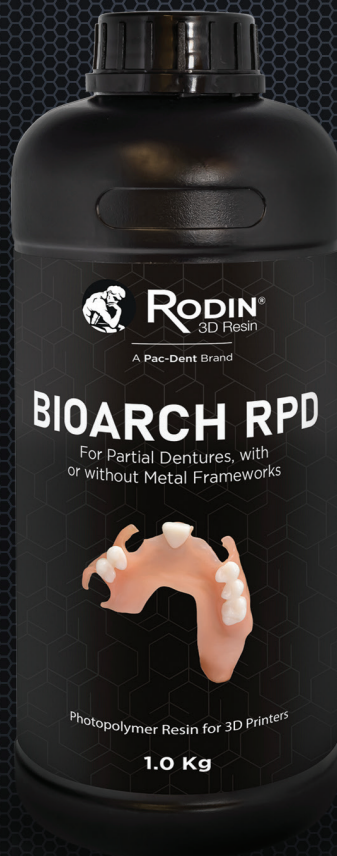


RODIN®
3D Resin

A Pac-Dent Brand

BioArch RPD

For Partial Dentures, with or without Metal Frameworks



Instruction For Use

RODIN BioArch RPD **Instructions for Use**

Revision 040926

Table of Contents

1. DEVICE DESCRIPTION	3
2. MATERIAL COMPOSITION	3
3. INTENDED CUSTOMER	3
4. INTENDED USE	3
5. CONTRAINDICATIONS	3
6. SAFETY INFORMATION	3
7. DESIGN GUIDELINES FOR BIOARCH RPD	4
7.1 General Surfaces	4
7.2 Tooth Arch Sockets and Locator Recesses	4
7.3 Runner Bars	4
7.4 Clasp Dimensions	4
8. VALIDATED EQUIPMENT	4
8.1 Validated 3D Printers	4
8.2 Validated Light-Curing Parameters	4
9. PRINTING PREPARATION	4
9.1 Mixing Recommendations	4
9.2 Mixing Resin in the Vat	4
9.3 Preparing Resin from the Bottle	5
9.4 Caution with Aluminum Build Plates	5
10. NESTING TIPS	5
10.1 Orientation Positioning	5
10.2 Support Placement	5
10.3 Minimum Support Diameter	5
10.4 Minimum Support Height	5
11. POST-PROCESSING PROCEDURES	6
11.1 Removal from Printer	6
11.2 Removing Excess Resin	6
12. CLEANING	6

12.1 Cleaning with Rodin Universal Cleaner Solvent	6
12.2 Cleaning with Isopropyl Alcohol Solvent	6
12.3 Support Removal	7
13. DENTURE ASSEMBLY AND CHARACTERIZATION	7
13.1 Denture Assembly Workflow	7
13.2 Characterizing	8
14. POST-CURING, FINISHING AND POLISHING	8
14.1 Post-Curing	8
14.2 Conventional Polishing	8
15. CHAIRSIDE ADJUSTMENTS AND REPAIRS	9
15.1 Chairside Adjustments	9
15.2 Reline, Pickup, and Repair Guidance	9
16. PATIENT CARE INSTRUCTIONS	9
16.1 Removal	9
16.2 Cleaning	10
16.3 Drying and Storage	10
16.4 Additional Tips	10
17. PRINTING ENVIRONMENT CONDITIONS	10
17.1 Light Exposure	10
17.2 Resin Handling	10
17.3 Temperature Control:	10
18. STORAGE CONDITIONS AND SHELF LIFE	11
19. DISPOSAL RECOMMENDATIONS	11
19.1 Classification of Waste	11
19.2 Disposal of Liquid Resin	11
19.3 Solid Resin Waste	11
19.4 Personal Protective Equipment (PPE) and Cleaning Materials	11
20. LEGAL DISCLAIMER	11
21. MANUFACTURER INFORMATION	12

1. DEVICE DESCRIPTION

Rodin BioArch RPD is a Class II biocompatible, light-curable resin specifically developed for 3D printing maxillary and mandibular removable partial denture (RPD) bases. The material may be used in removable partial dentures with or without a metal framework. BioArch RPD provides the strength, resilience, and dimensional stability required for long-term removable prosthetic applications while maintaining a precise fit and natural gingival esthetics. Its advanced formulation delivers excellent fatigue resistance and durability, allowing the prosthesis to withstand repeated functional loading and insertion/removal cycles.

Product Variants

- BioArch Neutral Rose
- BioArch Meharry
- BioArch Clear

2. MATERIAL COMPOSITION

Rodin BioArch RPD is a high-performance 3D printing material engineered specifically for removable partial dentures, comprised of:

- Methacrylate ester-based resins
- Ceramic filler
- Photoinitiator
- Photoinhibitor
- Pigments

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 BioArch RPD is a light-curable resin intended for the 3D printing of maxillary and mandibular removable partial denture bases for long-term, load-bearing intraoral use. The material may be used for removable partial dentures with or without a metal framework.

5. 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.

6. SAFETY INFORMATION

When handling uncured resin, the following personal protective equipment (PPE) is required:

- 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

7. DESIGN GUIDELINES FOR BIOARCH RPD

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

7.1 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.

7.2 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. Socket cement gap of the denture base design should be preset to 150 microns to allow for the tooth arch to passively fit.

7.3 Runner Bars

Add runner bars across the palate to stabilize maxillary and mandibular bases. This helps improve global accuracy and tissue adaptation.

7.4 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.

8. VALIDATED EQUIPMENT

8.1 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/>

8.2 Validated Light-Curing Parameters

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

<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.

9. PRINTING PREPARATION

9.1. Mixing Recommendations

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

9.2. Mixing Resin in the Vat

For resin that's already in the printer's vat:

- Use a silicone blade to gently and thoroughly mix the resin in the vat to ensure uniform consistency before printing.
- 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.

9.3. Preparing Resin from the Bottle

- Before using resin from a new bottle or one that has been sitting for a while, thoroughly mix the resin with a plastic spatula for several minutes.
- Alternatively, place the bottle on an automated roller for 30 minutes to ensure uniform mixing.
- If the resin has been stored for more than a month, roll the bottle for 1 hour before use to ensure uniform consistency.

9.4. 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. 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:

10.1 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.

10.2 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.

10.3 Minimum Support Diameter

Ensure supports have a minimum diameter of 1.0 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 0.5mm.

10.4 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 prosthetics necessitates strict adherence to the post-processing instructions. Below are the key steps to be followed:

11.1 Removal from Printer

- Gently detach the build platform from the 3D printer.
- Use an appropriate spatula to carefully remove the printed prosthesis from the build plate.

11.2 Removing Excess Resin

- Use compressed air to remove excess uncured resin from the printed prosthesis and build plate.
- Do not return resin that may have been contaminated by an aluminum build plate to the uncontaminated resin supply.

12. CLEANING

12.1 Cleaning with Rodin Universal Cleaner Solvent

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 with Isopropyl Alcohol Solvent

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. 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.

12.3 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.

13. DENTURE ASSEMBLY AND CHARACTERIZATION

13.1 Denture Assembly Workflow

Workflow 1 (Recommended) - Rodin N₂-Free Glaze

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

Workflow 2 - Rodin BioArch Clear Resin

- Apply Rodin BioArch Clear resin into the socket areas.
- Firmly press the sectioned or full denture tooth arch into the sockets.

- Remove excess resin from sulcus, embrasures, and occlusal areas with a brush or paper towel.
- Cure under an inert atmosphere (nitrogen) for complete surface polymerization.
- Coarse polish with 50-micron pumice, then final polish with fine diamond polishing paste and a cotton rag wheel.

13.2 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.

14. POST-CURING, FINISHING AND POLISHING

14.1 Post-Curing

- Use only validated light-curing devices and settings listed in Section 8.2.
- When compatible characterization products are applied, follow the applicable manufacturer's curing instructions.
- Avoid excessive light and heat exposure that may alter the color or properties of the resin or applied characterization materials.
- Post-curing in an inert environment, such as nitrogen, is recommended when applicable to improve surface polymerization, polishability, and high-shine retention.

14.2 Conventional 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.

15. CHAIRSIDE ADJUSTMENTS AND REPAIRS**15.1 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.

15.2 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**
Rodin Hard Reline Material Systems – 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.

16. PATIENT CARE INSTRUCTIONS

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

16.1 Removal

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

16.2 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 Rodin Soft Reline is present, avoid brushing beveled border areas in a manner that could debond the reline material

16.3 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.

16.4 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.

17. 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:

17.1 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'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.

17.2 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.

17.3 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 warm 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.

18. STORAGE CONDITIONS AND SHELF LIFE

- Store in the original tightly closed container in a cool, dry, and well-ventilated place.
- Recommended storage temperature: 4°C to 25°C (40°F to 75°F).
- Protect from direct sunlight, UV light, curing light sources, excessive heat, moisture, contamination, and ignition sources.
- Do not freeze.
- Keep the container upright and tightly closed when not in use.
- Refer to the product labeling for the expiration date.
- Do not use after expiration.

19. DISPOSAL RECOMMENDATIONS

19.1 Classification of Waste

Dispose of resin and resin-contaminated materials in accordance with applicable federal, state, and local regulations. Uncured resin should be treated as chemical waste and must not be discharged into drains, sinks, or the environment.

19.2 Disposal of Liquid Resin

Do not dispose of uncured liquid resin directly into the trash or down the drain. Unused or waste resin should be fully cured using an appropriate UV light source before disposal, where permitted by applicable regulations.

19.3 Solid Resin Waste

Ensure printed models, failed prints, supports, and other resin waste are fully cured before disposal. Fully cured resin waste may be disposed of as solid waste in accordance with applicable local regulations.

19.4 Personal Protective Equipment (PPE) and Cleaning Materials

Dispose of gloves and other PPE contaminated with uncured resin in accordance with applicable waste-disposal requirements. Paper towels, cloths, and other cleaning materials contaminated with uncured resin should be fully cured before disposal, where appropriate.

20. 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 The Company, 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.

21. MANUFACTURER INFORMATION



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