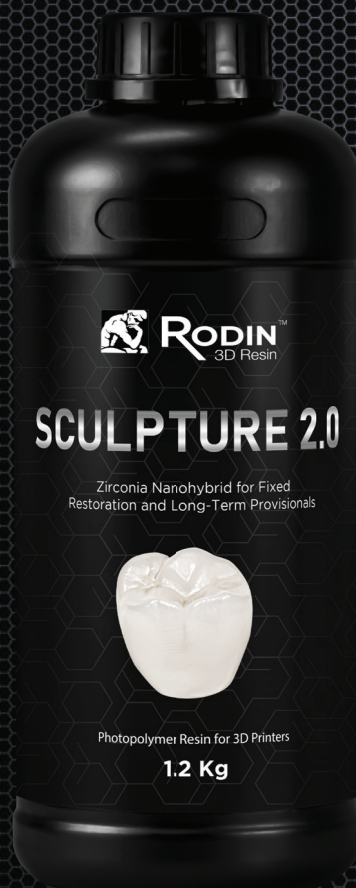




RODIN[®]
3D Resin

A Pac-Dent Brand

SCULPTURE



Instruction For Use

Rodin Sculpture Instructions for Use

Revision 090426

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1. DEVICE DESCRIPTION

Rodin Sculpture represents the pinnacle of dental fabrication technology, offering a state-of-the-art, light-curable resin that is both biocompatible and compliant with Class II medical device standards. Meticulously engineered for the dental industry, this device is uniquely tailored for crafting high-precision, permanent and temporary fixed dental restorations, providing dental professionals with a reliable and efficient solution for their practice.

2. MATERIAL COMPOSITION

Rodin Sculpture 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 Sculpture a Light-curable ceramic nanohybrid resin intended for fabrication of permanent single-unit restorations (crowns, inlays, onlays, veneers) and temporary multi-unit dental prosthetics including bridges, full-arch provisionals, and denture teeth. 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. 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).

6. SAFETY RECOMMENDATIONS

Recommended personal protective equipment includes:

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

7. NATURAL PREPARATION RECOMMENDATIONS

For optimal results, the following preparations are recommended:

- Chamfer margins
- Shoulder margins

8. DESIGN RECOMMENDATIONS FOR DENTAL RESTORATIONS

8.1. General Thickness Guidelines

Posterior Occlusal and Axial Walls:

A minimum thickness of 1.5mm is recommended for all crowns, bridges, onlays, and inlays.

Anterior Crowns and Bridges:

A minimum buccal wall thickness of 1mm is advised, with the following exceptions:

- Veneers: The buccal wall should have a minimum thickness of 0.5mm, and the incisal area should be at least 1mm thick.

Unit Limitations:

- A combination of anterior, posterior, or both should not exceed a total of 5 units.
- This prescription is most effective when alternating between abutment and pontic situations.

Bridge Connector Dimensions:

- Posterior Bridges: Connector area Height: 3mm x Depth: 3mm.
- Anterior Bridges: Connector area Height: 3mm x Depth: 2mm.

Contraindications for Rodin Sculpture:

- Cantilever or Maryland bridges are not suitable.
- Bridges including rests or PD (Precision Dental) attachments should be avoided.
- Patients diagnosed with bruxism are not recommended candidates for these restorations.

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. NESTING TIPS

10.1. Orientation

When 3D printing dental restorations such as crowns and bridges, it is recommended to position them with the occlusal side (the surface of the teeth used for chewing) facing the build plate. This orientation is suggested for achieving the best accuracy, especially for supporting the occlusal and incisal (biting edge) surfaces.

10.2. Support Placement

Supports are necessary structures in many 3D printing applications to stabilize the print. However, for dental restorations, it is advised to avoid placing supports in the intaglio (the inner surface of the restoration that fits over the tooth) or on the margins (edges) of the restorations. Placing supports in these areas can affect the fit and integrity of the final product.

10.3. Support Height

A minimum support height of 2mm is recommended. This height is likely chosen to provide enough stability to the structure during printing while still allowing for relatively easy removal after the print is completed. A height less than 2mm might not provide sufficient support, leading to breakage or deformation when removing the restoration from the build platform.

Following these nesting tips can help ensure that dental restorations are printed with optimal accuracy and structural integrity, minimizing the risk of breakage during the post-processing steps.

11. 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.

11.1. Mixing Resin in the Vat

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

- Use a silicone 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.

11.2. 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 to ensure the resin is thoroughly mixed and the ceramic fillers are uniformly suspended.

11.3. Caution with Aluminum Build Plates

Some 3D printers have aluminum build plates that can oxidize when in contact with uncured resin. This oxidation can change the color of the resin if it's reintroduced back into the vat or original bottle. Hence, it's important to be

cautious when dealing with such build plates to avoid color alterations in the printed restorations.

By following these mixing recommendations, users can maintain the integrity of the resin, leading to higher quality and more reliable dental restorations.

12. POST-PROCESSING INSTRUCTIONS

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:

12.1. Removal from Printer

Post-Printing Removal: Employ low-pressure air to dispel any uncured resin from the model and build plate.

Aluminum Build Plate Caution: 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.

12.2. 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.

13. CLEANING RESTORATIONS

13.1. 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.

13.2. Cleaning Recommendations: Isopropyl Alcohol (IPA 99%+)

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.

14. CHARACTERIZATION AND POST-CURING

14.1. Applying 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.

Product Selection

Use only products that are specifically designed for 3D printed restorations. 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.

14.2. Post-Curing

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.

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.

15. SUPPORT REMOVAL AND ADJUSTMENTS

Support Tip Removal: Employ a low-speed handpiece fitted with a dull carbide bur to excise support tips.

Adjustments: Utilize ceramic wheels, carbide, or diamond burs for necessary contour and occlusal adjustments.

Green State Adjustments: Execute all adjustments while the restoration is in its green state to avert potential 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.

16. FINISHING AND POLISHING

16.1. Layer Line Removal

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

16.2. Steam Cleaning

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

16.3. High Shine Polishing

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 restorations and provisional prostheses 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.

17. CHAIRSIDE ADJUSTMENTS AND CEMENTATION

17.1. 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.

17.2. 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.

17.3. Cementation Process

Surface Etching

Prior to cementation, it's recommended to etch the preparation surface of the tooth. This step creates a rougher surface, which enhances the bonding strength between the tooth and the restoration.

Choosing The Right Cement

A dual cure composite cement system is recommended for cementing the restoration in place. Dual cure cements combine the benefits of light curing (fast setting in exposed areas) and chemical curing (ensures setting in areas not reached by light).

Follow Manufacturer Instructions

Each cement system may have specific instructions regarding mixing, application, setting time, and light curing. Always follow the manufacturer's instructions carefully to ensure optimal bonding strength and longevity of the restoration.

17.4. Chairside Repairs

If any repairs are necessary after cementation, use the dual cure composite cement system to make these repairs, again following the manufacturer's instructions for application and curing.

By adhering to these guidelines, dental professionals can make precise chairside adjustments and ensure that the cementation process provides a durable and aesthetically pleasing outcome for the patient's dental restoration.

18. PATIENT CARE RECOMMENDATIONS

18.1. Daily Oral Hygiene

Toothbrush Selection

Use a soft or medium bristle toothbrush. Hard bristles can be abrasive to both natural teeth and restorations, potentially causing wear or damage.

Toothpaste Choice

Avoid using whitening toothpastes. These often contain abrasive particles designed to remove surface stains on natural teeth, but they can also wear away the surface of dental restorations, diminishing the topical stain and glaze, and potentially affecting appearance.

18.2. Additional Care Tips

Regular Dental Checkups

Schedule regular dental checkups and cleanings. This allows for professional monitoring of the condition of the restorations and overall oral health.

Avoid Hard Foods

Be cautious with very hard or sticky foods, as they can exert excessive force on restorations, leading to potential chipping or dislodgement.

Protective Appliance for Bruxism

If you have a habit of grinding or clenching your teeth (bruxism), consider using a nightguard to protect both natural teeth and restorations from excessive wear.

By following these care recommendations, patients can help ensure the durability and aesthetic integrity of their 3D printed dental restorations. Regular oral hygiene practices combined with professional dental care are key to maintaining both natural and restored teeth.

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'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.

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 CONDITIONS AND SHELF LIFE

20.1. Resin Vat Management

Dedicated Vats: Assign a dedicated resin vat for each resin type and shade to prevent cross-contamination.

Residual IPA: Ensure vats are completely free of isopropyl alcohol (IPA) residue before refilling with resin, as residual IPA may alter resin properties.

20.2. Resin Handling and Transfer

Original Container: Store resin in its original container to protect it from light, air exposure, and contamination.

Filtering: When transferring or recovering resin, use a non-metallic mesh strainer to remove debris.

20.3. Storage Environment

- Store the resin in its 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.

20.4. Shelf Life

- Periodically inspect stored resin for separation or changes in consistency and mix as recommended before use.
- Refer to the product labeling for the expiration date. Do not use after expiration.

21. DISPOSAL RECOMMENDATIONS

21.1. 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.

21.2. 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.

21.3. 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.

21.4. 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.

22. 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.

23. MANUFACTURER INFORMATION



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