



SCULPTURE

Ceramic Nanohybrid for Fixed Restorations
and Long-Term Provisionals

Instruction For Use

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Device Description

Rodin Sculpture: A Cutting-Edge Dental Fabrication Solution

The 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.

Material Composition

RODIN Sculpture Ceramic Nanohybrid Resin is comprised of:

- Methyl methacrylate resin
- Photo initiator
- Photo Inhibitor
- Pigment
- Ceramic

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 It is labeled for sales to dentists (or properly licensed practitioners) only. The Rodin Sculpture Nano-hybrid Ceramic Resin requires a CAD/CAM system, which includes components not part of the device:
- Digital restorative file from Dental CAD system
- Validated stereolithographic additive 3D printer
- Validated post curing light equipment.

Intended Use

Permanent Indications:

- Single-unit full contour crown restorations
- Single-unit inlay restorations
- Single-unit onlay restorations
- Single-unit veneer restorations

Temporary Indications:

- Multiunit bridges
- All-on-X immediate screw retain dentures
- Denture tooth arches

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).

PPE Recommendations

Recommended personal protective equipment includes:

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

Natural Preparation Recommendations

For optimal results, the following preparations are recommended:

- Chamfer margins
- Shoulder margins

Design Recommendations for Dental Restorations

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.

Validated 3D Printers

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

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

Nesting Tips

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.

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.

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.

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.

- 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 any ceramic fillers back into suspension, ensuring consistency in the printed object.

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.

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:

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.

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.

CLEANING RESTORATIONS

IPA Submersion Warning: Avoid submerging the printed restorations in isopropyl alcohol (IPA) for more than 5 seconds. Overexposure can result in a white, chalky surface upon drying.

Wiping Technique: Clean the restoration using a paper towel dampened with 99% IPA.

Detail Cleaning: Thoroughly cleanse embrasures, grooves, and intaglio surfaces using a toothbrush (manual or electric) soaked in 99% IPA.

Repeat Cleaning: Continue the cleaning process until a clean, matte finish is achieved.

SUPPORT REMOVAL

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.

Post-Curing Workflows

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.

Careful 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.

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 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 any residual material 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 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.

Validated Light Curing Parameters

For optimal results in post-curing of 3D printed dental restorations, utilize the following validated settings for each respective light-curing device:

Otoflash(Recommended)

- Total Flash Cycle Budget: **5000 cycles**

Dreve PCU LED N2

- Duration: **15 minutes**
- Intensity: **40%**

Ackuretta Curie

- Duration: **20 minutes**
- Settings: **P9, D2, BL ON**

Formlabs Form Cure

- Duration: **10 minutes**
- Temperature: **60°C**

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.

Chairside Adjustments and Cementation

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.

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.

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.

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.

Patient Care Recommendations

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.

Toothbrush 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.

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.

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 MATERIAL

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.

DOCUMENTATION AND RECORD KEEPING

Maintain Records: 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

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.²

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.

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



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