



RODIN[®]
3D Resin

A Pac-Dent Brand

EnVisionTM

VENEER SYSTEM

A Cutting-Edge Digital Veneer Solution



Instructions For Use

Rodin EnVision

Instructions for Use

Revision 090426

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1. DEVICE DESCRIPTION

The Rodin EnVision resin represents the pinnacle of dental fabrication technology, featuring a state-of-the-art, light-curable resin that is both biocompatible and compliant with Class II medical device standards. Meticulously engineered for cosmetic veneering applications, this product is uniquely tailored for crafting high-precision, permanent veneers, providing a reliable and efficient same-day solution for dental practices.

2. MATERIAL COMPOSITION

Rodin EnVision 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 EnVision is a biocompatible, light-curable resin intended for the fabrication of custom dental veneer restorations using compatible 3D printing systems. The restorations are intended to improve the esthetics of natural teeth through partial coverage of the facial tooth surface. The material may be used to fabricate thin, minimally invasive, and conventional veneers for permanent dental restorative applications.

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. PPE 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

General Thickness Guidelines:

Anterior Veneers

- The minimum design thickness of the buccal axial wall is 0.2mm.
- The minimum design thickness of the incisal edges is 0.5mm.

Posterior Veneers

- The minimum design thickness of the buccal axial wall is 0.2mm.
- The minimum design thickness if the mesio-buccal and disto-buccal cusps is 0.8mm.

9. VALIDATED EQUIPMENT

9.1. Validated 3D Printer

Please click on the link below for up-to-date information on validated 3D printers.

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

9.2. Validated Light Curing Devices

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

10. NESTING TIPS

- **Orientation:** When 3D printing veneer restorations, orient the restorations according to the validated printing workflow to optimize accuracy and support placement. 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.

11. MIXING RECOMMENDATIONS – PRINTING PREPARATION

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. This helps reintegrate any ceramic fillers back into suspension, ensuring consistency in the printed object.

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.

Note: For optimal physical properties of printed restorations and prosthesis, recommendation is to bottle roll for 15 minutes at 20 rotations per minute.

11.4. Printing Temperature

Maintain the resin at the recommended printing temperature for optimal viscosity and print performance. A printing temperature of approximately 21°C to 29°C (70°F to 85°F) is recommended. If the resin is cold prior to printing, allow it to reach the recommended printing temperature before use.

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: 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 remove the printed veneer restoration while minimizing the risk of deformation or damage.

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, working carefully around the perimeter until the printed restoration detaches. Keep the spatula parallel to the build plate during removal to minimize stress or damage to the printed restoration.

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)

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

1. Remove Excess Resin: Wipe away or blow off excess residual resin from the printed object using compressed air or a paper towel.

2. **Run Prewash Cycle 3-4 Minutes:** Place the object in an ultrasonic, vortex, or oscillating bath filled with IPA. Run the prewash cycle for 3 to 4 minutes.
3. **Scrub Surface (Optional):** After the prewash, dip a clean brush into fresh IPA and thoroughly scrub the entire surface of the object. Do not leave the part soaking in a bath during this step.
4. **Run Secondary Wash Cycle 3-4 Minutes:** Transfer the object to an ultrasonic, vortex, or oscillating bath filled with fresh IPA. Run this secondary cycle for 3 to 4 minutes.
5. **Dry the Object:** Immediately after removing the part from the secondary wash, blow off all remaining solvent using compressed air until the object is completely dry.
6. **Inspect for a Matte Finish:** Crucial before post-curing. Examine the object closely for any shiny spots.
 - If shiny areas are present: Residual resin remains. Do not run another full wash cycle. Spot-clean the shiny areas manually with a brush dipped in fresh IPA, then dry immediately with compressed air.
 - If the surface is completely matte: The object is clean and ready for characterization or post-curing procedures.

13.3. 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 prior 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.

14. CHARACTERIZATION AND POST-CURING

14.1. Applying Light Curable Stain and Glaze Product

Green State Application

Apply light-curable stain and glaze products while the printed parts are in 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.

14.2. 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.

14.3. Post-Curing

It is advised to post-cure the printed veneer restorations in an inert environment, such as nitrogen. This step enhances polishability and helps retain a high shine on the final product.

15. FINISHING AND POLISHING**15.1. 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.

15.2. Steam Cleaning

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

15.3. 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 veneer restorations have a smooth, high-quality finish that resembles natural teeth. Always use appropriate tools and compounds designed for dental materials to avoid damaging the restorations during the polishing process.

16. CHAIRSIDE ADJUSTMENTS AND CEMENTATION

16.1. 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.

Regaining Luster

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

16.2. Cementation Process

Surface Etching

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

Choosing the Right Cement

Please refer to the link below for Rodin EnVision Veneer Cement IFU.

<https://www.rodin-3d.com/support-resources>

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.

17. PATIENT CARE RECOMMENDATIONS

17.1. 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.

17.2. 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.

18. STORAGE CONDITIONS AND SHELF LIFE

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

18.1. Resin Vat Management

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

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

18.2. Resin Handling and Transfer

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. For optimal results, filter using a non-metallic mesh strainer prior to storing.

18.3. Storage Environment

- 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.

18.4. Shelf Life

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

19. DISPOSAL RECOMMENDATIONS

19.1. Classification of Waste

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

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

19.2. Disposal of Liquid Resin

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

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

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

19.3. Solid Resin Waste

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

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

19.4. 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.

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 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.

21. MANUFACTURER INFORMATION



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