



RODIN[®]
3D Resin

FLEXISPLINT

For Digital Corrective Oral Appliances



Instruction For Use

Table of Contents

Device Description	1
Rodin Flexisplint	
Material Composition	
Intended User	
Intended Use	
Contraindications	2
PPE Recommendations	
Design Considerations	
Increase Gap Offset	
Decrease Gap Offset	
Cement Gap Offset Recommendations	
Validated 3D Printers	3
Orientation Considerations	
Orientation	
Advantages	
Mixing Recommendations	
Preparing Resin from the Bottle	3-5
Post-Processing Instructions	
Removal from Printer	
Removing Excess Resin	
Cleaning Restorations	
Post-Curing Workflows	6-7
Validated Light Curing Parameters	
Workflow Recommendations	
Printing Environment Conditions	
Storage Recommendations	8
Resin Vat Management	
Resin Handling and Transfer	
Storage Environment	
Shelf Life	
Disposal Recommendations	9
Classification of Waste	
Disposal of Liquid Resin	
Solid Resin Waste	
Personal Protective Equipment (PPE) and Cleaning Material	10
Documentation and Record Keeping	
Regular Review and Training	
Legal Disclaimer	11
Pac-Dent Inc. Release of Liability	

Device Description

Rodin Flexisplint Resin: An advanced material specifically designed for creating clear, custom full arch mouth guards, snoring correction appliances, and occlusal bite splints. Renowned for its precision and comfort, this resin is ideal for both clinical and laboratory settings. It ensures a perfect fit tailored to individual patient needs and streamlines the production workflow, enabling the expedited delivery of high-quality protective and corrective dental products.

Material Composition

RODIN Flexisplint Resin is comprised of:

- Monomer
- Oligomer
- Photo initiator
- Photo Inhibitor
- Pigment

Intended User

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

The product is exclusively intended for use by trained professional dentists or dental lab technicians. Sales are restricted to:

- Mouth Guards
- Occlusal Splints
- Corrective Snoring Appliances

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

Design Considerations

Cement Gap Offset Recommendation

To achieve the optimal balance between a passive and retentive fit, it is recommended to set the cement gap offset within the range of 100 - 150 microns.

Increase Gap Offset:

If the guards fit too tightly, leading to patient discomfort or difficulty in removing the appliance or guard, it's advisable to increase the gap offset. This adjustment can alleviate excessive tightness and enhance patient comfort.

Decrease Gap Offset:

Should the guards be loose or prone to falling out post-insertion, decreasing the gap offset is recommended. This ensures a more secure fit, preventing the guard from dislodging easily.

Cement Gap Offset Recommendation

For the best performance of the guard or appliance, design them with a minimum thickness of 1.5mm or higher. This thickness is crucial for ensuring durability and effective protection.

These design considerations are essential to ensure that custom dental guards and appliances fabricated with Rodin FlexiSplint Resin meet the necessary standards of fit, comfort, and functionality.

Validated 3D Printers

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

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

Orientation Considerations

Orientation

Orientation Strategy: Position bite splints, night guards, corrective snoring appliances at a 15-degree incline with intaglio surfaces facing away from the build plate.

Advantages

Improved Dimensional Accuracy: This orientation helps maintain the true dimensions of the appliance and allows best fit for complete seating of guard or appliance, ensuring a comfortable fit.

Reduced Print Time: Direct contact with the build plate without the need for supports streamlines the printing process, leading to faster completion times.

Mixing Recommendations

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

Mixing Resin in the Vat: For resin that's already in the printer's vat:

Use a silicon blade to gently mix the resin, particularly aiming to re-suspend any settled ceramic particles at the bottom of the tank.

If a previous print has failed, strain the resin using a 50-micron mesh strainer to remove any debris. Metal strainers should be avoided as they can cause oxidation and alter the resin's color.

PREPARING RESIN FROM THE BOTTLE

- Before using resin from a new bottle or one that has been sitting for a while, stir the bottom of the bottle thoroughly with a plastic spatula for several minutes.
- Alternatively, place the bottle on an automated roller for 30 minutes to ensure even mixing.
- If the resin has been stored for more than a month, roll the bottle for 1 hour. This helps reintegrate 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 printed guards or appliances in isopropyl alcohol (IPA) for longer than 10 minutes in total. Overexposure to IPA can result in reduced strength of product.

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

Rinse Technique: Rinse printed guard or appliance with fresh 99% IPA using a squeeze bottle with a tapered nozzle. Rinse intaglio and implant channel surfaces to remove remaining uncured resin.

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

Support Removal: Grind away remaining support tips using a dull dental carbide bur or Scotch Bright wheel prior to light curing.

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.

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: **80%**

Ackuretta Curie

- Duration: **20 minutes**
- Settings: **P12, D10, BL ON**

Formlabs Form Cure

- Duration: **15 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/>

Workflow Recommendations

Traditional Finishing Method

For those seeking to achieve a high-quality finish on guards or appliances made with Rodin FlexiSplint Resin, it is recommended to post-cure the product using an inert gas prior to polishing. This step is crucial for several reasons:

Improved Polishing Efficiency: Post-curing with an inert gas enhances the ease and effectiveness of the polishing process when using traditional techniques.

Enhanced Shine Retention: This method not only ensures a smoother finish but also helps in retaining the high shine of the product over time.

Digital Finishing Method

Apply a thin layer of FlexiSplint resin to printed guards or appliances prior to curing for best bond strength. Ensure to light cure in combination with an inert gas to completely cure the candy coated surface.

Incorporating inert gas during post-curing significantly elevates the quality of the final product, ensuring that it not only performs well but also maintains a translucent, non-detectable finish.

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

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.

STORAGE ENVIRONMENT

Light Protection: Store resin containers in a dark place, away from direct sunlight and bright artificial light, to prevent inadvertent curing.

Dust-Free: Ensure the storage area is clean and free from dust. Dust particles can contaminate the resin, affecting the quality of the prints.

Temperature Control: Store resins at a consistent, moderate temperature, away from extremes of heat or cold. Extreme temperatures can affect the viscosity and curing properties of the resin.

SHELF LIFE

Manufacturer Guidelines: Adhere to the manufacturer's recommended shelf life for each resin. Over time, even well-stored resins can degrade and lose their optimal printing properties.

Regular Checks: Periodically inspect stored resins for signs of separation or changes in consistency. Stir or shake them as recommended by the manufacturer to maintain uniformity.

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

Disposal Recommendations

CLASSIFICATION OF WASTE

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

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

DISPOSAL OF LIQUID RESIN

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

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

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

SOLID RESIN WASTE

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

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

Personal Protective Equipment (PPE) and Cleaning Materials:

Gloves and Masks: Used gloves, masks, and any other PPE contaminated with resin should be disposed of in accordance with hazardous waste regulations.

Cleaning Materials: Materials used to clean resin spills or tools, such as paper towels or cloths, should also be cured if saturated with uncured resin before disposal.

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.

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 COMPANY’S LIABILITY UNDER THIS DISCLAIMER, IF ANY, SHALL BE LIMITED TO THE PURCHASE PRICE PAID BY THE USER FOR THE PRODUCT. IN NO EVENT SHALL THE COMPANY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE PRODUCT.

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



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