RODIN™ 3D Resin

Rodin Sculpture Instructions for Use

1. Device Description

Rodin Sculpture is a biocompatible, light-curable hybrid resin indicated for the fabrication of permanent crowns, inlays, onlays, and veneer restorations using 3D printing technology. Rodin Sculpture requires a computer-aided design and manufacturing (CAD/CAM) system including the following components not part of the device: intraoral scanner, design software, additive 3D printer, and light curing unit. Rodin Sculpture is recommended for use in tandem with validated 3D printers and post-curing devices listed below while following manufacturer's suggested instructions.

2. Composition

Composition	Range (% by weight)
Urethane Di methacrylate	22% - 30%
2-Hydroxy Ethyl Methacrylate	8.5% - 18.5%
Barium aluminoborosilicate	45% - 55%
Fumed silicon dioxide	1% - 3%
Ytterbium trifluoride	0% – 7%

Total content of inorganic fillers (particle size 3 µm) is approximately 51% by mass.

3. Clinical Benefits

Correction or reconstruction of functionally compromised natural dentition

4. Intended Use

Rodin Sculpture is intended for the reconstruction or correction of functionally compromised natural dentition by fabrication of customized 3D printed permanent restorations.

5. Patient Target Group

Rodin Sculpture is suitable for use in all patients without any age or gender restrictions.

6. Medical Condition

The device is used in patients who require restoration of teeth due to various dental conditions.

· Cavities/tooth decay

· Damaged or broken teeth

7. 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
- Licensed practitioners

8. Indications

Permanent indications:

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

9. Contraindications

Rodin Sculpture is contraindicated in a patient who is known to be allergic to any of the ingredients. Methyl methacrylate in Rodin Sculpture is a common ingredient in resins and acrylics which 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).

10. Side Effects and Residual Risks

In individual cases, contact allergies to products with similar composition have been described. Besides allergy, mild gum irritation, pulpitis, and mild tooth sensitivity due to post operative hypersensitivity may occur. Consult with your doctor for basic care to resolve these uncommon adverse effects.

Undesirable Side Effects	**Description**
Post-operative hypersensitivity	Tooth sensitivity may occur; however, it is uncommon.
Biological complication	Inflammation of gums or pulpitis surrounding the restoration. However, this can be resolved with basic oral care.
Allergic reaction	Potential for allergic reaction to the material.
Residual Risks	**Description**
Marginal discoloration	Marginal discoloration of the restoration after 2 years may occur but does not affect restoration function.
Secondary caries	Restoration may develop new caries.
Fracture	Minor fracture may occur but does not require full replacement.
Chipping	Chipping may occur but does not require full replacement.

11. Warnings

For dental use only.

Hazard statements as per MSDS

- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes eye irritation.
- May cause respiratory irritation.

Precautionary statements as per MSDS

- Avoid breathing vapors.
- Avoid release to the environment.
- Wear protective gloves / protective clothing / eye protection / face protection.
- Use only outdoors or in a well-ventilated area.
- If inhaled: Call a poison center / doctor if you feel unwell.
- If skin irritation or rash occurs: Get medical advice / attention.
- If eye irritation persists: Get medical advice / attention.
- Dispose of contents / container as per local and national regulations

12. Physical Properties

Flexural Strength (MPa)	160 MPa
Flexural Modulus (GPa)	6.5 GPa
Compressive Strength (MPa)	378 MPa
Rockwell Surface Hardness	74
Radio-Opacity (mm of Al)	200
Wavelength for curing (nm)	385 or 405 nm
Water Sorption (µg/mm^3)	<14.5 µg/mm^3
Water Solubility (µg/mm^3)	<1.0 µg/mm^3

13. PPE Recommendations

Recommended personal protective equipment includes:

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

14. Natural Preparation Recommendations

For optimal results, the following preparations are recommended:

- Chamfer margins
- Shoulder margins

15. Design Recommendations for Dental Restorations

General Thickness Guidelines:

- **Posterior Occlusal and Axial Walls:** A minimum thickness of 1.5mm is recommended for all crowns, onlays, and inlays.
- **Anterior Crowns:** 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.

16. Validated 3D Printers

Generate the printing file of the desired restoration by using appropriate software and deliver it to the printer. Follow the corresponding instructions for use of software and printer. Select the build style / INI file / material file for Rodin Sculpture in the printer software. Make sure that all software is up to date.

1. **ASIGA Printer (MAX UV & PRO 4K)**

- Hardware: Refer to the printer's manufacturer's manual.
- Software: Asiga® Composer
- Printing parameters:

Download the required parameter set from Asiga database. Maintain working temperature at 35 ± 3^{0}C and humidity at 20 – 80%.

- Slice thickness: 50 µm
- Optimal orientation: 0 degree tilted orientation
- Support point size: varies based on support type chosen
- Support density: perimeter of the restoration and occlusal region. The occlusal side must face the build platform.

2. **Phrozen Printer (Sonic 4K & Sonic 4K XL)**

- Hardware: Refer to the printer's manufacturer's manual.
- Software: DS Slicer
- Printing parameters:

Download the required parameter set from Phrozen database. Maintain working temperature at 25 ± 3^{0}C and humidity at 20 – 80%.

- Slice thickness: 50 µm
- Optimal orientation: 0 degree tilted orientation
- Support point size: varies based on support type chosen
- Support density: perimeter of the restoration and occlusal region. The occlusal side must face the build platform.

3. **Ackuretta Printer (SOL & SOL Plus)**

- Hardware: Refer to the printer's manufacturer's manual.
- Software: Alpha 3D
- Printing parameters:

Download the required parameter set from Ackuretta database. Maintain working temperature at 25 ± 3^{0}C and humidity at 20 – 80%.

- Slice thickness: 70 µm
- Optimal orientation: 0 degree tilted orientation
- Support point size: varies based on support type chosen
- Support density: perimeter of the restoration and occlusal region. The occlusal side must face the build platform.

Warning: Rodin Sculpture is suitable for manufacturing highly reliable dental products only when using approved compatible systems including the material parameters. If unapproved components or material parameters are used, there is a high risk of unreliable and / or unusable products which may endanger the safety of the user.

Caution: It is important to follow the instructions for use and maintenance instructions provided by the manufacturer for all system components.

17. 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 storedfor 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.

18. 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:

1. Removal from Printer

a. **Post-printing Removal:** Gently detach the build platform from the 3D printer.

b. **Restoration Removal:** Utilize a metal spatula, maintaining a perpendicular angle to the build plate, to carefully pry off the printed restoration.

2. Removing Excess Resin

a. **Resin Removal:** Employ low-pressure air to dispel any uncured resin from the model and build plate.

b. **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.

c. **Spatula Guidance:** Glide a metal spatula under the print base, encircling the perimeter until the print detaches.

3. Cleaning Restorations

a. **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.

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

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

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

4. Support Removal

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

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

c. **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.

Warning: The entire cleaning process should not take longer than 5 min as this could otherwise have a detrimental effect on the printed objects.

19. Post-Curing Workflows

Applying Light-Curable Stain, Glaze, or Composite Sheet Products

1. 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.

2. 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.

3. 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.

20. Post-Cure Procedures

1. 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.

2. 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.

21. Conventional Polishing Recommendations

Post-Curing:

1. 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:

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

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polishing compound designed for this purpose.

2. ***Steam Cleaning:***

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

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 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.

22. 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:

1. ***Otoflash (Recommended)***

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

2. ***Dreve PCU LED N2***

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

3. ***Ackuretta Curie Plus***

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

4. ***Formlabs Form Cure***

- Duration: **10 minutes**
- Temperature: 40˚C

Note: The times given only apply to regularly maintained equipment that guarantees a corresponding light intensity.

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.

23. Chairside Adjustments and Cementation

Chairside Adjustments:

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.

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.

Cementation Process:

1. ***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.

2. ***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).

3. ***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.

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.

24. Patient Care Recommendations

Daily Oral Hygiene:

1. ***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.

2. ***Toothpaste Choice:***

- Avoid using whitening toothpaste. 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:

1. ***Regular Dental Checkups:***

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

2. ***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.

3. ***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.

25. 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.

26. 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.

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.

27. 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:** Dispose of waste according to applicable legislation. Consult the local waste disposal expert about waste disposal. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

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.

28. Legal Disclaimer

Gingi-Pak Release of Liability

Gingi-Pak ("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 Gingi-Pak, 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.

Notice: Any serious incident that has occurred in relation to the device due to a malfunction should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

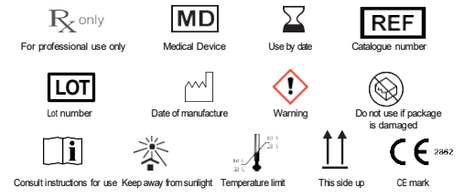
The Summary of Safety and Clinical Performance of Rodin Sculpture can be found in the European database on medical devices (EUDAMED–https://ec.europa.eu/tools/eudamed)

Manufacturer: The Belport Company, Inc.
DBA Gingi-Pak
4825 Calle Alto, Camarillo, CA 93012, U.S.A

Made in USA

https://gingi-pak.com/product/rodin-sculpture-ceramic-hybrid-3d-resin/

EC REP Lins Service & Consulting GmbH
Pranckhstrasse 47, 67061
Ludwigshafen am Rhein, Germany



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