



RODIN[®]
3D Resin

A Pac-Dent Brand

Palette 2.0

N₂- FREE Naturalizing Kit



Instruction For Use

Rodin Palette 2.0 Naturalizing Kit with Glaze N2-Free

Instructions for Use

Revision 090226

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1. DEVICE DESCRIPTION

Rodin® Palette 2.0 with Glaze N₂-Free is a light-curable staining and glazing system designed to enhance the esthetics of 3D-printed and conventional dental restorations and prosthetics. It enables dental professionals to characterize and color-match adjacent teeth and gingival tissues for intraoral and extraoral applications. Rodin® Palette 2.0 with Glaze N₂-Free supports precise color matching to natural dentition and gingiva tissues, delivering durable, high-shine finishes.

2. MATERIAL COMPOSITION

Glaze N₂-Free contains:

- Monomer
- Oligomer
- Photoinitiator
- Photoinhibitor

3. INTENDED CUSTOMER

The product is exclusively intended for use by:

- Trained professional dentists
- Trained professional prosthodontists
- Dental laboratory technicians

Sales are restricted to:

- Dental supply dealers
- Teaching institutions
- Government dental facilities

4. INTENDED USE

Palette 2.0 with Glaze N₂-Free is intended for intraoral or extraoral esthetic characterization enhancements of restorative and provisional dental materials.

5. INDICATIONS FOR USE

- Characterization of provisionals.
- Characterization of direct and indirect composite restorations, acrylic denture bases, and artificial acrylic teeth.
- Characterization of crown and bridge composite resin restorations or acrylic resins.

6. 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).

7. SAFETY INFORMATION

Always consult the applicable Safety Data Sheet (SDS) for the most complete information regarding hazards, handling, exposure controls, and disposal.

7.1. Recommended Personal Protective Equipment (PPE)

When handling uncured material, recommended PPE includes:

- Protective gloves
- Eye protection
- Protective clothing (lab coat or apron)
- Closed-toed shoes

7.2. Precautions

- Avoid vigorous shaking of Glaze N₂-Free, as it may introduce microbubbles and affect the high-shine appearance.
- Do not leave the Glaze N₂-Free bottle cap ajar. The material is sensitive to dust and ambient light contamination, which may adversely affect curing performance.
- Keep dispensing tips clean. Wipe the dispensing tip with a lint-free towel after each use.
- Securely close all containers immediately after use.
- Avoid direct skin or soft-tissue contact with uncured light-curable materials.

8. DIRECTIONS FOR USE

8.1. Surface Preparation

8.1.1 For 3D Composite Ceramic Systems

- Remove all remaining support tips and perform final contouring, contact adjustments, and occlusal refinements.
- Remove residual debris using compressed air.

Note:

- ✓ Avoid sandblasting or using unvalidated solvents that could remove the oxygen inhibition layer (OIL). Aluminum oxide media may embed into the surface, causing discoloration and compromising the chemical bond with Glaze N₂-Free.
- ✓ Avoid steaming printed restorations before applying Glaze N₂-Free, as residual moisture may result in an undesirable textured surface after curing.

8.1.2 For Zirconia, Lithium Disilicate, and PMMA Materials

- Perform final contact, contouring, and/or occlusal adjustments as needed.
- Sandblast all cameo surfaces with aluminum oxide to enhance mechanical retention.
- Remove residual debris and sandblasting media using a dental steam gun.
- Thoroughly dry the restoration with compressed air before applying Glaze N₂-Free.

Note:

- ✓ Do not subject Glaze N₂-Free-coated restorations to furnace firing cycles, as the glaze will burn off.
- ✓ Ensure zirconia and lithium disilicate restorations are sintered and final adjustments are completed before glaze application and light curing.

8.2. Palette Stain Application

Use the Palette 2.0 light-curable stains to characterize the restoration as required for the desired tooth or gingival appearance.

- Apply stain in controlled, thin layers to the prepared surface.
- Build characterization gradually to avoid excessive material thickness.
- Tack-cure stain layers as needed in accordance with the applicable curing instructions.
- After stain layering is complete, proceed with Glaze N₂-Free application and final curing.

8.3. Glaze N₂-Free Application

- Apply a thin coat of Glaze N₂-Free to the cameo surfaces using a conventional Kolinsky or synthetic porcelain brush.
- Remove excess glaze from intaglio surfaces, embrasures, and occlusal grooves to support proper seating, function, and esthetics.

- If desired, apply light-curable stains and tack-cure them according to the applicable instructions.
- After completing stain layering and tack-curing, apply a light second coat of Glaze N₂-Free to the cameo surfaces.
- Tack-cure the first glaze layer for 30 seconds, recoat as needed, and complete the final cure using the applicable validated curing parameters.

Note: Thoroughly clean the application brush with IPA after each use to prevent contamination.

8.4. Intraoral Reapplication / Touch-Ups

- Rinse the target area and dry thoroughly with compressed air.
- Roughen the target touch-up area with a fine diamond bur.
- Rinse to remove debris and thoroughly dry with compressed air.
- Check occlusal clearance. Allow approximately 0.1 mm clearance to compensate for the reapplied glaze layer; reduce the restoration as needed.
- Apply a thin coat of Glaze N₂-Free to the adjusted area.
- Cure using an appropriate intraoral spot-curing lamp according to Section 9.
- Buff with a goat-hair polishing wheel or cotton buff wheel if desired.
- Recheck occlusion and repeat adjustment and glaze application if required.

8.5. Recommended Use for Glaze N₂-Free

8.5.1 Extraoral Use (Preferred Method)

Glaze N₂-Free is primarily recommended for extraoral application before intraoral placement. This supports controlled polymerization and minimizes potential intraoral sensitivity.

8.5.2 Intraoral Use (If Necessary):

- Use a dental dam and cotton rolls to prevent uncured liquid material from contacting gingival or mucosal tissues.
- Monitor patient comfort during and after curing.
- Avoid prolonged or excessive curing in one location to minimize heat buildup.
- If discomfort occurs, immediately discontinue application and evaluate tissue response.

For intraoral curing, use a compatible light within the 385-515 nm wavelength range and follow the validated curing parameters below.

9. VALIDATED GLAZE N₂-FREE MINIMUM CURING PARAMETERS

DEVICE	SETTINGS
NK-Optik Otoflash	2,000 flash cycles (without nitrogen)
Ackuretta Curie+ Plus	5 minutes, power level 9, duty cycle 20%, BL On
Formlabs Form Cure	5 minutes, 40°C
LuxCreo iLuxCure Dental	P1-615, P2-20, P3-3 minutes
Nexa3D xCure	405 nm, 3 minutes, PWM 20%
Shining3D FabCure2	5 minutes, 40°C
Phrozen Wash and Cure	7 minutes
Handheld spot-curing lamp ~1200 mW/cm ²	10 seconds (3-4 cycles); 1-2 second break between cycles; 385-515 nm; approx. 0.5-inch distance
Handheld spot-curing lamp ~2000 mW/cm ²	3 seconds (4-5 cycles); 1-2 second break between cycles; 385-515 nm; approx. 0.5-inch distance

Disclaimer: The stated distance is suggested for optimal results; other distances may affect curing performance.

Note: Follow the minimum curing settings for the underlying 3D-printed substrate for best performance.

10. CHAIRSIDE ADJUSTMENTS

- Make necessary final contour, occlusal, or contact adjustments.
- Rinse and thoroughly dry the adjusted area using compressed air.
- When possible, remove the restoration or prosthesis from the patient's mouth, apply a thin coat of Glaze N₂-Free to the adjusted area, and cure using a validated desktop curing device.
- If the restoration is cemented in place, apply a thin coat of Glaze N₂-Free only to the adjusted area and cure with an appropriate handheld curing unit using the recommended curing protocol in Section 9.

11. STORAGE CONDITIONS AND SHELF LIFE

- Light Protection: Store Palette 2.0 / Glaze N₂-Free away from direct sunlight, UV light, and bright artificial light.
- Contamination Control: Keep containers tightly closed when not in use. Store in a clean, dust-free environment and keep dispensing components clean.

- Temperature Control: Store at a consistent, moderate temperature away from extremes of heat or cold.
- Shelf Life: 24 months when stored as directed.

12. DISPOSAL AND WASTE MANAGEMENT

Dispose of uncured light-curable materials and contaminated materials in accordance with applicable federal, state, and local requirements.

12.1. Liquid Material

- Do not dispose of uncured liquid material directly into trash, drains, or the environment.
- Fully cure residual material before disposal where permitted by applicable regulations.

12.2. Solid / Cured Material

- Ensure residual uncured material on used items is fully cured before disposal.
- Place cured waste in a suitable sealed bag or container as appropriate.
- Verify local disposal requirements before treating cured material as ordinary waste.

12.3. Workplace Controls

- Use appropriate PPE when handling uncured material and contaminated cleaning materials.
- Maintain waste-disposal records where required.
- Train personnel in applicable handling and disposal procedures.

13. ORDER INFORMATION

Glaze N₂-Free:

- 64031 - Glaze N₂-Free, 5 mL
- 64015 - Glaze N₂-Free, 15 mL

14. 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.

15. MANUFACTURER INFORMATION



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