



Instructions for Use - RODIN Palette Ceramic Resin Naturalizing Kit

Device Description

RODIN Palette Ceramic Resin Naturalizing Kit is a light-curing methacrylate based stain / glaze system for extraoral surface characterization of prefabricated teeth, partial and full denture bases, fixed dental restorations (such as crowns, bridges, inlays, onlays, veneers) made of hybrid ceramic, resin veneering materials, and CAD/CAM composites.

Indications for Use

Indicated for use with indirect and direct composite restorations and provisionals comprised of ceramic resin hybrid based systems.

Prescription Use Statement

Caution: Federal law restricts this device to sale by or on the order of dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Directions for Use

Avoid vigorous mixing of the glaze before application of the product. Introducing bubbles to the resin distorts the high-shine glaze appearance.

1. In the uncured state, remove all excess remaining supports tips and make contouring adjustments to the printed restoration as needed.
2. Using a steam gun, remove residual debris ensuring the restoration is free of dirt and bur markings.
3. Dry the restoration or provisional thoroughly with compressed air prior to applying RODIN Palette Ceramic Resin Naturalizing Kit glaze and colors.

4. Carefully apply RODIN Palette Ceramic Resin Naturalizing Kit glaze and colors to desired areas of restorations or provisionals using a fine tip (number 4) paint brush. Avoid applying to adaptive sensitive areas of intaglio surfaces of restorations and access holes of AOX provisionals.
5. Remove excess pooled glaze, especially on the anatomic surfaces that can lead to high occlusion.
6. Must light cure under an inert atmosphere (nitrogen) to fully cure the stain and glaze surfaces, increase durability, and increase abrasion resistance. Be sure to follow validated curing settings to avoid shade shifting of crowns and provisionals.
7. Check contacts, occlusion, and fit after post curing. Remove excess glaze from the inside of restoration if necessary, with glass beads or aluminum oxide (50µm particles) at PSI no greater than 15 lbs. of pressure. Reapply glaze if necessary and repeat steps 4 – 6.

Recommended Medical Grade Light Curing Devices

NK-Optic Otoflash G171 – Nitrogen required

Dreve PCU LED N2 – Nitrogen required

End user should refer to the original equipment manufacturer (OEM) labeling for printing machine and post-curing unit set-up and on-site validation.

End user should refer to the OEM labeling for maintenance/use-life guidelines for printing machine, post-curing unit, and associated tools.

Chairside Adjustments and Cementation

If making chairside adjustments, treat the restoration like a composite and use carbide burs to remove material and buff with acrylic polishing compounds to regain luster to adjusted areas.

Legal

Pac-Dent Inc. releases all legal liability if the end user deviates from instructional guidance and/or using invalidated equipment that may alter the function and/or performance of the medical device.

Contraindications

Avoid use of this product in patients with known allergies to acrylate / methacrylate monomers or acrylate / methacrylate polymers.

Precaution for Handling

Recommended PPE include the use of; nitrile or neoprene gloves, safety goggles, mask, lab coat, and closed toed shoes should be worn when handling methyl methacrylate resins.

Hazards Warning

Hazards and Precaution Statements

Contains esterification products of methacrylate polymer resin, photo initiator, filler, inhibitor and pigments.

- Call a POISON CENTER if ingested.
- May cause an allergic skin reaction if direct contact occurs.
- If skin irritation or rash occurs: Consult a physician for medical advice / attention.
- Causes eye irritation if direct contact occurs. Rinse with water immediately for 15 minutes.
- If eye irritation persists: Get medical advice / attention.
- Dispose of contents / container as per local, state, and national regulations.
- Avoid release to the environment. May cause long harmful effects to aquatic life.

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Manufactured by

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Revision Date

09/16/2022