

Restorite OrthoGrip Kit
Light Cure Orthodontic Adhesive System

Presentation:

Restorite OrthoGrip Composite - 5g Syringe x 1, Restorite OrthoGrip Primer - 5ml Bottle x 1,
Restorite Etching Gel - 3ml Syringe x 2, Application Needles x 10 , Microbrush x 10

Product Description :

Restorite OrthoGrip Kit bonds metal and ceramic brackets to tooth surfaces providing adequate working time for accurate brackets placement.

Indications:

Bonds metal and ceramic brackets to tooth surfaces

Restorite OrthoGrip Composite

Instructions for Use :

Preparation of Enamel : Clean area with Pumice prophylaxis (Aster Prophy), Rinse, isolate, and thoroughly air-dry (clean, oil- and-water-free compressed air) the surface area to be bonded.

Etching : Etch enamel using 37% phosphoric acid (Restorite Etching Gel) etchant for 15 seconds. Rinse thoroughly. Remove excess water by blotting the surface with an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, leaving the preparation visibly moist.

Restorite OrthoGrip Primer:

1. Dispense a drop of Restorite OrthoGrip Primer into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.
2. Apply two separate coats of Restorite OrthoGrip Primer, scrubbing the preparation with a micro brush for 10-15 seconds per coat.
3. Air-drying using an air syringe for at least 10 seconds till there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of Restorite OrthoGrip Primer if required.
4. Light cure for 20 seconds. Do not disturb site or probe site.

Restorite OrthoGrip Composite Application:

With the syringe apply a required amount of Restorite OrthoGrip Composite onto bracket base. Immediately after applying adhesive, lightly place bracket onto the tooth surface. Adjust bracket to final position, press firmly to seat bracket. A small amount of excess Restorite OrthoGrip Composite around bracket base can extrude remove the same without disturbing the bracket. Final adjustment must be made before the Restorite OrthoGrip Composite is cured. Using a conventional halogen curing light or a LED light, polymerize entire bonded surface for 20 seconds from the facial, mesial, and distal directions. The dispensed material should not be placed back in syringe and the material once applied shall not be reused.

Precaution

Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation and hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician.

Eugenol containing materials should not be used with this product because they may effect polymerization and interfere with the hardening process. Being sensitive to heat and light, the syringes should be kept away from direct sun light.

Contraindications:

It is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

Storage:

Store in cool and dry place away from direct light. Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a dark, cool & dry place.

Shelf Life:

3 years from the date of manufacturing.

Disposable Conditions:

To be disposed of based on the prevailing rule of the country in which it is used.

Restorite OrthoGrip Primer

Indication:

Primer to be used after etching gel of enamel and Restorite Ortho Composite while bonding of metal or ceramic brackets.

Delivery system: 5ml dropper bottle

Use of etchant is mandatory for both enamel surfaces. Restorite Etching Gel/ Etching Gel manufactured by Prime Dental Products, contains 37% weight phosphoric acid.

Recommendations -

Restorite OrthoGrip Primer requires etching of enamel as a part of the procedure. It is recommended that the surfaces be dry after rinsing. Excess surface moisture should be removed by blotting.

Restorite OrthoGrip Primer is cured by exposure to visible light at proper intensity Air used for drying should be free of oil and water contaminants.

Precautions for Dental Personnel and Patients -

- 1)Protective eyewear for patients and dental staff is recommended when using etchants. Avoid contact with oral soft tissue, eyes and skin. If accidental eye contact occurs, flush immediately with large amounts of water. For eye contact consult a physician.
- 2) Restorite OrthoGrip Primer contains mixture of various acrylates. including HEMA (2-hydroxyethyl- methacrylate). Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resins. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly used gloves. If adhesive contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.
- 3) Sensitivity: Some patients may experience transitory postoperative sensitivity. The risk of sensitivity can be minimized by the following measures:
- 4) Materials containing Clove oil and/or Eugenol will inhibit the polymerization of Restorite Bond.

Tooth Preparation: Remove minimal tooth structure. Use proper isolation. Use of a rubber dam is highly recommended. Use adequate pulp protection.

Primer Application: Use of compressed air is not recommended to remove pooled water remaining after the etch step blot excess moisture from the preparation using a cotton pellet or mini sponge. Apply Prime immediately after blotting.

Procedure-

Restorite OrthoGrip Composite Application:

With the syringe apply a required amount of Restorite OrthoGrip Composite onto bracket base. Immediately after applying adhesive, lightly place bracket onto the tooth surface. Adjust bracket to final position, press firmly to seat bracket. A small amount of excess Restorite OrthoGrip Composite around bracket base can extrude remove the same without disturbing the bracket. Final adjustment must be made before the Restorite OrthoGrip Composite is cured. Using a conventional halogen curing light or a LED light, polymerize entire bonded surface for 20 seconds from the facial, mesial, and distal directions. The dispensed material should not be placed back in syringe and the material once applied shall not be reused.

Etchant Syringe:

1. Protective eyewear for patients and staff is recommended when using the delivery system
 2. Prepare the Syringe: Remove cap from etchant syringe and SAVE. Twist a green disposable tip securely onto the syringe. Holding the syringe with the tip pointed away from the patient and any dental staff, express a small amount of etchant onto a dispensing pad. If clogged, remove the dispensing tip and express a small amount of etchant directly from the syringe. Remove any visible lump, if present, from the syringe opening. Replace dispensing tip and again express etchant. If clog remains, discard dispensing tip and replace with a new one. Bend the dispensing tip to a desired angle. Place bend midway along tip. Do not bend dispensing tip at its hub as this may cause the tip to break free.
 3. Storage: Remove used dispensing tip and discard. Twist on storage cap.
- Storage of the delivery syringe with a used dispensing tip or without storage cap will allow drying of the etchant and consequent clogging of the system. Replace storage cap with a new dispensing tip at next use. 4. If desired, the etchant may be extruded onto a dispensing pad and applied with a brush or other appropriate instrument.
- Bottle: Unscrew the cap to reveal the dropper. Squeeze out the exact number of drops you need into the disposable mixing well. When finished, screw the cap back on to the bottle.
- Storage: Store away from sunlight in cool and dry place. Refrigerate material, Do not freeze.

Restorite Etching Gel

Product Description:

Restorite Etching Gel is a formulation of 37% phosphoric acid in gel consistency indicated for enamel etching and dentin conditioning. It is as stable formulation that will not dry or thicken. Consistency is adjusted as stand up thixotropic gel, which is easy to dispense with needles provided.

Indications:

1. Direct composite restorations.
2. Pit & fissure sealant application.
3. Indirect restoration like composite or metal free ceramics along with recommended adhesive cements.
4. Bonding orthodontic brackets.

Contra Indications:

Direct exposure to pulp tissue should be avoided.

Precautions:

Avoid from applying on skin soft tissue and eye contact. In case of accident wash with clean water and consult physician. Phosphoric acid may dissolve base and liner material hence preferably should not be applied directly on theses material.

Procedure:

1. Restorite Etching Gel after dispensing should be applied with a small brush on enamel and dentin which has to be etched.
2. Material should be left in place for 15 seconds and washed with water. Dry area with oil free air.
3. It is recommended to avoid over drying. Dried area would appear chalky white.
4. If first application does not give desired visual indication, procedure should be repeated for further 15 seconds.

Storage & Shelf Life:

Store away from sunlight in a cool and dry place. Keep away from direct flame. Do not leave the syringe open. Always screw cap tightly back on to the syringe after each use. Do not use after expiration date.

Disposal Conditions:

To be disposed of based on the prevailing rules of the country in which it is used.