

QuiXX®

POSTERIOR RESTORATIVE

DIRECTIONS FOR USE – ENGLISH

Caution: U.S. federal law restricts this device to sale by or on the order of a dentist.

QuiXX® Posterior Restorative is a resin-based restorative material specially designed for posterior use. QuiXX® Posterior Restorative allows a simplified and fast application technique without compromising safety and efficacy. QuiXX® Posterior Restorative utilizes a new filler technology resulting in a unique high filler load as well as fluoride release. QuiXX® Posterior Restorative exhibits excellent performance relative to abrasion resistance and physical properties which are of special importance for occlusal stress-bearing restorations. QuiXX® Posterior Restorative is pre-dosed in Compules® tips for direct intra-oral application. QuiXX® Posterior Restorative is available in one universal shade. QuiXX® Posterior Restorative is used following application of XENO™ III Single Step Self-Etching Dental Adhesive, Prime&Bond® NT™ Adhesive System, or other adhesives designed for use with QuiXX® Posterior Restorative.

COMPOSITION

Urethane dimethacrylate (UDMA)
Triethyleneglycol dimethacrylate (TEGDMA)
Di- and trimethacrylate resins
Carboxylic acid modified dimethacrylate resin
Butylated hydroxy toluene (BHT)
UV stabilizer
Camphorquinone
Ethyl-4-dimethylaminobenzoate
Silanated strontium aluminum sodium fluoride phosphate silicate glass

INDICATIONS

QuiXX® Posterior Restorative is indicated as a direct restorative material for Class I and II cavities.

CONTRAINDICATIONS

QuiXX® Posterior Restorative is not indicated for use in patients with a known allergy to methacrylate resins or any of the other components.

WARNINGS

1. QuiXX® Posterior Restorative contains methacrylates that may be irritating to the eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. QuiXX® Posterior Restorative may cause sensitization by contact with skin or mucous membranes in susceptible persons. If accidental contact occurs, wash immediately with soap and water or rinse with plenty of water. If sensitization has occurred, discontinue use.
3. When using a DENTSPLY Caulk Compules® Tips Gun, dental professionals and patients should wear protective eyewear.

PRECAUTIONS

1. This product is intended to be used only as specifically outlined in these *Directions for Use*. Any use of this product inconsistent with the *Directions for Use* is at the discretion and is the sole responsibility of the practitioner.
2. Contact with saliva and blood during composite placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
3. Eugenol containing dental materials should not be used in conjunction with this product because they may interfere with hardening of the material.
4. This material has not been tested with curing outputs below 500 mW/cm².
5. **Storage:** QuiXX® Posterior Restorative Compules® tips are for single use and

should be discarded after use. Keep out of sunlight. To be stored at temperatures between 10°C/50°F and 24°C/75°F. Humidity can adversely affect the properties of unsealed Compules® tips. Therefore keep Compules® tips sealed in their blister pack until use. Under normal ambient conditions, unsealed Compules® tips stay usable for about 4 weeks.

6. Material should extrude easily from the Compules® Tips Gun. DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause ampule to eject from the Compules® Tips Gun.
7. Compules® tips are designed for one time use. Discard after use. Do not reuse.
8. Store and sterilize Compules® Tips Gun as indicated per manufacturer's instructions. If using a DENTSPLY Caulk Compules® Tips Gun, follow the instructions in the *Sterilization and Maintenance of Compules® Tips Gun Section*.

ADVERSE REACTIONS

Allergic contact dermatitis, oral mucosa irritation and other allergic reactions may occur in susceptible individuals when using QuiXX® Posterior Restorative. (see *Warnings*).

STEP-BY-STEP INSTRUCTIONS

1. **Preparation**
 - 1.1 Clean uninstrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro® Prophylaxis Paste. Wash thoroughly with water spray and air dry.
 - 1.2 Clean freshly instrumented enamel and dentin with spray and then air dry.
 - 1.3 Preparation may be kept to the minimum required for caries removal.
 - 1.4 Finishing of cavity margins with a fine finishing bur will contribute to marginal quality.
 - 1.5 After preparation, wash cavity thoroughly with air/water spray.
 - 1.6 To remove rinsing water blot-dry with a moist cotton pellet.
 - 1.7 Do not desiccate the dentin structure.
2. **Pulp Protection**

For direct or indirect pulp-capping protect the dentin close to the pulp (< 1mm) with a hard-setting calcium hydroxide liner (e.g. Dycal® liner), leaving the remaining cavity surface free for bonding with the adhesive.
3. **Conditioning and application of adhesive**

For conditioning and application instructions of adhesive, see the *Directions for Use* for either XENO™ III Single Step Self-Etching Dental Adhesive or Prime&Bond® NT™ Adhesive System products.
4. **Placement of QuiXX® Posterior Restorative**

Insert Compules® tip into the notched opening of the Compules® Tips Gun. Dispense QuiXX® Posterior Restorative directly into the cavity preparation. Due to the high depth of cure and low shrinkage for QuiXX® Posterior Restorative, placement in layers up to 4 mm thick is possible.

 - 4.1 Class I – QuiXX® Posterior Restorative may be placed in bulk (up to 4 mm).
 - 4.2 Class II – Fill the proximal box in bulk (up to 4 mm), level with the pulpal floor. Firmly adapt material to cavity walls using a suitable placing instrument. The remainder of the preparation may be filled in bulk (up to 4 mm).

5. **Curing**
 - 5.1 Cure each increment separately with a light-curing unit:
 - 20 seconds for units with an output of 500 to 800 mW/cm². **NOTE:** This material has not been tested with curing outputs below 500 mW/cm². Halogen and LED lights may be used if applicable set wavelength to cure camphorquinone.

- 10 seconds for both units with an output of 800 mW/cm² and more.

5.2 The tip of the light guide should be held as close as possible to the restoration during curing.

Important: Be sure to expose each area of the entire restoration to the curing light. Additionally, the restoration should be cured through lingual or buccal enamel walls.

6. Finishing

Begin finishing immediately after curing. Gross excess material may be removed with fluted finishing burs or diamonds. Finishing is best achieved by using Enhance™ Finishing System.

STERILIZATION AND MAINTENANCE OF COMPULES® TIPS GUN

Compules® tips are designed for one time use. Discard after use. Prior to sterilization, remove and properly discard used Compules® tip. Do not attempt to sterilize, disinfect, or reuse Compules® tips.

To clean the gun, the following procedure is recommended. It is recommended that the Compules® Tips Gun be disassembled for assured sterilization. Partially close the applicator gun and place thumb under the rear portion of the hinge. Push upward and lift hinge separating the Compules® Tips Gun, exposing the plunger. Remove residual restorative with a soft paper tissue and a suitable solvent (70% alcohol). The Compules® Tips Gun may be cleaned by scrubbing with hot water and soap or detergent. Rinse thoroughly and dry prior to sterilization.

For sterilization, the Compules® Tips Gun may be steam autoclaved after each use. **NOTE:** As with any plastic instrument, the Compules® Tips Gun may weaken over time. Discard the Compules® Tips Gun if any discoloration, corrosion or deterioration in performance is observed. To reassemble, insert plunger into Compules® Tips Gun barrel; press components together and snap hinge mechanism in place. Prior to each use check to make sure that the Compules® Tips Gun is fully engaged and in good working order.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard is used: "YYYY/MM"
2. The following numbers should be quoted in all correspondence.
 - Reorder number
 - Lot number on Compules® tips
 - Expiration date on Compules® tips

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