

Dyract® eXtra

Universal Compomer Restorative

DIRECTIONS FOR USE – ENGLISH

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

Dyract® eXtra compomer is a universal light-cured compomer-based restorative material suitable for restoration of all cavity classes in anterior and posterior teeth. Dyract® eXtra compomer allows a simplified and fast application technique and combines fluoride-releasing glass-ionomer chemistry with the strength and esthetics of a composite.

Dyract® eXtra compomer is to be used following the application of a suitable adhesive such as ProBOND® All Purpose Bonding Agent, Prime&Bond® NT™ Universal Dental Adhesive System, XENO® III Self Etch Adhesive or Xeno® IV One Component Light Cured Self Etch Adhesive. Use of other dentin/enamel adhesive systems with Dyract® eXtra compomer restorative material is at the discretion and sole responsibility of the dental practitioner.

This one-component, visible light cured compomer restorative is packaged in pre-dosed Compules® Tips for direct intra-oral application in 9 shades (1 accessory and 8 Vita® shades) to serve most clinical needs.

¹Vita® is a registered trademark of Vita-Zahnfabrik H. Rauter GmbH & Co.

COMPOSITION

Urethane dimethacrylate (UDMA)
Carboxylic acid modified dimethacrylate (TCB resin)
Triethyleneglycol dimethacrylate (TEGDMA)
Trimethacrylate resin
Camphorquinone
Ethyl-4-dimethylaminobenzoate
Butylated hydroxy toluene (BHT)
UV stabilizer
Strontium-alumino-sodium-fluoro- silicate glass
Highly dispersed silicon dioxide
Strontium fluoride
Iron oxide and titanium dioxide pigments

INDICATIONS

Direct restorative for all cavity classes in anterior and posterior teeth. The widths of class I and II cavities should be less than 2/3 of the intercuspal distance.

CONTRAINDICATIONS

1. Dyract® eXtra compomer is contraindicated for core build-up for full ceramic crowns.
2. Dyract® eXtra compomer is contraindicated for use in patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

1. Dyract® eXtra compomer contains polymerizable methacrylate monomers. Avoid prolonged or repeated contact with skin (allergic contact dermatitis), oral soft tissues, and eyes. Avoid prolonged inhalation. Do not take internally.
Eye contact: Dyract® eXtra compomer contains methacrylates which may be irritating to eyes. Before using this product wear protective glasses as well as covering the patient's eyes to protect from material. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
Skin contact: Dyract® eXtra compomer contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. If contact with skin occurs immediately wipe off thoroughly with

cotton and alcohol and then wash well with soap and water after contact. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.

Oral mucosa contact: Avoid contact with oral soft tissues. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa persists, seek medical attention immediately.

Ingestion: Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately. Contact regional Poison Control Center if necessary.

2. When using a 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. Insufficient data exist to support the use in cavities with isthmus widths greater than 2/3 the intercuspal distance, or when replacing a functional cusp. Excessive wear or restoration failure may result.
4. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
5. Eugenol-containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
6. Dyract® eXtra compomer material is light-cured material. Proceed immediately once material has been placed or protect from ambient light.
7. Material should extrude easily from the Compules® Tips. Use a gentle, even motion when exerting pressure on the Compules® Tips Gun. DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause the Compules® Tip to eject from the Compules® Tips Gun.
8. Compules® Tips are designed for one time use. Discard after use. Do not reuse.
9. Use with the DENTSPLY Caulk Compules® Tips Gun is recommended. If using another dispensing device, sterilization should be done based on the respective manufacturer's instructions.
10. **Storage:** Dyract® eXtra compomer 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. Protect from moisture. Do not freeze. Do not use after expiration date. Humidity can adversely affect the properties of unsealed Compules® Tips. Therefore keep Compules® Tips sealed in their blister pack until usage. Under normal ambient conditions, unsealed but unused Compules® Tips, tightly closed with cap, stay usable for about 4 weeks.
The DENTSPLY Caulk Compules® Tips Gun should be sterilized by following the instructions in the Sterilization and Maintenance of Compules® Tips Gun section. Compules® Tips Gun has an expected useful-life of one year from date of purchase.

ADVERSE REACTIONS

1. Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. See *Warnings*
2. Use as a core buildup material under full ceramic restorations may lead to premature restoration failure. See *Contraindications*

STEP-BY-STEP INSTRUCTIONS

1. **Shade Selection:** Shade selection should be made prior to the restorative procedure while the teeth are hydrated. Remove any extraneous plaque or surface stain. A Vita® Lumin® Vacuum shade guide may be used. The Dyract® eXtra compomer shade corresponds to the central part of the respective Vita® tooth.
2. **Cavity Preparation**
 - 2.1 Anterior Restorations: Use conservative cavity preparations for all Class III, IV and Class V restorations. Refinement of the cavo-surface margin (beveling) for enhancement of acid-etching and enamel bonding is recommended. **Technique Tip:** Esthetic masking of underlying intrinsic staining may require deeper preparation, allowing for adequate restorative material blending.
 - 2.2 Posterior Restorations: Cavity design requirements are essentially a conventional preparation with refinement of the cavo-surface margin for enhancement of acid etching. No residual amalgam or other base material should be left in the internal forms of the preparation which would interfere with light transmission and the hardening of the restorative.
3. **Placement of Matrix:** The use of a Mylar, Bimatrix, sectional (e.g. Palodent® Sectional Matrix System) or thin matrix band (e.g. AutoMatrix® Retainerless Matrix System) and subsequent burnishing of the matrix band will improve final interproximal contact and contour. PRE-WEDGING/Bitine® RING PLACEMENT IS ADVOCATED TO ACHIEVE SLIGHT SEPARATION AND FACILITATE ACCEPTABLE PROXIMAL CONTACT.
4. **Pulp protection, Tooth Conditioning/Dentin Pretreatment , Adhesive Application:** Refer to adhesive manufacturer's directions for pulp protection, tooth conditioning and/or adhesive application. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately to placement of Dyract® eXtra compomer material.
Optional Flowable Liner: Placement of a compatible flowable liner such as Esthet-X® flow Flowable Restorative or Dyract®/flow Flowable Compomer (available separately) prior to placement of Dyract® eXtra compomer restorative material is optional. If desired, follow manufacturer's directions for use.
5. **Placement of Dyract® eXtra Universal Compomer Restorative Material**
Pre-dosed Compules® Tips: Load Compules® Tips Gun with predosed Compules® Tip. Insert a Compules® Tip into the notched opening of the Compules® Tips Gun barrel. Be certain that the collar on the Compules® Tip is inserted first. Remove the colored cap from the Compules® Tip. The Compules® Tip may be rotated 360° to gain the proper angle of entrance into the cavity. To dispense the material into a cavity preparation, use a slow, steady pressure. Do not use excessive force. To remove the used Compules® Tip, be sure that the Compules® Tips Gun plunger is pulled back completely by allowing the handle to open to its widest position. Apply a downward motion to the front end of the Compules® Tip and remove.
 - 5.1 Anterior Placement: Dispense Dyract® eXtra compomer material directly into the cavity preparation from the Compules® Tip using slow, steady pressure. Excessive force is not necessary. Alternatively, material may be expressed onto a clean pad from the Compules® Tip and carried to the preparation with suitable placement instrument. Adapt, contour and shape with appropriate composite instruments. Material may be placed and light cured in increments up to 2mm. *See Curing, Step 6*
 - 5.2 Posterior Placement: Dispense Dyract® eXtra compomer material directly into the cavity preparation from the Compules® Tip using slow, steady pressure. Excessive force is not necessary. Alternatively, material may be expressed onto a clean pad from the Compules® Tip and carried to the preparation with suitable placement instrument.
 - 5.2.1 Class I and V: Dyract® eXtra compomer material may be placed and adapted in 2mm increments, light curing each increment. *See Curing, Step 6*
 - 5.2.2 Class II: Beginning in the proximal box, adapt a 2mm increment of Dyract® eXtra compomer material to cavity walls. Light cure (*see Curing, Step 6*). The remainder of the preparation may be filled in up to 2mm increments, each followed by light cure. *See Curing, Step 6* Prior to light curing, contour and shape the final increment with the operator's choice of clean carving and burnishing instruments.
Technique Tip: To minimize finishing time, contour marginal ridge first before occlusal anatomy. Shape margins and anatomy to final form.

6. **Curing:** Light cure each area of the restoration surface with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470nm. Minimum light output must be at least 500mW/cm² exposure for at least 10 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The Dyract® eXtra compomer material should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.
7. **Finishing and Polishing**
 - 7.1 Begin finishing immediately after curing. Gross excess may be removed and general outline form established with Prisma® Finishing Burs or other carbide or diamond finishing instruments. Additional finishing is recommended by the use of Enhance® Finishing System. See manufacturer's complete directions for use.
 - 7.2 To achieve a very high luster on Dyract® eXtra compomer material, it is necessary to complete the polishing. PoGo® One Step Diamond Micro-Polisher System and/or Prisma® Gloss™ Composite Polishing Pastes are recommended. See manufacturer's complete directions for use.

CLEANING AND DISINFECTION

Do not attempt to clean, disinfect or re-use Compules® Tips. Properly dispose used Compules® Tips.

STERILIZATION AND MAINTENANCE OF COMPULES® TIPS GUN

1. To clean the Compules® Tips Gun, the following procedure is recommended. Partially close the syringe and place thumb under the rear portion of the hinge.
2. Push upward and lift hinge separating the Compules® Tips Gun, exposing the plunger. If the plunger has excess material build-up clean with an alcohol moistened gauze. The Compules® Tips Gun may be cleaned by scrubbing with hot water and soap or detergent. It is not recommended to submerge Compules® Tips Gun into disinfection solutions.
3. The Compules® Tips Gun may be autoclaved. **NOTE:** As with any plastic instrument, the Compules® Tips Gun may weaken over time.
4. 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. Compules® Tips Gun is warranted for one year from date of purchase.
3. The following numbers should be quoted in all correspondence:
 - Reorder Number
 - Lot number on Compules® Tip
 - Expiration date on Compules® Tip

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