

## DIRECTIONS FOR USE – ENGLISH

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

Dyract<sup>®</sup>flow Flowable Compomer Restorative is a compomer restorative material with flow characteristics which make it ideal for small cavities in anterior and posterior teeth. Dyract<sup>®</sup>flow Restorative adapts to the cavity wall without the use of hand instruments. Dyract<sup>®</sup>flow Restorative, delivered in small syringes, or in pre-dosed Compula<sup>™</sup> Tips for direct intra-oral application is available in 7 shades: 5 Vita<sup>®</sup>shades, a translucent, and an opaque shade.

Dyract<sup>®</sup>flow Restorative is used following application of a suitable dentin/enamel adhesive and is compatible with all DENTSPLY adhesives designed for use with visible light cured compomer restoratives (See complete *Directions for Use* of selected adhesive). Use of other dentin/enamel adhesive systems with Dyract<sup>®</sup>flow Restorative material is at the discretion and sole responsibility of the dental practitioner.

## COMPOSITION

Strontium-alumino-fluoro-silicate glass; Phosphoric acid modified polymerizable monomers; Carboxylic acid modified macromonomers; Reactive diluent; Camphorquinone (CQ) Photoinitiator; Stabilizer; Colorants; Titanium dioxide

## INDICATIONS FOR USE

Dyract<sup>®</sup>flow Restorative is indicated for the following procedures:

1. Restoration of minimally invasive cavity preparations, pits and fissures, including air abrasion Class I and tunnel preparations.
2. Restoration of minimal, shallow Class V preparations, including incipient Class V abfraction and erosion lesions.
3. As a base/liner under composite, high-density composite and compomer Class I & Class II restorations.
4. Undercut blockout and filling of small defects in indirect restoration preparations.
5. Small margin defect repair in otherwise sound restorations.

## CONTRAINDICATIONS

Dyract<sup>®</sup>flow Restorative is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

## WARNINGS

1. Dyract<sup>®</sup>flow Restorative 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<sup>®</sup>flow Restorative 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<sup>®</sup>flow Restorative 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.

## PRECAUTIONS

1. This product is intended to be used as specifically outlined in the *Directions for Use*. Any use of this product inconsistent with the *Directions for Use* is at the discretion and 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. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
4. Dyract<sup>®</sup>flow Restorative should extrude easily. DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause the Compula<sup>™</sup> Tip to eject from the Compules<sup>®</sup> Tips Gun.
5. The Dyract<sup>®</sup>flow Restorative material syringe should be tightly closed immediately after use. Do not allow dispensing tip to remain as a syringe cap. Replace original cap tightly after each use. Discard and properly dispose dispensing tips after use, as the tips may clog if material is allowed to dry or set inside.
6. The Dyract<sup>®</sup>flow Restorative is light-cured material. Proceed immediately once material has been placed. Protect from ambient light.
7. Compula<sup>™</sup> Tips are designed for one time use. Discard after use. Do not reuse.
8. DENTSPLY Caulk supplies the appropriate dispensing tip for the Dyract<sup>®</sup>flow Restorative material syringe. This tip is the only tip that should be utilized for placement of the material.
9. Use of Compula<sup>™</sup> Tips with the DENTSPLY Caulk Compules<sup>®</sup> Tips Gun is recommended. Use with another manufacturer's dispensing device is at the discretion and sole responsibility of the practitioner. Prior to use, consult the respective manufacturer's instructions for compatibility, use and sterilization information.
10. Insufficient data exist to support the use in Class I cavities with isthmus widths beyond central groove areas, or when replacing a functional cusp. Excessive wear or restoration failure may result.
11. **Storage:** Dyract<sup>®</sup>flow Restorative Compula<sup>™</sup> Tips are for single use and should be discarded after use. Store syringe with original cap only. Keep out of sunlight. To be stored in a well ventilated place at temperatures between 10°C/ 50°F and 24°C/75°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date. Humidity can adversely affect the properties of unsealed Dyract<sup>®</sup>flow Restorative syringes.

Keep syringes and compulas sealed in their pouches until use. Under normal ambient conditions, unsealed syringes and compulas stay usable for approximately 8 weeks.

The DENTSPLY Caulk Compules<sup>®</sup> Tips Gun should be sterilized by following the instructions in the *Sterilization and Maintenance of Compules<sup>®</sup> Tips Gun* section. Compules<sup>®</sup> Tips Gun has an expected useful-life of one year from date of purchase.

## ADVERSE REACTIONS

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*)

## INTERACTIONS

Eugenol-containing dental materials should not be used in conjunction with this product because they may interfere with the hardening and cause softening of the polymeric components.

## STEP-BY-STEP INSTRUCTIONS FOR USE

**Direct Restoration, Class I, III, V, small blockouts and restoration repairs**

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 with a rubber cup and pumice or non-fluoridated prophylactic paste. A Vita Lumin<sup>®</sup> Vacuum shade guide may be used. The Dyract<sup>®</sup>flow Restorative shade corresponds to the central part of the respective Vita<sup>®</sup> tooth.
2. **Cavity Preparation:** Cavity design should be a minimal extension preparation with round internal line and point angles. Refinement of the cavo-surface margin (beveling) for enhancement of acid etching and enamel bonding is recommended. Unless repairing an otherwise sound restoration, intended to remain in place, 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<sup>®</sup> Sectional Matrix System) or thin matrix band (e.g. AutoMatrix<sup>®</sup> Retainerless Matrix System) and subsequent burnishing of the matrix band will improve final interproximal contact and contour. PRE-WEDGING/Bitine<sup>®</sup> 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<sup>®</sup>flow Restorative material.

## 5. Dispensing Dyract<sup>®</sup>flow Flowable Compomer Restorative Material

### 5.1 Syringes

- 5.1.1 Remove cap from the end of the syringe. To assure free flow of material from syringe, express a small amount onto pad, away from the patient field.
- 5.1.2 Attach disposable, black dispensing tip to end of the syringe. Turn tip clockwise 1/4 to 1/2 turn to assure that it is fully seated. Tug on tip to be sure that it is locked into the collar of the syringe.
- 5.1.3 Dyract<sup>®</sup>flow Restorative should flow freely with gentle pressure. DO NOT USE EXCESSIVE FORCE. If more than gentle pressure is required, remove from patient field and check for obstruction.
- 5.1.4 DISCARD AND PROPERLY DISPOSE DISPENSING TIP IMMEDIATELY AFTER USE. REPLACE ORIGINAL CAP. Do not store syringe with black dispensing tip in place. STORE ONLY WITH ORIGINAL CAP. **NOTE:** It is recommended to pull back slightly on the syringe plunger after use to prevent excessive flow of material.

### 5.2 Compula<sup>™</sup> Tips

- 5.2.1 The pre-dosed Compula<sup>™</sup> Tip provides the combination of a unit dose Compules<sup>®</sup> Tip with a metal cannula applicator tip.
- 5.2.2 Load Compules<sup>®</sup> Tips Gun with pre-dosed Compula<sup>™</sup> Tip. Insert Compula<sup>™</sup> Tip into the notched opening of the Compules<sup>®</sup> Tips Gun barrel. Be certain that the collar on the Compula<sup>™</sup> Tip is inserted first.
- 5.2.3 Remove the colored cap from the Compula<sup>™</sup> Tip. The Compula<sup>™</sup> Tip may be rotated 360° to gain the proper angle of entrance into the cavity.
- 5.2.4 Dispense the material into the cavity preparation using a slow, steady pressure. DO NOT USE EXCESSIVE FORCE.
- 5.2.5 To remove the used Compula<sup>™</sup> Tip, be sure that the Compules<sup>®</sup> 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 Compula<sup>™</sup> Tip and remove.

6. **Placement of Dyract<sup>®</sup>flow Restorative Material:** Dispense Dyract<sup>®</sup>flow Restorative directly into preparation site/tooth surface from the Compula<sup>™</sup> Tip or syringe tip using slow, steady pressure. Dyract<sup>®</sup>flow Restorative should extrude easily. DO NOT USE EXCESSIVE FORCE. Avoid lifting the tip while dispensing to minimize air entrapment. Any visible air bubbles should be pierced with a clean, sharp explorer prior to curing. Material may be placed and light cured in increments up to 2mm. (See *Curing, Step 7*) In deeper preparations it is recommended to place material in 2mm increments, thoroughly light curing each increment. For maximum light transmission and to minimize finishing, avoid overfilling cavity.
7. **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 550mW/cm<sup>2</sup> exposure for at least 20 seconds. For darker/opaque shades (A4 and A3-Opaque) cure for another twenty seconds. DENTSPLY manufactured advanced performance curing units have been shown to cure 2mm increments of most shades of Dyract<sup>®</sup>flow Restorative material in 10 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The Dyract<sup>®</sup>flow Restorative should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.
8. **Finishing and Polishing:**
  - 8.1 Begin finishing immediately after curing.
  - 8.2 If necessary, gross excess may be removed with Prisma<sup>®</sup> Finishing Burs or other carbide or diamond finishing instruments. Preferably, finishing is recommended by the use of Enhance<sup>®</sup> Finishing System. See manufacturer's complete *Directions for Use*.
  - 8.3 To achieve a very high luster on Dyract<sup>®</sup>flow Restorative, it is necessary to complete the polishing. PoGo<sup>®</sup> One Step Diamond Micro-Polisher system and/or Prisma<sup>®</sup>Gloss<sup>™</sup> Composite Polishing Pastes are recommended. See manufacturer's complete *Directions for Use*.

## STEP-BY-STEP INSTRUCTIONS FOR USE

### Cavity Liner

Prior to use as a cavity liner, follow steps 1 through 5 outlined above for:

1. Shade selection
2. Cavity preparation
3. Matrix placement
4. Pulp protection, Tooth Conditioning/Dentin Pretreatment, Adhesive Application
5. Dispensing (syringe or Compula<sup>™</sup> Tip).
6. **Placement:** Dispense Dyract<sup>®</sup>flow Restorative directly into preparation site/surfaces. For most cavity lining applications, a thickness of 1mm or less is recommended. With the exception of Class II proximal box (gingival) margins, cavity margins/conditioned enamel are usually closed with selected restorative material. Lining is generally confined to internal conditioned dentin surfaces. Avoid lifting the tip while dispensing to minimize air entrapment. Any visible air bubbles should be pierced with a clean, sharp explorer prior to curing. **Technique Tip:** Use of a clean instrument such as a sharp explorer may be used to evenly spread a thin layer of dispensed Dyract<sup>®</sup>flow Restorative material over prepared cavity (dentin) surfaces prior to curing.
7. **Curing:** Light cure each area of the lined 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 550mW/cm<sup>2</sup> exposure for at least 40 seconds for liner application.
8. If a thickness of material greater than 1mm is desired, repeat Placement Step 6 and Curing Step 7, placing material in 1mm increments and curing until desired thickness is reached.
9. Proceed immediately to complete the restoration per restorative material manufacturer's *Directions for Use*. For adhesive restorations, do not disturb or allow contamination of cured liner surface. If contamination occurs, follow adhesive manufacturer's directions for use for re-application of adhesive.  
**Technique Tip:** If surfaces remain undisturbed, additional application of adhesive between increments is neither necessary nor recommended.

## CLEANING AND DISINFECTION

To prevent Dyract<sup>®</sup>flow Restorative syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid syringe contamination. Repeated disinfection may damage label. Do not attempt to clean, disinfect or re-use Compula<sup>™</sup> Tips. Properly dispose used Compula<sup>™</sup> Tips.

## STERILIZATION AND MAINTENANCE OF COMPULES<sup>®</sup> TIPS GUN

1. To clean the Compules<sup>®</sup> 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<sup>®</sup> Tips Gun, exposing the plunger. If the plunger has excess material build-up, clean with an alcohol moistened gauze. The Compules<sup>®</sup> Tips Gun may be cleaned by scrubbing with hot water and soap or detergent. It is not recommended to submerge Compules<sup>®</sup> Tips Gun into disinfecting solutions.
3. The Compules<sup>®</sup> Tips Gun may be autoclaved. **NOTE:** As with any plastic instrument, the Compules<sup>®</sup> Tips Gun may weaken over time.
4. To reassemble, insert plunger into Compules<sup>®</sup> Tips Gun barrel, press components together and snap hinge mechanism in place. Prior to each use, check to make sure that the Compules<sup>®</sup> 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 correspondences:
  - Reorder number
  - Lot number on the syringe or Compula<sup>™</sup> Tip
  - Expiration date on the syringe or Compula<sup>™</sup> Tip

©2006 DENTSPLY International Inc. All Rights Reserved. Printed in U.S.A.

Vita Lumin Vacuum Shade Guide is not a registered trademark of DENTSPLY International Inc.

<sup>1</sup>Vita is a registered trademark of Vita-Zahnfabrik H. Rauter GmbH & Co.

*Manufactured in the U.S.A. by:*  
DENTSPLY Caulk  
38 West Clarke Avenue  
Milford, DE 19963  
Tel.: 1-302-422-4511

*Distributed by:*  
DENTSPLY Canada  
161 Vinyl Court  
Woodbridge, Ontario  
L4L 4A3 Canada