

Directions for Use

# Dyract<sup>®</sup> AP

## Advanced Performance Compomer Restorative

Dyract AP is a universal light-cured compomer-based restorative material suitable for cavities in anterior and posterior teeth.

Dyract AP compomer exhibits advanced performance regarding physical strength and abrasion resistance which is of special importance for occlusal stress-bearing restorations.

Dyract AP compomer allows a simplified and fast application technique and combines fluoride-releasing glass-ionomer chemistry with the strength and aesthetics of a composite.

Dyract AP compomer pre-dosed in Compules<sup>®</sup> tips for direct intra-oral application, is available in 14 Shades (12 Vita and 2 accessory shades).

Dyract AP compomer is used following application of Prime&Bond<sup>®</sup> NT<sup>™</sup>, a universal self-priming dental adhesive designed to bond the restorative to enamel and dentin.

**CAUTION:** US Federal laws restrict this device to sale by, or on the order of a dentist. Caution: For dental use only.

## COMPOSITION

### Dyract<sup>®</sup> AP

Polymerizable resins  
TCB resin  
Strontium-fluoro-silicate glass  
Strontium fluoride  
Photo initiators  
Stabilizers

### Prime&Bond<sup>®</sup> Prime&Bond<sup>®</sup> NT<sup>™</sup>

Di- and Trimethacrylate resins  
PENTA (dipentaerythritol penta acrylate monophosphate)  
Nano fillers- Amorphous Silicone Dioxide  
Photo initiators  
Stabilizers  
Cetylamine hydrofluoride  
Acetone

## INDICATIONS

Dyract AP compomer restorative is indicated for all cavity classes in anterior and posterior teeth. Until the results of continuing ongoing studies confirm the unrestricted use of Dyract AP compomer restorative in posterior teeth the width of class I and II cavities must be less than 2/3 of the intercuspal distance.

## CONTRAINDICATIONS

Direct or indirect pulp capping.  
Core build-up for full ceramic crowns.

Use in patients with a known allergy to dimethacrylate resins.

## WARNINGS

Prime&Bond NT adhesive system contains acetone. Acetone is highly flammable. Keep away from sources of ignition. Do not breathe vapor.

Prime&Bond NT adhesive system and Dyract AP contain polymerizable monomers which may cause sensitization (allergic contact dermatitis) in susceptible individuals. After contact with skin, wash thoroughly with soap and water. If skin sensitization or other allergic reaction occurs, discontinue use.

Avoid contact of Prime Bond NT with mucous membranes. After accidental contact, wash and rinse with plenty of water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

## STORAGE

The Prime&Bond NT bottle and Dyract AP Compules<sup>®</sup> Tips should be tightly closed immediately after use.

Keep out of sunlight.

Not to be stored at temperatures exceeding 25°C.

Keep Prime&Bond NT in a well ventilated place.

Humidity can adversely affect the properties of unsealed Compules<sup>®</sup> Tips. Therefore keep Compules<sup>®</sup> Tips sealed in their blister pack until usage. Under normal ambient conditions, unsealed Compules<sup>®</sup> Tips stay usable for about 12 weeks.

50°F-75°F (10°C-24°C).

## ⚠ PRECAUTIONS

Eugenol containing dental 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.

## ADVERSE REACTIONS

Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.

## 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. Use the Dyract AP shade guide provided which is made of original Dyract AP restorative.

Alternatively, a Vita Lumin<sup>®</sup> Vacuum shade guide may be used. The Dyract AP shade corresponds to the central part of the respective Vita<sup>®</sup> tooth.

### 2. Cleaning

Clean uninstrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro<sup>™</sup> Prophylaxis Paste. Wash thoroughly with water spray and air dry. Clean freshly instrumented enamel and dentin with water spray and then air dry.

### 3. Pulp Protection

For direct or indirect pulp-capping cover the dentin close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal<sup>®</sup> Liner) leaving the rest of the cavity surface free for bonding with Prime&Bond NT.

#### 4. Tooth Conditioning

For most restorative procedures with Dyract AP it is not necessary to condition the prepared tooth enamel. In this case, proceed to step 5.1. However, conditioning is recommended where maximum adhesion to enamel is desired to maintain optimal marginal integrity under occlusal stress (e.g. class IV and large class II restorations of the permanent dentition, where for cosmetic reasons beveled enamel margins are preferred).

##### 4.1 Application of Caulk® Tooth Conditioner

Gently extrude Caulk® Tooth Conditioner onto the dried cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentin for 15 seconds or less.

##### 4.2 Rinsing and Drying

Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds. Blot dry conditioned areas with a moist cotton pellet. Dentin should be blotted until there is no pooling of water, leaving a moist, glistening surface.

Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with vigorous water-spray, dry, and repeat conditioning procedure of enamel for 5 seconds only. Rinse and dry as described above. Proceed to step 5.2.

##### 5.1 Application of Prime&Bond NT Adhesive

**5.1.1** Dispense Prime&Bond NT Adhesive directly onto a clean disposable brush provided or place 2-3 drops into a clean well. Replace cap promptly.

**5.1.2** Using the disposable brush supplied, immediately apply generous amounts of Prime&Bond NT Adhesive to thoroughly wet all the tooth surfaces. This surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime&Bond NT Adhesive.

**5.1.3** Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat steps 5.2 and 5.3.

**5.1.4** Cure Prime&Bond NT Adhesive for 10 seconds using a curing light (e.g. ProLite®, Spectrum™).

**5.1.5** Place Dyract AP compomer restorative over the cured Prime&Bond NT Adhesive.

##### Important Note:

When using a high performance unit such as the curing lights manufactured by DENTSPLY, a curing time of 10 seconds is sufficient. For curing lights with an output lower than 300 mw/cm<sup>2</sup>, a curing time of 20 seconds should be observed.

#### 6. Placement of Dyract AP

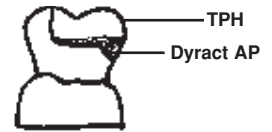
**Compules:** Insert Compules® Tips into the notched opening of the Compules® Tips Gun barrel.

Dispense Dyract AP compomer directly into the cavity preparation. In deep cavities, incremental placement and curing (in 3 mm layers or less) is recommended to minimize polymerization shrinkage.

**Syringes:** Dispense the necessary amount of Dyract AP from the syringe onto the mix pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the syringe upwards and turn the handle counter-clockwise.

#### 7. Class II Sandwich

**Apply** a thin layer of **Dyract® AP** compomer to cover the bottom of the cavity, below or gingival to the proximal contact point, and light cure for 40 seconds.



Then, proceed to **apply TPH® Spectrum™** hybrid composite in 2 mm layers, curing each layer separately.

Note: Dyract® AP compomer can be used in an “open” or “closed” sandwich technique.

#### 8. Curing

Cure each increment separately with a VLC dental polymerization unit separately for at least 40 seconds. The tip of the light guide should be held as close as possible to the restoration during curing. If a DENTSPLY Caulk unit or a device with compatible light power is used, the depth of cure for each shade is at least 3 mm. 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.

#### 9. 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 and Polishing System. A high final luster can be obtained by applying Prisma® Gloss™ and Prisma® Gloss™ Extra-Fine Polishing Pastes.

#### 10. Maintenance of Compules® Tips Gun

The Compules® Tips Gun is sterilizable by autoclave or cold sterilization solution following the manufacturers' instructions.

It is recommended that the Compules® Tips Gun be disassembled for assured sterilization. Partially close the Compules® Tips 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 compomer with a soft paper tissue and a suitable solvent (70% alcohol).

To reassemble, insert plunger into Compules® Tips Gun barrel, press components together and snap hinge mechanism in place.

#### BATCH NUMBER AND EXPIRY DATE

Do not use after expiration.

The batch number should be quoted in all correspondence which requires identification of the product.

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