

Prisma® AP.H®

VLC Hybrid Composite

DENTSPLY

DIRECTIONS FOR USE

For dental use only.

USA: Rx only.

1. PRODUCT DESCRIPTION

Prisma® AP.H® VLC Hybrid Composite is a visible light cured, radiopaque, composite restorative material for anterior and posterior restorations.

1.1 Delivery forms

Prisma® AP.H® Composite material is available in:

- Predosed Compules® Tips
- 4.5g syringes

Prisma® AP.H® VLC Hybrid Composite is available in 11 shades:

A2, A3.5, Extra Light (XL), Universal Opaque (UO), Light (L), Gray Brown (GB), Light Gray (LG), Dark Gray (DG), Light Yellow (LY), Dark Yellow (DY), Universal (U-LYG)

1.2 Composition

Urethane modified Bis-GMA resin; Bis-EMA; Triethyleneglycol dimethacrylate; Camphorquinone (CQ); Ethyl-4(dimethylamino)benzoate; Butylated hydroxy toluene (BHT); UV stabilizer; Barium aluminoborosilicate glass; Silicon dioxide; Fluorescent agent; Iron oxide pigments; Titanium dioxide pigment

1.3 Indications

- Restoration of all cavity classes in anterior and posterior teeth

1.4 Contraindications

Prisma® AP.H® Composite material is contraindicated for use with patients who have a known hypersensitivity to methacrylate resins.

1.5 Compatible adhesives

Prisma® AP.H® Composite material is used following application of a suitable dentin/enamel adhesive and is chemically compatible with conventional methacrylate-based dentin/enamel adhesives including DENTSPLY adhesives designed for use with visible light cured composite restoratives (see complete directions for use of selected adhesive).

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.



Safety alert symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

Prisma® AP.H® Composite material contains polymerizable methacrylates which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid contact with oral soft tissues/mucosa** to prevent inflammation. If accidental contact occurs, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

2.2 Precautions

1. This product is 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. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
4. Material should extrude easily DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause the Compules® Tip to rupture or to eject from the Compules® Tips Gun.
5. Compules® Tips may be used for direct intraoral application of restorative material into a cavity or for indirect application by first placing the restorative material on a pad. After intraoral use, discard Compules® Tips and do not reuse in other patients in order to prevent cross-contamination.
6. The Prisma® AP.H® Composite material syringe should be tightly closed immediately after use.

7. Use of Compules® Tips with the DENTSPLY Compules® Tips Gun is recommended.

8. Interactions:

- Eugenol- and hydrogen peroxide 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.
- Prisma® AP.H® Composite material is light-cured material. Therefore, it should be protected from ambient light. Proceed immediately once the material has been placed.
- If mineral-impregnated (e.g., ferric compounds) retraction cords and/or hemostatic solutions are used in conjunction with adhesive procedures, marginal seal may be adversely affected, allowing microleakage, subsurface staining and/or restoration failure. If gingival retraction is necessary, use of plain, non-impregnated cord is recommended.

2.3 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**

2.4 Storage

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product. Keep out of direct sunlight and store in a well ventilated place at temperatures between 10°-24°C/50°-75°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS

Direct Restoration

1. Shade Selection

Shade selection should be made prior to the restorative procedure while the teeth are hydrated. Remove extraneous plaque or surface stain with prophylaxis paste. Match the color coding on the shade guide with the colored cap of the Compule® Tip or the label on the syringe.

2. Cavity Preparation

- Prepare the cavity so that no residual amalgam or restorative material is left.
- Rinse surface with water spray and carefully dry it with air spray. Do not desiccate the tooth structure.
- Use a dental dam or cotton rolls to isolate the cavity from contamination.

3. Placement of Matrix

The use of a Mylar, 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 recommended.

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 Prisma® AP.H® composite material.

5. Placement of Prisma® AP.H® VLC Composite Restorative Material

Syringe

- Remove the cap.
- Turn the handle of the syringe slowly in a clockwise direction and dispense the necessary amount of the material onto a mixing pad.
- Point the front tip of the syringe upwards and turn the handle anti-clockwise to prevent oozing of the material.
- Immediately close the syringe with the cap.
- Protect the restorative material on the mixing pad against light.

Pre-dosed Compules® Tips



Danger of injury due to excessive force

- Apply slow and steady pressure on the applicator gun
- Do not use excessive force – Compules® Tip rupture or ejection from applicator gun may result.

- Insert a Compules® Tip into the notched opening of the Compules® Tips Gun. 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 or to the mixing pad. 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 Optional Flowable Liner: Placement of a compatible flowable liner (available separately) prior to placement of Prisma® AP.H® Composite material is optional. Follow manufacturer's directions for use.

Dispense Prisma® APH® Composite material directly into the cavity preparation/tooth surface 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 syringe 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).

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 550mW/cm² exposure for at least 20 seconds. For darker shades (DY, DG, GB) and opaque shades (UO) cure for another twenty seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The Prisma® APH® Composite material should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.



Inadequate polymerization due to insufficient curing

- Check compatibility of curing light.
- Check curing cycle.
- Check curing output before each procedure.

7. Finishing and Polishing

- Contour the restoration using finishing burs or diamond finishing instruments. Additional finishing is recommended by the use of Enhance® Finishing System. See manufacturer's complete directions for use.
- To achieve a very high luster on Prisma® APH® Composite 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.

4. HYGIENE



Cross-contamination of Compules® Tips

- After intraoral use do not reuse Compules® Tips.
- Properly dispose the intraorally used and/or contaminated Compules® Tips in accordance with local regulations.

4.1 Cleaning and disinfection of the syringe

- To prevent 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 package contamination.
- Disinfect contaminated syringes with a water-based hospital-level disinfection solution according to national/local regulations.
- Repeated disinfection may damage label. **NOTE:** Vigorous wiping can destroy the label. Wipe syringe gently.

4.2 Cleaning and disinfection of Shade Guide

- Disinfect the shade guide holder and individual tabs with a water-based hospital-level disinfection solution according to national/local regulations. Use of chlorine- (bleach), glutaraldehyde-, phenolic-, iodophor- or organic solvent (e.g. alcohol) based or containing products may over time affect the color shade.
- During disinfection, remove individual tabs from the shade guide holder.
- Follow the disinfectant manufacturer's Instructions for Use.
- After disinfection, clean the shade guide holder and individual tabs by scrubbing with water and soap.
- Rinse and dry.
- Do not autoclave the shade guide holder and individual tabs.

4.2 Sterilizing the Compules® Tips Gun

Disassembling

- Partially close the applicator gun and place your thumb on the rear part of the hinge.
- Push upwards and lift hinge. The applicator gun is separated in two parts and the plunger is exposed.
- Remove restorative material with a soft paper tissue and alcohol of 70%.
- The Compules® Tips Gun may be cleaned by scrubbing with hot water and soap or detergent.

Sterilization

- Sterilize the applicator gun by steam autoclave (2.1-2.4 bar and 135-138°C, 30-35 psi and 275-280°F) 3 minutes minimum holding time.
- It is not recommended to submerge Compules® Tips Gun into disinfection solutions.

Reassembling

- After sterilization insert plunger into the applicator gun cylinder.
- Press components together and snap hinge mechanism in place.
- Do not continue to use damaged or soiled applicator guns.

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "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
 - Expiration date



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