TPH®3
MICRO MATRIX RESTORATIVE

CE 0120

DENTSPLY CAULK

DIRECTIONS FOR USE – ENGLISH

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

TPH®3 Micro Matrix Restorative is a visible light activated, radiopaque composite restorative material for anterior and posterior restoration of primary and permanent teeth. It is to be used following the application of a suitable dentin/enamel adhesive and is compatible with all DENTSPLY adhesives designed for use with visible light cured composite restoratives (see complete *Directions for Use* of selected adhesive). Use of other dentin/enamel adhesive systems with TPH®3 Restorative Material is at the discretion and sole responsibility of the dental practitioner.

This one-component, visible light cured composite restorative is packaged in predosed Compules® Tips and 3gm Easy•Twist syringes in 13 Vita®[1] and 9 custom body shades, one opaque characterization shade and 3 enamel shades for a total of 26 shades. Shade matching has been optimized to the Vita® System. Refer to the available shade conversion table for matching Prisma® and Bioform® shades to available equivalent to TPH®3 shades.

TPH®3 Restorative Material may be used with separately available BisGMA-based tints and opaquers at the discretion and responsibility of the dental practitioner for individual custom characterization of the ultimate esthetic direct-placement restoration.

CUSTOM SHADES DESCRIPTION	TPH®3 SHADE	VITA® SHADES DESCRIPTION	TPH®3 SHADE
Light Shades (7)			
Bleach White	BW		
Extra Light	XL		
		Light Reddish Brown	A1
Light	L	Light	B1
Light Gray	LG	Light Gray	C1
Universal Body Shades: Reddish Brown (5)			
Light Medium	LB	Light Medium	A2
		Medium	A3
Dark Medium	DB	Dark Medium	A3.5
Universal Body Shades: Reddish Yellow (2)			
		Light Medium	B2
		Dark Medium	B3
Universal Body Shades: Gray (3)			
Medium	LYG	Medium	C2
		Dark Medium	C3
Characterization Shades (6)			
		Reddish Brown	A4
Dark Reddish Brown	DY		
Medium Gray Opaque	C2-O	Gray	C4
Gray Brown	XGB		
		Reddish Gray	D3
Enamels (3)			
Clear Translucent Enamel	CE		
Yellow Translucent Enamel	YE		
Light Incisal	B1-I		

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

COMPOSITION

The resin matrix of TPH®3 Restorative Material consists of a Bis-GMA adduct, Bis-EMA, and triethylene glycol dimethacrylate.
Camphorquinone (CQ) Photoinitiator
Stabilizer
Pigments

The filler combination consists of a mixture of barium alumino boro silicate glass and barium fluoro alumino boro silicate glass with a mean particle size below 1µm and nanofiller silica (particle size 10-20nm). This combination results in a composite with good strength and wear resistance for posterior use, combined with high surface luster and smoothness which is an essential property for anterior use of a composite.

INDICATIONS

1. TPH®3 Restorative Material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.
2. TPH®3 Restorative Material is indicated as a direct esthetic veneering restorative material and cosmetic reshaping (e.g., diastema closure, incisal lengthening).
3. TPH®3 Restorative Material is indicated for the indirect fabrication of inlays and onlays.

CONTRAINDICATIONS

TPH®3 Restorative Material is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

1. TPH®3 Restorative Material 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: TPH®3 Restorative Material 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: TPH®3 Restorative Material 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 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. The TPH®3 Restorative Material is light-cured material. Proceed immediately once material has been placed on pad or protect from ambient light.
5. Material should extrude easily from the Compules® Tip. 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.
6. Compules® Tips are designed for one time use. Discard after use. Do not reuse.
7. The TPH®3 Restorative Material Easy•Twist syringe should be tightly closed immediately after use.
8. Use of Compules® Tips with the DENTSPLY Caulk Compules® 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.

9. **Storage:** TPH®3 Restorative Material 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. Allow material to reach room temperature prior to use. Excessive humidity can adversely affect the properties of TPH®3 Restorative Material. Protect from moisture. Do not freeze. Do not use after expiration date.
   The TPH®3 Restorative Material shade guide should be disinfected by following the instructions in the *Cleaning and Disinfection* of the TPH®3 Shade Guide section.
   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

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 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.

USE OF THE TPH®3 RESTORATIVE MATERIAL SHADE GUIDE:

The TPH®3 Restorative Material shade ranges include Vita® A, B, C, D:
The Vita® A range has a brown influence; (reddish-brown)
The Vita® B range has a yellow influence (reddish-yellow)
The VIta® C range has a gray influence
The Vita® D range has a reddish, gray influence

The TPH®3 Restorative Material shade guide is to be used to accurately demonstrate the shade of the composite material. The TPH®3 Restorative Material shade guide tab is manufactured from the TPH®3 Restorative Material of the selected shade. The TPH®3 Restorative Material shade guide tab accurately matches the Vita® middle one third (body shade) of the Vita® guide. TPH®3 Restorative Material shade guides may be purchased through an authorized DENTSPLY Caulk distributor.

OPTIMIZING SHADE SELECTION

1. The opacity of TPH®3 Restorative Material has been scientifically designed to allow the tooth structure enamel and dentin to blend together with the composite with a life-like translucent result.
2. The final shade will ultimately result from an interaction of the thickness of the TPH®3 Restorative Material and surrounding tooth structure (either enamel or dentin). The intensity of the shade is related to the thickness or thinness of the final composite restorative material used.
3. The use of a mock-up is an excellent method for shade verification. The technique includes the use of the shade that has been selected in the thickness to approximate that of the final TPH®3 Restorative Material restoration. The material is placed on the clean, hydrated **unetched** tooth in the area of the cavity or restoration on the tooth. The TPH®3 Restorative Material is applied without etch or bonding agent, then cured thoroughly. The dentist, patient and ancillary dental support personnel can co-jointly view the shade selection result. After viewing, the composite material can be removed by the use of a dental explorer or scaler.
4. Be aware of room and ambient light effects on shade selection; Incandescent versus fluorescent lighting versus natural daylight (ideal light is northern exposure/outdoors/overcast).
5. Room accessories can influence shade selection as with colored walls/wall-paper reflection. Also, patient dental napkin should be removed. Observe tooth shades for short periods of time, using a blue background to "neutralize" the effect of extended shade viewing comparisons. Viewing blue background will have a relaxing effect on the viewing operator's photo/color optic discrimination. Eyes should be rested. It is useful to have ancillary corroboration on shade selection by dental personnel as well as by the dental patient.

STEP-BY-STEP INSTRUCTIONS

DIRECT RESTORATION

1. **Shade Selection**
   Before selecting the shade, teeth should be clean, hydrated and free of extrinsic material or stain. Please refer to the *Optimizing Shade Selection* section above.
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 TPH®3 Restorative Material.
5. **Placement of TPH®3 Restorative Material**
   5.1 *Easy•Twist Syringe:* Remove the cap from the Easy•Twist syringe by using lateral force. It is easier to remove the cap in a "snap-off" rather than a "pull-off" motion. Dispense the necessary amount of TPH®3 Restorative Material from the Easy•Twist 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 Easy•Twist syringe upwards and turn the handle counter-clockwise. Recap the Easy•Twist syringe. **Technique Tip:** Protect dispensed TPH®3 Restorative Material from premature polymerization via ambient light while current increment is adapted and light cured.
   5.2 *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.
   5.3 *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 TPH®3 Restorative Material is optional. If desired, follow manufacturer's *Directions for Use.*
   5.4 *Anterior Placement:* Dispense TPH®3 Restorative 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 or Easy•Twist 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)*
   5.5 *Posterior Placement:* Dispense TPH®3 Restorative 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 or Easy•Twist syringe and carried to the preparation with suitable placement instrument.
      5.5.1 Class I and V: TPH®3 Restorative Material may be placed and adapted in 2mm increments, light curing each increment. *(See Curing, Step 6)*
      5.5.2 Class II: Beginning in the proximal box, adapt a 2mm increment of TPH®3 Restorative 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 550mW/cm^2 exposure for at least 20 seconds. For darker shades (A4, C4, DY, XGB) cure for another twenty seconds. Some advanced performance curing units have been shown to cure 2mm increments of most shades of TPH®3 Restorative Material in 10 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The TPH®3 Restorative 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 TPH®3 Restorative 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.*

STEP-BY-STEP INSTRUCTIONS

FABRICATION OF INDIRECT INLAY/ONLAY

1. **Shade Selection**
   Final desired shade selection should be accomplished prior to tooth preparation. Before selecting the shade, teeth should be clean, hydrated and free of extrinsic material or stain. Select the TPH®3 Restorative Material shade guide shade tab that simulates best the final desired result. Mixing layered shades and various thicknesses will allow customized shade adjustability. Please refer to the *Optimizing Shade Selection* section.
2. **Cavity Preparation**
   Cavity design requirements are essentially a conventional preparation. Rounding of internal angles and refinement of the cavo-surface margin for enhancement of enamel bonding and finishing procedures is recommended. 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 luting cement. Refer to adhesive and/or luting cement manufacturer's directions for base/liner/pulp protection requirements.
3. **Impression, Master Cast Fabrication**
   3.1 Make an accurate impression of the preparation following manufacturer's directions for impression material chosen. A material that allows two pours is recommended. Alternatively, two impressions may be made.
   3.2 Prepare and place provisional restoration on the prepared tooth. Use non-eugenol containing material(s).
   3.3 Two casts will be fabricated. One working cast will be indexed and separated, per usual crown and bridge procedures. The second master cast will be used for final contour adjustment. Following impression material manufacturer's instructions for disinfection and impression casting, use of die stone is recommended for cast fabrication. Plating of the impression is not recommended. Additionally, an opposing cast should be prepared and articulated.
4. **Restoration Fabrication**
   4.1 Block out any preparation undercuts present. Apply separating medium and/or die spacer to separated die. In most cases, the restoration may be fabricated in no more than 3 increments, each up to 4mm depth.
   4.2 Apply first increment/shade, creating restoration body. Adapt to die, staying short of margins. Recommended light curing is accomplished by placing in Triad® Light Curing Unit (DENTSPLY Trubyte) for 2 minutes. Apply second, body layer, allowing cut-back for occlusal anatomy and final proximal contour. Repeat Triad® Light Curing. Prior to final "enamel" shade placement, custom staining with appropriate compatible stains may be accomplished per manufacturer's instructions. Apply final layer, slightly overfilling and covering all margins. Replace die into articulated model. Establish all external, proximal and occlusal contacts and anatomy. Slight lubrication of adjacent and opposing model teeth is recommended. Cure briefly (10 seconds) with hand-held visible curing light unit to fix contours. Remove die with restoration, place in Triad Unit for final 2 minute curing.
   4.3 When removing restoration from die, it may be necessary to scrape die stone away from restoration margins, to prevent accidental chipping of restoration. Clean any residual die stone from restoration. Carefully trim away visible flash beyond preparation margins with acrylic bur.
   4.4 Gently sandblast the internal surfaces with 50µ alumina abrasive. Remove visibly undercut material.
   4.5 Seat restoration onto preparation of uncut master cast, making adjustments as needed. Check for marginal integrity and overall fit and contour. Additional increments may be added if needed by roughening surface and applying compatible adhesive per manufacturer's instructions, followed by placement and light curing as outlined above.
5. **Finishing and Polishing (laboratory)**
   Complete as outlined in the above *Finishing and Polishing* section, Step 7 for Direct Restorations.
6. **Cementation**
   Recommended cementation technique is bonding using a dual-cure compatible adhesive and esthetic resin cement. Follow adhesive and cement manufacturer's instructions for prepared tooth and restoration surface pretreatments.
7. **Adjusting, Finishing and Polishing (clinically)**
   Following cementation, make all necessary occlusal adjustments and polish any clinically adjusted surfaces as outlined in the above *Finishing and Polishing* section, Step 7, for Direct Restorations.

CLEANING AND DISINFECTION

To prevent TPH®3 Restorative Material Easy•Twist 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 Compules® Tips. Properly dispose used Compules® Tips.

CLEANING AND DISINFECTION OF TPH®3 RESTORATIVE MATERIAL SHADE GUIDE

The TPH®3 Restorative Material shade guide holder and individual tabs may be cleaned by scrubbing with hot water and soap or detergent. The shade guide holder and individual tabs if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Disinfect the shade guide holder and individual tabs by spraying the shade guide holder and individual tabs with any recommended hospital-level dual or synergized quaternary ammoniums or immersing in hospital-level disinfectant such as dual or synergized quaternaries or glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Chlorine based (bleach), some phenolic-based agents and iodophor-based products should not be used as they may cause surface staining and/or color alteration. Agents containing organic solvents, such as alcohol, should be avoided, as they may tend to dissolve the plastic. Water-based disinfectant solutions are preferred. The disinfectant manufacturer's directions should be followed properly for optimum results.

Following disinfection, thoroughly rinse and dry the TPH®3 Restorative Material shade guide holder and individual tabs before storage. Autoclaving the TPH®3 Restorative Material shade guide holder and individual tabs is not recommended.

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 submerse 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/Easy•Twist Syringe
   - Expiration date on Compules® Tip/Easy•Twist Syringe

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