



TPH Spectra<sup>®</sup> ST  
Universal Composite Restorative

TPH Spectra<sup>®</sup> ST Effects  
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CAUTION: For dental use only.  
USA: Rx only

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## 1 Product description

**TPH Spectra® ST and TPH Spectra® ST Effects** Universal Composite Restoratives are visible light cured, radiopaque, composite restoratives for anterior and posterior restorations and cosmetic and functional reshaping of primary and permanent teeth.

The shading system for **TPH Spectra® ST and TPH Spectra® ST Effects** Universal Composite Restoratives are designed to achieve shade match to the full 16-shade VITA®<sup>1</sup> range with a minimized number of universal shades. The strong chameleon effect of 5 moderate translucency shades, named A1 to A4, provide coverage for the full 16-shade VITA®<sup>1</sup> range. TPH Spectra® ST Effects offers 2 dentin shades and 1 enamel shade that work with the TPH Spectra® ST universal shades in a simplified layering system to provide added opacity and/or translucency as needed in esthetically demanding cases. A custom blended shade guide is available to guide the clinician in shade selection, and a smart i-shade label can be applied to VITA®<sup>1</sup> shade guides for quick shade translation.

### Available Shades

Universal shades

A1 (= VITA®<sup>1</sup> shades A1, B1, C1)

A2 (= VITA®<sup>1</sup> shades A2, B2, D2)

A3 (= VITA®<sup>1</sup> shades A3, C2, D3, D4)

A3.5 (= VITA®<sup>1</sup> shades A3.5, B3, B4, C3)

A4 (= VITA®<sup>1</sup> shades A4, C4)

BW (Bleach White)

Dentin & Enamel Effect Shades: D1, D3, and E1

### 1.1 Indications

TPH Spectra® ST and TPH Spectra® ST Effects Universal Composite Restoratives are indicated for direct or indirect replacement of missing or deficient tooth structure in primary and permanent anterior and posterior teeth, e.g.:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

### 1.2 Contraindications

TPH Spectra® ST and TPH Spectra® ST Effects Universal Composite Restoratives are contraindicated for use with patients who have a known hypersensitivity to methacrylate resins.

### 1.3 Delivery forms

TPH Spectra® ST Universal Composite Restorative is available as HV (High Viscosity) and LV (Low Viscosity) viscosities for preferred handling. TPH Spectra® ST Effects is available as HV (High-Viscosity) only. Both TPH Spectra® ST and TPH Spectra® ST Effects are available in:

- Predosed Compules® Tips
- Syringes

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<sup>1</sup> Not a registered trademark of Dentsply Sirona, Inc.

#### 1.4 Composition

- Methacrylate modified polysiloxane (organically modified ceramic)
- Dimethacrylate resins
- Fluorescent pigment
- UV stabilizer
- Stabilizer
- Camphorquinone
- Ethyl-4(dimethylamino)benzoate
- Bis-(4-methyl-phenyl)-iodonium hexafluorophosphate
- Barium-aluminum-borosilicate glass
- Ytterbium fluoride
- Iron oxide pigments and titanium oxide pigments according to shade

##### **Filler system based on SphereTEC™.**

The filler system comprises barium glass, pre-polymerized filler and ytterbium fluoride:

HV: 78-80 weight-% or 60-62 volume-%

LV: 76-78 weight-% or 57-60 volume-%

Additional ingredients are catalysts, additives, stabilizers and pigments (~1 weight-%, according to shade).

The total amount of inorganic fillers is:

HV: 72-74 weight-% or 50-52 volume-%

LV: 71-72 weight-% or 48-50 volume-%

The particle size of the inorganic fillers ranges from 0.1 to 3.0 µm.



#### 1.5 Compatible adhesives

TPH Spectra® ST and TPH Spectra® ST Effects Universal Composite Restoratives are used following application of a suitable dentin/enamel adhesive and is chemically compatible with conventional (meth)acrylate-based dentin/enamel adhesives including Dentsply Sirona adhesives designed for use with visible light cured composite restoratives (see complete directions for use of selected adhesive).

## 2 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

The material contains methacrylates and polymerizable monomers which may be irritating to skin, eyes and oral mucosa and may cause sensitization by skin contact and allergic contact dermatitis in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, remove material with cotton and alcohol and wash thoroughly with soap and water. 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, remove material from the tissues. Flush mucosa with plenty of water and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

### 2.2 Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use.

Any use of this product inconsistent with these Instructions for Use is at the discretion and sole responsibility of the dental practitioner.

- If refrigerated, allow material to reach room temperature prior to use.
- Contact with saliva or blood composite placement may cause failure of the restoration.
- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- The syringes and Compules® Tips cannot be reprocessed. To prevent syringes (and Compules® Tips when used for indirect application) from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the devices are handled offside the dental unit with clean/disinfected gloves. Discard devices if contaminated.

- As additional precautionary measure, syringes may be protected from gross debris but not from all contamination by applying a protective barrier.
- After intraoral use, discard Compules® Tips and do not reuse in other patients in order to prevent cross-contamination.
- Use of Compules® Tips with the Dentsply Sirona Compules® Tips Gun is recommended.
- The Compules® Tips Gun is only intended to be used with Dentsply Sirona Compules® or Compula® Tips.
- For further information please refer to the Dentsply Sirona Compules® Tips Gun Instructions for Use.
- The shade guide and the individual shade guide tabs cannot be reprocessed. To prevent the shade guide and the individual shade guide tabs from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide and the individual shade guide tabs are handled with clean/disinfected gloves.
- The material should extrude easily. DO NOT USE EXCESSIVE FORCE. Excessive pressure may cause the Compules® Tip to rupture or to eject from the Dentsply Sirona Compules® Tips Gun.
- Tightly close syringes immediately after use.
- Interactions:
  - Do not use eugenol- or hydrogen peroxide-containing materials in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.

- TPH Spectra® ST and TPH Spectra® ST Effects restoratives are light-cured materials. Therefore, they 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

- Eye contact: Irritation and possible corneal damage.
- Skin contact: Irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Contact with mucous membranes: Inflammation. (See Warnings)

### 2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store in a well ventilated place at temperatures between 2 °C and 28 °C (35 °F and 82 °F).
- Keep out of direct sunlight and protect from moisture.
- Do not freeze.
- Do not use after expiration date.

### 3 Step-by-step instructions

#### 3.1 Direct Restoration

Such as: Cavity restoration, veneering, cosmetic and functional re-shaping, core build-up, splinting, amalgam, composite, ceramic and porcelain repairs.

##### 3.1.1 Shade selection

1. Prior to shade selection, clean the tooth surface with prophylaxis paste to remove plaque or surface stain.
2. Select the shade while teeth are hydrated.

TPH Spectra® ST restorative has been scientifically designed to allow the tooth structure enamel and dentin to blend together with the composite with a life-like translucent result. The 5 A shades of TPH Spectra® ST restorative adequately reproduce the traditional 16 VITA®<sup>1</sup> shades.

For esthetically demanding cases requiring special effects to achieve the desired esthetic result, TPH Spectra® ST Effects offers 2 dentin shades and 1 enamel shade that work with the TPH Spectra® ST universal shades in a simplified layering system to provide added opacity and/or translucency as needed.

For shade selection, there are two tools that may be used:

- The VITA® classical shade guide in combination with the i-shade label. The TPH Spectra® ST and TPH Spectra® ST Effects i-shade

label facilitates shade selection by assigning one of five TPH Spectra® ST Universal shades to each of the 16 VITA® shades, in addition to the appropriate TPH Spectra® ST Effects shades if enhanced esthetic effects are desired.

- The TPH Spectra® ST and TPH Spectra® ST Effects shade guide. The TPH Spectra® ST and TPH Spectra® ST Effects shade guide consists of tabs, which are manufactured from composite with optical properties close to those of TPH Spectra® ST and TPH Spectra® ST Effects.

##### 3.1.1.1 Shade selection with VITA®<sup>1</sup> classical shade guide and i-shade label



#### Have the i-shade label ready.

To make sure that the i-shade label is available chair-side, adhere it to the rear side of the VITA®<sup>1</sup> classical shade guide.

1. Select the VITA®<sup>1</sup> classical shade, which best matches the tooth to be restored.
2. Use the i-shade label (see table below) to identify the matching TPH Spectra® ST universal shade, and appropriate TPH Spectra® ST Effect shade(s) if enhanced esthetic effects are desired.

<sup>1</sup> Not a registered trademark of Dentsply Sirona, Inc.

Tooth shade according to the VITA® <sup>1</sup> Classical Shade Guide	A1	B1	C1	A2	B2	D2	A3	C2	D3	D4	A3,5	B3	B4	C3	A4	C4
Recommended TPH Spectra® ST universal shade	A1		A2			A3			A3,5			A4				
Recommended TPH Spectra® ST Effects shades	D1					D3										
	E1															

### 3.1.1.2 Shade selection with the TPH Spectra® ST and TPH Spectra® ST Effects shade guide

Use the shade tabs of the TPH Spectra® ST and TPH Spectra® ST Effects shade guide to select the shade closest to the shade of the area to be restored.



#### Avoid contamination of the shade guide.

To prevent the shade guide from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide is handled offside the dental unit with clean/disinfected gloves. For shade selection, remove individual tabs from shade guide holder.

### 3.1.2 Cavity preparation

1. Prepare the cavity so that no residual amalgam or restorative is left.
2. Use adequate isolation such as rubber dam.
3. Rinse surface with water spray and carefully remove rinsing water. Do not desiccate the tooth structure.

### 3.1.3 Matrix placement and wedging

1. Place a matrix (e.g. Mylar, Automatrix® matrix system, Palodent® Plus matrix system) and wedge. Burnishing of the matrix band will improve contact and contour. Pre-wedging or BiTine® ring placement is recommended.

### 3.1.4 Pulp protection, tooth conditioning/dentin pre-treatment, adhesive application

Refer to adhesive manufacturer's Instructions for Use 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 the material.

### 3.1.5 Application

Apply material in increments immediately after the application of the adhesive. The material is designed to be cured in increments up to a 2 mm depth/thickness.



## Using syringes



### Avoid contamination of the syringe.

To prevent the syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled offside the dental unit with clean/disinfected gloves.

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

## Using Compules® Tips



### Excessive force.

Injury.

1. Apply slow and steady pressure on the Compules® Tips Gun.
2. Do not use excessive force. Compules® Tip rupture or ejection from Compules® Tips Gun may result.

1. Insert Compules® Tip into the notched opening of the Compules® Tips Gun. Be certain that the collar on the Compules® Tip is inserted first.
2. 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.  
**DO NOT USE EXCESSIVE FORCE.**  
Indirect use: Dispense the necessary amount of material onto a mixing pad and protect against light. Apply material into the cavity with a plastic instrument.  
- or -  
Direct intraoral use: dispense the material directly into the cavity preparation using a slow, steady pressure.
3. 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.

**Optional Flowable Liner:** Placement of a compatible flowable liner (available separately) prior to placement of TPH Spectra® ST and TPH Spectra® ST Effects restoratives is optional. Follow manufacturer's directions for use.

### 3.1.5.1 Applying TPH Spectra® ST and TPH Spectra® ST Effects restoratives

1. Dispense the 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 or syringe and carried to the preparation with suitable placement instrument.

2. Adapt, contour and shape with appropriate composite instruments. Material may be placed and light cured in increments up to 2mm [3.1.6 Light-curing].

#### **Technique Tips:**

- Use a single opacity for most common cases: Because the TPH Spectra® ST universal shades are designed to replace both dentin and enamel, a single universal shade is sufficient for most restorations. If esthetic blending of more than one universal shade is desired, shade layers may be individually cured to form a foundation for subsequent shade placement.
- Use multiple opacities for esthetically demanding cases: For esthetically demanding cases such as a large Class IV or a through-and-through Class III, TPH Spectra® ST Effects dentin and enamel shades can be used with TPH Spectra® ST Universal shades in a simplified layering system to provide added opacity and/or translucency.
  - o Restore the palatal half of the tooth with the dentin shade\*. Leave room for the universal shade at the incisal edge.
  - o Place the universal shade along the incisal edge and cure the completed palatal layer.
  - o Restore the facial half of the tooth with the universal shade\*. If increased translucency along the incisal edge is desired, place the enamel shade there, then cure the completed facial layer.

\* Light curing of individual increments required when layer thickness reaches 2 mm.

TPH Spectra® ST and TPH Spectra® ST Effects restoratives resist slumping, allowing carving of the majority of anatomical form prior to visible light curing.

#### **3.1.6 Light curing**

1. Light-cure each increment with a suitable curing light designed to cure materials containing camphorquinone (CQ) initiator, i.e. peak spectral output 440-480 nm. Cure universal A shades, BW, and E1 increments for 10 seconds, and D1 and D3 shades for 30 seconds when using a curing light that has a minimum irradiance of 800 mW/cm<sup>2</sup>.  
Cure universal A shades, BW, and E1 for 20 seconds, and D1 and D3 shades for 40 seconds when minimum irradiance is between 550 mW/cm<sup>2</sup> and 800 mW/cm<sup>2</sup>.  
Refer to curing light manufacturer's Instructions for Use for compatibility and curing recommendations.

## Curing time for 2 mm increments

TPH Spectra® ST and TPH Spectra® ST Effects Curing Recommendations		
shades	Output mW/cm <sup>2</sup>	Curing Time
A1-A4, BW, E1	≥ 550	20 sec
	≥ 800	10 sec
D1, D3	≥ 550	40 sec
	≥ 800	30 sec

### Insufficient curing.



Inadequate polymerization.

1. Check compatibility of curing light.
2. Check curing cycle.
3. Check minimum irradiance.
4. Cure each area of each increment for the recommended curing time.

### 3.1.7 Finishing and polishing

1. Contour the restoration using finishing burs or diamonds.
2. Use Enhance® finishing devices for additional finishing.
3. Prior to polishing, check that surface is smooth and free of defects.
4. For achieving a very high luster of the restoration, we recommend Enhance PoGo®, finishing and polishing instruments or Prisma® Gloss™ Regular and Extrafine polishing paste.

For contouring, finishing, and/or polishing, follow the manufacturer's Instructions for Use.

All shades of TPH Spectra® ST and TPH Spectra® ST Effects restorative are radio-opaque, with a 1 mm radio-opacity equivalent to 2.0 mm radio-opacity of aluminum. Aluminum has a radio-opacity equivalent to that of dentin. Thus 1 mm of material having a radio-opacity equivalent to 1 mm of aluminum has a radio-opacity equivalent to that of dentin.

### 3.2 Indirect restoration: Inlay, onlay or veneer

#### 3.2.1 Shade Selection

Final desired shade selection should be accomplished prior to tooth preparation. Refer to the Shade Selection section above.

#### 3.2.2 Preparation

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. Refer to adhesive and/or luting cement manufacturer's directions for base/liner/pulp protection requirements.

### **3.2.3 Impression, Master Cast Fabrication**

1. Make an accurate impression of the preparation.
2. Prepare master cast and articulate opposing cast per usual technique

### **3.2.4 Restoration Fabrication**

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 2mm depth.
2. Apply first increment/shade, creating restoration body. Adapt to die, staying short of margins. Recommended light curing is accomplished by placing in Triad<sup>®</sup> Light Curing Unit (Dentsply Sirona) for 2 minutes. Apply second, body layer, allowing cut-back for occlusal anatomy and final proximal contour. Repeat Triad<sup>®</sup> 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.

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. Gently sandblast the internal surfaces with 50  $\mu$ m alumina abrasive. Remove visibly undercut material.
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.

### **3.2.5 Finishing and Polishing (laboratory)**

Complete as outlined in the above Finishing and Polishing Section for Direct Restorations.

### **3.2.6 Cementation**

Recommended cementation technique is bonding using a resin cement. Follow adhesive and/or cement manufacturer's instructions for prepared tooth and restoration surface pretreatments.

### **3.2.7 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 for Direct Restorations.

## 4 Hygiene



### Cross-contamination.

1. Do not reuse single use products. Dispose of in accordance with local regulations.
2. Reprocess reusable products according to the instructions.

### 4.1 Compules® Tips Gun

For reprocessing instructions please refer to the Instructions for Use of the Compules® Tips Gun, which is available on our webpage at [www.dentsplysirona.com](http://www.dentsplysirona.com) and [www.dentsply.eu/IFU](http://www.dentsply.eu/IFU).

If requested, we will send you a free printed copy of the Instructions for Use in the language you require within 7 days. In the USA, call 1-800-532-2855. Outside North America, use the order form provided on [www.dentsply.eu/IFU](http://www.dentsply.eu/IFU) for this purpose.

### 4.2 Compules® Tips – cross-contamination



### Cross-contamination.

Infection.

1. Do not reuse Compules® Tips. Dispose of Compules® Tips in accordance with local regulations.

## 4.3 Syringes – cross-contamination



### Cross-contamination.

Infection.

- The syringes cannot be reprocessed.
- To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Do not reuse syringes if contaminated.
- Dispose of contaminated syringes in accordance with local regulations.

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. The use of protective barriers is an additional precautionary measure against gross debris but not against all contamination. Incidental contact of the syringe with water, soap or a water-based hospital-level disinfection solution will not damage syringe body. Do not allow any solution contact with contained material. Discard composite material that has been in contact with any fluid or non-sterile instrument.

Repeated liquid contact may damage label. Dry the syringe with a lint-free single-use cloth.

**NOTE: Vigorous wiping can destroy the label. Wipe syringe gently.**

#### 4.4 Shade guide and individual shade guide tabs – cross-contamination



##### **Cross-contamination.**

Infection.

1. The shade guide and the individual shade guide tabs cannot be reprocessed.
2. To prevent the shade guide and the individual shade guide tabs from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide and the individual shade guide tabs are handled with clean/disinfected gloves. Do not reuse shade guide and the individual shade guide tabs if contaminated.
3. Dispose of contaminated shade guide and the individual shade guide tabs in accordance with local regulations.

#### 5 Lot number ( ) and expiration date ( )

1. Do not use after expiration date. ISO standard uses: “YYYY-MM” or “YYYY-MM-DD”
2. The following numbers should be quoted in all correspondence:
  - Reorder number
  - Lot number
  - Expiration date

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**[These Instructions for Use are based on Master Version 01]**

If you have any questions, please contact

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