



***TPH* SPECTRA™**
UNIVERSAL COMPOSITE RESTORATIVE

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1. Introduction

1.1. Background of Dental Restorative Composite

Dental restorative composites have been introduced into the field of conservative dentistry to minimize the drawbacks of the acrylic resins that replaced silicate cements (the first aesthetic materials available) in the 1940s. In 1955, Dr. Michael Buonocore used phosphoric acid to improve the adhesion of acrylic resins to the surface of the enamel, consequently pioneered total-etch bonding & adhesive dentistry. In 1962, Dr. Ray Bowen developed the bisphenol glycidylmethacrylate (Bis-GMA) monomer in an attempt to improve the physical properties of acrylic resins. These early, chemically cured composites required the base paste to be mixed with the catalyst, leading to problems with the proportions, mixing process and color stability. From 1970, composite materials were photo-polymerizable, eliminating the need for mixing and its drawbacks. At first, an ultraviolet light source was used to provide the required light energy, but its shallow polymerization and negative side-effects led to its replacement by visible (blue) light which is currently in use.

In general, dental composites encompass four main components: (1) the resin matrix or continuous phase comprising a combination of oligomer/monomer system, an initiator/co-initiator system and stabilizers; (2) filler consisting of inorganic particulates such as glass, and/or fused silica or mixed oxides such as silica-zirconia, with certain composites also comprise macro-filler based on pre-polymerized ground composite; (3) the coupling agent, usually an organo-silane that chemically bonds the reinforcing filler surface to the resin; (4) iron oxide pigments and sometimes radio-opacifier dispersed into the mixture of the resin matrix and surface modified filler to provide natural tooth colors and radio-opacity.

The resin matrix of dental composites is generally made up of a (1) system of mono-, di-, tri-functional monomers, multi-functional methacrylate oligomers or even high molecular weight polymers (e.g. Ormocer resin), (2) a free radical polymerization initiation system, which in photocurable composite resins most often is camphorquinone used in combination with a tertiary aliphatic amine co-initiator and (3) stabilizer such as butylated hydroxyl toluene (BHT) for maximizing the storage stability and in-use stability of the uncured resin composite. The monomer system represents the continuous phase and can be viewed as the backbone of the inorganic/ organic composite system. Bis-GMA and derivatives such as ethoxylated bisphenol A dimethacrylate (EBADMA) are widely used monomers for manufacturing current composites alone or in combination

with urethane dimethacrylate. Because BisGMA derived resins are highly viscous, to facilitate the manufacturing process and clinical handling they are diluted with other low-viscosity – low molecular weight – monomers, such as ethylene glycol dimethacrylate (EGDMA) or triethylene glycol dimethacrylate (TEGDMA) to name a few.

The filler or dispersed phase is designed to enhance the strength of the softer organic polymer phase and usually consists of glass particles of different compositions, sizes, and size distributions. Filler size is only one of several parameters that affect the overall properties of a composite resin. The filler type, shape, and amount, as well as the filler/resin coupling agent contribute to the material and handling performance.

1.2. TPH Spectra™ Features & Benefits

TPH Spectra™ Universal Composite Restorative is a visible light cured, radio-opaque, composite restorative material fully compliant with ISO and ADA standards. TPH Spectra™ Universal Composite Restorative is intended to be used as a dental restorative material that can be used as a direct restorative for all cavity classes in anterior and posterior teeth, as a direct esthetic veneering restorative material and for the indirect fabrication of inlays and onlays.

TPH Spectra™ Universal Composite Restorative is built on DENTSPLY/Caulk's legendary TPH composite family which has over twenty years of proven clinical success since the first launch of Prisma TPH in 1992, followed by TPH Spectrum in 1996, and most recently TPH³ in 2004. The TPH composite family has exhibited exceptional clinical performances and great commercial success due to their excellent physical properties, remarkable handling characteristics, and outstanding quality control.

With the ever increasing demands of one universal composite that can cover both anterior and posterior applications, along with higher needs of simplified shading system, there is a true clinical aspiration for a single universal composite system that can provide both creamy and stiff handling, easier shade selection system, better staining resistance, and still maintain well balanced esthetic and physical properties. Hence, TPH Spectra™ Universal Composite Restorative was developed to meet all these desired clinical and patients needs that can greatly improve the efficiency and productivity of clinician's ever-increasing composite restorations, as well as achieve the patients' increased demands for more esthetic and color stable composite restorations.

The TPH Spectra™ Universal Composite Restorative's major feature and benefit are summarized below:

Feature	Benefit
Dual Handling Options	Ensure handling meets preference of doctor
Simplified Shading	Easy shade match Reduced # of shades to stock in inventory
Stain Resistance	Color of completed restoration does not change over time
Optimized Filler Package	Excellent Polish and Physical Properties

1.3. Composition

TPH Spectra™ Universal Composite Restorative has two different filler loadings to offer two drastically different handling options, in order to accommodate different handling preferences from different clinicians under different restoration circumstances. For example, TPH Spectra™ LV (Low Viscosity) provides spreadable handling so materials flows with the instruments and goes where clinicians want it to go. TPH Spectra™ HV (High Viscosity) provides a firm, sculptable handling. Regardless of the handling desired for particular indications, either viscosity of TPH Spectra™ Universal Composite Restorative is suited to be used universally in both anterior and posterior restorations.

TPH Spectra™ HV (High Viscosity) has incorporated 77.2 wt% / 57.0 vol% filler and TPH Spectra™ LV (Low Viscosity) has 75.5 wt% / 54.6 vol% filler. The resin matrix contains urethane modified Bis-GMA resin; TEGDMA; Polymerizable Dimethacrylate Resin; Camphorquinone (CQ) photoinitiator; Ethyl-4(dimethylamino)benzoate photoaccelerator; Butylated hydroxy toluene (BHT); UV stabilizer; Silanated barium-alumino-borosilicate glass; Silanated barium-boron-fluoro-alumino-silicate glass; Silicon dioxide; Fluorescent agent; Synthetic Inorganic Iron oxide pigments, and Titanium dioxide.

2. Indications for Use

- TPH Spectra™ Universal Composite Restorative material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.
- TPH Spectra™ Universal Composite Restorative material is indicated as an anterior direct esthetic veneering material.
- TPH Spectra™ Universal Composite Restorative material is indicated for the indirect fabrication of inlays and onlays.

CONTRAINDICATIONS

- TPH Spectra™ Universal Composite Restorative material is contraindicated for use with patients who have a known hypersensitivity to methacrylate resins.

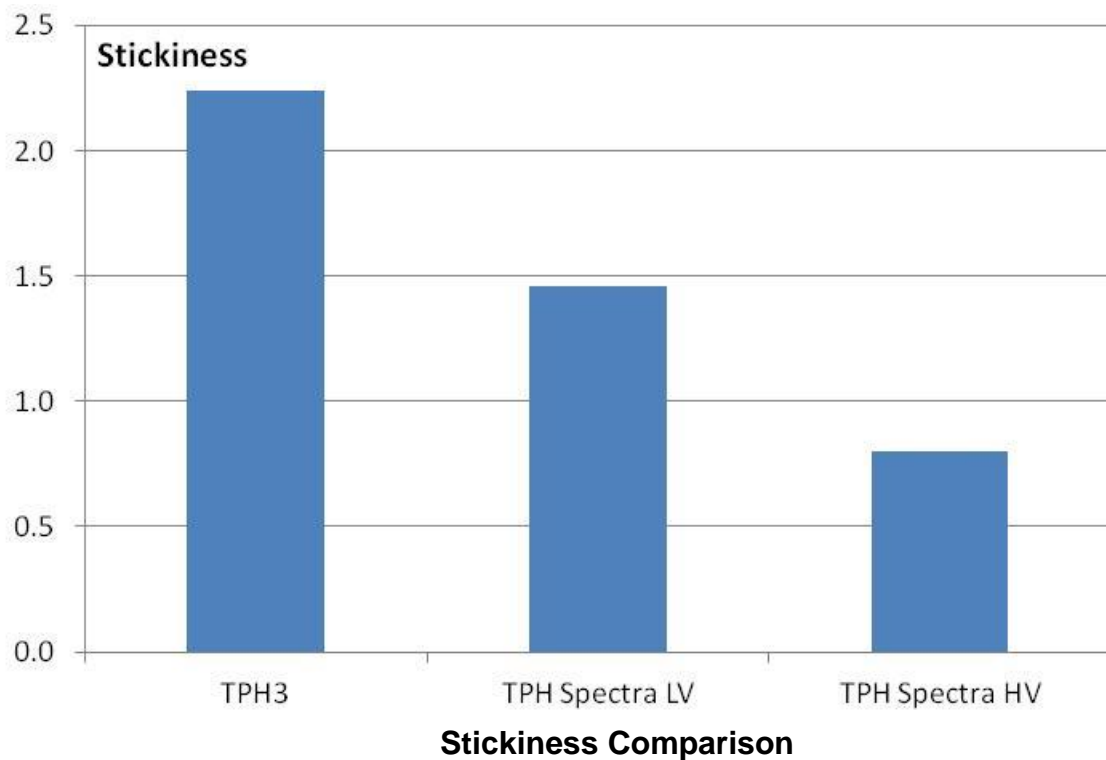
3. Physical Properties

The data presented in the following sections represents those *in vitro* test procedures that are designed to closely approximate clinically relevant properties of the TPH Spectra™ Universal Composite Restorative material. All results for individual test results presented were performed in the same laboratories under identical conditions wherever possible. Thus, within each group of test results, comparison among products may be inferred. Caution should be applied when attempting to compare similar test results from different laboratories due to potentially different test conditions, parameters, etc. Where noted, accepted, standardized International Standards Organization (ISO) test methods were utilized in performing the testing.

3.1. Handling Investigation

Unlike conventional single consistency composite, TPH Spectra™ Universal Composite Restorative offers two drastically different handling options, hence making it able to accommodate different handling preferences from different clinicians under different restoration circumstances.

Stickiness Measurement: Dentsply Internal Method. TA.XT Plus Texture Analyzer (Texture Technologies inc.) with a temperature control chamber was used. Stickiness was tested at 35.5 ± 0.5 °C. A stainless steel spherical probe is guided to contact a composite with constant load and pulled back. The maximum separation distance (Stringiness) is measured to characterize the stickiness of composite. Lower value is less sticky.



As revealed in the stickiness test results above, both TPH Spectra™ LV and TPH Spectra™ HV have achieved reduced stickiness as compared to original TPH³, especially for TPH Spectra HV. The combination of reduced stickiness, improved slump resistance and low tack force make either viscosity of TPH Spectra ideal for universal use (anterior and posterior restorations).

3.2. Shade Simplification

Based on TPH Composite family's legendary history and clinically proven success, TPH Spectra™ Composite is able to offer superior color adaptation (Chameleon Effect) because of the well balanced refractive index matches between resin matrix and filler system and fine-tuned shading system. The TPH Spectra™ Universal Composite Restorative shade guide is to be used to accurately demonstrate the shade of the composite material. The TPH Spectra™ Universal Composite Restorative shade guide tab is manufactured from the TPH Composite materials of the selected shade.

TPH Spectra™ Universal Composite 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 basic shades of TPH Spectra™ Universal Composite Restorative adequately reproduce many of the traditional Vita® shades. See the shade coverage table below:

TPH Spectra™ Universal Composite Restorative Shades

TPH Spectra™ Shades

	B1	A1	A2	C2	A3	A3.5	A4
B1	●	●	●	●	●		
A1	●	●	●	●	●		
B2	●	●	●	●	●		
D2			●	●	●		
A2			●	●	●	●	
C1			●	●	●	●	
C2			●	●	●	●	●
D4			●	●	●	●	●
A3			●	●	●	●	●
D3			●	●	●	●	●
B3			●	●	●	●	●
A3.5				●	●	●	●
B4				●	●	●	●
C3					●	●	●
A4						●	●
C4						●	●

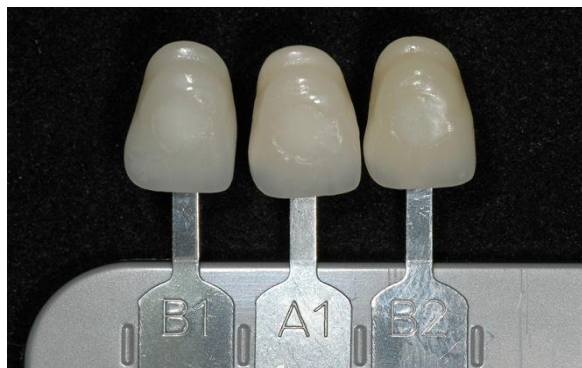
VITA® Shades
(Dark → Light)

TPH Spectra™ Universal Composite Restorative shade coverage was determined by the shade matching / blending of TPH Spectra™ restorations in Vita® Classical Shade tabs. In the center of each Vita® Classical Shade tab, a cavity of 2-3 mm in diameter and 2 mm in depth was prepared. The cavity was restored with TPH Spectra™ Restorative material. The restoration was finished and polished by Dentsply Enhance® Finishing System. The restored tab was wetted with a thin film of glycerin and the shade match / blending was judged by a color panel comprised of individuals certified in color matching.

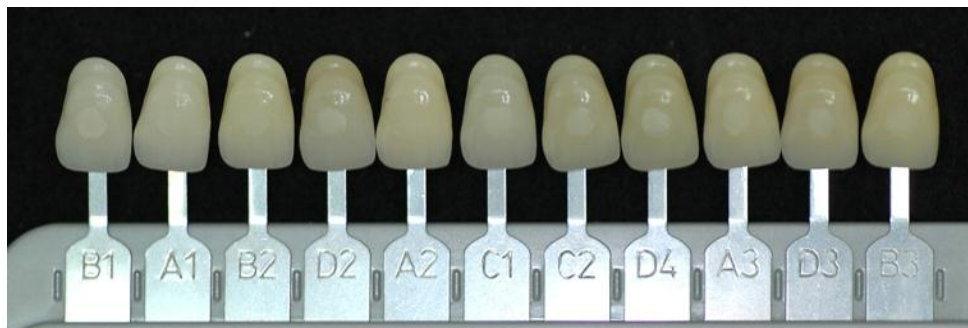
The excellent color blending and multiple Vita®-shades matching capability of TPH Spectra™ is demonstrated in the following pictures, where each shade of TPH Spectra™ is filled into various Vita®-shade tabs with pre-drilled holes and then light cured:



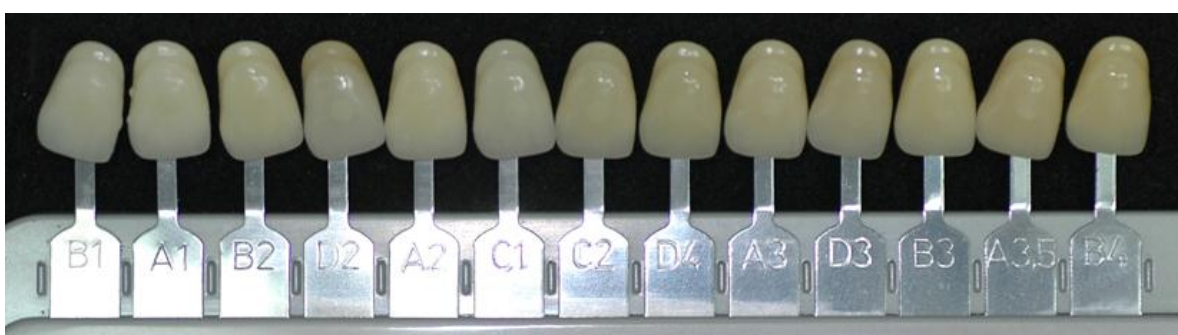
B1 shade of TPH Spectra™ filled into various Vita® Shade Tab



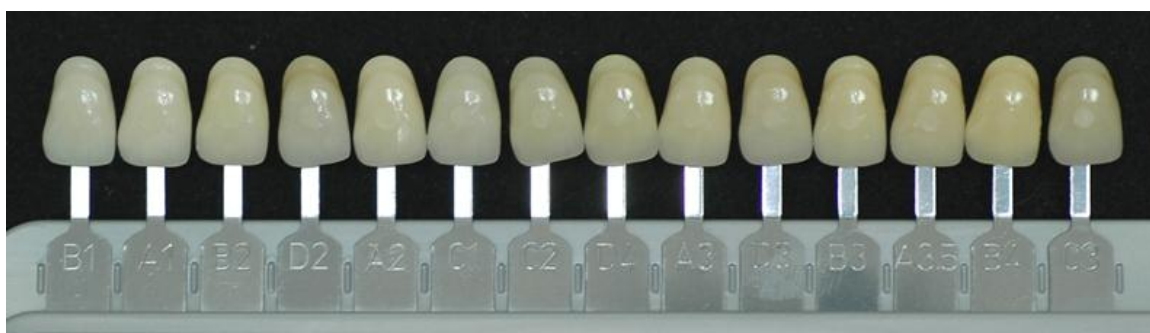
A1 shade of TPH Spectra™ filled into various Vita® Shade Tab



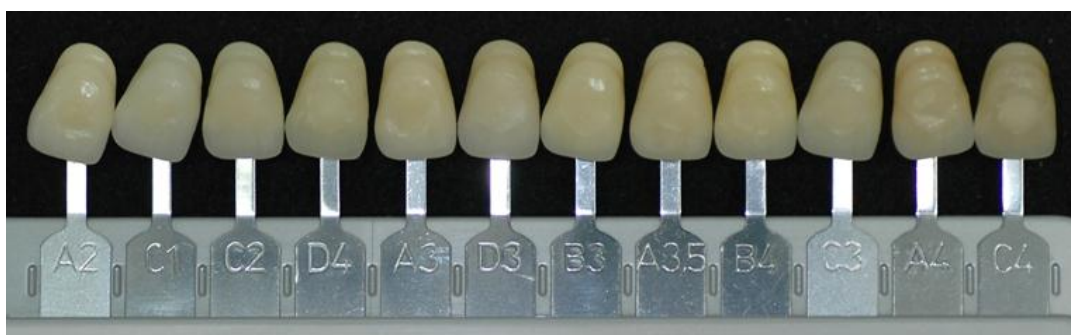
A2 shade of TPH Spectra™ filled into various Vita® Shade Tab



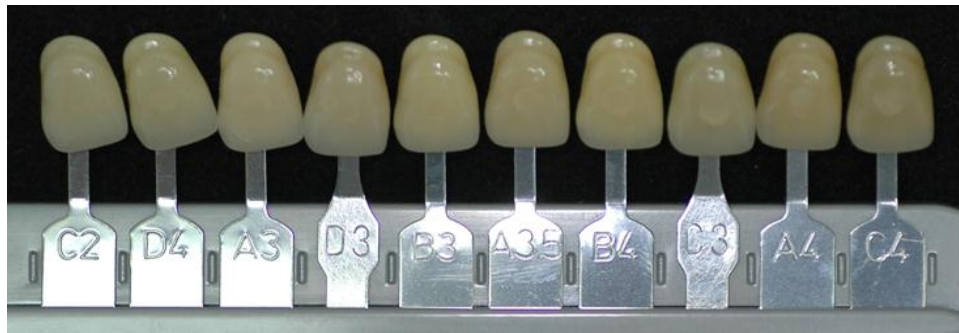
C2 shade of TPH Spectra™ filled into various Vita® Shade Tab



A3 shade of TPH Spectra™ filled into various Vita® Shade Tab







A3.5 shade of TPH Spectra™ filled into various Vita® Shade Tab



A4 shade of TPH Spectra™ filled into various Vita® Shade Tab

Additional Complementary shades are available for extended characterizations.

 LV LOW VISCOSITY		 HV HIGH VISCOSITY	 LV LOW VISCOSITY Complementary Shades
A1		A1	LB
A2		A2	DB
A3		A3	L
A3.5		A3.5	LG
A4		A4	LYG
B1		B1	C3
C2		C2	B2
 UNIVERSAL COMPOSITE RESTORATIVE			B3
			C1
			C4
			D3
			BW
			XL
			DY
			XGB
			B1-I
			CE
			YE
			C2-O

3.3. Depth of Cure: ISO 4049

ISO 4049 Depth of Cure. The restorative material was light cured for 20 seconds in a stainless steel mold with a cylindrical chamber, 4mm in diameter and 6mm deep and a Whatman No. 1 filter paper background with a Spectrum 800 halogen light at an intensity of $\sim 550 \text{ mW/cm}^2$ or a Smart IQ² LED light at an intensity $< 550 \text{ mW/cm}^2$. The uncured side was scraped away immediately after cure using a plastic spatula and the thickness of the remaining, cured composite was measured by a micrometer. The depth of cure was the remaining thickness divided by two.

ISO 4049:2009E Depth of Cure (higher is better)

Material	TPH Spectra A2
Halogen Light Depth of Cure, mm	2.8
LED Light Depth of Cure, mm	2.9

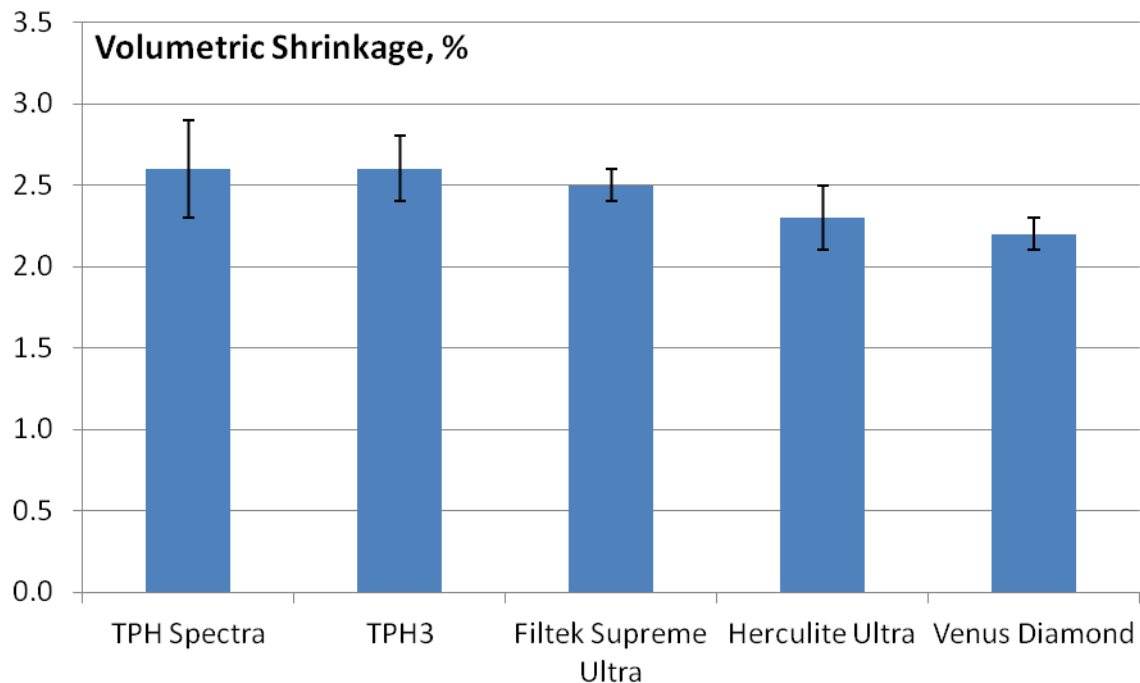
TPH Spectra™ Universal Composite Restorative material may be placed and light cured in increments up to 2mm. Both TPH Spectra™ LV and TPH Spectra™ HV materials have a depth of cure over 2.0 mm per ISO 4049 method under either halogen light or LED light, therefore meet ISO 4049 requirement.

3.4. Polymerization Shrinkage

The polymerization shrinkage was evaluated using DENTSPLY/Caulk's internal method. Cured composite specimens were prepared by curing the composite in a stainless steel mold, 2.5 mm thick x 10mm in diameter, with Halogen light Spectrum 800 for 60 seconds each side at the room temperature. The densities of uncured and 24 hour post-cured restorative materials were determined by Helium Pycnometer (MicroMeritics AccuPycII 1330/1340). The volume shrinkage was calculated as:

$$\% \text{ volumetric shrinkage} = [\text{density}(\text{cured}) - \text{density}(\text{uncured})] / \text{density}(\text{cured}) \times 100$$

Volumetric Shrinkage

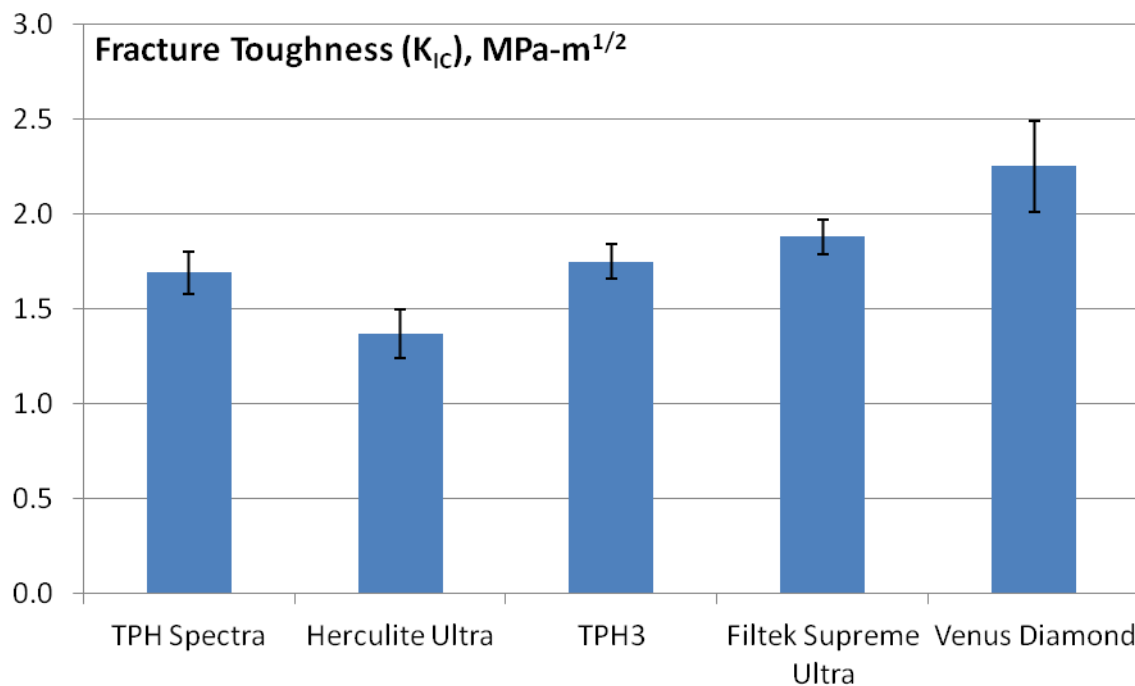


The polymerization shrinkage of TPH Spectra™ Universal Composite Restorative material is statistically equivalent to Filtek Supreme Ultra, Herculite Ultra, and Venus Diamond restorative materials.

3.5. Fracture Toughness

The fracture toughness was investigated using DENTSPLY/Caulk's internal method (as currently there is no ISO method for dental composites). Stainless steel mold with a stick-shaped chamber, dimensions 25 x 2 x 5 mm was filled with composites and covered with a Mylar sheet. The stick-shapes specimens were prepared by light curing the composite for 20 seconds 3 times each side with a Spectrum 800 halogen light at a light intensity of 550 mW/cm². After storage in deionized water at 37°C for 24 ± 2 hours, the specimens were cut a 2.3 - 2.7 mm deep notch by a high speed table saw. The fracture toughness was obtained in the compressive mode under a three-point loading with Instron 3366 at a crosshead speed of 0.50 mm/min.

Fracture Toughness

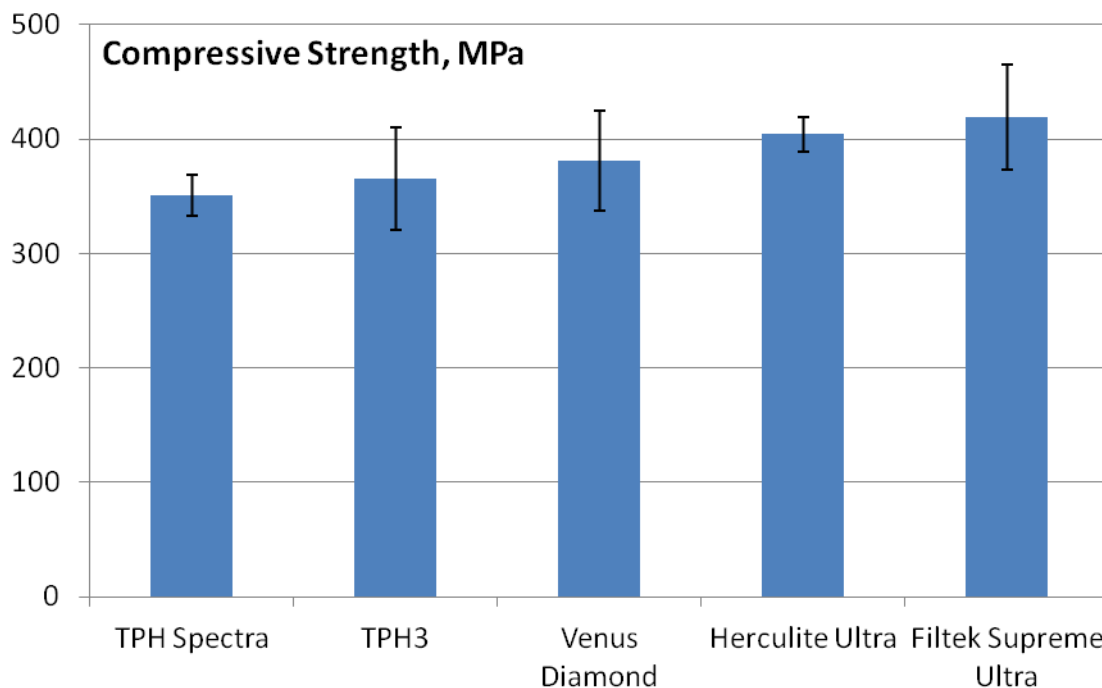


The fracture toughness of TPH Spectra™ Universal Composite Restorative material is statistically equivalent to TPH³ restorative material, and higher than Herculite Ultra material.

3.6. Compressive Strength

Compressive strength was measured based on DENTSPLY/Caulk's internal method. Glass mold, for the preparation of a cylindrical specimen, 7 mm long x 4mm in diameter, was filled with restorative composite and sandwiched between two Mylar cover sheets. The composites were light cured both sides for 20 seconds with a Spectrum 800 halogen light at a light intensity of 550 mW/cm². After storage in deionized water at 37°C for 24 hours, the specimens were polished to 6mm long x 4mm in diameter using 600 grit sand paper. The compressive strength was obtained with Instron 3366 at crosshead speed of 5 mm/min.

Compressive Strength



The compressive strength of TPH Spectra™ Universal Composite Restorative is statically equivalent to that of Filtek Supreme Ultra, TPH³, and Venus Diamond restorative materials.

3.7. Polishability

The polishability resin composites and compatibility of resin composite to a certain finishing / polishing system is mainly determined by the filler size and filler nature in the composite. For composites with multi-mode fillers (fillers with different sizes), the larger size fillers generally dominate the polishability. The finish/polish system used also plays an important role. The nature of the resin system, such as the compliance or the brittleness responses of the resin to the finishing / polishing system, plays a relatively minor role in the polishability and compatibility.

Principal Investigators:

Dr. Yanfang Ren, DDS, PhD, MPH, and Dr. Hans Malmstrom, DDS, University of Rochester Eastman Institute for Oral Health, Rochester, NY, USA

Objective:

The purpose of this study is to evaluate surface finish and gloss of Caulk composite polishing systems on TPH Spectra™, and compare it to other competitors' polishing system on their own composite.

Methods:

15 each 10x3mm round disks were prepared for each group. Composites were placed in a round 10x3mm Teflon mold and mylar sheets were placed over each surface of the uncured composite to prohibit oxygen inhibition. Glass plates were placed over the mylar sheets and pressed with claps to extrude the excess material. The specimens were then light-cured in a TRIAD 2000 visible light-curing unit (Dentsply) for two minutes on each side. Immediately after the light-curing cycle the specimens were taken from the mold and one side of each specimen were finished with a #320 sand paper with light pressure removing the initial shiny surface resulting from curing against the Mylar sheets. Specimens of each resin composite were then paired with the polishing system listed below. One person performed the finishing and polishing. Each polishing device was used only once, the polishing motion was circular and constant. The polishing devices were used dry and the same slow-speed hand piece was used for all experiments.

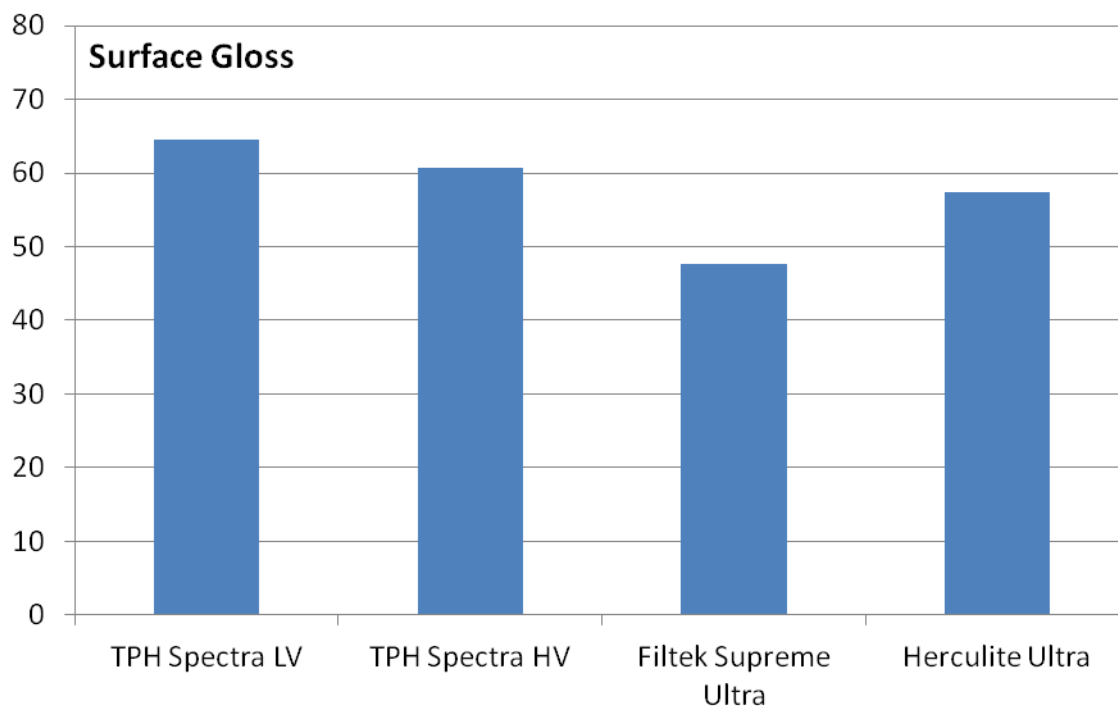
Gloss were measured using a small-area glossmeter (Novo-Curve, Rhopoint Instrumentation, East Sussex, UK), with a square measurement area of 2 × 2 mm and 60° geometry. Gloss measurements were expressed in gloss units (GU). A black polycon container were placed over the specimen during measurements to eliminate the influence of the overhead light.

Products Investigated:

Resin Composites	Polishing Systems
Filtek Supreme Ultra A2 enamel shade (3M ESPE)	Sof-Lex discs (<i>3M/ESPE</i>) Finishing: Coarse + Medium Polishing: Fine + Superfine
Herculite Ultra A2 (Kerr)	OptiDisc (<i>Kerr</i>) Finishing : Extra coarse + Coarse/Medium Polishing: Fine + Extrafine
TPH Spectra LV (Dentsply Caulk)	Finishing: Enhance finishing discs (<i>Dentsply Caulk</i>) Polishing: PoGo polishing discs (<i>Dentsply Caulk</i>)
TPH Spectra HV (Dentsply Caulk)	Finishing: Enhance finishing discs (<i>Dentsply Caulk</i>) Polishing PoGo polishing discs (<i>Dentsply Caulk</i>)

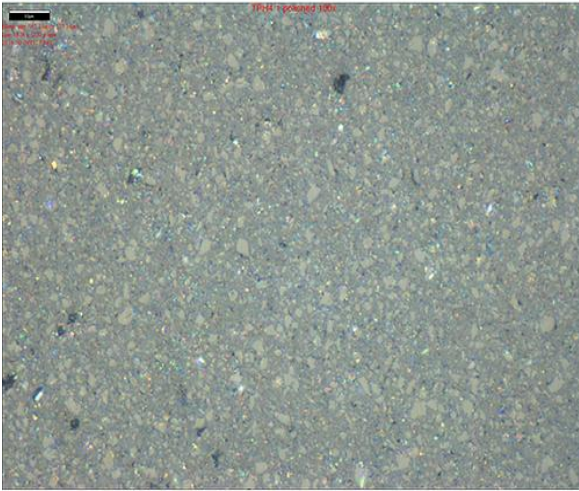
Surface Gloss (higher is better):

Overall, TPH Spectra™ materials polished with Enhance and Pogo disks are superior to other products in term of surface gloss.





500x, bar = 50 um

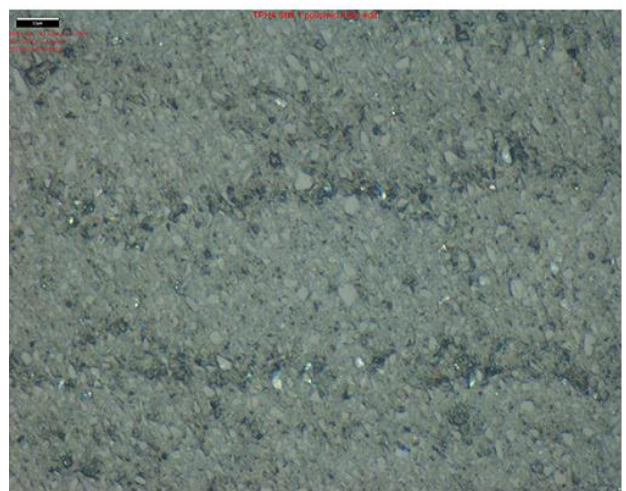


2000x, bar = 10 um

TPH Spectra™ LV

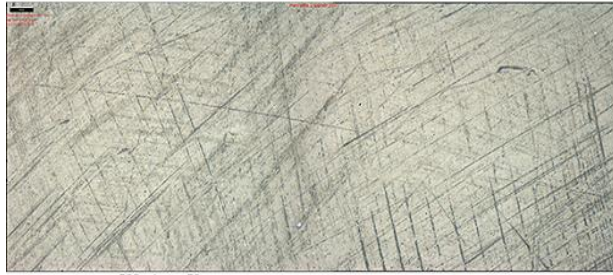


500x, bar = 50um



2000x, bar = 10um

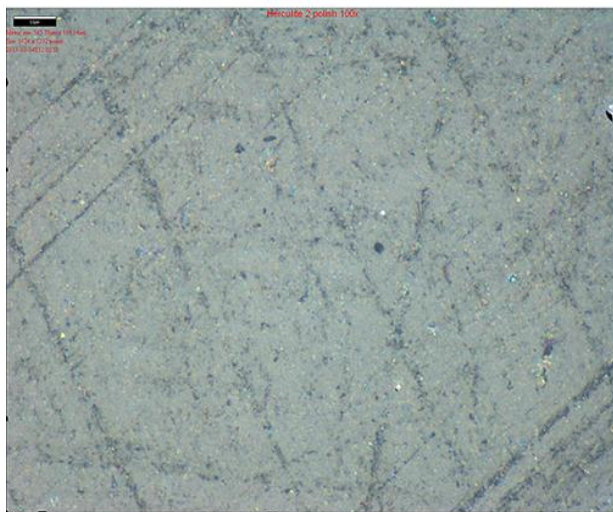
TPH Spectra™ HV



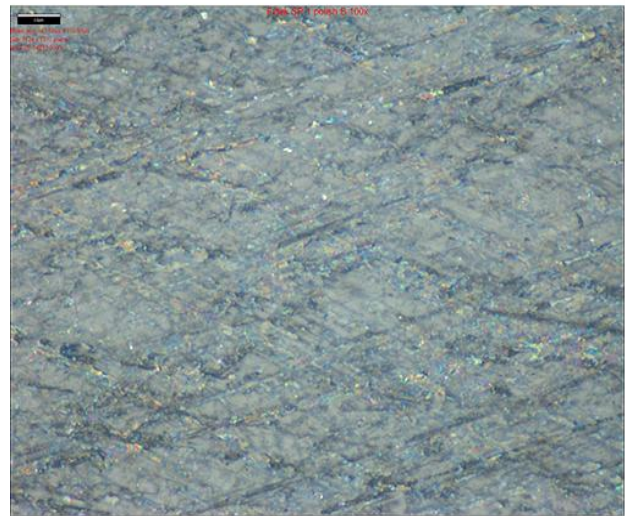
500x, bar = 50um



500x, bar length = 50 microns



2000x, bar = 10um



2000x, bar length = 10 microns

Herculite Ultra

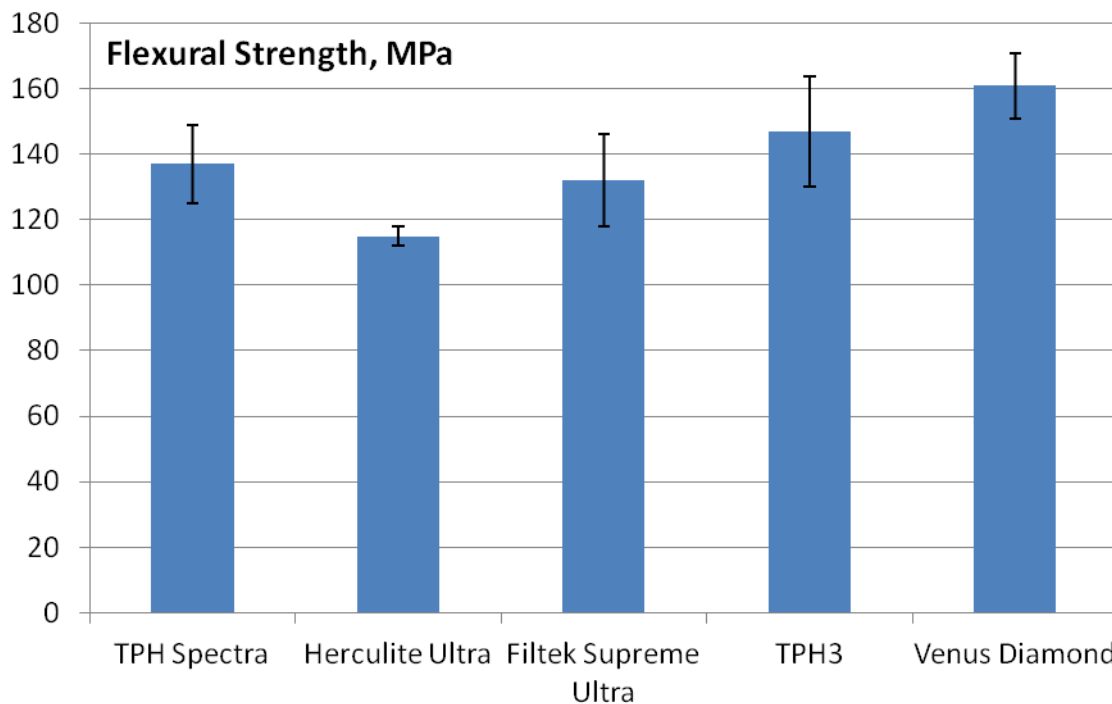
Filtek Supreme Ultra

3.8. Flexural Strength and Modulus

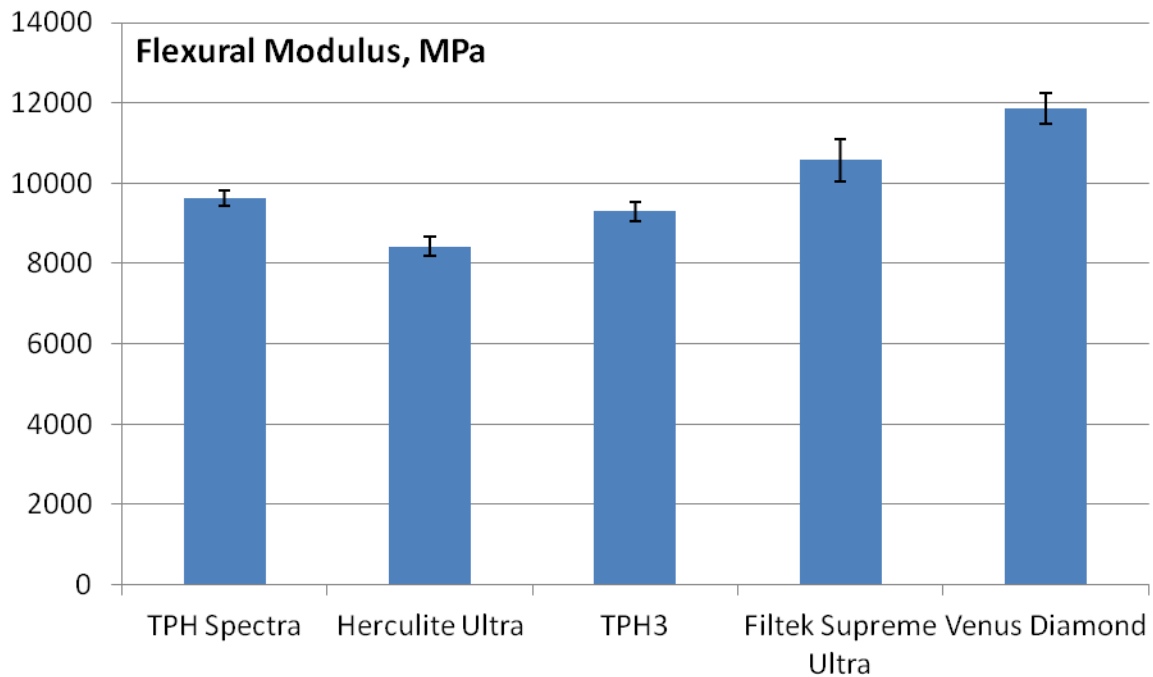
ISO 4049 - Flexural Strength. Stainless steel mold with a stick-shaped chamber, dimensions 25 x 2 x 2 mm was filled with composites and covered with a Mylar sheet. The stick-shapes specimens were prepared by light curing the composite for 20 seconds 3 times both sides with a Spectrum 800 halogen light at a light intensity of 550 mW/cm². After storage in deionized water at 37°C for 24 hours, the flexural strength was obtained in compressive mode under a three-point loading with Instron 3366 at a crosshead speed of 0.75 mm/min.

Flexural strength measures the strength of the material under 3-point bending. Flexural modulus measures the stiffness of the material.

Flexural Strength



Flexural Modulus



Both the flexural strength and flexural modulus of TPH Spectra™ Universal Composite Restorative material are not statistically different from those of TPH³ material.

3.9. Radiopacity

The radiopacity was measured based on ISO 4049. 1.0 mm thick disk composite specimen was cured in disk stainless steel mold, 1mm thick x 30mm in diameter, with Triad 2000 for 2 minutes each side. Radiopacity of a restorative material was determined by comparing the optical density of a radiograph of a 1.0 mm thick cured material to that of a 0.5, 1, 1.5, 2.0, 2.5, 3.0 mm stepped standard aluminum block.

Radiopacity (higher is better)

Material	TPH Spectra LV	TPH Spectra HV
Radiopacity, mm Al	2.13	2.15

Radiopacity indicates the visibility of composite restorations on X-ray radiographs. As shown in the following radiograph, the restoration with TPH Spectra™ Universal Composite Restorative material (on the right side) has better visibility than the restoration with a radio-translucent restorative material (on the left side).



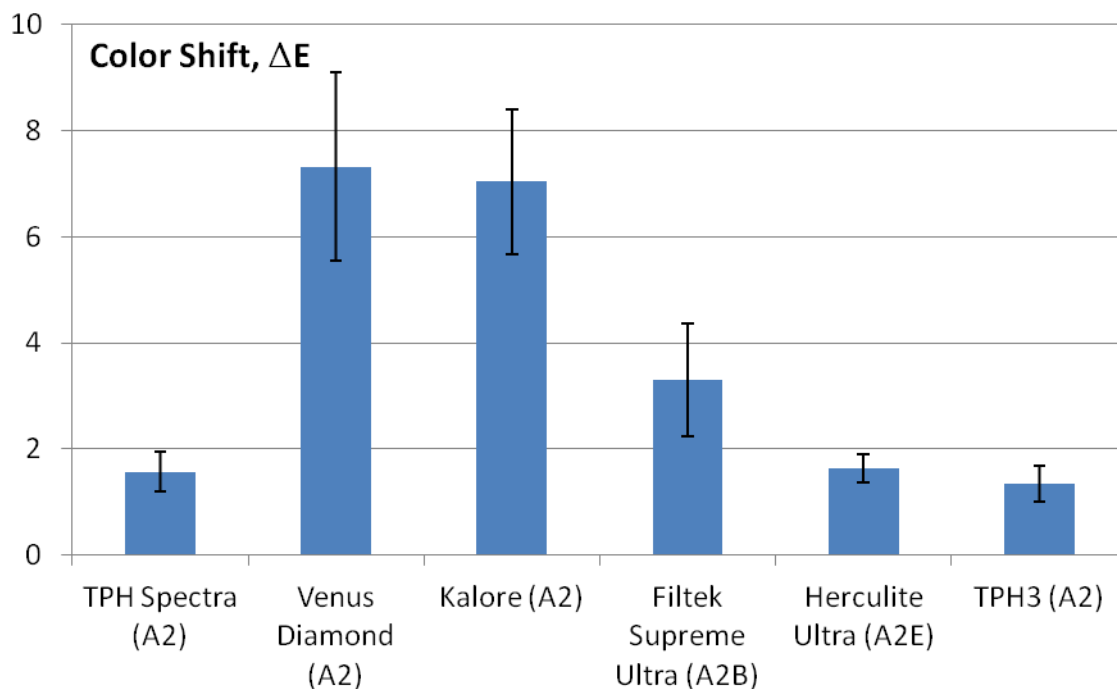
3.10. Staining Resistance

Cured composite specimens were prepared by curing the composite in a stainless steel mold, 1 mm thick x 15 mm in diameter, with Triad 2000 curing light for 2 minutes each side at room temperature. The cured specimens were post-treated at 37°C in DI water for at least 24 hours. The treated specimens were soaked in 30 mL red wine (Cashmere by Cline Cellars) at the room temperature for 24 hours. After soaking for 24 hours at room temperature each chip was vigorously rinsed under water for approximately 5 seconds on both sides, then blotted dry with Kimwipes. The color values (CIE - L, A, B values) of each color chip were determined by X-rite Color Eye before and after the red wine staining.

The color difference after the red wine staining is calculated as:

$$\Delta E = \sqrt{(\Delta A)^2 + (\Delta B)^2 + (\Delta L)^2}$$

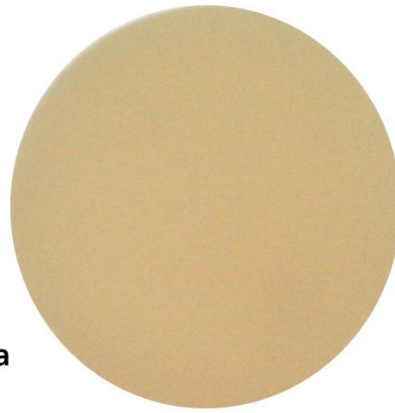
Color Shift after Staining



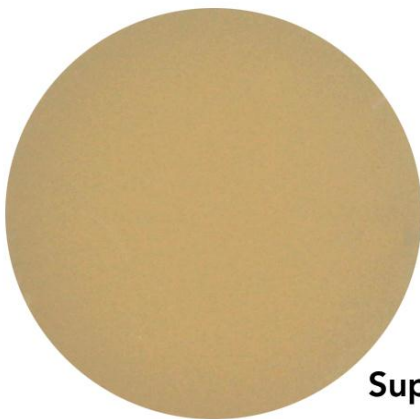


Prior to Staining

TPH Spectra

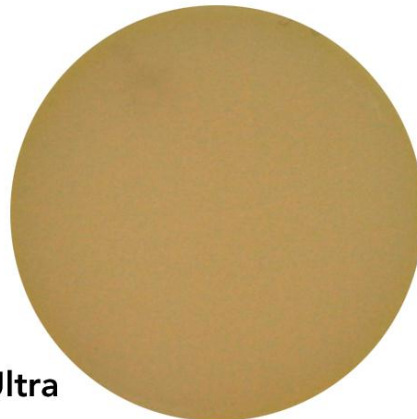


After Staining



Prior to Staining

**Filtek
Supreme Ultra**



After Staining

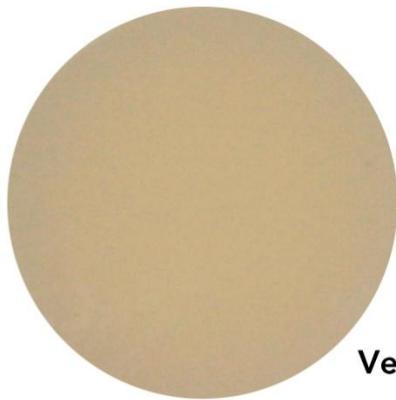


Prior to Staining

Kalore

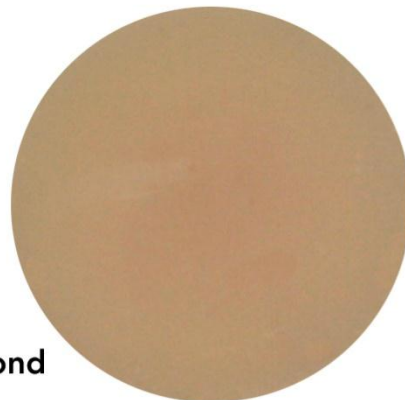


After Staining



Prior to Staining

Venus Diamond



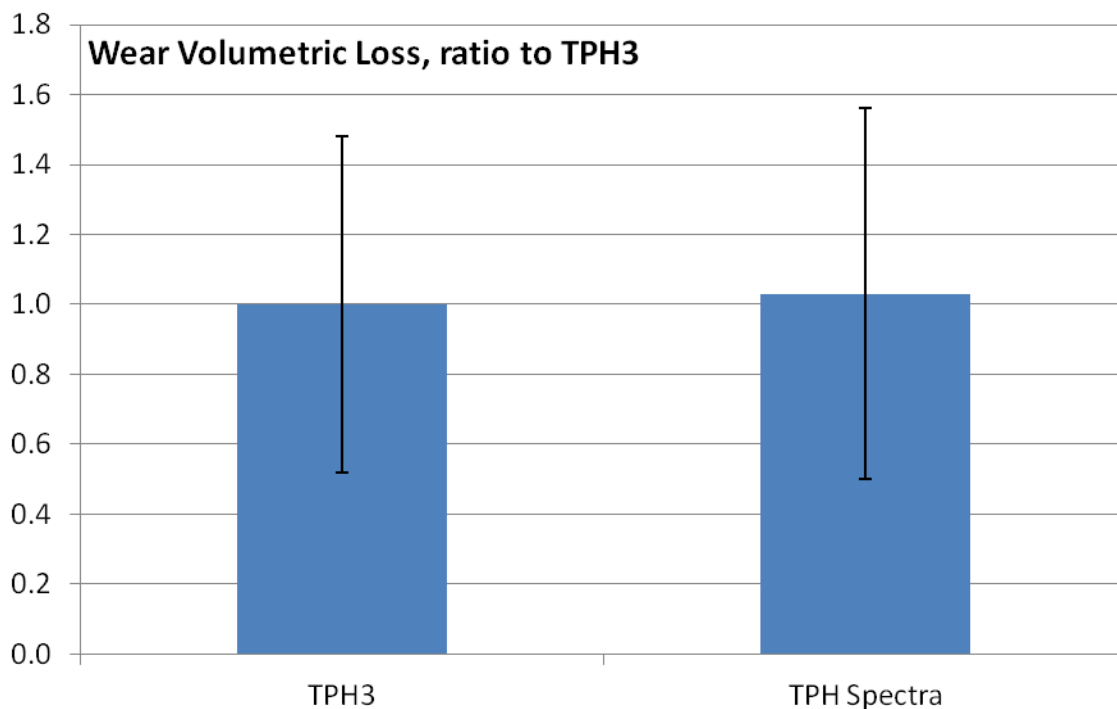
After Staining

It can be found Venus Diamond, Kalore, and Filtek Supreme Ultra restorative materials have a much larger color shift (much worse red wine staining resistance) as compared to TPH Spectra™ Universal Composite Restorative material, which has statistically equivalent color shift to TPH³ material after red wine staining. The excellent stain resistance of TPH Spectra™ Universal Composite Restorative material will greatly improve its esthetic and service life of restoration.

3.11. Three-Body Wear Resistance

The three-body wear resistance was evaluated using DENTSPLY/Caulk's internal method. Cured composite specimens were prepared by curing the composite in a stainless steel mold, 3 mm thick x 20 mm in diameter, with Triad curing light for 2 minutes each side at room temperature. The cured specimens were post-treated at 37°C in DI water for at least 72 hours. The treated specimens were loaded onto the Leinfelder wear testing machines, using PMMA particle / water as the media. The wear testing ran 500K cycles under 75N load at 2Hz. The wear volume loss was measured by Talysurf CLI 1000 profilometer (Taylor Hobson Precision).

Wear Volumetric Loss)



It was found the three-body wear volumetric loss of TPH Spectra™ Universal Composite Restorative material is statically equivalent to that of TPH³ material, which has a very long, good track record of excellent wear resistance.

3.12. Water Solubility & Water Sorption

This test was based on ISO 4049. The light cured specimens (1 mm thick by 15 mm in diameter) were transferred, to a desiccators maintained at 37⁰C. After 22 hours, the specimens were removed and stored in a second desiccator maintained at 23⁰C for 2 hours and then weighed. This cycle was repeated until a constant mass, m₁, was obtained. After the final drying, measurements were made of the diameter and the thickness in order to calculate the volume, V. The specimens were immersed in water at 37⁰ C for 7 days in such a way that they are vertical, having a minimum of 3 mm separation between specimens. After 7 days, the specimens were removed, washed with water, surface water blotted until free from visible moisture, dried in the air for 15 seconds, and weighed 1 min. after removal from the water. This mass was recorded as m₂. After this weighing, the specimens were reconditioned to constant mass in the desiccator. Record the constant mass as m₃.

The values for water sorption, Wsp, were calculated using the following equation:

$$Wsp = (m_2 - m_3) / V$$

The values for solubility, Wsl, were calculated using the following equation:

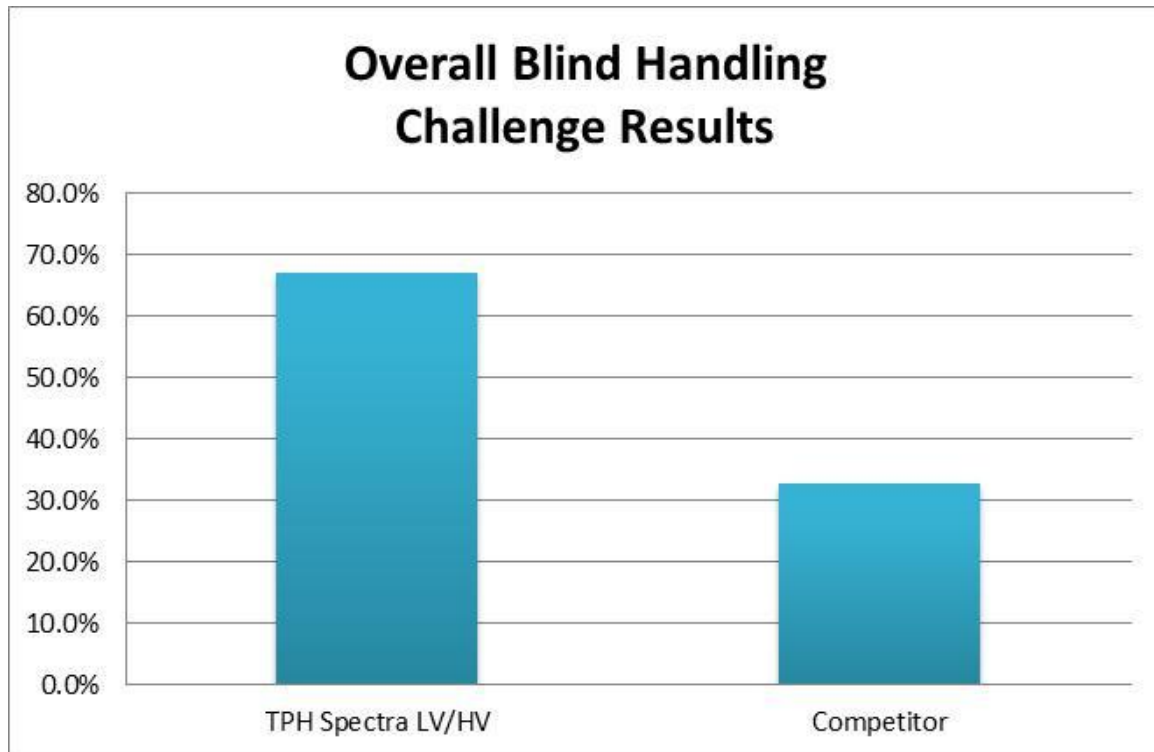
$$Wsl = (m_1 - m_3) / V$$

Material	Water Sorption, µg/mm ³	Water Solubility, µg/mm ³
TPH Spectra™	11.0	0

TPH Spectra™ Universal Composite Restorative material has the water sorption less than 40 µg/mm³ and water solubility less than 7.5 µg/mm³, therefore meets ISO 4049 requirement.

4. Handling Evaluation

A blind handling evaluation was conducted in office settings between TPH Spectra™ LV, TPH Spectra™ HV and a variety of commercially available composites. Each material was dispensed on a mixing pad and designated with a code to ensure it was not revealed throughout the course of the evaluation which composite was TPH Spectra and which was the clinician's currently used composite. After dispensing, the clinician was asked to evaluate each composite using their own composite instrument on the mix pad or in supplied tooth models replicating Class I and II restorations. Results of the evaluation reveal that 67% of doctors prefer TPH Spectra™ in a blind evaluation with 70% of those doctors preferring TPH Spectra™ HV and 30% preferring TPH Spectra™ LV materials.



5. Property Summary

TPH Spectra™ – Technical Data	Value	Unit
Fracture Toughness	1.69	MPa*m ^{1/2}
Flexural Strength (ISO 4049)	137	MPa
Flexural Modulus	9636	MPa
Compressive Strength	351	MPa
Volumetric Shrinkage	2.6	%
Water Sorption (ISO 4049)	11.0	µg/mm ³
Water Solubility (ISO 4049)	0.0	µg/mm ³
Depth of Cure (A2, ISO 4049)	2.8	mm
Radiopacity (ISO 4049)	2.1	mm Al
Work Time (ISO 4049)	68	second
Filler Content (weight / volume)	LV (75.5 / 54.6) HV (77.2 / 57.0)	%
Filler Size (average)	1.35	µm

Vita, Filtek Supreme Ultra, Herculite Ultra, Venus Diamond, Kalore, Sof-Lex, OptiDisc are not registered trademarks of DENTSPLY International.

6. Photos of Clinical Examples

The TPH Spectra™ Composite is able to offer superior color adaptation (Chameleon Effect) because of the well balanced refractive index matches between resin matrix and filler system and fine turned shading system. As demonstrated in the clinical photos shown below, the TPH Spectra™ Universal Composite Restorative has been scientifically designed to allow the enamel and dentin to blend together with the composite with life-like esthetic results, while only using single shade of TPH Spectra™.



Before



After (only A3.5 Shade used)



Before



After (only A2 Shade used)

Dentistry courtesy of Dr. Jason Goodchild

7. Directions for Use



TPH Spectra™

Universal Composite Restorative

DIRECTIONS FOR USE – ENGLISH

For dental use only.
USA: Rx only.

1. PRODUCT DESCRIPTION

TPH Spectra™ Universal Composite Restorative is a visible light cured, radiopaque, composite restorative material for anterior and posterior restorations and cosmetic veneering. 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 Spectra™ Composite Material is at the discretion and sole responsibility of the dental practitioner.

1.1 Delivery forms*

TPH Spectra™ Composite material is available in:

- Low Viscosity and High Viscosity
- Predosed Compules® Tips
- 3g Easy•Twist syringes

*Some delivery forms may not be available in all countries.

Both Low and High Viscosity TPH Spectra™ Composite materials are available in the most commonly used Vita® shades. Additional complementary shades are available in Low Viscosity for esthetically demanding applications. Refer to the available shade

conversion table for matching Prisma® and Bioform® shades to available equivalent to TPH Spectra™ Composite material shades.

TPH Spectra™ Composite material may be used with separately available methacrylate-based tints and opaquers at the discretion and responsibility of the dental practitioner for individual custom characterization of the ultimate esthetic direct-placement restoration.

BASIC VITA® SHADES – Available in HV and LV

Light Shades (2)

Light Reddish Brown	A1
Light	B1

Universal Body Shades: Reddish Brown (3)

Light Medium	A2
Medium	A3
Dark Medium	A3.5

Universal Body Shades: Gray (1)

Medium	C2
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Characterization Shades (1)

Reddish Brown	A4
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COMPLEMENTARY SHADES – Available in LV

Light Shades (5)

Bleach White	BW
Extra Light	XL
Light	L
Light Gray	LG
Light Gray	C1

Universal Body Shades: Reddish Brown (2)

Light Medium	LB
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Dark Medium DB

Universal Body Shades: Reddish Yellow (2)

Light Medium B2

Dark Medium B3

Universal Body Shades: Gray (2)

Medium LYG

Dark Medium C3

Characterization Shades (5)

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

1.2 Composition

- Urethane modified Bis-GMA resin
- TEGDMA Triethyleneglycoldimethacrylate
- Polymerizable Dimethacrylate Resin
- Camphorquinone (CQ) photoinitiator
- Ethyl-4(dimethylamino)benzoate photoaccelerator
- Butylated hydroxy toluene (BHT)
- UV stabilizer
- Silanated barium-alumino-borosilicate glass
- Silanated barium-boron-fluoro-alumino-silicate glass
- Silicon dioxide
- Fluorescent agent
- Synthetic Inorganic Iron oxide pigments

- Titanium dioxide

1.3 INDICATIONS

1. TPH Spectra™ Composite material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.
2. TPH Spectra™ Composite material is indicated as an anterior direct esthetic veneering material.
3. TPH Spectra™ Composite material is indicated for the indirect fabrication of inlays and onlays.

1.4 CONTRAINDICATIONS

TPH Spectra™ Composite material is contraindicated for use with patients who have a known hypersensitivity to methacrylate resins.

1.5 Compatible adhesives

TPH Spectra™ Composite material is used following application of a suitable dentin/enamel adhesive and is chemically compatible with DENTSPLY methacrylate-based dentin/enamel 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

1. TPH Spectra™ 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 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. 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 TPH Spectra™ Composite material Easy•Twist 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.
 - TPH Spectra™ 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 2°-24°C/35°-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

3.1 Direct Restoration – Cavity Restoration, Cosmetic Veneering

1. Shade Selection:

Before selecting the shade, teeth should be clean, hydrated and free of extrinsic material or stain. The TPH Spectra™ Composite shade guide is to be used to accurately demonstrate the shade of the composite material. The TPH Spectra™ Composite shade guide tab is manufactured from the TPH Spectra™ Composite material of the selected shade.

TPH Spectra™ Composite 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 basic shades of TPH Spectra™ Composite adequately reproduce many of the traditional Vita® shades. See the shade coverage table below:

TPH Spectra™ Shades

TPH Spectra™ Shades

	B1	A1	A2	C2	A3	A3.5	A4
B1							
A1							
B2							
D2							
A2							
C1							
C2							
D4							
A3							
D3							
B3							
A3.5							
B4							
C3							
A4							
C4							

(Dark → Light) VITA® Shades

Additional Complementary shades are available for extended characterizations.

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®/Palodent® Plus 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/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 TPH Spectra™ Composite material.

5. Placement of TPH Spectra™ Universal Composite

Easy•Twist 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 TPH Spectra™ Composite material is optional. Follow manufacturer's directions for use.

Dispense TPH Spectra™ 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 Easy•Twist syringe and carried to the preparation with suitable placement instrument. Adapt, contour and shape with appropriate composite instruments. Ensure material is intimately adapted to cavity walls prior to curing. Material may be placed and light cured in increments up to 2mm (see Curing, Step 6).

Technique Tip: For esthetic blending of shades, shade layers may be individually cured to form a foundation for subsequent shade placement.

TPH Spectra™ Composite material resists slumping, allowing carving of the majority of anatomical form prior to visible light curing.

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 at a distance not greater than 5mm from surface. Some advanced performance curing units have been shown to cure 2mm increments of most shades of TPH Spectra™ Composite material in 10 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The TPH Spectra™ 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 TPH Spectra™ 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.

3.2 Indirect restoration - Inlay, Onlay

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

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. Impression, Master Cast Fabrication

Make an accurate impression of the preparation, prepare master cast and articulate opposing cast per usual technique

4. Restoration Fabrication

- 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.
- 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.
- 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.
- Gently sandblast the internal surfaces with 50m alumina abrasive. Remove visibly undercut material.

- 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 for Direct Restorations.

6. Cementation

Recommended cementation technique is bonding using a dual cure 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 for Direct Restorations.

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 TPH Spectra™ 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.

4.3 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

Vita is not a registered trademark of DENTSPLY International.



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