

Spectrum[®]TPH[®]

Syringe Starter Pack Resin-based dental restorative system

The **Spectrum[®]TPH[®]** Restorative System is based on the research and experience of leading clinicians. Created to give perfect restorations with a minimum of application procedures, the Spectrum TPH Restorative System helps you with your routine treatment reducing components and treatment steps.

New effective 3-component system:

DeTrey[®] Conditioner 36 – a universal and well-proven way to etch enamel, to remove the smear layer, and to condition dentine in a one-step procedure.

Prime&Bond[®] NT is a universal self-priming dental adhesive designed to bond composite and Dyract[®] compomer materials to enamel and dentine as well as to metals and ceramic. Prime&Bond NT combines primer and adhesive in a single bottle. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.

Spectrum TPH – a visible-light activated, radiopaque sub-micron hybrid composite for anterior and posterior restorations. The composite is pre-dosed in Compules[®] tips or delivered in traditional Syringes and is available in a selection of precise Vita^{®1} shades.

CAUTION: For dental use only.

COMPOSITION

DeTrey Conditioner 36

- Phosphoric acid
- Highly dispersed silicon dioxide
- Detergent
- Pigment
- Water

Prime&Bond NT

- Di- and trimethacrylate resins
- Functionalised amorphous silica
- PENTA (dipentaerythritol penta acrylate monophosphate)
- Photoinitiators
- Stabilisers
- Cetylamine hydrofluoride
- Acetone

¹ Vita is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co.

Spectrum TPH

- Bis-GMA-adduct (adduct of 2,2- Bis[4-(2-hydroxy-3-methacryloyloxypropoxy)-phenyl] propane with hexamethylene diisocyanate)
- Bis-EMA (2,2-Bis[4-(2-methacryloyloxyethoxy)-phenyl]propane)
- TEGDMA (3,6-Dioxaoctamethylene-dimethacrylate)
- Photo initiators
- Stabilizers
- Bariumaluminiumborosilicate (mean particle size < 1.5 µm)
- Highly dispersed silicon dioxide (particle size 0.04 µm)

Information on the filler according to ISO 4049-1988:

The particle size of the inorganic fillers is 0.04 to 5 µm. The percentage by volume of total inorganic fillers is 57% the percentage by weight is 77%.

INDICATION

Spectrum TPH is indicated for all cavity classes in anterior and posterior teeth.

CONTRAINDICATIONS

DeTrey Conditioner 36

Application to dentine close to the pulp (less than 1 mm).

Prime&Bond NT

Direct or indirect pulpcapping.

Prime&Bond NT/Spectrum TPH

Spectrum TPH and Prime&Bond NT Adhesive are contraindicated for use with patients that have a history of severe allergic reaction to methacrylate resins.

WARNINGS

1. Spectrum TPH and Prime&Bond NT contain methacrylates (polymerisable monomers) which may be irritating to skin and eyes. Avoid contact with oral tissues, eyes and skin. If accidental contact occurs, flush affected area with generous amounts of water. In case of contact with the eyes, immediately rinse with plenty of water and seek medical attention. After contact with skin, wash immediately with plenty of soap and water.
2. Spectrum TPH and Prime&Bond NT may cause sensitisation by skin contact in susceptible persons. If skin sensitisation occurs, discontinue use.
3. Prime&Bond NT contains acetone. Acetone is highly flammable. Keep away from sources of ignition – no smoking. Do not breathe vapour. Take precautionary measures against static discharges.
4. DeTrey Conditioner 36 contains 36 % phosphoric acid. Causes burns. Avoid contact with oral tissues, eyes and skin. If accidental contact occurs, flush affected area with generous amounts of water. In case of contact with the eyes, immediately rinse with plenty of water and seek medical attention. After contact with skin, wash immediately with plenty of soap and water.
5. DeTrey Conditioner 36 gel should extrude easily: **DO NOT USE EXCESSIVE FORCE.** Replace original cap of DeTrey Conditioner 36 tightly after each use to avoid evaporation. Discard needle after use, as needles may clog if gel is allowed to dry inside.

PRECAUTIONS

Prime&Bond NT

Avoid Prime&Bond NT saturating gingival retraction cord. If Prime&Bond NT soaks into the cord, it may set hard and bond the cord to the underlying tooth surface making removal difficult.

INTERACTIONS WITH OTHER DENTAL MATERIALS

DeTrey Conditioner 36

Some liners and bases may be etched by phosphoric acid. In general, this does not impair their barrier function.

Prime&Bond NT

If H₂O₂ has been used to clean the cavity, proper rinsing is essential. Higher concentration H₂O₂ may interfere with the setting of polymerisable material and should not be used prior to the application of Prime&Bond NT.

Prolonged and intensive contact with acetone-containing products may lead to minute dissolution of the outermost surface of calcium hydroxide materials. This has no detrimental effect on the adhesion to the cavity walls.

Prime&Bond NT/Spectrum TPH

Eugenol-containing dental materials should not be used in conjunction with these products because they may interfere with setting and cause softening of the polymeric components of these materials.

ADVERSE REACTIONS

Prime&Bond NT

The following adverse reaction has been associated with the use of acetone solutions and acrylate monomers:

- Reversible inflammatory changes of the oral mucosa after accidental contact.

Spectrum TPH

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

DOSAGE AND APPLICATION

Shade Selection

Shade selection should be made prior to the restorative procedure while the teeth are hydrated. Prophylaxis with pumice and water to remove any extraneous plaque or surface stain. Use the Spectrum TPH shade guide provided with samples of original Spectrum TPH restorative material. The colour coding dot on the shade guide matches the coloured label on the syringe.

Alternatively, a Vita Lumin® Vacuum shade guide may be used. The Spectrum TPH shade corresponds to the central part of the respective Vita tooth.

Cavity Preparation

- 1. Anterior Restorations.** Use the cavity preparations for the acid etch technique (bevelled enamel margins), for all Class III, IV and Class V restorations.
- 2. Posterior Restorations.** Cavity design requirements are essentially a conventional preparation with refinement of cavo-surface margins for enhancement of acid-etching. No residual amalgam or other base material should be left on the internal surfaces of the preparation which would interfere with light transmission and the hardening of the restorative.

Moisture Control

Surface cleanliness is paramount for the development of adhesion. Isolate prepared tooth from contamination with saliva, sulcus fluid, or blood with adequate measures (rubber dam).

Pulp Protection

In deep cavities cover the dentine close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal®) leaving the rest of the cavity surface free for bonding with Prime&Bond NT. Glass-ionomer or other eugenol-free base materials may be used, if wished.

Placement of the Matrix

Use a transparent matrix system with proper wedging for proximal contacts. Pre-wedging is advocated to achieve slight separation and facilitate optimal proximal contact.

Acid Conditioning of Enamel and Dentine (Total Etch Technique)²

It is recommended to follow the Total Etch Technique described below.

Application of DeTrey Conditioner 36

Attach disposable needle to end of syringe. Needle tip may be bent for easy access.

Gently extrude DeTrey Conditioner 36 gel (36 % phosphoric acid) to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentine for 15 seconds or less.

Rinsing and Drying

Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 15 seconds.

Remove excess water from the rinsed cavity with a soft blow of air. Avoid desiccating the dentine, leave a moist surface.

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

Application of Prime&Bond NT

One layer of Prime&Bond NT is applied:

1. Dispense Prime&Bond NT directly onto a fresh Applicator Tip³ or onto a disposable brush. Alternatively, dispense into a fresh DENTSPLY Applicator Dish³ or standard dappen dish.
2. Immediately apply ample amounts of Prime&Bond NT to thoroughly wet all tooth surfaces. This surface should be saturated which may necessitate additional application of Prime&Bond NT.
3. Leave the surface undisturbed for 20 seconds.
4. Remove solvent by blowing with air from a dental syringe for at least 5 seconds. Surface should have a uniform, glossy appearance. If not, repeat steps 2 to 4.
5. Light-cure for a minimum of 10 seconds⁴. Ensure uniform exposure of all cavity surfaces.
6. Immediately place Dyract compomer over the cured Prime&Bond NT.

² Alternatively to the Total Etch Technique, the conventional Enamel Etch Technique can be followed. In this case, the enamel margins only are treated with DeTrey Conditioner 36 for 20 to 60 seconds. Then rinse and dry as described below.

³ DENTSPLY Applicator Dish and Applicator Tips are available from your dental dealer.

⁴ When using a high-performance unit such as the curing-lights manufactured by DENTSPLY, a curing time of 10 seconds is sufficient. For curing lights with an output lower than 500 mW/cm², a curing time of 20 seconds should be observed.

Placement of Spectrum TPH

Dispense the necessary amount of Spectrum TPH restorative material from the Syringe onto the mixing pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the syringe upwards and turn the handle anti-clockwise.

Incremental placement (in 3 mm levels or less) and curing of posterior composite restorations is recommended to minimise polymerisation shrinkage. Cure each increment separately.

IMPORTANT: BE SURE TO EXPOSE THE ENTIRE RESTORATION FOR THE APPROPRIATE TIME.

Curing

Expose each area of the restoration surface to a VLC polymerisation unit (e.g. DENTSPLY ProLite™, Spectrum™) for at least 20 seconds. The composite should be additionally exposed to a VLC polymerisation unit through lingual or buccal enamel walls. For pin build-ups the restorative material should be polymerised around each pin before additional material is added.

Specific exposure times and depths of cure for the different shades are given in the table below:

Time/Depth of Cure

Using DENTSPLY VLC Polymerisation Units

Shades ⁵	Exposure time (seconds)	Through restorative material only	Through 1 mm of enamel
A2, A3, A3.5, B1, Incisal-B1	20	3 mm	2 mm
B2, B3, C2, C3	40	4 mm	3 mm
Opaque-A2, Opaque-A3.5	20	2 mm	1 mm
A4	40	3 mm	2 mm

Finishing

Begin finishing immediately after curing. Gross excess composite may be removed with fluted finishing burs or diamonds. Additional finishing and polishing is obtained by using Enhance™ Finishing and Polishing Discs. A high final lustre can be obtained on Spectrum TPH by applying Prisma® Gloss™ or Prisma Gloss Extrafine.

STORAGE

All products

Do not store above 24 °C. Keep out of direct sunlight.

DeTrey Conditioner 36

Replace cap immediately after use.

⁵ Approximate shade match to Vita® (body).

Prime&Bond NT

The Prime&Bond NT bottle should be tightly closed immediately after use. Keep in a well ventilated place.

Spectrum TPH Syringes

Replace cap upon extrusion of composite to protect the contents from light.

BATCH NUMBER AND EXPIRY DATE

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

Do not use after expiry date.

If you have any questions, please contact:

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