

DIRECTIONS FOR USE

Prime & Bond[®] NT[™]

Nano-Technology Dental Adhesive

Prime & Bond[®] NT[™] is a light-cure self-priming dental adhesive designed to bond composite materials and Dyract[®] AP compomer to enamel and dentin as well as to metals and ceramic.

Prime & Bond[®] NT[™] combines primer and adhesive in a single container. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.

Prime & Bond[®] NT[™] is available in a 4.5 ml tri-laminated bottle and in pre-dosed, 0.125ml disposable containers for single patient use.

Caulk Tooth Conditioner Gel is included in Prime & Bond[®] NT[™] Economy Kit.

For routine dual cure procedures, please see the Prime & Bond[®] NT[™] Dual Cure bonding system instructions that include the Prime & Bond[®] NT[™] and Self Cure Activator components.

Caution: U.S. Federal Law Restricts This Device To Sale By Or On The Order Of A Dentist.

COMPOSITION:

Prime & Bond[®] NT[™]:

Di- and Trimethacrylate resins
PENTA (dipentaerythritol penta acrylate monophosphate)
Nanofillers-Amorphous Silicon Dioxide
Photoinitiators
Stabilizers
Cetylamine hydrofluoride
Acetone

Caulk 34% Tooth Conditioner Gel:

Phosphoric Acid
Highly dispensed silicon dioxide
Colorant
Water

INDICATIONS:

1. Direct composite and compomer restorations.
2. Veneers.
3. Composite, ceramic and metal repairs.
4. Cavity varnish for use with fresh amalgam.

CONTRAINDICATIONS:

Prime & Bond[®] NT[™] Nano-Technology Light Cured Adhesive System is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins and for direct application to dental pulp tissue (direct pulp capping).

Caulk 34% Tooth Conditioner is contraindicated for use on soft tissue including oral mucosa, eyes and dental pulp tissue.

WARNINGS:

Prime & Bond[®] NT[™] Nano-Technology Light Cured Dental Adhesive contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. Wash thoroughly with soap and water after contact. If skin sensitization or other allergic reaction occurs, discontinue use.

Prime & Bond[®] NT[™] Nano-Technology Light Cured Dental Adhesive contains acetone. Acetone is highly flammable. Keep away from sources of ignition. Do not breathe vapor.

Prime & Bond[®] NT[™] Nano-Technology Light Cured Dental Adhesive contains methacrylate which may be irritating to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Caulk 34% Tooth Conditioner Gel contains phosphoric acid, which can cause burns of soft tissue. Avoid contact with oral soft tissues, eyes and skin. If accidental contact with the eyes, immediately rinse with plenty of water and seek medical attention. Do not take internally.

PRECAUTIONS:

Caulk 34% Tooth Conditioner Gel should extrude easily: DO NOT USE EXCESSIVE FORCE. Replace original cap of Caulk Tooth Conditioner Gel tightly after each use to avoid evaporation. Discard needle after use, as needles may clog if gel is allowed to dry inside.

Eugenol-containing dental 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.

Prime & Bond® *NT*TM Nano-Technology Light Cured Dental Adhesive bottle should be tightly closed immediately after use.

Single dose containers are intended for single use only, and should be discarded after use. Do not re-seal or re-use.

Keep out of sunlight. Not to be stored at temperatures exceeding 25°C. Keep Prime & Bond® *NT*TM Nano-Technology Light Cured Dental Adhesive in a well ventilated place.

Adverse Reactions:

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

Step-by-Step Instructions for Use:

1. DIRECT RESTORATION (COMPOSITE RESIN AND COMPOMERS)

1.1 Cleaning

Clean uninstrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as NuproTM Prophylaxis Paste. Wash thoroughly with water spray and air dry.
Clean freshly instrumented enamel and dentin with water spray and then air dry.

1.2 Pulp Protection

For direct and indirect pulp capping, cover the dentin 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*TM Nano-Technology Light Cured Dental Adhesive.

1.3 Tooth Conditioning/Dentin Pretreatment

When used as a bonding agent for composite materials, it is recommended to follow the total etch technique described in 1.3.1: When used as a bonding agent for compomer materials in non-stress bearing situations, acid etching is optional.

1.3.1 Application of Caulk 34% Tooth Conditioner Gel

After application of rubber dam or other suitable isolation technique, apply Caulk 34% Tooth Conditioner Gel. Attach disposable needle to end of syringe. Needle tip may be bent for easy access. Gently extrude Caulk 34% Tooth Conditioner Gel (34% phosphoric acid) to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentin for 15 seconds or less.

Alternatively the conventional Enamel Etch Technique can be followed. In this case, the enamel margins only are treated with Caulk 34% Tooth Conditioner Gel for at least 15 seconds.

1.3.2 Rinsing and Blot Drying

Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds. Blot dry conditioned areas with a moist cotton pellet. For best results, saturate a cotton pellet and remove excess water from the pellet by blotting it on a gauze pad before using the pellet to blot the tooth. Proceed immediately to application of Prime & Bond® *NT*TM.

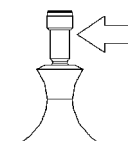
Important Note:

- The goal of blot drying is to provide the correct amount of "wetness" on the tooth surface by removing all excess moisture and yet avoiding desiccating the dentin. Do not rub the tooth surface when blot drying. Dentin should be blotted until there is no pooling of water, leaving a moist, glistening surface.
- Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, repeat procedure beginning at step 1.1.

1.4 Application of Prime & Bond® *NT*TM Nano-Technology Adhesive

Unit Dose Container

1. Insert unit dose into holder, placing thumb on top portion of the unit dose.
2. Firmly apply pressure until container separates.
3. Holder may be placed on the tabletop or held between fingers for convenience.
4. Insert disposable applicator brush tip into opening to saturate.



Conventional Bottle

Dispense Prime & Bond® *NT*TM adhesive directly onto a clean disposable brush provided, making sure that the bottle does not come in direct contact with the brush, or place 2-3 drops of Prime & Bond® *NT*TM adhesive into a clean well. Replace cap promptly.

Application of Prime & Bond NT™

Using the disposable brush or applicator tip, immediately apply generous amounts of Prime & Bond® NT™ adhesive to thoroughly wet all the tooth surfaces. This surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime & Bond® NT™ adhesive.

Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. **Surface should have a uniform glossy appearance.** If not, repeat application and air dry.

Cure Prime & Bond® NT™ adhesive for 10 seconds using a curing light (i.e., ProLite®, Spectrum®).

Important Note:

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 300 mw/cm², a curing time of 20 seconds should be observed.

Place direct restoration over the cured Prime & Bond® NT™ adhesive.

2. VENEERS

2.1 Cleaning; see section 1.1

2.2 Tooth Conditioning/Dentin pretreatment: See Section 1.3

2.3 Application of Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive: See Section 1.4

2.4 Preparation of restoration. Treat bonding surface of restoration according to manufacturers or to dental laboratory instructions, i.e. etching or mechanical roughening. Apply Caulk Silane Coupling Agent to ceramic or porcelain restoration.

2.5 Prepare and apply resin cement according to Manufacturer's instructions.

3. COMPOSITE, CERAMIC AND AMALGAM REPAIRS

3.1 Roughen the fractured composite surface as much as possible with a diamond bur. Create mechanical retention where possible. For best results, sandblast the area to be repaired with an Intra-Oral Microetcher (Danville Engineering). Rubber dam is recommended with high speed evacuation. Rinse microetched areas for 15-20 seconds with water. Air dry. Note: Bevel porcelain margins before etching.

3.2 Etch tooth with Caulk 34% Tooth Conditioner Gel for 15 seconds. Etch restoration with hydrofluoric acid. Rinse with water for 10 seconds. Air-dry.

Note: Apply Caulk Silane Coupling Agent to porcelain surfaces to be repaired following manufacturer's instructions.

3.3 Apply and light-cure Prime & Bond® NT™ Adhesive as described for direct restorations, see section 1.4.

3.4 Complete repair with placement and curing of the proper shade(s) of Esthet•X™ micro matrix restorative or TPH Spectrum® Universal composite.

4. CAVITY VARNISH FOR USE WITH FRESH AMALGAM

When used as a cavity varnish, Prime & Bond® NT™ Nano-Technology Light Cured Adhesive System is not an amalgam adhesive.

4.1 Finish preparation.

4.2 If preparation is in close proximity to the pulp, a layer of Dycal® should be placed.

4.3 Rinse and carefully air-dry cavity preparation, but do not desiccate exposed dentin.

4.4 Apply and light-cure Prime & Bond® NT™ Adhesive as described for direct restorations, see section 1.4.

4.5 Place and condense amalgam (e.g. Dispersalloy®) as per usual technique.

Note: Acid etching of prepared cavity (enamel or enamel/dentin) is optional prior to placement of Prime & Bond® NT™ Adhesive.

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