

INSTRUCTIONS FOR USE

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I. Introduction

Infinix™ Universal Bond is a resin-based bond system consisting of a self-etch Prime and a light-cured Bond. It is designed to enhance penetration into prepared enamel and dentin surfaces and to establish strong adhesion between mineralized dental surfaces and restorative materials. The Prime and Bond treats both dentin and enamel. The product is supplied in multi-dose primary packaging. Each bottle contains 5ml of Prime and 5ml of Bond.

II. Symbols Glossary

The following symbols may appear in the product documentation or on the labels attached to the product:

Symbol	Symbol Name	Symbol Description
	Manufacturer	Indicates the name and address of the manufacturer.
	Date of manufacture	Indicates the date when the device was manufactured.
	Use by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalog number so that the device can be identified.
	Temperature limitations	Indicates the temperature limits to which the medical device can be safely exposed.
	Keep dry	Indicates a medical device that needs protection from moisture.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Caution	CAUTIONS are directions which if not followed could cause damage to the product described in this Instructions for Use and/or any other device.
	Consult information for user manual	Indicates the need for the user to consult the instructions for use.

Symbol	Symbol Name	Symbol Description
	Prescription Device	Caution: In the United States, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

III. Indications for Use

- 1) Direct restorations using light-cured composite resin.
- 2) Cavity sealing as a pretreatment for indirect restorations.
- 3) Treatment of hypersensitive teeth and/or exposed root surfaces.
- 4) Intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics or composite resin using light-cured composite resin.
- 5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin.
- 6) Core build-ups using light-cured or dual-cured composite resin.
- 7) Cavity sealing under amalgam restorations.
 - * For indications 1, 2, 3, 6 and 7 the device exhibits an antibacterial cavity cleansing effect.

IV. Intended user

The device is designed to be used by dentists only (Rx only).

V. Patient Target Group

Children and adults regardless of gender.

VI. Contraindication

Infinix™ Universal Bond is contraindicated in patients with a history of hypersensitivity to methacrylate monomers.

VII. Possible Side Effects

The oral mucosa may turn whitish when contacted by the agent due to the coagulation of protein. This is a temporary phenomenon that will disappear in a few days.

VIII. Incompatibility

- Do not use eugenol containing materials for pulp protection or temporary sealing, since the eugenol could retard the bonding system curing process.
- Do not use hemostatics containing metallic compounds, since they may impair adhesion, and the remaining metallic compounds may cause discoloration in the layer or surrounding gingiva.
- Do not use hydrogen peroxide prior to restoration as it may impair adhesion and compromise restoration.

IX. Precautions

9.1 SAFETY PRECAUTIONS

- The product contains substances that may cause allergic reactions. Avoid use of the product in patients with known allergies to methacrylate monomers or any other components.
- If the patient demonstrates a hypersensitivity reaction, such as rash, eczema, features of inflammation, ulcer, swelling, itching, or numbness, discontinue the use of the product and seek medical attention.
- Avoid direct contact with the skin and/or soft tissue to prevent hypersensitivity. Wear gloves or take appropriate precautions when using the product.
- If the product comes in contact with human body tissues, take the following actions:
 - < If the product gets in the eye > Immediately wash the eye with copious amounts of water and consult a physician.
 - < If the product comes in contact with the skin or oral mucosa > Immediately wipe the area with a cotton pledget or a gauze moistened with alcohol, rinse with copious amounts of water.

- Use caution when using the product to prevent swallowing.
- Avoid looking directly at the dental curing light when curing the product.
- Keep the product out of reach of children.
- Avoid using the same disposable brush tip for different patients to prevent cross infection. Discard the tip after use and sterilize the brush tip handle.

For MSDS information please contact your local subsidiary.

9.2 HANDLING AND MANIPULATION PRECAUTIONS

- The Bond will set to a gel if left under an operating light or natural light (sunlight from windows). Apply the Bond within 3 minutes from dispensing.
- The Prime will evaporate when left in mixing dish for extended amount of time. Dispense the necessary amount of Prime into a well of the mixing dish immediately before application.
- The emitting tip of the dental curing light should be held as near and vertical to the Bond surface as possible. If a large resin surface is to be light cured, it is advisable to divide the area into several sections and light-cure each section separately.
- Low intensity of light causes poor adhesion. It is advisable to check the dental curing light intensity using an appropriate light evaluating device at appropriate intervals and the lamp for service life. In addition, check the curing light tip for contaminants.
- The bottle caps should be tightly closed when the product is not in use. The bottles should not be left cap-free.

9.3 STORAGE PRECAUTIONS

- If the liquid does not flow easily, shake the bottle before using.
- The product must be used by the expiration date indicated on the package.
- Operation and storage temperature is 15-25°C/59-77°F.
- Keep away from extreme heat or direct sunlight.
- Replace the bottle cap immediately after the liquid has been dispensed from the bottle.
- The product must be stored in proper places where only dental practitioners can access it.

X. Infinix™ Universal Bond Components

Please see the outside of the package for contents and quantity.

10.1 PRIMER (SELF-ETCHING PRIME)

Principal ingredients:

- Ethanol (Abs)
- Urethane dimethacrylate (UDMA)
- 10-Methacryloyloxydecyl dihydrogen phosphate (10-MDP)
- Water

10.2 BOND

Principal ingredients:

- Camphorquinone (CQ)
 - Benzoin methyl ether (BME)
 - Butylated hydroxytoluene (BHT)
 - Ethyl 4-methylaminobenzoate (EDB)
 - Bisphenol A-glycidyl methacrylate (Bis-GMA)
 - Triethylene glycol dimethacrylate (TEGDMA)
 - Quaternary-Ammonium Silica-dioxide (QASI)*
- * Clinical studies demonstrate that the presence of QASI in this device improve clinical outcomes have not been conducted.

10.3 ACCESSORIES NEEDED IN THE CLINIC

- Disposable brush tips
- Brush tip handles
- Mixing dish
- Light blocking plate

XI. Clinical Procedures

11.1 DIRECT RESTORATIONS, CAVITY SEALING AND TREATMENT OF HYPERSENSITIVE TEETH OR EXPOSED ROOT SURFACES USING LIGHT-CURED COMPOSITE RESIN

11.1.1 Cleaning tooth structure

An adequately cleaned cavity assures maximum adhesive performance. Be sure the cavity is adequately cleaned.

11.1.2 Moisture control

To produce optimal results, avoid contamination of the treatment area from saliva or blood. A rubber dam is recommended to keep the tooth clean and dry.

11.1.3 Cavity preparations

Remove any infected dentin and prepare the cavity in the usual manner.

11.1.4 Pulp protection

Any actual or near pulp exposure could be covered with a hard setting calcium hydroxide material. There is no need for cement lining or basing. Do not use eugenol materials for pulp protection.

11.1.5 Acid etching uncut enamel

Infinix™ Universal Bond is a self-etching prime and bond system. There is no need for etching enamel or dentin. However, it is not contraindicated. If there is a need for placing resin over uncut enamel, apply phosphoric acid dental etch to the uncut enamel for 20 seconds according to the manufacturer's instructions.

Caution
The use of Prime alone over uncut enamel may not condition sufficiently and could cause marginal discoloration.

11.1.6 Tooth surface treatment with Prime

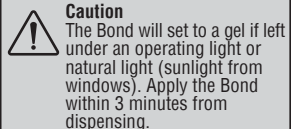
- 1) Dispense the required amount of Infinix™ Prime into a mixing well immediately before application.

Caution
The Prime will evaporate when left in mixing dish for extended amount of time.

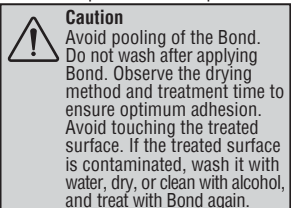
- 2) Apply Prime to the entire cavity wall with a disposable brush tip in a scrubbing motion for 20 seconds. Use caution not to allow saliva or gingival exudate to contact the treated surfaces.
- 3) After conditioning the tooth surface, evaporate the volatile ingredients with a mild air stream for 5 seconds.

11.1.7 Bond Application

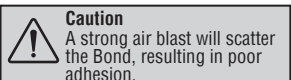
- 1) Dispense the necessary amount of Infinix™ Bond into a well of the mixing dish.



- 2) Apply Bond to the entire surface of the cavity with a disposable brush tip.



- 3) Create a uniform Bond film using air flow for 5 seconds.



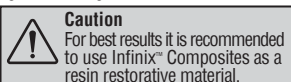
- 4) Curing: Light-cure the Bond for 10 seconds with a dental curing light. This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of at least 1000 mW/cm² in the 400-500nm range.

11.1.8 Direct restorations using light-cured composite resin

To obtain optimal results, it is recommended to use Infinix™ composites, light-cure, finish and polish according to the manufacturer's instructions.

11.1.9 Cavity sealing and treatment of hypersensitive teeth or exposed root surfaces

Apply a thin coat of Infinix™ Universal Bond (Prime and Bond) to the tooth, and light-cure according to the Instructions for use. Where applicable, apply a thin coat of Infinix™ Flowable Composite on the bonding surface. Remove unpolymerized resin with a cotton pledget moistened with alcohol or apply glycerin gel on the finished restoration and light cure it again.



11.2 INTRAORAL REPAIRS OF FRACTURED CROWNS/BRIDGES MADE OF PORCELAIN, HYBRID CERAMICS OR COMPOSITE RESIN USING LIGHT CURED COMPOSITE RESIN

11.2.1 Preparation of fractured surfaces

- 1) Facing material surfaces (non-metal): Using a diamond point, remove a layer of the fractured surface, and place a bevel at the marginal area.
- 2) Metal surface: Roughen the metal surface with a diamond point.

11.2.2 Acid etching of facing material surface

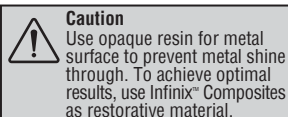
Apply phosphoric acid dental etching gel to the facing material surface and leave it in place according to the manufacturer's instructions. If the adherent surface extends to uncut enamel, apply phosphoric acid dental etching gel syringe to the enamel surface and leave it in place for 20 seconds according to the manufacturer's instructions.

11.2.3 Precious metal surface

When precious metal is used, apply metal prime (not included) according to the manufacturer's instructions.

11.2.4 Porcelain treatment

- 1) Use Hydrofluoric acid (not included), according to the manufacturer's instructions.
- 2) Use silane-based primer for porcelain (not included) according to the manufacturer's instructions.
- 3) Apply Infinix™ Bond to the porcelain-treated fractured surfaces with a disposable brush tip.
- 4) Create a uniform bond film using gentle air flow for 5 seconds.
- 5) Light-cure the Bond for 10 seconds with a dental curing light according to the instructions for use.
- 6) Apply Infinix™ Universal Composite over adhesive layer, light-cure, finish and polish according to the manufacturer's instruction for use.



11.3 TREATMENT OF PROSTHETIC APPLIANCES

Treatment of prosthetic appliance made of esthetic materials (porcelain, hybrid ceramics or composite resin) can be accomplished using a primer in conjunction with porcelain bond activator (not included) according to the manufacturer's instructions.

11.3.1 Acid etching of adherent surface

Apply phosphoric acid dental etching gel to the adherent surface according to the manufacturer's instructions.

11.3.2 Porcelain treatment

Use the same procedure described in 11.2.4.

11.3.3 Cementing

Cement the prosthetic appliance using adequate cement according to the manufacturer's instructions.

11.4 CORE BUILD-UPS USING LIGHT-CURED OR DUAL-CURED COMPOSITE

11.4.1 Use the same procedures described in 11.1.1-11.1.7.

11.4.2 Use core build-up materials according to manufacturer's instructions.

11.5 CAVITY SEALING UNDER AMALGAM RESTORATIONS

11.5.1 Use the same procedures described in 11.1.1-11.1.2.

11.5.2 Cavity preparations

Prepare the cavity in the normal manner for an amalgam restoration.

11.5.3 Use the same procedures described in 11.1.4-11.1.7.

11.5.4 Amalgam filling

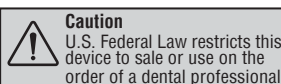
Perform the amalgam restoration according to the manufacturer's instructions.

XII. Disposal

Used packages are considered as biohazard and need to be discarded as biohazard waste in accordance with local regulations.

XIII. Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.



LIMITED WARRANTY AND LIMITATION OF LIABILITY

Nobio Ltd. ("Nobio") warrants that the product shall be free from defects in material and workmanship prior to its stated expiration date. In case that the product is found by Nobio to be defective, user's sole remedy will be limited to replacement of the defective product, in accordance with Nobio's then current RMA policy. No cash refunds will be allowed for a returned product. Nobio is not responsible for costs incurred for removal or placement of dental restorations, including labor, practice expenses, or pain and suffering. Without derogating from the foregoing, replacement resulting from accident, neglect, abuse, failure of supportive tooth or tissue structure is not covered under the terms of this warranty. Nobio will not be liable for any loss or damage, direct, consequential, special or otherwise, arising out of the application or use of or the inability to use the product. Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith. Subject to the full compliance with the applicable use instructions, in the event that, despite the above, a court with valid jurisdiction or other competent authority declares that Nobio is in any way liable, then Nobio's total aggregate liability in connection with the application or use or inability to use this product, shall in no event exceed the amounts paid by the user to Nobio.

Note Any serious incident that has occurred in conjunction to our device, must be reported to Nobio (at the address listed below) and to the competent authority of the member state in which the user is established.

Manufacturer: Nobio Ltd. 8 Hamatechet Kadima Israel 6092000	Contact Information: Israel: +972-50-3088511 US: (844) INFINIX / (844) 463-4649 customer-care@nobio.com
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