

 Single Component Self-Etch Adhesive

 Adhesivo autograbable de un solo componente

 Adhésif monocomposant automordançant



 **570-0603**

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Natural Elegance® Universal Bond
 INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

Universal Bond is a light-curable single component self-etch adhesive designed to bond composite resins to most dental surfaces. These surfaces include dentin, enamel, zirconia, alumina, metals, porcelain, lithium disilicate, and composite restorations.

INDICATIONS FOR USE

Universal Bond is a primer and adhesive used for:
 • Conditioning of zirconia, alumina, and metal definitive restorations prior to cementation, e.g., crowns, posts, inlays, and onlays
 • Adhesive repair of defects in zirconia, alumina, metal and composite restorations currently affixed to a patient's dentition
 • Adhesive for bonding composites and other dental restorative materials to enamel or dentin

SINGLE-USE DEVICES

Unit Dose containers are single-use devices, and are provided non-sterile. Single-use devices must not be reused. Reuse of a single-use device may cause harm to the patient in the transfer of blood, tissue, or saliva that may contain infectious disease. Use in accordance with instructions within "Unit Dose Delivery" below.

MULTI-USE DEVICES

Dropper Bottles are multi-use devices and are provided non-sterile. Use in accordance with instructions within "Bottle Delivery" below.

PRECAUTIONS

- Read the SDS for safety information. Universal Bond contains methacrylate monomers that may produce allergic reactions in some individuals by contact with skin, eyes, or oral mucosa. Always wear suitable personal protective equipment. Patient protective eyewear is recommended.
- Use of this product in any way not specifically described in this Instruction for Use is the sole responsibility of the practitioner. Universal Bond is intended for use by a licensed dental practitioner only.
- Use appropriate isolation techniques to prevent saliva and blood contamination of bonding surfaces.
- Do not place Universal Bond adjacent to eugenol-containing materials or any other agents that may inhibit the bonding strengths of Universal Bond.
- Universal Bond is not for direct pulp capping.
- Avoid allowing contact of Universal Bond with the oral tissue.
- Do not allow pooling of the adhesive.
- Always keep Universal Bond away from sources of heat, including, but not limited to, direct sunlight.
- Refrigeration is recommended.

INSTRUCTIONS FOR USE

Please keep 'Instructions for Use' as a reference guide during all procedures as an easy guide for use. They are meant to help the user as a guide when using Universal Bond and should be only used as noted.

Bottle Delivery

- Always shake the bottle well before use.
- Remove cap from the dispenser bottle and hold the bottle tip vertically straight down.
- Gently squeeze dispenser bottle to dispense 1-2 drops in a clean and unused mixing well
- Replace and tighten cap immediately.
- Keep the adhesive away from direct light and use it as soon as possible.
- Do not cross contaminate.

Unit Dose Delivery:

- Always shake the unit dose well before use.
- Hold the large end of the Unit Dose in either hand. Grasp the opposite end with the other hand. Firmly apply separating pressure until the two parts separate.
- Insert a disposable applicator into Unit Dose and saturate the applicator tip. Rewet as needed.
- Keep the adhesive away from direct light.
- Do not cross contaminate. Unit Dose is for single patient use only.

TOOTH PREPARATION

Self-etching technique:

1. Prepare cavity preparation by removing all debris with spray of oil free water and blot with clean cotton pellet or air dry with oil free air. Do not desiccate the tooth surface.

Total-etching technique:

1. Prepare cavity preparation by removing all debris with spray of oil free water.
2. To further enhance bond strength, the enamel may be selectively etched. This step is optional.
- Apply a commonly used phosphoric acid containing etching materials onto the prepared and unprepared (if present) enamel and dentin and allow etching for 15 seconds.
- Rinse thoroughly with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
- Do not desiccate the tooth surface.

Enamel selective-etching technique:

1. Prepare cavity preparation by removing all debris with spray of oil free water.
2. To further enhance bond strength, the enamel may be selectively etched. This step is optional.
- Apply a commonly used phosphoric acid containing etching materials onto the prepared and unprepared (if present) enamel and allow etching for 15 seconds.
- Gently rinse thoroughly with oil free water spray and blot with clean cotton pellet or air dry with oil free air. Do not desiccate the tooth surface.

Unprepared Tooth Enamel

1. A commonly available clinical method (e.g. polishing paste or powder blasting) should be used to clean the enamel surface. Gently rinse thoroughly to remove all debris with oil free water spray and air dry with oil free air.
2. Continue by the use of "Enamel selective-etching technique" or "Total-etching technique".

Note: To have the best performance, always prepare and etch tooth enamel.

APPLICATION

- To ensure maximum bond strength, cross contamination with external fluids (e.g. saliva, blood or sulcular fluids) should be avoided.
- The use of rubber dam is highly recommended to ensure a dry environment and prevent soft tissue exposure.

PROCEDURE FOR USE

• Direct Restorations:

Bonding composites to dentin and enamel

Cavity sealing before amalgam placement

• Indirect Restorations:

Veneers, crowns, bridges, inlays, onlays made of composite, zirconia, alumina, porcelain, precious metal, non-precious metal, and lithium disilicate (used in conjunction with a luting cement)

1. Apply copious amount of Universal Bond to prepared surface with disposable applicator and scrub for 20 seconds. (For larger restorations, e.g., MOD, apply an additional layer of Universal Bond by re-wetting applicator.) Do not light cure adhesive in between layers.
2. With oil free air, gently air dry the adhesive for at least 5 seconds to evaporate solvent. Do not blow away the adhesive. Continue with a stronger air stream (5-10 seconds) until the film no longer moves. The Universal Bond should appear glossy.
3. Light-cure Universal Bond for 10 seconds with a dental curing light (minimum 600 mw/cm2).
4. The surface is now ready for direct restoration to bond a composite.

Note: Universal Bond is compatible with both light cured and dual/auto cured composites.

• Intraoral repairs with light curing composites on surfaces made of composite, zirconia, alumina, porcelain, precious metal, non-precious metal, and lithium disilicate

1. See section "Preparation for Repairs" below

PREPARATION FOR REPAIRS

Preparation of Composite Restorations

1. Remove all the loose and cracked sections of an existing restoration with a rotary bur or other dental abrasive instruments.
2. Gently rinse thoroughly to remove all of the residue and debris and thoroughly clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
- Do not contaminate.
- The surface should appear chalky- if not repeat 'sand blasting' and thoroughly clean
3. Apply Universal Bond as directed within section "Procedure for Use" above.

Preparation of Silica based materials- Lithium Disilicate, Feldspathic Porcelain:

1. Remove all the loose and cracked sections of the restoration with a rotary bur or "Sand Blasting" using ≤50µm aluminum oxide powder with HVS (high volume suction), abrade all surface to be repaired.

2. With the use of a rotary diamond abrade all surface to be repaired.
3. Gently rinse thoroughly to remove all of the residue and debris and thoroughly clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
- Do not contaminate.
4. For the best results, etch 'repairing' surfaces with hydrofluoric acid for 15 seconds. Then gently rinse thoroughly to remove all of the etchant and clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
5. Apply Universal Bond as directed within section "Procedure for Use" above.

Note: The use of etching with phosphoric acid will weaken the adhesion.

Preparation of Non-Silica based materials including Zirconia, Alumina, Porcelain, and Precious Metal, Non-precious Metal:

1. Remove all the loose and cracked sections of the restoration with the use of a rotary diamond or "Sand Blasting" using ≤50µm aluminum oxide powder with HVS (high volume suction), abrade all surface to be repaired. Gently rinse to remove all of the excess powder with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
2. Apply Universal Bond as directed within section "Procedure for Use" above..

Note: The use of etching with phosphoric acid prior to Universal Bond application may weaken the adhesion to all ceramic materials and metals (e.g. Zirconia).

STORAGE:









Store at or below 77°F (25°C). Do not freeze. Use at room temperature.

DISPOSAL

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations. To dispose of unused material, replace cap and dispose of in accordance with local and state regulations (refer to SDS as appropriate).

DEFINITIONS OF SYMBOLS

The following symbols may appear on the product packaging or labeling.

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1	5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1	5.1.5
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1	5.1.4
	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	EN ISO 15223-1	5.3.6
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1	5.3.2
	Rx only	Caution: Federal law restricts this device to sale by or on the order of a dentist	US Code of Federal Regulations, Title 21	801.15(c)(1)(i)(F)
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223- 1	5.4.2

Adhesivo universal Natural Elegance® INSTRUCCIONES DE USO
DESCRIPCIÓN DEL PRODUCTO

El adhesivo universal es un agente de adhesión fotopolimerizable y monocomponente de autograbado diseñado para adherir resinas compuestas a la mayoría de superficies dentarias. Estas superficies incluyen dentina, esmalte, circona, alumina, metales, porcelana, disilicato de litio y restauraciones con composite.

INDICACIONES DE USO

- El adhesivo universal es una imprimación y un agente adhesivo que sirve para:
- acondicionar circona, alumina y restauraciones definitivas con metal antes de la cementación, por ejemplo, coronas, postes, inlays y onlays;
 - reparar defectos en la circona, la alumina y las restauraciones con metal y composite fijadas a la dentadura del paciente;
 - unir al esmalte o a la dentina composites y otros materiales para restaurar los dientes.

DISPOSITIVOS DE UN SOLO USO

Los envases de dosis individuales son dispositivos de un solo uso y se suministran no esterilizados. Los dispositivos de un solo uso no pueden reutilizarse. Reutilizar un dispositivo de un solo uso puede ser perjudicial para el paciente debido a la posibilidad de transferencia de sangre, tejido o saliva que contenga enfermedades infecciosas. Utilice el dispositivo de acuerdo con las instrucciones que figuran a continuación en el apartado «Formato monodosis».

DISPOSITIVOS MULTIUSOS

Los frascos gotero son dispositivos multiusos y se suministran no esterilizados. Utilice el dispositivo de acuerdo con las instrucciones que figuran a continuación en el apartado «Formato frasco».

PRECAUCIONES

- Lea la HDS para consultar la información de seguridad. El adhesivo universal contiene monómeros de metacrilato que pueden causar reacciones alérgicas en algunos individuos en caso de contacto con la piel, los ojos o la mucosa oral. Lleve siempre un equipo de protección personal adecuado. Se recomienda ofrecer al paciente protección ocular.
- Si el médico utiliza este producto de un modo distinto al especificado en las presentes instrucciones de uso, lo hará bajo su exclusiva responsabilidad. El adhesivo universal está previsto para ser utilizado únicamente por odontólogos colegiados.
- Utilice técnicas de aislamiento adecuadas para evitar que la saliva y la sangre contaminen las superficies de adhesión.
- No coloque el adhesivo universal junto a materiales que contengan eugenol o cualquier otro agente que pueda inhibir la fuerza adhesiva del adhesivo universal.
- El adhesivo universal no está indicado para recubrimiento pulpar directo.
- Evite que el adhesivo universal entre en contacto con el tejido oral.
- No permita que se formen acumulaciones de adhesivo.
- Mantenga siempre el adhesivo universal alejado de fuentes de calor como, por ejemplo, la radiación solar directa.
- Se recomienda refrigerarlo.

INSTRUCCIONES DE USO

Conserve las «Instrucciones de uso» como guía de referencia durante todos los procesos a modo de guía de uso sencilla. Están diseñadas para ayudar al usuario mientras utiliza el adhesivo universal, que solo deberá usarse tal como se indica.

Formato frasco

- Agitar siempre el frasco antes de usarlo.
- Retirar el tapón del frasco dispensador y colocar el gotero en vertical apuntando hacia abajo.
- Apretar suavemente el frasco para dispensar 1-2 gotas en un recipiente de mezclado limpio y sin usar
- Volver a colocar el tapón de inmediato y apretarlo.
- Mantener el adhesivo alejado de la luz directa y utilizarlo lo antes posible.
- Evitar la contaminación cruzada.

Formato monodosis:

- Agitar siempre la dosis individual antes de usarla.
- Sujetar el extremo largo de la dosis individual en una mano. Agarrar el extremo opuesto con la otra mano. Tirar con firmeza de cada extremo en direcciones opuestas hasta que las dos partes se separen.
- Introducir un aplicador desechable en la dosis individual y saturar la punta del aplicador. Rehumedecer según sea necesario.
- Mantener el adhesivo alejado de la luz directa.
- Evitar la contaminación cruzada. Dosis individual para uso en un único paciente.

PREPARACIÓN DEL DIENTE

Técnica de autograbado:

1. Preparar la cavidad eliminando cualquier resto con un spray de agua sin aceite y secar con un rollo de algodón limpio o con aire seco y sin aceite. No desecar la superficie del diente.

Técnica de grabado total:

1. Preparar la cavidad eliminando cualquier resto con un spray de agua sin aceite.
2. Para potenciar aún más la fuerza adhesiva, puede grabarse el esmalte de manera selectiva. Este paso es opcional.
- Aplicar un ácido fosfórico de uso común que contenga materiales de grabado sobre el esmalte y la dentina preparados y no preparados (si procede) y dejar actuar el agente de grabado durante 15 segundos.
- Rociar abundantemente con spray de agua sin aceite y secar con un rollo de algodón limpio o con aire seco y sin aceite.
- No desecar la superficie del diente.

Técnica de grabado selectivo del esmalte:

1. Preparar la cavidad eliminando cualquier resto con un spray de agua sin aceite.
2. Para potenciar aún más la fuerza adhesiva, puede grabarse el esmalte de manera selectiva. Este paso es opcional.
- Aplicar un ácido fosfórico de uso común que contenga materiales de grabado sobre el esmalte preparado y no preparado (si procede) y dejar actuar el agente de grabado durante 15 segundos.
- Rociar con cuidado con spray de agua sin aceite y secar con un rollo de algodón limpio o con aire seco y sin aceite. No desecar la superficie del diente.

Esmalte dental no preparado

1. Para limpiar la superficie del esmalte, debe seguirse un método clínico común (por ejemplo, pasta de pulido o chorreado). Rociar con cuidado y abundantemente para eliminar cualquier residuo con spray de agua sin aceite y con aire seco y sin aceite.
 2. Continuar aplicando la «técnica de grabado selectivo del esmalte» o la «técnica de grabado total».
- Nota: Para obtener los mejores resultados, preparar y grabar siempre el esmalte dental.

APLICACIÓN

- Para garantizar la máxima fuerza adhesiva, deberá evitarse la contaminación cruzada con fluidos externos (saliva, sangre o

