

Prior to use, carefully read the instructions for use. EN



Fig. 1
Abb. 1
şek. 1

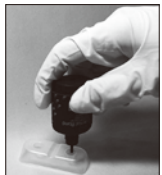


Fig. 2
Abb. 2
şek. 2

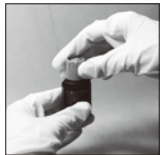


Fig. 3
Abb. 3
şek. 3

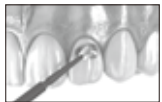


Fig. 4
Abb. 4
şek. 4



Fig. 5
Abb. 5
şek. 5



Fig. 6
Abb. 6
şek. 6



Fig. 7
Abb. 7
şek. 7

SOLARE UNIVERSAL BOND

ONE COMPONENT UNIVERSAL LIGHT-CURED ADHESIVE

For use only by a dental professional in the recommended indications.

INDICATIONS FOR USE

- Bonding of light cured composites and acid modified composites (compomers) to tooth structure.
- Bonding of dual cured luting and core build up composites to tooth structure as long as these materials are light cured.

CONTRAINDICATIONS

- Pulp capping.
- Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer, or acetone.

NOT TO BE USED

- In combination with chemically cured composite resin.
- In combination with eugenol containing materials as eugenol may hinder SOLARE UNIVERSAL BOND from setting or bonding properly.
- In combination with desensitizers as desensitizers may hinder SOLARE UNIVERSAL BOND from setting or bonding properly.
- In combination with dual cured luting and core build up composites unless both SOLARE UNIVERSAL BOND and these materials are individually light cured.

DIRECTIONS FOR USE

1. CAVITY PREPARATION

Prepare tooth using standard techniques. Make sure that the temporary material is thoroughly removed from the surface. Use rubber dam for protection. Dry the prepared tooth surfaces by gently blowing with an air syringe.

Note:

For pulp capping, use calcium hydroxide.

2. TECHNIQUE SELECTION

Select out of the following 3 technique options:

a) Self-etch technique

Apply SOLARE UNIVERSAL BOND to bur-cut enamel and dentin, without a separate etching step.

Note:

Non bur-cut enamel should always be treated with a 35-40% phosphoric acid gel for 10 seconds, rinsed with water for 5 seconds and gently dried.

b) Selective etching of enamel

Prior to applying SOLARE UNIVERSAL BOND to enamel and dentin, etch enamel only with 35-40% phosphoric acid gel for 10-15 seconds, rinse for 5 seconds and gently dry.

c) Total-etch technique

Prior to applying SOLARE UNIVERSAL BOND to enamel and dentin, etch enamel and dentin with 35-40% phosphoric acid gel for 10-15 seconds, rinse for 5 seconds and gently dry.

3. APPLICATION

a) Prior to dispensing, shake the bottle of SOLARE UNIVERSAL BOND thoroughly (Fig.1). Dispense a few drops into a clean dispensing dish (Fig. 2). Replace bottle cap immediately after use (Fig. 3).

b) IMMEDIATELY apply to the prepared enamel and dentin surfaces using the disposable applicator (Fig. 4).

c) Leave undisturbed for 10 seconds after the end of application (Fig.5).

d) Then, dry thoroughly for 5 seconds with oil free air under MAXIMUM air pressure. Use vacuum suction to prevent splatter of the adhesive (Fig. 6). The final result should be a thin adhesive film with the appearance of frosted glass and which does not visibly move under further air pressure.

Note:

1) When removing from refrigerator after long-term storage, leave SOLARE UNIVERSAL BOND to stand at room temperature for several minutes prior to use.

2) Apply SOLARE UNIVERSAL BOND immediately as the material contains a volatile solvent.

3) Remove excess material remaining on the tooth (other than the surfaces to be bonded) using a sponge or cotton pellet as residue material is hard to remove after light curing.

4) Should the applied material be contaminated with water, blood or saliva prior to light curing, wash and dry the tooth and repeat the procedure by re-applying material.

4. LIGHT CURING

Light cure using a visible light curing unit (Fig.7).

Irradiation time	Distance from light guide tip	
	<10 mm	>10 mm
Halogen / LED (700 mW/cm ²) : 10 seconds	10 seconds	20 seconds
High power LED (more than 1200 mW/cm ²)	5 seconds	10 seconds

Note:

- Light cure completely for an effective bonding strength. Lower light intensity may cause insufficient adhesion.
- Use a protective light shield or similar protective eye wear during light curing.

5A. PLACEMENT OF LIGHT CURED COMPOSITES AND COMPOMERS

After having light cured the adhesive, follow manufacturer's instructions for use in order to place, contour and light cure the composite resin material of choice.

5B. PLACEMENT OF DUAL CURED COMPOSITES

After having light cured the adhesive, make sure to light cure the dual cured composite material separately. Self curing only will result in insufficient bonding strength.

6. FINISHING

Adjust restoration, finish and polish using standard techniques.

STORAGE

Store at room temperature (1-28°C) (33.8-82.4°F). If not in use for a prolonged period of time, store in refrigerator.

PACKAGE

SOLARE UNIVERSAL BOND Refill 5mL
SOLARE UNIVERSAL BOND Refill 2.5mL

Note:

All packaging types may not be available in all countries.

CAUTION

- SOLARE UNIVERSAL BOND is flammable. Do not use near open flame. Keep away from sources of ignition. Do not store large quantities in one area. Keep away from direct sunlight.
- SOLARE UNIVERSAL BOND is volatile. Use in a well ventilated place. Advise patients to breathe through nose.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- In case of contact with oral tissue or skin, immediately remove with a sponge or cotton pellet. After the restorative treatment is finished, rinse thoroughly with water.
- If the tissue contacted by the material turns white or forms a blister, advise the patient to leave the affected area undisturbed, until the mark disappears, usually in 1-2 weeks. To avoid contact, it is recommended to apply cocoa butter to the area where rubber dam cannot cover.
- Avoid inhalation or digestion of material.
- When spilt on the table or floor, immediately wipe off with a dry cloth.
- Do not mix with other products.
- Dispose of all waste according to local regulations.
- In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
- Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at:

<http://www.gceurope.com>
<http://www.gcamerica.com>
<http://www.gcasiadental.com>
<http://www.gcindiadental.com>
<http://www.gclatinamerica.com/>

They can also be obtained from your supplier.

CLEANING AND DISINFECTING:

MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

DO NOT IMMERSER. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional / national guidelines.

Undesired effects- Reporting:

If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en as well as to our internal vigilance system: vigilance@gc.dental In this way you will contribute to improve the safety of this product.

Last revised: 09/2019

Rx Only

CE 2797

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PRINTED IN JAPAN

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