ENA BOND Universal Bonding

Instructions for use

(EN) ENGLISH

1. Description

Ena Bond Universal Bonding is a single-component, self-etching, light-cured dental adhesive which enables filling composites to be safely and reliably bonded onto natural dental enamel.The adhesive can be used in both self-etch and selective etch techniques.
Ena Bond Universal Bonding is compatible with all conventional light-cured composite materials.

2. Indications

- Direct, light-cured composite restorations onto natural teeth.
- Indirect restorations made from composite and ceramic (inlays, onlays, veneers, crowns) with light-cured and dual-cured luting composites e. g. with Root Cem Viscous.
- Repairs to fractured composite fillings.

3. Contraindications

- Do not bring into contact with exposed pulp tissue.
- Do not use if there is insufficient lighting (e. g. when fastening root canal posts).

4. Composition

Phosphate ester, carboxylic acid ester, methacrylate, photoinitiators, water, ethanol, fumed silica.

5. Use of Ena Bond Universal Bonding in Direct Restorations

5.1. Preparation

Prepare the cavity by applying the usual techniques used in adhesive dentistry. It is important to prevent saliva or blood from contaminating the cavity to ensure optimal results. It is strongly recommended that the area is kept as dry as possible by using a rubber dam. Apply an underfilling material if necessary (e. g. glass ionomer cement).

Protecting the Pulp

In the case of very deep cavities, the area around the pulp must be coated with a thin layer of calcium hydroxide underfilling material and coated with a suitable material (e. g. glass ionomer cement). Leave the rest of the cavity open to „bond“.

5.2. Pre-Treating the Tooth

Selective Enamel Etching

Apply the etching gel (37% phosphoric acid gel) carefully onto the edges of the enamel and leave for 30 seconds. Rinse the gel thoroughly and dry with oil-free compressed air. Enamel bonding can be further improved through selective enamel etching. Unprepared enamel must be conditioned with phosphoric acid. Please observe the instructions for use on the phosphoric acid etching gel.

Self-Etch Process

It is not necessary to etch once again with etching gel.

5.3. Applying the Adhesive

The surface that is going to be conditioned must not be touched or contaminated with saliva before Ena Bond Universal Bonding is applied. Place a sufficient amount of Ena Bond Universal Bonding into a mixing tray and apply with a disposable applicator. Continue using the material quickly (within a max. of 3 minutes). The bottle must be carefully resealed immediately after use. Apply the material over the entire cavity wall and leave for at least 20 seconds.This is the minimum amount of time that the material should be left. Remove any excess material with oilfree compressed dry air until it is not possible to see any freely moving liquid film. If the area becomes contaminated, it is necessary to clean, condition

and use compressed dry air all over again. Next, light cure the adhesive following the instructions provided in the table.

Polymerisation

Type	Light Intensity	Polymerisations Time
Halogen lamp / LED lamp	500 mW/cm^2 -1200 mW/cm^2	10 seconds

5.4. Applying the Composite Material
Apply the composite material following the applicable manufacturer's instructions for use.

6. Applying Ena Bond Universal bonding for Indirect Restorations from Composite or Ceramic
(inlays, onlays, veneers, crowns)
The luting composite must be completely light cured after inserting the indirect restoration.

6.1. Preparing the Cavity
Prepare the cavity by applying the usual techniques used in adhesive dentistry. In the case of very deep cavities, the area around the pulp must be coated with a thin layer of calcium hydroxide underfilling material and coated with a suitable material (e. g. glass ionomer cement). Leave the rest of the cavity open to „bond".

6.2. Checking the Fit and the Occlusion of the Restoration
In the case of delicate restorations, it is necessary to check the fit very carefully before bonding in order to prevent fractures. If necessary, it is possible to make corrections using a fine diamond tool operated at medium speed and only applying gentle pressure. Re-polish the surfaces that have already been ground. We recommend the use of a retraction thread to improve control over the restoration's fit and to help remove excess material.

6.3. Composite Surface Treatment
Dry and prepare the inner surfaces of the restoration by sandblasting and using cleaning solutions such as ethanol. It is important to avoid cleaning the surfaces with phosphoric acid as this can weaken the adhesive bond. Coat the surfaces with a thin layer of Ena Bond Universal Bonding.

6.4. Ceramic Surface Treatment
Prepare in accordance with the manufacturer's instructions for use.

6.5. Pre-Treating the Tooth
Selective Enamel Etching
Apply the etching gel carefully onto the edges of the enamel and leave for 30 seconds. Rinse the gel thoroughly and dry with oil-free compressed air. Enamel bonding can be further improved through selective enamel etching. Unprepared enamel must be conditioned with phosphoric acid. Please observe the instructions for use on the phosphoric acid etching gel.
Self-Etch Process
It is not necessary to etch once again with etching gel.

6.6. Applying the Adhesive
The surface that is going to be conditioned must not be touched or contaminated with saliva before the Ena Bond Universal Bonding is applied. Place a sufficient amount of Ena Bond Universal Bonding into a mixing tray and apply with a disposable applicator. Continue using the material quickly (within a max. of 3 minutes). The bottle must be carefully resealed immediately after use. Apply the material over the entire cavity wall and leave for at least 20 seconds.This is the minimum amount of time that the material should be left. Remove any excess material with oilfree compressed dry air until it is not possible to see any freely moving liquid film. If the area becomes contaminated, it is necessary to clean, condition and use compressed dry air all over again. Next, light cure the adhesive following the instructions provided in the table.

Polymerisation

Type	Light Intensity	Polymerisations Time
Halogen lamp / LED lamp	500 mW/cm^2 -1200 mW/cm^2	10 seconds

6.7. Inserting the Restoration and Removing Excess Material

Apply the luting composite on the inner side of the restoration in accordance with the manufacturer's instructions. Using gentle pressure, move the restoration into position and fix it into place. Remove excessive luting composite immediately. Take particular care to ensure that excess composite is removed as quickly as possible in areas that are difficult to reach (approximal, gingival margins) before the material hardens. Coat the edges of the restoration with glycerine gel/air blocker straight after the excess composite has been removed. This prevents an oxygen inhibition layer from forming. The gel can be rinsed with water once the luting material has completely hardened. After checking that the restoration has been placed correctly, the luting composite can be polymerised with the polymerisation lamp (500 mW/cm^2 - 1200 mW/cm^2) for at least 20 seconds per surface. Light cure the adhesive following the instructions provided in the table.

Polymerisation

Type	Light Intensity	Polymerisations Time
Halogen lamp / LED lamp	500 mW/cm^2 -1200 mW/cm^2	20 seconds per surface

6.8. Finishing Off the Completed Restoration

Remove the retraction thread. Check the occlusion and functional movement and correct if necessary. Polish the edges of the restoration.

7. Repairs to Fractured Composite Fillings

Remove caries, if present. Clean the surfaces of the teeth and the composite restoration. Prepare a micro-retentive surface, e. g. using a fine diamond tool operated at medium speed and only applying gentle pressure. Clean using a cleaning solution such as ethanol and dry. It is important to avoid cleaning the surfaces with phosphoric acid as this can weaken the adhesive bond. Coat the surfaces with a thin layer of Ena Bond Universal Bonding. Next, follow the process described under point 6.6 (Applying the Adhesive).

8. Important Information

If the restoration process takes a long time, it is important to remove the surgical lights at regular intervals to avoid the material from hardening too quickly. The product may only be used for the applications described in the indications. A curing light should be used to carry out the polymerisation process that has an emission spectrum in the range of 350 - 500 nm. The light intensity provided by the polymerisation lamp must be at least 500 mW/cm^2. The required physical properties can only be achieved using lamps that operate properly. It is therefore necessary to check the lamp in accordance with the manufacturer's instructions on a regular basis. The light aperture on the polymerisation lamp should be held as close to the bonding surface as possible and should be held in a vertical position. Ensure that all areas are polymerised when polymerising a large area, e. g. it may be necessary to divide a large area into several sections and to polymerise each section separately. The most important prerequisite for achieving maximum adhesive strength values is to ensure that adhesives are used correctly. It is important to leave the bonding agent for at least 20 seconds. Ensure that all dentine and enamel surfaces are moistened with adhesive. Do not leave any excess moisture on the surfaces. Do not mix the adhesive with other bonding agents. The material must be carefully dried with a gentle stream of air. Light cure the adhesive for 10 seconds with a polymerisation lamp. After the composite is applied to the wet surface, Ena Bond Universal Bonding and the composite achieve optimum adhesive strength together and create oxygen-free conditions. The manufacturer assumes no liability for damages resulting from improper use.

9. Storage Instructions

Close the bottle tightly immediately after use.
Do not use beyond the stated expiry date (see the label or packaging): Storage temperature: 2 - 25°C
If the product is not used for an extended period, it is recommended that it is stored in a refrigerator.
Avoid contaminating the contents of the bottle by avoiding the use of contaminated disposable brushes.

10. Safety Warning

May cause allergic skin reaction.

11. Safety Instructions
Avoid inhaling vapour/aerosol.Wear protective gloves.
IN CASE OF CONTACT WITH THE SKIN: wash thoroughly with plenty of water.
If the product causes skin irritation or a rash, seek medical advice/attention.

12. Side Effects
Adverse effects from using this medical product correctly are extremely rare. However, immune responses (e. g. allergies) or discomfort in specific areas cannot be completely ruled out in theoretical terms. Please inform us if you experience any unwanted side effects, even in cases of doubt.

13. Contraindications / Interactions
If the patient is hypersensitive to any of the ingredients, this product should not be used or may only be used under the strict supervision of the attending physician/dentist. In these cases, we can provide detailed information on request regarding the composition of the medical product that has been supplied. The dentist must take into account any known cross-reactions or interactions between this medical product and other materials in the mouth when this product is used. Phenolic substances (e. g. eugenol, wintergreen oil) inhibit the product's ability to polymerise.We therefore recommend that underfilling materials that are used do not include these types of substances. Alkaline abrasives can have an adverse effect on Ena Bond Universal Bonding.

14. Package
REF: COSM300U
Contents: 5 ml

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