

ParaBond

Instructions for use

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Please read the Instructions for Use carefully before using the product.

PRODUCT DESCRIPTION

ParaBond is a chemically curing bonding agent. The benefit of the medical device is the bonding to dental materials and hard tissues. ParaBond consists of the self-conditioning non-rinse conditioner (NRC) and the self-curing adhesive (Adhesive A and B).

INTENDED USE

ParaBond is suitable for:

- Bonding to dental hard tissues and chemically or dual-curing restorative materials.

COMPOSITION

Component*	wt % in NRC	wt % in adh. A	wt % in adh. B
Solvents (water, ethanol)	40-50	20-30	> 95
Methacrylate monomers	40-50	50-60	–
Etching agents (maleic acid, 2-acrylamido-2-methylpropanesulphonic acid)	5-10	10-30	–
Additives	–	–	1-5

* Components present in very low concentrations (<1.0%) are not listed.

INDICATIONS

Treatment and restoration of hard structures in the mouth i.e. due to:

- Caries
- Endodontic treatment
- Cosmetic treatment
- Tooth defects to be restored

CONTRAINDICATIONS

- Proven hypersensitivities to ingredients contained in ParaBond.
- If it is impossible to keep the working area dry.

SAFETY INSTRUCTIONS

Safety

- Keep out of the reach of children.
- If the product comes into contact with the oral mucosa, simply rinse with water.
- If the product gets into the eyes, wash them out thoroughly with water and then consult an ophthalmologist.
- Disposable brushes are intended for single use only.
- Close bottles after each use to avoid cross-contamination.

Residual risks

Users should be aware that any dental intervention in the oral cavity involves certain risks. Some of these risks are:

- Loss of marginal integrity / restoration.
- Postoperative sensitivity / irritation of gingiva / secondary caries / endodontic complications.
- Discoloration / wear.

SIDE EFFECTS / INTERACTIONS

ParaBond ingredients can cause sensitivity in predisposed persons. Phenolic and other substances which inhibit polymerisation (e.g. zinc oxide eugenol), must not be allowed to come into contact with ParaBond.

USER / PATIENT GROUP

The product shall be used by qualified dental professionals only.

Suitable for all patient groups.

Note: This product has not been specifically tested in vulnerable patient groups such as children or pregnant or lactating women.

PREPARATION

Use a dental dam (e.g. from COLTENE) for safety reasons and for draining. Clean tooth with pumice.

PROPER USE

1. Bonding to dental hard tissues and chemically or dual-curing restorative materials

1.1. Preparing the cavity

According to the principle of the adhesive restoration technique. If indicated, a punctiform cap should be placed near the pulp using a material suitable for use as pulp caps. Finish the enamel with a diamond grinder in case of contamination.

1.2. Pretreatment of other materials

Pretreatment is performed depending on the material. Unless otherwise specified in the instructions for use of the respective manufacturer, the following recommendations apply:

Composite	Roughen area for restoration
Metal	Roughen area for restoration
Zirconia	Sandblast area for restoration. Important: Do not use phosphoric acid on sandblasted surfaces as this may result in reduced adhesion values.
Silicate ceramic	Extraoral: Etch the inside of the restoration with hydrofluoric acid (HF) Intraoral: Roughen area for restoration

1.3. Conditioning of the cavity

a) Self-etch technique: Conditioning with ParaBond NRC.

Dispense one drop of NRC into the mixing well. Pick up with disposable brush and massage into the cavity for 30 s. Gently blow off excess NRC for 2 s.

b) Total-etch technique: Etch enamel and dentine.

Apply a phosphoric acid based etching gel (i.e. Etchant Gel S, COLTENE) according to the manufacturer's instructions on enamel and dentine. Then rinse thoroughly with water until all residues have been removed. Dry the cavity with oil-free compressed air.

Important: Do not let the dentine dry out too much.

1.4. Application of ParaBond Adhesive A & B

Dispense one drop of Adhesive A and Adhesive B into the mixing well and mix.

Note: When stored in the refrigerator, the processing time from the start of mixing is 2 min. Higher storage temperatures accelerate the system.

Massage the mixed adhesive system into the cavity or the restoration surface with a disposable brush for 30 seconds. Remove excess adhesive with a gentle stream of air for 2 s.

Note: The time between applying the adhesive and cementing must not be longer than 5 min. Otherwise repeat.

Note: Avoid too thick adhesive layer. This can impair the accuracy of fit of an indirect restoration and lead to premature hardening of the cement.

1.5. Luting

Use direct/indirect restoration material according to the manufacturer's specifications.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

Clean the product after use with 70% ethanol solution or commercially available dental disinfectant (e.g. OPTIM 1, COLTENE). Dispose of in case of suspected or identified contamination.

SHELF LIFE / STORAGE

Expiry date & LOT: See primary packaging

Storage temperature: 4-8°C / 39-46°F

Shelf life after first opening: 3 months

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Close bottle immediately after use.

DISPOSAL

Dispose of product waste according to applicable legislation. Special country-specific regulations may apply. Dispose only of completely emptied packages together with household waste in compliance with official regulations.

REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an

appropriate medical specialist to mitigate potential harm.

SAFETY DATA SHEET / SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

www.coltene.com



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Glossary



Consult instructions for use



Keep away from sun light



Temperature limitation



Marking of Conformity Europe



Identification for Ukraine



Legal Manufacturer



Expiry Date



Batch Code



RX only



Medical Device



Unique Device Identifier



European Authorized Representative



Importer



Reference Number

COLTENE International Dental Group

Dent4You AG
Bahnhofstrasse 2
CH-9435 Heerbrugg

Made in Switzerland by
Coltene/Whaledent AG
Feldwiesenstrasse 20
CH-9450 Altstätten

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