

# ONE COAT 7 UNIVERSAL

## Instructions for use

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

### PRODUCT DESCRIPTION

ONE COAT 7 UNIVERSAL is a universal light-curing single-component bonding agent. The benefit of the medical device is the bonding to dental materials and hard tissues.

### INTENDED USE

ONE COAT 7 UNIVERSAL is suitable for:

- Bonding to dental hard tissues and light-curing or dual-curing restorative materials.
- Sealing of dentine and fissures.

### COMPOSITION

Component*	wt %
Solvents (water, ethanol)	40 - 50
Methacrylate monomers	25 - 35
Etching agents (e.g. 10-MDP, polyacrylic acid)	10 - 20
Fillers (amorphous silica, SiO <sub>2</sub> )	1 - 10

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

### INDICATIONS

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

- Caries
- Endodontic treatment
- Cosmetic treatment
- Tooth defects to be restored
- Deep tooth fissures

### CONTRAINDICATIONS

- Proven hypersensitivities to ingredients contained in ONE COAT 7 UNIVERSAL.
- 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.
- Single dose units are intended for single use only. Repeated use increases the risk of cross-contamination.
- Use is only possible under the condition that sufficient incident light is ensured.
- Contains nano materials (bonded particles).

#### 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

ONE COAT 7 UNIVERSAL ingredients can cause sensitivity in pre-disposed persons. Phenolic and other substances (e.g. zinc oxide eugenol) which inhibit polymerisation, must not be allowed to come into contact with ONE COAT 7 UNIVERSAL.

### 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 light-curing 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. <b>Important:</b> Do not use phosphoric acid on sand-blasted surfaces as this may result in reduced adhesion values.
Silicate ceramic	<b>Extraoral:</b> Etch the inside of the restoration with hydrofluoric acid (HF) <b>Intraoral:</b> Roughen area for restoration

##### 1.3. Conditioning of the cavity

###### a) Self-etch technique: No etching necessary.

Proceed according to Section 1.4.

**Important:** In case of unpolished enamel, etch with etching gel.

###### 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. 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.

###### c) Selective-etch technique: Only etch the enamel areas.

Proceed as in b) for enamel areas. Then continue according to Section 1.4.

##### 1.4. Application

**a) Bottle:** Shake the bottle well before use. Dispense one drop of ONE COAT 7 UNIVERSAL into a mixing well and immediately protect from light with a well cover. Pick up with a disposable brush.

**b) Single Dose:** Snap off the safety cap and pick up ONE COAT 7 UNIVERSAL with a disposable brush.

Massage ONE COAT 7 UNIVERSAL into the cavity or the restoration surface with a disposable brush for 20 s. Gently blast with oil-free compressed air for 5 s, then light cure for 10 s (halogen or LED polymerisation units with a light intensity > 800 mW/cm<sup>2</sup>, with lower light output, the light curing time is prolonged accordingly).

**Note:** Avoid too thick adhesive layer. This can impair the accuracy of fit of an indirect restoration.

##### 1.5. Luting

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

### 2. Sealing of dentine and fissures

Proceed as in Sections 1.3 and 1.4. For fissure sealing, additionally coat with a suitable material.

### 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.

**Note:** Dispose of ONE COAT 7 UNIVERSAL Single Dose units after use.

### 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](http://www.coltene.com)



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### Glossary



Consult instructions for use



Keep away from sun light



Single use only



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  
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