

ONE COAT 7 UNIVERSAL

Instructions for use

EN

Definition

ONE COAT 7 UNIVERSAL is a universal, light-curing, one-component bonding agent for adhesive restoration technique, applicable in self-etch, selective-etch or total-etch technique.

Optionally, ONE COAT 7 UNIVERSAL can be used with One Coat 7.0 Activator for chemically curing materials. Please follow the instructions for use of One Coat 7.0 Activator.

Composition

Methacrylates
Photoinitiators
Ethanol
Water

Indications

ONE COAT 7 UNIVERSAL is indicated for:

- Direct filling using composite materials or compomers
- Bonding of indirect restorations (inlays, onlays, veneers and crowns) made of ceramic or composite
- Bonding of composite to ceramic, composite, metal and amalgam
- Dentin sealing

Application techniques

- Self-Etch: Apply ONE COAT 7 UNIVERSAL directly on enamel and dentin
- Selective-Etch: Etch Enamel first. Then apply ONE COAT 7 UNIVERSAL on enamel and dentin.
- Total-Etch: Etch Enamel and dentin first. Then apply ONE COAT 7 UNIVERSAL on enamel and dentin.

Contraindications

Proven hypersensitivities to ingredients of ONE COAT 7 UNIVERSAL.

Inadequate oral hygiene.

If it is impossible to keep the working area dry.

Side effects

Ingredients of ONE COAT 7 UNIVERSAL can cause sensitivity in predisposed persons.

Interactions

Avoid contact of ONE COAT 7 UNIVERSAL with phenolic containing materials and other substances which inhibit polymerization (e.g. zinc oxide eugenol).

Applications

1. Direct filling technique

1.1 Cavity preparation

According to the principle of the adhesive restoration technique.

For pulp protection, a small amount of hard setting calcium hydroxide cements should be placed close to the pulp. Finish the enamel again with a diamond bur.

In case of uncut enamel, etch with phosphoric acid gel or clean with pumice. Then thoroughly rinse with water and gently dry the enamel.

For isolation, the use of a rubber dam (e.g. from HYGENIC/ROEKO) is recommended.

1.2 Conditioning

a) No conditioning required in self-etch technique.

b) For Selective-Etch technique: etch enamel only. And for

c) Total-Etch technique: etch enamel and dentin. Apply for b) and c) phosphoric acid gel (e.g. ETCHANT GEL S) according to the manufacturer's instructions for use. Afterwards rinse thoroughly with water ensuring that all residues have been removed. Dry the cavity with oil-free air.

Important: Do not desiccate dentin.

1.3 Application

Bottle:

Shake bottle well before using. Dispense a drop of ONE COAT 7 UNIVERSAL into the mixing well and apply it to the cavity using a disposable dental brush. Rub the surface for 20 s and gently dry with oil-free air for 5 s. Light cure for 10 s (halogen or LED curing light with a light intensity > 800 mW/cm²). At lower light intensity exposure time is extended accordingly.

Single Dose:

Open the Single Dose immediately before use. Discard safety cap and apply ONE COAT 7 UNIVERSAL to the cavity using a disposable dental brush. Rub the surface for 20 s and gently dry with oil-free air for 5 s. Light cure for 10 s (halogen or LED curing light with a light intensity > 800 mW/cm²). At lower light intensity exposure time is extended accordingly.

Note: Avoid pooling of adhesives. This can impair the accuracy of fit.

1.4 Composite or compomer restoration

Use restoration material according to manufacturer's instructions for use.

2. Bonding of inlays, onlays, veneers and crowns

Important: For the use of ONE COAT 7 UNIVERSAL must be ensured that sufficient incident light penetrates through the complete restoration. According to the manufacturer's specifications.

2.1 Pretreatment of the restoration

Procedure depends on the material and according to the manufacturer's instructions for use.

2.2 Cavity preparation

According to step 1.1

2.3 Conditioning

According to step 1.2

2.4 Application

According to step 1.3

2.5 Luting

According to the manufacturer's instructions for use.

3. Bonding to other materials

3.1 Preparation of ceramics

According to the manufacturer's instructions for use.

3.2 Preparation of metal and amalgam

According to the manufacturer's instructions for use. Afterwards clean with a steam cleaner or acetone and dry with oil-free air.

3.3 Preparation of composite material

Roughen the composite surface using a diamond bur or sandblast with 50µm aluminium oxide. Clean the surface (e.g. with phosphoric acid), rinse and dry with oil-free air.

3.4 Application

Apply ONE COAT 7 UNIVERSAL onto the surface using a disposable dental brush. Rub the surface for 20 s and gently dry with oil-free air for 5 s. Light cure for 10 s (halogen or LED curing light with a light intensity > 800 mW/cm²). At lower light intensity exposure time is extended accordingly.

Note: Avoid pooling of adhesives. This can impair the accuracy of fit.

4. Dentin sealing

According to step 1.1, 1.2 and 1.3.

Emergency measures, symptoms, antidotes

In case of direct contact with the oral mucosa, simply rinse with water. In case of contact with eyes, rinse thoroughly with water. Get medical attention for assessment and further treatment.

Notes

Protect dispensed adhesive from light by using the mixing well cover.

Only supplied to dentists and dental technicians or upon their instructions.

Keep out of the reach of children!

Only dispose of completely empty packages.

Shelf life and labelling

Expiry date and **LOT** number can be found on the containers and outer packaging.

Do not use the product beyond its expiry date.

Storage

4 - 8 °C / 39 - 46 °F

Do not expose to direct sunlight or other heat sources.

Hygiene tips

For optimal hygienic conditions using ONE COAT 7 UNIVERSAL, the following instructions are recommended:

- Disposable dental brushes and Single Doses are for single patient use only.
- Close the bottle immediately after use. Clean with standard disinfectants.

Caution

Federal law restricts this device to sale by or on the order of a dentist.

SAFETY DATA SHEET / SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

www.coltene.com



Glossary



Consult instructions for use



Single use only



Keep away from sun light



Temperature limitation



Notified body registration number



Identification for Russia



Identification for Ukraine



Legal manufacturer



Expiry date

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