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SoloCem

Instructions for use **EN**

Please read the instructions for use carefully before using the product.

PRODUCT DESCRIPTION
SoloCem is a self-adhesive, dual-curing, radiopaque composite cement. The clinical benefit of the dental material is reconstruction of tooth morphology.

INTENDED USE
SoloCem is intended for:
- Permanent cementation of indirect restorations
- Permanent cementation of root canal posts

COMPOSITION

Component*	wt %
Methacrylate derivates	20-35
Barium aluminium boron silicate glass	60-75
Amorphous silica	1-10
4-META	5-10
MDP	1-5
Zinc oxide	1-5

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

INDICATIONS
Permanent restoration of hard structures in the mouth.

CONTRAINDICATIONS
Contraindicated in the case of hypersensitivity to any of the ingredients.

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 in the eyes, wash them out thoroughly with water and then consult an ophthalmologist.
- For hygienic reasons, the mixing tips are intended for single use only.
- Always wear gloves.
- 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
SoloCem ingredients can cause sensitivity in predisposed persons. Phenolic and other substances (e.g. zinc oxide eugenol) which inhibit polymerization, must not be allowed to come into contact with SoloCem.

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.

PROPER USE
- Do not remove mixing tip after use.
- To speed up the curing process or to reduce the inhibition layer, polymerization can be achieved by light curing. For restorations (max. 2 mm thickness) approx. 20 s per side/surface, for root posts 30 s. Use halogen or LED polymerization units with a light intensity > 800 mW/cm². With lower light output, the light curing time is prolonged accordingly.
- Do not let the dentine dry out too much.

1. Pretreatment of interior side of restoration/contact surfaces
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)

2. Luting of crowns, bridges, inlays, onlays
2.1. Optional: pretreatment of the cavity
If desired, enamel can be etched selectively. Etching of the dentine should be avoided. To improve the bond strength, enamel and dentine can be pretreated additionally with ONE COAT 7 UNIVERSAL.

2.2. Application of SoloCem
2.2.1. Remove the safety cap or mixing tip. Press a small amount of the material onto a paper towel until the base and catalyst both flow in equal amounts from the opening. This achieves a homogenous mixture.
2.2.2. Wipe off the opening with a paper towel. Attach the mixing tip and tighten with ¼ turn clockwise (90°). Press out the material and discard until even, homogeneous paste flows.
2.2.3. Apply SoloCem directly to the interior surfaces of the restoration and/or to the preparation if necessary (for concave forms to prevent air cavities).
2.2.4. Next, fix the restoration in place by applying light pressure.
2.2.5. Remove coarse, uncured excess with a spatula or other suitable instrument while holding the restoration in position while applying increased pressure. As soon as SoloCem attains a gel-like consistency, any excess may no longer be removed.
2.2.6. Remove finer excess after brief polymerization of 3 s or after chemical curing.
2.2.7. Light cure if desired.

3. Luting on implant abutments
3.1. Application of SoloCem
3.1.1. Remove the safety cap or mixing tip. Press a small amount of the material onto a paper towel until the base and catalyst both flow in equal amounts from the opening. This achieves a homogenous mixture.
3.1.2. Wipe off the opening with a paper towel. Attach the mixing tip and tighten with ¼ turn clockwise (90°). Press out the material and discard until even, homogeneous paste flows.
3.1.3. Apply SoloCem directly to the interior surfaces of the restoration and/or to the implant abutments or stumps if necessary (for concave forms to prevent air cavities).
3.1.4. Next, fix the restoration in place by applying light pressure.
3.1.5. Remove coarse, uncured excess with a spatula or other suitable instrument while holding the restoration in position while applying increased pressure. As soon as SoloCem attains a gel-like consistency, any excess may no longer be removed.
3.1.6. Remove finer excess after brief polymerization of 3 s or after chemical curing.
3.1.7. Light cure if desired.

4. Post cementation
4.1. Select an appropriate root post system (e.g. ParaPost Fiber Lux, ParaPost Taper Lux)

4.2. Pretreatment of root canal
4.2.1. Prepare the root canal according to the respective manufacturer's specifications.

4.3. Application of SoloCem
4.3.1. Remove the safety cap or mixing tip. Press a small amount of the material onto a paper towel until the base and catalyst both flow in equal amounts from the opening. This achieves a homogenous mixture.
4.3.2. Wipe off the opening with a paper towel. Attach the mixing tip and tighten with ¼ turn clockwise (90°). Press out the material and discard until even, homogeneous paste flows.
4.3.3. Apply SoloCem directly from the syringe into the prepared root canal.
4.3.4. Apply SoloCem directly to the root post and then place the post in the root canal applying light pressure. Remove excess.
4.3.5. Light cure if desired.

5. Finishing
As soon as SoloCem has been cured, it can be worked and finished with rotary instruments.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE
For the syringe, the use of a disposable sleeve is recommended. Dispose of in case of suspected or identified contamination.

SHELF LIFE / STORAGE
Expiry date and 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.

DISPOSAL
Dispose of cured or uncured 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.

TECHNICAL DATA
Filler particle distribution 0.1-5 µm
Filling ratio by weight approx. 69%
Filling ratio by volume approx. 43%
Polymerization begins with first contact between base and catalyst.
Radiopacity: 4 mm Al*
*Radiopacity of 1 mm aluminum (Al) is equivalent to that of dentin, 2 mm (Al) is equivalent to enamel.

	Room temperature 23 °C / 73 °F	Intraoral 37 °C / 99 °F
Working time	approx. 120 s	approx. 60 s
Oral setting time	-	approx. 180 s

High temperatures accelerate setting, low temperatures slow down the setting process. SoloCem is light-sensitive and should not be exposed to intense light for a prolonged period, particularly the surgical light.

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 (SDS) /
SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)
www.coltene.com

CE 0123 UA.TR.120

Glossary

Consult instructions for use
Marking of Conformity Europe
Conformity mark Ukraine
Restricted device for professional use only (Rx ONLY)
Medical Device (MD)
Legal Manufacturer
European Authorized Representative (EU REP)
Importer
Reference Number (REF)
Manufacturing Date
Expiry Date
Batch Code (LOT)
Unique Device Identifier (UDI)
Single use only
Keep away from sun light
Temperature limitation

COLTENE International Dental Group
Dent4You AG
Bahnhofstrasse 2
CH-9435 Heerbrugg

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

Service Center
service@coltene.com

COLTENE