

ParaCore

Instructions for use

EN

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

PRODUCT DESCRIPTION

ParaCore is a dual-curing, radiopaque composite core build-up and cementing material. The clinical benefit of the dental material is reconstruction of tooth morphology.

INTENDED USE

ParaCore is intended for

- Core build-ups
- Permanent cementation of indirect restorations
- Permanent cementation of root canal posts

COMPOSITION

Component*	wt %
Methacrylate derivates	25-35
Barium aluminium boron silicate glass	55-70
Amorphous silica	1-10

* 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

ParaCore ingredients can cause sensitivity in predisposed persons. Phenolic and other substances (e.g. zinc oxide eugenol) may not come in contact with ParaCore, since they will inhibit polymerization.

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.
- The overall procedure time between applying the adhesive and the cementation procedure should not exceed 5 min. If this time is exceeded, repeat the bonding procedure again starting from 1.4/2.3/3.3 accordingly.
- If the adhesive layer is too thick, it can impair the fit of the restoration.
- To speed up the curing process or to reduce the inhibition layer, polymerization can be achieved by light curing.
- Too much adhesive residue will accelerate the setting time of the ParaCore material.
- Do not let the dentine dry out too much.

1. Post cementation

1.1. Select an appropriate root post system (e.g. ParaPost Fiber Lux, ParaPost Taper Lux)

1.2. Pretreatment of root canal

1.2.1. Prepare the root canal according to the respective manufacturer's specifications.

1.3. Applying ParaBond Non-Rinse Conditioner according to the manufacturer's IFU.

1.4. Applying ParaBond Adhesive according to the manufacturer's IFU

1.5. Application of ParaCore

1.5.1. 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 homogeneous mixture.

1.5.2. 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.

1.5.3. Apply ParaCore directly from the syringe into the prepared root canal using the Root Canal Tip.

Note: It is not recommended to use a lentulo spiral to introduce ParaCore material into the root canal.

1.5.4. Apply ParaCore directly to the root post and then place the post in the root canal applying light pressure. Remove excess.

1.5.5. Light cure if desired.

2. Core Build-Ups

2.1. If necessary, place a matrix band

2.2. Applying ParaBond Non-Rinse Conditioner according to the manufacturer's IFU. Alternatively, use 35% phosphoric acid (e.g. Etchant Gel S. COLTENE) according to the manufacturer's IFU.

2.3. Applying ParaBond Adhesive according to the manufacturer's IFU

2.4. Application of ParaCore

2.4.1. 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 homogeneous mixture.

2.4.2. 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.

2.4.3. Apply ParaCore directly from the syringe into the prepared tooth.

2.4.4. Light cure if desired.

3. Cementation of crowns, bridges, inlays, onlays

3.1 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)

3.2. Applying ParaBond Non-Rinse Conditioner according to the manufacturer's IFU. Alternatively, use 35% phosphoric acid (e.g. Etchant Gel S. COLTENE) according to the manufacturer's IFU.

3.3. Applying ParaBond Adhesive according to the manufacturer's IFU

3.4. Application of ParaCore

3.4.1. 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 homogeneous mixture.

3.4.2. 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.

3.4.3. Apply ParaCore directly to the interior surfaces of the restoration and/or to the preparation if necessary (for concave forms to prevent air cavities).

3.4.4. Fix the restoration in place by applying light pressure.

3.4.5. Remove coarse, uncured excess with a spatula or other suitable instrument while holding the restoration in position while applying increased pressure.

3.4.6. Light cure if desired.

4. Finishing

As soon as ParaCore has been cured, it can be 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

Technical data according to ISO 4049, Type 2, Class 3

Average filler particle size: 2 µm

Range of particle size: 0.1-5.0 µm

Percentage by volume of total inorganic fillers: approx.50%

Percentage by weight of total inorganic fillers: approx.68%

Radiopacity: 2.7 mm Al*

*Radiopacity of 1 mm aluminum (Al) is equivalent to that of dentin, 2 mm (Al) is equivalent to enamel.

Polymerisation begins with first contact between base and catalyst.

		Room (23°C/73°F)	Intraoral (35°C/95°F)
ParaCore	Working Time	approx. 80s	approx. 30s
	Oral setting time	approx. 240s	approx. 120s
ParaCore Slow	Working Time	approx. 160s	approx. 60s
	Oral setting time	approx. 330s	approx. 200s

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)

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Glossary	
	Consult instructions for use
	Marking of Conformity Europe
	Identification for Ukraine
	RX only
	Medical Device
	Legal Manufacturer
	European Authorized Representative
	Importer
	Reference Number
	Manufacturing Date
	Expiry Date
	Batch Code
	Unique Device Identifier
	Single use only
	Keep away from sun light
	Temperature limitation

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