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ParaCore 5ml

Instructions for use **EN**

Definition
ParaCore is a composite-based, dual-cured, radiopaque core build up material in syringes. ParaCore is also suitable for use in cementing root posts and indirect restorations.

ParaBond® Adhesive is a chemical cured, self-conditioning Adhesive System for enamel and dentin. It consists of a Non-Rinse Conditioner and a chemical-curing adhesive (Adhesive A and B).

Shades
ParaCore is available in three colours:
- Dentin, for aesthetic restoration work
- White, to differentiate tooth structure
- Translucent, for restorations for anterior teeth

Composition
ParaCore contains:
Methacrylates
Fluoride
Barium glass
Amorphous silica

ParaBond Non-Rinse Conditioner (NRC) contains:
Water
Acrylamidosulfonic acid
Methacrylate

ParaBond Adhesive A contains:
Methacrylates
Maleic acid
Benzoyl peroxide

ParaBond Adhesive B contains:
Ethanol
Water
Initiators

Technical data
Complies with ISO 4049

Average filler particle size:	2 µm
Range of particle size:	0.1-5.0 µm
Percentage by volume of total inorganic filler:	approx. 50 %
Percentage by weight of total inorganic filler:	approx. 68 %

Clinically Measured Times
Polymerisation begins upon first contact between base and catalyst.

ParaCore

	Room Temperature 23 °C / 73 °F	**Intraoral 37 °C / 99 °F**
Working Time	ca. 80 s	ca. 30 s
Setting Time (not including working time)	ca. 240 s	ca. 120 s

ParaCore SLOW

	Room Temperature 23 °C / 73 °F	**Intraoral 37 °C / 99 °F**
Working Time	ca. 160 s	ca. 60 s
Setting Time (not including working time)	ca. 330 s	ca. 200 s

Working Time
Working time is dependent upon temperature. Higher temperatures shorten working time; lower temperatures lengthen it. ParaCore is light-sensitive and should not be exposed to intense light, especially the operating lamp, for more than 30 seconds prior to polymerisation.

Light-curing time
Light-curing time (to light from halogen or LED-polymerisation lamps; light power >800 mW/cm²): 20 s per side/surface for a 2 mm-thick layer. Lower-intensity light results in a correspondingly longer light-curing time.

Indications
- Permanent cementation for all types of root canal posts
- Core build-ups
- Permanent cementation of crowns, bridges, inlays, onlays (ceramic, metal, and composite)

Contra-indications
Hypersensitivity due to any of the elements within ParaCore. Inadequate oral hygiene. If the working area can not be kept completely dry during application.

Side effects
Elements of ParaCore may lead to sensitivity or an allergic reaction for patients with a predisposed condition.

Interactions with other agents
Phenolics and other substances (e.g. zinc oxide eugenol) may not come in contact with ParaBond, since they will inhibit polymerization.

Application
Tooth isolation
A dry working field is the basis for the best results. The use of a rubber dam (e.g. Hygenic® or Roeko® Dental Dam) is recommended.

Note: The post cementation and core build up techniques have been described as two separate techniques. It is however possible to simultaneously complete the post cementation and core build up technique together using one ParaCore mixing / root canal tip. Please see the included step-by-step cards for more information.

A. Post cementation
Clinical tip:
Preparation of the working field will provide an optimal and efficient procedure.

1. Select a suitable endodontic post system (e.g. ParaPost® Fiber Lux™, ParaPost® Taper Lux™)
2. Prepare the root canal according to the manufacturer's instructions for use.

Applying ParaBond Non-Rinse Conditioner
3. Dispense Non-Rinse Conditioner into the mixing well.
4. Apply Non-Rinse Conditioner into the prepared post space preparation of the root canal and onto the contact surfaces (preparation/cavity) using a brush. Massage for 30 s.
5. Remove excess Non-Rinse Conditioner from the root canal using paper points.
6. Dry contact surfaces (preparation/cavity) using a gentle stream of air for 2 s.

Applying ParaBond Adhesive
7. Mix one drop of Adhesive A together with one drop of Adhesive B into the mixing well.

Note: The working time is 2 min from the start of mixing (when material is stored in the refrigerator). Higher temperatures will accelerate the setting time of the material.

8. Apply mixed adhesive components into the prepared post space preparation of the root canal and onto the contact surfaces (preparation/cavity) using a brush. Massage for 30 s. If desired, a lentulo spiral can be used to ensure complete wetting of the root canal.
9. Remove excess adhesive from the root canal using a paper points.
10. Dry adhesive bond layer using a gentle stream of air for 2 s.

Note: Too much adhesive residue will accelerate the setting time of the ParaCore material in the root canal.

Important: The overall time between applying the adhesive and the post cementation should not exceed 5 min. If this time is exceeded, repeat the procedure again starting from A.7.

Using ParaCore to Cement Posts
11. Remove the syringe plug or used mixing tip. Extrude a small amount of material directly out of the syringe onto a paper towel/tissue, until it is evident that equal amounts of base and catalyst are being extruded. This will ensure that optimal mixing is achieved.
12. Immediately wipe off excess material from the orifice. Attach the mixing tip and twist clockwise (90 degrees) to lock in place.
13. Dispense 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.

14. Coat the root canal post completely with the mixed ParaCore material. Insert the post into the root canal using gentle pressure. Remove excess ParaCore material using the appropriate instrumentation. After each use, disinfect the mixing tip with disinfectant; and do not remove.
15. Prepare the core build up as soon as the ParaCore material has completely cured. The ParaCore material can be light-cured for 30 s to accelerate polymerization or to reduce the inhibition layer.

B. Core Build-Ups

Applying ParaBond Non-Rinse Conditioner
1. Dispense Non-Rinse Conditioner into the mixing well.
2. Apply Non-Rinse Conditioner onto the entire preparation/cavity using a brush. Massage for 30 s.
3. Dry excess Non-Rinse Conditioner using a gentle stream of air for 2 s.

Alternative: 35 % phosphoric acid can be used for etching instead of Non-Rinse Conditioner (according to the manufacturer's instructions for use).

Applying ParaBond Adhesive
4. Mix one drop of Adhesive A together with one drop of Adhesive B into the mixing well.

Note: The working time is 2 min from the start of mixing (when material is stored in the refrigerator). Higher temperatures will accelerate the setting time of the material.

5. Apply mixed adhesive components onto the contact surfaces (preparation/cavity) using a brush. Massage for 30 s.
6. Dry the adhesive bond layer using a gentle stream of air for 2 s.

Important: The overall time between applying the adhesive and the core build up should not exceed 5 min. If this time is exceeded, repeat the procedure again starting from B.4.

Application of ParaCore
7. Remove the syringe plug or used mixing tip. Extrude a small amount of material directly out of the syringe onto a paper towel/tissue, until it is evident that equal amounts of base and catalyst are being extruded. This will ensure that optimal mixing is achieved.
8. Immediately wipe off excess material from the orifice with a paper towel/tissue. Attach the mixing and twist clockwise (90 degrees) to lock in place.
9. If necessary, place a matrix band around the prepared tooth.
10. Apply ParaCore directly to the preparation. After use, clean off the mixing tip with disinfectant (do not remove).

Note: Root canal mixing tip for ParaCore can be easily shortened using a scalpel to decrease the extrusion force during core build-ups.

Note: it is important that there be enough healthy tooth structure remaining (1.5 mm apical around the tooth stump) so that the appropriate ferrule effect can be created.

11. The compound can be polymerised with light in order to speed up the hardening process or minimise the inhibition layer.

C. Cementation of Crowns, Bridges, Inlays, Onlays
Conditioning the preparation/cavity
1. Clean the preparation/cavity with water and then dry excess water using a gentle stream of air for 2 s. Do not over dry the dentin.

Applying ParaBond Non-Rinse Conditioner
2. Dispense Non-Rinse Conditioner into the mixing well.
3. Apply Non-Rinse Conditioner onto the entire preparation/cavity using a brush. Massage for 30 s.
4. Dry excess Non-Rinse Conditioner using a gentle stream of air for 2 s.

Alternative: 35 % phosphoric acid can be used for etching instead of Non-Rinse Conditioner (according to the manufacturer's instructions for use).

Applying ParaBond Adhesive
5. Mix one drop of Adhesive A together with one drop of Adhesive B into the mixing well.

Note: The working time is 2 min from the start of mixing (when material is stored in the refrigerator). Higher temperatures will accelerate the setting time of the material.

6. Apply mixed adhesive onto the preparation/cavity using a brush. Massage for 30 s.
7. Dry adhesive residue using a gentle stream of air for 2 s.

Note: Excessive adhesive residue will accelerate the setting time of the ParaCore material.

Important: The overall time between applying the adhesive and the cementation should not exceed 5 min. If this time is exceeded, repeat the procedure again starting from C.5. Excessive amount of adhesive should be avoided, since this can influence the fitting accuracy of the final restoration.

Conditioning the inner surfaces/contact surfaces of the restoration
Always condition the contact surfaces of the restoration according to the manufacturer's instructions for use.

Note: After conditioning the restoration, rinse it thoroughly, dry with oil free air and protect against contamination (e.g. moisture, fingerprints). The bond strength can be improved by applying an extremely thin layer of adhesive to the inner surfaces of the restoration. This can, however, accelerate polymerization of the ParaCore material.

Important: If the adhesive layer is too thick, it can impair the fit of the restoration.

Application ParaCore
8. Remove the syringe plug or used mixing. Extrude a small amount of material directly out of the syringe onto a paper towel/tissue until it is evident that equal amounts of base and catalyst are being extruded. This will ensure that optimal mixing is achieved.
9. Immediately wipe off excess material from the orifice using a paper towel/tissue. Attach the mixing tip and twist clockwise (90 degrees) to lock in place. After each use, disinfect the mixing tip with disinfectant; and do not remove.

Note: Root canal mixing tip for ParaCore can be easily shortened using a scalpel to decrease the extrusion force.

10. Apply ParaCore directly from the 5 ml syringe into the inner surfaces of the restoration and/or if necessary (to prevent trapped air voids with concave shapes) to the preparation.
11. Afterwards, place the restoration in position using slight pressure.
12. Remove rough excess (e.g. brush, spatula) and hold the restoration in position with increased pressure.
13. The compound can be polymerised with light in order to speed up the hardening process or minimise the inhibition layer.

Finishing
A rotating instrument can be used to work on ParaCore as soon as the material has cured.

Emergency measures
In case of direct contact with oral mucosa, rinsing with tap water is sufficient. In case of direct contact with eyes, rinse thoroughly with water (10 min); and consult an eye specialist immediately.

Notes
Only supplied to dentists and dental laboratories or upon their instructions. Keep out of the reach of children! Should not be used after expiry date. Properly seal all containers after each use to prevent contamination.

Shelf life and labelling
The expiration date and LOT number is printed on the immediate container(s) and external packaging. Do not use after the expiration date.

Storage
ParaCore should be stored in the refrigerator (4–8 °C / 39–46 °F). After first application, ParaCore material can be stored at room temperature (approx. 23 °C / 73 °F), if it used quickly.
Avoid exposure to direct sunlight or other heat sources.

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

CE 0123

SAFETY DATA SHEET
www.coltene.com

Glossary

Consult instructions for use

Keep away from sun light

Temperature limitation

Notified body registration number

Identification for Russia

Legal manufacturer

Expiry date

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