REV-02-2022 30002050 02.22

ParaCore 25ml

Instructions for use **EN**

Definition
ParaCore is a dual cured, radiopaque composite core build-up material which uses a cartridge system. ParaCore is also appropriate for use in cementing root posts.

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 two colours:
– Dentin, for aesthetic restoration work
– White, to differentiate tooth structure

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. 52 %
Percentage by weight of total inorganic filler:	approx. 74 %

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

	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

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 longer than 30 seconds before polymerisation.

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

Chemical Hardening
ParaCore hardens chemically within around 4 minutes. Polymerisation begins upon first contact between base and catalyst.

Indications
– Permanent cementation for all types of root canal posts
– Core build-ups

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.

A. Post cementation
Note:
** 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.

Use of ParaCore to cement Root 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.

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

13. 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.
14. 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: The preparation should include at least 1.5 mm of sound tooth structure around the circumference of the preparation for the desired ferrule effect.

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

Finishing
ParaCore can be finished using rotary instrumentation once the material has completely cured (e.g. light-cured or chemically-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 restric

CE 0123 UA.TR.120

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
Identification for Ukraine
Legal manufacturer
Expiry date

Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten/Switzerland
T +41 71 757 5300
F +41 71 757 5301
info.ch@coltene.com

COLTENE