ORATEMP C&B

TEMPORARY CROWN AND BRIDGE MATERIAL

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description : OraTemp C&B (crown and bridge material) is both self cured and light curable composite material for the fabrication of short term temporary restorations (upto 3 weeks). Based on multi-functional methacrylate esters, this two-component system has filling material-like properties. With the help of dispensing gun, the material can be applied directly from the cartridge without causing any bubbles to form a temporary restorations.

Composition :

Base : Ethoxylated Bisphenol A Dimethacrylate, Triethylene Glycol Dimethacrylate, Fillers, Titanium dioxide, Initiators.

Catalyst : Ethoxylated Bisphenol A Dimethacrylate, Triethylene Glycol Dimethacrylate, Fillers, Accelerator, Photoinitiator and Pigments.

Intended Purpose / Intended Use : It is intended to be used for the manufacturing of temporary crown and bridges.

Indications for Use : ♦ Fabrication of temporary crowns, bridges, inlays, onlays, and veneers. ♦ Fabrication of short term temporary restorations. ♦ Lining material for prefabricated temporary crowns made of composite .

Instructions for Use :

Preparatory Work :

1. Take an alginate, silicone, or polyether impression from the intact row of teeth. Instead of an impression, a laboratory-made vacuum-formed template or, for single crowns, a preformed crown can be used for shaping. **2.** To enhance the strength of the temporary restoration, remove interproximal grooves in the impression. If required due to tight spacing conditions, enlarge the relevant sites by cutting. **3.** For easy replacement in the mouth, relieve undercuts. **4.** With missing teeth or gaps in the molar area, cut a groove into the impression to produce a stable, bar-shaped connection in the temporary restoration.

Working Time : 1 min to 1 min 20 sec. Place OraTemp C&B into the impression or into the matrix/model and reposition in the mouth.

Setting Time : 2 min to 2 min 30 sec.

The above processing times are applicable to products which have been stored and proceed at temperature of 23° C/74° F and at 50% relative humidity. Higher temperatures shorten these times, while lower temperatures extend them. The size of the restoration also has an impact on the setting times : as the size of the work piece increases, the setting accelerates.

Initial Dosing : Remove and discard the cartridge lid. Under no circumstances should the cartridge lid be used to reseal the cartridge as this could result in the inclusion of air bubbles. Check whether both cartridge openings are free from obstruction and remove obstructing material, if any, with a suitable instrument. Before a mixing tip is applied for the first time, squeeze paste out onto a mixing pad until the base and catalyst pastes are at the same level. Discard the paste which has been squeezed out.

Application : It takes the material a certain amount of time to emerge from the newly attached mixing tip. The flow of material is interrupted as soon as the pressure on the handle is reduced. Material that has set inside the mixing tip should not be extruded by force, as this may damage both the cartridge and the mixing tip. Core build-ups which are fabricated using composites, compomers, or resin modified glass ionomer cements must be sealed off before the application of OraTemp C&B *e.g.*, using Vaseline. (Note: The applied vaseline or any lubricant should be removed from the prepared tooth using ethyl alcohol wipe prior to cementation of the provisional restoration).

♦ First, install a new mixing tip. ♦ Prior to each application, extrude a small (pea-sized) amount of paste from the mixing tip onto a mixing pad and discard this material. ♦ Subsequently load the dried impression or vacuum-formed template in the relevant spaces from the bottom up. *Reposition the impression or vacuum-formed template in the mouth/on the model.

1. The material attains a hard-elastic consistency within 1 min 40 sec after the onset of mixing. The material and the impression or vacuum-formed template must be removed from the mouth/model within 2 min 10 sec after the onset of mixing.
2. Check the setting process by observing the excess material in the mouth or on the matrix/model.
3. The curing time can be accelerated by exposing the provisional restoration to a standard dental curing light (Blue light with a wavelength between 450 mm and 470 nm) for 20 seconds per surface.

♦ Keep the filled mixing tip on the cartridge to serve as a closure until the next use. The notch on the cartridge and the cap (for closing) as well as dispensing tip must be in line.

♦ The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

Finishing : Completely remove the oxygen inhibition layer from the surface of temporary restoration using alcohol wipes(*e.g.*, wipes containing ethyl alcohol) once the material is completely cured (not earlier than 5 minutes after the onset of mixing). Polish if desired, *e.g.*, with Sof-Lex™ polishing disks. After the product has cured completely, remove any residues. If necessary, finish and polish the temporary restoration using fine carbide burs. Do not breathe polishing dust. Use mouth protective device, safety glasses and aspiration.

Cementation : Insert the temporary restoration with a commercial temporary cement, OraTemp NE. Eugenol containing cements may impair the setting of composite luting cements to be used at a later time in the final luting step. If a composite cement is to be used for the final luting step, seat the temporary restoration with a eugenol-free cement. After Cementation thoroughly examine and explore the sulcus and surrounding dentition. Remove any residuals of the temporary material or cement from the mouth.

Warnings : Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin occurs, immediately wipe off thoroughly with cotton soaked in alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs, discontinue the use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

Precautions : When finishing the temporary, sand dust may get into the eyes and respiratory tract. Wear face mask and goggles. Do not inhale the sanded dust and use an evacuator. Do not remove or reverse the cap as this may cause premature setting of the material inside the cartridge.

Contraindications : Do not use in patients, If allergic to methacrylate resins.

Storage Conditions : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life : 2 years from the date of manufacturing.

Presentation :

Ref : 11005

1 x 67g Cartridge (Base + Catalyst Paste), 16 x Applicator Tips, 1 x Instruction Manual.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

Prevest DenPro Limited
Unit II, Export Promotion Industrial Park
(EPIP), Bari Brahmana, Jammu-181133,
India. www.prevestdenpro.com
Customer Care No. : + 91 8899074151
Email : customercare@prevestdenpro.com
Made in India

EC REP
Obelis s.a
Boulevard General Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732 59 54. Fax. +(32) 2 732 60 03
E-mail : mail@obelis.net

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" REF Symbol for "CATALOGUE NUMBER"

EC REP SYMBOL FOR "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION" Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "DO NOT REUSE"

Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.