

140*185mm

DiaDent®

DIA-PROSEAL™

Root Canal Sealing Material

CE 0197

DIA-PROSEAL Root Canal Sealer is two-component systems that react via an epoxide/amine chemical reaction to cause setting.

INTENDED USE

DIA-PROSEAL is used for permanent sealing of root canals in secondary dentition with gutta percha point.

PROPERTIES

- Setting time : within 3~4 hours

PRECAUTION

- 1) Check the expiration date before use. Check to see if the material contains any impurities or debris before use. Do not use if the material has any discoloration or has hardened.
- 2) Dentists must read the manufacturer's manual thoroughly before using the product.
- 3) Prepare all the devices and accessories needed before proceeding with the procedure.

Note 1.

PREPARATION OF THE ROOT CANAL

Prior to application of DIA-PROSEAL, thoroughly clean the root canal. If hydrogen peroxide has been used for irrigation, it is essential to make sure that the canal is free of any traces of rinsing solution. This is to avoid reaction of DIA-PROSEAL which would result in the formation of bubbles. If sodium hypochlorite and hydrogen peroxide are used alternately for canal irrigation, use hypochlorite as the last agent.

Note 2.

DIA-PROSEAL resins are mixed to produce a root canal filling material of excellent sealing capacity. As a result of its close adaptation to the root canal walls and its very small contraction during setting, DIA-PROSEAL allows tightly sealing root canal obturation of excellent tissue compatibility. DIA-PROSEAL complies with the requirements of ISO 6876 for dental root canal filling materials.

DIRECTIONS FOR USE

Application Method

- 1) Isolate the site with rubber dam. Prepare and shape the root canal.
- 2) Remove any debris inside the root canal. Disinfect and clean the root canal thoroughly with Sodium Hypochlorite or EDTA solution and dry it completely.
- 3) Open the safety cap of DIA-PROSEAL and squeeze out the base material (yellow) and the catalyst material (white) in 1:1 ratio from the dual syringe onto a mixing pad. (Due to the different viscosity of the base material and the catalyst material, they may be dispensed at a different speed.)
- 4) Using a mixing stick or metal spatula, mix the base material (yellow) and the catalyst material (white) for 10-20 seconds until they are completely mixed together and have turned into an ivory color.
- 5) Measure the length of the root canal by using an electronic apex locator or a file. Select a gutta percha point accordingly. Apply and coat a small amount of the mixture to the gutta percha point and insert the point towards the apex slowly. Alternatively, dentists may choose to apply the mixture with a paper point, a reamer, or Dia-Spiral Filler (Lentulo spiral). In order to prevent the formation and entrapment of air bubbles and overfilling the canal, the mixture-coated points must be inserted very slowly in a clockwise direction during obturation and withdrawn in a counter clockwise direction. If Lentulo spiral is used, advance and withdraw the Lentulo spiral slowly to the apex at very low speed.
- 6) Once the procedure is done, take an X-Ray to check the seal.

Removal Method

DIA-PROSEAL can be removed by alternative irrigation with solutions of EDTA such as NaOCl and H₂O as well as file manipulation by using the file used last in enlarging the root canal. The use of ultrasonic equipment would make it much easier. Fill the root canal permanently after confirming the disappearance of the symptom.

STORAGE & TRANSPORTATION

- 1) Make sure the cap is tightly closed after use.
- 2) Avoid direct sunlight and store at room temperature (2°C~27°C) in a dry place.
- 3) Do not store near inflammable objects.
- 4) Keep out reach of children.

CAUTION

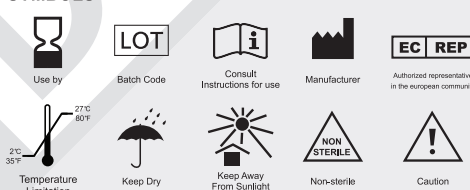
Warnings

- 1) This product must be used by professional dental practitioners only. The instructions and cautions must be followed and observed carefully.
- 2) This product must not be used on patients who are allergic to any component of the product or on patients who are experiencing inflammation.
- 3) This product must not be prescribed for internal use/application.
- 4) Rubber dam placement is necessary to protect the respiratory tract before the procedure.
- 5) Avoid contact with skin and eyes. In case of skin contact, immediately remove material with cotton and alcohol and wash thoroughly with soap and water. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- 6) Do not overfill the root canal with too much sealer as damage of periapical tissue may occur.
- 7) Do not ingest. If accidental ingestion occurs, have patient drink plenty of water and seek medical attention.
- 8) Do not use after expiration date.
- 9) Tightly close the cap after each use.
- 10) Federal law restricts this device to sale by or on the order of a dentist
- 11) While mixing the base and the catalyst, do not apply heat.
- 12) Do not polymerize the mixture (i.e. do not use any curing light on the mixture)
- 13) Do not mix with any other product.

Contraindication

Hypersensitivity against epoxy resins, amines or other components of the root canal filling material.

SYMBOLS



SHELF LIFE

2-year shelf life from the date of manufacture (when stored as advised)

WARRANTY AND LIMITATION OF LIABILITY

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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