

**1. Indications for Use**

DIA-ROOT BIO MTA is used for pulp capping (direct pulp capping or partial pulpotomy) and repair of root perforation. Other indications for use include: repair of root resorption, root end filling, apexification, and pediatric pulpotomy.

**2. Properties**

DIA-ROOT BIO MTA is a white powder composed of biocompatible ceramic material that can be set by mixing in with distilled water.

**3. Instructions****A. Precautions before use**

- 1) Read the Instructions for Use carefully and thoroughly before use.
- 2) Isolate the tooth to be treated with a rubber dam.

**B. Instructions for use****[Direct pulp capping & repair of perforation]**

- 1) Isolate the tooth with rubber dam and form cavity prep using a high speed bur and avoiding tissues close to the pulp.
- 2) Thoroughly remove decay closest to pulp with a new sterilized high speed diamond bur.
- 3) Rinse the prepared cavity, pulp exposure site and perforation site sufficiently with copious amount of 5.25% NaOCl.
- 4) If bleeding occurs, control bleeding by compressing the hemorrhagic region with NaOCl soaked cotton pellet.
- 5) Mix DIA-ROOT BIO MTA with distilled water thoroughly for 30 seconds at the following ratio\*. Depending on the ambient temperature and humidity, add more distilled water if the mixture hardens or dries up. Fill the cavity after sufficient mixing.

\* **Mixing Ratio = 0.5g : 0.225g (0.225 cc)**  
(DIA-ROOT BIO MTA : Distilled Water)

- 6) If bleeding occurs, apply a thin layer of DIA-ROOT BIO MTA first and control bleeding by pressing it with a cotton pellet. Then apply the remaining DIA-ROOT BIO MTA.
- 7) After setting is complete, apply a strong stream of water on the hardened DIA-ROOT BIO MTA with a 3 way syringe to check for any wash-out. If any material is washed away, remove the restoration in its entirety and refill the cavity.
- 8) Using appropriate instruments, form a cavity of DIA-ROOT BIO MTA that does not disrupt the line angle of the cavity. When doing so, all the dentinal tubules close to the pulp should be covered by DIA-ROOT BIO MTA, with a minimum thickness of 3mm. If it is difficult to meet these conditions, crown restoration should be done.
- 9) Take an X-ray to confirm whether any DIA-ROOT BIO MTA inadvertently entered the pulp chamber. If so, prescribe medication for pain control. If radiographically discernible dead space exists, remove the restoration in its entirety and perform the process over again.
- 10) Cover DIA-ROOT BIO MTA with resin or glass ionomer to avoid contamination with saliva.

**[Partial pulpotomy of anterior teeth]**

- 1) Isolate the tooth with rubber dam and form cavity prep using a high speed bur and avoiding tissues close to pulp.
- 2) Remove decay closest to pulp thoroughly with a new sterilized high speed diamond bur.
- 3) Open the pulp chamber and irrigate to remove pulp up to the appropriate depth with a new sterilized high speed bur.
- 4) Rinse the cavity prep sufficiently with copious amount of 5.25% NaOCl until bleeding stops.

- 5) Mix DIA-ROOT BIO MTA with distilled water for 30 seconds at the following ratio and add distilled water when the mixture hardens or dries according to the ambient temperature and humidity. Fill the cavity after sufficient mixing.

\* **Mixing Ratio = 0.5g : 0.225g (0.225 cc)**  
(DIA-ROOT BIO MTA : Distilled Water)

- 6) Remove excess water with sterilized cotton pellet and compactly squeeze the empty space inside the pulp cavity.
- 7) Before DIA-ROOT BIO MTA hardens, add the rest of the DIA-ROOT BIO MTA to fill the cavity.
- 8) After setting is complete, apply a strong stream of water on the hardened DIA-ROOT BIO MTA with a 3 way syringe to check for wash-out. If any material is washed away, remove the restoration in its entirety and proceed to root canal treatment as retreatment may cause pulpal infection.
- 9) Remove the top part of DIA-ROOT BIO MTA partially and apply resin or glass ionomer according to instructions.

**[Partial pulpotomy of posterior teeth]**

- 1) Isolate the tooth with rubber dam and form cavity prep using a high speed bur and avoiding tissues close to pulp.
- 2) Remove decay closest to pulp thoroughly with a new sterilized high speed diamond bur.
- 3) Open and irrigate all pulp horns with a new sterilized high speed diamond bur. Thoroughly remove the remnant pulp tissue on the axial wall of the cavity.
- 4) Rinse the cavity prep sufficiently with copious amount of 5.25% NaOCl until bleeding stops.
- 5) Mix DIA-ROOT BIO MTA with distilled water for 30 seconds at the following ratio and add distilled water when the mixture hardens or dries according to the ambient temperature and humidity. Fill the cavity after sufficient mixing.

\* **Mixing Ratio = 0.5g : 0.225g (0.225 cc)**  
(DIA-ROOT BIO MTA : Distilled Water)

- 6) Remove excess water with sterilized cotton pellet and compactly squeeze the empty space inside the pulp cavity.
- 7) Before DIA-ROOT BIO MTA hardens, add the rest of the DIA-ROOT BIO MTA to fill the cavity.
- 8) After setting is complete, apply a strong stream of water on the hardened DIA-ROOT BIO MTA with a 3 way syringe to check for wash-out. If any material is washed away, remove the restoration in its entirety and proceed to root canal treatment as retreatment may cause pulpal infection.
- 9) After preparation of the tooth, remove part of the exterior of DIA-ROOT BIO MTA, and apply resin or glass ionomer according to instructions. When doing so, a minimum 3 mm layer of DIA-ROOT BIO MTA must remain in close proximity to pulp to protect the pulp from secondary infection.

**[Pulpotomy of deciduous teeth]**

- 1) Isolate the tooth with rubber dam and form cavity prep using a high speed bur and avoiding tissues close to pulp.
- 2) Remove decay closest to pulp thoroughly with a new sterilized high speed diamond bur.
- 3) Open the pulp chamber and irrigate to remove pulp up to the appropriate depth with a new sterilized high speed bur.
- 4) Rinse the formed cavity thoroughly with 5.25% NaOCl.
- 5) Mix DIA-ROOT BIO MTA with distilled water for 30 seconds at the following ratio\* and add distilled water when the mixture hardens or dries according to the ambient temperature and humidity. Fill the cavity after sufficient mixing.

\* **Mixing Ratio = 0.5g : 0.225g (0.225 cc)**  
(DIA-ROOT BIO MTA : Distilled Water)

- 6) After setting is complete, apply a strong stream of water on the hardened DIA-ROOT BIO MTA with a 3 way syringe to check for wash-out. If any material is washed away, remove the restoration in its entirety and proceed to root canal treatment as retreatment may cause pulpal infection.
- 7) A glass ionomer or resin is used to form the core to protect it from saliva.

**[Root end filling]**

- 1) After approaching the apical lesion by forming a flap, resect the root depth of 3 mm with a surgical bur.
- 2) Using an ultrasonic tip (low power), perform a root end cavity preparation to a depth of 3 mm.
- 3) If bleeding occurs, control bleeding by compressing the hemorrhagic region (i.e. using a cotton pellet along with a hemostatic agent such as NaOCl)
- 4) Dye the area with methylene blue dye to check for cracks or the presence of accessory canals in the apical region and observe with a microscope.
- 5) Remove excess moisture in the formed apical cavity.
- 6) Mix DIA-ROOT BIO MTA with distilled water for 30 seconds at the following ratio\* and add distilled water when the mixture hardens or dries according to the ambient temperature and humidity.  
\* **Mixing Ratio = 0.5g: 0.225g (0.225 cc)**  
**(DIA-ROOT BIO MTA: Distilled Water)**
- 7) Using a carrier (such as a Centrix® gun), dispense an adequate amount of DIA-ROOT BIO MTA material into the root-end cavity.
- 8) Gently compact the DIA-ROOT BIO MTA root repair material with a small plugger. Apply the material incrementally and compact. Repeat this process until you get a pull-back with an instrument smaller than the size of the cavity.
- 9) Remove excess material and clean the surface of the root with a moist piece of gauze or cotton pellet.
- 10) After setting is complete, rinse thoroughly with saline and check for wash-out. There should be no wash-out whatsoever.
- 11) Take a radiograph to confirm placement of DIA-ROOT BIO MTA. If the placement is not sufficient, irrigate DIA-ROOT BIO MTA out of the canal and repeat the placement procedure.
- 12) Close the surgical opening after confirming the root end cavity is sufficiently sealed.

**C. Storage and management after use**

- 1) Discard the remaining products that are already mixed with distilled water. Do not reuse.
- 2) Keep the product tightly sealed and store in a dry area at room temperature. Avoid direct sunlight, high temperature and humidity (Relative humidity below 60%).

**D. Disposal**

- 1) Seal it with medical waste and dispose of it.

**4. Cautions****A. Cautions**

- 1) This product should only be used by a dental professional and instructions for use and precautions should be carefully observed.
- 2) Avoid contact with skin and eyes. In case of contact, rinse immediately with copious amounts of water and seek medical advice.

- 3) Do not let children and elderly handle the product.
- 4) In rare cases, this product may cause hypersensitivity reactions. If so, discontinue use and consult a physician.

**B. General precautions**

- 1) Improper storage can reduce the performance and the shelf life of the product.
- 2) Do not use this product for any other purpose than its intended purpose.
- 3) If the contents of the product come into contact with eyes, immediately flush with plenty of water.
- 4) Do not use the product after the expiration date.

**C. Contraindications**

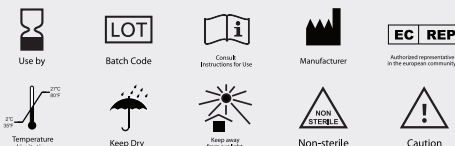
- 1) The product should not be used for other dental purposes except for the purpose of pulp repair and restoration.
- 2) Do not use product on patients with reported sensitivity to any of its components.

**D. Precautions for application**

- 1) Avoid contact with water other than intended use as the material hardens once in contact with any moisture.
- 2) Excess moisture deteriorates the efficiency of DIA-ROOT BIO MTA.
- 3) This product should be applied immediately after mixing.
- 4) To prevent pre-reaction by moisture in the atmosphere, the product should be stored in a sealed container until ready for use.
- 5) To clean and reuse the spatula, remove the remaining product at the end of the spatula using a disposable cotton pad or a disposable cotton ball soaked in alcohol. After removing the product, wipe the spatula three or more times with a disposable cotton pad/ball moistened and soaked with alcohol.

**5. Shelf life**

3 years from the manufacture date when stored and kept according to instructions.

**6. Symbols**

**Rx Only, For Dental Professional Use Only**

**7. 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.

**Contact Information**

**DiaDent Group International**  
16, Osongsangmyeong 4-ro, Osong-eup,  
Heungdeok-gu, Cheongju-si,  
Chungcheongbuk-do, 28161, Korea  
Tel : 82-43-266-2315 Fax : 82-43-262-8658  
www.diadent.co.kr diadent@diadent.co.kr

**DiaDent Group International Inc.**  
11-3871 North Fraser Way, Burnaby,  
B.C., Canada, V5J 5G6  
Tel : 1-604-451-8851 Fax : 1-604-451-8865  
www.diadent.com diadent@diadent.com

**DiaDent Europe B.V.**  
Antennestraat 70, 1322AS  
Almere, the Netherlands  
Tel : 31-36-549-8607 Fax : 31-36-536-7317  
www.diadent europe.com  
diadent@diadent europe.com

**EC REP**

DiaDent Europe B.V.  
Antennestraat 70, 1322 AS  
Almere, the Netherlands  
Tel : 31-36-549-8607