

Identification Number:231AABZX00017000

Controlled Medical Device – Root Canal Repair Material

TMR-MTA cement Mielle

[Indications]

It is indicated in cases of perforations, internal resorption, reverse root filling, pulp capping, pulpotomy, apexification, and apexogenesis.

[Contraindications and Prohibitions]

- ・DO NOT ATTEMPT TO USE FOR PURPOSES OTHER THAN INTENDED USE.
- ・DO NOT USE THIS PRODUCT ON PATIENTS WHO HAVE A HISTORY OF ALLERGY SUCH AS IRRITATION TO THIS MATERIAL AND THE COMPONENTS OF THIS MATERIAL.

[Shape, Composition and Principles]

1. Shape, Composition

This product consists of the following items and contains the ingredients below:

State	Ingredients
Powder	Calcium silicate, Calcium aluminate, Zirconium dioxide, Silicon dioxide, others

2. Color: White, Light ivory

3. Principle

This product turns into paste form by mixing with purified water, and is setting by hydration reaction.  
This product is a bioceramic endodontic cement composed of several mineral oxides.

[Reference Information]

Setting time (37℃): Within 30 min.(Standard moisture ratio 20%)	(Testing method: ISO 6876)
X-ray detectability: Yes	(Testing method: ISO 9917-1)

[Intended Use and Effect / Efficacy]

Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesion, Via canal treatment of root perforation due to internal resorption, Surgical treatment of root perforation due to internal resorption, Periapical surgery with reverse filling, Pulp capping, Pulpotomy, Apexogenesis, Apexification

[Instructions for Use]

- (1) Sterilize a glass pad, a metal spatula and all instruments for the insertion of this product.
- (2) Place this product on a dental mixing paper or a mixing glass pad.
- (3) Drop appropriate amount of purified water near the powder. The standard ratio of powder and liquid is 1g of liquid against 4g of powder (moisture ratio: 20%). Sterile purified water should be used as purified water.
- (4) Mix the powder and purified water with a spatula etc. for about 30 sec. to make it into paste form evenly.
- (5) Place the cement on the selected site with a sterilized appropriate instrument.
- (6) Condense the cement with sterilized appropriate instrument.

[N.B.: Technical Directions and Points for Attention]

- (1) Due to the high hygroscopicity of this product, the cap of container should be opened just before the product is taken out and close the cap immediately after taken out.
- (2) Be careful not to drop water into the container.
- (3) Do not use the product in case where it is setting in the container.
- (4) After the treatment, pulp vitality should be checked by X-ray etc. every 3 to 6 months as necessary.
- (5) In case of using a mixing paper, use a water-repellent type.
- (6) Take note that the strength of set material gets lower if the amount of water is not appropriate when mixing.
- (7) Take note that excessively or inadequately mixing will increase the viscosity of mixed material.
- (8) Take note that the working time gets shorter when the room temperature is higher and it gets longer when the room temperature is lower.

- (9) The working time gets shorter if the mixed material is dried. Therefore, cover the mixed material with a wet gauze etc. to prevent the drying in case where longer working time is needed.
- (10)Take note of the setting time of this product.
- (11)Do not use this product in areas of the tooth in contact with the gingival sulcus or it will be completely dissolved.
- (12)Only use this product after remission of acute signs and symptoms of the endodontic disease. The acidic pH of endodontically compromised sites (lesions) prevents its setting reaction.
- (13)Apply this product carefully. Similar to other endodontic cements, it is resorbed if extruded. However, the excess of any cement may impair the healing process.
- (14)Do not use this product to fill a root canal. Its viscosity is inadequate for this procedure and very difficult to remove in case of a reentry.
- (15)Instruments used for application of the paste should not be cross-used between patients.

[Precautions]

- (1) Do not use this product with other products.
- (2) Use immediately after mixing in order to prevent the drying of the mixed material.
- (3) Use as soon as possible after opening the package.
- (4) Be careful of accidental ingestion of patients.
- (5) Use eye protection, mask and gloves when handling this product.
- (6) Use sterile saline solution for rinsing the cavity.
- (7) Use a low concentration of 3-10% sodium hypochlorite to clean the cavities.
- (8) If the moisture ratio at the time of kneading is not appropriate, it may cause poor setting, so the moisture ratio at the time of kneading should be in the range of 20-30%.
- (9) Remove excess paste using a sterile cotton ball.

[Important Basic Cautions]

- (1) When this product is used for pulp capping, it should be used for the cases of an accidental exposure of 2 mm or less in a non-infected pulp due to cavity formation or trauma.
- (2) Stop using and remove this product immediately in cases of any signs of allergy such as irritation or rash appearing in patients, and then advise to seek medical advice.
- (3) Operators must discontinue use if any signs of irritation or rash appear and seek medical advice.
- (4) Pay attention to prevent adhesion of this product and the mixed material to oral soft tissue or skin. Use rubber dam to prevent oral mucosa and lips from contacting. In case of adhesion to oral mucosa, wipe off with a cotton ball immediately and wash sufficiently with water once the operation is completed. In case of adhesion to the skin, wipe with an alcohol-soaked cotton swab immediately and wash with running water.
- (5) Use eye protection, mask and gloves when handling this product. In case of eye or skin contact, wash abundantly with water.
- (6) In case where this product or the mixed material gets into the eyes, wash immediately with plenty of running water and advice to seek medical attention.
- (7) Do not use water flow with a three-way syringe or similar devices when the product is not fully cured, as this may cause insufficient curing or leakage of the product.

[Storage]

- ・Store this product avoiding high temperature, humidity and direct sunlight.
- ・Tightly seal and store to avoid deterioration by humidity.

[Expiry Date]

- ① This product must be used before the expiry date\* printed on the package.
- ② The expiry date printed on the package is based on our authentication.
- ③ The expiry date printed on the package refers to use expiry date.  
\*(e.g.: EXP YYYY-MM indicates YYYY 'year'/MM 'month' (last day) as the expiry date)

[Package]

[Single Item]		
Shade	Amount	Package
White	0.2g x 3 pcs	Micro Tube
Light Ivory		
White	3g	Glass Container
Light Ivory		
White	10g	
Light Ivory		



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