

Rx only

ROOT CANAL FILLING MATERIAL

**ENDOSEAL<sup>®</sup> MTA**  
Mineral Trioxide Aggregate

PREMIXED INJECTABLE PASTE

3 g Syringe X 1 EA + 24 gauge Tip X 20 EA + Storage cap X 5 EA  
2 g Syringe X 1 EA + 24 gauge Tip X 20 EA + Storage cap X 5 EA  
(REF No. 00000 or 00307)

#### PRODUCT DESCRIPTION

This product is the root canal sealer conforming to ISO 6876. This is a pre-mixed and pre-loaded syringe type that can be hardened by absorbing the moisture around the root canal.

#### PURPOSE OF USE

Permanent root canal obturation

#### PHYSICAL, CHEMICAL AND BIOLOGICAL PROPERTIES (according to ISO 6876)

- Setting time : no longer than 12.3 min+10%
- Flow : above 17 mm
- Film thickness : below 50 µm
- Solubility : below 3.0 %
- Radiopacity : The same radiopacity as that of aluminum of above 3 mm in thickness

#### PRECAUTIONS FOR USE

##### 1. WARNINGS

- 1) Do not use in patients with allergic reaction to chemicals.
- 2) For dentists use only.
- 3) If large amounts of material are pushed into the mandibular canal, remove it with surgical method immediately. (according to state-of-the-art policy)

##### 2. GENERAL PRECAUTIONS

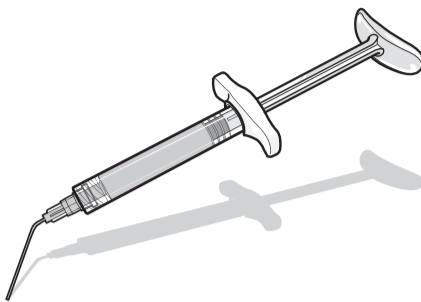
- 1) Always check if the package is damaged before use.
- 2) Do not use for other purposes.
- 3) Keep in a sealed container before use to prevent chemical reaction by carbon dioxide with moisture in the air.
- 4) Do not contact unhardened sealer with the skin or mucous membrane. If contact occurs, rinse with large amounts of water immediately.
- 5) Wear protective gloves, mask and glasses.
- 6) The product must be stored at room temperature avoiding high temperature and humidity.

##### 3. INTERACTIONS

- 1) The product should be used immediately after replacing the 24 gauge tip because it will be hardened when in contact with air.
- 2) If there is no apical lesion but there is apical stop, it is recommended to use ultrasonic device to make the root canal filling evenly.
- 3) In order to deliver ultrasonic waves, apply the device to tweezers holding a master cone.

##### 4. APPLICATIONAL PRECAUTIONS

- 1) Make sure that the sealer comes out smoothly through the tip.
- 2) The root canal must be dried before filling.
- 3) There is a possibility that a large amount of sealer may go beyond the root apex if there is external resorption due to the apical lesion. In this case, the application of ultrasonic waves to the master cone should be omitted.



#### DIRECTION FOR USE

##### 1. PREPARATION PRIOR TO USE

- 1) Always check if the package is damaged before use.
- 2) The tip should be changed with a new one prior to use, and make sure that the sealer comes out smoothly.

##### 2. DIRECTION FOR USE

###### 1) When the root canal is filled with sealer and master cones.

- ① After root canal preparation is completed, disinfect and dry the root canal.
- ② Choose the master cone.
- ③ Replace the 24 gauge tip.
- ④ Do not insert a 24 gauge tip deeper than apical third of the root canal.
- ⑤ Inject the sealer into root canal until it is seen at the root canal orifice.
- ⑥ Insert the master cone into the root canal and push it to the apical stop softly.
- ⑦ Hold the master cone with tweezers and apply ultrasonic waves.
- ⑧ There is a possibility that a large amount of sealer may go beyond the root apex, if there is external resorption due to the apical lesion. In this case, the application of ultrasonic waves to the master cone should be omitted.
- ⑨ Cut the master cone at the root canal orifice.
- ⑩ Take radiographs.

###### 2) When the root canal is filled with sealer.

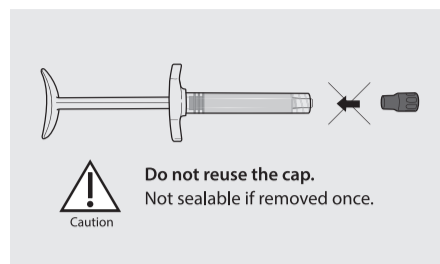
- ① After root canal preparation is completed, disinfect and dry the root canal.
- ② Replace the 24 gauge tip.
- ③ Check if the sealer releases smoothly from the 24 gauge tip.
- ④ Inject the sealer into root canal.
- ⑤ Take radiographs.

##### 3) Removal of Sealer

When the sealer is filled with the master cone together in the root canal, it is removed with the conventional removal method of the master cone.

#### INSTRUCTIONS FOR STORAGE

- 1) The product must be stored at room temperature avoiding high temperature and humidity.
- 2) The product uses immediately after replacing the 24 gauge tip because it will be hardened when in contact with air.
- 3) A new 24 gauge tip must be used in next use.
- 4) After use do not recap the used 24 gauge tip, twist the storage cap provided with the product tightly onto the syringe head.
- 5) Once the gray cap, which was initially fastened to the syringe, is separated, it will not be sealed even if it is fastened again. It must be sealed using the enclosed storage cap.
- 6) Place syringe with the storage cap in the provided pouch. Seal the pouch completely.
- 7) Tighten the storage cap immediately after use to minimize the product from contamination and infection during storage.



#### SHELF LIFE

See expiration date on the package.

#### SYMBOLS

- Non-sterile
- Temperature limit
- Consult instructions for use
- Batch code
- Date of manufacture
- Use-by date
- Manufacturer
- Authorized representative in the European community
- Caution
- Do not use if package is damaged
- Keep away from sunlight
- Keep dry
- Medical Device

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