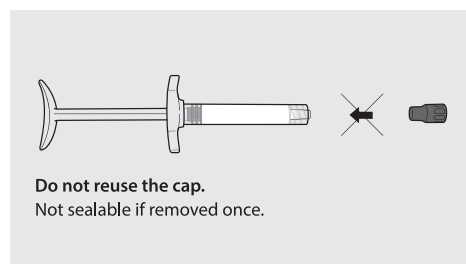
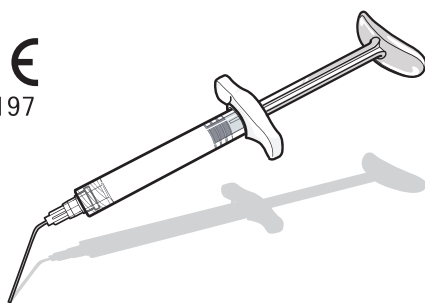




White ROOT CANAL FILLING MATERIAL
ENDOSEAL[®] MTA
 Mineral Trioxide Aggregate
PREMIXED INJECTABLE PASTE

3 g Syringe X 1 EA + 24 gauge Tip X 20 EA + Storage cap X 5 EA

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PRODUCT DESCRIPTION

White ENDOSEAL MTA is a root canal sealer conforming to ISO 6876, in a pre-loaded syringe that does not require any pre-mixing and is set by absorbing moisture from the root canal environment.

The sealer can be used either alone or in combination with gutta-percha obturating cones, injected gutta-percha material or core-carriers, master cones.

INDICATIONS FOR USE

Permanent root canal obturation.

- Intended user

The product is only to be used in a clinical or hospital environment by qualified dentists.

Application field: Obturation of the enlarged, shaped, cleaned and disinfected root canal.

- Intended application

This product is applicable for all patients requiring root canal procedures in teeth of the permanent dentition or in teeth of the primary dentition when there is no permanent successor.

COMPOSITION

Zirconium dioxide, Dimethyl sulfoxide, Calcium silicate, Lithium carbonate, other solvent, and thickening agent (e.g. Polyvinyl alcohol, Polyvinyl pyrrolidone).

PHYSICAL, CHEMICAL PROPERTIES

- Setting Time : 2-4 hours
- Flowability : > 17 mm
- Radiopacity : Equivalent to 3 mm of aluminum or more in thickness
- Film thickness : 50 μm
- Solubility : < 3 %

PRECAUTIONS FOR USE

1. WARNINGS :

- Do not use in patients allergic to any of the chemical materials (Dimethyl sulfoxide).
- Avoid overfilling: When overfilling with obturation material occurs, it is usually tolerated very well by the surrounding tissue. In cases where larger amounts of material are pressed into the mandibular canal, maxillary sinus or nasal cavity immediate removal of the material is usually indicated.

2. GENERAL PRECAUTIONS

(important guidelines and precautions)

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children or adolescents.
- Check the product and packaging for abnormal condition and damage before use.
- Do not use other than for intended use.
- Do not use after expiry date.
- Keep in pouch provided before use to prevent a potential adverse reaction by carbon dioxide and moisture present in the atmosphere.
- Use of a dental dam is considered as the standard of care.
- The product must be stored at room temperature (15 - 25°C) avoiding high temperature and humidity.
- The product should be used immediately after replacing the 24 gauge tip because it can harden when in contact with air.
- Avoid skin contact to prevent corrosion. If contact with skin occurs, immediately remove with cotton pellet and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.
- It is recommended to wear protective clothes (gloves, glasses, masks, and waterproof gown) when using this product because unset material may cause corrosion

3. PRECAUTIONS DURING APPLICATION

- Dry the root canal with paper points.
- 24 gauge tip are intended for single use only. Do not reuse in order to prevent cross-contamination or malfunction.
- In cases of apical external resorption care must be taken to prevent extrusion of the sealer beyond the confines of the root canal.
- To reduce the risk of discoloration of the teeth, it should be applied carefully to aesthetic areas to avoid exposure to saliva.

ADVERSE REACTIONS

No adverse reaction has been reported to date.

STEP BY STEP INSTRUCTIONS

1. PRIOR TO USE

- Determine the potential for an allergic reaction to any of the components of the product.

2. APPLICATION PROCEDURE

1) To fill root canal with sealer and gutta-percha master cone

- ① Disinfect and dry the root canal after root canal preparation is completed.
- ② Choose the master cone that can be inserted to working length and fits snugly the apical preparation size.
- ③ Remove and discard the grey syringe cap and extrude a small amount of sealer and discard.
- ④ Place a new 24 gauge tip on the syringe.
- ⑤ Check if the sealer can be extruded smoothly.
- ⑥ Insert the 24 gauge tip no farther than to the middle third of the root canal.
- ⑦ Inject the sealer into the root canal until it is visible at the root canal orifice. Maintain the tip of the needle immersed in the sealer during injection in order to avoid the inclusion of voids.
- ⑧ Insert the master cone into the root canal and push it to the apical stop.
- ⑨ Avoid excessive pressure to minimize or prevent extrusion of root filling materials beyond the apical foramen.
- ⑩ Cut and remove the coronal portion of the master cone at the root canal orifice.
- ⑪ Compact the coronal portion of the cone with an appropriately sized and fitted plugger.
- ⑫ Take radiographs for verification.

2) To fill root canal with sealer only

- ① Disinfect and dry the root canal after root canal preparation is completed.
- ② Remove and discard the grey syringe cap and extrude a small amount of sealer and discard.
- ③ Place a new 24 gauge tip on the syringe.
- ④ Check if the sealer can be extruded smoothly.
- ⑤ Insert the needle up to 1-2 mm short of the preparation working length, if possible.
- ⑥ Inject the sealer into root canal carefully and slowly, starting from the apex and moving in coronal direction while filling the canal.
- ⑦ Take radiographs for verification.

3) Retreatment - Removal of sealer

When a master cone is used, removal is achieved using conventional retreatment methods.

INSTRUCTIONS FOR STORAGE

- The product must be stored at room temperature (15 - 25°C) avoiding high temperature and humidity.
- After use do not recap the used 24 gauge tip, remove and dispose tip as per national laws and recommendations of local authorities.
- Clean the outside of the syringe and remove any excess sealer and twist the storage cap provided with the product tightly onto the syringe head.
- Place the syringe into the foil pouch and ensure to seal the pouch.

SHELF LIFE

2 years from date of manufacture.

DISPOSAL

Adhere to national laws and recommendations of local authorities for proper disposal.

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

We just mimic nature
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