

AH Plus® Bioceramic Sealer

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*FOR DENTAL USE ONLY
FOR PROFESSIONAL USE ONLY*

INSTRUCTIONS FOR USE

1 PRODUCT DESCRIPTION

AH Plus® Bioceramic Sealer 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.

2 COMPOSITION

- Zirconium Dioxide
- Tricalcium silicate
- Dimethyl sulfoxide
- Lithium carbonate
- Thickening agents

3 PHYSICAL AND 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%.

4 INTENDED 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.

Indications for use

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.

5 CONTRAINDICATIONS

None.

6 WARNINGS AND PRECAUTIONS

6.1 Warnings

- Do not use in patients allergic to any of the components of AH Plus® Bioceramic Sealer.
- **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.

6.2 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 or 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.
- Wear protective gloves, mask and glasses. Use of a dental dam is considered as the standard of care.
- AH Plus® Bioceramic Sealer must be stored at room temperature (15 - 25°C) avoiding high temperature and humidity.
- AH Plus® Bioceramic Sealer should be used immediately after placing the 24-gauge tip because it can harden when in contact with air.

6.3 Precautions during application

- Dry the root canal with paper points.
- AH Plus® Bioceramic Sealer 24 gauge tips 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.

6.4 Adverse reactions

No adverse reaction has been reported to date.

7 STEP BY STEP INSTRUCTIONS

7.1 Prior to use

Determine the potential for an allergic reaction to any of the components of AH Plus® Bioceramic Sealer.

7.2 Application procedure

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.

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.

Retreatment - Removal of sealer

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

7.3 Instructions for storage

- AH Plus® Bioceramic Sealer 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.

8 SHELF LIFE

2 years from date of manufacture.

9 DISPOSAL

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

Distributor



Maillefer Instruments Holding Sàrl
Chemin du Verger 3
CH-1338 Ballaigues
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Manufacturer



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