


BIOSEAL™

Bioceramic Endodontic Sealer

Instructions For Use

Rx Only For Dental Use Only

Caution: U.S. Federal law restricts this material to sale by, or on the order of, a dentist.


 Consult Instructions for use

 Nonreturnable if seal is broken

 Consult MSDS/SDS: www.edsdental.com

 Shelf Life: 36 Months

 Store at room temperature in resealable pouch

 Do not use if package is damaged

 Do not re-use the Intra Canal Tips

Contraindications:

Do not use Bioseal Bioceramic Endodontic Sealer in patients with a known allergy to any of the product's ingredients.

Precautions:

 Keep Dry

- Keep Bioseal Bioceramic Endodontic Sealer tightly closed in its sealed package and stored at room temperature in a dry area, to avoid moisture contact, which could induce the setting process

- Use the syringe cap to keep the syringe tightly closed when not using Bioseal Bioceramic Endodontic Sealer.

- Do not use excessive force to apply Bioseal Bioceramic Endodontic Sealer into the root canal

- Ensure that the rubber dam is properly placed so as to completely isolate the operating field.

- In the case of a wide apical foramen, an apexification of the root should precede the root canal filling.

- Avoid contact of Bioseal Bioceramic Endodontic Sealer with the skin, mucus membranes and eyes. Unset Bioseal Bioceramic Endodontic Sealer can cause irritation. Please refer to the MSDS/SDS for the first aid procedures.

Product Description:

EDS Bioceramic sealer (Bioseal) is a ready-to-use injectable bioceramic cement paste developed for permanent root canal filling and sealing applications. EDS Bioceramic Sealer (Bioseal) is an insoluble, radiopaque material based on a calcium silicate and calcium phosphate composition, which requires the presence of water to set and harden. EDS Bioceramic sealer (Bioseal) does not shrink during setting and demonstrates excellent physical properties. EDS Bioceramic sealer (Bioseal) is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal Tips.

Indications For Use:

- Permanent obturation of the root canal following vital pulp-extirpation.
- Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.
- Suitable for use in single cone and lateral condensation technique.

Working Time:

Bioseal Bioceramic Endodontic Sealer can be applied immediately and introduced directly into the root canal. The working time can be more than 4 hours at room temperature.

Setting Time:

Setting time is 4 hours measured according to ISO 6876:2012 and ANSI/ADA Specification No. 57:2000 for Endodontic Sealing Materials. However, in very dry root canals, the setting time can be more than 10 hours.

Composition:

Bioactive Glass, polyanionic polymers, Chlorhexidine, Host-inclusion particles, Zirconium oxide, calcium silicates, calcium phosphate, monobasic, β -tricalcium phosphate, calcium hydroxide, filler and thickening agents.

Standard:

BioSeal Bioceramic Endodontic Sealer meets the requirements of ISO 6876:2012 for Dental Root Canal Setting Materials and ANSI/ADA Specification No. 57:2000 for Endodontic Sealing Materials.

Interaction:

The setting time of Bioseal Bioceramic Endodontic Sealer is dependent upon the presence of moisture in the dentinal tubules. The amount of moisture required for the setting reaction to occur reaches the root canal by means of the dentinal tubules. Therefore, it is not necessary to add moisture in the root canal prior to performing the obturation.

Removal of Root Canal Filling:

Conventional techniques can be used for the removal of BioSeal Bioceramic Endodontic Sealer as used in combination with Gutta Percha Points. Piezo Electric Ultrasonics (with water spray) can also be used.

Note:

- Discard the Intra Canal Tips after each application. Do not re-use the tips.
- Keep the syringe cap clean and free of moisture. When not in use, keep the syringe cap in the pouch.

Directions For Use:

1. Prior to the application of Bioseal Bioceramic Endodontic Sealer, thoroughly prepare and irrigate the root canal using standard endodontic techniques.
2. Remove the syringe cap from the Bioseal Bioceramic Endodontic Sealer syringe. Securely attach an Intra Canal Tip with a clockwise twist to the hub of the syringe.
3. Insert the tip of the syringe into the canal no deeper than the coronal one third (1/3). Gently and smoothly dispense a small amount of Bioseal Bioceramic Endodontic Sealer into root canal by compressing the plunger of the syringe. Using a #15 hand file or something comparable, lightly coat the canal walls with the existing sealer in the canal. Express a small amount of sealer on a mixing pad, then coat the master gutta percha cone with a thin layer of sealer and very slowly insert it into the canal. The master gutta percha cone will carry sufficient sealer to the apex.

Note: The precise fit of the Gutta Percha master cone creates excellent hydraulics and for that reason it is recommended that the practitioner use a small amount of sealer. Furthermore, it is also important to insert the master cone very slowly to its final working length.

4. If desired, place additional gutta percha points into the canal using standard condensation techniques.

5. Using a heat source, burn off the gutta percha cones at the orifice, apply a slight amount of vertical condensation, and remove any excess sealer with a moist cotton ball or swab.

6. Bioseal Bioceramic Endodontic Sealer will remain part of the permanent root canal filling.

7. After each application, remove the Intra Canal Tip from the syringe with a counterclockwise twist to the hub of the syringe and discard. Clean the outside of the syringe and remove any excess paste, place the syringe cap tightly onto the syringe hub, and place the syringe into the resealable pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.



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