BIO CERAMIC SEALER - SIGILLO BIO - ROOTSEAL BC

(Bioceramic Root Canal Sealing Material)

INSTRUCTIONS FOR USE (Please read carefully before use)

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PRODUCT DESCRIPTION: Bio Ceramic Sealer is a calcium silicate based root canal sealing and filling material. It is a ready to use flowable paste system, used for sealing / filling the root canal after complete removal of the infected pulp tissue. Bio Ceramic Sealer is radiopaque and is white in color and can be used in aesthetic regions of teeth.

MATERIAL OF CONSTRUCTION: Calcium Silicate, Zirconium Oxide in compatible media.

INDICATIONS: To seal and fill the root canals of teeth.

INTENDED USE: Sealing and filling of root canals during obturation in the secondary dentition with or without the aid of obturation points.

SETTING TIME: Less than 5 hours and 30 minutes (ISO 6876:2012).

PROCEDURE & PRODUCT HANDLING: Isolate the tooth using rubber dam. Prepare the root canals by mechanical cleaning and dry the canals using paper points to avoid any remnants of the irrigating solutions.

- Attach a disposable tip onto the Bio Ceramic Sealer syringe and then insert it in the root canal.
- Slowly push the syringe bar in the canal to fill the root canal and slowly pull the syringe out of the canal.
- Insert the gutta-percha master point into the root canal.
- Cut the upper part of gutta-percha using a dental appliance (heated plugger).
- Extra Bio Ceramic Sealer should be removed using a cotton swab or water-soaked cotton pellets.
- Place a moist cotton pellet in the pulp chamber for initiating the setting of Bio Ceramic Sealer.
- Seal the prepared cavity using a nonhygroscopic intermediate restorative material, ensuring proper coronal seal to prevent contamination from external oral fluids.

CAUTION / WARNING:

1. Device to be used by a qualified dentist or dental technician only.
2. Do not insert material under pressure into the canal. Do not press the syringe too hard when injecting Bio Ceramic Sealer because it may extrude the material beyond the root canals and cause pain to the patient.
3. Make sure that an x-ray is taken according to the procedure to confirm complete sealing of the root canal.
4. Should not be used for filling root canals of deciduous teeth.

PRECAUTIONS:

1. Always use a rubber dam for isolation before using this product. Avoid contact of device with skin and mucosa, avoid contact with eyes. Avoid inhalation of fumes. Do not take internally.
2. Eye contact: if the product comes in contact with eye, it may cause irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
3. Skin contact: avoid contact of unset paste with skin or mucosa, it may cause skin sensitization. If contact with skin occurs immediately wipe off thoroughly with cotton and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.
4. Do not use hygroscopic temporary restorative material as it may interfere with setting of Bio Ceramic Sealer.
5. Wear suitable gloves and protective glasses to avoid accidental exposure to skin and eyes.
6. Do not transfer the excess material back into the container to avoid contamination.

CONTRAINDICATIONS:

1. Do not use the product if the patient is allergic to any of the ingredients.
2. Do not use the product on mucosa or skin.
3. Not intended for use beyond the confinement of root canals of teeth.

INTERACTIONS WITH OTHER DENTAL MATERIALS: Bio Ceramic Sealer may react with the irrigating solutions accidentally left in the root canal after irrigation, hence advised to dry the canal completely before introducing the sealer. Kindly communicate and inform the manufacturer with complete details in case of any incidences of interaction not mentioned here.

ADVERSE REACTIONS: No such reactions have been noted. Kindly communicate and inform the manufacturer in details of any instance.

PACKAGING: Multidose plastic dispensing syringe, with pre-bent applicator tips / cannulas.

STORAGE CONDITIONS: Keep away from direct sunlight. Keep locked up and out of the reach of children. Store at a temperature between 10°C to 30°C. Keep the container tightly closed to avoid contamination.

SHELF LIFE: 2 years from the date of manufacturing.

DISPOSAL: Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

LOT Symbol for "BATCH CODE"	Symbol for "USE BY"	Symbol for "NON STERILE"
Symbol for "KEEP DRY"	Symbol for "CAUTION"	Symbol for "CONSULT INSTRUCTIONS FOR USE"
REF Symbol for "CATALOGUE NUMBER"	Symbol for "KEEP OUT OF THE REACH OF CHILDREN"	Symbol for "MANUFACTURER"
Symbol for "DO NOT USE IF PACKAGE IS DAMAGED"	30°C 10°C Symbol for "TEMPERATURE LIMITATION"	Symbol for "KEEP AWAY FROM SUNLIGHT"
MD Symbol for "MEDICAL DEVICE"	IN Symbol for "COUNTRY OF MANUFACTURE"	

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Kindly retain the instructions for use & packaging box until the complete use of the product / expiry.

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.