

CERAFILL PUTTY

BIOCERAMIC MATERIAL FOR PERMANENT ROOT REPAIR



Product Description : Cerafill Putty is a ready-to-use, premixed, bioceramic paste developed for pulp capping, permanent root repair and Permanent Obturation / Filling of root canals. It is an insoluble, radiopaque material, which requires the presence of water to set and harden.

Composition : MTA, Radiopacifiers, Thickeners and Fillers.

Intended Purpose / Intended Use : Ready to use, premixed, bioceramic material for permanent root repair and permanent obturation/filling of root canals.

Indications for Use :

- Pulp Capping
- Permanent Obturation / Filling of root canals
- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification

Instructions for Use :

1. Prior to the application of Cerafill putty, thoroughly prepare and irrigate the application site using standard techniques. Root canal/Dentinal surfaces must be kept moist.
2. Remove the syringe cap from the syringe and gently extrude the material by compressing the plunger of the syringe.
3. Remove the desired amount of material extruding from the syringe using a sterile plastic instrument (of your choice) and place the material onto the desired application site.
4. Remove excess material from the application site with an appropriate instrument. After each application, place the syringe cap tightly onto the syringe hub, clean the outside of the syringe and remove any excess paste, and place the syringe into the foil pouch and ensure to seal the pouch.
5. Store the pouch in a dry area at room temperature.
6. Cerafill Putty is packaged in a multiple dose container (Syringe). Opening and closing of the container does not affect the shelf life of the device.
7. After each application, remove the disposable tip from the syringe with a counter clockwise 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 foil pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.
8. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

Note:

1. Keep the syringe cap clean and free of moisture.
2. Disinfect the exterior surfaces of the syringe and syringe cap (once it is tightly sealed onto the syringe prior to storage to reduce the risk of cross- contamination).
3. The syringe can be handled with a hygienic single-use dental barrier sleeve for infection control.
4. The setting time of Putty is dependent upon the presence of moisture in the dentin and could be delayed in the dry environment.

A. Pulp Capping (Indirect)

1. Isolate the tooth with a rubber dam and complete cavity preparation using a high speed bur.
2. Remove all infected carious area using a round bur at low speed.
3. Rinse the internal surface of the cavity preparation. Remove excessive moisture or hemorrhage with a dry cotton pellet.
4. Using an appropriate instrument, pack an adequate amount of calcium hydroxide based paste (Calcigel or Calplus) over the floor of dentin and pack the material, expanding onto sound dentin. Remove excess with a hand excavator, a micro brush or a cotton pellet.
5. Cover Cerafill Putty with a thin layer of glass ionomer cement and extend onto lateral dentin cavity wall. Proceed the restoration according to manufacturer's instructions.

B. Pulp Capping (Direct)

1. Isolate the tooth with a rubber dam and complete cavity preparation using a high speed bur.
2. Remove all infected carious area using a round bur at low speed.
3. Once pulp is exposed, rinse the cavity and pulp exposure site. If bleeding occurs, achieve hemostasis by placing a cotton pellet dampened with Hemostatic material (Hemostal) or sterile saline gently onto the pulp exposure site.
4. Using an appropriate instrument, pack an adequate amount of Cerafill Putty over the exposure site and pack the material, expanding onto sound dentin. Remove excess with a hand excavator, a microbrush or a cotton pellet.
5. Cover Cerafill Putty with a thin layer of glass ionomer cement and extend onto lateral dentin cavity wall. Proceed the restoration according to manufacturer's instructions.

C. Repair of Root Perforation/Resorption

1. Isolate the tooth with a rubber dam. Debride the root canal using suitable instruments and irrigate.
2. To disinfect the canal, place calcium hydroxide based dressing (Calcigel or Calplus) within the canal and place a temporary restoration over it for a week.
3. At the next visit, isolate the tooth using a rubber dam and remove calcium hydroxide paste.
4. Control excess moisture by paper points. Isolate the root canal and identify the perforation.
5. Using a suitable instrument such as plugger or paper points, apply Cerafill Putty to the perforation. Place a moist cotton pellet in the root canal and seal the root canal by the temporary restoration.
6. At the next visit, isolate the tooth with a rubber dam and examine if the material is the perforation. Place a moist cotton pellet in the root canal and seal the root canal by the temporary restoration.
6. At the next visit, isolate the tooth with a rubber dam and examine if the material is fully set, if not, remove the material and repeat the application.
7. If Cerafill Putty is fully set, obturate the root canal to complete the treatment.

D. Root End Filling

1. Gain access to the root-end and resects the root with a surgical bur.

2. Using an ultrasonic tip, prepare the root end cavity with a depth of 3~5 mm.
3. Isolate the area and control excess moisture with paper points. Control the hemorrhage with an appropriate method.
4. Apply Cerafill Putty to the root canal using the suitable instruments.
5. Remove excess material and clean the surface of the root.
6. Check the adequate placement of Cerafill Putty using an X-ray.

E. Apexification

1. Isolate the tooth with a rubber dam. Debride the root canal using suitable instruments and irrigate the canal.
2. To disinfect the canal place calcium hydroxide based dressing (Calcigel or Calplus) within the canal and place a temporary restoration over it for a week.
3. At the next visit, isolate the tooth using a rubber dam and remove calcium hydroxide based dressing (Calcigel or Calplus). Clean the root canal using suitable instrument and irrigate the canal.
4. Using the suitable instruments such as a plugger or paper points, apply Cerafill Putty to the root canal. Create a 3~5 mm apical barrier of Cerafill Putty.
5. Remove excess material and clean the surface of the root.
6. If Cerafill Putty is fully set, obturate the root canal to complete the treatment.

Warnings :

1. Do not use Cerafill Putty in people allergic to calcium silicates or any other components of this product.
2. Avoid eye contact to prevent irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. Avoid skin contact to prevent possible allergic response. Unset material may cause irritation and therefore contact with skin and mucous membrane should be avoided. In case of contact, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue the use and seek medical attention.
3. Do not swallow or take internally. If accidental swallowing occurs, drink lot of water. If nausea or illness develops, seek medical attention. *Avoid overfilling. When overfilling occurs, the material is usually tolerated very well by the surrounding tissue. The material should be immediately removed in cases of extrusion into the mandibular canal, maxillary sinus or any other vital structures.

Precautions:

1. This product is intended to be used as specifically outlined in the Instructions for use. Any use of this product inconsistent with the Instructions for use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective clothing, eyewear, and gloves.
3. The solubility and essentially basic nature of Cerafill Putty composition requires that it is used only in situations where it can be protected adequately from the intraoral environment.
4. To achieve good results, use of a rubber dam or adequate isolation is recommended. A moist root canal/dentine is necessary to ensure proper setting.
5. Increased humidity and elevated temperature will reduce available work time and set time.

Contraindications: Hypersensitivity against calcium silicates or other components of the root canal filling material.

Storage Conditions: This product should be used at room temperature. Do not refrigerate. Contact with water should be strictly avoided. Inadequate storage conditions could shorten shelf life and product performance. We recommend to store at temperature between 10°C (50°F) and 24°C (75°F).

Shelf Life : 2 years from the date of manufacturing.

Presentation :

Ref. : 40069

Trial Pack : 1 x 0.5g Premixed Syringe

Ref. : 40049

Trial Pack : 1 x 1.2g Premixed Syringe, 7 x Applicator Tips.

Ref. : 40049-1

Regular Pack : 1 x 2g Premixed Syringe, 10 x Applicator Tips.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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Symbol for "DO NOT RE-USE" UDI Symbol for "UNIQUE DEVICE IDENTIFIER"
LOT Symbol for "BATCH CODE" USE-BY DATE Symbol for "USE-BY DATE" NON STERILE Symbol for "KEEP DRY"
CAUTION Symbol for "CAUTION" CONSULT INSTRUCTION FOR USE REF Symbol for "CATALOGUE NUMBER"
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION
DO NOT USE IF PACKAGE IS DAMAGED Symbol for "KEEP OUT OF THE REACH OF CHILDREN" MANUFACTURER
TEMPERATURE LIMIT Symbol for "KEEP AWAY FROM SUNLIGHT" MEDICAL DEVICE

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instructions 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. For feedback, complaints and reporting of unexpected events contact customer care.