

# CERAFILL RCS

## BIOCERAMIC ROOT CANAL FILLING AND SEALING MATERIAL



### Product description :

Cerafill RCS root canal filling and sealing material is a ready to use injectable premixed filling and sealing material which is based on the bioceramic technology. It is alumina free calcium silicate based material with excellent handling characteristics and superior physical properties. It is a radiopaque material which requires water to set and harden.

### Composition :

Calcium Silicates, Calcium Phosphates, Zirconium Oxide, Calcium Sulphate, Fillers, Accelerators and thickening agents.

**Intended Purpose / Intended use:** It is used as a root canal sealer for permanent filling of root canals.

### Indications for Use :

1. Permanent obturation / filling of root canals.
2. As a root canal sealer for teeth of the permanent dentition in combination with root canal points. (suitable for single cone and lateral condensation).

### Instructions for Use :

The cement requires no mixing as it is supplied as a premixed paste in a preloaded syringe with disposable intracanal delivery tips. Prior to the application of the material, the prepared root canal should be dried using a paper point. Avoid over drying as the sealer needs moisture to completely set and harden.

The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

### 1. Sealer technique :

#### A. Conventional method :

The sealer can be dispensed from the syringe on a mixing pad and delivered to the root canal space by carrying it with a gutta-purcha point or an endodontic instrument.

#### B. Tip delivery technique :

Remove the syringe cap and attach the intracanal delivery tip. Insert the tip into the coronal third of the root canal space and smoothly dispense a small amount of material by compressing the syringe plunger. Coat the walls of the canals evenly using a #15 endodontic file or a gutta-purcha point. In case of lateral condensation place additional gutta-purcha points coated with the sealer.

After obturation the gutta-purcha is cut at the orifice using a heat source. Excess sealer in the root canal chamber should be wiped off using a cotton balls or swabs.

### 2. Filling technique :

The material can also be used for filling the root canal space independently. In that case, proper care should be taken to prevent extrusion of material. An apical limiting barrier is strongly advised in such cases.

### Warnings :

a. The sealer may cause sensitization in susceptible people. Do not use Cerafill RCS in people allergic to calcium silicates or any other components of this product.

b. 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.

c. Do not swallow or take internally. If accidental swallowing occurs, drink lots 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 in to the mandibular canal.

### 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 RCS 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.

5. Exposure to moisture and elevated temperature will affect the setting time and working time as well as the consistency of the material.

6. Pulling back the plunger will cause the moisture in the air to entrap inside the syringe that may cause the premature setting of the material.

7. Do not refrigerate the material, instead store in cool & dry place with <50% relative humidity.

8. Do not reuse the disposable syringe tips, to avoid potential cross contamination between the patients.

### Contraindications :

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

### Storage conditions :

This product should be used at room temperature. 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) and keep syringe cap tightly closed. Follow the recommended storage conditions appropriately. Failure to do so may cause premature set of the material inside the syringe.

**Shelf Life :** 2 years from the date of manufacturing.

### Presentation :

Ref. : 40061

**Trial Pack :** 1 x 0.5g Premixed Syringe, 03 x Capillary Tips

Ref. : 40037

**Trial Pack :** 1 x 1.2g Premixed Syringe, 10 x Capillary Tips

Ref. : 40037-1

**Regular Pack :** 1 x 2g Premixed Syringe, 10 x Capillary Tips (Pouch Pack)

Ref. : 40037-2

**Regular Pack :** 1 x 2g Premixed Syringe, 10 x Capillary Tips (Box Pack)

Ref. : 40057

**Regular Pack :** 1 x 3g Premixed Syringe, 10 x Capillary Tips (Box Pack)

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

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**UDI** Symbol for "UNIQUE DEVICE IDENTIFIER"

**LOT** Symbol for "BATCH CODE" **USE-BY DATE** Symbol for "USE-BY DATE" **NON STERILE** Symbol for "NON STERILE" **KEEP DRY** Symbol for "KEEP DRY"

**CAUTION** Symbol for "CAUTION" **CONSULT INSTRUCTION FOR USE** Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER"

**EC REP** SYMBOL FOR "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

**KEEP OUT OF THE REACH OF CHILDREN** Symbol for "KEEP OUT OF THE REACH OF CHILDREN" **MANUFACTURER** Symbol for "MANUFACTURER" **DO NOT USE IF PACKAGE IS DAMAGE** Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

**TEMPERATURE LIMIT** Symbol for "TEMPERATURE LIMIT" **KEEP AWAY FROM SUNLIGHT** Symbol for "KEEP AWAY FROM SUNLIGHT" **MED** Symbol for "MEDICAL DEVICE"

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. For feedback, complaints and reporting of unexpected events contact customer care.