

## CeraBio RCS (Bioceramic Root Canal Sealer)

CeraBio RCS is a premixed, ready-to-use bioactive bioceramic root canal sealer formulated using innovative mineral micro-aggregate chemistry with Active Biosilicate Technology. It is designed for permanent obturation of root canals in combination with gutta-percha points and provides excellent sealing, biocompatibility, and bioactivity.

### COMPOSITION

Calcium Silicates, Calcium Aluminate, Calcium Hydroxide, Zirconium Oxide, Dispersing Agent

### PROPERTIES

- Biocompatible formulation with high mineral purity and monomer-free composition, reducing the risk of adverse tissue reactions
- Bioactive properties with hydroxyapatite formation at the tooth-sealer interface and mineralization of dentinal structures
- High alkaline pH for antimicrobial activity
- Excellent sealing ability through crystallization within dentinal tubules creating a tight seal
- Does not exhibit setting shrinkage
- Easily removable during retreatment procedures
- Ready-to-use formulation
- Suitable for conventional and single-cone obturation techniques

### INDICATIONS

- Permanent root canal obturation in conjunction with gutta-percha points in teeth with vital or necrotic pulp
- Root canal filling after retreatment procedures
- Single-cone obturation techniques
- Cold lateral condensation techniques
- Thermoplastic obturation techniques

### CONTRAINDICATIONS

- Do not use in patients with known hypersensitivity or allergy to any component of the material
- Do not use for applications other than intended use

### PRECAUTIONS

- Product intended for professional dental use only
- Use personal protective equipment (gloves, masks, protective eyewear) during handling
- Use rubber dam isolation during all procedures
- Avoid direct contact with eyes, skin, and oral soft tissues
- In case of contact with eyes or skin, rinse immediately with copious amounts of water and seek medical advice if irritation persists
- Avoid overfilling and excessive extrusion into periapical tissues
- Do not use the material as a sole filling material without gutta-percha cones

- The material is moisture-sensitive; tightly close the syringe immediately after use
- Avoid contamination with saliva, blood, or other materials
- Product should only be used after adequate infection control and cleaning of the canal system
- Excessive drying of the canal should be avoided because moisture within dentinal tubules initiates the material setting reaction

### ADVERSE REACTIONS

- No known adverse reactions have been reported when the product is used as directed and storage, transportation, and application instructions are followed.

### TECHNICAL INFORMATION

- Ready-to-use biocompatible formulation
- Setting time: approximately 4.5 hours after placement
- pH: approximately 12.5
- Antibacterial and bacteriostatic properties due to high alkalinity
- Radiopacity: approximately 8 mm aluminum equivalent
- No setting shrinkage
- Suitable for conventional, single-cone, and thermoplastic filling techniques

### DIRECTIONS FOR USE

#### Preparation of Syringe and Applicator Tip

- Attach the applicator tip securely to the syringe
- Disinfect the syringe and applicator assembly before use
- Use a disposable protective barrier sleeve over the syringe to minimize cross-contamination
- Confirm material flow before intra-canal application
- Apply gentle pressure to avoid excessive extrusion
- Retract the plunger slightly after use to stop material flow
- Remove excess material from the applicator tip and securely recap the syringe immediately after use
- Clean and disinfect the syringe after each use
- Discard contaminated syringes if exposed to blood or saliva contamination

#### A. Root Canal Obturation – Lateral Condensation Technique

- Administer anesthesia as required and place rubber dam isolation
- Perform biomechanical preparation of the root canal
- Attach the applicator tip to the syringe
- Dry the canal with absorbent paper points without excessively drying dentin
- Apply CeraBio RCS directly into the apical third of the canal

- Coat the master gutta-percha cone with CeraBio RCS and insert according to the final preparation size
- Complete obturation using the lateral condensation technique
- Verify obturation radiographically
- Remove excess gutta-percha using heated instruments and perform vertical compaction
- Remove excess sealer and complete coronal sealing and restoration

#### B. Single-Cone Technique

- Administer anesthesia as required and place rubber dam isolation
- Complete biomechanical preparation of the root canal
- Attach the applicator tip to the syringe
- Dry the canal with absorbent paper points without excessive dehydration
- Apply CeraBio RCS into the apical third of the canal
- Insert the master gutta-percha cone
- Verify obturation radiographically
- Remove excess gutta-percha with heated instruments and perform vertical compaction
- Remove excess material and complete coronal restoration

### IMPORTANT NOTES

- CeraBio RCS does not undergo setting shrinkage
- Suitable for use with conventional, single-cone, and thermoplastic obturation techniques
- Use standard gutta-percha removal techniques during retreatment procedures
- Moisture from dentinal tubules initiates the setting reaction; avoid excessive canal drying
- Excessive material extrusion beyond the apex should be avoided

### PRESENTATION

Ref. No.: PL-0223 - CeraBio RCS - 1 × 2 g Syringe, 5 × Applicator Tips, 1 × Instructions for Use

### STORAGE CONDITIONS

- Store in a dry and well-ventilated area at 15°C–30°C
- Do not refrigerate
- Keep away from moisture and direct sunlight
- Do not store near ammonia, ammonium nitrate, chlorine-containing products, or disinfectants containing these ingredients
- After use, keep the syringe inside the aluminum self-sealing pouch
- Improper storage may result in hardening of the material due to its hygroscopic nature

### SHELF LIFE

3 years from the date of manufacture.

### DISPOSAL

Dispose of product and packaging according to local regulations for dental and medical waste.

### CONTACT

**Prevalent Healthcare LLP**, Poongode Road, Karutheni, Malappuram, Kerala – 679339, India.  
Ph.: +91 4931257954 Email: info@prevalentonline.com  
www.prevalentonline.com

Failure to comply with the specified storage conditions may alter the working characteristics of the material and reduce its shelf life.

The manufacturer is not responsible for any loss of quality resulting from non-compliance with the specified conditions for transportation, storage, and use of this product. The user assumes full responsibility for using the material for any purposes other than those specified by the manufacturer. This material is intended solely for professional dental use. Application must be carried out strictly according to the instructions for use. The manufacturer accepts no liability for damages resulting from failure to follow the provided instructions or for use beyond the stipulated applications. The user is responsible for assessing the material's suitability for any purpose not explicitly stated in this instruction sheet. The descriptions and data provided do not constitute a warranty of attributes and are not legally binding.

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

Symbol for "TEMPERATURE LIMITATION"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN"

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

Symbol for "KEEP AWAY FROM SUNLIGHT"

Symbol for "MANUFACTURER NAME & ADDRESS"

Symbol for "CONSULT INSTRUCTION FOR USE"

Symbol for "CATALOGUE NUMBER"

Symbol for "MEDICAL DEVICE" Symbol for "KEEP DRY"

Symbol for "NON STERILE" Symbol for "USE BY"

Symbol for "BATCH CODE" Symbol for "CAUTION"

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