



**WARNING: US Federal Law restricts this device to sale by or on the order of a dentist professional.**

Rx Only

For Dental Use Only

#### PRODUCT TRADE NAME

- Injectable Root Canal Bioceramic Sealer

#### COMMON NAME

- Root Canal Sealer

#### MODEL

- C-Root SP

#### SPECIFICATIONS

- Preloaded Syringe: 2g ; 1g; 0.5g

#### PRODUCT DESCRIPTION

C-Root SP Injectable Root Canal Bioceramic Sealer is a convenient premixed ready-to-use, injectable white hydraulic bioceramic paste developed for permanent root canal filling and sealing applications. C-Root SP is an insoluble, radiopaque and aluminum-free material based on a strontium silicate composition, which requires the presence of water to set and harden. C-Root SP does not shrink during setting and demonstrates excellent physical properties. C-Root SP is packaged in a preloaded syringe and is supplied with disposable Intra Canal tips. C-Root SP may be delivered into the canal via the disposable tips or it can be delivered via traditional methods.

#### 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.
- C-Root SP is suitable for use in the single cone and lateral condensation technique.

#### CONTRAINDICATION

- Do not use C-Root SP in patients with a known allergy to any of the product's ingredients. An allergic reaction may require re-treatment.

#### PRECAUTIONS

- Discard the disposable Intra Canal tips after each application. Potential cross-contamination may occur if disposable tips are re-used. Do not re-used the tips.
- Do not sterilize C-Root SP or the disposable tips. Failure to follow these instructions could damage the product and/or distort the tips, resulting in procedural delays or user inconvenience.
- Cleaning:**
  - 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.
  - The C-Root SP syringe should be mantled with a hygienic single-use barrier sleeve for infection control for direct intra-oral use.
- Ensure there is continuous flow of C-Root SP and the placement site is completely filled. Failure to do so may result in procedural delays.
- Ensure that any bleeding is under control prior to placing C-Root SP as the material may wash out of the placement site and require re-treatment.

#### STORAGE

- C-Root SP must be stored in a dry area at room temperature.
- Closely follow the recommended storage conditions. Failure to do so will cause the material to prematurely set resulting in re-treatment of material placement or user inconvenience. To avoid prematurely inducing the setting process closely follow these guidelines:
  - Use the syringe cap to keep the syringe tightly closed when the material is not in use. Keep the syringe cap free from moisture.
  - Keep C-Root SP tightly sealed in its pouch and store at room temperature in a dry area to avoid moisture contact.

#### WARNINGS

- Use personal protective equipment to avoid contact of C-Root SP with the skin, mucus membranes and eyes. Unset C-Root SP may cause irritation. Please refer to the Safety Data Sheet (SDS) for the first aid procedures.
- Do not use excessive force to apply the material into the root canal as

this may cause patient sensitivity, discomfort and/or pain, or breakage of the syringe plunger.

- Always inspect the syringe prior to use. Using a syringe with illegible reference markings could lead to overfilling or under filling of the root canal site.
- C-Root SP has not been tested in pregnant women or nursing mothers.
- Procedural delays or user inconvenience may be experienced if the disposable tip is not inspected prior to use. If C-Root SP does not flow out of the disposable tip or if the tip feels stiff, discard the tip and use a new tip.
- Always check the expiration date of the product to prevent procedural delays or user inconvenience (e.g. material becomes brittle or will not set).
- Overfilling the root canal may lead to patient sensitivity, foreign body inflammation, maxillary sinus aspergillosis, paresthesia of anesthesia due to nerve impingement or may require surgical removal of the overfill.
- Carefully read package labeling to ensure use of the appropriate bioceramic material. Failure to do so may cause user or patient inconvenience.
- Multiple continuous applications of material using the syringe delivery system may cause hand fatigue.
- Please ensure that the carton and pouch have not been opened or damaged, as this indicates that the barriers have been breached.

#### ADVERSE REACTION

- If the patient should experience any unusual pain, swelling or discomfort orally or in the jaw region following treatment of C-Root SP, please advise the patient to seek medical attention.

#### INTERACTIONS WITH OTHER DENTAL MATERIALS

- None known

#### EQUIPMENT

- Hand file(s)
- Moist cotton balls or swabs
- Gutta percha points and paper points

#### WORKING TIME

No mixing is required. C-Root SP can be applied immediately and introduced directly into the root canal. The working time can be more than 1.5 hours at room temperature.

#### SETTING TIME

Setting time is 8 hours. However, in very dry root canals, the setting time can be more than 8 hours.

#### COMPOSITION

Zirconium Oxide, Strontium Silicates, Calcium Phosphates, Calcium Hydroxide, Tantalum Oxide and Filler Agents.

#### INTERACTIONS

The setting time of C-Root SP is dependent upon the presence of moisture in the dentin. The setting reaction can proceed quickly in root canals, which have been inadequately dried. 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 placing the material.

#### REMOVAL OF ROOT CANAL FILLING

Conventional techniques can be used for the removal of C-Root SP as used in combination with gutta percha points. Piezo Electric Ultrasonics (with water spray) can also be used.

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

#### DIRECTIONS FOR USE:

- Prior to the application of C-Root SP, thoroughly prepare and irrigate the root canal using standard endodontic techniques.
- Dry the canal as you normally would using paper points.
- Sealer Delivery Methods: both of the following sealer delivery methods are effective.

The clinician should utilize whichever method they are most comfortable with:

##### a. Traditional Method:









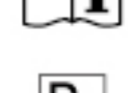
Coat the primary gutta percha point or a small hand file with C-Root SP (extra-orally) and use the point or file to apply C-Root SP to the canal walls.

##### b. Tip Delivery Method:

Remove the syringe cap from the C-Root SP syringe. Securely attach a disposable Intra Canal tip with a clockwise twist to the hub of the syringe. The disposable tips are flexible and can be bent to facilitate access to the root canal. 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 (1-2 reference markings) of C-Root SP into the root canal by compressing the plunger of the syringe. Using a 15# hand file or any comparable hand file, lightly coat the canal walls with the existing C-Root SP in the canal. Then coat the master gutta percha cone with a thin layer of C-Root SP and very slowly insert it into the canal. The master gutta percha cone will carry sufficient C-Root SP 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 C-Root SP. Furthermore, it is also important to insert the master cone very slowly to its final working length. If using a warm vertical technique, see the instructions for use for your powered heat source.
- If desired, place additional gutta percha points into the canal using standard condensation techniques.
  - Using a heat source, burn off the gutta percha cones at the orifice, apply a slight amount of vertical condensation, and remove any excess C-Root SP with a moist cotton ball or swab.
  - C-Root SP will remain part of the permanent root canal filling.
  - After each application, remove the disposable 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 foil pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.

#### KEY TO SYMBOLS

	Catalogue number
	Batch code
	Use-by date
	Caution
	Store at room temperature
	Keep dry
	Do not re-use the disposable Intra Canal Tips
	Do not use if package is damaged
	Consult instructions for use
	Rx only