INSTRUCTIONS FOR USE

iRoot® SP
Innovative BioCeramix Inc. Sealing Paste

Innovative BioCeramix Inc. IBC
Injectable Root Canal Sealer
BioCeramic Technology

CONTRAINDICATION
- Do not use iRoot 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 single use disposable tips are re-used. Do not re-use the tips.
- iRoot SP and the disposable Intra Canal tips are not designed to be sterilized. Please do not sterilize iRoot 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:
  a. 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.
  b. The iRoot 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 iRoot 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 iRoot SP, as the material may wash out of the placement site and require re-treatment.

STORAGE
- iRoot 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:
  a. Use the syringe cap to keep the syringe tightly closed when the material is not in use. Keep the syringe cap free from moisture.
  b. Keep iRoot 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 iRoot SP with the skin, mucus membranes and eyes. Unset iRoot 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 application into the root canal site. Using a syringe with illegible reference markings could lead to overfilling or underfilling of the root canal site.
- iRoot 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 iRoot 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.

Rx Only **For Dental Use Only**

- 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 iRoot 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

PRODUCT DESCRIPTION
iRoot SP Injectable Root Canal Sealer (iRoot SP) is a convenient premixed ready-to-use, injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot SP does not shrink during setting and demonstrates excellent physical properties. iRoot SP is packaged in a preloaded syringe and is supplied with disposable Intra Canal tips.

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.

iRoot SP is suitable for use in the single cone and lateral condensation technique.

WORKING TIME
No mixing is required. iRoot SP can be applied immediately and introduced directly into the root canal. The working time can be more than 30 minutes at room temperature.

SETTING TIME
Setting time is 4 hours. However, in very dry root canals, the setting time can be more than 10 hours.

COMPOSITION
Zirconium oxide, calcium silicates, calcium hydroxide, calcium phosphate monobasic and filler agents.

INTERACTIONS
The setting time of iRoot 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 iRoot SP as used in combination with gutta percha points. Piezo Electric Ultrasonics (with water spray) can also be used.

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U.S. Patent Nos.: 7,553,362, 7,575,628, 8,343,271, 8,475,811
European Patent Nos.: 1861341 A4, 2142225 B1

DIRECTIONS FOR USE:
1. Prior to the application of iRoot SP, thoroughly prepare and irrigate the root canal using standard endodontic techniques.
2. Dry the canal as you normally would using paper points.
3. 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 iRoot SP (extra-orally) and use the point or file to apply iRoot SP to the canal walls.
   b. Tip Delivery Method:
   Remove the syringe cap from the iRoot 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 iRoot 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 iRoot SP in the canal. Then coat the master gutta percha cone with a thin layer of iRoot SP and very slowly insert it into the canal. The master gutta percha cone will carry sufficient iRoot 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 iRoot 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.

4. If desired, place additional gutta percha points into the canal using standard condensation techniques.
5. Using a heat source, burn off the gutta percha cones at the orifice, apply a slight amount of vertical condensation, and remove any excess iRoot SP with a moist cotton ball or swab.
6. iRoot SP will remain part of the permanent root canal filling.
7. 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.

Symbol	Meaning	Standard (if applicable)
REF	Catalogue number	ISO 15223-1
LOT	Batch code	ISO 15223-1
	Use by date	ISO 15223-1
QTY	Quantity	N/A
25°C 77°F / 10°C 50°F	Temperature limitation Store at room temperature	ISO 15223-1
	Keep dry	ISO 15223-1
	Do not re-use (The disposable Intra Canal Tips)	ISO 15223-1
	Do not use if package is damaged	IS0 15223-1
	Consult Instructions For Use; Follow eIFU website listed	ISO 15223-1
NON STERILE	Non-sterile	ISO 15223-1
MD	Medical Device	ISO 15223-1
	Irritant	GHS
	Manufacturer/Legal Manufacturer	ISO 15223-1