

# BIO-C SEALER ION<sup>+</sup>

## ENGLISH

### DEFINITION

Bioceramic root canal sealer ready to use.

### INTENDED PRODUCT USE

Sealing the root canal of permanent teeth.

### INDICATIONS

1. Sealing the root canal of permanent teeth;
2. Internal resorption treatment.

### COMPOSITION

Calcium and magnesium silicate, calcium sulfate, potassium sulfate, zirconium oxide, silicon dioxide and dispersing agent.

### TECHNICAL INFORMATION

- Setting time: ≤ 240 minutes
- Radiopacity: 8 mm Al (> 3 mm Al ISO 6876)

### PRECAUTIONS

- Carefully read and understand all instructions before using. The effective use of BIO-C SEALER ION<sup>+</sup> depends on an accurate diagnosis and precise operative procedure.
- Place rubber dam isolation prior to all BIO-C SEALER ION<sup>+</sup> procedures.
- BIO-C SEALER ION<sup>+</sup> is a permanent non-resorbable sealer. Do not use to fill completely a root canal without gutta percha point(s).
- BIO-C SEALER ION<sup>+</sup> is highly sensitive to moisture. Close the packaging after use with suitable pressure to prevent undesirable setting inside the syringe.
- BIO-C SEALER ION<sup>+</sup> should be stored at room temperature (25°C/75°F); DO NOT refrigerate. Keep syringe tightly closed. Moisture will reduce the shelf life of the material. Exposure of the sealer will cause drying and possibly undesirable setting inside the syringe.
- Dry the canal with paper points; the moisture from the dentin tubules will initiate the BIO-C SEALER ION<sup>+</sup> setting reaction. DO NOT use any alcohol solution (Ethanol) prior to the obturation.
- BIO-C SEALER ION<sup>+</sup> will set tardily when exposed to air on the mixing pad. BIO-C SEALER ION<sup>+</sup> only sets in the presence of moisture.
- BIO-C SEALER ION<sup>+</sup> shall be used only after the infection is controlled. BIO-C SEALER ION<sup>+</sup> setting does not occur within acidic pH.
- Verify flow prior to applying intraorally. If resistance is met, replace delivery tip and re-check.
- To avoid expelling BIO-C SEALER ION<sup>+</sup> past the foramen, keep the delivery tip at a maximum limit of 4mm short of the working length. Use a rubber stop to establish the extent of tip penetration. Make sure that the tip is loose during insertion of the sealer inside the canal.
- DO NOT wedge the delivery tip inside the canal. DO NOT "pump" delivery tip or the master gutta percha point while expressing material into the canal.
- To avoid clogging, use only recommended tips to deliver BIO-C SEALER ION<sup>+</sup>. Verify flow prior to applying intraorally. DO NOT overfill. While expressing BIO-C SEALER ION<sup>+</sup> and withdrawing

tip, the operator should note sealer coming on the cervical third of the canal.

- Sterilize delivery tips before use. DO NOT reuse delivery tips. Delivery tips are intended for single patient use only. Discard after each patient. Properly dispose tips and empty syringes after use.
- Disinfect BIO-C SEALER ION<sup>+</sup> syringe with an intermediate level disinfectant after each patient.
- Wear safety goggles, mask and gloves when handling BIO-C SEALER ION<sup>+</sup>. In case of contact with eyes or soft tissue, rinse with copious amounts of water.
- BIO-C SEALER ION<sup>+</sup> is NOT intended to be used in primary teeth.
- BIO-C SEALER ION<sup>+</sup> is NOT resorbable. DO NOT overfill the canal. When a large amount of material is overfilled, immediate surgical removal of the material should be considered, as with all root canal materials.
- DO NOT allow BIO-C SEALER ION<sup>+</sup> to be ingested.
- DO NOT use the product after expiration date.
- DO NOT use the product if packaging is damaged.
- DO NOT use in patients that report sensitivity to the formula components.
- Product NOT tested in pregnant and lactating women.
- Keep the product away from children.

*NOTE: For SDS and additional information, please go to [www.angelus.ind.br](http://www.angelus.ind.br)*

### USE TECHNIQUE

#### Procedure with delivery tips

1. Use a disposable plastic cover on the syringe to avoid cross-contamination;
2. Sterilize delivery tips before use. Properly dispose tips after use;
3. Verify flow prior to applying intraorally. If resistance is met, replace applicator tip and re-check. Use very light pressure during insertion of BIO-C SEALER ION<sup>+</sup>;
4. Keep the delivery tip at a maximum limit of 4mm short of the working length and loose in the canal. Use a rubber stop to establish the extent of tip penetration. DO NOT wedge the delivery tip inside the canal.
5. Recap the syringe immediately after removing the tip.

#### BIO-C SEALER ION<sup>+</sup> OBTURATION PROCEDURE (PERMANENT TEETH)

##### A. LATERAL CONDENSATION (LATERAL COMPRESSION)

1. Instrument, clean and disinfect canals thoroughly;
2. Use the preferred irrigation protocol. Final irrigation should be with distilled water;

*CAUTION: DO NOT USE ALCOHOL BASED SOLUTIONS AS A FINAL IRRIGATION. OVERDRYING THE CANAL WILL INHIBIT THE SETTING OF BIO-C SEALER ION<sup>+</sup>. CHECK PRODUCT INFORMATION BEFORE USING.*

3. Evacuate liquid from canals using a proper cannula;
4. Dry canal with paper points for 1-2 seconds each (point should be damp 1-3 mm at tip). Canal should be damp, not desiccated, prior to obturating with BIO-C SEALER ION<sup>+</sup>;

*CAUTION: DO NOT desiccate canal as this will cause delay of setting time.*

5. Fit gutta percha master point to length, with tug back, for each canal;
6. Verify fit radiographically. Remove gutta percha point from canal and set aside;
7. Remove BIO-C SEALER ION<sup>+</sup> cap from syringe by twisting

counter clockwise;

- Attach delivery tip to the syringe by twisting clockwise to lock;  
**CAUTION: Make sure that the tip is tightly locked.**
- Verify flow prior to applying intraorally. If resistance is met, replace tip and re-check;
- Insert the delivery tip into canal to within 4mm of working length or shorter if binds in canal. Use a rubber stop to establish the extent of tip penetration. DO NOT wedge the delivery tip inside the canal;

**CAUTION: To avoid expressing BIO-C ION+ beyond the foramen, DO NOT force the tip or sealer into tight canals.**

- Express BIO-C SEALER ION+ with light pressure while withdrawing tip;
- Fill canal space to canal orifice ONLY;
- Slowly insert the master cone and seat to working length. DO NOT make back-and-forth pumping movements. Make space with spreaders laterally and use accessory cones to fill space as needed;
- Trim excess gutta percha with a hot instrument;
- Clean the excess of sealer at the pulp chamber with water.

Restore using the preferred technique;

**CAUTION: Replace the syringe cap immediately after use. Disinfect the syringe with intermediate level disinfectant. Dispose the delivery tip.**

## B. SINGLE CONE (HYDRAULIC COMPRESSION)

- Instrument, clean and disinfect canals thoroughly;
- Use the preferred irrigation protocol. Final irrigation should be with distilled water;

**CAUTION: DO NOT use alcohol-based solutions (Ethanol) as a final irrigation. Over drying the canal will inhibit the setting of BIO-C SEALER ION+.**

- Evacuate liquid from canals using a proper cannula;
- Dry canal with paper points for 1-2 seconds each (point should be damp 1-3mm at tip). Canal should be damp, not desiccated, prior to obturating with BIO-C SEALER ION+;

**CAUTION: DO NOT desiccate canal as this will cause delay of setting time.**

- Fit gutta percha master point master to length, with tug back, for each canal;
- Verify fit radiographically. Remove gutta percha point from canal and set aside;
- Remove BIO-C SEALER ION+ cap from syringe by twisting counter clockwise;
- Attach delivery tip to the syringe by twisting clockwise to lock;  
**CAUTION: Make sure that the tip is tightly locked.**
- Verify flow prior to applying intraorally. If resistance is met, replace tip and re-check;

- Insert the delivery tip into canal to within 4mm of working length or shorter if binds in canal. Use a rubber stop to establish the extent of tip penetration. DO NOT wedge the delivery tip inside the canal;

**CAUTION: To avoid expressing BIO-C SEALER ION+ beyond the foramen, DO NOT force the tip or sealer into tight canals.**

- Express BIO-C SEALER ION+ with light pressure into canal while withdrawing tip;
- Fill canal space to canal orifice ONLY;
- Slowly insert the master cone and seat to working length. DO NOT make back-and-forth pumping movements;
- Trim excess gutta percha master point with a hot instrument;
- Use a proper spreader to compact the gutta percha point vertically;

- Clean the excess of sealer at the pulp chamber with water.

Restore using the preferred technique;

**CAUTION: Replace the syringe cap immediately after use. Disinfect the syringe with intermediate level disinfectant. Dispose the delivery tip.**

## BIO-C SEALER ION+ INTERNAL RESORPTION PROCEDURE)

- Perform the instrumentation/irrigation with superior attention to the pathologic enlarged area caused by the internal resorption;
- Apply BIO-C TEMP (Angelus Ind.) intracanal dressing material according the instructions of use;
- Confirm the presence of the intracanal dressing material in the entirely canal extension radiographically;
- After a minimum period of 2 weeks, remove the intracanal dressing material from the canal;
- Proceed with one of the above described BIO-C SEALER ION+ obturation procedures, making sure that the pathologic enlarged area is properly filled with sealer.

## RETREATMENT

- BIO-C SEALER ION+ can be removed for re-treatment or post placement;
- Perform the preferred retreatment technique. Ultrasonification is indicated to more efficient obturation removal.

## STORAGE

- Keep the product in a dry and ventilated place between 15 and 30°C (60 to 85°F) and relative humidity below 60%.
- Do not refrigerate.

\* Product exclusively to be used by dentists.

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## RX ONLY

### Symbology

	For care, see accompanying documents.		Single use accessories.
	Keep under shelter of the sun.		Non-sterile.
	Minimum and maximum temperature limit.		Keep dry.

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**ATTENTION:** This product must be used according to the instructions described in this manual. The manufacturer is not responsible for failure or damage caused by incorrect handling or use.