



EndoSequence® BC TEMP™:
Instructions for Use

DEFINITION

Ready-to-use bioceramic paste for intracanal dressing.

INDICATIONS

- 1. Intracanal dressing in endodontic treatment of teeth with pulp necrosis and retreatments.
- 2. Intracanal dressing in cases of perforations, external and internal resorptions, prior to the use of BC RRM Paste or BC RRM Putty.
- 3. For the treatment of incomplete root formation (rhizogenesis)

COMPOSITION

Calcium Silicates, Calcium Aluminate, Calcium Oxide, base Resin, Calcium Tungstate, and Titanium Oxide.

TECHNICAL DATA

- Ready-to-use biocompatible product
- High alkalinity - pH: 12±1
- High radiopacity: ≥ 9 mm of the Aluminum scale, according to ISO 6876

DIRECTIONS FOR USE

A. APPLICATION TIPS USAGE

- 1. Sterilize application tips prior to use
- 2. Position the application tip in syringe
- 3. It is recommended to use a disposable plastic cover on the syringe to avoid cross-contamination
- 4. Confirm the material output of the syringe prior to direct application in the canal
- 5. Position the tip and syringe assembly properly into the canal and slightly press the plunger to avoid excessive product output
- 6. Before closing the syringe, retract the plunger to stop the outflow
- 7. After use, wipe excess material from the

tip of the syringe and close with proper pressure to prevent moisture from entering and causing the product to dry

8. Clean and disinfect the syringe in subsequent uses to avoid cross-contamination

B. INTRACANAL APPLICATION

- 1. Anesthetize, install the absolute insulation, and perform the biomechanical preparation of the duct and, in cases of internal resorption, use curettes for the elimination of tissue
 - 2. Dry the canal with absorbent paper cones
 - 3. Dispense the initial portion of material from the tip of the syringe that may be slightly hardened
 - 4. Connect the application tip to the syringe
 - 5. Insert the tip of the syringe near to the dental apex
 - 6. Apply BC TEMP by gradually withdrawing the syringe to obtain complete filling of the canals
 - 7. Remove excess paste from the pulp chamber
- Important: make the changes, if necessary, until the signs and symptoms normalize.
- 8. Final removal of BC TEMP prior to canal sealing should be performed using Sodium Hypochlorite associated with the use of a K-file, with movement of the file against the walls of the root canal;
 - 9. Then, irrigate with 17% EDTA solution and, if possible, activate EDTA with Ultrasonic Tip in 3 cycles of 10 seconds of duration
 - 10. Seal the canal with a sealer like BC® SEALER and Gutta-Percha cones
 - 11. Perform the sealing of the coronary opening.

WARNINGS

- The product is sensitive to moisture, so properly close the packing with proper pressure to prevent it from drying.
- Do not store in a refrigerator.

- Do not reuse the application tips.
- Clean and disinfect the syringe in subsequent uses to avoid cross-contamination.

PRECAUTIONS

- Wear safety goggles, facemask, and gloves when handling the product. In case of contact with eyes or skin, wash with water
- Do not use the product after the expiration date
- Do not use the product if packaging is damaged
- Do not use in patients with reported sensitivity to components of the formula
- Product not tested on pregnant and lactating women
- Keep out of the reach of children
- The product should remain in the patient's root canal chamber temporarily (not exceeding 29 days).

STORAGE

- Keep the product in a dry and ventilated place between 15 and 30°C (59 and 86°F) and relative humidity lower than 60%.
- Do not store in a refrigerator

**Product of exclusive use by Dentists*

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SYMBOLLOGY

	See instruction for use.		Keep dry.
	Keep protected from sunlight.		Maximum temperature limit.
	Non sterile.		Minimum temperature limit.

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.



EndoSequence® BC TEMP™: Safety Data Sheet

1. IDENTIFICATION

Product Identifier	
Trade Name	Product Identifier Number
BC TEMP .5G 4P	5028170U0
BC TEMP TIPS 20P	5028171U0

Product Use:
Ready-to-use bioceramic paste for intracanal dressing.

Restrictions on Use: For dental use only.

Supplier/Distributor:
Brasseler U.S.A. Dental, LLC, One Brasseler Boulevard, Savannah, Georgia 31419, USA, 800.241.4522

Emergency phone and email: For Chemical Emergency ONLY (spill, leak, fire, exposure, or Accident) call: CHEMTRECTel: 1-800-262-8200 (USA) +1 703-741-5500 (International)

2. HAZARDS IDENTIFICATION

GHS Classification
Hazard/Danger Classification:

Health Hazards				
Hazard Class	Category	Signal word	Hazard Statement	Pictogram
Skin reaction	1, 1A and 1B	Warning	Causes skin irritation	
Eye irritation	2A	Warning	Causes serious eye irritation	

Precautionary Statements (GHS-US)
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, eye protection.

Response (GHS-US)
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation occurs: Get medical advice /attention.
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P231 - Specific treatment: Wash skin thoroughly with cool water and pH-neutral soap or a mild detergent intended for use on skin.
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.

Physical Hazards
This product reacts in contact with moisture and water producing a strong alkaline material.

Environment hazard
Not applicable.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CAS N°	EC N°	Name	Classification according to Regulation (EC) No 1278/2008 (CLP)
12168-85-3	2353369	Tricalcium silicate	May cause an allergic skin reaction (1, 1A e 1B) H317
1344-95-2	215-710-8	Dicalcium silicate	
12042-78-3	234-932-6	Tricalcium aluminate	Causes serious eye irritation (2) H319
Other Additives (radiopacifier, dispersing and fillers agents): According to the technical information, individually or in the mixture these materials are not classified as health hazards, thus do not contribute to the classification of these products.			

4. FIRST AID MEASURES

Routes of exposure	Most important Symptoms/Effects, Acute and Delayed	First Aid Treatment
Skin	Skin irritation	Wash with plenty of cool water and pH-neutral soap. Seek medical treatment in all cases of prolonged exposure to material, freshly cured product, or prolonged wet skin exposure to the paste.
Eye	Severe eye irritation	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If eye irritation occurs: Get medical advice /attention.
Inhalation	Irritation to the moist mucus membranes of the nose, throat and upper respiratory system	Remove person to fresh air and keep comfortable for breathing. Inhalation of large amounts of BC TEMP requires immediate medical attention.
Ingestion	Irritation to the digestive tract	Do not induce vomiting. If person is conscious, use water to rinse out the mouth and have the person drink plenty of water.

5. FIRE-FIGHTING MEASURES

Conditions of Flammability: Non-Combustible.
Suitable Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Unsuitable Extinguishing Media: There is no restriction on the type of extinguisher.
Specific Hazards Arising From the Product: None.
Advice for Fire-fighters: Firefighters should always wear full protective gear to fight any fire. Prevent spillage from entering drains or water courses.

6. ACCIDENTAL LEAKAGE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing as described in Section 8. Collect the material using a scoop.
Environmental Precautions: Prevent spillage from entering drains or water courses.
Methods and Material for Containment and Cleaning Up: Collect the material using a scoop. Dispose of waste material according to local, state and federal regulations. Collect the moist product and store in appropriate containers.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle with care. Avoid direct contact with the skin. Avoid contact with ammonia, ammonium nitrate, chlorine or chlorine-containing items.

Conditions for Safety Storage: Store in a dry place. Standard temperature and pressure do not affect the product. Store away from foods and drinks. Do not store next to ammonia, ammonium nitrate, chlorine or chlorine-containing items.

8. EXPOSURE CONTROL / PROTECTION

Control Parameters	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the work place.	
Appropriate Engineering Controls	Well ventilation.	
Individual Protections Measures, Such as Personal Protective Equipment (PPE)	Eye/face Protection 	Safety glasses. Activities, in which the paste may come into contact with eyes, use safety glasses. Be careful when using contact lenses when working with BC TEMP.
	Skin Protection 	Protective work clothing. Avoid contact with the paste. In cases of prolonged exposure to paste, use waterproof clothing and gloves to avoid skin broker. When required, use waterproof boots to eliminate exposure of toe and heel. In case of skin irritation, wash the affected area and, if necessary, seek medical attention.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	State: Paste	Upper/Lower Flammability or Explosive Limits	Not available
	Color: Slightly yellow		
Odour	No distinct odour	Vapour Pressure	Not available
Odor Threshold	Not available	Vapour Density	Not available
pH after hydration	≥12	Relative Density	Not available
Melting point/ Freezing Point	Not available	Solubility (with water)	Low
Initial Boiling Point and Boiling Range	Not available	Partition Coefficient n-octanol/water	Not available
Flash Point	Not available	Auto-ignition Temperature	Not available
Evaporation Rate	Not available	Decomposition Temperature	Not available
Flammability	Not available	Viscosity Temperature	Not available

10. STABILITY AND REACTIVITY
Reactivity: Contact with liquid or water will result the hydration of the product and formation of calcium hydroxide (caustic).
Chemical Stability: Product stable in normal conditions.
Possibility of Hazardous Reactions: Not Available.
Conditions to Avoid: Not applicable.
Incompatible Materials: Acids, ammonia, nitrate, ammonium salts, aluminum metal and chlorine.
Hazardous Decomposition Products: Decomposition will not occur spontaneously.

11. TOXICOLOGICAL INFORMATION

Toxicity, Environmental Fate, Physical/Chemical Data, or Other Data Supporting
Environmental Hazard Statements: No recognized unusual toxicity to plants or animals.

Emergency Overview: BC TEMP is a paste that poses little immediate hazard. A single short-term exposure to the paste is not likely to cause serious harm. However, exposure of sufficient amount and duration (either single or multiple) to moist product can cause serious, potentially irreversible tissue (skin or eye) destruction in the form of chemical (caustic) burns, including third-degree burns. The same type of tissue destruction can occur if wet or moist areas of the body are exposed for sufficient duration to the product.

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effects
Eye	Irritation or Inflammation	Single	Moderate	Blindness in severe cases
Skin	Mild Irritation, skin dryness	Single	Mild	Severe skin damage
Inhalation	Irritation to moist mucous membranes of the nose, throat and upper respiratory system.	Repeated	Mild	Lung injury can occur
Ingestion	Internal discomfort or irritation to the digestive tract.	Single	Mild	Ill effects are possible if large amounts are consumed

Likely Routes of Exposure	Target Organs	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye	Eye	Not available	Not available
Skin	Skin	Not available	Not available
Inhalation	Mucous membranes of the nose, throat and upper respiratory system.	Not available	Not available
Ingestion	Digestive system	Not available	Not available

Medical Conditions Aggravated by Exposure: Pre-existing upper respiratory and lung diseases.
Carcinogenicity: Ingredients not listed as carcinogens.

12. ECOLOGICAL INFORMATION

Toxicity: Not available.
Persistence and Degradability: Not available.
Bioaccumulative Potential: Not available.
Mobility in Soil: Not available.
Other Adverse effects: Not available.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Avoid contact with skin and eyes. Refer to Section 8 for personal protection measures. Dispose of waste and contaminated product in a suitable sealed container. Dispose of product according to local and federal regulations. Do not dispose of product down drains or from entering sewage systems.

Physical/Chemical Properties Affecting Disposal Options: No known precautions.
Special Precautions for Incineration or Landfill: Not applicable.

14. TRANSPORTATION INFORMATION

UN Number: Not applicable.
UN Proper Shipping Name: BC TEMP
Transport Hazard Class(es): Not applicable.
Environmental Hazards: Not applicable.
Precautions for User: Not applicable.
Transport in Bulk (According to Annex II of MARPOL 73/789 and IBC Code): Not applicable.

15. REGULATORY INFORMATION

Status under USDOL-OSHA Hazard Communication Rule, 29 CFR 1910, 1200: Status under USDOL-OSHA Hazard Communication Rule, 29 CFR 1910, 1200- The major components of BC TEMP (calcium silicate compounds are considered to be “hazardous chemicals” under this regulation; thus, the product should be part of hazard communication program(s).

Hazard Category under SARA (Title III), Section 311 and 312: The major components of BC TEMP (calcium silicate compounds) qualify as “hazardous substances” with delayed health effects.

Status under REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; This device is classified as an irritant: - Skin irritation (Category 2) - Eye irritation (Category 2).

16. OTHER INFORMATION

Date of Preparation: 09.01.2020
This product should be used according to manufacturer’s directions. Safety precautions presented above may not be adequate for all individuals or situations. Inexperienced product users should obtain proper training before using or handling this product. Users have the responsibility to comply with all laws and procedures applicable to the products’ safe handling and use, determine the suitability of the product for its intended use, and understand possible hazards associated with mixing this product with other materials. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. The supplier and/or manufacturer of this product shall not be held liable for damage resulting from handling, misuse or from contact with this product.

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