



FiteBac® Antimicrobial Cavity Cleanser
2% K-21 QAS (Quaternary Ammonium Silicate)

Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed Dentist.

Do not use if device is opened or damaged upon receipt.

DESCRIPTION

FiteBac® Antimicrobial Cavity Cleanser with 2% K21 QAS is an antimicrobial aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations. It is recommended for application directly onto prepared tooth surface after tooth preparation or etching to clean the area that will be sealed under the restoration. Bottle should be shaken for 2-4 seconds just before each use. This product is provided non-sterile. Clinical studies have not been conducted to demonstrate that this device results in improved clinical outcomes. This product has been shown effective against the following microorganisms.

<i>Streptococcus mutans</i>
<i>Actinomyces naeslundii</i>
<i>Lactobacillus acidophilus</i>
<i>Candida albicans</i>

INDICATIONS FOR USE

The FiteBac® Antimicrobial Cavity Cleanser with 2% K21 QAS is an antimicrobial aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations.

COMPOSITION

2% K21 QAS (Quaternary Ammonium Silicate) in an ethanolic solution.

PRECAUTIONS

1. For dental use only.
2. For use by dentists or dental professionals only.
3. K-21 QAS may be an eye and skin irritant. If eye contact occurs, flush with plenty of water; seek medical attention if irritation persists. In case of contact with skin, wash with soap and water.

INSTRUCTIONS FOR USE

Do not use if device is opened or damaged upon receipt. To avoid cross-contamination, do not touch dropper tip to any surface.

WITH DIRECT COMPOSITE RESTORATIONS

1. Isolate tooth and prepare the cavity. Rinse with water and air dry.
2. Etch enamel and dentin for 15 seconds with phosphoric acid according to manufacturer's instructions. Rinse with water and leave surface slightly moist (non-desiccated).
3. Shake bottle 2-4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the prepared surface using brush or absorbent pellet.
4. Remove puddled solution with a new absorbent pellet, leaving site moist.
5. Apply an adhesive according to manufacturer's instructions.

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WITH INDIRECT COMPOSITE RESTORATIONS

1. Complete tooth preparation, rinse with water for 10 – 20 seconds or as recommended by a dental professional, leaving preparation slightly moist.
2. Shake bottle for 2-4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the prepared surface using a brush or absorbent pellet for 20 seconds.
3. Air dry to remove excess solution. Do not desiccate.
4. Proceed with placement of provisional restoration.
5. When patient returns for cementation appointment, remove provisional restoration.
6. Clean the preparation with a slurry of pumice and water, or microetch, rinse and dry.
7. Etch enamel and dentin for 15 seconds with phosphoric acid according to manufacturer's instructions. Rinse with water for 10 – 20 seconds and leave preparation slightly moist (non-desiccated).
8. Shake bottle for 2-4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the preparation using a brush or absorbent pellet.
9. Remove puddled solution with a new absorbent pellet, leaving site moist. Do not dry.
10. Apply an adhesive according to manufacturer's instructions.
11. Continue with cementation of indirect restoration.
12. For cementation of RMGI cements follow 5, 6, then proceed to cementation.

DISPOSAL

Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

STORAGE

Store at room temperature. Maintain capped bottle in upright position at room temperature (68-77° F / 20-25° C).

Safety Data Sheet available at www.FiteBacDental.com

CONTRAINDICATIONS

Do not use on patients with known sensitivities to any of the device components.

DESCRIPTION OF SYMBOLS

	Manufacturer		Non-Sterile
	Batch Code		Consult Instructions for Use
	Flammable		Caution
	Do Not Use if Package is Damaged		Expiration Date

WARRANTY

FiteBac® Dental will replace products if proven to be defective. FiteBac® Dental does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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