



Largent Health, LLC
7842 Hickory Flat Highway
Woodstock, GA 30188

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% K-21 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% K-21 QAS is an antimicrobial aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations.

COMPOSITION

2% K-21 QAS (Quaternary Ammonium Silicate) in an ethanolic solution.

PRECAUTIONS

- For dental use only.
- For use by dentists or dental professionals only.
- 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 UTILIZING TOTAL ETCH ADHESIVES / TECHNIQUES

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

WITH DIRECT COMPOSITE RESTORATIONS UTILIZING SELF-ETCH TECHNIQUE

- Isolate tooth and prepare the cavity. Rinse with water and air dry, ensuring to leave surface slightly moist (non-desiccated).
- Shake bottle 2 - 4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the prepared surface using brush or absorbent pellet.
- Gently air dry to remove puddled solution, or dry using a new absorbent pellet, leaving site moist.
- Apply your bonding agent of choice according to manufacturer's instructions.

WITH BONDED INDIRECT RESTORATIONS

- Complete tooth preparation, rinse with water for 10 - 20 seconds or as recommended by a dental professional, leaving preparation slightly moist.
- 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.
- Air dry to remove excess solution. Do not desiccate.
- Proceed with placement of provisional restoration utilizing desired temporary cement.
- When patient returns for cementation appointment, remove provisional restoration.
- Clean the preparation with a slurry of pumice and water, or microetch, rinse and dry.
- 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).
- Shake bottle for 2 - 4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the preparation using a brush or absorbent pellet.
- Gently air dry to remove puddle solution, or dry using a new absorbent pellet, leaving site moist.
- Apply your bonding agent of choice according to manufacturer's instructions.
- Continue with cementation of indirect restoration utilizing resin cement of your choice.

WITH LUTED INDIRECT RESORATIONS

- Complete tooth preparation, rinse with water for 10 - 20 seconds or as recommended by a dental professional, leaving preparation slightly moist.
- 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.
- Air dry to remove excess solution. Do not desiccate.
- Proceed with placement of provisional restoration utilizing desired temporary cement.
- When patient returns for cementation appointment, remove provisional restoration.
- Clean the preparation with a slurry of pumice and water, or microetch, rinse and dry.
- Shake bottle for 2 - 4 seconds just before use. Apply FiteBac® Antimicrobial Cavity Cleanser generously to the preparation using a brush or absorbent pellet.
- Gently air dry to remove puddled solution, or dry using a new absorbent pellet, leaving site moist.
- Gently, and quickly, wet the preparation using air-water syringe, then air-dry leaving site moist.
- Apply your luting cement of choice according to manufacturer's instructions.

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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