INSTRUCTIONS FOR USE – BRACEPASTE FLUORIDE SEALANT

This IFU is applicable to all current and previous generations of this product.

1. IDENTIFICATION OF THE COMPANY

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2. IDENTIFICATION OF THE PRODUCT

Product Name: BracePaste® Fluoride Sealant
Product Description: Orthodontic Light-Curing Adhesive Primer/Sealant

3. INTENDED PURPOSE/INDICATIONS FOR USE

BracePaste® Fluoride Sealant is a light cure primer/sealant intended to be used in the orthodontic bonding procedure (direct or indirect) of orthodontic bondable devices by preparing the bonding surface during orthodontic treatment to the etched enamel.

BracePaste® Fluoride Sealant is indicated for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by trained dental professionals and/or orthodontists.

4. PERFORMANCE CHARACTERISTICS

BracePaste® Fluoride Sealant is a light cure primer/sealant that prepares the enamel surface during orthodontic treatment to promote adhesion to the bonding surface by wetting the bonding surface of the object to be bonded.

5. CONTRAINDICATIONS & SIDE EFFECTS

American Orthodontics sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as working sequence of the medical devices.

If a patient has known allergies against or hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. The clinician should consider known interactions and cross reactions of the product with other materials already in the patient's mouth before using the product. With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely.

6. WARNINGS

- For professional use only.
- Review applicable product SDS prior to use.
- Wear hand, eye, face protection when handling. Avoid breathing vapors, spray, and composite dust.
- Do not use after expiration date.
- Do not re-use used/dispensed sealant. Dispose of used/dispensed sealant in accordance with local and governing laws.
- Use proper debonding techniques to avoid enamel damage.
- This product is not indicated for use to bond composite / plastic brackets.
- Phenolic substance (i.e., Eugenol, wintergreen oil) will inhibit polymerization. Do not store near phenolic products or products containing Eugenol or wintergreen oil.
- This product contains tetramethylene dimethacrylate, diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, which is known to produce allergic skin reactions in certain sensitive individuals.
- Warning: May cause an allergic skin reaction.

- If skin or soft tissue is exposed to product, thoroughly wash area.
- If skin irritation or rash occurs: Get medical advice / attention.
- If on clothing: Remove contaminated clothing and wash before reuse.
- BracePaste® Fluoride Sealant has been verified using BracePaste® Adhesive and American Orthodontics' Acid Etchant.

7. INSTRUCTIONS

GENERAL

1. Bring product to room temperature prior to use (Temperature Range: 68°-77°F (20°-25°C)).
2. When complete with application of products, wipe tip of primary packaging clean with a solvent-free dry cloth and replace cap to protect product from exposure to light.

TOOTH PREPARATION

1. Using oil-free prophy paste, prophy the surfaces to be bonded.
2. Rinse thoroughly with water and dry teeth with oil / moisture free compressed air.
3. Following the manufacturer's instructions for use, apply acid etchant to the enamel surface. Rinse thoroughly with water and dry teeth with oil / moisture free compressed air.

PRIMER/SEALANT APPLICATION

NOTE: If using other primer/sealant or bond enhancer systems, consult the manufacturer's instructions for use. The below procedure is only relevant to American Orthodontics' BracePaste® Fluoride Sealant.

1. Shake bottle well and dispense a small amount of primer into well.

CAUTION: If more primer is needed, use a new well to dispense into to avoid cross-contamination.

2. Dip and completely saturate brush tip.
3. Apply a thin, uniform coat of primer/sealant to the entire etched surface of the tooth.

CAUTION: Avoid touching gingival area.

4. Re-dip brush into well for each additional tooth.
5. **OPTIONAL:** Light cure 5 seconds per tooth with an orthodontic LED curing light with an output of 3000 mW/cm2 and wavelength 420 – 480 nm.
6. Proceed with bonding bondable device according to the BracePaste® instructions for use. Primer/sealant can be cured simultaneously with BracePaste® Adhesive.

NOTE: BracePaste® Fluoride Sealant is designed to be re-applied periodically during orthodontic treatment. The presence of the sealant can be identified under UV light.

PRIMER/SEALANT RE-APPLICATION

1. Remove orthodontic wire.
2. **As needed, prepare exposed enamel per "TOOTH PREPARATION" Steps 1-3.**
3. Follow "PRIMER/SEALANT APPLICATION" Steps 1-4 on exposed enamel.
4. Light cure 2 x 3 seconds per tooth with an orthodontic LED curing light with an output of 3000 mW/cm^2 and wavelength 420 – 480 nm.

NOTE: Other light cure settings should be tested prior to use.

PRIMER/SEALANT REMOVAL

1. At the conclusion of treatment, the remaining sealant should be removed with an abrasive polisher.

NOTE: The presence of the sealant can be identified under UV light.

8. STORAGE

- Store between 38 - 77 °F (3 - 25 °C).
- Do not expose materials to elevated temperatures or intense light.
- When not in use, store capped product at room temperature and keep container tightly sealed.
- Shelf life at room temperature is per the expiration date on the product packaging. Rotate inventory to optimize shelf life.

9. DISPOSAL

Dispose of sealant and packaging material in accordance with local and governing laws.

10. STERILIZATION

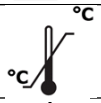
This product is labeled as non-sterile. The devices are also designed, manufactured, and packaged as non-sterile.

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11. SERIOUS INCIDENT REPORTING SECTION

If, during the use of this device or as a result of its use, a serious incident has occurred please report it to the manufacturer and/or the competent authority of the Member State in which the user and/or patient is established.

REGULATORY INFORMATION

	MANUFACTURER		USE-BY SYMBOL WITH EXPIRATION DATE
	EC REP		TEMPERATURE LIMIT
	CE MARK		KEEP AWAY FROM LIGHT
	RX ONLY		NOT STERILIZED
	MEDICAL DEVICE		INSTRUCTIONS FOR USE
	REF NUMBER		CAUTION
	LOT NUMBER		**DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT IFU**