AMERICAN ORTHODONTICS

INSTRUCTIONS FOR USE – BONDING AGENTS

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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® Adhesive	BracePaste® MTP	BracePaste® Band and Build LC	Acid Etchant (Gel/Liquid)
Product Description	Orthodontic Light-Curing Adhesive	Orthodontic Light-Curing Adhesive Sealant/Primer	Orthodontic Light-Curing Band Cement	37% Phosphoric Acid Etchant

3. INTENDED PURPOSE/INDICATIONS FOR USE

Bonding agents are used for orthodontic treatment as diagnosed by a trained dental professional or orthodontist.

4. PERFORMANCE CHARACTERISTICS

Bonding Agents are used by trained dental professionals/orthodontists to bond orthodontic appliances to teeth. These products may maintain or promote the bond between an orthodontic appliance and the patient's teeth. The appropriate Bonding Agents is chosen by the trained dental professionals/orthodontists and are installed according to the selected treatment plan for a specific patient.

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 & PRECAUTIONS

ALL PRODUCTS:

- 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.
- Dispose of product in accordance with local and governing laws.

LIGHT-CURE PRODUCTS

- Use proper debonding techniques to avoid enamel damage.
- Phenolic substance (i.e., Eugenol, wintergreen oil) will inhibit polymerization. Do not store near phenolic products or products containing Eugenol or wintergreen oil.
- These products contain acrylate monomers which are known to produce allergic skin reactions in certain sensitive individuals.

- Avoid contact with mucous membranes and skin in an uncured state.
- If skin irritation or rash occurs, get medical advice/attention.

BRACEPASTE® ADHESIVE
- This product is not indicated for use with chemical-lock plastic/composite brackets.

BRACEPASTE® MTP
- Warning: This product contains 2-HEMA (2-hydroxyethyl methacrylate). May cause an allergic skin reaction.
- If on skin, wash with plenty of water.
- This product is not indicated for use to bond composite/plastic brackets.

BRACEPASTE® BAND & BUILD LC
- Warning: This product contains tetramethylene dimethacrylate. May cause an allergic skin reaction.
- Ceramic crowns and veneers can splinter or break when removing the band.

ACID ETCHANT
- Acid Etchant contains phosphoric acid and is corrosive. May cause severe skin burns and eye damage. Avoid contact with eyes, mucous membrane, and skin.
- Wear suitable protective clothing, gloves, goggles/face mask.
- If on skin (or hair): Remove immediately all contaminated clothing. Rinse skin with water/ shower.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor.
- Acid Etchant contains Copper Polyphthalocyanine and Quinoline Yellow/FD&C Yellow No. 10. Patients who are sensitive or allergic to these dyes should not be in contact with this product.

7. INSTRUCTIONS

GENERAL
1. Bring adhesives 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.

ACID ETCHING

NOTE: If using other gel etching systems, consult the manufacturer's instructions for use. The below procedure is only relevant to American Orthodontics' Acid Etchant.

1. Isolate the teeth for etching.
2. Applying Acid Etchant:
    a. Acid Etchant Liquid (bottle):
        i. Dispense product into well.
        ii. Dip brush tip into well.
        iii. Apply etchant on the entire area to be bonded.
        iv. Re-dip brush into well for each additional tooth.
    b. Acid Gel (syringe):
        i. Place disposable tip on the syringe.
        ii. Verify flow of etchant prior to applying intra-orally.
        iii. Apply etchant on the entire area to be bonded.

CAUTION: Do not rub Acid Etchant onto enamel. Avoid placing Acid Etchant onto soft tissue.

3. Allow 30 seconds for etching enamel (60 seconds for etching deciduous teeth).
4. Rinse each tooth thoroughly with water for 10 seconds (20 seconds for gel etch) to stop etching process and to ensure total removal of etchant.
5. Dry teeth thoroughly with oil/moisture free compressed air. The etched area should appear frosty white. If not, re-etch for an additional 10-15 seconds, rinse and dry.
6. Remove demineralized particles.

PRIMER 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® MTP.

1. Dispense a small amount of primer into well.

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

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

CAUTION: Avoid touching gingival area.

4. Re-dip brush into well for each additional tooth.
5. Using moisture/oil-free air compressed air, gently blow air on each tooth, aiming the airstream perpendicular to the labial surface of the tooth until a thin, uniform layer of primer remains.

BRACKET ADHESIVE APPLICATION

NOTE: If using other bracket adhesive, consult the manufacturer's instructions for use. The below procedure is only relevant to American Orthodontics' BracePaste® Adhesive, BracePaste® Adhesive Color Change.

NOTE: Do not apply adhesive onto brackets until patient is ready to be bonded.

1. Dispense a small amount of adhesive onto bracket base from primary packaging.
2. Work the adhesive into the bracket mesh.
3. Immediately after applying adhesive, place bracket onto tooth surface.
4. Adjust bracket to final position. Press firmly to seat bracket.

NOTE: If final positioning will be delayed, cover patient's mouth with a dark colored mask or other article to avoid premature curing by ambient light.

5. Gently remove excess adhesive from around the bracket base without disturbing the bracket.

PRECAUTION: Follow manufacturer's instructions for use for the handling, proper use and recommendations for eye protection when using the curing light.

6. Hold the curing light stationary at approximately 1-2 mm above interproximal contact for metal appliance and perpendicular to ceramic appliance surface and cure the adhesive **with an orthodontic LED curing light with an output of 3000 mW/cm² and wavelength 420 – 480 nm. Refer to the chart below to determine curing conditions when using the Blue Ray 3.**

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

Appliance	Curing Light: Blue Ray 3 Mode: 3 second mode	Curing Light: Blue Ray 3 Mode: 5 second mode
Metal Brackets	**3 seconds mesial + 3 seconds distal**	**5 seconds mesial + 5 seconds distal**
Ceramic Brackets	**3 seconds total through bracket**	**5 seconds total through bracket**
Buccal Tubes	**3 seconds mesial + 6 seconds occlusal**	**5 seconds mesial + 10 seconds occlusal**
Bands & Crowns	**Not approved for use**	**Not Approved for use**

BAND CEMENT APPLICATION

NOTE: If using other band cement, consult the manufacturer's instructions for use. The below procedure is only relevant to American Orthodontics' BracePaste® Band and Build LC.

NOTE: Acid Etching is not necessary to attach orthodontic bands; however, it is recommended if especially high forces are expected during treatment.

NOTE: Do not apply band cement onto band until patient is ready to be bonded.

1. Apply a bead of BracePaste® Band and Build LC to the inside of the band.
2. Seat band onto the desired tooth.
3. Remove any excess band cement.

PRECAUTION: Follow manufacturer's instructions for use for the handling, proper use and recommendations for eye protection when using the curing light.

4. Position the curing light tip near the occlusal surface of the tooth and cure the band cement for a total of 12 seconds – 3 seconds per cusp **using an orthodontic LED curing light with an output of 3000 mW/cm² and wavelength 420 – 480 nm.**

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

8. STORAGE

- Store between 50 - 77 °F (10 - 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.

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9. DISPOSAL

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

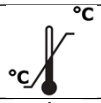
10. STERILIZATION

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

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 and the competent authority of the Member State in which the user and/or patient is established.

12. 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**