

INSTRUCTIONS FOR USE – BracePaste Prime Plus

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

1. IDENTIFICATION OF THE COMPANY

	American Orthodontics 3524 Washington Avenue Sheboygan, WI 53081 USA	24 HR EMERGENCY TELEPHONE NUMBER +1 920 457 5051
EC REP	MT Promedt Consulting GmbH Ernst-Heckel-Straße 7 66386 St. Ingbert Germany	Telephone for Information +1 920 457 5051
	2797	

2. IDENTIFICATION OF THE PRODUCT

Product Name: BracePaste® Prime Plus

Product Description: Orthodontic Primer

3. INTENDED PURPOSE/INDICATIONS FOR USE

BracePaste Prime Plus is a light-cure primer / sealant intended to be used in the bonding procedure (direct or indirect) of orthodontic bondable devices by preparing the bonding surface during orthodontic treatment. BracePaste Prime Plus is indicated for the following bonding surfaces: any dental structure containing zirconia, alumina, metals, glass ceramic, dentin, enamel, and composites.

4. 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 and to notify patients of the potential side effects. 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.

5. WARNINGS

- For professional use only.
- Review applicable product SDS prior to use.
- Warning: This product contains 2-HEMA (2-hydroxyethyl methacrylate). May cause an allergic skin reaction.
- This product contains acrylate monomers which are known to product allergic skin reactions in certain sensitive individuals.
- Avoid contact with mucous membranes and skin in an uncured state. If skin or soft tissue is exposed to product, thoroughly wash area.
- If skin irritation or rash occurs, get medical advice/attention.
- Wear hand, eye, face protection when handling. Avoid breathing vapors, spray, and composite dust.
- Do not use after expiration date. See individual component labels for specific expiration dates.
- Do not re-use used/dispensed product. Dispose of used or contaminated accessories. Dispose of product in accordance with local and governing laws.
- 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.
- BracePaste Prime Plus has been verified using BracePaste Adhesive and AO Acid Etchant.

INSTRUCTIONS FOR USE – BracePaste Prime Plus

6. INSTRUCTIONS

6.1 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 from exposure to light.

6.2 Tooth Preparation

1. Using oil-free prophyl paste, prophyl the surfaces to be bonded.
2. Rinse thoroughly with water and dry teeth with oil/moisture free compressed air.

6.3 Acid Etch (enamel and dentin only)

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

1. Apply acid etching system to teeth surfaces following the manufacturer's instructions.
2. Rinse each tooth thoroughly with water (10 seconds for liquid etchant, 20 seconds for gel etchant) to stop etching process and to ensure total removal of etchant.
3. Dry teeth using moisture/oil-free compressed air. Dry teeth should appear frosty white. If not, re-etch for an additional 10-15 seconds, rinse, and dry.

The below etching times are only relevant to American Orthodontics' products.
If using other etchant, consult the manufacturer's instructions for use.

Enamel	30 sec
Deciduous Teeth	60 sec
Dentin	15 sec

6.4 Priming Substrates

6.4.1 Enamel Surfaces

- i. Prophyl, rinse, dry (per Section 6.2)
- ii. Etch enamel surface (per Section 6.3)
- iii. Dispense primer into well. Tightly cap bottle to prevent evaporation.
 CAUTION: If additional primer is needed, dispense product into a new well to avoid cross-contamination.
- iv. Dip and completely saturate brush tip.
- v. Apply a uniform coat of primer to the entire etched surface of the tooth.
- vi. Re-dip brush into primer for each additional tooth.
- vii. Using moisture/oil-free compressed air, gently blow air on each tooth to evaporate the solvent until a glossy, immobile film layer results.
- viii. Follow chosen adhesive instructions for appropriate bonding procedures.

6.4.2 Dentin Surfaces

- i. Prophyl, rinse, dry (per Section 6.2)
- ii. Etch dentin surface (per Section 6.3)
- iii. Dispense primer into well. Tightly cap bottle to prevent evaporation.
 CAUTION: If additional primer is needed, dispense product into a new well to avoid cross-contamination.
- iv. Dip and completely saturate brush tip.
- v. Apply a uniform coat to the entire etched surface of the tooth.
- vi. Re-dip brush into primer for each additional tooth.
- vii. Using moisture/oil-free compressed air, gently blow air on each tooth to evaporate the solvent until a glossy, immobile film layer results.
- viii. Light cure for 6 seconds with curing light (recommended specifications: 3,000 mW/cm² ± 10%, 420 – 480 nm; Blue Ray).
- ix. Follow chosen adhesive instructions for appropriate bonding procedures.

6.4.3 Composite, Acrylic, or Metal (gold, amalgam, stainless steel) Surfaces

- i. Prophyl, rinse, dry (per Section 6.2)
- ii. Sandblast the surface, rinse the surface with water, and dry using moisture/oil-free compressed air.
- iii. Dispense primer into well. Tightly cap bottle to prevent evaporation.
 CAUTION: If additional primer is needed, dispense product into a new well to avoid cross-contamination.
- iv. Dip and completely saturate the brush tip.
- v. Apply a uniform coat of primer to the entire etched surface of the tooth.
- vi. Re-dip brush into primer for each additional tooth.

INSTRUCTIONS FOR USE – BracePaste Prime Plus

- vii. Using moisture/oil-free compressed air, gently blow air on each tooth to evaporate the solvent until a glossy, immobile film layer results.
- viii. Light cure for 6 seconds with curing light (recommended specifications: 3,000 mW/cm² ± 10%, 420 – 480 nm; Blue Ray).
- ix. Follow chosen adhesive instructions for appropriate bonding procedures.

6.4.4 Porcelain or Zirconia Surfaces

- i. Prophyl, rinse, dry (per Section 6.2)
- ii. Sandblast the surface, rinse the surface with water, and dry using moisture/oil-free compressed air.
PORCELAIN SURFACE ONLY: apply porcelain conditioner to the prepared tooth surface according to manufacturer's instructions.
- iii. Dispense primer into well. Tightly cap bottle to prevent evaporation.
CAUTION: If additional primer is needed, dispense product into a new well to avoid cross-contamination.
- iv. Dip and completely saturate the brush tip.
- v. Apply a uniform coat of primer to the entire etched surface of the tooth.
- vi. Re-dip brush into primer for each additional tooth.
- vii. Using moisture/oil-free compressed air, gently blow air on each tooth to evaporate the solvent until a glossy, immobile film layer results.
- viii. Light cure for 6 seconds with curing light (recommended specifications: 3,000 mW/cm² ± 10%, 420 – 480 nm; Blue Ray).
- ix. Follow chosen adhesive instructions for appropriate bonding procedures.

6.5 At the conclusion of treatment, any primer/sealant remaining on the tooth surface can be removed with an abrasive polisher.

7. 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.

8. 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 in which the user and/or patient is established.

9. TRANSPORT

- Transport with temperatures between 35°-80°F (2°-27°C).
- Harsh or rough handling may cause damage to product.

INSTRUCTIONS FOR USE – BracePaste Prime Plus

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		CONSULT INSTRUCTIONS FOR USE
	REF NUMBER		CAUTION IS NECESSARY WHEN OPERATING THE DEVICE
	LOT NUMBER		