

1. IDENTIFICATION OF THE COMPANY

Company Name

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

+1 920 457 5051

Telephone for Information

+1 920 457 5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: BracePaste™ Band and Build LC
Product Description: Orthodontic Light-Curing Band Cement
Product Part Number: REF Various Part Numbers



CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

3. INDICATIONS FOR USE, DOMAIN OF USAGE

A light-cure orthodontic band cement intended to bond orthodontic bands to teeth.

4. CONTRAINDICATIONS

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. This will include any sterilization procedures.

6. SIDE EFFECTS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury and/or contraindications that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly. During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

7. WARNINGS & PRECAUTIONS

- Wear gloves when handling.
- Avoid contact with mucous membranes and skin in an uncured state.
- Use proper debonding techniques to avoid enamel damage.
- Ceramic crowns and veneers can splinter or break when removing the band.
- Phenolic substance (i.e. Eugenol) will inhibit polymerization. Do not store near phenolic products or products containing Eugenol.
- Do not store near products containing wintergreen as this will negatively affect the results of polymerization.
- Do not use after expiration date. Dispose of product in accordance to local and governing laws.

8. PRE-STARTING PROCEDURES

Tooth Preparation

1. Using a rotary instrument with a rubber cup or brush, prophylax the enamel surface(s) to be bonded.
2. Do not use prophylax pastes which contain oil. This can leave a film that will inhibit the etch.
3. Rinse thoroughly and dry teeth with oil/moisture free compressed air.

Acid Etching

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

9. STEP-BY-STEP INSTRUCTIONS

Band Adhesive Application

NOTE: Do not apply adhesive 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 flash.

4. Cure the adhesive by positioning the curing light tip in close proximity to the occlusal surface of the tooth and irradiate for a total of 12 seconds – 3 seconds per cusp. After light curing, the adhesive is completely cured. The curing time indicated refers only to hand lamps with a light intensity of >1500 mW/cm².
5. When completed, wipe syringe tip clean with a solvent-free dry cloth and replace cap to protect adhesive from exposure to light.

PRECAUTION: If using other curing light, follow manufacturer's directions for the handling, proper use and recommendations for eye protection when using a curing light. Otherwise, reference American Orthodontics Instructions for Use (IFU) for Blue Ray 3.

11. STORAGE AND TRANSPORT CONDITIONS

Storage

- Do not expose materials to elevated temperatures or intense light.
- Do not store material in proximity to eugenol-containing products or products that contain wintergreen, as this may inhibit the proper adhesive curing.
- Store between 50 – 77 °F (10 – 25 °C)
- Shelf life at room temperature is per the expiration date on the syringe label. Rotate inventory to optimize shelf life.
- Light sensitive. Do not expose uncured adhesive to ambient light for extended periods of time. When not in use, store syringes with caps at room temperature.

Transport

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

12. DISPOSAL CONSIDERATIONS


American Orthodontics' products are designed and manufactured for single use and, once removed from the patient's mouth, must be disposed of properly. American Orthodontics expressly disclaims any liability for the spread of disease or personal injury caused by reuse. It is the primary responsibility of the dental professional and/or orthodontist to follow applicable laws relating to the disposal of used orthodontic medical devices.

13. WARRANTY LIABILITY

Buyer's remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller's option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

14. REGULATORY INFORMATION

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SEE INSTRUCTIONS FOR USE



STORE BETWEEN 50-77°F (10 – 25 °C)

 **1434**



NON STERILE



CAUTION CONSULT IFU



KEEP AWAY FROM DIRECT SUNLIGHT

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE TO OR ON THE ORDER OF A DENTIST/ORTHODONTIST. SEE WWW.AMERICANORTHO.COM FOR SYMBOL GLOSSARY

The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. **Reasonable safety precautions must always be observed.**