

1. IDENTIFICATION OF THE COMPANY

Company Name

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

(920) 457-5051

Telephone for Information

(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: General Adhesive

Product Description: Orthodontic Adhesive

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

American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

Adhesives are intended for use as an orthodontic bonding agent for Metal Brackets, Ceramic Brackets, Buccal Tubes and other Orthodontic appliances to the tooth's surface.

Acid Etching Agent is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

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

- Acid Etching Agent contains phosphoric acid and is corrosive. Avoid contact with eyes, mucous membrane and skin. Refer to American Orthodontics' SDS: "Phosphoric Acid".
- This product contains acrylate monomers and which are known to produce allergic skin reactions in certain sensitive individuals. Refer to American Orthodontics' SDS: "Orthodontic Adhesive".
- Wear gloves when handling.
- This product is not indicated for use to bond composite/plastic brackets.
- Do not use after expiration date. Dispose of product in accordance to local and governing laws.
- Phenolic substance (i.e. Eugenol) will inhibit polymerization. Do not store near phenolic products or products containing Eugenol.
- Use proper debonding techniques to avoid enamel damage

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

1. Dispense etching agent onto mixing pad.
2. Isolate the teeth for etching.
3. Dab the etching agent onto the entire area to be bonded. Do not rub etching agent onto enamel. Avoid placing etching agent onto soft tissue.
4. Allow 30 seconds for etching (60 seconds for deciduous teeth).
5. Rinse each tooth with water/air spray for 10 seconds (20 seconds for gel etch) to stop etching process. The etched area should appear frosty white. If not, re-etch for an additional 10-15 seconds.
6. Remove demineralized particles.

9. STEP-BY-STEP INSTRUCTIONS

General Instructions

1. Review any applicable SDS and instructions for Use
2. Bring adhesives to room temperature before use (Temperature Range: 68°-77°F (20°-25°C))
3. Follow relevant application procedures as outlined below.

Carpule Adhesive Application

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

1. To insert carpule into dispenser, open dispenser handle as wide as possible. Pull plunger toward opened handle. Place carpule tip into the barrel slot.
2. Seat the carpule in the barrel by pushing the carpule forward (away from the handle) as far as possible. Push plunger towards carpule. Close handle grip until plunger contacts the carpule.
3. Dispense a small amount of adhesive paste onto bracket base using a slow, steady pressure. Use the tip to work the adhesive into the bracket mesh. **When completed, wipe carpule tip clean with a solvent-free dry cloth and replace cap.**
4. To remove the used carpule, open the dispenser handle as wide as possible. Pull plunger away from carpule. Turn dispenser upside down to drop the carpule into hand.

Syringe Adhesive Application

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

1. With the syringe, apply a small amount of adhesive paste onto bracket base. Use sparingly. Use the syringe tip or spatula to work the adhesive into the bracket mesh. **When completed, wipe syringe tip clean with a solvent-free dry cloth and replace cap.**

Placement and Curing

1. Immediately after applying adhesive, place bracket onto tooth surface.
 2. 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.
3. Gently remove excess adhesive from around the bracket base without disturbing the bracket.
 4. Hold the curing light stationary at a distance of 1-2 mm above interproximal contact for metal appliance and perpendicular to ceramic appliance surface.

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.

Refer to the chart to determine the curing conditions for optimal bond strength. If your curing light does not appear on this chart, please refer to your light manufacturer’s instructions for curing conditions.

Appliances	Blue Ray 3 (3 second mode)
Metal Brackets	3 seconds mesial + 3 seconds distal
Ceramic Brackets	3 seconds total through bracket
Buccal Tubes	3 seconds mesial + 6 seconds occlusal

5. Archwires may be placed immediately after curing the last bracket.

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, as this may inhibit the proper adhesive curing.
- Store at room temperature between 68° - 77°F (20°-25°C)
- Shelf life at room temperature is per the expiration date on the kit box. 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 68° - 77°F (20°-25°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



Emergo Europe • Molenstraat 15 • 2513 BH The Hague • The Netherlands



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SEE INSTRUCTIONS FOR USE



NON STERILE



WARNING



KEEP AWAY FROM DIRECT SUNLIGHT



SINGLE USE ONLY



STORE BETWEEN 68°F - 77°F



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.**