

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: MR Lock LC
Product Description: MR Lock LC Band Cement Kit
Product Part Number: REF 001-975
Patent Number:

Material:

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.

MR Lock LC is to be used for bonding orthodontic bands and crowns.

4. CONTRAINDICATIONS & WARNINGS

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.

Do not use after expiration date.

Wear gloves when handling.

5. 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.

This product contains acrylate monomers and which are known to produce allergic skin reactions in certain sensitive individuals.

6. STEP-BY-STEP INSTRUCTIONS

1. SCALE gingival margins following removal of separators.
2. PROPHY the enamel surfaces to be bonded. Do not use prophy pastes that contain oil or fluoride. Rinse thoroughly and dry teeth with oil and moisture-free compressed air. It is not necessary to acid etch the teeth.
3. ISOLATE teeth to be banded.
4. LOAD a carpule into the dispensing instrument. Squeeze slowly, fully loading the inside of the band with cement. Smooth with a small spatula if desired.
5. ENSURE teeth are fully dry prior to final seating of bands.
6. SEAT band and remove excess cement with a scaler or cotton roll.
7. CURE cement. With halogen lights, cure from the occlusal for 10 seconds per cusp (40 sec total). For LED or other high powered lights, cure from the occlusal for 5 seconds per cusp (20 sec total). Extend curing time if amalgams or composite resins are present in tooth.

7. KEYS TO SUCCESS WITH MR LOCK CEMENT

- Ensure teeth are fully dry prior to placing cement-loaded bands.
- Shield any loaded bands from ambient light until ready to be placed.

- Ensure full cement coverage of the inside surface of each band.
- Verify the intensity of your curing light and extend curing time if amalgams or composite are present in teeth.

8. STORAGE AND TRANSPORT CONDITIONS

Do not use after expiration date.
Store away from direct light.
Store between 2°C - 24°C.

9. 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.

Dispose of product in accordance to local and governing laws.

10. 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.

11. REGULATORY INFORMATION

 MT Promedt Consulting GmbH • Altenhofstrasse 80 • 66386 St. Ingbert, Germany


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 SEE INSTRUCTIONS FOR USE

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MADE IN USA

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.**