

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: Impressa/Chrome Alginate Impression

Product Description: Impression Material

Product Part Number: REF 861-130

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.

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.

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.

6. STEP-BY-STEP INSTRUCTIONS

Fast setting compliant with ISO 21563 specification. Impressa/Chrome does not require special treatment before use. Impressa/Chrome is a dust-free material, however caution is advised when opening the bag and withdrawing the powder. While mains water may be used, the declared times were measured by mixing the powder with deionized water at 23°C. Vigorously mix the powder with water. When using specific mechanical mixers for alginate-based impression materials follow the manufacturer's instructions. Follow the chromatic phase indications which ensure that the product is mixed perfectly and inserted into mouth at the right moment. Variations in temperature and/or water hardness and the speed and/or friction during mixing cause small changes in the working time in the initial setting time, which are automatically indicated by the color changes. Wash, rinse, and shake the impression and pour the model. The model can be poured within up to 100 hours with excellent results.

*Measurements taken at 23°C with deionized water.



+



2 Water
Measures 40ml

2 Powder
Measures 18g



23° C
73° F



Mixing Time*
60 Seconds

Working Time*
90 Seconds

Oral Cavity Time
30 Seconds



Initial Setting Time
1 Minute and 40 Seconds

8. CAUTION

Do not breathe in alginate dust
Use in a well-ventilated area
Use of a mask to avoid exposure is recommended

9. STORAGE AND TRANSPORT CONDITIONS

The impression must be stored in a sealed plastic bag without adding anything else. Do not leave the impression exposed to air or immersed in water. Keep the container tightly closed, in a cool, dry place.

10. 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.

11. 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.

12. REGULATORY INFORMATION



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NOT STERILIZED



KEEP AWAY FROM DIRECT SUNLIGHT



STORE BELOW 25°C



See Instructions for Use



Single Use Only

MADE IN USA

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.**