INSTRUCTIONS FOR USE – Impressa/Chrome Alginate

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

1. IDENTIFICATION OF THE COMPANY

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CE	www.americanortho.com/resources/instructionsfor-use/	

2. IDENTIFICATION OF THE PRODUCT

Product Name: Impressa/Chrome Alginate
Product Description: Impression Material

3. INDICATIONS FOR USE

Impressa/Chrome is to be prescribed only by licensed dental professional and/or orthodontic professionals to patients during orthodontic treatment.
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 & 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. 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.

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.

5. WARNINGS & PRECAUTIONS

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

6. 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 main 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.

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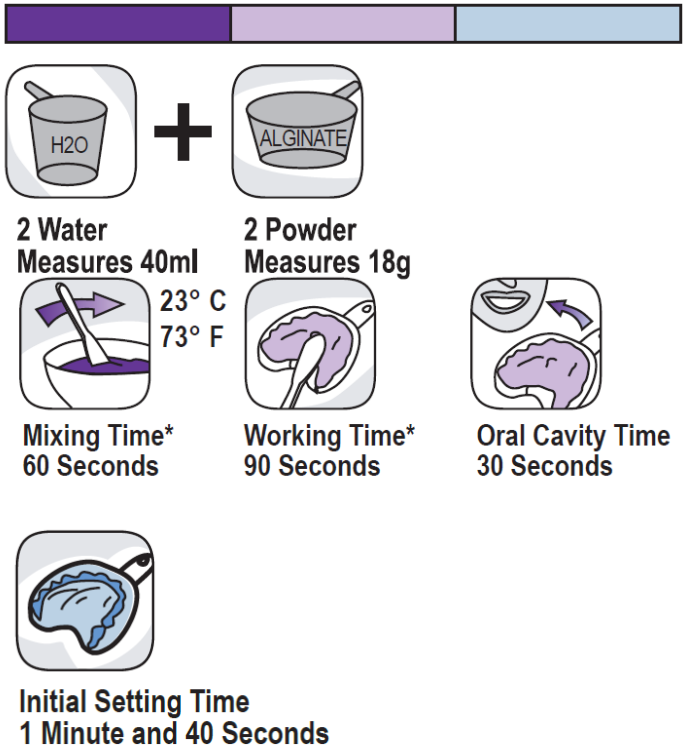

7. STORAGE

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.

8. DISPOSAL

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.

9. SERIOUS INCIDENT REPORTING

If, during the use of this device or as a result of its use, a serious incident has occurred or a product performance issue has been observed, please report it to the manufacturer and/or its authorized representative or your local affiliate, and to your national authority.

10. REGULATORY INFORMATION

	MANUFACTURER	STERILE	NOT STERILIZED
EC REP	EC REP	MD	MEDICAL DEVICE
CE	CE MARK	REF	REF NUMBER
℞ ONLY	RX ONLY	LOT	LOT NUMBER
	KEEP AWAY FROM DIRECT SUNLIGHT		CONSULT INSTRUCTIONS FOR USE
2	SINGLE USE ONLY		STORE BELOW 25°C