


OC-PRO-003 WI-005 Revision 1	Instructions For Use	
	For Ortho-Care Alginate	

Instructions for Use (IFU) for Ortho-Care Alginate

Product Description and Intended Use

Alginate is a highly elastic, irreversible hydrocolloid impression material and it is one of the most frequently used dental materials. It is simple, cost-effective, has an extensive shelf-life and is an indispensable part of dental and orthodontic practice, alginate is made from seaweed or kelp and only takes around 120 seconds to harden once mixed with water, alginate impressions are also easy to perform. The setting time can be controlled by the temperature of the water used, additionally they are mildly flavoured (red-fruit flavoured) – this being advantageous for the patient. Further advantages include a high tear resistance of the alginate, the ability to be poured twice with gypsum and it is presented in an attractive fuchsia coloured powder.

The intended patient group for such products is all patients who require dental or orthodontic treatment, this can range from teenagers and adolescents who may require orthodontic braces or the elderly who may require impressions for their dentures.

REF	DEVICE DESCRIPTION (TRADE NAMES)
9001-IE002	Ortho-Care Alginate

Indications for Use

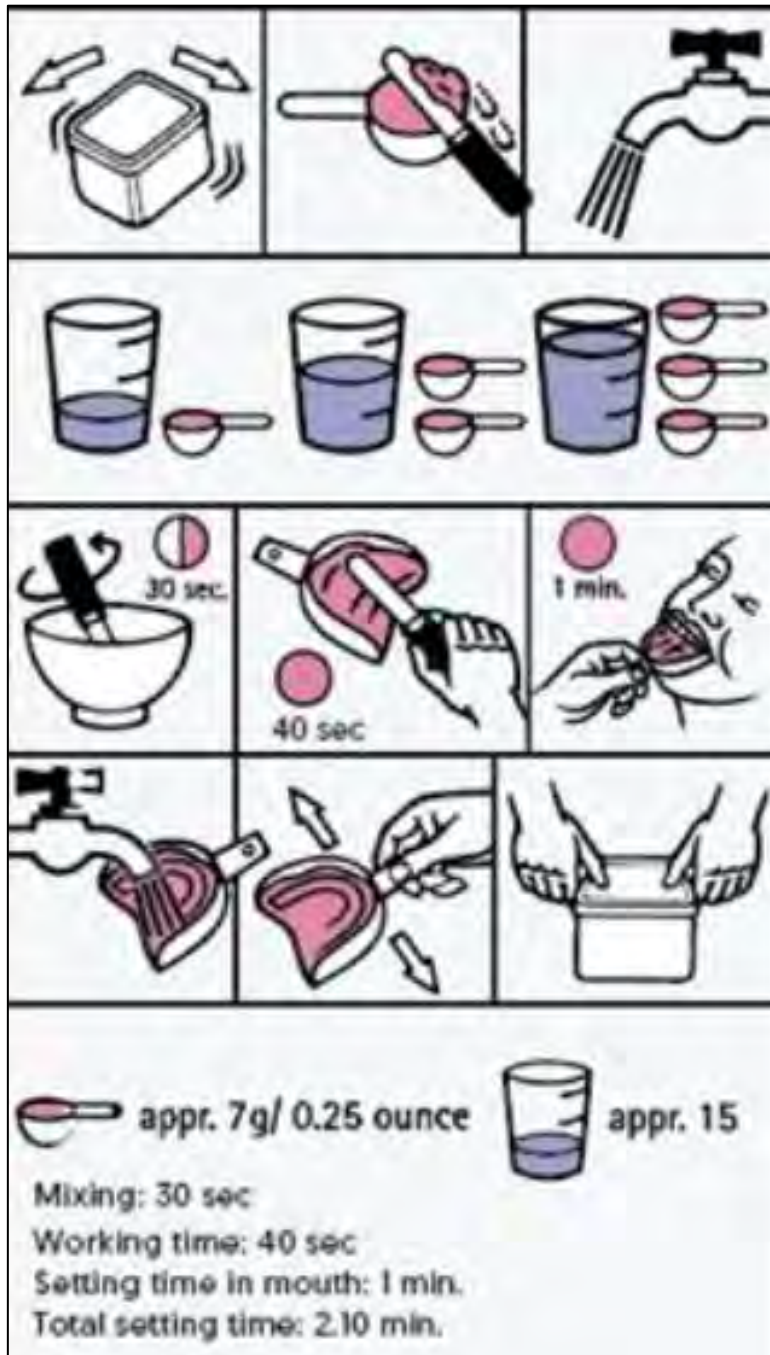
Indicated for use to create impressions of the oral cavity.

Instructions for Use

Once the powder has been mixed with water, a smooth paste is formed, this paste is then loaded into an orthodontic impression tray and placed into the mouth of the patient. After approximately 60 seconds, the paste will begin to harden due to a chemical reaction, an accurate impression of the mouth will then be created. When the impressions are removed no deformations will occur due to the elastic nature of the alginate. The impression will then be poured by gypsum, or dental stone, creating a precise model of the situation in the mouth, allowing a dental technician to construct a well-fitting orthodontic/dental appliance.

The below infographic is used on the product packaging.

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Storage and Disposal

Store in a cool and dry place. Please follow local regulations on disposal of this product and ensure disposal in clinical waste if this material has been in contact with the patient.

Performance Characteristics and Clinical Benefit

The clinical benefit of the subject device is demonstrated by its performance.

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Warnings

Rare cases of allergic reactions occurring in some patients have been reported after the use of alginate, if this is the case the patient is urged to seek medical advice. In patients with a hyper gag reflex, the impressions may be harder to take as the alginate material will be in close proximity to the soft tissue at the back of the patient's throat, a local anaesthetic may be used to numb the soft palate in severe cases. Some patients may report that they can't breathe during the procedure, however this can be overcome by the patient breathing slowly and deeply through their noses.

Contraindications

Alginate impression materials is contraindicated in patients with a history of severe allergic reaction to crystalline silica, calcium sulphate or potassium titanium fluoride. In such cases it is advised to use alginate-free impression material.


Reporting Serious Incidents

Any serious incident that has occurred in relation to use of this product should be reported without undue delay to Ortho-Care and the competent authority for the country in which the incident occurred.

Basic Composition

- Alginate: app. 14% w
- Calcium sulphate: app. 10% w
- Fillers: app. 70% w
- Retarder, stabilisers, pigment, and flavour: app. 6% w

Symbols

 <p>Store in a cool and dry place</p>	 <p>REF 9001-IE002</p>	<div style="border: 1px solid black; padding: 2px; display: inline-block;">MD</div>
 <p>Ortho-Care (UK) Ltd, 1 Riverside Estate, Saltaire, BD17 7DR, West Yorkshire UK. Tel: +44 (0)1274 533233 Email: info@orthocare.co.uk</p>	<div style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, MALTA</p>	

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