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| OC-PRO-003<br>WI-006 | <b>Instructions For Use</b>                                     |  |
| Revision 2           | <b>For Fresh &amp; Go Aligner and Retainer Cleaning Tablets</b> |  |

## Instructions for Use (IFU) Fresh & Go Aligner and Retainer Cleaning Tablets

### Product Description and Intended Use:

This is a product intended for cleaning a medical device (an orthodontic appliance) but not for disinfecting or sterilising. The claimed action is to help maintain the clarity of the appliance, keep the appliance fresh and help remove stains. The tablet has a cool mint flavour. The users would be wearers of dental/orthodontic appliances, therefore this demographic would be pre-adolescents, adolescents and adults.

| REF      | DEVICE DESCRIPTION (TRADE NAMES)      |
|----------|---------------------------------------|
| 9001-237 | Appliance Cleaning tablet, pack of 36 |
| 9001-238 | Appliance Cleaning tablet, pack of 96 |

### Indications for Use:

Suitable for cleaning the following removable dental and orthodontic appliances:

- Clear Retainers
- Wire Retainers
- Bruxing Appliances
- Night Guards
- Clear Aligners
- Sports Mouthguards
- TMJ Appliances

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Instructions for Use:

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Dissolve tablet in 280ml of warm but NOT hot water.
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Add appliance to effervescent solution for 15-30 mins, or 15 mins exactly for wire appliances.
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Wash hands thoroughly.
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Rinse in water at room temperature for 30 seconds.
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Discard the solution after one use.

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**Storage and Disposal:**

Store in a cool and dry place. Discard solution after one use and dispose of tablets and solution in accordance with local regulations.

**Performance Characteristics and Clinical Benefit:**

The clinical benefit of the subject device is demonstrated by its performance in cleaning the dental/orthodontic appliance.

**Warnings:**

Do not use if you are sensitive to any of the ingredients. Keep out of reach of children. Do not swallow/place in mouth, the tablet or the solution. Harmful if inhaled. Avoid contact with eyes. If solution/tablet makes contact with eyes rinse thoroughly with water. Avoid excessive skin contact. Immediately seek medical advice if severe irritation develops and/or tablet or solution is ingested. Discard cleaning solution after one use. Dispose of tablets and solution in accordance with local regulations. Do not mix with any other cleaners.

**Contraindications:**

This product is contraindicated for any individuals with allergies to the listed ingredients. Not to be used on any appliances other than those indicated for use. Not to be used directly on the appliance without diluting it in the specified amount of water.


**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.

**Ingredients:**

Sodium Bicarbonate, Citric Acid Anhydrous Granular, Potassium Peroxymonosulfate, Sodium Carbonate Anhydrous, Sodium Percarbonate, Sodium Laurylsulfate, Tetra Acetyl Ethylenediamine (TAED), Sodium Benzoate, VP/VA Copolymer, Polyethylene Glycol-180 (PEG-180), Peppermint Oil, Indigo Dye.

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**Other Information and Symbols related to Instructions for Use:**

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|--|---|---|
| <br>Store in a cool and dry place   | <br>                         |  |
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