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| OC-PRO-003-WI-007<br>Revision 1 | <b>Instructions For Use</b>               |  |
|                                 | <b>For Ortho-Care Pro-Jet Bite Wafers</b> |  |

## Instruction for Use (IFU) of Orthodontic Pro-Jet Bite Wafers

### Product Description

Pro-Jet Bite Wafers, of the Orthodontic Impression Tray product family, are made of SABIC® PP 48M10 – 00900 Polypropylene. They are available in 2 different sizes: 2 mm (blue) and 4mm (white).

**REF** **150-001** ORTHOCARE PRO-JET BITE WAFERS WHITE 4MM, **150-002** ORTHOCARE PRO-JET BITE WAFERS BLUE 2MM

### Intended and Indications for Use

The Pro-Jet Bite Wafer is intended for use to carry the impression material into the mouth, place it against the dentition for recording dental impressions, and retaining the impression when set.

They are specifically indicated for use to record protrusive registration of the mandible to help improve accuracy of appliance construction bite registration. These plastic jigs can be used with either wax or silicone occlusal registration materials.

The device maintains the patient's incisal opening at 2mm (blue) or 4mm (white) and a sagittal position of the mandible through the three lower slots.

The product is to be used by dental professionals on patients requiring orthodontic treatment.

### Instructions for Use

#### Impression Preparation

1. Select the correct size Pro-Jet Bite Wafer. Place the middle of the lower slots on to the lower central incisor teeth for a patient bite trial.
2. Ask the patient to protrude the mandible and while you hold the Bite Wafer in place, help the patient to close into the large groove in the top of it. This will help the patient to locate the Bite Wafer as required at a later stage once the wax has been added.
3. Remove from the patient's mouth and add a wax block to each arm of the Pro-Jet Bite Wafer. Soften  $\frac{1}{4}$  of a sheet of dental wax, and form it into a roll, then cut it into two pieces. Melt the core of each piece with a hot wax knife.
4. Place each wax piece on to the sides of the Pro-Jet Bite Wafer.


#### Impression Formation

5. Position back in the patient's mouth while the wax is still soft and follow the earlier trial procedure.
6. While the mandible is held in the protrusive position, press the extruded wax on to the buccal aspect of the premolars and molar teeth.
7. Remove the Pro-Jet Bite Wafer with the wax impressions from the patient's mouth and chill in cool water.

*Where an edge to edge incisal contact is required:*

- a. Using a 2mm (Blue) Pro-Jet Bite Wafer, use the technique as above.

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- b. Cut the Pro-Jet Bite Wafer at the point where the incisal edges of the upper and lower anterior teeth meet using a heavy-duty wire cutter.
- c. Replace in the mouth and have the patient close further into the soft wax until the incisal teeth meet in an edge-to-edge location.

**Storage**

Store in a cool, dry place.

**Disposal**

Used dental appliances may be considered a biohazard. Follow your country-specific laws, directives, standards, and guidelines for the disposal of used devices.

**Performance Characteristics and Clinical Benefits**

No claims of clinical performance are made for the Pro-Jet Bite Wafers. The device is not designed to serve any diagnostic or therapeutic purpose and is only for use as intended for containing dental impression material and facilitating dental impression recording.

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

**Contra-indications**

None specified.

**Warnings & Precautions**

Patients with a history of allergic reactions to plastics should not use this product. Pro-Jet Bite Wafers are single use only.

**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.

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

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