
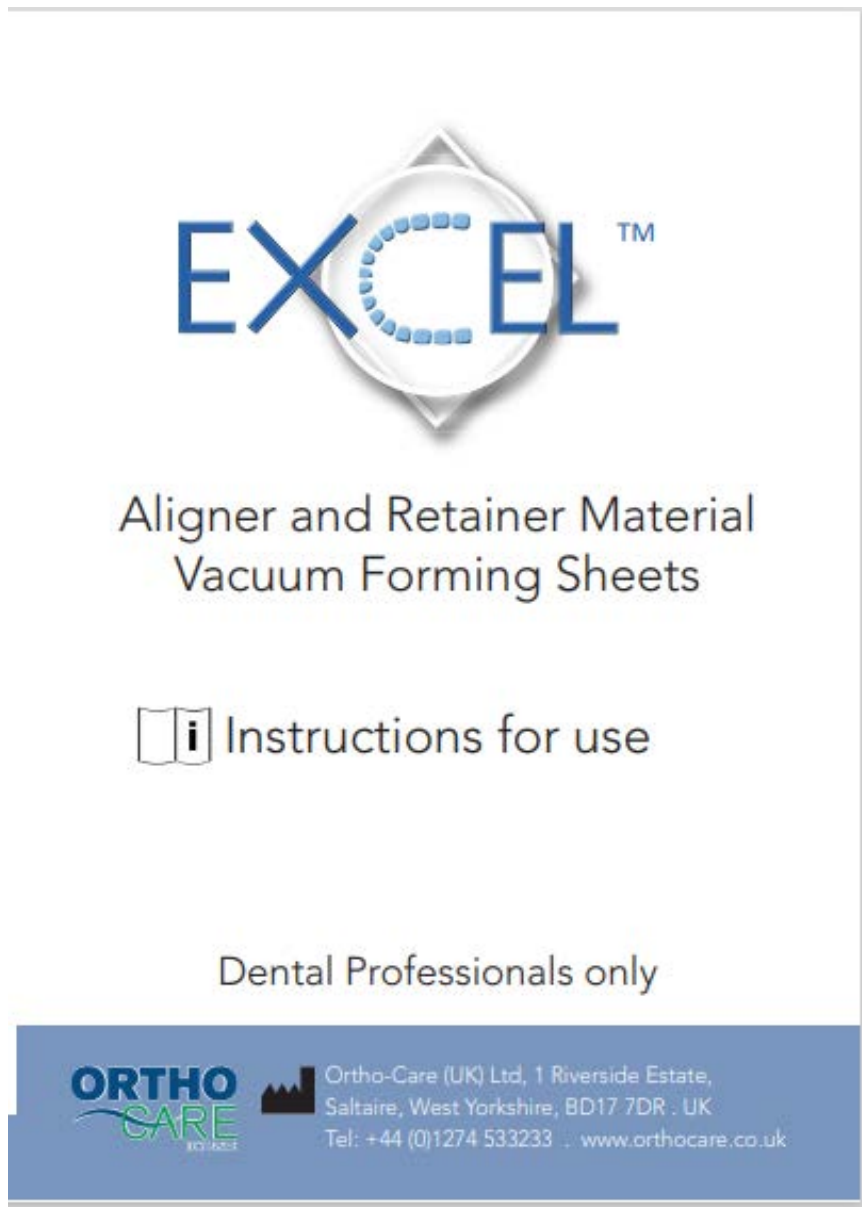



OC-PRO-003-WI-004 Revision 3	Instructions For Use	
Issue Date: 30-Jan-2025	For Vacuum Forming Sheets – Excel Aligner and Retainer Material	

The following is the booklet IFU that is sold with the Vacuum Forming Sheets – Excel Aligner and Retainer Material.



OC-PRO-003-WI-004 Revision 3	Instructions For Use	
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Excel Indications for use – Dental Professionals only

Excel sheets intended use are to fabricate aligners, retainers, splints, bleaching trays and many other dental appliances.

Patient Group

Patients who have undergone dental/orthodontic treatment and/or deemed by a healthcare professional to require a dental or orthodontic appliance.

Contraindication

Do not use if patient has allergy to PETG.

Storage

Store in a cool dry place out of direct sunlight.
Once the foil sachet has been opened, the sheets should be ideally used the same day to avoid moisture contamination.
Alternatively place the remaining sheets in a self-sealing plastic bag. Failure to do so may result in bubbling when heating.

Warnings

Avoid use on patients with plastic allergies.
Excel requires high heat prior to forming so care needs to be taken to avoid skin burns.
Care needs to be taken of sharp edges and not to scratch the device during preparation.


Composition

100% PETG (Polyethylene terephthalate glycol) and polythene peelable film.
A full safety data sheet is available on request.

Performance Characteristics and Clinical Performance

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

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IMPORTANT

Excel sheets have a thin protective plastic film on both sides – one clear and one green or white.

The green or white film should face the heating element and the clear film face the plaster model.

Directions for vacuum/pressure forming

Ensure the plaster model is trimmed correctly – flat on the base and approximately 20mm (3/4") in height.

A horse shoe shape should be used with the palate removed.

Remove the protective clear and green or white films and ensure the side that had the green/white film faces the heating element.

Note – If you prefer, the clear film may be left on.

It will maintain the brilliant clarity and also make it easier to remove from the plaster model.

Vacuum Forming

Allow the heating element to prewarm before moving the sheet towards it.

Heating times vary due to different heating elements and therefore a visual check is required to know when the sheet is ready.

Failure to heat sufficiently will result in poor adaptation on the model.

As the sheet heats it will become soft and eventually start to sag.

Allow it to sag no more than 15mm (1/2").

Immediately turn on the vacuum and pull the sheet over the model.

Leave the vacuum on for appx 15-20 seconds.

It is recommended that as soon as the sheet has formed around the model it be chilled immediately using a freeze spray (REF 9001-004A).

Always ensure the plastic is cold before attempting to remove it from the model.

If the appliance is too thin it is because the sheet has been heated too long and allowed to sag too far.

Pressure forming

Follow the machine manufacturers instructions whilst ensuring the green/white film side of the sheet faces the heating element.




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The following is a guide for use with pressure formers:

Thickness	Biostar Code*	Druformat*
.030" (0.75mm)	113	55 seconds
.040" (1.00mm)	133	70 seconds

* Times and codes are based on a preheated machine

REF 9001-420	EXCEL BLANKS .040" 5 X 5" SQUARE
REF 9001-421	EXCEL BLANKS .040" 125MM ROUND
REF 9001-422	EXCEL BLANKS .040" 120MM ROUND
REF 9001-424	EXCEL RETAINER .030" 120MM ROUND
REF 9001-425	EXCEL RETAINER .030" 125MM ROUND

Removal and Polishing

Always ensure the plastic is cold on the model before removal.

Failure to do so will result in distortion and a poor fit.

A chill/refrigerant spray is recommended as it rapidly cools and contracts the plastic to the model, resulting in a better adaptation (REF 9001-004A).

Remove the plastic from the plaster model then trim with a small pair of crown scissors (REF 60-001).

Finally use silicone polishers to remove any sharp edges (REF 9001-970).

Disposal

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.

Reporting Serious Incidents

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

Date of Issue of IFU 30/Jan/2025 . Change Control Number 2024-CC-055

