


OC-PRO-003 WI-004	Instructions For Use	
Revision 1	For Vacuum Forming Sheets	

Instructions for Use (IFU) Vacuum Forming Sheets

Product Description and Intended Use

Vacuum Forming Sheets are intended to be vacuum formed to create appliances such as retainers, aligners, teeth whitening trays and many other products manufactured from blister die forming. Once an impression is taken of the oral cavity the vacuum forming sheets will be made based on that appliance. Intended patient population is any person who required an orthodontic appliance and conditions which are to be treated, monitored, or diagnosed with vacuum forming sheets include but are not limited to:

- Discoloured/yellow teeth.
- Bruxism (teeth grinding)
- Contact sports
- Snoring
- Sleep apnoea
- Un-aligned teeth.

REF	DEVICE DESCRIPTION (TRADE NAMES)
9001-420	EXCEL BLANKS .040 5 X 5" SQUARE (ORTHO CARE)
9001-421	EXCEL BLANKS .040 125MM RD (ORTHO CARE)
9001-422	EXCEL BLANKS .040 120MM RD (ORTHO CARE)
9001-424	EXCEL RETAINER .030 120MM ROUND (ORTHO CARE)
9001-425	EXCEL RETAINER .030 125MM ROUND (ORTHO CARE)


Indications for Use – Dental Professionals only

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

USE METHOD

1. Use outside the scope of this product is prohibited.
2. Do not place in a hot and humid place.
3. This product must be heated before use, so caution must be taken to prevent burns.
4. When using this product, the scratched protective film on the plastic surface must be removed.
5. Caution must be taken to prevent the fingers from scratching whilst using this product.
6. Only qualified dental/orthodontic professionals must use this product.

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Directions for vacuum/pressure forming

Ensure the plaster model is trimmed correctly – flat in the base and approximately 20mm (3/4”) in height. A horseshoe 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 plastic model.

Vacuum Forming

Allow the heating element to prewarm before moving the sheet towards it. Heating times may vary due to different heating elements and therefore a visual check is required to know when the sheet is ready. 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 pill the sheet over to the model. Leave the vacuum on for approximately 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.

The easiest and cleanest way to do this is using an electric hotknife (REF 9001-250). If the appliance is too thin, it is because the sheet has been heated for too long and has been allowed to sag too far. Failure to heat sufficiently will result in poor adaptation on the model.

Pressure Forming

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

The following may prove useful:

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.

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.

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) The

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easiest way to remove the plastic from the plaster model is with a Hotknife (REF9001-250). Once removed trim with a small pair of crown scissors (REF 60-001). Finally use silicone polishers to remove any sharp edges (REF 9001-970).

Storage

Store in a cool, dry place, out of direct sunlight. Once 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.

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.

Performance Characteristics and Clinical Benefit

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

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.

Contraindications

The vacuum forming sheet is made of PETG, people with an allergy to this material are prohibited to use the product.

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.

Composition

Primarily PETG (Polyethylene terephthalate glycol). A full COSHH sheet is available on request.

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Other Information and Symbols related to Instructions for Use:

Store in a cool and dry place			
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www.orthocare.co.uk/acatalog/resouces.html