

	Instructions for Use (IFU) of MP2 Orthodontic Cold Cure Acrylic Resin	Rev 01
	OC-PRO-003-WI-009	Issue Date: 29-Sep-2026

Compliant to the Medical Device Regulation 2017/745

For Use by Dental Professionals Only

Product Codes:

REF	DEVICE DESCRIPTION (TRADE NAMES)
2131-004	MP2 ACRYLIC POLYMER POWDER 10Kg
2131-005	MP2 CLEAR ACRYLIC MONOMER LIQUID 2.5L
2131-006	MP2 PINK ACRYLIC MONOMER LIQUID 2.5L
2131-007	MP2 ACRYLIC POLYMER POWDER 50Kg
2131-011	MP2 ACRYLIC POLYMER POWDER 1Kg
2131-012	MP2 CLEAR ACRYLIC MONOMER LIQUID 500mL
2131-013	MP2 PINK ACRYLIC MONOMER LIQUID 500mL

1. Device description

General description of the device

The material is based on methyl methacrylate and complies to BS EN 20795-2:2013 Type 1 when constructed precisely following the instructions contained herein.

These instructions are specifically tailored for MP2-manufactured components and are not relevant for use with any other products.

Intended purpose

Intended use

Orthodontic dental acrylic is designed for a self-curing dental acrylic intended for use in the manufacturing of orthodontic appliances.

Intended clinical benefits

Specifically engineered for prosthetic components like denture bases and denture teeth, it is designed for long-term use within the oral cavity, ensuring durability and reliability.

Patient population

The device alone is not intended for use in a specific medical condition. The targeted populations are patients who exhibit a degree of edentulousness, and those who require spatial normalisation of their natural teeth.

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- All ethnic groups
- All nationalities
- All genders

Intended user

The device is supplied as powder/liquid systems to qualified professional personnel. It is a medical device used in dentistry by professionals including dentists, dental laboratory technicians, dental assistants and prosthodontists. The final clinical application and use is the final decision of the dental professional and outside of OrthoCare and Makevale's direct control.

These instructions for use are provided solely for the use of fully trained and independently qualified/validated dental technicians or professionals, working in an environment which is completely compliant with all acceptable medical device regulations for the finished device, pertinent to the market it is in.

2. Components

The medical device is a poly-methyl methacrylate polymer, where monomeric methyl methacrylate makes up over 90% of the final device.

Physical data

Powder: liquid ratio 1.3g : 1ml

3. Use by date

The powder has a shelf life of 5 years, while the liquid has a shelf life of 3 years. Once opened the liquid component must be used before the end of shelf life. Despite this, the device, once constructed, may exceed these durations in its useful lifespan. Reports suggest that after 5 years, up to 50% of patients may require replacement of the device.

4. Transport and Storage

Transport of liquids under caution – UN1247, Hazard Class 3, flammable liquids, Packing Group II. Long term storage at room temperature (max 30°C can be tolerated) and avoid prolonged exposure to sunlight. Do not store above 50°C for periods longer than 2 weeks. Keep containers tightly closed when not in use. See powder and liquid SDS for further instructions on transport and handling.

Dental professional to advise patient on after care. General accepted advice given by

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BDTA suggests cleaning with clean water twice daily by brushing and overnight soaking in clean water.

It is recommended that at least every 4 weeks, the final constructed device is completely removed from the buccal cavity for thorough cleaning with agents specific for the device and as recommended by the dental professional.

Waste disposal: Do not empty monomer liquid into drains.

5. Instructions for Use

Preparation before use

Preparation and construction should be conducted within an ideal ambient temperature range of 16-25°C, however temperatures up to 30°C can be tolerated. Transfer the orthodontic powder and liquid into the dispenser bottles. Cut the ends from each dispenser bottle spout to provide the desired flow of powder and liquid.

Soak the model in water for approximately 7-10 minutes and then use a pressure flask filled with water at 2-3 bar pressure to ensure any trapped air is removed. Remove excess water from the model using a paper tissue and then coat surface with Plaster Coating Solution and allow to dry thoroughly.

Procedure and method

Model Construction

Caution: Liquid flash point 10 °C – do not mix or store near sources of ignition.

Recommended ambient temperature for mixing and packing is 23 °C.

The ‘salt and pepper’ technique is recommended for construction of the orthodontic appliance. Hold the prepared model at an angle to present the working area uppermost and in a horizontal plane. Sprinkle Ortho powder in a thin layer onto the model and drip Ortho resin liquid onto the powder until the powder appears saturated. Add more powder and repeat the process until an approximately 2-3 mm layer of thickness is achieved. Too much liquid added at any one time may result in excessive flow. This can be corrected by the addition of more powder. The orthodontic resin should be of a firm consistency with adequate control of flow. Trim excess material at this stage while the material is still in a rubbery dough stage using a sharp instrument. Apply a little monomer with a brush to smoothen the model surface. The orthodontic resin has a working time of approximately 5 ± 2 minutes at 23°C ± 2 °C.

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Curing of Material

Fill the pressure flask with water at 45-60 °C and place the model carefully in the flask. Close the lid and pressurise the flask to a minimum of 2 bar (30 psi) pressure. Keep the flask under pressure for a minimum of 15 minutes, then release the pressure, remove the cured specimen and trim and polish in the usual manner.

Note : After all curing cycles, bench cool the flask for 30 minutes prior to immersing in cold water before de-flasking. Finish and polish in the usual manner. Store finished denture wrapped in damp tissue in a polythene bag.

Disposal

Avoid pouring monomer liquid into drains. It is the responsibility of the dental practice to handle waste appropriately according to local regulations and to ensure proper measures are taken during final disposal.

6. Caution during use

Indication For Use

Complete or partial arch replacement oral prosthetic devices offer comprehensive coverage for missing teeth, utilising support from the surrounding soft and hard tissues within the oral cavity.

Contra-indication

People with known allergies to methacrylates should only use with suitable protection. Some sensitisation may occur when the liquid component is exposed to skin and safety gloves should be worn. Certain patients are unable to tolerate the wearing of appliances made from methacrylates.

Precaution

Caution: Contains methyl methacrylate monomer. H225 Highly flammable liquid or vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May cause a respiratory irritation. Avoid prolonged skin contact with unpolymerised material and excessive inhalation of monomer vapour especially with people with known allergies in particular to methacrylates.

Safety Advice: Product should be used and container should be kept in a well-ventilated place. Product should be used in accordance with local regulations; use a suitable respirator and/or fume hood. P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P261 Avoid breathing

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dust/fumes/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+361+353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P501 Dispose of contents/container in accordance with local regulations. If you exhibit any adverse symptoms after exposure to the products, seek medical advice immediately. After use wash hands thoroughly with soap and water. For further information request the material safety datasheet.

Technical Advice

The manufacturer Makevale Ltd. warrants that the material contained in this package shall conform to relevant internationally laid down standards and tested accordingly. When used in accordance with the given directions and employing good laboratory practices, the product will achieve optimum results. These instructions are valid only for the product as supplied and not for derivatives resulting from its use. The advice given here is in good faith but the product should always be tested as to the suitability for the intended processes and uses.

Residual risks

The primary substance released through diffusion from the device is the unreacted residual monomer. Prolonged exposure of saliva to the material results in the expansion of gaps between polymer chains, facilitating the diffusion of unreacted monomer. Consequently, substances leached from the denture bases into saliva can trigger adverse allergic reactions in oral tissues.

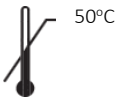
To reduce even further any unreacted monomer, it is advised to place the constructed denture in water and bring the temperature up to 70°C and maintain this temperature for 90 minutes. Then bring to boil and continue boiling for 30 minutes. Allow to cool sufficiently before handling.

Undesirable side-effects

The device has the potential to release residual monomer, which may lead to allergic reactions, mouth soreness and a burning sensation in patients.

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7. Symbols used on labelling

Symbol	Description and Information
	The name of the manufacturer and the address of its registered place of business. Makevale Ltd Valley House, Marsh Lane Ware, Herts SG12 QP United Kingdom
	The Name of the distributor and the address of its registered place of business Ortho-Care (UK) Ltd 1 riverside Estate, Saltaire, West Yorkshire, BD17 7DR, UK Tel: 00 44 1274 533233 www.orthocare.co.uk
	EU Authorised Representative Eurolink Europe Compliance Ltd. 25 Herbert Place Dublin DO2 AY86 Republic of Ireland
	Unique Device Identifier
	Medical Device
	Product reference
	Lot/Batch Number
	Shelf life
	Maximum Temperature

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	CE Marking
	Avoid Rain Water
	Avoid Direct Sunlight
	More information available