

Instructions for use

(EN)

BASIS FLOW II (Type 2, Class 2, According to ISO 20795-1; Type 1, According to ISO 20795-2)

【Intended Use】 Fabrication of denture base, repair of denture base, fabrication of orthodontic appliances

【Indication for Use】 Tooth Loss, malocclusion

【Intended Population】 Target age: 3 to 125 years old, Gender: Irrelevant

【Intended User】 Dentists or dental technicians

【Contra-indications】 Use in patients allergic to Methylmethacrylate

【Directions for Use】

1. Apply a denture base separating agent (Apollon Sep) to a plaster model evenly and allow to dry. In cases where a resin tooth is used, apply liquid or make a vent hole on the basal surface of the tooth to improve retention.
2. Weigh appropriate amount of each powder and liquid (Mixing Ratio: <Powder:Liquid> = <100 g : 60 mL>) and mix for 20 seconds at 23°C. Eliminate air bubbles using vibrator for about 10 seconds.
3. After cooling the plaster model to room temperature (1-30°C), it is poured in after about 30 seconds from the start of mixing at 23°C. The plaster model is ready to be filled.
4. Pour the mixture to the filling phase (30 seconds - 3 minutes).
5. Pressure-polymerize the resin for 30 minutes at 55°C and 0.2MPa in a pressure pod.
6. Allow the flask to cool to room temperature and then dig out the denture.
7. Polish using conventional method.
8. Place the cured resin in a container of water to allow residual monomer dissolution before use.
(Maximum residual monomer content: 4.2%)

【Caution】

1. Do not use for purposes other than those mentioned in the manual.
2. Do not touch the liquid or the mixture of powder and liquid directly. If either comes in direct contact with skin, wipe with alcoholic cotton and wash with running water. In case the liquid comes into contact with eyes, wash well with running water and consult a doctor immediately.
3. Ventilate room well while working.
4. Do not mix with other curing resins.
5. Do not use microwaves for polymerization.
6. Liquid material is flammable and irritating. (Flash point 11°C) Powder material is combustible. Keep the product away from fire.
7. Do not leave the material near a heat source or in direct sunlight.
8. If a crack appears in the denture, stop use immediately.
9. To avoid inhalation of dust, always use a mask and dust collector when working. Use protective eye wear.
10. To prevent damage, refrain from unnecessary polishing or grinding.
11. The product is for professional use only.
12. For maintenance (cleaning), use commercially available denture brushes and denture cleaners.
13. This material is a single-use medical device. Once the denture is fabricated, it cannot be used for other patients.

【Note】

1. Should the patient show any symptoms of hypersensitivity stop using the material and immediately consult a doctor.
2. Should the laboratory technician show any symptoms of hypersensitivity stop using the material and immediately consult a doctor.
3. Do not use on patients who have experienced any previous hypersensitivity, such as rashes, dermatitis or itchiness due to methacrylic monomer.
4. Laboratory technicians, who have experienced any previous hypersensitivity, such as rashes, dermatitis or itchiness due to methacrylic monomer, are advised to use gloves and not to touch the material directly.
5. (To the user and/or patient) Any serious incident that has occurred in relation to the device should be reported to the manufacturer, and the competent authority of the Member State in which the user and/or patient is established.

【Storage】

- Store in a cool place (1 - 30°C) away from heat source or direct sunlight.
- Keep out of reach of non authorized personnel. Keep under constant supervision.
- Always seal the material after use.
- Do not store the products in large quantities.
- Place a fire extinguisher both in workshop and in storage area.

【Disposal information】

Remaining stocks must be disposed of according to the corresponding national legal requirements.

【Potential Hazard】

This product may cause allergic reactions such as rashes and dermatitis.

【Symbol Marks】

The meanings of the symbols on package are as follows,

Symbol Marks	Meaning	Symbol Marks	Meaning	Symbol Marks	Meaning
	Medical device		Do not use if package is damaged		Manufacturer
	Consult instruction for use		Keep away from sunlight		Lot number
	Do not reuse		Flammable		Use-by date
	Unique device identifier		Prescription only		CE marking

【Manufactured by:】



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