

Instructions for use

Generic Device Term	Product Name
Acrylic resin teeth	NEW ACE, MILLION, NAPERCE, EFUCERA AC, FLAT AC
Composite resin teeth	EFUCERA-A, EFUCERA-P, EFUCERA PX SOLUUT PX, CROWN PX,
Acrylic resin teeth (FX)	FX ANTERIOR, FX POSTERIOR, EFUCERA FX
Acrylic resin teeth (NS)	CROWN NS, EFUCERA NS

【Intended Use】 Ready-made resin artificial teeth for dentures

(Specifications of the intended purpose) Restoration of Masticatory Function / Speech Improvement / Aesthetic Enhancement

【Indication for use】 Tooth Loss

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

【Intended User】 Dentists or dental technicians who make dentures

【Contra-indications】 Use in patients allergic to Methylmethacrylate

【Clinical benefits to be expected】 Restoration of masticatory function, phonation, and aesthetics

【Performance characteristics】 Conforms to ISO 22112: 2017 Dentistry – Artificial teeth for dental prostheses, And hardness; 21Hv0.2 or more (enamel) only composite resin teeth

【The disinfection method after denture creation】 Once the dentures are completed, please remove dirt through ultrasonic cleaning and disinfect them with commercially available denture cleaning solution.

【Directions for Use】

1. **Making the denture:** It depends on preferred manufacture method.
2. **Polish method:** Polishing with diamond paste or other abrasives using a brush or cloth buffing.

【Caution】

1. It does not adhere to the resin for denture bases except the acrylic resin of the powder and liquid type. Therefore, preprocess it according to the designated method of the denture base resin maker.
2. **For composite resin teeth:** Do not use strong alkaline (more than pH10) gypsum dissolution materials or dentures cleaners. The composite resin teeth may become cloudy. YAMAHACHI DENTAL “Break” is recommended for the gypsum dissolution materials.
3. To remove coloration due to pigmentation in the mouth (caused by cigarette smoke, etc.), apply polishing sand, polish with a denture brush, then apply glazing agent and polish with a soft-bristle brush.
4. Do not temporarily fix the resin teeth with cyanoacrylate-based superglue. When taking out the denture after polymerizing, the surface of the resin teeth may be detached or broken.
5. After correcting the shape, the area should be polished thoroughly.
6. Do not excessively grind the product together as it may cause damage.
7. An undercut should be provided on the basal plane of the tooth if necessary to strengthen the bond with the denture base.
8. Handle the plaster forceps carefully during denture excavation to avoid possible damage to the denture base.
9. To avoid inhalation of dust, always use a mask and dust collector when polishing.
10. Clean the dentures before placing it on the patient.
11. Please instruct patients to keep their dentures underwater after removal to prevent deformation.
12. Please advise patients to see their dentist regularly as the resin teeth wear down with use.

【Important Note】

1. Should the patient show any symptoms of hypersensitivity stop using the material and immediately consult a doctor.
2. Should the dentist or 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 and itchiness with methacrylic monomers.
4. (Risks of reuse) If resin teeth are reused, there is a risk of the deterioration of oral health due to the use of resin teeth with an incorrect occlusion. There is also a risk of infection.
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】

- Since acrylic resin is flammable, it should be stored away from heat and ignition sources.
- Store away from high temperature, high humidity and direct sunlight.
- Properly store and control so that they cannot be accessed by non authorized personnel.

【Disposal information】

When disposing of medical devices, please comply with the disposal regulations and laws of the country in which you are disposing of them.

【Potential Hazard】

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

【Manufactured by:】

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