Instructions for use of



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# ESTETIC acrylic teeth CE MD

Please read these instructions carefully before using the product. The instruction is available on the website <u>www.wiedent.com.pl</u> in the tab: product / acrylic teeth / Estetic acrylic teeth.

# Intendend use

ESTETIC acrylic teeth are a class I medical device intended for the making of removable dentures. **Description** 

ESTETIC acrylic teeth are made of three layers: the neck, dentine and enamel, mimicking the structure of natural teeth. The neck layer is the softest one as it needs to accommodate any flexing and ensure strong bonding with the denture plate. The hardest layer is the outer enamel. Its hardness is similar to that of natural teeth. Wiedent ESTETIC teeth, like the natural teeth, have a fluorescent effect. They are produced in 62 moulds, upper and lower anterior and upper and lower posterior, in two shade scales - universal V (16 shades) A1 - D4 and WIEDENT (13 shades) A1-R5. The 14 selected moulds are produced in two bleached shades of the universal V scale - 0M1 and 0M3. Our extensive range enables meeting all patient's needs both in terms of shape and shade. ESTETIC teeth meet the requirements of the international standards EN ISO 22112 and EN ISO 7491.

# Raw materials used for production

ESTETIC acrylic teeth are made of powders - polymers based on methyl methacrylate and allyl methacrylate containing benzoyl peroxide (PMMA) and pigments, as well as liquids - methyl methacrylate monomer (MMA) and 1,4 butandiol dimethacrylate (1.4 BDDMA).

# **Direction for use**

Adhesion with the denture plate is enhanced further thanks to a deep transverse groove at the bottom of each of the posteriors. **Should this groove need to be ground down then denture retention is recommended.** Before setting the teeth in the denture plate any wax residues should be removed with boiling water and the teeth degreased with an acrylic monomer. The teeth can withstand temperatures of up to 100°C and after the polimerization process bonding them with the denture plate they retain a glossy surface, which can be easily polished.

#### Warnings and recommended precautions

- danger to the prosthetist may be inhalation of dust while grinding teeth,

- It is recommended to use an exhaust hood and a dust mask during these works.

The manufacturer recommends that the following guidelines be included among the instructions for the patient:

- acrylic teeth dentures used by the patient inconsistently with their intended use may pose a threat to their health because, just like natural teeth, they are exposed to surface abrasion, chipping or complete breakage from the prosthesis during use,
- removable dentures made of acrylic teeth should be removed from the oral cavity for a night break,
- dentures should be cleaned with a tooth brush using an ordinary tooth paste or other substances specially formulated for denture cleansing,
- in order to avoid any damage to its surface dentures should not be immersed in any strongly alkaline or acidic substances,
- damaged dentures should only be repaired by a prosthetist or dentist,
- the fit of dentures should be periodically checked,
- dentures not suitable for further use do not require specific treatment, are recyclable and can be disposed of with municipal waste.

# The storage and transport conditions

Estetic teeth should be stored a clean and dry place. During storage and transport, the temperature should be kept between 3 and 30°C and direct sunlight and heat sources should be avoided. They must be used within 10 years from the date of manufacture mainly due to possible deterioration of the packaging.

# Legal basis

Estetic acrylic teeth meet the requirements of Regulation (EU) 2017/745 of the European Parlament and of the Council.

# Symbols on the packaging

Manufacturer

- Consult instructions for use
- **CE** Mark of product conformity with requirements of Regulation (EU) 2017/745 of the European Parlament and of the Council



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Temperature limit

- Keep away from sunlight
- MD The product is a medical device
- LOT Batch code
- Use-by date

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