C E 0123

Instruction manual

Status 01/2024

1. General Concerns the anterior, posterior and composite teeth and the tunnel wax developed by Gebdi Dental

Products. These instructions contain guidance that must be followed to ensure proper use and compliance with safe conditions. It is essential to read them, and in particular the instructions,

before using them for the first time.

1.1. Product All anterior teeth from item no. 23201 until item no. 28517

All posterior teeth from item no. 20001 until item no. 22516
All composite posterior teeth from item no. 29001 until item no. 29516

Tunnel wax white Item no. 78200

1.2. Manufacturer address

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www.gebdi-dental.com **Dental technical questions:** +49 7733 94 10 20

2. General information

The above-mentioned products are to be used by dental technicians for dental restorative needs in the patient's mouth and are manufactured according to the dentist's specifications.

2.1 Shelf life (use by) and durability

The shelf life (use by) of the teeth is 10 years and the shelf life of the tunnel wax is 4 years. No data is available for the service life. This depends on many factors, such as dental hygiene, eating habits, processing by the dentist or dental technician... This is assessed by regular visits to the dentist.

5. Indication

For the fabrication of complete and partial dentures based on PMMA (polymethyl methaacrylate), as well as for easier positioning of Tribos teeth with tunnel wax.

3.1. Instructions for use

Only trained and experienced dental technicians bring the skills required for the proper use of this medical products with the necessary prerequisites.

The above-mentioned products are semi-finished medical articles and must be further processed professionally and according to proven and common methods. In the case of wax try-ins in the patient's mouth, it is recommended to reinforce the junctions between the wax and the denture teeth as much as possible to prevent the teeth from erupting during the try-in.

3.2. Lineup

All common set-up methods are possible. Lateral and protrusion movements must be able to be reproduced with the articulator and corresponding preliminary information from the dentist (progeny, cross-dentition and bite registrations). Care must be taken to ensure that there is adequate clearance during these movements. The teeth must not be weakened by too thin grinding in order to avoid later fractures.

The tunnel wax offers the optimum positioning aid especially for acrylic teeth with a tunnel shape, but can also be used for all other tooth shapes by cutting the tunnel wax to size.

3.3. Connection of acrylic teeth to denture base

After the fitting in the patient's mouth and before inserting the denture base, the teeth are cleaned of wax residues and the underside to the denture base is lightly ground. If necessary, slight undercuts and application of monomer can be created. All measures contribute to a good bond between the acrylic/composite tooth and the denture base. Hot or cold polymers, as well as injection methods, can be used as denture base.

In all other respects, the prosthetic material manufacturer's instructions and their contraindications must be taken into account. a

3.4. Insertion of the denture

Before placing the denture in the patient's mouth, cleaning and disinfection must be performed in accordance with good clinical craft practice.

4. Storage instructions

All waxes and plastic/composite teeth should be stored away from contamination and direct sunlight, in a dry place and protected from temperatures below 30°C. A visual inspection of the entire tooth surface should be carried out Milled teeth should no longer be used for reasons of stability or color deviations and should be disposed of. Store the remaining plastic/composite teeth back in the tooth cabinet and the remaining tunnel wax in the original packaging.

5. Contraindication

In case of extreme bite conditions, where the necessary free space of the mouth movements cannot be created and in case of bite conditions, which do not guarantee sufficient stability to the denture base or affect the acrylic tooth in its overall stability.

Based on our evaluations, no allergic reactions have occurred or are known at this time. Notwithstanding this, any incidents of allergic reaction observed or detected in patients must be reported immediately.

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If allergic reactions are known to occur in the patient, the products mentioned in point 1.1 should not be used.

6. Safety instructions

The denture teeth should be ground slowly, with little pressure and suitable plastic burs in order not to cause any material defects (cracks, chipping). If this is not observed, plastic can become hot during milling and cause burns on the skin. Do not dispense with eye protection, mouth protection and suction equipment during processing.

7. Customer service

In case of any problems related to processing or suggestions for improvement, it is mandatory to note the lot number and contact Gebdi Dental Products GmbH.

7.1. Disposal

After the denture has been placed in the mouth, the product must be handled as hazardous medical waste. Please observe your regional regulations

8. For attention

All legally valid regulations for ordering, processing and disposal must be taken into account **In case of improper use, all warranty and liability claims become void!**

9. Symbols

	Manufacturer			
(€ 0123	CE mark with number of the notified body			
Ţ <u>i</u>	Observe operating instructions			
淡	Protect from sunlight			
	Upper temperature limit (up to 30°C)			
R _{k only}	FOR DENTAL PROFESSIONALS ONLY (USA)			
NON	Non-sterile product			
REF	Order number			
LOT	Batch number			
<u>~~</u>	Date of manufacture			
\square	Usable until			
CH REP	Swiss authorized representative			

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