

PRESIDENT

The Original

putty / putty soft / putty super soft / fast putty soft

Instructions for use

EN

Carefully read the instructions prior to use.

Product description

PRESIDENT The Original is a two-component impression material based on addition-curing polyvinylsiloxanes. This includes the correction materials (PRESIDENT The Original regular body, light body and Xtra light body) and the tray materials (PRESIDENT The Original putty, putty soft, fast putty soft, putty super soft, heavy body and MonoBody). After manual mixing of base and activator or mixing with the mixing tip, the PRESIDENT The Original materials form pastes which are used individually or in combination as dental impression material, usually together with a standard commercial or individual impression tray and using conventional impression techniques.

Intended use

PRESIDENT The Original is intended for the recording of the current physical situation in a patient's mouth („dental impression material“) for the purpose of repairing, reshaping or replacing the patient's teeth.

Composition PRESIDENT The Original putty

Addition-curing silicone elastomer, putty.

- Polyvinylsiloxanes
- Colour: yellow

Composition PRESIDENT The Original putty soft

Addition-curing silicone elastomer, putty.

- Polyvinylsiloxanes
- Colour: brown

Composition PRESIDENT The Original fast putty soft

Addition-curing silicone elastomer, putty.

- Polyvinylsiloxanes
- Colour: brown

Composition PRESIDENT The Original putty super soft

Addition-curing silicone elastomer, putty.

- Polyvinylsiloxanes
- Colour: orange

Indications for Use

- Impression material for pick-up impression in the double mix technique
- Tray material for corrective impression technique

Contraindications

- Do not use in the case of known allergies to ingredients of the PRESIDENT The Original impression materials.
- Loose teeth can be further loosened or extracted by taking an impression.

Safety instructions

⚠ WARNING

- Impressions that come into contact with the oral mucosa may be contaminated. Observe disinfection instructions.
- Only supplied to dentists and dental laboratories or upon their instructions.

NOTICE

- Always wear non-latex gloves when working. Skin secretions, latex gloves and surfaces contaminated by latex gloves have a negative effect on the setting process of polyvinylsiloxanes. Only touch the material and the surfaces of which the impression is taken (teeth, preparations, retraction cords etc.) with vinyl / nitrile gloves. Compounds containing eugenol or haemostatic substances can also impede perfect setting. If hydrogen peroxide is used for disinfection, it is recommended to thoroughly rinse with lukewarm water afterwards in order to avoid bubble formation. In order to guarantee good cohesion with the correction material, the primary impression should be carefully cleaned and dried before further use.
- High temperatures accelerate setting, low temperatures slow down the setting process.
- Material combinations with impression materials of other manufacturers are not permitted.
- Contains nano materials (bonded particles)

Side effects / Interactions

No harmful reactions or secondary effects on patients and / or dental personnel are known.

User / patient group

The use of PRESIDENT The Original impression materials in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with special qualifications. Suitable for all patient groups.

PREPARATION

Trays

All impression trays that have been designed for dental use, either prefabricated or individual, can be used for impression taking. For perfect adhesion, we recommend applying or spraying a thin layer of COLTENE Adhesive or Adhesive AC to the trays before use. This

prevents detachment of the impression material during removal from the oral cavity. Detailed information on the application can be found in the COLTENE Adhesive or Adhesive AC Instructions for Use.

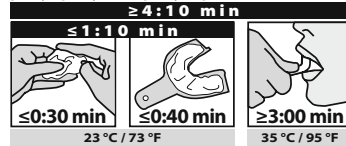
PROPER USE

Dosage

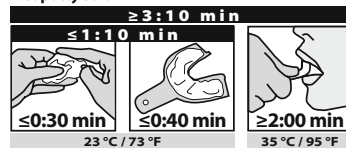
Measure out level scoopfulls of Base and Catalyst from the container.

Processing times

putty / putty soft / putty super soft



fast putty soft



Mixing

Take the Base and Catalyst with the fingertips and start mixing. Knead the compound with the fingertips until the colour is uniform, but for at least 30 seconds. Using a stopwatch is recommended. If a mechanical mixing device is used, observe the manufacturer's instructions. After successful mixing, form a strand with the material and immediately place it in the impression tray.

Impression

Insert the impression tray with the impression material into the oral cavity and press for 2-3 seconds and keep in situ until set completely.

Test methods for correct application

Material residue needs considerably more time to set at room temperature than in the patient's mouth. You should therefore check intraorally if the material is set before removing from the mouth. If the manual pressure test does not leave a pressure mark in the impression material after the time specified in the chapter on „Processing times“, the impression can be removed from the patient's mouth. However, if the test leaves a visible pressure mark in the material, the material is not yet fully set.

CLEANING & DISINFECTION

Cleaning of the impression

After the initial impression is removed from the patient's mouth, it must be rinsed thoroughly before the correction materials are applied. After cleaning, the final impressions can be disinfected with commercially available disinfectant solutions (e.g. Dürr Dental SE, MD 520 impression disinfection) specifically designed for dental impression materials and dried using compressed air.

Cleaning of trays

The impression can be removed with a blunt instrument. Adhesive residues can be dissolved by placing in commercially available universal solvents or benzine.

Manufacture of models

The ideal time lies between 30 min and 72 h after taking the impression. The surface tension will be reduced and pouring will be facilitated if the impression is briefly washed out with a detergent and rinsed thoroughly in lukewarm clear water afterwards. All industry-standard dental stone model materials (e.g. Fujirock Dental Stone, Hard Rock Dental Stone) can be used.

Shelf life and storage

- Expiry date: see primary packaging
- Storage temperature: 15-23°C / 59-73°F
- Relative humidity: 50% ± 10%
- Shelf life after first opening: 3 months

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Close containers immediately after use.

Disposal

PRESIDENT The Original impression materials can be disposed of in small quantities in household waste. PRESIDENT The Original impression material which comes into contact with the patient's mouth must be disposed of in accordance with country-specific regulations.

Technical data according to ISO 4823

Measurements were taken at 23°C / 73°F room temperature and 50% relative humidity.

Mixing time (15ml):	00:30 min
Total working time:	1:10 min
Oral setting time (35 °C / 95 °F):	3:00 min
putty / putty soft / putty super soft	

fast putty soft

2:00 min

Reporting obligation

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

For SDS see

www.coltene.com

Glossary

- Consult instructions for use
- Keep away from sun light
- Temperature limitation
- Notified body registration number
- Identification for Russia
- Identification for Ukraine
- Legal Manufacturer
- Expiry Date
- Batch Code
- RX only
- Medical Device
- Manufacturing Date
- Unique Device Identifier
- European Authorized Representative
- Reference Number

Coltene/Whaledent AG

Feldwiesenstrasse 20
9450 Altstätten/Switzerland
T +41 71 757 53 00
F +41 71 757 53 01
info.ch@coltene.com