

# PRESIDENT System 360

## The Original

### 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 System 360 heavy body

Addition-curing silicone elastomer, heavy-bodied consistency.

- Polyvinylsiloxanes
- Colour: caramel

#### Composition PRESIDENT The Original System 360 MonoBody

Addition-curing silicone elastomer, medium-bodied consistency.

- Polyvinylsiloxanes
- Colour: blue

#### Indications for Use

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

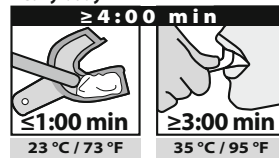
##### Trays

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.

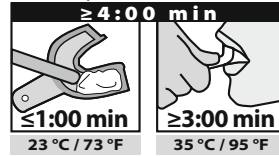
#### PROPER USE

##### Processing times

##### Heavy body



##### MonoBody



#### Preparation System 360 (SYS360) hard cartridge

1. Hold the SYS360 hard cartridge facing upwards with the outlet channels closed.
2. Gently clip the safety cap of the outlet channel while holding it upwards; then remove and discard the safety cap.
3. Insert the SYS360 hard cartridge according to the manufacturer's instructions for use of the mixing machine.
4. Start the mixing machine and extrude material out of the outlet channel without the mixing tip until equal amounts of base and catalyst are dispensed. This ensures that the plungers are at the same height to achieve an optimal mix.
5. Carefully wipe off extruded material with a paper towel. Avoid mixing of the Base and Catalyst in the outlet channels under all circumstances.
6. Attach a yellow dynamic mixing tip onto the outlet channels of the SYS360 hard cartridge. Pay attention that the hexagon section of the yellow dynamic mixing tip is correctly aligned onto the drive shaft.
7. When the yellow dynamic mixing tip is correctly placed, the yellow fixation ring must be positioned over the dynamic mixing tip and turned to the right (clockwise 1/4 turn) until it is securely fastened. The mixing components inside the yellow dynamic mixing tip must rotate when the machine is started.
8. Before every use, reject the first 3 cm of mixed impression material and press out the following material without interruption.
9. Fill the mixed impression material directly into the selected impression tray. In order to prevent the formation of air voids, the yellow dynamic mixing tip should always remain immersed in the material.
10. In order to prevent excess material coming out, the plungers of the mixing machine should be disengaged after extruding material.
11. The yellow dynamic mixing tip should be left on the SYS360 hard cartridge until the next application, since it acts as a seal. It should be wiped with a disinfection solution.
12. To remove the yellow dynamic mixing tip, the fixation ring must be turned counter-clockwise and removed. The fixation ring is reusable!
13. Before the next application, check to ensure that the outlet channels of the SYS360 hard cartridge are not clogged and that equal amounts of material can be extruded. Proceed according to point 5.
14. Remove the empty SYS360 hard cartridge out of the mixing machine and dispose according to local regulations.

#### Dynamic Mixing Tip yellow

The yellow dynamic mixing tip should be left on the cartridge until the next application, as it acts as a seal. To guarantee trouble-free application, we recommend that the yellow dynamic mixing tip be used exclusively.

#### 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 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 benzene.

#### 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.

#### 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):	0:15 min
Total working time:	1:00 min
Oral setting time (35 °C / 95 °F):	3:00 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](http://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

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