

PRESIDENT System 360 Monobody / heavy body

The Original

Instructions for use

EN

Please read the Instructions for Use carefully before using the product. Keep for later reference.

PRODUCT DESCRIPTION

PRESIDENT The Original is a two-component impression material based on addition-curing polyvinylsiloxanes. 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

Addition-type silicone elastomer, polyvinylsiloxanes, fillers, surfactants, pigments

Medium bodied consistency

- Colour: blue

Heavy bodied consistency

- Colour: caramel

INDICATION

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

CONTRAINDICATION

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

SAFETY INSTRUCTIONS

- Impressions that came into contact with the oral mucosa may be contaminated. Observe disinfection instructions.
- Do not use latex gloves. Always use vinyl / nitrile gloves to touch the material and the surfaces of which the impression is taken (teeth, preparations, retraction cords etc.).
- Compounds containing eugenol or haemo-static substances can also inhibit setting.
- If hydrogen peroxide is used for disinfection, it is recommended to thoroughly rinse with lukewarm water afterwards to avoid bubble formation.
- 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 product shall be used by qualified dental professionals only. Suitable for all patient groups including children, elderly people and pregnant women.

PREPARATION

Trays

All impression trays that have been designed for dental use, either prefabricated or individual, can be used for impression taking. For reliable adhesion, we recommend applying a thin layer of COLTENE Adhesive (AC) 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



Mixing

1. Hold the SYS360 Cartridge facing upwards with the outlet channel 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 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 using a paper towel to avoid contamination between the base and catalyst in the outlet channels.
6. Attach a yellow dynamic mixing tip onto the outlet channel of the SYS360 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 right (clockwise . turn) until it is securely fastened. The mixing components inside of the yellow dynamic mixing tip must rotate when the machine is started.
8. Before every use reject the first 3 cm of the 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 Cartridge until the next application, since it acts as a seal. It should be wiped with a disinfection solution.
12. To remove the used 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 Cartridge are not clogged and that equal amounts of material can be extruded. Proceed according to point 5 as follows.

Impression

Apply the impression material to the impression tray. Insert the impression tray into the oral cavity and keep in situ until set.

Avoid using excessive amount of silicone for impression taking due to the risk of overflow material being swallowed.

TESTMETHOD FOR CORRECT APPLICATION

Always check intraorally whether the material is set or not. If the manual pressure test does not leave a pressure mark in the impression, it 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.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

Cleaning of the impression

After cleaning, the final impressions can be disinfected with dental disinfectant solutions (e.g. OPTIM 1 liquid, COLTENE) and dried using compressed air.

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/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

Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)

TECHNICAL DATA

Measurements according to ISO 4823.

Mixing time (15ml):

0:15 min

Working time:

1:00 min

Time in mouth:

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.

In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

SAFETY DATA SHEET

www.coltene.com



GLOSSARY

	Consult instructions for use
	Keep away from sun light
	Temperature limitation
	Marking of Conformity Europe
	Identification for Ukraine
	Legal Manufacturer
	Expiry Date
	Batch Code
	RX only
	Medical Device
	Manufacturing Date
	Unique Device Identifier
	European Authorized Representative
	Importer
	Reference Number

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