

AFFINIS System 360: putty / heavy body / MonoBody / heavy body BLACK-EDITION

Instructions for use

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

PRODUCT DESCRIPTION

AFFINIS is a two-component impression material based on addition-curing polyvinylsiloxane. After manual mixing of base and catalyst or mixing with the mixing tip, the AFFINIS 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

AFFINIS 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

Putty Consistency

- Colour: blue-grey

Heavy bodied consistency

- Colour Heavy Body: caramel
- Colour Black Edition: black

Medium bodied consistency

- Colour MonoBody: ice blue

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

- Impression materials 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 haemostatic 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 patient's and / or dental professionals 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 (AC) Instructions for Use.

PROPER USE

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 turn 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

Depending on the impression method, apply the impression material in the patient's mouth or 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.

Optional: autoclavable impressions

The following points should be observed when autoclaving impressions:

- Only use autoclavable components (e.g. PRESIDENT Tray AC, COLTENE Adhesive AC).
- Rinse and clean impression thoroughly under flowing, lukewarm water.
- Impressions can be autoclaved directly after taking the impression.
- Autoclave in steam sterilizer at 134 °C / 273 °F (Prion program)

When sterilizing implant impressions, be sure to clarify in advance with the manufacturer, whether or not the implant components (e.g. impression posts, etc.) are autoclavable.

Manufacture of models

The ideal time is between 0.5 h - 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.

AFFINIS Putty System 360

| | |
|-----------------------|----------|
| Mixing time: | 0:15 min |
| Working time: | 1:00 min |
| Time in mouth: | 3:30 min |

AFFINIS Black Edition System 360

| | |
|-----------------------|----------|
| Mixing time: | 0:15 min |
| Working time: | 1:00 min |
| Time in mouth: | 2:20 min |

AFFINIS heavy body System 360

| | |
|-----------------------|----------|
| Mixing time: | 0:15 min |
| Working time: | 1:00 min |
| Time in mouth: | 2:00 min |

AFFINIS MonoBody System 360

| | |
|-----------------------|----------|
| Mixing time: | 0:15 min |
| Working time: | 1:00 min |
| Time in mouth: | 2:30 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



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GLOSSARY

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| | 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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