

AFFINIS Cartridges: 75ml / Black Edition / heavy body / fast heavy body / MonoBody

Instructions for use

EN

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.

Heavy bodied consistency

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

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
- Tray material for dual arch 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

Mixing Cartridge

1. Insert cartridge in dispenser.
2. Remove the safety cap.
3. Activate the lever and press a small amount of material onto a paper towel until equal amounts of base and catalyst are dispensed from the outlet channel. This ensures that the plungers are at the same height to achieve an optimal mix.
4. Attach the mixing tip onto the cartridge and twist a ¼ turn clockwise (90 °) to lock it in place.
5. Press out the impression material with a smooth, constant action of the lever. Avoid abrupt movement

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

To prevent cross-contamination the use of cartridge sleeves is recommended. In case of suspected or identifiable contamination, please dispose of. The mixing tip serves as seal until the next application and prevents contamination of the material. Store the material in horizontal position. Remove the used mixing tip immediately before the next application, check again for smooth flow of the impression material and attach a new mixing tip.

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 heavy body BLACK EDITION

Mixing time: 0:10 min
Working time: 1:00 min
Time in mouth: 2:20 min

AFFINIS heavy body

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

AFFINIS fast heavy body

Mixing time: 0:15 min
Working time: 0:50 min
Time in mouth: 1:20 min

AFFINIS MonoBody

Mixing time: 0:10 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



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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