

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

## Instructions for use

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Please read the Instructions for Use carefully before using the product.

### PRODUCT DESCRIPTION

AFFINIS is a two-component impression material based on addition-curing polyvinylsiloxane. This includes the wash materials (AFFINIS regular body, fast regular body, light body, fast light body, AFFINIS PRECIOUS regular body and light body) and the tray materials (AFFINIS putty, putty soft, fast putty soft, putty super soft, heavy body, fast heavy body, MonoBody and AFFINIS BLACK EDITION). 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

### INDICATIONS FOR USE / CLINICAL BENEFIT

- 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 AFFINIS impression materials.
- Loose teeth can be further loosened or extracted by taking an impression.

### SAFETY INSTRUCTIONS

#### ⚠ WARNING

- Impression materials 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

- 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 use of AFFINIS 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 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.

### Casting 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.

### 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.*

### SHELFLIFE / STORAGE

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

Protect against exposure to heat and sun.

### 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.

### SAFETY DATA SHEET www.coltene.com



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#### Glossary



Consult instructions for use



Keep away from sun light



Temperature limitation



Marking of Conformity Europe



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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