

# AFFINIS<sup>®</sup> putty soft / fast putty soft / putty super soft

## 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

### Putty consistency

- Colour base (fast) putty soft: brown
- Colour base putty super soft: orange
- Colour catalyst: light grey

### INDICATIONS FOR USE / CLINICAL BENEFIT

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

### CONTRAINDICATIONS

- Do not use in the case of known allergies to ingredients
- 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

Take the Base and Catalyst with the fingertips and start mixing. Knead the compound with the fingertips until the colour is uniform. 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

#### 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

AFFINIS impression materials can be disposed of in household waste. AFFINIS impression material which comes in contact with the patient's mouth must be disposed of, in accordance with country-specific regulations.

### TECHNICAL DATA

Measurements according to ISO 4823.

#### AFFINIS<sup>®</sup> putty soft

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

#### AFFINIS<sup>®</sup> fast putty soft

Mixing time:	0:30 min
Working time:	1:00 min
Time in mouth:	1:50 min

#### AFFINIS<sup>®</sup> putty super soft

Mixing time:	0:25 min
Working time:	1:00 min
Time in mouth:	2:00 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.

### SAFETY DATA SHEET

[www.coltene.com](http://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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