

AFFINIS[®] Cartridges: light body / regular body / fast light body / fast regular body / PRECIOUS light body / PRECIOUS regular body

Instructions for use

EN

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

Light bodied consistency

- Colour: green
- Colour AFFINIS PRECIOUS light body: silver

Regular bodied consistency

- Colour: blue
- Colour AFFINIS PRECIOUS regular body: gold

INDICATIONS FOR USE / CLINICAL BENEFIT

- Correction material for the corrective impression technique
- Injection material for the double mix technique
- Injection material for the dual arch technique
- Lining impression material

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.

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 or 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 universal mixing tip onto the cartridge and twist a ¼ turn clockwise (90 °) to lock it in place.
5. Place the oral tip on the mixing tip.
6. Press out the impression material with a smooth, constant actuation 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

Wipe off the product after use with >70% ethanol solution or common dental disinfectant (e.g. OPTIM 1 wipes, COLTENE). Do not remove the tip. 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. To prevent cross-contamination the use of cartridge sleeves is recommended. In case of suspected or identifiable contamination, please dispose of.

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.

SHELF LIFE / 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[®] light body / regular body

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

AFFINIS[®] fast light body / fast regular body

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

PRECIOUS[®] light body / regular body

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

Coltene/Whaledent AG

Feldwiesenstrasse 20
9450 Altstätten/Switzerland
T +41 71 757 53 00
F +41 71 757 53 01
info.ch@coltene.com

COLTENE