

# Instructions For Use

## Cavex ColorChange

CE 0197

### Product description

Alginate impression material is a powder, containing alginate, calcium sulphate and sodium pyrophosphate as the reactive components, combined with an inert filler (diatomaceous earth), stabilisers, pigment and flavour.

It is used by the professional user (the dentist and/or the dental assistant) for the manufacturing of a dental impression material by mixing it with water.

The mixed paste is intended for making impressions of the mouth as a basis for the positive gypsum cast for the dental technician. It stays in contact with the patient for 1 or 2 minutes.

Cavex ColorChange is an alginate impression material for dental use.

Cavex ColorChange has a setting time that makes it a suitable general purpose alginate impression material, that can also be used by the orthodontist. A special feature of Cavex ColorChange is a change of colour during the processing of the product at all stages that are relevant to the dentist.

### Composition

The basic composition of both Cavex ColorChange is as follows:

Raw Material	App. % w
Alginate	14
Calcium sulphate	10
Fillers	70
Retarder, stabilisers and flavour	6
Colour indicators	Trace amount

### Indication for use

Cavex ColorChange is a new-generation alginate which changes colour during the working process. Thanks to the adapted reaction mechanism the impressions made with Cavex ColorChange are 9 days dimensional stable when properly stored in a firmly sealed plastic bag (100% R.H.). Cavex ColorChange is suitable both for general dental practice and for orthodontics. The colour change effect makes it particularly attractive for paediatric dentistry.

Dental impression materials in general are designed for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. Alginate impression materials are general-purpose impression materials that normally are not used for making accurate impressions, for instance for crowns and bridges. They are widely used for making study models, first impressions for the construction of trays, situation models, working models.

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## **Contra-indications & Warnings**

### Contra-indications

In cases of a known allergy to any of the ingredients of the alginate impression materials.

### Swallowing

A minor risk under normal conditions in the dental office. The patient will first react by retching. When swallowed, the alginate impression material will be excreted the natural way.

### Hypersensitivity- or allergic reactions

These phenomena are extremely rare. It is known that a very limited number of people may show slight allergic reactions to the flavour used.

### Instructions for Use not respected

It should be acknowledged that the dentist is the actual manufacturer of the medical device "alginate impression material" to be used on the patient.

In case the storage conditions are not respected (storage at a too high temperature and/or humidity), the consistency might become too thin and the setting time in the mouth too long for convenient working, before the actual quality of the impression and the gypsum cast is impaired.

In case the powder/water ratio deviates too much from the advised ratio, or the mixing procedure is not good, or the finished impression is wrongly treated before it is poured in gypsum, the final gypsum cast can be of a poor quality in terms of surface texture or even its dimensions.

In all cases, the worst that can happen is a gypsum cast of poor quality. The dental technician will then normally get in touch with the dentist in order to discuss an improvement on the dentist's side. If he fails, or did not notice the poor quality, the end result could be a prosthesis with a bad fit that has to be corrected or made again.

## **Handeling**

### **Dosing**

- Stir the powder to loosen it well.
- Scoop it from the storage box with a light, swift movement and then stroke the powder smooth: do not compress the powder in the scoop.
- Mix water (at room temperature) and powder in the mixing cup.
  - \* for a partial impression 1 scoop + 1/3 beaker of water
  - \* for a full impression 2 scoops + 2/3 beaker of water
  - \* for an extra-large impression 3 scoops + full beaker of water
  - \* for stiff alginate (1) 3 scoops + water (high viscosity level)

*Ideal mixing ratio: 21.2 g = 3 measuring scoops: 46 ml = 1 full beaker.*

*You can make the mixture thinner or thicker by adding more or less water respectively.*

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## (1) Cavex stiff alginate technique

The impression technique to make an accurate first (functional) impression for a stable denture. It is the combination of an impression tray with rim lock for edentulous jaws e.g. Schreinemakers'full denture tray system" and stiff (high viscosity) Cavex alginate. Stiff alginate is the normal amount of powder with 30% less water. The high viscosity alginate pushes the soft tissue aside As a result the anatomical details, even the frenae are clearly visible. The gypsum model can be lined-out accurately and fully, which enables the dental technician to ensure that the individual tray is a perfect fit. The result: a stable denture and satisfied patient.

### Mixing

- During the purple phase (approx. 30 sec.) mix until a smooth, homogeneous mixture is obtained.
- The colour change from purple to pink indicates the end of the mixing time.
- Fill the tray with the pink impression material and use a wettened finger to stroke it smooth.
- Make sure that the patient has rinsed the mouth with warm water in the mean time.

### Taking the impression

- Within 1 minute after mixing, place the tray containing the pink impression material into the patient's mouth applying gentle pressure.
- The colour change from pink to white indicates that the tray is ready for removal from the mouth.
- Remove the tray from the mouth in a single rapid movement.
- Rinse the tray under cold running water to remove saliva and any residues.
- Remove any excess water, but leave the surface moist. Never blow-dry!

### Making the plaster models

- Immediately after rinsing, pour out the plaster impression and make a second plaster model if desired.
- If immediate pouring is impossible, store the still humid impression in a firmly sealed plastic bag to obtain 100% relative humidity. This is essential for optimum results at a later pouring.
- Make the plaster model within 9 days of the impression taking.

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## Mixing scheme Cavex ColorChange

	mixing	filling + placing	Setting in mouth
	30 sec.	1 minute	1 minute
	Purple	Pink	White
<b>total working time</b>			
	1 minute 30 sec.		
<b>setting time</b>			
	2 minutes 30 sec.		

### Note.

1. The working/setting times increase with a lower (water) temperature. At higher temperatures the times become shorter.
2. The water hardness has the same effect: the harder the water used for mixing, the shorter the working/setting time.

## **Intended Patient(s)**

Dental impression materials in general are designed for taking impressions of the oral cavity as first step in a prosthetic, orthodontic or restorative dental treatment plan. Therefore dental impression materials are used for both children and adults. For children it's mostly used for orthodontic treatments and for adults more for restorative dental treatment plan and prosthetics.

## **Intended User(s)**

Cavex Alginate Impression Materials are only used by dental professionals (dentist, dental technician, dental nurses).

## **Clinical benefits**

The technique for taking dental alginate impressions is widely used for making study models, first impressions for the construction of trays, situation models and working models. The dental practitioner obtains in a fast, easy and economically friendly way a very accurate anatomical model of the oral cavity. Specific benefit for the patient is the ease of impression taking with pleasant taste.

This dental impression alginate is available in Fast Set, which means that it is cured after one minute. Due to Cavex ColorChange's elastic properties, this alginate product is highly suitable for orthodontic clinics.

A useful feature of Cavex ColorChange is a change of colour during the processing of the product at all stages that are relevant to the dentist.

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## Claims

- Indicates three color changes
- Nine days of dimensional stability
- Tear and deformation-resistant
- Detail reproduction of at least 25 µm
- Maximum compatibility with plaster
- Short setting time
- Highly elastic
- Dust-free

## Product characteristics and specifications

Cavex ColorChange is in full compliance with EN ISO 21563:2021 "Impression Materials – Alginate".

Characteristic	ISO 21563	Cavex ColorChange	Unit
Appearance powder	Unif. Pink powder, free from foreign materials	Unif. Pink powder, free from foreign materials	
Appearance mixed alginate	Homogeneous, smooth surf. Free from lumps & granules	Homogeneous, smooth surf. Free from lumps & granules	
Flavour	Peppermint flavour	Peppermint flavour	
Working time; 1:30 min	0 – 0,25	0 – 0,25	mm
Initial setting time	1:40 – 2:20	1:40 – 2:20	min
Detail reproduction	20 µm line reproduced (before & after disinfect.)	20 µm line reproduced (before & after disinfect.)	
Gypsum compatibility	50 µm line reproduced	50 µm line reproduced	
Elastic recovery	95 - 100	95 - 100	%
Strain in compression	5 – 20	5 – 20	%
Tear strength	0,38 – 2	0,38 – 2	N/mm
Labelling & instr for use	Must comply	Must comply	

- Measured with deionised water at 23 °C

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## **Combination products:**

### **Cavex ImpreSafe**

Highly effective dental impression disinfectant.  
The disinfection fluid is compatible with alginate, polyether, and silicone impressions.

### **Cavex GreenClean**

Smart solution for cleaning dental impression trays, instruments, and other accessories. Not by scratching or sanding, but simply by dissolving alginate and gypsum residues.

### **Cavex ScanSpray**

Developed to optimize the scannability of alginate impressions. The addition of titanium dioxide enables even the smallest details to be clearly scannable. This powder-based spray is suitable for any type of dental impression material.

### **Cavex Alginate Adhesive**

Optimizes both the mechanical and chemical connection between the impression tray and the alginate. The product prevents detachment of the impression from the tray when it is taken out of the patient's mouth.

### **Cavex Alginate Accessories**

The following accessories are available:

- The alginate container for controlled storage and exact dosing of the alginate powder.
- The water dosing bottle for a controlled, constant water temperature and exact dosing of the water.
- The flexible mixing bowl with mixing spatula (spatula also available in metal)

### **Cavex Alginate Mixers**

#### Cavex Alginate Mixer II:

Enhances dental impression performance by standardizing the alginate mixing procedure and eliminating even the slightest occasional imperfections. Consequently, dental professionals are assured of a smooth and homogeneous mixture, free of lumps or air bubbles.

#### Cavex Alginate Mixer 3:

Consistently delivers evenly mixed alginates with perfectly predictable properties. In addition to consistent quality, the Cavex Alginate Mixer 3 also offers significant time savings. Preparation, processing, and cleaning become a matter of just seconds. Desired mixing programs can be selected at the touch of a button using the innovative, user-friendly touchscreen:

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## **Special advice**

According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

## **Storage advice**

Do not store at temperatures higher than 25°C (77°F). Do not use this material beyond its expiry date. Avoid direct exposure to sunlight. Close containers firmly after use and keep out of reach of children.

## **Disposal information**

Dispose of in accordance with local regulations. Do not dispose of contents or partially emptied packaging in household waste or allow them to enter the sewage system.

Cavex Holland BV  
Fustweg 5  
2031CJ Haarlem  
The Netherlands  
T +31 23 5307700  
dental@cavex.nl

Made in The Netherlands

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