

# Instructions For Use

## Cavex Impressional

**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.

### **Composition**

The basic composition of both Cavex Impressional Normal Set and Cavex Impressional Fast Set is as follows:

Raw Material	App. % w
Alginate, gelling agents	15
Calcium sulphate	10
Fillers	69
Retarder, stabilisers, pigment and flavour	6

### **Indication for use**

Cavex Impressional is a dustfree alginate impression material with a creamy consistency. It is available in Normal Set and Fast Set and suitable both for general dental practice and for orthodontics. It has exceptional good elastic properties and a high tear-resistance which makes it even more suitable for orthodontics. Thanks to the blue colour the impression is very good readable. The impression surface is very smooth, which gives an excellent gypsum compatibility.

### **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

# Instructions For Use

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.*

### **(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 rimlock 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**

- Mix both components together carefully and thoroughly for 20 - 30 seconds until a smooth and homogeneous mixture is obtained.
- Fill the tray immediately and use a wetted 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 (fast set) 1½ minute (normal set) after mixing, insert the filled impression tray into the patient's mouth applying gentle pressure.
- Allow the impression material to set in the mouth for 1½ minute (fast & normal set).
- 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!

# Instructions For Use

## 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 impression in a firmly sealed plastic bag and add a few drops of water to achieve a relative humidity of 100%. This is essential for optimum results at a later pouring.
- Make the plaster model within 48 hours after taking the impression.

## Mixing scheme Cavex Impressional

	mixing	filling + placing	Setting in mouth	
Normal Set	30 sec.	1 minute 30 sec.	1 minute 30 sec.	
Fast Set	30 sec.	1 minute	1 minute	
	total working time			
Normal Set	2 minutes			
Fast Set	1 minute 30 seconds			
	setting time			
Normal Set	3 minutes 30 sec.			
Fast Set	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.

# Instructions For Use

## Claims

- Unique combination of high elasticity and tear strength
- Detail reproduction of 25 µm
- Optimal gypsum compatibility
- Clearly legible blue color
- Spearmint aroma
- Dust-free
- Suitable for the alginate hydrocolloid technique
- Short setting time

## Product characteristics and specifications

Cavex Impressional Normal set and Cavex Impressional Fast Set are in full compliance with EN ISO 21563:2021 "Impression Materials – Alginate".

Characteristic	ISO 21563		Cavex Impressional		Unit
	Normal set	Fast Set	Normal set	Fast Set	
Appearance powder	Unif. blue powder, free from foreign materials	Unif. blue powder, free from foreign materials	Unif. blue powder, free from foreign materials	Unif. blue powder, free from foreign materials	
Appearance mixed alginate	Homogeneous, smooth surf. Free from lumps & granules	Homogeneous, smooth surf. Free from lumps & granules	Homogeneous, smooth surf. Free from lumps & granules	Homogeneous, smooth surf. Free from lumps & granules	
Flavour	Spearmint flavour	Spearmint flavour	Spearmint flavour	Spearmint flavour	
Working time; 2:00 min	0 – 0,25	0 – 0,25	0 – 0,25	0 – 0,25	mm
Initial setting time	2:10 – 2:50	1:40 – 2:20	2:10 – 2:50	1:40 – 2:20	min
Detail reproduction	20 µm line reproduced (before & after disinfect.)	20 µm line reproduced (before & after disinfect.)	20 µm line reproduced (before & after disinfect.)	20 µm line reproduced (before & after disinfect.)	
Gypsum compatibility	50 µm line reproduced	50 µm line reproduced	50 µm line reproduced	50 µm line reproduced	
Elastic recovery	95 - 100	95 - 100	95 - 100	95 - 100	%
Strain in compression	5 – 20	5 – 20	5 – 20	5 – 20	%
Tear strength	0,38 – 2	0,38 – 2	0,38 – 2	0,38 – 2	N/mm
Labelling & instr for use	Must comply	Must comply	Must comply	Must comply	

# Instructions For Use

## **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:

# Instructions For Use

## **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

Our technical advice, whether verbal, in writing or by way of trials, is given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. It does not release you from the obligation to test the products supplied by us as to their suitability for the intended processes and uses. The application, use and processing of the products are beyond our control and, therefore, entirely your own responsibility. Should, in spite of this liability be established for any damage, it will be limited to the value of the goods delivered by us and used by you. We will, of course, provide consistent quality of our products within the scope of our General Conditions of Sale and Delivery.

Version: AA096IFU.00

Date: 13-2-2023