

Instructions For Use

Cavex Orthotrace

CE 0197

Product description

Cavex Orthotrace is an alginate impression material for dental use.

Cavex Orthotrace has an extra fast setting time, high elasticity, high tear resistance, can be poured twice with gypsum and is presented in an attractive fuchsia-coloured powder with a red-fruit flavour. Therefore, Cavex Orthotrace is particularly suited for orthodontics.

Cavex Orthotrace is also dust free: the powder is treated in such a way, that no dust is generated during dosing and mixing. This facilitates the mixing process through easy absorption of water by the powder, offering the orthodontist convenient and hygienic handling.

After mixing with water, a smooth paste is formed that is loaded into an impression-tray and placed in the mouth of the patient. After hardening of the paste, due to a chemical reaction, an accurate impression is obtained, that can be taken out of the mouth without any deformation, because of its elastic nature.

By pouring the impression with gypsum, or dental stone, a precise model of the situation in the mouth can be prepared, allowing the dental technician to construct a well-fitting orthodontic appliance.

Composition

The basic composition of both Cavex Orthotrace is as follows:

Raw Material	App. % w
Alginate, gelling agents	14
Calcium sulphate	10
Fillers	70
Retarder, stabilisers, pigment and flavour	6

Indication for use

Developed with orthodontic practices in mind. With its extra-fast setting and robust consistency, this alginate does not flow into the back of the mouth, so the gag reflex is avoided. The pleasant combination of red fruit fragrance and attractive magenta color is also inviting for the patient to bite into.

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

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.

(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 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.

Instructions For Use

Taking the impression

- Within 40 seconds 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 1 minute.
- 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 impression in a firmly sealed plastic bag 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 Orthotrace

	mixing	filling + placing	Setting in mouth
	30 sec.	40 sec.	1 minute
	total working time		
	1 minute 10 sec.		
	setting time		
	2 minutes 10 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).

Instructions For Use

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.

Claims

- Clearly legible pink color
- Pleasant fruit aroma
- Extra fast setting
- Rapid water absorption
- Highly elastic
- Short Setting time

Product characteristics and specifications

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

Characteristic	ISO 21563	Cavex Orthotrace	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	Red Fruit flavour	Red Fruit flavour	
Working time; 1:30 min	0 – 0,25	0 – 0,25	mm
Initial setting time	1:40 – 2:20	1:25 – 1:50	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	

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: AA380IFU.00

Date: 13-2-2023