Instructions For Use

Cavex SiliconA

CE 0197

Product description

Cavex SiliconA is based on addition curing elastomeric polysiloxane suitable for inlays, crown and bridges, partial and edentulous impressions utilising the common impression techniques.

The Cavex SiliconA is a variable consistency system that can be combined individually for the desirable impression techniques: either Single-step technique (sandwich) or Two-step technique (double impression). Cavex SiliconA impression material is composed of:

- Soft Putty a kneadable yellow putty with a high consistency
- Heavy Body heavy consistency green paste
- Injection Type low consistency blue paste
- Bite paste with high final Shore D hardness of 40.

Composition

Function	Raw Material
Solvent	Poly dimethyl siloxane
Solvent	Paraffine
Filler	Calcium carbonate
Filler	Silicon dioxide
Reactive component	Catalyst
Colour	Pigment

Indication for use

Inlays, onlays, crowns, bridges, (partial) dentures.

Intended Patient(s)

Cavex SiliconA is an elastic impression material which can be used for anyone in need of the above mentioned indications.

Intended User(s)

Cavex SiliconA will only be used by dental professionals (dentist).

<u>Handling</u>

Practical tips

Please visually inspect for damage before use. Do not use damaged products. Mixing tips and bite registration tips are for single use only.

Dispense a small amount of material from a 50 ml cartridge before attaching a mixing tip. After use, leave the mixing tip on the cartridge to keep it closed.

Immediately before the next use, remove the mixing tip and attach a new one.

When bite registration materials based on polyvinyl siloxane are touched with latex gloves, retraction solutions or freshly inserted composite fillings, it can change the curing behaviour. Cavex SiliconA Bite should be at room temperature when used (23°C/73°F). Lower temperatures, for example when the materials are stored in a refrigerator can extend the working time, and higher temperatures can shorten it.

Hardened polyvinyl siloxanes are chemically resistant. Clothes can be permanently stained if the contact material is not completely cured. Cavex SiliconA Bite is used with the Cavex Cavex SiliconA assortment

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Indications	Technique	Tray material	Syringe material	
Inlay, onlay, crown and	Two stage	Putty or Heavy body	Injection Type	
bridge	Single stage Putty or Heavy body		Injection Type	
	Monophase	Heavy body	Heavy body	
Partial denture (frame)	Monophase	Heavy body	Heavy body	
Full denture	Functional	Putty or Heavy body	Injection Type	
Implant	Single stage	Heavy body	Injection Type	
	Monophase	Heavy body	Heavy body	

Overview of indications / impression techniques:

Contra-indications & Warnings

Swallowing

A minor risk under normal conditions in the dental office. The patient will first react by retching. When swallowed, the silicones impression materials 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

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.

Warnings:

In case the base/catalyst 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.

Combination products:

The SiliconA dispensing gun can be used in combination with:.

- Cavex SiliconA Heavy body
- Cavex SiliconA Injection

The SiliconA mixing Tip green (1:1) can be used in combination with

- Cavex SiliconA Heavy body
- Cavex SiliconA Bite

The SiliconA mixing Tip yellow (1:1) can be used in combination with

Cavex SiliconA Injection type

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Product characteristics and specifications

Requirements according to ISO 4823 for Dental silicone impression materials are listed together with the typical values for Cavex SiliconA:

Characteristic	Putty	HB	INJ	Bite	
Appearance	yellow	green	blue		
Mixing time	< 45				sec.
Total working time	1 ½	2	2	>2	min.
Time in mouth	31⁄2	31⁄2	31⁄2	1⁄2	min.
Total setting time	51/2	51/2	51⁄2		min.
Consistency	< 35	< 35	>36		mm
Detail reproduction	75	50	20		μm
Linear dimensional change	0,22	0,15	0,17		%
Gypsum compatibility	75	50	20		μm
Elastic recovery	99,7	99,7	99,6		%
Strain in compression	2,6	2,2	2,5		%
Hardness Shore D				40	

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.

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