Product Information On					
Cavex SiliconA Putty Cavex SiliconA Heavy Body Cavex SiliconA Injection Type Cavex SiliconA Bite					
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1. Introduction

Cavex SiliconA & Cavex SiliconA Bite

Cavex SiliconA impression material is composed of a kneadable yellow Soft Putty with a very high consistency, a heavy consistency green paste (Heavy Body), and a low consistency blue paste (Injection Type). The Cavex SiliconA is a variable consistency system that can be combined individually for the desirable impression techniques: either Single-step (Sandwich) or Two-step technique.

Cavex SiliconA can be combined with Cavex SiliconA Bite. This user-friendly bite registration material offers an high accuracy, combined with short processing and setting times.

Cavex SiliconA shows excellent hydrophilic properties, thus improving wettability and leading to better reproduction of subgingival areas. Pouring of the impressions can take place 60 minutes after the impression is removed from the mouth and all commercially available modelling stones can be used.

Cavex SiliconA & Cavex SiliconA Bite is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Cavex SiliconA & Cavex SiliconA Bite bears the CE marking of conformity.

2. Composition

The following materials are used in Cavex SiliconA & Cavex SiliconA Bite:

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

3. Manufacturing

The manufacturing of Cavex SiliconA & Cavex SiliconA Bite is the result of gradually mixing all raw materials into a homogeneous coloured substance. Quality controls ensure the good quality of Cavex SiliconA & Cavex SiliconA Bite after the manufacturing process.

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4. Laboratory control

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

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	

5. <u>Shelf-life test</u>

Cavex SiliconA & Cavex SiliconA Bite can be guaranteed for a period of 36 months (3 years), when kept in its original packaging, provided the product is unopened and stored in a cool and dry place.

After an impression is taken, the impressions are dimensionally stable for at least 7 days.

6. Quality Control

A batch of Cavex SiliconA or Cavex SiliconA Bite, that has passed all the tests, is released for sales. In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

7. <u>Statement of non-toxicity</u>

We hereby declare, that Cavex SiliconA & Cavex SiliconA Bite can be safely used and is non-toxic to the patient as well as to the dental team.

