

USER GUIDE VERTEX SOFTSIL 25

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Foreword

The following user guide contains instructions for dentists, dental prosthesisists and dental technicians for working Vertex SoftSil 25 into a flexible layer under a dental prosthesis base. Vertex SoftSil 25 is intended exclusively for professional dental work. Vertex SoftSil 25 is treated using conventional dental methods and instruments and special grinding instruments in the form of a grinding cap and grinding wheel. These grinding instruments are supplied separately by Vertex-Dental B.V. as a set and are available from dealers. A grinding cap and special polishing disc on a mandril are used for contour correction of Vertex SoftSil 25, available separately. The user guide indicates transferable instructions for the prosthesis wearer on cleaning the prosthesis.

1. Introduction

Vertex SoftSil 25 is a flexible lining material on a vinyl polysiloxane base. Vertex SoftSil 25 is applied to the jaw side of dental prostheses that are made of hard plastic on a polymethylmethacrylate base. Examples include flexible silicone linings under full or partial prostheses. Vertex SoftSil 25 can be applied under a dental prosthesis base directly (chairside) or indirectly (laboratory). The technical instructions we provide in this guide should be followed closely by the user. Deviations from these instructions, no matter how minor, may have a negative effect on the intended result and will not guarantee the quality of the result.

2. Description and effect

Vertex SoftSil 25 is a 2-component silicone material (polyaddition type) packaged in a cartridge with automix cannulae. When an automix cannula is applied to the cartridge and the cartridge is placed in a dosing handle, the system is ready for application. After the automix cannula has been passed, the silicone components are blended into a mixture that is homogeneous in terms of mix and colour. The mix of silicone components is self-polymerising. The bond between the hard plastic and the flexible silicones is created using a primer. After correction, the surface border between the hard plastic and the flexible silicones is finished with a 2-component soft varnish. Vertex SoftSil 25 has a Shore A hardness grade of 25. Vertex SoftSil 25 has polymerisation shrinkage of < 0.1 %. Vertex SoftSil 25 complies with ISO 10139-2 and is CE certified.

3. Contraindication

Allergic reactions in wearers to a flexible silicone lining under a dental prosthesis base are rare. Deviation from the indicated treatment has a negative effect on the chemical and physical quality of the silicone layer. Ask a doctor for a diagnosis in the event of an allergic reaction.

4. Storage conditions and use-by date

Store the packaging containing silicone components in a cool ($\leq 23^{\circ}\text{C}$) and dry environment. Close the packaging properly after each use. The silicone components have a use-by date indicated on the product label. After the use-by date, the silicone components are no longer guaranteed in terms of treatment.

5. Preparing hard plastic

Using the grinding cap, remove previously applied lining from the prosthesis. On the process / palate side, grind away a layer of hard plastic with a depth of 1 to 2 millimetres. On the labial, buccal and lingual sides, grind away a shoulder preparation with a height of 2 to 3 millimetres and a depth of 1 millimetre. Clean and degrease the prosthesis with pure alcohol and allow the prosthesis to dry. Brush the surface of the prosthesis that has been ground (roughed) with Vertex SoftSil 25 primer. Allow the primer to dry for 1 minute.

6. Preparing cartridge for use

Above all, make sure the prosthesis surface is prepared as in [point 5](#). Place the cartridge in the dosing handle. Remove the cap from the cartridge. Squeeze the dosing handle until both silicone components come out of the opening. Apply an automix cannula to the opening. Squeeze the handle to apply the required amount of silicone mix to the prepared prosthesis surface. Leave the automix cannula attached to the cartridge until the next use. Do not replace the cap – use the attached automix cannula after application as a cap on the cartridge. Place a new automix cannula on the cartridge for every next application.

7. Application - chairside method

Apply the silicone mix to the prepared prosthesis surface. Apply the silicone mix in a layer 2 mm thick. Make sure the total prepared prosthesis surface is covered with the silicone mix within a maximum of 1 minute (ambient temperature $\leq 23^{\circ}\text{C}$), then place the prosthesis in the wearer's mouth and close the jaw to occlusion. Then allow the wearer to make functional movements with the prosthesis in place for a maximum of 3½ minutes. The silicone mix polymerises in $\pm 5\frac{1}{2}$ minutes. After polymerisation, remove the prosthesis from the wearer's mouth

application time 1 minute max.	functional movement 3½ minutes max	polymerisation after $\pm 5\frac{1}{2}$ minutes
total processing time including application time is $\pm 5\frac{1}{2}$ minutes		

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8. Application - laboratory method

Remove surplus impression material and correct contours with wax where necessary. Make a plaster model under prosthesis with impression material. Secure the plaster model and prosthesis with plaster in a divisible pressing cuvette. Insulate plaster against plaster using alginate separation fluid (e.g. Vertex Divosep). During embedding (second phase), make sure the disassembled prosthesis can be removed and replaced in the plaster. Open the cuvette when the plaster has hardened and remove the prosthesis from the cuvette. Brush alginate separation fluid on the plaster surface in both halves of the cuvette. Remove the impression material from the prosthesis. Prepare the surface of the prosthesis as described in [point 5](#). Place the prepared prosthesis back in the plaster in the cuvette. Apply the silicone mix to the prepared prosthesis surface in a layer 1 mm thicker than the quantity of plastic ground away. Make sure the total prepared prosthesis surface is covered with the silicone mix in a maximum of 1 minute (ambient temperature $\leq 23^{\circ}\text{C}$). Close the cuvette and press it shut using light pressure. Leave the cuvette under pressure in the press for 30 minutes or place the cuvette in a cuvette brace for 10 minutes in a pressure vessel at a temperature of 40° - 45°C for polymerisation.

9. Finishing silicones

Remove major surplus silicone material with small scissors. Grind away minor surplus silicone material with the grinding cap to the desired contour. Grind the corrected silicone areas smooth with the special grinding wheel using light pressure and a speed of 10,000 – 15,000 rpm.

10. Varnishing transition area

Use the Vertex SoftSil 25 varnish for final finishing of the transition areas between the silicone lining and the hard plastic that have been ground smooth. Mix both varnish components in a 1 to 1 ratio. Mix 5 drops of varnish base with 5 drops of varnish catalyst into a homogeneous mixture. Brush the mixture onto the ground areas. The varnish mixture polymerises in 5 minutes. After polymerisation, the varnish layer is ready for use.

11. Trouble-shooting

Phenomenon	Possible cause	Solution
- loss of retention between silicone lining and hard plastic	- hard plastic retention surface is contaminated - primer applied incorrectly	- grind away enough hard plastic and clean retention surface sufficiently with alcohol before applying primer - improve primer application method
- silicone layer hardens after a period of wear	- prosthesis cleaned incorrectly - reaction to medication - reaction to abnormal saliva composition	- instruct wearer on correct prosthesis cleaning method - not indicated in terms of remedy - not indicated in terms of remedy
- discoloration of silicone lining	- discoloration resulting from food or stimulants	- instruct wearer on cleaning after meals

Defects in the silicone lining cannot be repaired. In the event of defects, replace the silicone lining completely, taking the above solutions into consideration. Production of raw material and product per batch may cause colour differences in the silicone lining.

12. Silicones and packaging waste

Silicone remnants and silicone packaging are not environmentally harmful. Deliver silicone remnants and packaging waste to a collection point for waste material.

Instructions for cleaning prosthesis

Instruct the prosthesis wearer directly or indirectly to clean the prosthesis twice a day with cold water, mild soap and a soft brush. If a prosthesis cleaner is used (preferably one with a natural base), instruct the wearer to follow the instructions for the cleaner closely. Discourage the use of hot water and unsuitable cleaners or methods as these will cause irreversible damage to the prosthesis.

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