

(Instruction For Use)

CE

Vertex™ ThermoSens Rigid

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Preface

The following instructions for use are for dental technicians who use Vertex™ ThermoSens Rigid as a dental prosthesis base. Vertex™ ThermoSens Rigid is intended exclusively for professional dental work and treated using conventional dental methods and instruments. This instruction for use provides also information about safety and environmental aspects, a safety datasheet is available on www.vertex-dental.com and at local dealers.

In case more information is needed about the processing of Vertex ThermoSens™ Rigid a film and pictures are available on the website. For extra training, the Vertex™ Academy provides a course to learn the technique and processing the product

1. Introduction

Vertex[™] ThermoSens is a thermoplastic material to be used for dental prothesis. The product is based on a compounded mixture of Polyamide and pigments. Because Vertex[™] ThermoSens is on a polyamide basis and to be used as a thermoplastic in the injection technique, the product is suitable for people allergic for residual monomer, since the product doesn't contain residual monomer.

Vertex™ ThermoSens Rigid is intended for removable full and partial dentures as wel as splints, telescope constructions and temporary crown and bridge constructions..

The technical instructions provided in this instruction for use should be followed. Any deviation may lead to a negative effect on the intended result and will not guarantee the quality of the end product.

2. Description and effects

The technique for Vertex™ ThermoSens Rigid is based on injection technique. The technique can be done with an automatic or manual injection machine. The preparations of the model and flask are according to the standard procedures of the dental technique.

The pigments and the vaines in Vertex™ ThermoSens Rigid are built in the raw material through the production process, this leads to an equal distribution of pigments and vaines in the denture.

3. Contra-indication

An allergic reaction of wearers to denture base material is rare. The amount of pigments and vaines in the denture base is reduced as much as possible. Any deviation from this instruction for use may have negative effect on the chemical and physical quality of Vertex[™] ThermoSens Rigid. In case of an allergic reaction, please contact a medical physician.



4. Hazard & Precauton (H & P phrases)

The product Vertex™ ThermoSens Rigid exists of polyamide and has got no identification requirements according Directive 67/548/EEG.

<u>Inhalation:</u> In case of visual irritation caused by inhalation of vapours during thermal processing of the product, supply fresh air and seek possible medical attention.

<u>Contact with skin:</u> Cool down melted material on skin with water. Do not remove the melted material. Skin burns need to be medical treated.

Contact with eyes: flush with plenty of water.

Contact with hands: with dust covered skin, need to be washed with water and soap. Dust of the material may extract moisture from skin. Frequently use skin protection crème.

Information about the handling of the product can be found in the safety datasheet, which is available on www.vertex-dental.com.

5. Storage conditions, expiry date and transport

Store the product in the original packaging at roomtemperature in a dry area.

Close the packaging after each use. The expiry date of the product is mentioned on the product label. In case of exceeding the expiry date, the product is no longer guaranteed in terms of treatment. Vertex™ ThermoSens Rigid can be freely transported.

6. Processing Vertex™ ThermoSens Rigid

Pretreatment synthetic teeth

Since there is no chemical bonding between synthetic teeth and VertexTM ThermoSens, a mechanical bonding must be obtained. Make a hole mesial to distal through the tooth, using a small cutter of 0.9-1.3 mm. Then a second hole must be made from the bottom of the tooth, ending in the first hole. This T-connection is the only bonding between the tooth and VertexTM ThermoSens Rigid. For more bonding, the downside of the tooth can be treated with VertexTM Teeth grinder.

Pretreatment flask

Always work on fresh plaster surfaces. Use at least class III or IV plaster for the model and for embedding the wax prosthesis in the flask.

Apply Sprue Wax Soft for injection sprues. Use Sprue wax soft 4.5mm for side sprues and 9.5mm for the main sprue.

When you use Vertex[™] putty 1:1, only apply on the bucal and labial side to protect your wax up. The use of putty can improve your work, because of the material properties. Do not apply occlusaal this can cause a bite increase. <u>Use putty with a shore hardness of at least 80!</u> Press the Vertex[™] Putty 1:1 firmly on to the denture make retention in the Vertex[™] Putty 1:1.

Insulate plaster from plaster with alginate separation fluid (e.g., VertexTM Divosep). Heat the flask in water at \pm 70°C for about 7 minutes. The modelling wax is then plastic enough and the flask can be opened. Take the base plate and modelling wax away immediately after opening the flask and rinse the plaster in the flask with clean boiling water to remove modelling wax remnants.

Before placing the cartridge in the injectionmachine, spray the cartridge with silicone spray. During the pre heating of the cartridge it is advised to heat flask. This can be done by placing the open flask for 15 minutes in a warm water bath of $\geq 90^{\circ}$ C. About 2 minutes prior to injection, remove the flask from the water bath. Dry the flask and treat the injectable surfaces with a separation fluid suitable for injection technique, e.g. VertexTM Thermoflow. Do <u>not</u> use an alginate separation fluid, this will burn during the injectionproces and may have negative effect on the endresult.

When using the Thermoject 22 machine, pre heating can be done on top of the machine. After removing the modelling wax and the base plate rinse the plaster in the flask with clean boiling water to remove modelling wax remnants.then dry the flask and treat the injectable surfaces with a separation fluid suitable for injection technique, e.g. VertexTM Thermoflow. Do <u>not</u> use an alginate separation fluid, this will burn during the injectionproces and may have negative effect on the endresult. Place flask on top of the machine, both cartridge and flask will now heat up. Machine will inject automatically after pre heating time has elapsed.



Processing times

The temperature, heating time and pressure depends on the type of injectionmachine used and the diameter of the cartridge.

It is recommend to calibrate the temperature inside the injectionmachine, using a thermocouple. In case the calibration shows a temperature difference between the display and the thermocouple, adjust the difference in temperature in the temperature setting.

It is highly recommended not to exceed a temperature of 310 Degrees Celsius.

For 22mm cartridges M and L handle a pre heating time of 18 minutes and a pressure of 6.5 bar at 290°C.

For 22mm cartridges XL handle a pre heating time of 20 minutes and a pressure of 6.5 bar at 290°C.

For 25 mm cartridges handle a pre-heating time of 18 minutes and a pressure of 8.5 bar at 270-280°C

There is no difference in heating time between M, L and XL size cartridges.

Injection

When the cartridge is placed in the injectionmachine, the cartridge is ready for injection after 18/20 minutes. After injection remove the flask from the machine.

For more information about the injection see the instructions for use of the Injection machine.

Cooling down

After the flask is removed from the injectionmachine, the flask must be bench cooled for at least 30 minutes. With this annealing proces, the shrinkage is reduced as much as possible. After the annealing proces the flask must be placed in cold water for 20 minutes. Accelerating this process may have negative effect on the endresult.

Finishing

.To finish the denture, use a cutter at low speed and low pressure. Use rubber disks for a pre polishing finish. To polish you can use a fine-grained pumice and Vertex high shine brushes. To shine first use polish paste and then Thermo Gloss Emulsion.

Warning: scratches made by coarse sandpaper or coarse pumice or other kind of materials, are very hard to remove.

To clean a ThermoSens denture do not use any chemical cleaning agents. Therefore Vertex Proclean is advised because it consist on natural ingredients only.

7. Error analysis

Phenomenon	Possible cause	Solution
- the product is not fully injected	- low injection temperature	- ensure correct injection temperature
	- not enough pressure	- ensure correct pressure
- Not fully injected clasps	- the clasps are modelled too thin	- model the clasps thicker
- bite raising	- too much Vertex™ Putty 1:1	- use less Vertex™ Putty 1:1,
	used.	make a thin layer of putty.
- Tooth becomes loose	- too small holes for T-joint	- use at least 0.10 cm cutter for the
		preparation of the T-joint
	- no T-joint	- prepare a T-joint in the tooth
	- wax residues in the T-joint	- clean the T-joint with boiling
		water



	- too low injection temperature	- ensure correct injection temperature
- plaster remnants on plastic	- thin edges are not rounded - defects in separation layer - wrong type of plaster is used	- remove thin edges - improve separation method use type 3 or 4 platser only
- Discoloration of product after injection	too high injection temperature too long pre-heating time of the cartridge	- ensure correct injection temperature - ensure correct pre-heating time
Material has become brittle after injection	too high injection temperatureincorrect annealingproces	- ensure correct injection temperature - ensure correct annealing proces
- Shrinkage	- too low Injection temperature	- ensure correct injection temperature
	- incorrect annealingproces	- ensure correct annealing proces
- Embedding plaster expands from flask	- wrong Class of gypsum used for embedding	- ensure use of at least Class III gypsum for embedding

Differences in colour nuance may occur due to production in batches of the raw material and product.

8. Plastic and packaging waste

The product Vertex™ ThermoSens and the cartridges are not environmentally harmful. Deliver plastic and packaging waste to a collection point for waste material.

9. Instructions for denture cleaning

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

10. Delivery units

The product Vertex™ ThermoSens Rigid is available in the following packaging sizes:

Cartridge 22 mm size l	M	Bulk 200 g
Cartridge 25 mm size l	M	Bulk 400 g
Cartridge 22 mm size I	_	Bulk 1000 g
Cartrdige 25 mm size I	_	Bulk 4000 g
Cartridge 22 mm sixe 2	XL	Bulk 20000 g
Cartridge 25 mm size 2	XL	
-		

Available shades:	TTR	T03
	TTRV	T05
	TS	T07
	TCL	T10
	TA2	TA3
	TBL	TCLV

Additional products: Vertex™ Thermo Twisted drills, available in 0.9 and 1.3 mm

Vertex[™] Thermo Flow Vertex[™] Thermo Gloss paste Vertex[™] Thermo Gloss emulsion Vertex[™] Thermo Silicone polisher

Vertex™ Thermo Sprue wax, available in 4.5 and 9.5 mm





Vertex™ Thermo Flask

Vertex™ ThermoSens Cartridge 22 mm size M empty

Vertex[™] ThermoSens Cartridge 25 mm size M empty Vertex[™] ThermoSens Cartridge 25 mm size L empty Vertex[™] ThermoSens Cartridge 25 mm size L empty Vertex[™] ThermoSens Cartridge 25 mm size XL empty Vertex[™] ThermoSens Cartridge 25 mm size XL empty

Manufacturer

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