Instruction For Use

CE

NextDent™ SG
(surgical guide)

Preface

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The following instructions for use are for dental technicians, dentists and oral surgeons who use NextDent™ SG as a dental surgical guide material. NextDent™ SG is intended exclusively for professional dental work. This instruction for use provides also information about safety and environmental aspects, a safety datasheet is available on www.nextdent.com and at local dealers. In case more information is needed about the processing of NextDent™ SG material contact the NextDent Office. Also see information at the end of this document.

1. Introduction

NextDent™ SG is a monomer based on Acrylic esters for manufacturing of 3D-printed surgical guides. Suitable for printing all types of surgical guides. NextDent™ SG is a class I material and CE-certified.

2. Description and effects

NextDent™ SG can be used in combination with all laser and DLP based 3D printers which support NextDent materials.

3. Contra-indication

NextDent™ SG should not be used for any other purpose than dental surgical guides only.
Any deviation from this instruction for use may have negative effect on the chemical and physical quality of NextDent™ SG In case of an allergic reaction, please contact a medical physician.

4. Hazard & Precaution (H & P phrases)

Inhalation:
Irritating to respiratory system. High atmospheric concentrations may lead to irritation of the respiratory tract, dizziness, headache and anesthetic effects.

Skin contact:
May cause sensitization by skin contact. Irritating to skin, repeated and/or prolonged contact may cause dermatitis.

Eye contact:
High vapor concentration may cause irritation.

Ingestion:
Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.

Protection:
Wear protection when handling NextDent™ SG Protective glasses and nitrile gloves are advised. Information about the handling of the product can be found in the safety datasheet, which is available on www.nextdent.com.

Hazard Phrases:	H317	May cause an allergic skin reaction
	H413	May cause long lasting harmful effect to aquatic life

5. Storage conditions, expiry date and transport

Store the product in the original packaging at room temperature in a dry and dark area, preferably not exceeding 25°C. 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.

6. Processing NextDent™ SG

We advise to use nitrille gloves when using NextDent™ SG until post-curing.
Before using NextDent™ SG, make sure to shake the product in the original packaging for approximately 5 minutes. Color deviations may occur when shaken insufficiently.

Make sure that you work as clean as possible, dirty reservoirs or machines can cause deformation and therefore failure of the printed objects!
Pour the liquid material in the reservoir of the 3D-printing machine. Start the machine. Follow the instructions for use for the printer. These are delivered together with the pinter. When the machine has finished its program remove the building platform from machine. Place the platform on some paper or cloth with the builded jobs facing upwards. The printed jobs can know be removed from the platform using a putty knife. Rinse the printed jobs twice in an alcohol solution (96%) to get rid of any excess material, making use of an ultrasonic bath. Rinse the first time for three minutes, second time for two minutes The second rinse must be carried out with a clean alcohol solution (96%). Rinsing in alcohol solution should not take longer than 5 minutes, as this will cause defects in the printed parts.
After cleaning make sure the printed part is dry and free of alcohol residu. Than place the printed jobs in a UV- light curing box for final polymerization. Time of curing depends strongly on type of lamps/ lightbox used. The final properties and also final color depend on the post curing process. Post-curing is an UV-light treatment to ensure that NextDent materials obtain full polymer conversion, through this the residual monomer is reduced to a minimum and the highest mechanical properties are obtained. This procedure is a necessary step to produce a biocompatible end-product. We strongly advice to make use of the Vertex™ LC-3*D*Print Box.

Specific curingtime NextDent™ SG

NextDent Material	Time min.	Wavelength nm	Total output Light Watt	UV lightbox output W*sec=J kJ
SG	10	Blue UV-A + UV-Blue 315-400 + 400-550 nm	UV-A 108 UV-Blue 108	129,6

The specifications of the NextDent materials are determined on the basis of test plates, produced on a DLP 405 3D printer. With the corresponding settings which are registered in the software. The unit used at NextDent has 4x 18W/71 lamps (Dulux L Blue) and 4x 18W/78 lamps (Dulux blue UV-A). The calculated output is based on the UV light UVA lamp Blue. Please notice that the light sources and the printing machine need a routine maintenance following the manufacturer instructions

7. Finishing

Remove any support structures and finish jobs if necessary, using conventional dental methods and instruments. Differences in color nuance may occur due to production in batches of the raw material and product or inadequate shacking of the original packaging before use.

8. Plastic and packaging waste

The product NextDent™ SG in its polymerized form is not environmentally harmful. Residual waste material in its liquid state should be delivered to a collection point for waste material.

9. Instructions for cleaning and disinfecting

NextDent 3D-printing material should be cleaned with non chemical products. If disinfecting before intended use is required, an ethanol solution can be used. NextDent™ SG can be sterilized by making use of an autoclave or using gamma-ray sterilisation. Please make sure that the Surgical Guide is fully post-cured before sterilisation! This is important with regard to form stability. For post-curing procedure please see § 6 Processing NextDent™ SG.

10. Delivery units

The product NextDent™ SG is available in the following packaging size: 1000 gr.

Explanation of symbols on labelling

CE	**:** CE mark		: Keep away from sunlight
LOT	: Batch number of product		: Consult instructions for use
	: Manufacturer		: Use-by date

Distributor

NextDent B.V. Centurionbaan 190 3769 AV Soesterberg The Netherlands	Telefoon E-mail Website	: +31 88 616 04 40 : info@nextdent.com : www.nextdent.com

Manufacturer

Vertex-Dental B.V. Centurionbaan 190 3769 AV Soesterberg The Netherlands	Telefoon E-mail Website	: +31 88 616 04 40 : info@vertex-dental.com : www.vertex-dental.com