For more information, please contact:

Distributor

NextDent B.V. Centurionbaan 190 3769 AV Soesterberg The Netherlands

+31 88 616 04 40 info@nextdent.com www.nextdent.com

Manufacturer

Vertex-Dental B.V. Centurionbaan 190 3769 AV Soesterberg The Netherlands

+31 88 616 04 40 info@vertex-dental.com www.vertex-dental.com



www.nextdent.com

NextDent, the leading manufacturer of dental materials for 3D printing.

NextDent B.V. is an independent subsidiary company under the Vertex Global Holding. NextDent's mission is to become the worldwide leading manufacturer of CE-certified and biocompatible dental 3D printing materials. NextDent's Research and Development team is constantly searching for the best possible solutions in order to become a benchmark for 3D printing materials in the dental field. The company's focus is on development of custom-made 3D printing solutions in close cooperation with our customers.

© 2016 Vertex-Dental B.V. All Rights Reserved

NextDent" is a registered trademark of Vertex-Dental B.V. used under a temporary license granted by NextDent B.V. Neither. NextDent B.V. nor any of its affiliates is responsible for the manufacturing of the product(s).

ORTHO CLEAR

Monomer based on acrylic esters for manufacturing of 3D-printed dental appliances such as splints and retainers





Leading manufacturer of dental materials for 3D printing

Instruction For Use Ortho Clear

NextDent[™] Ortho Clear is a monomer based on acrylic esters for manufacturing of 3D-printed dental appliances such as splints and retainers. NextDent[™] Ortho Clear is Class Ila CE-certified.

The following instructions for use are for dental professionals who use NextDent™ Ortho Clear as a dental splint material. NextDent™ Ortho Clear 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™ Ortho Clear material contact the NextDent office. Also see information at the end of this document

NextDent[™] Ortho Clear is a monomer based on acrylic esters for manufacturing of 3D-printed dental appliances such as splints and retainers for permanent use (> 30 days). NextDent[™] Ortho Clear is Class IIa CE-certified.

Page 4 of 4 Page 1 of 4

Description and effects

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

Contra-indication

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

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.

Eve 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[™] products. Protective glasses and 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:

Pictogram





Signal word Warning

Hazard statements

H315 Causes skin irritation

H317 May cause an allergic skin reaction

H319 Cause serious eye irritation

H411 Toxic to aquatic life with long-lasting effects

Processing / Post-curing

Make sure that you work as clean as possible, dirty reservoirs or machines can cause deformation and therefore failure of the printed objects!



Shake for 5 minutes before use

Before using NextDent™ Ortho Clear, make sure to mix the product in the original packaging for 5 minutes. Color deviations and print failures may occur when shaken insufficiently.



Fill printerreservoir

Pour the liquid material in the reservoir of the 3D-printing machine.



For printer settings see IFU of 3D Printer

Follow the instructions for use of the printer. These are delivered together with the pinter.



Remove printed parts from platform

When the machine has finished its program remove the building platform from the machine. Place the platform on some paper or cloth with the built jobs facing upwards. The printed jobs can know be removed from the platform using a suitable knife.



Cleaning Pieces step 1

Rinse the printed jobs for three minutes in an alcohol solution (>90%) to eliminate any excess material, using of an ultrasonic bath.



Cleaning Pieces step 2

Rinse for two minutes in a clean alcohol solution (>90%).

Rinsing in a alcohol solution should not take longer than 5 minutes, as this may cause defects in the printed parts.



Post-Cure

After cleaning make sure the printed parts are dry and free of alcohol residual. Then place the printed jobs in a UV- light curing box for final polymerization.

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 required mechanical properties are obtained. This procedure is a necessary step to produce a biocompatible end-product. We strongly advice to make use of the NextDent™ LC 3D Printbox.

Specific curing-time NextDent™ Ortho Clear

NextDent Material	Time (min.)	Wavelength (nm.)	Total output Light (Watt)	UV lightbox output W*Sek=J (kJ)
Ortho Clear	10	Blue UV-A 315-400 UV-Blue 400-550	UV-A 72 UV-Blue 72	129,6

The unit used at NextDent has 6x 18W/71 lamps (Dulux L Blue) and 6, 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.

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.

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. Do not expose to UV-light and moisture.

Plastic and packaging waste

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

Cleaning instructions

NextDent[™] 3D-printing material should be cleaned with nonchemical products. If disinfecting before intended use is required, an ethanol solution can be used.

Delivery units

The product NextDent™ Ortho Clear is available in the following packaging sizes: 1000 gr.

Explanation of symbols on labelling



CE mark with NB number



Batch number of product



Manufacturer



Keep away from sunlight



Consult instructions for use



Use-by date

Page 2 of 4 Page 3 of 4