

NextDent

by 3D SYSTEMS

Ortho Flex

US 3D Print resin for the manufacturing of dental splints and retainers

US Instruction For Use

Introduction

The following instructions for use are for dental professionals who use NextDent Ortho Flex as a material for dental splints and retainers. NextDent Ortho Flex is intended exclusively for professional dental work. This instruction for use also provides information about safety and environmental aspects. In case more information is needed contact the reseller.

Intended use

NextDent Ortho Flex is a 3D print resin intended for the manufacturing of 3D printed dental splints and retainers. To retain the regulated dentition.

NextDent Ortho Flex is intended exclusively for professional dental work.

Description & Effects

Fabrication of splints and retainers with NextDent Ortho Flex requires a computer-aided and manufacturing (CAD/CAM) system that includes the following additive printer and post-cure unit:

Printing			
Printer	Brand	Type	Software
	3D Systems	NextDent 5100 Figure 4	3D Sprint

Post-Curing			
Post-cure unit	Brand	Type	Software
	NextDent	LC-3DPrint Box	n.a.

Printer and resin must be optimized to each other in order to get complete and precise printed parts. Differences in color nuance may occur due to:

- production in batches;
- inadequate shaking and mixing of the original packaging before use;
- inadequate stirring in the resin tray before use;
- insufficient post-curing;

Contra-indications

NextDent Ortho Flex should not be used for any other purpose than as a 3D print resin for the manufacturing of dental splints and retainers. Any deviation from this instruction for use may have an adverse effect on the chemical and physical quality of NextDent Ortho Flex. In case of an allergic reaction, please contact a medical physician.

Hazard & Precautions



Danger

Hazardous ingredients

2-phenoxyethyl acrylate;
4-(1-oxo-2-propenyl)-morpholine;
methacrylate ester monomer;
diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide; acrylate ester

Hazard statements

H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H361 - Suspected of damaging fertility or the unborn child. H373 - May cause damage to organs through prolonged or repeated exposure. H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements

P201 - Obtain special instructions before use. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P305+P351+P338 +P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. P321 - Specific treatment (see supplemental first aid instruction on this label). P391 - Collect spillage.

Processing & Post-Curing

Make sure that you work as clean as possible, dirty reservoirs or equipment can cause deformation and therefore failure of the printed objects! It is advised to use nitrile gloves when handling the NextDent resins up until the Finishing step.

Thoroughly mix before using



Mix the product for at least 5 minutes prior to use. We advise to use the NextDent LC-3DMixer. Print failures may occur when shaken insufficiently.

Fill printer reservoir



Make sure the temperature of the resin is between 18 and 28 °C / 64 and 82 °F and prevent exposure to (sun)light. Pour the resin in the reservoir of the 3D printer. If the product is stored in a closed resin tray garage, make sure to stir the resin before each subsequent use. Do not mix different batches of the same product.

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Angulation



When printing a part with NextDent Ortho Flex, make sure you use an angulation between 80° and 90° in relation to the platform.

For printer settings see manual of 3D Printer



Follow the instructions for use of the 3D printer user guide NextDent 5100.

Remove printed parts from platform



When the 3D printer has finished its program remove the building platform from the machine. Do not leave the printed parts in the printer overnight. Place the platform on some paper or cloth. Do not remove the supports of the printed part at this stage. The printed parts can now be removed from the platform using a suitable tool, without taking off the supports. Post processing of the printed parts needs to be executed as soon as possible.

Cleaning printed parts - Step 1



Clean the printed parts for three minutes in ethanol (>90%) to remove any excess resin, using an ultrasonic bath or comparable wash-system.

Cleaning printed parts - Step 2



Clean the printed parts, still with supports, for another two minutes in clean ethanol (>90%). The total cleaning time in ethanol should not take longer than 5 minutes, as this may cause defects in the printed parts.

Post-Curing



After cleaning and drying, let the printed parts rest for at least 10 minutes to make sure that the printed parts are free of ethanol residue. Then place the printed parts, still with supports, in a UV-light curing box for final polymerization. This procedure is a necessary step to produce a biocompatible end product. Make use of the NextDent LC-3DPrint Box. To obtain color/color stable cured parts use the prescribed curing time mentioned in the table below. Let the parts cool to room temperature before handling.

Finishing

Remove any support structures and finish cured parts if necessary. Finish the cured parts using conventional dental methods and instruments. NextDent 3D printed cured parts should be cleaned with nonchemical products.

Storage conditions, expiry date and transport

Store the resin in the original packaging or in a closed resin tray garage, preferably at room temperature in a dry and dark 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. Do not expose to UV-light. Standard transport conditions apply to this product. There are restrictions for transport related to hazardous substances (UN3082), see SDS for special transport requirements.

Waste disposal

NextDent resins in its polymerized form are not environmentally harmful. NextDent resins in its liquid state should be treated as chemical waste. Special disposal requirements are applicable, check by your local, federal, or other regulatory agencies for disposal requirements.

The following information should be transferred from dental professional to patient:

- Periodic check-ups by a dentist or orthodontist are required to monitor changes in the position and structure of the dentition of the patient that uses a splint or retainer.
- In case of breakage of a NextDent Ortho Flex device, potentially damage the mucosa, the palate or other parts of the patients mouth or esophagus can occur. Contact a dentist or orthodontist.
- In case of an allergic reaction, contact a medical physician.
- NextDent Ortho Flex devices can be cleaned with non-aggressive and non-abrasive dental cleaning products.

Delivery units

NextDent Ortho Flex is available in one color.
1 kg

If you choose not to follow this Instruction for Use, Vertex Dental cannot be held accountable for adverse effects on the biological, chemical and physical quality of device printed with NextDent Ortho Flex.

Specific curing time for NextDent LC-3DPrint Box

NextDent Material	Curing time	Curing temperature
Ortho Flex	30 minutes	min. 60°C / 140 °F

Please notice that the UV-light box and the 3D printer need a routine maintenance following the manufacturer instructions. The optimal polymerization is achieved with a preheating period of 15 minutes.

Light output & Wavelength
108 Watt UV-A (315-400 nm) 108 Watt UV-Blue (400-550 nm)

UV lightbox temperature range	UV lightbox irradiance output
60-80°C / 140 - 176°F after 15 minutes of use	5 mWatt / cm ²

Explanation of symbols on labelling



US Batch number of product



US Consult instructions for use



US Manufacturer



US Use-by date



US Keep away from sunlight



US Caution: Federal law restricts this device to sale by or on the order of dentist