

# Base

US For manufacturing of full or partial removable denture bases

## US Instruction For Use

### Intended use

NextDent Base is for dental professional use only and intended for the manufacturing of denture bases to support artificial teeth to form full or partial removable dentures.

### Description & Effects

The product is an acrylic resin system, polymerized via a photo initiator in a 3D printer setting. The product must be used in combination with VAT based 3D printers that support NextDent resins. Printer and resin must be optimized to each other in order to get complete and precise printed parts. Fit of the parts strongly depends on design and library used. Please take features like undercuts and spacers in consideration when designing the parts.

### 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.

### Performance characteristics

The product is compliant with the relevant performance requirements defined in ISO 20795-1. The product is indicated for (partially) edentulous patients that have been indicated, upon professional user's decision, for placing removable dentures.

### Contra-indications

The product is contra-indicated for persons allergic to acrylics or acrylic derivatives.

### Warnings

- Do not use when the package is damaged.
- If visible gelation and polymerization of the resin in the 3D printer reservoir occurs, discard the print resin material and clean out.
- Remaining resin in the 3D printer reservoir must not be poured back into the bottle.
- 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 garage before use
- insufficient post-curing
- If printer and resin are not optimized to each other this may have an adverse effect on the accuracy and physical quality of printed parts.
- Wear UV protective glasses when operating the 3D printer and/or lightbox.
- Use nitrile gloves when handling the NextDent resins up until the Finishing step.
- Any deviation from this instruction for use may have an adverse effect on the quality of the product.
- Vertex Dental is not responsible for any adverse effects, safety or performance issues when not following the manufacturer's instructions for use.
- Use the product before its use-by date.

### Hazard & Precautions



### Warning Contains

Methacrylate ester monomer; (octahydro-4,7-methano-1H-indenediyl)bis(methylene) diacrylate; 3,3,5-trimethylcyclohexyl methacrylate; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

### Hazard statements

H315 - Causes skin irritation.  
H317 - May cause an allergic skin reaction.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.  
H411 - Toxic to aquatic life with long lasting effects.

### Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
P280 - Wear protective gloves, eye protection, face protection.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P273 - Avoid release to the environment.

Safety Data Sheet is supplied on request.

### 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!

### Shaking



Shake the bottle prior to use to obtain a uniform color.

### Fill printer reservoir



Resin temperature must be between 18 and 28 °C / 64 and 82 °F. Prevent exposure to (sun)light. Pour resin in 3D printer reservoir. If resin is stored in closed resin tray garage, stir resin before each subsequent use. Do not mix different batches of the same resin. Do not pour resin back into the bottle.

### For printer settings see manual of 3D Printer



Follow 3D printer instructions for use (e.g. user guide NextDent 5100).

### Remove printed parts from platform



When 3D printer program has finished, remove building platform from machine. Place platform on paper or cloth. Remove printed parts from platform with suitable tool. Do not remove supports of printed parts at this stage.

### Cleaning printed parts - Step 1



Clean printed parts for 3 min. in ethanol (>90%) or isopropyl alcohol (>90%) to remove any excess resin using an ultrasonic bath, NextDent Wash or comparable wash-system.

### Cleaning printed parts - Step 2



Clean for another 2 min. in clean ethanol (>90%) or isopropyl alcohol (>90%). Total cleaning time in ethanol must not take longer than 5 min. This may cause defects in printed parts.

### Post-Curing



After cleaning and drying, printed parts must rest for 10 min. to ensure parts are free of ethanol residue. Place printed parts in UV-light curing box for final polymerization (e.g. NextDent LC-3DPrint Box). Post-curing is an UV-light treatment to ensure NextDent printed parts obtain optimal polymer conversion; residual monomer is reduced to a minimum and required mechanical properties are obtained. This procedure is necessary to produce biocompatible end product. To obtain color/color stable cured parts, use prescribed curing time in table below.

### Specific curing time for NextDent LC-3DPrint Box

Preheat LC-3DPrintbox
15 min.
Curing time
45 min.
Curing temperature
≥ 60 °C / ≥ 140 °F
Light output & Wavelength
108 Watt UV-A (315-400 nm) 108 Watt UV-Blue (400-550 nm)
Lightbox irradiance
5 mWatt/cm <sup>2</sup>

### Bonding of teeth

Bonding of artificial acrylic teeth to the printed part is possible, see methods and table below for different types of teeth. Apply a little drop of the bonding agent in the pocket before placing the teeth in the pockets. It is advised to roughen the prefab and milled acrylic teeth before luting.

- Method A: Apply the artificial teeth before the post-curing process.
- Method B: Apply the artificial teeth after the post-curing process and polymerize the bonding agent according to the instructions for use of the product.

### Bonding table

Type of teeth	Pre-fab acrylic teeth	Milled teeth (PMMA)	3D printed artificial teeth
Bonding agent			
NextDent Base	N/A	N/A	Method A
2 component self-curing acrylic resin	Method B	Method B	N/A

### Finishing

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

### Storage and transport conditions

Close the packaging properly after each use. Store the resin in the original packaging or in a closed resin tray garage, at room temperature in a dark area. Do not expose to UV-light. Standard transport conditions apply to this product. There are no restrictions for transport related to hazardous substances.

### 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.

### Information for dental professionals to patients

- Do not use when you have a known allergy for acrylics or acrylic derivatives.
- In case of an allergic reaction, do not use the resin or the device. Contact a medical physician
- Patients using the device should have periodic check-ups by a dental professional.
- When the device breaks this can potentially damage the mucosa, the palate or other parts of the patients mouth or esophagus. Do not use a broken device. Contact a dental professional.
- Clean the device with non-aggressive and non-abrasive dental cleaning products.
- Should any serious incident or injury with the patient occur, report this to Vertex-Dental and competent authority.

For more information contact the reseller.

### Explanation of symbols on labelling

**LOT**

EN Batch code



EN Manufacturer



EN Keep away from sunlight

**UDI**

EN Unique device identifier

**REF**

EN Catalogue number



EN Consult instructions for use



EN Use-by date



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



EN Do not use if package is damaged and consult instructions for use