Instruction For Use

NextDent™ Gingiva Mask.

Preface

1. Introduction
2. Description/ indication
3. Contra-indication
4. Hazard and Precaution (H&P phrases)
5. Storage conditions, expiry date and transport
6. Processing
7. Finishing
8. Error analysis
9. Plastic and packaging waste
10. Cleaning instructions
11. Delivery units
   Explanation of symbols on labelling
   Distributor
   Manufacturer

Preface

The following instructions for use are for dentists, orthodontists and dental technicians who use NextDent™ Gingiva Mask. NextDent™ Gingiva Mask 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™ Gingiva Mask material contact the NextDent Office. See also information at the end of this document.

1. Introduction

NextDent™ Gingiva Mask is a monomer based on Acrylic esters for manufacturing of 3D-printed gingiva masks. Suitable for printing all types of gingiva masks. NextDent™ Gingiva Mask is a non-medical product used only for manufacturing flexible parts on 3D printed dental models.

2. Description and effects

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

3. Contra-indication

NextDent™ Gingiva Mask should not be used for any other purpose than for dental work only. Any deviation from this instruction for use may have negative effect on the chemical and physical quality of NextDent™ Gingiva Mask. 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™ Gingiva Mask. 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:
- H315 Causes skin irritation
- H317 May cause an allergic skin reaction
- H319 Cause serious eye irritation
- H401 May cause long lasting harmful effect to aquatic life
- H411 Toxic to aquatic life with long lasting effects

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™ Gingiva Mask

We advise to use nitrile gloves when using NextDent™ Gingiva Mask until post-curing. Before using NextDent™ Gingiva Mask, make sure to shake the product in the original packaging for approximately 5 minutes.

**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 printer. When the machine has finished its program remove the building platform from the machine. Place the platform on some paper or cloth with the builded jobs facing upwards. The printed jobs can now 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 part.

After cleaning, dry the parts and 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 depend on the post curing process. We strongly advice to make use of the Vertex-Dental™ LC 3Dprint Box.
If the print jobs are still sticky after the curing process, repeat the second rinse step in alcohol solution (96%).

**Specific curing time NextDent™ Gingiva Mask**

<table>
<thead>
<tr>
<th>NextDent Material</th>
<th>Time min.</th>
<th>Wavelength nm</th>
<th>Total output UV-A light Watt</th>
<th>UV lightbox output W*sec=J kJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingiva Mask</td>
<td>10</td>
<td>Blue UV-A + UV-Blue 315-400 + 400-550 nm</td>
<td>UV-A 108 UV-Blue 108</td>
<td>129,6</td>
</tr>
</tbody>
</table>

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. Please note 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 shaking of the original packaging before use.

8. **Plastic and packaging waste**

The product NextDent™ Gingiva Mask 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. **Cleaning instructions**

NextDent 3D-printing material should be cleaned with non chemical products.

10. **Delivery units**

The product NextDent™ Indirect Bonding Tray is available in the following packaging size: 1000 gr.

**Explanation of symbols on labelling**

- ☀: Keep away from sunlight
- LOT: Batch number of product
- 📚: Consult instructions for use
- 🍀: Manufacturer
- ⌚: Use-by date
### Distributor

<table>
<thead>
<tr>
<th>NextDent B.V.</th>
<th>Telefoon</th>
<th>: +31 88 616 04 40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centurionbaan 190</td>
<td>E-mail</td>
<td><a href="mailto:info@nextdent.com">info@nextdent.com</a></td>
</tr>
<tr>
<td>3769 AV Soesterberg</td>
<td>Website</td>
<td><a href="http://www.nextdent.com">www.nextdent.com</a></td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Manufacturer

<table>
<thead>
<tr>
<th>Vertex-Dental B.V.</th>
<th>Telefoon</th>
<th>: +31 88 616 04 40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centurionbaan 190</td>
<td>E-mail</td>
<td><a href="mailto:info@vertex-dental.com">info@vertex-dental.com</a></td>
</tr>
<tr>
<td>3769 AV Soesterberg</td>
<td>Website</td>
<td><a href="http://www.vertex-dental.com">www.vertex-dental.com</a></td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>