RAYSHAPE NightGuard Soft

Instructions For Use

This product should be used for its intended purpose as directed in the instructions for use. Please read this manual carefully before use.

Intended Use

RAYSHAPE NightGuard Soft is a liquid photopolymer resin - intended for the fabrication of orthodontic and dental products such as mouthguards, nightguards, splints, retainers and bleaching trays.

Intended Users

Dental products produced by 3D printing are intended to be fabricated by trained dental technicians or qualified specialist staff in a dental laboratory. The finished products may be used exclusively by trained specialists within the specified area of application.

Contraindications

1. Contraindicated in individuals allergic to acrylates or related components.
2. Direct intraoral contact with uncured or partially uncured resin is prohibited.

Model Specifications

The corresponding relationships of different specifications and models are listed below.

Product Name	Model	Shade	Net Content
NightGuard Resin	NightGuard Soft	Translucent	1 kg/bottle

Device Description

For use in DLP/LCD 3D printers with 405 nm wavelength.

Warning and Precautions

1. Cleaning with solvent or grinding the resin shall be performed in a well-ventilated area using appropriate protective equipment.
2. Shade variations may occur if the resin is not properly shaken or mixed in the original packaging before use, if the resin in the tank is not adequately stirred prior to printing, or if incorrect post-curing procedure is used.
3. Material Reuse: The remaining resin in the resin tank can be reused. You may use a filter to ensure the resin is free from any cured particles to avoid print failures. The remaining material in the tank can be poured back into the resin bottle upon filtration. This process can be repeated until the material in the bottle is fully consumed. Please note that in the case of reuse, the resin must be filtered and poured back into the same bottle.
4. It shall not be used for any purpose other than its intended indications for use.
5. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Storage

1. Store in a cool, dry place and away from light.

2. The container shall be kept tightly closed at all times and shall be carefully closed immediately after each use.

Fabrication of Device

The resin has been validated according to the recommended workflow. Instructions for use shall be followed, as failure to do so may compromise safety and performance.

Any deviation from these instructions may negatively impact the physical and/or chemical properties of the resin and the biocompatibility of the printed products.

1. Designing

1.1 Create the object (STL data set) using commercial CAD software intended for dental applications.

2. CAM

2.1 It is recommended to prioritize positioning the model at a 45-degree incline. If inclined printing is not feasible, position it vertically and set the Z compensation value to 0.3 mm.

2.2 Minimum wall thickness for the design is 1 mm.

2.3 It is recommended not to merge supports for printing.

3. Before printing

3.1 Clean the printer's build plate and vat.

3.2 Ensure that the resin is tempered to ambient temperature (20-25℃) prior to print.

3.3 Pour the resin into the resin vat to at least the minimum fill line.

3.4 Remove bubbles with a clean spatula if present.

4. 3D Printing

5. Remove printed parts from the build plate

6. Washing and Drying

6.1 Use ethanol (95% or higher) or isopropyl alcohol, clean with an ultrasonic cleaner for ≤60s. At least two cleaning cycles are necessary, and the last wash should always use clean alcohol or IPA. Dry the part completely before post-curing.

7. Post-curing

7.1 Place the part in a post-curing machine, make sure to place the part flat without stacking.

7.2 RAYSHAPE NightGuard Soft is compatible in post-curing machine with UV wavelength of 405 nm.

7.3 Allow part to cool completely before removing from the post-curing machine.

8. Reclaiming

8.1 Make sure to reclaim resin after filtering with a mesh screen with pore sizing <200 microns.

Disposal Considerations

1. RAYSHAPE NightGuard Soft is not an environmental hazard in its final, fully cured state.

2. Dispose of contents and containers in accordance with applicable local, regional, national, and international regulations and in compliance with the safety data sheet.

Symbol Guide

The below table provides reference for symbols that may appear on the resin bottle label.

	Consult Electronic Instructions For Use		Keep Away From Sunlight
	Keep Dry		Use-by Date
	Batch Code		Date Of Manufacture
	Warning		Fragile, Handle With Care
	Caution		Manufacture
	CE Marking		Recyclable Corrugated Cardboard
	Stacking Limit By 4		Recyclable Claim
	This Way Up		Handle With Care



HAZARDS: Direct contact with the skin, may cause skin irritation or allergic reaction. If in the eyes, the product may cause serious eye irritation. If inhaled, the product may cause respiratory irritation, allergy, asthma symptoms, or breathing difficulties in case of long-term exposure.

Manufacturer

Name: SUZHOU LAIXIN 3D TECHNOLOGY CO., LTD.

Address: Building 1, No.9 Suhong West Road, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Pilot Free Trade Zone, Suzhou, Jiangsu 215000, China.

E-mail: info@rayshape3d.com

Web: www.rayshape3d.com

EC REP

TransMed Global Consulting, S.L.
Avenida Pablo VI 9, 3, 1B, 28224, Madrid, Spain (“TransMed”).