RAYSHAPE

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# RAYSHAPE Surgical Guide Resin

## 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 Surgical Guide Resin is a liquid photopolymer resin intended for the fabrication of surgical guides. This material is an alternative to traditional surgical guide material.

## 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 |
|---|---|---|---|
| Surgical Guide Resin | SG V2 | 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 place it horizontally, with the mating surface facing away from the platform.

3. Before printing

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

3.2 Shake the resin bottle thoroughly for at least 1 minute, then pour the resin into the resin vat to at least the minimum fill line.

3.3 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 Surgical Guide Resin is compatible in post-curing machine with UV wavelength of 405nm.

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 Surgical Guide Resin 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

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EC REP

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