SGR-28

Resin for stereolithography 3D printing

EN Instructions for use

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Symbols and manufacturer information

CE	European Conformity		Consult electronic instructions for use
	Use by date		Keep away from sunlight
LOT	Batch code	REF	Catalog number
	Manufacturer		Temperature limit
MD	Medical device	UDI	Unique device identifier
	Warning: read MSDS		Caution
	Environmental hazard		

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CE MD

Before using SGR-28 3D printing resin, please familiarize yourself with these Instructions For Use (further - IFU) and following accompanying documentation:

1. Application guide for printing and post-processing requirements to ensure the correct and safe usage of SGR-28 material. Find the application guide for this material at https://ameralabs.com/application-guide/sgr-28-application-guide/.
2. Material Safety Data Sheet (further – MSDS) for detailed safety and environmental information is available at https://ameralabs.com/msds/.
3. Technical Data Sheet (further – TDS) for full details regarding mechanical properties is available at https://ameralabs.com/docs/datasheets/SGR-28-TDS.pdf

Any deviation from this instruction or accompanying documentation may have an adverse effect on the chemical and physical quality and safety of the final product.

1 INTRODUCTION AND INDICATIONS FOR USE

Introduction

The following IFU are for dental professionals who use SGR-28 material for the fabrication of custom dental appliances. This instruction also provides information about safety and environmental aspects.

Intended purpose

SGR-28 resin is a light-curable polymer-based resin designed for the fabrication of biocompatible, short-term use, removable dental appliances by 3D printing. It is intended for 3D printing dental accessories such as dental surgical guides.

Indications for use

SGR-28 is a photopolymer resin indicated for 3D printing biocompatible dental surgical guides to aid in implant placement surgeries. 3D printed surgical guides allows the accurate transfer of the pre-operative digital surgical plan into a physical guide, supporting precise positioning of instruments or implants during the surgical procedure.

Contraindications

SGR-28 material should not be used with a known allergy or hypersensitivity history to photopolymer resins. In case of an allergic reaction, stop immediately and consult a doctor.

Device manufactured using SGR-28 3D printing resin should not be left in contact with patient tissues for more than 24 hours (cumulative).

SGR-28 should not be used for any other purpose than defined in Intended purpose.

Intended patient population

All patients and populations in which a clinician has prescribed a treatment associated with the intended purpose, except the ones with a known allergy or hypersensitivity history to photopolymer resins.

Intended users

The product is intended for use exclusively by dental professionals such as dentists, dental technicians, and prosthodontists, who produce dental appliances.

Clinical benefit

The use of dental appliances, such as a surgical guides, improves accuracy (assists user to place or direct surgical dental implants into the bone with increased accuracy and precision) and reduces operative time.

2 SAFETY

Material associated warnings

SGR-28 in its uncured state contains monomers that polymerize during 3D printing. Please read MSDS of SGR-28 material which is available at https://ameralabs.com/msds/ for hazards associated with liquid material.

The uncured liquid resin is not safe for contact with food, drinks, or the human body. In its liquid, uncured state, this resin is a hazardous chemical. Use protective gloves and glasses at all times when handling it. Provide adequate ventilation. Store resin away from direct sunlight. Resins are classified as dangerous chemicals and must be disposed of properly in designated containers. Resin bottles, empty or full, must never be disposed of or poured into general waste.

Material packaging associated precautions

Please inspect the material package (bottle) before using. Do not use the resin if package is damaged in any way.

Material use associated precautions

Nitrile gloves together with protective eyewear must be worn at all times when handling uncured resin. For more information regarding correct handling of SGR-28 material, please refer to MSDS available at https://ameralabs.com/msds/.

Apart from a patient, there are residual risks to environment like damage to aquatic life. Please follow disposal instructions carefully.

Users (e.g. dental technicians) should never underestimate safety importance. So please follow recommended usage and safety instructions to avoid hazardous situations and harm that could be caused by residual risks of eye damage, dermatitis, respiratory irritation, allergic skin reaction, damage to internal organs, sensitization. If you have any concerns or additional information is required, please contact manufacturer.

Information for patient safety

- Clinician before use of the product should ask patient of any known allergy or sensitivity to photopolymer resins. SGR-28 material should not be used for patients with a known allergy or hypersensitivity history to photopolymer resins, especially acrylate and methacrylate based materials.
- In case of an allergic reaction, stop use immediately and consult a doctor immediately.
- Do not use 3D printed appliances if they are damaged, deformed or with visible cracks.

- If there are signs of incorrect manufacturing and/or post-processing procedure like residue of liquid material, cleaning agents etc. the appliance should be remade to avoid potential injury.

If signs of extreme wear, deterioration, and/or perforations appear, the appliances should be replaced to avoid material failure and/or potential bodily injury.

3 PERFORMANCE AND CHARACTERISTICS

For full details regarding mechanical properties, please refer to TDS which is available at https://ameralabs.com/docs/datasheets/SGR-28-TDS.pdf SGR-28 material has been tested in accordance with ISO 10993-1 and meets applicable biocompatibility requirements.

4 SPECIFIC MANUFACTURING CONSIDERATIONS

Please refer to Application guide available at https://ameralabs.com/application-guide/sgr-28-application-guide/ before working with SGR-28 3D printing material. Scan the following QR code to access usage guidelines.

Thorough understanding of this procedure is critical to ensure the correct and safe usage of this 3D printing resin.

Hardware: please refer to Application guide.

Software: please refer to Application guide.

Object positioning, thickness and orientation: please refer to Application guide.

3D printing settings: please refer to our 3D printing settings.

Recommended post-curing and processing equipment: please refer to Application guide.

Use environment: Maintaining optimal environmental conditions is essential for successful 3D printing with photopolymer resins, particularly in dental applications where precision and material properties are crucial. Here are the key considerations for creating and preserving an ideal printing environment:

Ventilation: For safe use of the SGR-28 3D printing material during the 3D printing and post-processing ventilation of at least 4 times/hour air exchange is recommended.

Temperature: No heating or heated chamber needed. Just let the resin reach room temperature (20–25 °C) before you print.

Light exposure: Photopolymer resins are sensitive to UV and certain types of artificial light. Prolonged exposure can cause unintended curing or degradation of the resin's properties.

Direct sunlight can rapidly cure photopolymer resins. It's important to store resin bottles and tanks away from windows or areas that receive direct sunlight. If possible, use lighting that does not emit UV wavelengths, or keep the resin covered and shielded from ambient light when not in use.

Cleanliness: Ensure that the resin tank and tools used for stirring or handling the resin are clean to avoid introducing contaminants that can affect print quality and cleanliness of the final product.

Always keep resin bottles tightly sealed when not in use. This prevents contamination from dust or other particles and minimizes the risk of accidental light exposure.

Biocompatibility: To ensure biocompatibility compliance, SGR-28 resin was validated with dedicated resin tank of a 3D printer, build platform, washing equipment and post-processing tools that were not mixed with any other resin.

Process requirements

3D printing

Validated compatible 3D printing equipment together with recommended settings could be found in the Application guide.

Support removal

Supports should be removed either after 3D printing or post-curing. Failing to do so properly could cause injury. Please refer to Application guide on how to remove supports properly.

Washing

Recommended washing procedure and suitable equipment could be found in Application guide.

Post-curing

Correct post-curing procedure and compatible equipment could be found in Application guide.

Additional post-processing

Any additional post-processing that is required to ensure safe usage could be found in Application guide.

Sterilization, cleaning and disinfection

For sterilization recommendations, please refer to Application guide.

The appliances may be cleaned and disinfected according to internal facility protocols. Tested methods of disinfection:

1. Soak the finished product in clean and fresh 70% IPA for 5 minutes.
2. Soak the finished product in clean and fresh 2% chlorhexidine solution for 2 minutes.

It is important not to leave the part in the disinfection solution for longer than 5 minutes.

After disinfection, examine the part for damage or cracks to ensure that produced part meets performance requirements.

Storage

Produced appliances should be stored in closed and opaque containers. Excess light exposure could affect the properties and performance of the polymer. Produced appliances must be used within one month of manufacturing to ensure safe workflow.

Please store SGR-28 3D printing resin only in original packaging at 5°C - 40°C. It is important not to exceed 50°C for prolonged periods of time when in storage.

Keep product bottle always closed, away from children, ignition sources, light sources, direct sunlight.

Disposal guidelines

Properly cured and post-cured 3D printing resin is non-hazardous and could be disposed of as regular waste.

However, pay special attention to post-curing procedures as partly post-cured object that is disposed as regular waste could cause environmental damage. Unused liquid resin and solvents should be disposed in accordance with local regulations. Contaminated packaging of liquid resin should also be disposed in accordance with local regulations.

If there is a chance that object could be considered biohazardous, please follow facility waste procedures for correct disposal.

Adverse events

To report serious injury (temporary or serious permanent deterioration of health, a serious public health threat, or death), contact MB Labsamera (info@ameralabs.com, +370 602 42209) and your local Competent Authority.