CIT-25

Resin for stereolithography 3D printing

EN Instructions for use

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EN

Resin for stereolithography 3D printing

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		

MB Labsamera
Draugystes st. 14
Kaunas, 51259
Lithuania
+370 602 42209

CE MD

Before using CIT-25 3D printing resin, please familiarize yourself with these Instructions For Use (further - IFU) and following accompanying documentation:

- Application guide for printing and post-processing requirements to ensure the correct and safe usage of CIT-25 material. Find the application guide for this material at https://ameralabs.com/application-guide/CIT-25-application-guide/.
- Material Safety Data Sheet (further – MSDS) for detailed safety and environmental information is available at https://ameralabs.com/msds/.
- Technical Data Sheet (further – TDS) for full details regarding mechanical properties is available at https://ameralabs.com/docs/datasheets/CIT-25-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 CIT-25 material for fabrication of custom dental appliance. This instruction also provides information about safety and environmental aspects.

Intended purpose

CIT-25 resin is a light-curable polymer-based resin designed for the fabrication of biocompatible, transient use, removable dental appliances by 3D printing. It is intended for 3D printing dental accessories such as dental impression trays.

Indications for use

CIT-25 is a photopolymer resin indicated for 3D printing biocompatible custom impression tray models to aid to produce accurate patient's dental model for further procedures such as denture production.

Contraindications

CIT-25 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 CIT-25 3D printing resin should not be left in contact with patient tissues for more than 60 minutes (cumulative).

CIT-25 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

Custom 3D printed resin impression trays maintain uniform impression material thickness and rigid support, which limits distortion compared to stock trays, giving more accurate working casts.

2 SAFETY

Material associated warnings

CIT-25 in its uncured state contains monomers that polymerize during 3D printing. Please read MSDS of CIT-25 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 resin. For more information regarding correct handling of CIT-25 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. CIT-25 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/CIT-25-TDS.pdf CIT-25 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/CIT-25-application-guide/ before working with CIT-25 3D printing material. Scan the following QR code to access Application guide.

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 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 CIT-25 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: Uncured resin is not biocompatible. To ensure biocompatibility compliance, product made of CIT-25 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.

Cleaning and disinfection

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 CIT-25 3D printing resin only in original packaging at 5°C - 40°C.

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.