

INTENDED USE:

PORTUX 3D SG resin is a product indicated for the fabrication of surgical guides by 405 nm LCD and 405 and 385 nm DLP stereolithography. It should only be used by dental professionals or technicians trained in the handling of 3D printing resins.

COMPOSITION:

The resin is a mixture of:

- -Acrylic monomers
- -Photoinitiators (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)
- -Additives
- -Dyes

DESCRIPTION:

PORTUX 3D SG is a low viscosity 3D printing resin, suitable for the manufacture of sterilizable surgical guides, with excellent precision and definition, faithful to the digital design. The post-cured and sterilized guides are characterized by a light blue and translucent color, without yellowing or color degradation. PORTUX 3D SG is compatible with LCD and DLP stereolithography printers, with wavelengths between 385 and 405nm.

INSTRUCTIONS FOR USE:

- •Shake the container for at least twenty minutes on a mechanical vibration device or roller before opening the product for the first time. This ensures proper operation in the printer and color reproducibility.
- •Shake the resin vigorously before pouring it into the printer.
- •Print with the resin according to your printer's instructions for handling and use.

Post-processing of printed guides:

- -Clean the guides in isopropyl or ethyl alcohol (>90%), preferably using ultrasonic equipment or shaker to facilitate cleaning. Immerse the impressions in a container with used alcohol for 5 minutes and, subsequently, immerse them in clean alcohol for the same time. It is recommended to use compressed air between cleanings to remove excess resin inside cavities or critical areas of the impression.
- -Remove the guides from the alcohol and dry them, either by gently applying compressed air or in an oven at 40°C for 30 minutes. IMPORTANT: Avoid curing wet or humid impressions, as this affects the precision and final definition of the impressions.
- -It is recommended to adapt the titanium rings to the guide before post-curing. Once adapted, cure the part in a NextDent LC-3DPrintBox chamber for 30 minutes as follows:
- 15 minutes exposure.
- 5 minutes rest.
- 15 minutes exposure.
- After post-curing, it is recommended to autoclave the guide for steam sterilization at a temperature of 121°C for 16 minutes.

WORKING IN CONJUNCTION WITH OTHER DEVICES:

The surgical guides printed with PORTUX 3D SG resin must be previously designed in a planning software, considering the type and brand of the implant to be used during the surgical procedure. The selection of the implant will determine the brand and type of the titanium ring to be adapted in the guide and the guided surgery kit, composed of drills and spoons, to be used during the procedure.

RESIDUAL RISKS:

- -Allergic reactions can be generated by contact with the unpolymerized material or by the release of unpolymerized substances, which can be avoided by carrying out the post-curing process within the indicated time. In addition, biocompatibility tests guarantee the safety of the device during its use.
- -Infections can occur if the device is not sterilized before being introduced into the patient's oral cavity, which is avoided by sterilizing the device according to the indicated parameters.
- -It is possible that the printed guides have dimensional discrepancies with the titanium ring and/or the guided surgery kit, therefore it is necessary to carry out an appropriate design in the software of the guide

to be printed, in addition to carrying out an adequate parameterization of the resin on printing equipment.

-Due to extreme conditions during the sterilization process, fractures or distortion of the printed guide may be induced, which may make its use impossible. This can be mitigated by carrying out the

sterilization process according to the indicated parameters.

-Improper storage of the resin can generate a change in the polymerization properties of the product, making it impossible to use, which is avoided by storing the resin correctly, protected from light, and returning it to its original container after use.

CONTRAINDICATIONS:

The use of surgical guides printed with PORTUX 3D SG resin is contraindicated in patients with proven allergic reactions to products derived from methacrylate resins.

WARNINGS:

This product should not be used in an application other than that specified in the intended use. Surgical guides printed with PORTUX 3D SG are biocompatible for times less than 24 hours, if the instructions for use defined in this document are followed. They should not be used for longer than the specified time.

PRECAUTIONS:

Use in children, pregnant or lactating women is not recommended.

STORAGE:

The product must always be kept within its original packaging at room temperature (< 30°C), avoiding the following conditions:

- Direct exposure to sunlight or other types of radiation.
- High heat or humidity sources.
- Dust or any other type of contamitnant.

FINAL DISPOSAL:

Do not dispose this product in water sources or sewage systems. This product should not be discarded in soil or subsoil. Disposal should be carried out through an authorized waste management company, in accordance with national and local regulations.

SHELF LIFE:

3 years.

