



INSTRUCTION FOR USE

SHERAprint-ortho plus / UV

03.07.2017
GA31370A
GA31430A
CE 0123

Light-curing resin based on (meth)acrylate, biocompatible, for the generative fabrication of bite splints, surgical guides, X-ray templates for DLP printers with LED 405nm / UV-LED 385nm

1. Important notes

This is a medical device, only to be used by trained specialist personnel.

SHERAprint-ortho plus / UV was developed for the application in dental laboratory and has to be used in accordance with the instructions for processing and safety. SHERA will not be responsible for damages caused by faulty or improper use of system and materials.

2. Indication

Bite splints, surgical guides and X-ray templates for implant dentistry, occlusal orthos, fixation and transfer keys.

3. Processing

3.1 General Information

- the properties of the final product depend, among other things, on post-processing. Correct post-exposure is important for biocompatibility. Therefore it must be ensured that the light curing unit is in good condition and that the moulds are completely cured (observe process description).
- minimum material thickness for the design is 1.5 mm.
- maximum curing depth* at direct post-exposure: clear 6 mm
* In case of large objects and exposure on both sides, the material thickness can be up to 12 mm (Example SHERAprint-ortho plus / UV with a curing depth of 6 mm).
- polish surface mechanically.
- processing temperature 23 °C ± 2 °C.

3.2 Manufacturing process

Data preparation and fabrication of the support structure according to the instructions of the CAD software manufacturer.

- Construction process

Generation of a print job complying with machine and material parameters.

- Post-processing

If possible, post processing should commence immediately following the construction process. After raising the platform, a drip-off time of approx. 10 minutes is recommended.

- Pre-cleaning

Remove construction components from the platform and clean in a separate container with SHERAultra-p for max. 3 minutes in an ultrasonic bath.

- Cleaning

Then clean the openings, drill holes and gap areas thoroughly with a soft tooth brush and a bit of SHERAultra-p in order to remove material rests. Afterwards also clean with air pressure and if necessary remove the construction components of the supporting structure.

- Main cleaning process

The main cleaning process is performed in a separate container with fresh SHERAultra-p for max. 3 minutes in an ultrasonic bath. Before drying check the openings as well as the additional drill holes and, if necessary, remove the material rests with a soft tooth brush and a bit of SHERAultra-p.

The total cleaning time should not exceed 10 minutes.

- Drying

Heat the construction components for 30 minutes in a furnace to approx. 40 °C to remove the solvent residues from the cleaning process.

- Post-exposure

Post-exposure is performed with a xenon photo flash unit with 2 x 2000 flashes (for example SHERAflash-light plus) under inert gas conditions (nitrogen), rotate components in between. We do recommend letting the construction components cool down in between these two procedures.

- Surface processing

Remove the surface by grinding. The surface may be polished.

4. SHERAprint-ortho plus UV (385nm)

4.1 Sterilisation

- Locally applicable regulations and hygiene guidelines are to be observed.
- Important: after main cleaning and prior to post-curing, the components to be sterilised are to be dried, e.g. to be heated in a furnace to approx. 40 °C for 30 minutes to remove remaining solvent from the cleaning process.
- SHERAprint-ortho plus UV is validated for the „W&H Lisa 522, Program UNIVERSAL 121 “ sterilisation process.

Technical data

Start	
Ventilation	-0.86 bar
Steam injection	+0.10 bar
Ventilation	-0.84 bar
Steam injection	+0.50 bar
Ventilation	-0.83 bar
Heating	
Sterilisation	121 °C; 1.06-1.08 bar; 15 min
Pressure relief	
Drying	24 min
Ventilation	
End	

Steam sterilisation may only be performed with equipment that complies with the standards EN 13060 and EN 285. Validation of the sterilisation processes was conducted according to EN ISO 17664.

- Responsibility for sterility lies with the user.

4.2 Disinfection

- SHERAprint-ortho plus UV can be disinfected with a disinfectant (for example, SHERAIMPRESSION DISINFECTANT) using the immersion technique (5 minutes). After disinfection, the objects are rinsed for at least 30 seconds with running water of potable quality.

5. SHERAprint-ortho plus (405nm)

- Do not use heat-based methods for disinfection of sterilisation. This could possibly deform the workpiece.

6. Safety

- Please follow the instructions on the safety data sheet!
- Be sure to use personal protective equipment (protective gloves and protective glasses) during processing.
- Avoid direct contact with the liquid material and the components prior to post-curing. Irritating to eyes and skin (sensitisation is possible).
- After contact with eyes rinse thoroughly with water immediately and consult a doctor.
- After contact with skin wash immediately with water and soap.
- The biocompatibility is only guaranteed in case of complete polymerisation.

7. Storage

- SHERAprint-model plus / UV is to be stored dry (at 15 °C – 28 °C) and protected from light. Minimal influence of light can already induce polymerisation.
- Always keep container tightly sealed, immediately close the container carefully after each use.

8. Contraindication

Contains (meth)acrylics and phosphine oxide.

Some ingredients of SHERAprint-ortho plus / UV may cause allergic reactions in predisposed persons. In such cases refrain from using the product. SHERAprint-ortho plus / UV only insert intraorally in completely polymerised state.

9. Adverse effects

Product may cause allergic reactions.

Warranty

SHERA Werkstoff-Technologie GmbH & Co. KG is certified according to DIN EN ISO13485 and guarantees for the products, due to a thorough quality control system, a flawless quality of its products. Our instructions for use are based on the results of our test laboratory. The technical data given can only be guaranteed if the processing is carried out as mentioned. The user is self-responsible for processing of the products. We are not liable for faulty results as SHREA has no influence on the processing. Nevertheless possibly arising claims for damages relate to the value of the products only.

