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CURO resins | Instructions for use

CURO Crown, Element Model Beige, Element Model White, Gingiva, Guide, IBT, Ortho Model, Model, ProCast, ProDenture, ProGingiva, ProSplint, Tray.

1. Product description

The CURO devices are light curing 3D printing resins for the production of dental custom-made parts by commercial users. They are suitable with 385 nm and 405 nm wavelength, unless otherwise stated on the label.

The target patient group for medical devices is defined as adults and adolescents.

2. Indication

3D printing resin for the additive production of:

CURO Crown A1	Temporary crowns and bridges	MD CE
CURO Crown A2	Temporary crowns and bridges	MD CE
CURO Crown A3.5	Temporary crowns and bridges	MD CE
CURO Crown B3	Temporary crowns and bridges	MD CE
CURO Element Model Beige	Dental models	
CURO Element Model White	Dental models	
CURO Gingiva	Gingiva masks	
CURO Guide	Drill guides	MD CE
CURO IBT	Transfer templates for the bracket positioning	MD CE
CURO Ortho Model	Dental models	
CURO Model	Dental models	
CURO ProCast	Cast	

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CURO ProDenture Dark Pink	Denture bases	MD CE
CURO ProDenture Light Pink	Denture bases	MD CE
CURO ProGingiva	Gingiva masks	
CURO ProSplint	Bite splints	MD CE
CURO Tray	Individual impression trays	MD CE

3. Contraindication

The material should not be used for any purposes other than the additive manufacturing of the specified dental parts. Do not use the polymerized material if you are allergic to any of the ingredients (contains methacrylate monomers and oligomers).

4. Risk minimization and safety instructions

- Improper use and deviations from the described processing will lead to an impairment of quality and biocompatibility as well as undesirable mechanical properties of the final part.
- Biocompatibility is only guaranteed if used properly. All printed parts should only be processed once fully polymerized.
- The light curing of the printed parts takes place in a suitable light curing unit, see table in point 5.3. Finishing.
- After completion of the construction process, the printed part should be cleaned with a suitable cleaning solution (e.g. isopropanol 99% or an alcohol-free solvent).
- The LOT No. must be specified for each process that requires identification of the material.
- For additively manufactured medical products, storage in water for 24 hours is recommended.
- Observe all recommended settings for the printer and the light curing device.
- Read and observe the Material Safety Data Sheet (MSDS) before use.
- For the safety against breakage, observe the usual material wall thicknesses when creating customized products (see processing guide).
- The correct personal protective equipment (nitrile gloves, protective goggles, protective clothing) must be worn when handling CURO products and non-cured printed parts.
- Avoid any contact with skin and eyes before light curing. The CURO product can irritate eyes and skin.
- In rare cases, allergic reactions to components of CURO products can occur. In the event of accidental contact, follow the “First Aid Measures” (rinse thoroughly with water and consult a doctor if necessary). See separate MSDS (Material Safety Data Sheet).

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- Use by qualified personnel only. Keep out of the reach of children.

5. Processing steps
Please see the relevant processing guide

5.1 Printing
Follow the respective guidelines of the printer and the software for best practice. Pay attention to clean work. Contamination on the 3D printer can cause defects in the printed part and damage the material tray. Shake the CURO bottle before use and fill enough material into the tray. Remove any occurring bubbles with a clean instrument. Ensure the processing temperature is between 18-28° C (64 to 84 F).

5.2 Cleaning after printing
Wipe off any residues of the printing resin with a clean spatula.
Afterwards remove the build platform from the printer and release the printed parts with a suitable instrument (eg.: cutter knife) from the build platform. Then ideally cut off the support structures manually.

Clean printed parts according to the following recommendations:

Device	**Cleaning Solution**	**Cleaning Time**	**Resins**
Dual tank washer (CLEANI with Dual Tanks)	95%~99% alcohol (Isopropyl or Ethanol)	Twice for 3 min	CURO Crown* CURO Element Model, CURO Ortho Model, CURO Model, CURO Gingiva, CURO Guide, CURO I-B-T, CURO ProCast* CURO ProDenture* CURO ProGingiva CURO ProSplint, CURO Splint, CURO Tray
Single tank washer (CLEANI with Tank Plus)	95%~99% alcohol (Isopropyl or Ethanol)	5 min	
Hand wash Ultrasonic cleaner	Do not submerge in IPA or use an IPA-free solution	5 min	CURO Crown CURO ProCast, CURO ProDenture

**These resins can be cleaned with alcohol (Isopropyl or Ethanol), however when submerged in alcohol a white layer may appear that can be removed with subsequent sandblasting.*

Subsequent drying of the printed part with compressed air and controlling of the cleaning result. You can recognize sufficient cleaning by a matt surface. Shiny areas require spot cleaning with cleaning liquid and a brush. Keep cleaning until no more shiny areas occur.

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Complete the post-treatment of the printed parts quickly and adhere to the time specifications. Above all, avoid unnecessarily long baths (no longer than 10min total) in the cleaning fluid and long waiting times between the steps.

5.3. Finishing

Light curing time in the light curing device (CURIE, CURIE Plus) for each CURO resin:

Resin	Time	Intensity	Duty Cycle	Bottom Light
CURO Crown A1	5 min	**CURIE**: 13 **CURIE Plus**: 10	8	ON
CURO Crown A2	5 min	**CURIE**: 13 **CURIE Plus**: 10	8	ON
CURO Crown A3.5	5 min	**CURIE**: 13 **CURIE Plus**: 10	8	ON
CURO Crown B3	5 min	**CURIE**: 13 **CURIE Plus**: 10	8	ON
CURO Element Model Beige	10 min	13	8	ON
CURO Element Model White	10 min	13	8	ON
CURO Gingiva	20 min	13	8	ON
CURO Guide	6 min	10	8	ON
CURO I-B-T	10 min	13	8	ON
CURO Ortho Model	10 min	13	8	ON
CURO Model	10 min	13	8	ON
CURO ProCast	5 min	13	8	ON
CURO ProDenture Dark Pink	10 min	13	8	ON
CURO ProDenture Light Pink	10 min	13	8	ON
CURO ProGingiva	15 min	16	10	ON
CURO ProSplint	15 min	8	1	ON
CURO Splint	10 min	6	8	ON
CURO Tray	7 min	13	8	ON

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The final properties as well as the final color depend on the light curing process.
When light curing in other light curing devices, a comparably high energy input must be ensured (200 W).
This depends on the light source used and the exposure time (UVA radiation source (315-400 nm), 10 minutes)).

6. Polishing and final cleaning
The dental parts produced with CURO resins can be polished and repaired in a conventional way. Please see the relevant processing guide.
Final cleaning: A final cleaning is done with detergent and water in a cold ultrasonic bath (5 minutes) until no polishing agent residues can be seen and felt on the printed part. Then rinse the printed part in clear water for 30 seconds until no more foam formation is visible due to the detergent.

7. Notes for the laboratory / for the dentist to hand out the device to the patient
Before the printed parts are incorporated, a storage in water for 24 hours is recommended.
Disinfection as standard is not necessary for oral, non-surgically invasive products.

Use a disinfectant bath, which is especially suitable for 3d printed parts, if you want to ensure hygiene when handing over the medical device to your customer. Spectrum of activity: bactericidal including TBC, yeasticidal, limited virucidal (HIV, HBV, HCV, Sars-CoV-2).

Advice to the medical device patient (if applicable).
Removable custom-made items should be cleaned under running water after wearing. Don’t use any toothpaste or denture cleaner. Then keep dry until next wear.

8. Technical data
Please refer to the separate MSDS (Material Safety Data Sheet).

9. Composition
Mixture of acrylate and methacrylate resins, photoinitiators (phosphine oxide), additives, dyes.

10. Storage
Close the bottle carefully after each use. Store CURO products closed, dry and protected from light at 5-30 ° C. Even a small amount of light can trigger the polymerization. Do not use it after the expiry date.

11. Disposal
Dispose of liquid printing resin according to official regulations. Must not be disposed of together with household waste. Do not empty into drains.

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Information

All Ackuretta products are free of material and manufacturing defects and always have flawless quality. Our user recommendations are based on a careful determination of practice-related values from our dental laboratory. Achieving the guaranteed quality and usability of the product requires strict compliance with all process steps specified in the product files in a two-tier quality control. The user is responsible for operation and proper use of the material. The medical products are intended for use as custom-made products by dental technicians in accordance with local regulations.
Report all serious incidents (death, serious deterioration of health, serious risk to public health) that have occurred in connection with the medical device to the manufacturer and the competent authority of the member state.

If defects appear in the material within the warranty period, the user only has a right to replacement of the material. Ackuretta is liable for neither losses nor damage caused by this material, irrespective of whether this damage is direct or indirect, and especially collateral or consequential damage, regardless of the legal basis.
According to statutory regulations, Ackuretta is liable for direct damage to the material based on a deliberate act or gross negligence by its legal representatives or executive staff and for personal damage. Any liability for the material and damage as a consequence of using it are excluded if the user has not observed the specified process steps.

Symbols

	See instruction for use	λ 385 - 405 nm	Wavelength
	Expiry date		Attention: environmental hazard
LOT	Lot number		Attention: irritant
REF	Article number		Attention: corrosive
MD	Medical device		Wear gloves
CE	CE mark		Shake well before using
	Keep away from sunlight		Distributor
	Temperature limitation		Manufacturer