

UNI-P Crown™

Light-curing 3D printable resin-based material for the correction or reconstruction of functionally compromised natural dentition (e.g., missing teeth or deficient teeth) by manufacturing of customized 3D-printed dental prostheses

For professional dental use only.

Patient Population: Any human undergoing dental treatment related to the procedures listed below under "Indications". The definitive patient group is diagnosed on a case-by-case basis by a licensed dental professional and there are no exclusions for specific patient groups.

INDICATIONS

- UNI-P Crown is a light-curing, flowable polymer based on methacrylic acid ester for production of 3D-printed temporary crowns, inlays, onlays, veneers, and bridges.
- UNI-P Crown may only be used in combination with the specified printers and recommended equipment and in compliance with manufacturer instructions.

PROPERTIES

- Class II (US) / Class IIa (EU) medical device.
- Radiopacity value above 2.5 mm Aluminium. (Radiopacity is defined as the ability of a material to be visible in x-ray photographs.)
- Viscosity of 185-200 cP at 23°C.
- Flexural strength of >100 MPa (ISO 10477:2020 and ISO 4049:2019).
- Compressive strength of >300 MPa (ISO 9917-1:2003).
- Flexural Modulus of >2500 MPa (ISO 10477:2020 and ISO 4049:2019).
- Bi-axial flexural strength of >130 MPa (ISO 6872-1:2003).
- Available in shade A2 (Universal) and in shades A1, A3, B1 upon request.

CONTRAINDICATIONS

- Not to be used on exposed pulp.
- The use of the medical device is contraindicated if the patient is known to be allergic or sensitive to any of its ingredients.
- Do not use in excess.

CAUTION

- UNI-P Crown contains polymerizable monomers which may cause allergic contact dermatitis in susceptible patients and damage the pulp. Avoid contact with skin, eyes, and soft tissue. Wash thoroughly with water after contact. If skin sensitization occurs or if known allergy to methacrylate resin exists, discontinue use.
- UNI-P Crown contains materials which: sensitive to light / irritating to eyes / harmful if swallowed / irritating to respiratory system and skin / may cause sensitization by skin contact. For complete symbols guide see below.
- In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol and rinse with water.
- In case of contact with eyes, rinse with water and seek medical attention.
- Personal protective equipment such as gloves, face mask and safety eyewear should always be worn.
- Note – The use of noncompliant devices might impair the function of the restoration. Sole responsibility for correct application is assumed by the user and is beyond control of B.J.M. Laboratories Ltd. B.J.M. Laboratories Ltd. does not assume any responsibility and liability for damaged caused by misuse.

COMPOSITION

UDMA, TEGDMA, dental glass and silica. Total content of inorganic fillers (particle size 0.2 – 0.7 µm) is 5-10% by mass.

INTENDED USE

UNI-P Crown is to be used with 3D-printers from ASIGA for production of temporary crowns and bridges, inlays, outlays and veneers, production of artificial teeth for subsequent insertion into a denture base.

REQUIREMENTS

Printer: ASIGA MAX UV & PRO 4K (385 nm wavelength).

Post Curing Unit: Otoflash G171 (NK-Optik) or ASIGA Cure Flash (ASIGA)

INSTRUCTIONS FOR USE

The following instructions must be observed during tooth preparation: Make sure to avoid tangential, spring edge or lip preparations as they are contraindicated with printed restorations. Therefore, exercise special care when using

instruments with a round tip and do not introduce them any further than up to half their diameter at maximum. Please note that tangential preparations are technically unfeasible and would result in too thin, i.e. unstable and over-contoured, crown margins.

The following applies to the model modelled on the computer:

See illustration 1a for specified **minimum wall thicknesses** for the respective indication: the wall thickness must not be undercut even after manual grinding.

The following applies to temporary bridges: connector area at least 16 mm². The connector area should be as large as possible – see illustration 1b. For physical stability, the height of the connector is more important than the width. Doubling the width results in only doubling the strength, while doubling the height results in eight times the strength. Oval connector area is therefore recommended.

Make sure that enough supports are generated. It is recommended to place the supports on the occlusal surface.

1. Generating Printing File:

Generate the printing file of the desired restoration by using appropriate software (ASIGA Composer) and deliver it suitable to the printer. Please observe the corresponding instruction for use of software and printer. Select the build style / INI file / material file for UNI-P Crown in the printer software. Make sure that all software is up to date.

2. ASIGA Printer (MAX UV & PRO 4K):

- 2.1. Hardware – Please refer to the printer's manufacturer's manual for this information.
- 2.2. ASIGA printer software – Composer - Please refer to the printer's manufacturer's manual for this information.
- 2.3. Printing parameters – Download the required parameter set from the B.J.M. website or from ASIGA users library. A working temperature of 30°C (86°F) must be maintained.
 - 2.3.1. Slice thickness: 50 µm.
 - 2.3.2. Optimal orientation: 0 degree tilted orientation.
 - 2.3.3. Support point size: varies based on support type.

3. Printing:

Work as clean as possible, as dirty tray or machine can cause deformation/ discoloration and therefore failure of the printed object.

Briefly shake the liquid material and pour it into the 3D-printing machine tray.

Start the printing process by following the instruction for use of the printer.

Caution – Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specifications. This is explicitly not recommended and is the responsibility of the user. In case of questions the user should contact the manufacturer for a list of validated software and process hardware.

4. Cleaning:

After the printing process is completed, remove the building platform from the machine. During removing the restoration and the following cleaning steps, wearing gloves (nitrile gloves) and protective goggles are advised.

Place the platform on a piece of paper or cloth with the built jobs facing upwards.

Remove the printed jobs from the platform by using a suitable instrument (putty knife). Roughly snap off the support structure. To remove excess material, use an ultrasonic device with isopropyl alcohol (IPA) for 3 minutes. Afterwards, clean the printed job with a cloth and possibly a brush soaked in an isopropyl alcohol (IPA) solution until all resin remains are completely removed. Then dry the printed jobs thoroughly with an air syringe.

Warning – Protect light-curing products from strong light sources.

5. Finishing the printed job – drying and curing:

To achieve the desired material properties and biocompatibility, post-curing of the completely dried and cleaned printed objects is necessary. For final polymerization place the printed jobs in a UV-light box.

Note – time of curing depends greatly on type of lamps / lightbox used. The final properties and the final color depend on the post-curing process. Post-curing is a UV-light treatment to ensure that UNI-P Crown materials obtain full polymer conversion, the residual monomer is reduced to a minimum and the highest mechanical properties are achieved.

This procedure is a necessary step to attain a biocompatible end-product. Before post curing it is recommended to wait for 30 minutes in a 37°C heated chamber.

It is recommended to use the UV-Flash device "Otoflash G171" by NK-Optik (2 x 2000 flashes, turn around after 2000 flashes, UV-bloc bowl with-out nitrogen). In general, all lightboxes for light-curing veneering materials can be used that cover a wavelength range of 320 - 500 nm. Lightboxes with integrated flashlight allow shorter exposure time compared to conventional lamps. Always follow the respective

Symbols used on packaging

Consult instructions for use	Irritant	Catalogue number
Temperature limit 15°C (59°F) min / 35°C (95°F) max	Medical device	Date of manufacture
Use by date	Batch code	Manufacturer
Keep away from sunlight	Shake well before use	



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instruction for use of the polymerization unit.

Caution – Wear nitrile gloves, safety glasses, and dust mask is advised during this finishing process.

6. Finishing the printed job – polishing:

Remove leftovers of the support structure with a cutting-disk. Blast the surface of the printed job with blast polishing material carefully (50 µm at maximum blasting pressure of 1.5 bar).

Afterwards, prepare the restoration starting with a diamond football bur (coarse) to smooth supports connection points. Continue working the restoration with diamond flame bur (super fine).

Polish to a high gloss and shine using diamond composite spiral rubber polisher (medium and fine).

Finish the restoration with a diamond polishing paste using a leather buff for application.

7. Fastening the temporary crowns and bridge, inlays, onlays, and veneers:

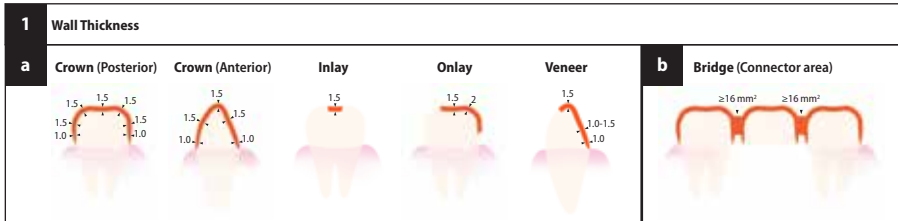
In the case of definitive single crowns, the inside of the crowns should be roughened with a sandblast (Al2O3, 110 µm). Then, as usual, fix it definitively with a temporary resin cement material such as Cem-Implant and Q-Temp or any other resin cement available on the market.

8. Additional advice in the cases of:

- a. The print has failed partially or completely; b. Particulates of polymerized residues are visible in the resin tray or stick to the bottom: remove the resin tray from the printer and filter the resin through a fine 190 Microns paint strainer.
- c. Contamination, evident gelation, or polymerization is observed after filtering: discard and replace the UNI-P Crown material with a new batch. Do not mix different batches of UNI-P Crown material.

STORAGE AND DISPOSAL

- The recommended storage temperature is between 15°C (59°F) and 35°C (95°F).
- Keep product in original packaging.
- Keep away from direct sunlight.
- Do not freeze.
- If refrigerated, allow the material to reach room temperature.
- To obtain SDS or IFU visit www.bjmlabs.com.
- Do not use after expiration date. See expiry date on the label.
- Shelf life is 2 years after the date of manufacturing.
- Empty product can be safely disposed after use in an intended regular waste container. The product does not require special disposal instructions or precautions and is harmless to the environment.



2 Work Flow																																									
a Print settings		b Wash cycles		c Before post curing		d Post curing																																			
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