Carbon®

DB4000™

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# Impact Denture Base Instructions for Use

**Product Description:** DB 4000 High Impact Denture Base is a photocurable, methacrylate-based dental resin designed for the fabrication of dental prosthetics using additive manufacturing on Digital Light Processing (DLP) 3D printers (wavelength = 385 nm). DB 4000 High Impact Denture Base is intended to be used within a computer-aided design and manufacturing (CAD/CAM) digital dentistry system that includes a 3D scanner, design software, 3D printer, and a UV post-cure unit (wavelength = 385-405 nm). The use of DB 4000 High Impact Denture Base is intended exclusively for professional dental work for the fabrication of dental devices for fully edentulous patients, which includes full removable dentures, overdentures, try-ins and temporary dentures. This resin is designed to meet the ISO 20795-1:2013 standards for high impact denture base materials. The user should review and follow all applicable product labeling, including instructions for use and user manuals, for any components that are used in conjunction with DB 4000 High Impact Denture Base. **Strict adherence to all labeling and instructions is critical when producing a safe printed dental device using DB 4000 High Impact Denture resin.**

**Indications for Use:** DB 4000 High Impact Denture Base is indicated for the fabrication of dental devices for fully edentulous patients using additive manufacturing on 3D printers. This includes the fabrication of full removable dentures, overdentures, try-ins and temporary dentures. Fabrication of dental devices using DB 4000 High Impact Denture Base requires a digital denture file, digital light synthesis (DLP) 3D printer and curing light equipment. DB 4000 High Impact Denture Base can be utilized as an aid in bonding the denture teeth to the denture base.

**Patient Population and Medical Treatment:** DB 4000 High Impact Denture Base dental devices are intended for use by fully edentulous patients and are suitable for use by the general population, including adults and children.

**Contraindications:**

- Do not use DB 4000 High Impact Denture Base printed devices in patients with known hypersensitivity or allergy to (meth)acrylate monomers, oligomers or acrylic-containing products.

- Do not use DB 4000 High Impact Denture Base printed devices in patients with active oral infections, unhealed oral surgical sites or compromised oral mucosa.

**CAUTION:** US Federal law restricts the device to sale by, or on the order of a dental professional.

**Adverse Reactions:**

- Direct contact with uncured resin may induce skin sensitization in susceptible individuals. Proper ventilation and personal protective equipment should be used when printing and post processing DB 4000 High Impact Denture Base.

- Allergic reactions to the printed device, including oral mucosal irritation, inflammation, or contact dermatitis may occur in patients sensitive to (meth)acrylate-containing materials. Failing to follow DB 4000 High Impact Denture Base IFU could result in printed devices that contain uncured resin, which could cause an allergic reaction in susceptible patients.

- Improper fit of the printed device may cause tissue irritation, soreness or ulceration.

- Printed device fracture may occur if fabrication parameters are not followed or if subjected to excessive force.

**Warning and Precautions:**

- Follow all compatible printer instructions and post-processing times for the fabrication of a dental device using DB 4000 High Impact Denture Base.

- DB 4000 High Impact Denture Base should only be used on validated 385 nm wavelength DLP 3D printers.

- Review the DB 4000 High Impact Denture Base SDS and follow all instructions for proper personal protective equipment when handling the liquid resin and uncured printed parts.

- Store DB 4000 High Impact Denture Base in a cool (17-25°C), dry place, protected from light. Ensure the cap is tightly closed while not in use. DB 4000 High Impact Denture Base must be used before its expiration date.

- Agitate the resin before each use. Inverting the bottle at least 10 times is recommended to fully rehomogenize any pigment particles that may have settled in storage.

- Clean the printer build platform and cassette prior to printing with a different resin shade. It is not recommended that different shades are mixed.

- Unused resin remaining in the cassette after printing should be filtered through a mesh screen (<200 microns) before storing for reuse. Do not leave resin in the cassette for extended periods of time and minimize exposure to ambient light.

- DB 4000 High Impact Denture Base is a single-cure system that may be reused within its expiration date. When reusing resin ensure resin is a smooth liquid, has not gelled, and is homogeneously mixed. Dispose of resin if any gelation is present. Shake the resin bottle for 30 seconds prior to dispensing to redistribute any pigment that has settled.

**Compatible Equipment:** DB 4000 High Impact Denture Base is designed for fabrication on validated DLP 3D printers (wavelength = 385 nm) and with validated post cure units (wavelength = 385 nm). Refer to the protocol sheet via the QR code below to see validated hardware and procedures. Validated cure units are also noted in the curing sections of this IFU.

**Directions for Use:**

**Dispensing DB 4000** High Impact Denture Base:

1- Invert the bottle at least 10 times to ensure proper mixing of the resin prior to dispensing.

2-Pour the resin directly into the printing cassette

**Printing DB 4000** High Impact Denture Base **Dental Devices:**

1- Only use the validated printers, print settings and post-processing equipment to ensure the printed dental devices are accurate and safe for use. Refer to the QR code above for all validated equipment and settings.

2- Following the CAD software manufacturer's directions for use, prepare your dental device design. Import the design onto the 3D printer.

3- Follow the validated printing instructions. Refer to the QR code above.

**Washing DB 4000** High Impact Denture Base **Dental Devices:**

1- Remove the supports prior to post-processing.

2- Wash the printed parts in a fresh IPA bath for two (2) minutes with an orbital shaker (140 RPM).

3- Remove and transfer the parts to a fresh IPA bath and repeat step 2.

4- Remove printed parts from the IPA bath and allow them to dry completely (air dry for at least 30 min or blow dry using compressed air).

5- Ensure all residual resin is removed from the parts. Excess liquid resin can be removed with an IPA-wetted soft brush in the isolated area.

NOTE: Printed parts should not exceed five (5) minutes of IPA exposure. Excess solvent exposure may result in degradation of mechanical properties and performance.

**Assembly:**

**If you are using a UV-curable tooth, please follow the below instructions.** The preferred tooth IFU must be compatible with validated post-cure processes.

**Tooth Bonding:**

1- Follow the preferred tooth IFU up until bonding instructions.

2- Place a drop of either liquid DB 4000 High Impact Denture Base resin or preferred UV-curable tooth bonding adhesive in each tooth pocket.

3- Insert each tooth into its corresponding pocket. Gently wipe away excess resin or adhesive if it spills out of the tooth pocket.

4- Use a tack cure light with 405 nm or lower wavelength on each pocket for 15-30 seconds. Once all the teeth are placed and tack cured, the device is ready for the post cure.

**Post-Curing DB 4000** High Impact Denture Base **Assembled 3D Dental Device:**

1- Ensure the printed and washed parts are completely dry before placing them in the cure unit.

2- Place the assembled denture into the cure unit with the intaglio surface facing down and the teeth facing up.

3- Follow the curing program for the UV curing unit you are using. You may also follow the QR code and reference the protocol sheet for validated curing instructions.

Dentsply Digital Cure Regular Unit 120V - 240V
- Setting: Preset Cycle
- Program: Lucitone
- LED Test cycle: 20 seconds
- Tack cure: 12 seconds
- Heat: 10-15 minutes
- Cure: 25 minutes
- Cool: up to 30 minutes

Dentsply Digital Cure Large Capacity 120V
- Program: Lucitone Digital Appliances
- Preheat: 30 minutes
- Cure: 60 minutes at 80° C

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**If you are NOT using a UV-curable tooth, please follow the below instructions.**

1- Ensure the printed and washed denture base parts are completely dry before placing them in the cure unit.

2- Place the denture base into the cure unit with the intaglio surface facing down and the tooth pockets facing up.

3- Follow the curing instructions in the section above for the applicable curing unit.

4- After cure, follow standard tooth bonding IFU.

Note: More than one post-cure can negatively impact device performance. Do not post -cure the final device

**Notification:**

- DB 4000 High Impact Denture Base has been validated using the software, printers and process parameters outlined in the QR code link. Any other processing procedures, printers or software used for the fabrication of the indicated dental devices with DB 4000 High Impact Denture Base will be out of compliance with DB 4000 High Impact Denture Base use and FDA clearances. Users must follow the provided instructions to use DB4000 to make the denture base device.

- If there are any serious incidents that occur in relation to a dental device fabricated with DB 4000 High Impact Denture Base, please report to Carbon (support@carbon3d.com).

- Please inform Carbon Inc (support@carbon3d.com) if you receive any damaged or unintentional opened bottles of DB 4000 High Impact Denture Base before use.

**Directions for Finishing:**
**Polishing:** DB 4000 High Impact Denture Base dental devices are compatible with common polishing equipment.

**Patient Cleaning Instructions:** DB 4000 High Impact Denture Base dental devices are single-patient, customized, multi-use oral appliances that should be cleaned between usages. The patient should clean the appliance with mild soap and warm water, or any over-the-counter mild cleaning agents indicated for oral devices. Store dry in a container. Do not soak overnight in water or cleaning solution.

**Repairing:**
It is recommended that dental devices are remade using the original design file in the case of damage.

**Disposal Considerations:** Resin remaining in the cassette after printing may be filtered (<200 micron mesh) and stored according to the proper storage conditions indicated on the label. Unused or expired resin should be considered hazardous waste and should be disposed of in accordance with all local, regional, national, and international regulations

**MRI Safety Information:** DB 4000 High Impact Denture Base resin is MR safe.




Symbol Glossary: https://learn.carbon3d.com/materials/carbon-db-4000

**Manufacturer:**

Carbon, Inc.
1272 Borregas Ave
Sunnyvale, CA 94089
1-650-285-6307
productstewardship@carbon3d.com