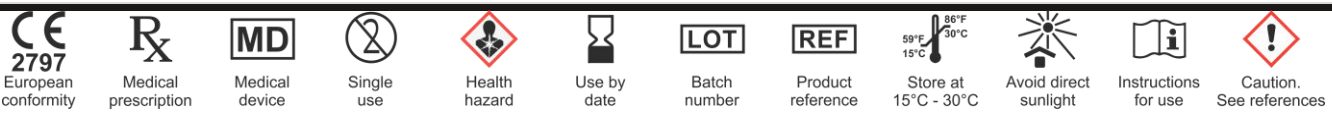
Printer compatibility 385nm (UV)



Instructions For Use (IFU) - DentaBASE – Part Number: 03569

Introduction:
The following instructions for use are for dental professionals who use Asiga DentaBASE as a material for denture bases.
This instruction for use also provides information about safety and environmental aspects.
In case more information is needed, contact the reseller.

Intended Use & Indications:
Asiga DentaBASE is intended exclusively for professional dental work.
Asiga DentaBASE is a 3D print resin intended for the manufacturing of 3D printed denture bases. The denture bases produced are suitable for dental indications including removable dentures for edentulous patients.

Description & Effects:
Asiga DentaBASE is intended be used in combination with DLP based 3D printers (i.e. Asiga Max Series, Asiga Ultra Series or Asiga Pro Series) that support Asiga resins. Printer and resin must be optimized with respect to each other in order to produce complete and precise printed parts.
If the printer and resin are not optimized with respect to each other this may have an adverse effect on the accuracy and physical quality of printed parts.
DLP based 3D printers and post-curing lightboxes make use of a light source to polymerize the Asiga resin.
Therefore, operators are advised to wear UV protective glasses when operating a 3D printer and/or lightbox.
Differences in colour nuance may occur due to: production in batches; inadequate shaking and mixing of the original packaging before use; inadequate stirring in the DentaBASE resin before use; insufficient post-curing.

Asiga DentaBASE is intended for single use only. During 3D printing the resin material undergoes a polymerization reaction to manufacture a denture base and cannot be reused.

The fabrication of denture bases from Asiga DentaBASE requires equipment and software presented below:

Element	Description	Name
Design	Scanner	3Shape TRIOS, iTero Element, Medit 1700
	Design Software	3Shape Dental System, Exocad
Printing	Printer	Asiga DLP Printers (i.e. Asiga Max Series, Asiga Ultra Series or Asiga Pro Series). (Refer to Printer Settings below for details using the latest material ini file.)
	CAD File	
	Material	Asiga DentaBASE
Post-curing	Post-cure unit	NK Optik Otoflash G171
Bonding and Finishing	Bonding Agent	Asiga DentaBASE

Always follow the applicable user guides supplied with the scanner, design software, printer and post-cure unit.

Clinical Benefit:
The clinical benefit of Asiga DentaBASE is the ability to 3D print denture bases which are used to form removable dentures for edentulous patients.

Performance Characteristics:
Asiga DentaBASE has been evaluated in accordance with ISO 20795-1:2013 and ISO 10993-1:2018, and has been confirmed to meet the applicable mechanical and biocompatibility requirements for denture base resins.

Contra-Indications:
Asiga DentaBASE should not be used for any other purpose than as a 3D print resin for the manufacturing of printed denture bases.
Any deviation from this instruction for use may have an adverse effect on the chemical and physical quality of Asiga DentaBASE.
In case of an allergic reaction, please contact a medical physician.

Printer compatibility 385nm (UV)

CE 2797 European conformity | Medical prescription | MD Medical device | Single use | Health hazard | Use by date | LOT Batch number | REF Product reference | Store at 15°C - 30°C | Avoid direct sunlight | Instructions for use | Caution. See references

Hazard & Precautions:
Contains 7,7,9 (or 7,9,9)-trimethyl-4,13-dioxo-3, 14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate; Diphenyl (2,4, 6-trimethylbenzoyl) phosphine oxide; Tetrahydrofurfuryl methacrylate.
Direct contact with uncured resin may induce allergic skin reaction in susceptible individuals.

Please refer to Asiga product safety data sheet for DentaBASE. For material SDS or technical assistance, contact your Asiga resellers or open a support ticket in your account online https://www.asiga.com/accounts/support/

Only use DentaBASE resin material with scanners, printers, post-curing units, design software, material ini files, bonding agents, etc, that have been specifically identified per the instructions in this document.

Processing & Post-Curing:
Ensure the 3D printer is clean prior to use, including the imaging area and any optical surfaces. Ensure the material tray is clear of solid debris prior to commencing a print. The presence of solid particles in the resin may cause deformation or failure of the printed objects.
Nitrile gloves should be worn at all times when handling Asiga liquid resins up until the finishing step. Avoid contact with skin. If contact with skin occurs, wash thoroughly with cold soapy water. If contact with eyes occur, remove any contact lenses and flush with cold water and seek immediate medical assistance.

Mixing Before Use:
In Bottle: Agitate/shake bottle vigorously prior to pouring for at least one minute.
In Material Tray: Stir material with a soft spatula. Take care not to damage the film of the Material Tray.
This step is necessary to re-disperse the (possible) pigment sediment from the bottom of the vessel.
Colour deviation and print failures may occur if insufficiently mixed.

Fill Material Tray:
Ensure the temperature of the resin is between 15 and 30°C / 59 and 86°F and prevent exposure to direct sunlight.
Pour the resin into the material tray of the 3D printer.

Printer Settings:
Asiga DentaBASE is optimised to build parts using light with 385nm wavelength.
For Printer Settings, See manual or user guides of Asiga 3D Printers (Asiga Max Series, Asiga Ultra Series or Asiga Pro Series).
Ensure the film of the Material Tray is clear of any debris before starting the print.
Ensure you are using the latest material ini file. You can access the latest material ini file for this material in your Asiga account online here: https://www.asiga.com/accounts/#tab_material

Washing:
Wash parts in at least 98% pure isopropyl alcohol (IPA) in a well ventilated area.
Best results are achieved when using a pre and post wash.

1. Using an ultrasonic cleaning device:
- Pre-wash bath: 2 minutes.
- Post-wash bath: 2 minutes.

Important: Ensure a dedicated IPA bath is used for washing DentaBASE parts. Do not wash in IPA that has previously been used for washing other materials. Allow parts to dry thoroughly before post-curing.

Post-Curing:

1. After washing and drying, let the printed parts rest for at least 30 minutes to ensure that the printed parts are free of alcohol residue.
2. Place the printed parts in UV curing unit “NK Optik Otoflash G171” for 2000 flashes.
3. Turn parts over and allow to cool.
4. Cure for a further 2000 flashes. Total: 4000 flashes (2 x 2000 flashes each side).

Post-curing is an UV-light treatment to ensure that DentaBASE printed parts obtain optimal polymer conversion. Through this the residual monomer is reduced to a minimum and the required mechanical properties are obtained. We advise use of the NK Optik Otoflash G171 post-curing box. Place parts inside the G171 Otoflash chamber on the support mesh, do not use a plastic tray inside the chamber. Inert gas is not required. Please see NK Optik Otoflash G171 user guide.

Soaking:
After post-curing, soak DentaBASE parts in fresh drinkable water at room temperature for 60 minutes.

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2797 European conformity | Medical prescription | Medical device | Single use | Health hazard | Use by date | Batch number | Product reference | Store at 15°C - 30°C | Avoid direct sunlight | Instructions for use | Caution. See references

Bonding of Teeth:
Artificial teeth printed in Asiga DentaTOOTH (supplied separately) may be bonded to Asiga DentaBASE printed parts. Artificial teeth may be bonded either before or after the post-curing step. After bonding teeth using DentaBASE as the adhesive, the post-curing & soaking processes defined above must be performed again. The following procedure is recommended: After the DentaBASE components are printed, washed and dried according to the instructions in this document, apply fresh DentaBASE liquid resin to the printed DentaBASE part where the teeth interface, and apply the teeth in place over the resin. Apply sufficient DentaBASE resin to fill the bonding gap. Wipe excess resin away with a dry lint-free cloth. Perform the post-curing and soaking steps defined in this document. Note the bonding process is to be performed at ambient temperature to ensure the correct colour is achieved.

Finishing:
Remove any support structures and finish cured parts, if necessary, using conventional dental methods and instruments. Please use specialized rotary instruments for machining and polishing plastic materials. Make sure you do not exceed the maximum rotation speed as suggested by the instrument manufacturer, during finishing. DentaBASE printed cured parts should be cleaned with water or wiped clean with ethanol.

Storage Conditions, Expiry Date & Transport:
Store the resin in the original packaging at room temperature in a dry, cool and dark area. Close the packaging after each use.
The expiry date of the product is mentioned on the product label along with the lot number.
Store in bottle for up to 36 months in a cool dark place.
The product performance is no longer guaranteed once the expiry date is exceeded. Do not expose to UV-light.
Standard transport conditions apply to this product. There are no restrictions for transport related to hazardous substances.

Waste Disposal:
Dispose any remaining resin material from the printer after use. Do not reuse leftover resin.
Asiga resin in its polymerized form is not environmentally harmful thus can be disposed of in general waste. Asiga resin in its liquid state should be treated as chemical waste. Special disposal requirements are applicable, check with your local, federal, or other regulatory agencies for disposal requirements.

Information for Dental Professionals & Patients:
Asiga DentaBASE should not be used in patients with known allergies or hypersensitivity to photopolymer resin materials. Dental professionals should check patient history before using the product to 3D print denture bases.
The following information should be transferred from dental professional to the patient.

3D Printed Denture Bases, Care and Maintenance:
The following information should be transferred from dental professional to patient:

1. Periodic check-ups by a dentist or denturist are required to monitor changes in the form & structure of the residual ridges of the patient that uses a denture.
2. In case of breakage of a denture, potential damage to the mucosa, the palate, or other parts of the patient's mouth or esophagus can occur. If this occurs, stop using the device and contact a dentist.
3. In case of an allergic reaction to the denture, discontinue use and contact a medical physician.
4. Asiga DentaBASE denture bases can be cleaned with non-aggressive & non-abrasive dental cleaning products. Inspect dentures for cracks after cleaning and discard if damage or cracks are present.
5. If significant wear or deterioration of the denture base is detected, material failure may occur and potentially cause injury. Stop using the denture and contact a dentist.
6. In case of significant discomfort associated with use of the denture, stop using the device and contact a dentist.

Device Lifetime:
Test data supports a device lifetime of 36 months for denture bases printed with DentaBASE resin. Device lifetime will vary between individual patients however devices should be replaced at least every 36 months.

Rx Only (US):
Caution: Federal law restricts this device to sale by or on the order of a dentist.

Reporting of Serious Incidents (EU):
For any serious incident that has occurred to the printed devices should be reported to the manufacturer & the competent authority of the Member State in which the user and/or patient is established.

Delivery Units:
Asiga DentaBASE is available in 1 colour only: Pink, 1kg

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