



Printer compatibility 385nm (UV)



European conformity



Medical prescription



Medical device



Health hazard



Use by date



Batch number



Product reference



Store at 15°C - 30°C



Avoid direct sunlight



Instructions for use



Caution. See references

Instructions For Use – DentaTOOTH

DentaTOOTH A1: PN/03624, DentaTOOTH A2: PN/03625, DentaTOOTH A3: PN/03626, DentaTOOTH B1: PN/03810, DentaTOOTH B2: PN/03812, DentaTOOTH B3: PN/03814.

Introduction:

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

Intended Use:

Asiga DentaTOOTH is intended exclusively for professional dental work. Asiga DentaTOOTH is a 3D print resin intended for the manufacturing of 3D printed denture teeth and temporary dental restorations. The denture teeth produced are suitable for dental indications including removable dentures. The dental restorations produced are suitable for dental indications including temporary crowns, bridges, inlays, onlays and veneers.

Description, Indications & Effects:

Asiga DentaTOOTH is intended be used in combination with DLP based 3D printers (i.e. Asiga Max 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 DentaTOOTH resin before use; insufficient post-curing.

Contra-Indications:

Asiga DentaTOOTH should not be used for any other purpose than as a 3D print resin for the manufacturing of denture teeth and dental restorations. Any deviation from this instruction for use may have an adverse effect on the chemical and physical quality of Asiga DentaTOOTH. In case of an allergic reaction, please contact a medical physician. For any serious incident that has occurred to the printed devices should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Hazard & Precautions:

Please refer to Asiga product safety data sheet for DentaTOOTH. Federal law restricts this device to sale by or on the order of a dentist. 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/>

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:

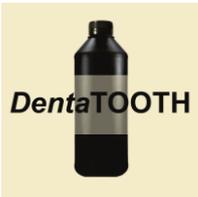
In Bottle: Agitate/shake bottle vigorously prior to pouring for at least one minute.
 In Material Tray: Stir material with a soft spatula. Take care not to damage the film of the Material Tray. This step is necessary to re-disperse the (possible) pigment sediment from the bottom of the vessel. Colour 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 DentaTOOTH 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 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



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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: 30 seconds.
 - Post-wash bath: 30 seconds.

Important: Ensure a dedicated IPA bath is used for washing DentaTOOTH parts. Do not wash in IPA that has previously been used for washing other materials. Wiping any resin residue away with a dry cloth is permitted should there be any remaining after the IPA washing steps. 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. Repeat steps 2 and 3, resulting in a total of 8000 flashes (4 x 2000 flashes).

Post-curing is an UV-light treatment to ensure that DentaTOOTH 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 DentaTOOTH parts in fresh drinkable water at room temperature for 60 minutes.

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. DentaTOOTH printed cured parts should be cleaned with water or wiped clean with ethanol.

Finishing:

Remove any support structures and finish cured parts, if necessary, using conventional dental methods and instruments. Please use specialized rotary

Bonding of Teeth:

Artificial teeth printed in Asiga DentaTOOTH may be bonded to Asiga DentaBASE (supplied separately) printed parts or prepared patient teeth. When bonding to Asiga DentaBASE, follow the instructions described in the Asiga DentaBASE Instructions for Use. When bonding to prepared patient teeth, first ensure the printed DentaTOOTH parts are post-processed using the instructions above, then follow the instructions for the bonding agent being used. Note the bonding process must be performed at ambient temperature to ensure the correct colour is achieved.

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 on printer for up to 4 weeks with hood closed or 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:

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.





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**Information for Dental Professionals & Patients:**

The following information should be transferred from dental professional to patient:

1. Periodic check-ups by a dentists 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. Contact a dentist.
3. In case of an allergic reaction, contact a medical physician. In case of concerns relating to temporary dental restorations, contact a dentist.
4. Asiga teeth made from DentaTOOTH can be cleaned with non-aggressive & non-abrasive dental cleaning products.

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 DentaTOOTH is available in Vita shades A1, A2, A3, B1, B2, B3 with capacity of 1kg.

