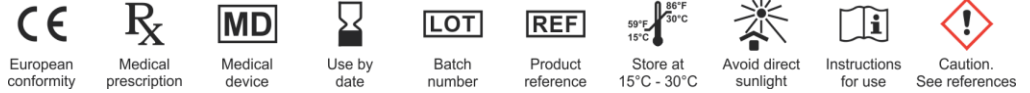




Printer compatibility 385nm (UV)



**Instructions For Use (IFU) - DentaGUIDE – Part Number / 04504**

**Introduction:**

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

**Intended Use:**

Asiga DentaGUIDE is intended exclusively for professional dental work. Asiga DentaGUIDE is a 3D print resin intended for the manufacturing of 3D printed dental surgical guides. Asiga DentaGUIDE is not intended for long term use (longer than 30 days) within the oral cavity. The surgical guides produced are suitable for all dental indications including dental implant surgical guides, crown and bridges applications. This product is CE certified for the manufacture of Class I medical devices.

**Description, Indications & Effects:**

Asiga DentaGUIDE is intended to 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 DentaGUIDE resin before use; insufficient post-curing.

**Contra-Indications:**

Asiga DentaGUIDE should not be used for any other purpose than as a 3D print resin for the manufacturing of dental surgical guides. Any deviation from this instruction for use may have an adverse effect on the chemical and physical quality of Asiga DentaGUIDE. 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 DentaGUIDE. 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 DentaGUIDE 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](https://www.asiga.com/accounts/#tab_material)



Printer compatibility 385nm (UV)



European conformity



Medical prescription



Medical device



Use by date



Batch number



Product reference



Store at 15°C - 30°C



Avoid direct sunlight



Instructions for use



Caution. See references

**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: 10 minutes.
  - Post-wash bath: 5 minutes.

Important: Ensure a dedicated IPA bath is used for washing DentaGUIDE 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 for 5 minutes then repeat. Total: 8000 flashes (4 x 2000 flashes).

Post-curing is an UV-light treatment to ensure that DentaGUIDE 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 DentaGUIDE 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. If disinfecting before intended use is required, an ethanol solution can be used. DentaGUIDE maintains its mechanical properties upon standard steam sterilisation protocol using an autoclave. It is recommended to use the following method of sterilisation:

- Place the dental surgical guide in a standard sterilisation pouch.
- Apply sterilisation by placing the pouch containing the dental surgical guide in an autoclave for 15 minutes at 121°C or 3 minutes at 134°C. Make sure no mechanical forces are applied to the guide during sterilisation.
- Let the dental surgical guide cool down to room temperature before using the device. Make sure no mechanical forces are applied to the dental surgical guide during the cooling down period.
- Please make sure that the dental surgical guide is fully post-cured before sterilisation. This is important with regard to form stability. For post-curing procedure, please see section above.

Asiga printed cured parts should be cleaned with nonchemical products.

**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.

**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 base, 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.
4. Asiga DentaGUIDE devices can be cleaned with non-aggressive & non-abrasive dental cleaning products.

**Delivery Units:**

Asiga DentaGUIDE is available in 1 colour only: Clear, 1kg.

