

# INSTRUCTIONS FOR USE - DDN GUIDE

## - SURGICAL GUIDE -

### Instructions for use

#### Description:

The DDN Surgical Guide is a dental implant guided surgery solution for partially and fully edentulous patients. The DDN Surgical Guide may be gum-supported, teeth-supported or pin-supported. The product is for single use only and is custom made for each patient.

#### Disclaimer of liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendations provided by Digital Dental Network and associated genuine implant company. Non-recommended use of products will cancel any warranty or other obligation of Digital Dental Network. The user of DDN Guide products has the duty to determine whether or not any product is suitable for each specific patient and circumstance. Digital Dental Network disclaims any liability, stated or implied, and shall have no responsibility for any damages, direct or indirect, arising out of or in connection with any errors in professional judgment or practice in the use of Digital Dental Network products. The clinician also has the duty to regularly study the latest developments regarding Digital Dental Network products and their applications. In case of doubt, the clinician shall contact Digital Dental Network. Since the processing and surgical application of this product is under the control of the clinician, they are his/her responsibility. Digital Dental Network assumes no liability whatsoever for damages arising thereof.

#### Indications:

Dental implants are to be integrated in the jawbone (osseointegration) using a surgical guide. This process is used for anchoring or supporting tooth replacements in either jaw. Restorations range from a single tooth to a fixed/removable full dental arch or overdenture applications to restore chewing function.

#### Contraindications:

It is contraindicated to proceed to a dental implant surgery for patients: deemed medically unfit for an oral surgery intervention;

- with allergies or hypersensitivity to chemical ingredients of used materials (Polymethyl methacrylate, stainless steel, or other materials used by the manufacturers of compatible guided surgery kits);
- with insufficient bone volume, unless a bone augmentation protocol can be considered;
- for whom adequate implant size, quantity and/or position cannot be achieved to provide a safe support for functional loads.

#### Instructions for clinician:

We strongly recommend that clinicians, either new or experienced in dental implantology, should ensure they are comfortable with the referred documentation before undertaking surgery using medical

devices for the first time. Digital Dental Network can provide or suggest additional documentation to help guiding the manipulations.

The clinician's judgment shall always supersede all general and/or case-specific instructions and recommendations made in any Digital Dental Network documentation.

You may contact a Digital Dental Network representative or visit for [www.digitaldentalnetwork.com.au](http://www.digitaldentalnetwork.com.au) more information.

#### General precautions/Warnings:

One hundred percent implant success can never be guaranteed. With respect to pediatric patients, routine treatment is not recommended until the end of the jawbone growth has been properly documented. Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation. It is strongly recommended that Digital Dental Network products are used only with the compatible products mentioned in this document. Combining components that are not deemed compatible by Digital Dental Network can lead to mechanical instrument failure, patient harm or unsatisfactory results.

Do not use the product if altered.

#### Precautions/Warnings – Pre-surgery:

A careful clinical and radiological examination of the patient must be performed prior to surgery treatment planning to determine the psychological as well as physical condition of the patient. Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of their bone or soft tissue (e.g., cigarette smoking, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships, reappraisal of the treatment option may be considered. Bone augmentation process shall be performed before planning the implant surgery.

#### Precautions/Warnings – During Surgery:

Maximum attention must be paid to ensure that the surgical guide does not move in any direction from the intended position when being manipulated with instruments.

Since the surgical guide's geometry is patient-specific, areas of weakness may appear and precaution must be taken to minimize flexural loads and prevent breakage.

Precaution must be taken to ensure no instruments fall into the patient's throat.

#### Precautions/Warnings – Post-surgery:

The clinician is advised to provide patients with regular follow up examinations and to inform them about good oral hygiene practice.

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### Compatibility :

DDN Guide has full compatibility with over 50 GENUINE implant manufacturers and with 3000 implants and guided surgery kits based on which a DDN I Guide may be designed. The choice of the compatible guided surgery kit is left to the clinician 's discretion and must be pre-determined during the treatment planning phase. The compatible guided surgery kit's instructions for use, to be obtained from the manufacturer, shall be consulted prior to its use together with the Digital Dental Network and the DDN Guide. Compatibility include but not limited to

- Straumann, Neodent, Biohorizons, Neoss, Nobel, MIS, Southern Dental Implants, Zimmer, Megagen, Osstem

### Cleaning and Disinfection

Below are instructions for the cleaning and disinfection of DDN Guides. For more information, please contact Digital Dental Network for cleaning and sterilisation protocols (infection control).

### Warnings:

All DDN Guides are delivered non-sterile and are for single use only. Surgical guides must be cleaned and disinfected before use.

### Limitation on reprocessing:

If the surgical guide is visibly damaged or has undergone any unwanted modification, please contact Digital Dental Network.

### Manual cleaning and disinfection:

- Gamma sterilization using a dose of 25–50 kGy
- Steam sterilization for four (4) minutes at 132 °C (270 °F) with fractionated pre-vacuum.
- Completely immerse in a 2% Chlorhexidine solution for 10 minutes at room temperature prior to surgery.

### Rinsing:

Following removal from the Chlorhexidine solution, thoroughly rinse the guide by immersing it completely in a large volume of sterile water.

Keep the guide totally immersed for a minimum of 1 minute.

Manually flush with large volumes (not less than 100 mL) of rinse water.

Remove the guide and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.

Repeat the procedure two (2) additional times, for a total of three (3) rinses, with large volumes of fresh water to remove Chlorohexidine residues. Residues may cause serious effects. Refer to the Chlorohexidine instructions for use for more details.









### Maintenance, inspection and testing:

Make a visual inspection for cleanliness with magnifying glasses. If necessary, perform reprocessing process again until the guide is visibly clean.

### Storage:

Store the sterilised guide in a clean, dry and dust free environment at modest temperatures of 5°C to 40°C / 41°F to 104°F.

### Symbol Glossary

	Use-by date
	Fragile, handle with care
	Consult instructions for use
	Keep away from heat
	Do not re-use
	Upper Temperature limit
	The device has not been subjected to a sterilization process
	Batch code