DECLARATION OF CONFORMITY FOR CUSTOM-MADE MEDICAL DEVICE

The SMART way of implant placement

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DECLARATION OF CONFORMITY FOR CUSTOM-MADE MEDICAL DEVICE

Manufacturer: **Dicomlab Dental Ltd.**

Registered office: HU-6726 Szeged, Szent-Györgyi Albert u. 2.

I hereby declare that this dental implant surgical guide**,**

ID:

as a custom-made medical device

complies with

the general requirements specified in Annex XII of the Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and is capable of the performance intended by the manufacturer.

I declare that this device has been pecifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. I declare that I have fulfilled my legal obligation as an economic operator to register this device.

I declare that this device complies with the General Safety and Performance Requirements specifief in MDR Annex I.

Pursuant to MDR Annex XIII, I keep available for the competent national authorities documentation that indicates the device's manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of MDR.

Pursuant to Chapter II Article 2 (8) of MDR, I shall keep this Declaration of Conformity available for the competent authorities for a period of at least 10 years after the last device covered by this Declaration of Conformity has been placed on the market.

Pursuant to Chapter VII, Section 2, Article 87 (1) of MDR, I shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88.

Szeged, 06.12.2023.

Dr. Varga Endre
CEO

Valid from 06.12.2023. (version: v03)

SMART GUIDE DENTAL IMPLANT

SURGICAL GUIDE INSTRUCTIONS FOR USE

Contents of the SMART Guide dental implant surgical guide package:

- Instructions for Use
- Surgical protocol
- Implantation guide
- Declaration of Conformity

Read the instructions carefully before use.

CHECKLIST

- Check the integrity of the packaging and implant guide.
- Make sure that the identifiers on the implantation guide and the individual surgical protocol match.
- Check the fit of the implantation guide.
- Check the condition of the sleeves and the accessibility of the sleeves.

SMART GUIDE SURGICAL GUIDE CLEANING AND STERILIZATION

The surgical guide is not shipped sterile. Clean and sterilize the device as per the instructions before use.

Attention! Use of a non-sterile device can lead to infection.

Caution! The SMART GUIDE surgical guide is a single-use product and must not be reused. Reuse may cause changes in mechanical, chemical and/or biological properties and may cause cross-contamination.

Cleaning suggestion:

1. Remove the guide from the packaging pouch.
2. Place in 3% Gigasept solution for 15 minutes
3. Rinse thoroughly in distilled water
4. Allow the guide to dry.
5. Place the cleaned guide in an autoclavable bag.

Do not put in a dishwasher or use thermal disinfection.

Sterilization recommendations:

1. Place the guide bag in the autoclave for 15 minutes at 121°C (249.8°F) or 3 minutes at 134°C (273.2°F).
2. During sterilization, make sure that no physical pressure is applied to the guide.
3. Allow the guide to cool to room temperature before use.
4. Please make sure that the guide is not physically impacted during the re-cooling process.
5. Heat changes the color of the material, which does not affect its quality.
6. Please do not deviate from the recommended sterilization! This may cause deformation of the guide.

CHECKING THE FIT

Check the fit of the implantation guide in the surgical site before use.

In the case of edentulous jaws, the guide will show the soft tissue whitening under pressure. In the case of partial missing teeth, the fit checking windows help.

If necessary, you may remove material from the implantation guide, as long as it does not interfere with its interior, dimensional stability or its fit. WARNING: You may make such modifications at your own professional discretion and at your own risk. WARNING: Do not make any modifications to the sleeve!

SURGICAL PROTOCOL

The surgical protocol helps you and your assistant to prepare for surgery and contains all the information you need for the preparation of the bone socket for the implant. All surgical protocols are automatically generated based on your surgical plan and uploaded to the SMART Cloud online platform, so they are available to you on a digital display during surgery.

If the surgical protocol is followed, the surgery is performed safely and easily with the SMART Guide implantation guide.

The surgical protocol includes:

- the name and identifier of the case
- the name of physician
- the image of the implantation guide
- the description of the surgical instruments
- the type and size of the planned implants
- a table summarizing the surgical plan

The devices and implants indicated in the surgical protocol correspond to those defined in the patient-specific plan created in the SMART Guide planning software module.

STORAGE

- Keep and transport SMART Guide implantation guide only in its original packaging.
- Store the implantation guide in a dry, dark place, out of direct sunlight.

QUALITY

All SMART Guide dental implant surgery guides are made exclusively at Dicomlab Dental Ltd. Both the digital design and the physical production of implantation guides are carried out according to strict requirements and audited processes and protocols. SMART Guide dental implant surgical guides have the appropriate medical certifications and undergo strict quality control.

- - The implantation guide is shipped in non-sterile protective packaging.
- - The implantation guide's material properties may be altered by UV light.

The user must report a serious adverse event involving the medical device to the manufacturer and to the competent authority of the Member State where the user is established.

MANUFACTURER'S INFORMATION

The device is a custom-made, non-sterile, non-active, non-implantable device. It is designed for continuous use in the oral cavity for less than 60 minutes under normal conditions.

Device name

SMART Guide dental implant surgical guide

Manufacturer's name and address

Dicomlab Dental Ltd., H-6726 Szeged, Szent-Györgyi Albert street 2.

Purpose of the device, indications, contra-indications

The purpose of the device is to facilitate dental implant surgery in a patient-specific manner. The device is designed by the user in the SMART Guide surgical planning software module on a case-by-case basis for a specific patient. The device is used exclusively for dental implantation and the indications and contraindications are the same as for dental implantation. No device-specific contraindications are known.

Adverse reactions

If the device is in close and direct contact with soft tissues for prolonged periods of time, the physical contact may cause mild local irritation, especially at pressure points and in susceptible individuals. After removal of the device, this side effect resolves spontaneously within 1 hour and does not otherwise affect the patient's health.

Printing material

NextDent SG
NextDent SG is a biocompatible printing material specifically designed for printing dental implant surgery guides, which is a medical device classified as a Class I risk according to Regulation 745/2017 (EU) MDR. Its chemical composition is that of an acrylic acid ester, a monomeric liquid that polymerises to a solid state during the printing process.

Patient group

The product can be used for dental implant treatment in patients with complete or partial tooth loss.

Application

For dental use only!
The device should only be used by a qualified dental implantologist, following the general guidelines of dental implantology practice, in accordance with the surgical protocol for the device. ATTENTION! The device is custom-made according to the anatomy of the patient and can therefore only be used for the patient for whom it is intended. ATTENTION! The procedural protocol for this custom-made device may only be used in combination with a device with the same identification number as shown on the protocol. Always check that the protocol and device ID number match before use. The use of a device and protocol with different identification numbers can lead to property damage, accidents, injuries, or permanent health damage! WARNING! Use surgical guide only with the surgical kit specified in the surgical plan and protocol, use of other devices may lead to malfunction or accident! WARNING! Always check the fit of the drill bits to be used in the sleeve and their free movement in the sleeve before starting the operation! If the drill bit cannot be inserted perpendicularly into the sleeve or cannot be moved freely, do not force the insertion, and do not start the operation! Always insert the drill bits perpendicularly into the sleeves during surgery, avoid inserting them at an angle, or forcing the drill bits, as this may damage the instruments and cause the surgery to fail.

Clinical benefits

The clinically proven benefit of using this device is that it significantly improves the accuracy of dental implant placement (the correspondence between the planned position and the actual position) compared to conventional free-hand placement, especially regarding angular misalignment. The device can optionally minimize the invasiveness of the surgical intervention if transgingival access preparation is applied.

Risks

The only known risk associated with the use of the device, which is documented in the literature, is that, depending on the patient's anatomy, the device may have weak points in the material during manufacture, which could cause the device to break. Although the incidence of this is extremely low according to the international literature, it is advisable to verify the structural stability of the device before it is placed in the oral cavity, e.g. by placing it on a plaster cast of the patient's dentition and simulating the fixation of the appliance during surgery. This procedure can prevent breakage of the device in the patient's oral cavity. If the device does break under these circumstances, there is no additional health risk to the patient, but the device should be removed from the oral cavity immediately and the surgery postponed or completed without the use of the device, depending on the progress of the procedure.

Disposal of the guide

The guide is not considered hazardous waste before use.
After use, their disposal shall be subject to the hazardous waste legislation.

Date of publication of this user manual 06. 12. 2023. (v08)

Product markings

	Manufacturer name, address
	Non sterile device
	Single use only
	Fragile
	Instruction for Use
	Production time
	Expiry date
	Serial number (ABC123)
	Autoclavable at 134 °C
	Medical device