

INSTRUCTIONS FOR USE – Dental Instruments / Tools



Manufacturer:

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INDICATIONS FOR USE

The TAG Dental by NOGA Medical (here and after referred to as “TAG”) Implant Systems are intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. TAG’s Instruments/tools are intended to be used for dental implant placement procedures in the bone of the upper or lower jaw arches, and in prosthetic restoration. The instruments are intended to provide the dental surgeon the ability to manipulate, prepare, and adjust the dental implants and associated accessories during implantation/restoration procedures.

CONTRAINDICATIONS

- TAG instruments/tools Should be used only by practitioners who are licensed and trained to perform these procedures.
- Surgical & Dental Instruments should not be used for anything other than their intended use.
- All contraindications relevant to oral surgery, apply for cases of implant placement procedures. For details, please refer to NOGA implants instructions for use

WARNINGS AND PRECAUTIONS

- Inform us and your competent authority in the case of notice of life-threatening incidents or a severe deterioration in health status related to one of our products
- Carefully read these instructions. The sale and use of this device is restricted to, or by the order of, licensed dentist.
- Devices shall be used in accordance with these instructions for use.
- The instruments are supplied non-sterile and must be cleaned and sterilized prior to use according to the cleaning and sterilization instructions.
- Use of non-sterile components may lead to infection of tissues or infectious diseases.
- All instruments used in surgery must be maintained in good condition and care must be taken that the instruments do not damage the implants or other components.
- improper care and maintenance of the device may cause injury to the patient.
- Inappropriate use of instruments may result in damaged or broken instruments.
- Proper cleaning, handling, sterilization and standard routine maintenance will ensure that the instruments perform as intended and will extend their useful life.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.
- Instruments manufactured from different metals or with special coating, should be processed separately to avoid electrolytic action between the different metals.
- Before use, inspect the instruments for possible damage, wear or non-functioning parts.
- Damaged or defective instruments should not be used or processed.
- Allergy or hypersensitivity to material used is possible.
- Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry.
- Replace instruments after a maximum of 10 uses or when damaged or dull.

RISKS

Drill breakage, drill deformation, damage to product’s surface, damage to the bone, nerve injuries, and thermal tissue damage.

MATERIALS

Surgical invasive dental instruments are made of stainless steel or titanium alloy. Other instruments/ tooling are made of biocompatible materials such as Acetal, PEEK, Rilsan, CrCo and Gold.

CLEANING AND STERILIZATION INSTRUCTIONS

These cleaning and sterilization instructions have been validated for preparing reusable instruments for further use. It is the responsibility of the end user to ensure that the cleaning and sterilization is actually performed using appropriate equipment, materials, and personnel to achieve the desired result.

Preparation

- Clean instruments as soon as possible after use.
- Remove excessive soil with a disposable wipe or brush.

Note: Prior to sterilization, instruments should be cleaned as described below.

MANUAL CLEANING

Cleaning Instructions

- Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions.
- Soak soiled instruments for a minimum of 10 minutes. Do not exceed 30°C.
- When cleaning, fully immerse the instrument in the cleaning solution to avoid aerosol generation. Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices. When cleaning Instruments with cannulations or lumens (i.e. tubes), or holes, use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the cannula, lumen, or hole. Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic cleaning solution to flush hard to reach internal areas. When cleaning articulating instruments, (those with moveable parts), brush with a soft non-metallic bristle brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features, to free trapped blood and debris. If the components of the instrument can be retracted, retract or open the part while cleaning the area. For instruments with flexible shafts, flex the instrument under the cleaning solution.

Rinsing Instructions

Rinse the instrument thoroughly with filtered water at 38–49°C, agitate for a minimum of 1 minute; repeat rinse at least two additional times. When rinsing, pay particular attention to flush the cannulations, lumens, or holes with warm tap water. Also pay particular attention to internal areas and moveable parts. Actuate moveable parts while rinsing. If the components of the instrument can be retracted, retract or open the part while rinsing the area.

For instruments with flexible shafts, flex the instrument under the rinse solution.

Drying Instructions

Dry the instrument immediately after final rinse. Use filtered compressed air to dry internal areas.

INSPECTION AFTER CLEANING

- Inspect all instruments before sterilization or storage to ensure the complete removal of soil from surfaces, tubes and holes, moveable parts.
- If soil is still present, re-clean the instrument.

INSPECTION AND FUNCTIONAL TESTING

- Visually inspect the instrument and check for damage and wear.
- Cutting edges should be free of nicks and have a continuous edge.
- Jaws and teeth should align properly.
- Moveable parts should have smooth movement without excessive play.
- Locking mechanisms should fasten securely and close easily.
- Long, thin instruments should be free of bending and distortion.

STERILIZATION

- The TAG instruments are supplied non-sterile and must be sterilized before use.
- Package trays/instruments with a barrier wrap material in accordance with local procedures, using approved standardized wrapping.
- Use a validated, properly maintained and calibrated steam sterilizer.
- Effective steam sterilization can be achieved using the following cycles:

Cycle Type Temperature Minimum Exposure Time

Gravity 134°C for 10 minutes; Drying time: 40min

Pre-vacuum 134°C for 3 minutes; Drying time: 20min

STORAGE



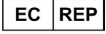












Store the sterilized instruments dry and dust-free place, at room temperature.

DISPOSAL

The instruments are to be disposed of as per legislation of the relevant user country.

LABELING

Symbols on the product package and labels should be interpreted as follows

							
Consult instructions for use: eIFU: www.tagdent.com/ifu	Manufacturer	Authorized Representative in the European Community	Number of units	CE Mark for Class IIa Products	CE Mark for Class I Products	Medical device	Non-Sterile
							
Do not use if package is damaged	Date of manufacture	Lot Number	Catalogue No.	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician		Unique device identifier	Do Not Reuse