

INSTRUCTIONS FOR USE – Dental Superstructure / Abutments



Manufacturer:

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INDICATIONS FOR USE

The TAG Dental by NOGA Medical (here and after refers to as “TAG”) Implant Systems are intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. Angular and straight abutments are designed for both single tooth and bridges (more than one tooth) Standard and angular multi-unit abutments are intended for use to support multiple tooth prosthesis in the mandible or maxilla.

Healing caps and cover screws are intended for use with the implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Ball attachment are designed for removable dentures.

A summary of the safety and clinical performance (SSCP) can be found at TAG Dental by NOGA Medical website <https://tagdent.com/> or upon request to Noga Medical's mailbox at info@nogamed.com.

CONTRAINDICATIONS

General contraindications associated with elective surgery should be observed.

Allergic or hypersensitive response to Ti-6Al-4V alloy (titanium, aluminum, vanadium).

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.
- Superstructures/Abutments should be placed and restored only by practitioners who are licensed and trained to perform these procedures.
- TAG's Superstructures/Abutments have not been evaluated for safety and compatibility in the MR environment. TAG's Superstructures/Abutments have not been tested for heating or migration in the MR environment.
- The only allowed modification to the abutments is to shorten the abutment approximately 2mm below to the height of adjacent teeth. Do not shorten the abutment to length less than 4 mm due to the concern of prosthetic retention.
- Plastic cylinder with Ti base is intended to be casted straight only.

ABUTMENT INSTALLMENT PROCEDURE

- Remove the healing abutments or cover screws with a hex screwdriver. Now implants are visible and the relevant abutment can be installed.
- Verify that the selected abutment is the one required for installation.
- Insert the abutment into the implant, securing it with a light finger pressure, and fix it with a screwdriver and hex wrench and ratchet torque at 30-35Ncm.

Abutments	Type	Range
Healing cap/ anatomic healing cap		-5/5.8mm diameter H up to 6mm
Straight abutment	Straight	4/5/5.8 mm diameter H up to 6mm
Temporary abutment	Straight	H up to 3mm
	Angulated	Up to 25° H up to 3mm
Angled abutment	Angulated	Up to 25° H up to 3mm
Angled with shoulder abutment	Esthetic	Up to 25° H up to 3mm
Ball Attachment	Straight and Angulated	Up to 30° H up to 4mm
Equator abutment	Straight	H up to 5mm
Ti base abutment	Straight	H up to 3mm
Castable abutment with Ti/gold/CoCr/acetal base	Castable	Various

Abutments	Type	Range
Multi-unit Angled abutment	Straight and Angulated	Up to 30° H up to 4mm

MULTI-UNIT ABUTMENTS

The Multi-Unit abutments are intended to provide edentulous patients with an efficient and effective restoration using only four or six implants to support full-arch prosthesis.

Follow casting and burnout instructions as recommended for abutments. Multi-Unit plastic cylinder is intended to be casted straight only and connected to the multi-unit abutment.

CAD/CAM ABUTMENTS

TAG's Milling abutments for CAD/CAM are intended to be used in conjunction with NOGA Medical system dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.

EQUATOR ABUTMENT

The self-locating design allows a patient to easily seat their denture. The overdenture abutments are intended for single use on a single patient

RECOMMENDED CASTING PROCEDURE

• Waxing Procedure

Place the plastic sleeve on top of the analog in the model and secure it with the abutment screw. If necessary, shorten the plastic so there is approximately 2 mm of clearance with the opposing dentition and approximately 2 mm below to the height of adjacent teeth.

The minimum abutment length must be 4 mm. Once the correct occlusal height is achieved, proceed with conventional crown and bridge waxing procedures.

• Burnout & casting

Follow casting and burnout instructions as recommended by the dental alloy manufacturer.

It is recommended that the final restoration be placed using a 30-35Ncm torque.

The use of burn-out should follow state-of-the-art dental lab technician common practice.

FOLLOW UP CARE

- Patients should be instructed in appropriate oral hygiene and care of the implants and restorations.
- Periodic follow up appointments should be made to confirm and maintain adequate function of the implants and the health of the surrounding tissues.

STERILIZATION

- The TAG Abutments are supplied non-sterile for single use 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

Pre-vacuum 132°C for 4 minutes; Drying time: 15min

Pre-vacuum 134–135°C for 3 minutes; Drying time: 15min

LABELING

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

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