INSTRUCTIONS FOR USE - DENTAL IMPLANTS

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This document applies to TAG Dental by NOGA Medical Dental Implants (Massif, Axis, Crestone, RobiCone)

INDICATIONS FOR USE

The TAG Dental by NOGA Medical (here and after refers to as "TAG Dental") Implant Systems are intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
A summary of the safety and clinical performance (SSCP) for TAG Dental implants by NOGA Medical 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.

DEVICE DESCRIPTION

TAG Dental implants are intended for surgical placement in the upper or lower jaw, for supporting the single or partially edentulous Mandibular and/or Maxillary Alveolar process. The implants are appropriate for immediate loading, when sufficient primary stability is achieved along with appropriate Occlusal loading.
The implants are manufactured from biocompatible materials (Titanium Alloy - TI 6AL 4V ELI), and went through special surface treatment, as part of the manufacturing process.
The implants are supplied sterile (single-use) and ready for use, subjected to expiration date. Each implant is provided with cover screw component inside its sterile package.
The intended users are qualified and authorized dental surgeons, skillful and knowledgeable in required restoration techniques.
The patient target groups are persons with adult jaws to whom none of the contraindications apply that are related to dental implantations.
The implants family consists of 4 (four) sub-families and includes the following implants types:
Axis - self-tapping, conical, screw typed implant.
Crestone – self-tapping, one piece, screw type implant.
Massif - self-tapping, conical, screw typed implant.
RobiCone - self-tapping, conical, screw typed implant.

TAG Dental implants are to be used in combination with cover screws, healing caps and abutments for prosthetic reconstruction. It is highly recommended to use only original TAG Dental prosthetic parts with TAG Dental implants.

CONTRAINDICATIONS

TAG Dental implants should not be used in patients who have contraindicating systemic or uncontrolled local diseases such as:
Cardiovascular disorders associated with high endocarditic risk, Coronary insufficiency, Cancers and radiation of the facial region in the past five years, weakened immune system, Diabetes, Bone metabolism disorders, Hemophilia, Poor general state of health, inadequate wound healing capacity, maxillary and mandibular growth not completed, unfavorable anatomic bone conditions, Periodontal disease, Poor oral hygiene, bruxism, Inadequate bone or blood supply, Unrealistic patient expectations or poor patient motivation, Psychological disorders, Smoking, Drug abuse or alcoholism, Steroid use, Allergy to Titanium, Aluminum or Vanadium.

TEMPORARY CONTRAINDICATIONS

- Systemic infection, local oral and respiratory infection
- Anatomical or Pathological implications such as; Insufficient alveolar bone width and height to surround the implant with at least 1.5 millimeters of bone; Inadequate bone height where proper implant placement would encroach within 2mm of the mandibular canal, sinus floor, etc.
- Malignancies
- Pregnancy
- Inadequate bone volume unless augmentation procedure can be considered.

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.
- Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures.
- Adequate preoperative studies should be performed to examine the anatomic structures and to assess the biomechanical, functional, and esthetic requirements of each case.
- Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis.
- Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success.
- Risks of implant placement and restoration include, but are not limited to: infection, implant failure, loss of bone and soft tissue, unfavorable aesthetic result, anesthesia, dysesthesia and paresthesia in the oral and facial areas, sinus infection, dislodgement of implants and instruments in the surrounding structures, damage to adjacent teeth, non-restorable implants, fracture of implants or restorative components, and loosening of implants or restorative components.
- Patients must be informed of all potential risks and provide a conscious, written consent for the procedure.
- Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant.
- It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin or other injuries.
- Each implant system has specific design characteristics for mating implants, abutments, prosthetic components, and instrumentation. Combining instruments and components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory aesthetic results.
- The **Crestone and 3.3 mm implants** are indicated for placement in the incisor region, the Crestone implants are not intended to provide an angle correction.
- One-hundred percent success cannot be guaranteed. Lack of adequate quantity and/or quality of remaining bone, infection, inadequate surgical technique, poor patient oral hygiene and generalized disease are some potential causes for failure of osseointegration. Both, immediately after surgery or after osseointegration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable implant angulation.
- With respect to children, routine treatment is not recommended until completion of alveolar growth has been verified.
- The TAG Dental implants and accessories have not been evaluated for safety and compatibility in the MR environment. The TAG Dental implants and accessories have not been tested for heating or migration in the MR environment.
- All efforts must be made to minimize damage to the host tissue. In particular special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection.
- The surgical procedure requires a high degree of precision and care. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration.
- Please refer to our web site for the specific sequence of drills for each implant type and size. Special care should be taken to avoid over or under preparation of the osteotomy.
  Implants should be inserted in such a way that they are stable and lack any mobility.
- 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.
- Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry.
- After the implant installation, the surgeon’s evaluation of bone quality and initial stability will determine when implants may be loaded.
- An appropriate follow-up protocol should be followed.
- Implants are supplied sterile and are for single use only - DO NOT RESTERILIZE.
- Reprocessing the Implant may result in biocontamination, degraded performance or loss of function.
- Do not use after the expiration date.
- Do not use an implant if it has been opened (i.e.: the shrink-wrap was tampered) or the packaging has been

damaged.
- If tampering or damage exists contact your TAG Dental Representative.
- The only allowed modification to the abutments is to shorten the abutment approximately 2 mm 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.

INSTRUCTION FOR OPENING THE IMPLANT PACKAGE

The implant is packed in a double tube placed inside a carton box containing labels.

1. Open the carton box and take out the implant tube.
2. Remove the shrink-wrap that wraps the implant tube (shrink-wrap ensures the implant was not previously opened).
3. Carefully open the outer tube by turning the cap and pull to open the cap (the O-ring located inside the cap ensures the sealing of the tube).
4. Drop the sterile inner sleeve into a sterile area.
5. The implant is located inside the sleeve, hold the sleeve straight and carefully turn the white cap and pull to open it.
6. Connect an insertion tool to a contra angle (for motor insertion) or to a ratchet (for manual insertion). Use the assembly for removing the implant from the sleeve.
7. The cover screw located in the white cap can be removed with a screwdriver by turning gently counter-clockwise.

IMPLANT INSTALLMENT

For recommended surgical procedures please refer to surgical protocol as described in product catalogue. Follow the detailed recommended drilling sequence below.
Recommended implant insertion torque: 35-60Ncm. Avoid excessive force when placing the implant into the osteotomy.
In case the implant gets stuck during installation or max. torque is achieved before fully seated, rotate the implant counter-clockwise using drilling machine in reverse mode or manual torque wrench to release the resistance of insertion and continue the installation with back and forward rotation.

STERILIZATION

The TAG Dental implants are supplied sterile by gamma radiation for single use.

MATERIALS

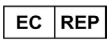
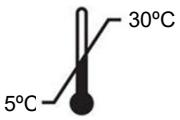
TAG Dental implants are made out of medical grade titanium alloy.

DISPOSAL

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

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	Date of manufacture	Do not resterilize	Sterilized using gamma irradiation Single sterile barrier system
									
Do not use if package is damaged	Use-by date	Lot Number	Catalogue No.	Number of units	Unique device identifier	Temperature limit		Keep dry	Keep away from sunlight

IMPLANTS RECOMMENDED DRILLING SEQUENCE

AXIS / ROBICONE

Drill RPM *	Implant Diameter (mm)					Bone Type
	3.3	3.75	4.2	5	6	
1500-1200	Marking drill ⌀1.9					D3-D4 Soft Bone
1200-900	Pilot drill ⌀2					
700-500	Twist drill ⌀ 2.5	Twist drill ⌀ 2.8				
600-400			Conical drill ⌀3.2			
500-300				Conical drill ⌀3.8		
400-200					Conical drill ⌀4.5	
**	2.8	Conical drill ⌀3.2	Conical drill ⌀3.8	Conical drill ⌀4.5	Conical drill ⌀5	D1-D2 Hard Bone
300-200		Contersink ⌀3.75	Contersink ⌀4.2	Contersink ⌀5	Contersink ⌀6	

MASSIF

Drill RPM *	Implant Diameter (mm)				Bone Type
	3.75	4.2	5	6	
1500-1200	Marking drill ⌀1.9				D3-D4 Soft bone
1200-900	Pilot drill ⌀2				
700-500	Twist drill ⌀ 2.8				
600-400		Twist drill ⌀ 3.2			
500-300			Twist drill ⌀3.8		
400-200				Twist drill ⌀4.5	
400-200				Twist drill ⌀5	
**	Twist drill ⌀3.2	Twist drill ⌀3.8	Twist drill ⌀4.5	Twist drill ⌀5.5	D1-D2 Hard Bone
300-200	Contersink ⌀ 3.75	Contersink ⌀4.2	Contersink ⌀ 5	Contersink ⌀ 6	

CRESTONE

Drill RPM *	Implant Diameter (mm)		Bone Type
	3	3.5	
1500-1200	Marking drill ⌀ 1.9 mm		D3-D4 Soft bone
1200-900	Pilot drill ⌀ 2mm		
700-500	Twist drill ⌀ 2.5mm		
500-300		Twist drill ⌀ 2.8mm	
500-301	2.8	3.2	D1-D2 Hard Bone

All procedures do not replace the professional judgement of the surgeon

* Drill RPM range is only a recommendation

** Recommended Drill RPM range depends on the diameter of the drill