1. Definition

Naxis Implants is a dental implant system that covers a wide range of implants made in medical grade titanium component. Naxis Implants are designed to be surgically placed in the upper or lower jaw and serve as the basis for tooth restoration and to replace the root of the tooth. The implant, consisting of the implant itself and the closing screw, is packaged in a titanium tube, followed by a blister pack under clean room conditions, and sterilized by gamma rays. Abutments, healing caps and superstructures are attached to the implant to hold the prosthesis in the jaws of patients with partial or complete tooth loss.

Abutments, healing caps, transfers, analogues, suprastructures and accessories are shipped non-sterile.

2. Operating Instructions

The main condition for a successful implant procedure; the bone is suitable for the implant in terms of both height and width and can lift this process.

Information about these dimensions can be obtained from the tomography scan image of the implant site using traditional methods necessary for successful implant operation.

Moreover; The surgeon should carefully examine the blood vessels, bones, upper sinus, nasal cavity, all soft tissue spaces in the area to be implanted, and their location relative to the targeted implant site.

The implant procedure should be performed in a sterile environment using sterile surgical instruments. It is recommended to use physiodispensers, depth gauges and direction indicators. Insert the implant into the prepared bone cavity. Take the surgical torque pad and insert the implant screwdriver piece included in the surgical kit into the ratchet. Continue screwing the implant clockwise until the implant is fully embedded. Remove the implant screwdriver from the scabbard, attach the implant cap, and suture the surgical site.

Naxis Implants can only be used with abutments and superstructures manufactured by Naxis Medikal.

Caution: The abutment height should not be less than 4mm for a single unit restoration. Angular corrections cannot be made on cast "superstructures" (eg PTA and PH).

Due to the small size of the prosthetic components, a high level of care must be exercised to avoid accidental ingestion or aspiration by the patient.

3. Indications

Naxis Implants is a dental implant system that aims to surgically replace crowns, bridges or dentures in edentulous patients in the maxilla and/or mandible arch. It aims to support prosthetic devices such as dentures and restore the patient's chewing functions. The system is designed for use in single tooth application or multiple tooth applications. Prostheses can be screwed or cemented to the abutment. Naxis Implants dental implant system can be loaded immediately if primary stability requirements are met.

4. Contraindications

Contraindications specific to oral surgery with other implant materials should be observed. These include patients taking corticosteroids or anticonvulsants, and patients receiving radiation therapy or other immunosuppressive treatments. Breastfeeding or pregnant women, or people with abnormal BUN, creatinine, or serum calcium values

are not suitable candidates. Patients with diabetes, cardiovascular disease, hypertension above 170/110 mm Hg, crush fracture due to osteoporosis, respiratory disease, thyroid or parathyroid disease, as well as patients diagnosed with a malignant tumor within five years or with nodule enlargement, tenderness or unexplained lump or head or neck People with masses in the region should also be excluded. It cannot be applied in patients with edema, pain in the lymph nodes, and protrusions in the head and neck region. Implant procedures should not be performed in individuals with active osteolytic, inflammation, or infection in the implant area. Below is a list of contraindicated items:

- Disabling or uncontrollable diseases,
- Pregnancy, hemophilia, anemia or other bleeding problems, steroid use, prophylactic antibiotics, fragile diabetes, Ehlers-Danlos syndrome,
- Osteoradionecrosis, renal failure, organ transplantation, anticoagulant therapy, unexplained hypersensitivity, fibrous dysplasia, regional enteritis,
- The practitioner has not received adequate training,
- Conditions, diseases, or treatments that significantly reduce recovery, e.g. radiation therapy,
- Psychiatric diseases that prevent the patient from understanding and complying with the necessary procedures,
- Unrealistic patient expectations. Inaccessible prosthodontic reconstruction, inability of the patient to provide oral hygiene for a long time,
- Intense tobacco use
- The patient has hypersensitivity to certain components of the implant,

5. Risk

The risks associated with the surgical procedure fall into four main categories:

1. Instant anesthesia and surgery risks
2. Psychological and psychiatric risks
3. Medical threats with long-term involvement
4. Long-term toxic effects of implants on health

Below is a list of pathophysiological problems that can occur in the different systems of the human body that may affect the potential risk.

a. Heart failure, coronary artery diseases, deterioration of heart rhythm.
b. chronic wheezing disease
c. Diseases of the digestive system, hepatitis, insufficient absorption, infectious diseases of the intestinal tract.
d. Nephratonia and urinary tract diseases.
e. Endocrine diseases, diabetes, thyroid diseases, adrenal body and basal glands.
f. Hematological diseases, anemia, leukemia, coagulation problems.
g. Muscoskeletal system diseases, arthritis and osteoporosis.
h. Neurological disorders, apolectic seizure, Parkinson's disease and mental retardation.

6. Important warning

Inadequate training of the practitioner is the main risk factor for the success of the implant procedure and can endanger the patient's health. For this reason, implant procedures should not be performed without receiving appropriate training from a certified institution.

Measures

1. If the implant or packaging appears damaged or has been opened, or if sterility is questioned for any reason, the implant **MUST NOT be used.**
2. The implant is offered for single use. **DO NOT USE RE-STERILIZED.**
3. Implant use may require pre-operative antibiotic prophylaxis.
4. It is known that titanium reacts with fluoride in fluoride toothpastes. The use of fluoride toothpaste is not recommended in patients who have had implants.
5. Small diameter implants and angled abutments are not recommended in the molar region of the mouth.
6. Naxis Implants dental implant systems have not been evaluated for safety and compatibility in the MR environment. Naxis Implants dental implant systems have not been evaluated for heat or displacement in the MR environment.
7. Since our product carries the risk of infection after use, it should be considered as medical waste.

7. Storage

8. Sterilization

The implant is in sterile packaging. Products should be used sterile. The box cover should not be opened in any way before the moment of use. The implant has been sterilized by Gamma Irradiation.

DO NOT AGAIN STERILE PRODUCTS!!

Set parts are not sterile.

9. Storage and Transport

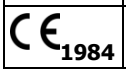
Products should be kept in their original packaging. In case of damage to the sterile tube, the product should not be used. Implants should be stored in a dry place away from direct sunlight and the upper temperature limit value is 23°C. Improper storage methods can lead to material and design damage and device failure. See labels for specific storage and handling rules.

10. Limited Warranty

For re-implantation in failed implant cases, Naxis Medikal will provide free implants to the patient under the following conditions:

In the 6-month period following the first signs of implantation failure, Naxis Medikal will provide a new implant when written notification of this failed implantation and the form approved by the manufacturer company and follow-up inspection document, appropriate x-ray films showing the patient's oral cavity and the rejected implant are sent.

11. Explanation of Marks Used on the Label

	It is disposable.
	Read the contents of the package before use
	Keep away from direct sunlight
	Device sterilized using irradiation
	Do not disturb the sterility
	Do not use if package is damaged
	Store in dry place
	Upper temperature limit value 23°C
	Attention
	Producer
	Party Code
	Catalog Number
	The sale of the device to anyone other than dental professionals is prohibited.
	Notified Body Number

1. Product Description

naxis Abutments ; It is used to establish a connection between the prosthesis and the implant body. Naxis Implants consist of different types, sizes and platforms.

1.1. Abutment :

It is produced to fix the prosthetic restoration and the implant body together and is divided into 2 (two) groups. naxis Abunmetn is screwed in. These abutment types and their intended use are mentioned below. Technical details and design details can be seen on the Technical Drawing.

1.1.1. Abutment (No Step):

It is permanently placed on the implant so that dentures can be attached . With its octagon (octagon) design, it allows the physician to load in 8 different positions in the area used . Its marginal form imitating the gingival anatomy provides excellent aesthetics. With its 15° and 25° angled alternatives and different gingival height options, it offers the most appropriate solution in terms of aesthetics and function. It can be prepared in or out of the mouth. Designed for cementable and integrated abutment crown restorations. It is especially preferred for non-aesthetic and high margin areas . It has 2 different platforms, SP (Small Platform), BP (Broad Platform).

1.1.2. Straight Abutment (Cascade):

It is permanently placed on the implant so that dentures can be attached . With its octagon (octagon) design, it allows the physician to load in 8 different positions in the area used. Its marginal form imitating the gingival anatomy provides excellent aesthetics. With its 15° and 25° angled alternatives and different gingival height options, it offers the most appropriate solution in terms of aesthetics and function. It can be prepared in or out of the mouth. Designed for cementable and integrated abutment crown restorations. It has 2 different platforms, SP (Small Platform), BP (Broad Platform).

1.1.3. Multi- Unit Abutment :

Monoblock is a one-piece superstructure. unit Abutment models offer an effective fixed restoration solution in partially edentulous or total edentulous cases. With its 17° and 30° angled alternatives and different gingival height options, it offers the most appropriate solution in terms of aesthetics and function. It has 2 different platforms, SP (Small Platform), BP (Broad Platform).

1.1.4. ball Abutment :

It is used as a snap prosthesis in cases of total edentulism. It has 2 different platforms: SP (Small Platform) and BP (Broad Platform).

1.1.5. locator Abutment :

It is used as a snap-in prosthesis in cases of total edentulism. It is used as a snap-in prosthesis in cases of total edentulism. It has 2 different platforms: SP (Small Platform) and BP (Broad Platform).

1.1.6. TI Base Abutment :

It is used in bridge and bar restorations. It has 2 different platforms: SP (Small Platform) and BP (Broad Platform).

1.1.7. healing Abutment :

After the osseointegration process, it is attached to the Implant and ensures that the tooth has an aesthetic appearance. It has 2 different platforms: SP (Small Platform) and BP (Broad Platform).

1.2. cover Screw :

dental It is available in implant packages and belongs to the sterile product group. dental When the implants are placed in the patient's mouth, the closure screws are attached to it. During the osseointegration process , the patient remains in his mouth and is not exposed to any load. It is produced from Titanium Grade 4 material. It has 2 different platforms: SP (Small Platform) and BP (Broad Platform).

2. Purpose of usage

Naxis Implants;

It is used to support prostheses and to form crowns and bridges.

3. Indications

- Complete and partially edentulous patients
- Jaw and facial defects
- excessively resorbed complete tooth deficiencies characterized by crest
- In patients who have difficulties in the use of removable partial dentures

- In patients who refuse to use removable prostheses
- In patients who want to have their teeth prepared
- Fixed prosthesis patients with very long spaces
- In severe damage to any edentulous area or soft tissues where the full denture sits
- Due to its high fracture strength, it can be used even in individuals with excessive overbite , bruxism or foreign body biting habits.
- Its use is higher than ceramic abutments in the posterior region and in cases where the height of the abutment is less than 7 mm and the axial thickness is less than 0.7 mm due to the patient's mouth closure, and in cases where the abutment should be angled more than 30 surgically .
- the posterior region and as a bridge abutment. Metal abutments themselves have no risk of breakage.

4. Contraindication

- Active Infection
- Foreign body sensitivity / material allergy (this should be determined and necessary precautions should be taken)
- The condition of the bone structure and insufficient bone density (implant and abutment performance depends on bone condition and density)
- unstable
- Relaxation
- dislocation
- When the edentulous space is narrowed by opposing and adjacent teeth
- In cases where the crown length of the abutment teeth is too short,
- parafunctional habits such as bruxism
- winged bridge (Kantilever) use is designed
- Auxiliary teeth are not used if they lack adequate periodontal support.
- your surgeon; failure to follow surgical operation prescription and/or inadequate surgical practice
- to adapt to the scallop structure of the gingiva
- Deep gingival pockets formed as a result of not placing the implant deeper in order to provide a suitable aesthetic
- Cementation of the crown and removal of cement residues is difficult
- Metallic blue reflection visible under the gingiva, aesthetic negativity in patients with thin gingival structure or high smile line
- When the patient smiles, the corner of the abutment will appear as a metal band , worse than the metal reflection from the collar . This metal tape poses an aesthetically unacceptable problem.

5. Warnings and Precautions

- Before the operation, the patient should be informed about the surgical risks and the positive and negative effects should be explained.
- The patient should be warned that the implanted device has a certain lifespan during which normal bone cannot replace, may be damaged by strenuous activity or trauma, and may be replaced in the future .
- The surgeon should review the product-specific surgical technique before performing the surgical procedure. naxis The implant supplier can provide technical information as needed. For this case, please Naxis Please contact the implants sales representative.
- implant is extremely important. Considering the appropriate type and size, the patient's age and activity levels, bone density are preferred depending on whether they have undergone any previous surgical operation.
- Naxis prostheses should be applied by securing respiration during oral use. Components or tools may injure the patient.

Failure to follow these instructions may result in any or all of the following;

- Negative effect on breathing
- Ingestion of an ingredient
- Prolongation of the healing process

Moreover;

- naxis Its abutments and other accessories have not been evaluated for safety and compatibility in a magnetic resonance environment.
- naxis Its abutments and other accessories have not been evaluated for heating and migration in a magnetic resonance environment .
- Small diameter abutments should not be used where high mechanical loads are required.

6. Compatibility Information

- The patient should be informed about the surgical risks before the operation and the positive and negative effects should be explained.

- The patient should be warned that the implanted device has a certain lifespan during which normal bone cannot replace, that hard objects can be damaged by tooth fracture or trauma, and may be replaced in the future.

- Read the product user manual before use.

- Do not use with implants supplied from different metals and different manufacturers. naxis In cases where implants are used, Naxis must be used again. Abutments and accessories should be used.

- The product is for single use only. Do not reuse.

- Check the expiry date of the product before use.

- Do not use the product if there is a foreign substance or contamination in the package or on the product.

- Do not use the product that has fallen to the ground.

- Since there is a risk of infection, dispose of the product as medical waste within the framework of legal procedures after use. naxis Implant and prosthetic parts are available in a variety of configurations. Abbreviations are used to assist on each product label. Remove the healing cap or temporary healer and rinse thoroughly then dry the inside of the implant . Remove the optimizer from the working model.

Cleaning, disinfection and sterilization of dental healers are described in Chapters 7 and 8.

The healer is placed in the mouth of patients.

NOTE: The screw is tightened after the abutment is properly placed. Abutment with suitable screw Be sure to fix the implant .

Tighten the abutment screw with the corresponding screwdriver.

7. Cleaning and Disinfecting

naxis Its abutments and accessories are delivered non-sterile. Before placing the products in the patient's mouth, they must be cleaned, disinfected and sterilized. Before using the devices, the recommendations in the procedure should be followed and cleaned, disinfected and sterilized;

- It should be washed under running water by brushing inside and outside with a brush.
- As a pre-treatment, you can clean the products manually using ultrasonic support, automatic method or disinfection methods.
- When using the automatic method and disinfection method, the appropriate detergent should be selected and the manufacturers' instructions for use should be followed.

8. Sterilization

NOTE: Sterilization materials that you are sure of and that have appropriate biological indicators should be used.

Recommended Sterilization Method

System elements are delivered in clean condition, but are not sterile. Before use, reusable hand tools must be pre-cleaned and all system elements must be sterilized by following the methods specified below.

In accordance with ISO 17665-1:2006, AAMI TIR 12:2004 and other relevant standards

METHOD	LOOP	HEAT	MINIMUM TIME
Steam	Vacuum	134 °C	18 min .

9. Product MRI Compatibility Information

naxis Implants dental Implant systems have not been evaluated for safety and compatibility in the MR environment. naxis Implants dental Implant systems have not been evaluated for heat or displacement in the MR environment.

10. Procedure

- Be sure to secure the prosthetic attachment by securing the abutment during polishing or other laboratory procedures .
- Insert the abutment into the implant analog on the working model.
- Make sure the analog-abutment joint retainer elements are properly aligned.

- the abutment by hand tightening the master screw .

10.1.naxis Clinical Use of Abutment

The original abutment is obtained from the laboratory. Remove the healing cap or temporary healer and rinse thoroughly then dry the inside of the implant . Remove the optimizer from the working model.

- Cleaning, disinfection and sterilization of dental healers are described in sections 7 and 8.
- The healer is placed in the patient's mouth.

NOTE: After the abutment is properly placed, the screw is tightened.

- Abutment with suitable screw Be sure to fix the implant .
- Tighten the abutment screw with the corresponding screwdriver.

10.2.Torque Usage

abutments and/or implants may occur when torques are greater than 35 Ncm .

Torque value less than the recommended value may cause loosening of the abutment . It can lead to abutment and implant losses.

NOTE: The abutment or its components are tightened to the specified amount of torque . Screws must not be removed, otherwise a new screw must be used.

Follow these instructions for the safe and correct use of Naxis products. It is the user's responsibility to use the device in accordance with the instructions.

The Naxis product is used as part or link to an overall concept. Product sales by third parties are not Naxis distributors. In these cases, Naxis does not include any warranty or liability.

10.3.Use of Products

10.3.1.finger switch; removes the healing cap inside the mouth.

10.3.2.gingiva Former ; It stays in the patient's mouth for 1 week and 10 days, allowing the patient's gingiva to be shaped.

10.3.3. Impression Piece; it ensures that the patient's mouth shape and the implant are fully outside, allowing space for the technician to work on the model.

10.3.4. Abutment ; Implant abutments remain in the mouth for a lifetime in order to make both aesthetic and functional crowns on the patient's implant in the mouth after the healing period is over.

10.3.5. Analogue

It is the part used to measure the implant size in the mouth for the technician to work on the model.

10.3.6. Abutment Screw

It is the part used to fix the implant and abutment .

11. Product Shelf Life Information

The product does not have a specified shelf life. The useful life of the products has been determined as 10 years with the support of the literature.

12. Explanation of Marks Used on the Label

	It is disposable.
	Read the contents of the package before use
	Attention
	Producer
	Party Code
	Catalog Number
	It is not sterile.
	Notified Body Number