

## 1. Definition

Naxis Implants is a dental implant system covering 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 function as tooth root replacement , forming the basis for dental restoration. The implant, consisting of the implant itself and the closure screw, is packaged in a titanium tube under clean room conditions, followed by a blister pack, and sterilized with 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, superstructures and accessories are shipped non-sterile.

## 2. Instructions for Use

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

Information about these dimensions can be obtained from the tomography scan image of the implant area using traditional methods required for successful implant procedure.

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

The implant procedure should be performed in a sterile environment using sterile surgical instruments. It is recommended to use physiodispenser , depth measurement and direction indicators. Insert the implant into the prepared bone space. surgical torque Take the ratchet and insert the implant screwdriver part included in the surgical set into the ratchet . Continue screwing the implant clockwise until the implant is completely embedded . Remove the implant screwdriver from the implant , replace the implant cap, and suture the surgical area.

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

**Caution:** In single unit restoration, abutment height should not be less than 4mm. Angular corrections cannot be made on cast "superstructures" (e.g. PTA and PH).

, a high degree of caution must be exercised to avoid accidental swallowing or aspiration by the patient.

## 3. Indications

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

## 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 immune-suppressing 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 greater than 170/110 mm Hg, crush fracture due to osteoporosis, respiratory disease, thyroid or parathyroid disease, as well as patients diagnosed with a malignant tumor or a nodule enlargement, tender or unexplained lump in the head or neck within five years. People with masses in the area should also be excluded. It cannot be applied to patients with edema,

pain in the lymph node area, or protrusions in the head and neck area. Implant procedures should not be performed on people with active osteolysis, inflammation, or infection at the implant site. Below we list contraindication items:

- Disabling or uncontrollable diseases,
- Pregnancy, hemophilia, white blood cell deficiency or other bleeding problems, steroid use, prophylactic antibiotics, brittle diabetes, Ehlers-Danlos syndrome,
- Osteoradionecrosis, renal failure, organ transplant, anticoagulant therapy, unexplained hypersensitivity, fibrous dysplasia, regional enteritis,
- The practitioner has not received sufficient 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, patient's inability to maintain oral hygiene,
- The patient has hypersensitivity to certain components of the implant,

## **5. Risk**

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

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

- a. Heart failure, coronary artery diseases, heart rhythm disturbances.
- b. Chronic wheezing disease
- c. Diseases of the digestive system, hepatitis, malabsorption, infectious diseases of the intestinal tract.
- d. Nephrotic and urinary tract diseases.
- e. Endocrine diseases, diabetes, thyroid diseases, adrenal body and basal glands.
- f. Hematological diseases, anemia, leukemia, clotting problems.
- g. Musculoskeletal system diseases, arthritis and osteoporosis.
- h. Neurological disorders, apoplectic seizure, Parkinson's disease and mental retardation.

## **Important warning**

Lack of adequate training on the part of the practitioner is the main risk factor for the success of the implant procedure and can jeopardize the health of the patient. For this reason, the implant procedure should not be performed without receiving appropriate training from a certified institution.

## Measures














1. The implant is offered for single use. DO NOT RE-STERILIZE AND USE.
2. Implant use may require pre-operative antibiotic prophylaxis .
3. Small diameter implants and angled abutments are not recommended in the molar area of the mouth.
4. 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 dislodgement in the MR environment.

## Limited Warranty

reimplantation in cases of failed implants, Naxis Medical will provide free implants to the patient under the following conditions:

During the 6-month period following the first signs of implantation failure, Naxis Medical will provide a new implant when written notification of this failed implantation is made and the follow-up inspection document with the form approved by the manufacturing company, appropriate x-rays showing the patient's oral cavity and the rejected implant is sent.

## 6. Description of the Signs Used on the Label

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