

1. Definition:

Nucleoss Dental Implant System is an in-bone dental implant system with implants and related abutments, healing caps, surgical instruments. T6&T6 Torq Implants are compatible with T6 Superstructures and T6 Surgical Set. See product label for product code, specification, date of manufacture and expiry date.

Nucleoss dental implants are manufactured from pure Grade 4 titanium according to ISO 5832-2 standard.

Chemical Composition:

N %Max	C %Max	H %Max	O %Max	Fe%Max	Ti%Max
0.05	0.08	0.0125	0.4	0.5	Balance

Nucleoss Dental Implants (T6 and T6 Torq) have an SLA surface. Sandblasted pure titanium is surface treated with thermal acid. The body becomes hydrophilic after surface treatment.

Each implant package has a lot number on it. In addition, each implant package contains three Lot number labels. These lot number labels must be attached to the patient's file and panoramic X-ray for retrospective traceability of the product..

2. Intended Use:

Nucleoss T6 and T6 Torq Dental Implants are surgically implanted into the lower or upper jaw bone and used to support artificial dentures used to restore the patient's chewing function.

3. Indications:

Nucleoss T6 and T6 Torq dental implants are indicated for functional oral rehabilitation of the upper or lower jaw of fully or partially edentulous patients. They can be used for immediate or late implantation after loss or extraction of natural teeth. T6 Implants are designed for delayed loading after 12 weeks. T6 Torq Implants can be placed immediately for single tooth and/or multiple tooth restorations when good primary stability is achieved and with appropriate occlusal loading for restoration of masticatory function.

4. Target Patient Population and Target User:

The target patient population is people with adult jaw structure where none of the contraindications for dental implantation apply. The target users are dentists licensed in dentistry.

5. Contraindications:

High blood pressure, cardiovascular disease, diabetes, bone metabolism disorders, uncontrolled bleeding disorders, inadequate wound healing capacity, inadequate oral hygiene, serious internal medical problems, incomplete development of the upper and lower jaw, poor general health, uncooperative and unmotivated patients, drug, alcohol or smoking addiction, psychoses, functional disorders resistant to long-term treatment, xerostomia (dry mouth), granulocytopenia (lack of white blood cells), Ehlers Danlos syndrome, radiation therapy, osteoradionecrosis, weakened immune system, renal failure, organ transplantation, fibrous dysplasia, crohn's disease, steroid, corticosteroid or anticonvulsant use, prophylactic antibiotics, creatinine, serum calcium, titanium allergy, uncontrolled endocrine disorders, anticoagulation drugs, haemorrhagic diathesis, bruxism, parafunctional habits, unfavourable anatomical bone conditions, uncontrolled periodontitis, temporo-mandibular joint disorders, treatable pathological diseases of the mandible or changes in the oral mucosa, pregnancy, breastfeeding, osteoporotic fracture, respiratory disease, thyroid or parathyroid diseases. Patients with active osteolytic, inflammation, diagnosed malignancy, nodular growths, tenderness, unexplained swelling of the head or neck, infectious conditions at the implant site. Unrealistic patient expectations. Unattainable prosthetic reconstructions. Inadequate training of the practitioner.

6. Warnings and Precautions:

Observance of precautions and warnings ensures safe handling and application.

- NucleOSS Dental Implant System products are manufactured by Şanlılar Med. Kim. San. Tic. Ltd. Şti. Brand usage and sale of products can only be realised by Şanlılar and its business partners.
- All models in the NucleOSS Dental Implant system (T6 and T6 Torq) should be applied according to NucleOSS Surgical and Prosthetic protocols.
- It should be kept out of the reach of children.
- Implants of different sizes are used according to the diameter and length suitable for the application area, use abutment compatible with the implant.
- Inform the patient before and after the surgical operation.
- Do not open the tube cap in any way until the moment of use. Never use uncapped or deformed tubes.
- The patient's health condition must be suitable for the operation.
- Use drills suitable for the diameter and length of the implant.

- The implant tube must be removed from the blister with gloves on a sterile cloth. Implants with broken protection ring or damaged packaging should not be used.
- Against the risk of contamination, the implant should be placed in the opened slot as soon as it is removed from the sterile tube, without touching or touching anywhere.
- Implants are in sterile packaging. Do not sterilise a second time.
- Previously used implants cannot be reused.
- Nucleoss Dental Implants do not require training and device installation before use. If you need training in use, you can get help from our website (<https://www.nucleoss.com/>) or you can contact the relevant dealer or Şanlılar Tıbbi Cihazlar Med. Kim. San Tic. Ltd. Şti..

7. Points to Consider / Precautions:

Implants should not be placed in bones other than the maxilla or mandible.

Always select the implant with the largest diameter that can be supported by the available bone thickness, bone quality, interdental space and expected masticatory forces. Special care should be taken to ensure proper implant alignment when relatively high loads are expected.

During the placement of the product, the dentist and auxiliary personnel must use appropriate personal protective equipment (PPE) to prevent the risk of interpersonal infection. The procedure should not be performed without gloves and masks.

Before surgery

A clinical and radiological examination of the patient should be performed preoperatively to determine the patient's suitability for treatment and to determine the patient's psychological and physical condition.

Special attention should be paid to patients with localised or systemic factors that may interfere with the bone or soft tissue healing process or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in the lateral tooth or bone, bisphosphonate therapy).

The device has not been evaluated in paediatric/adolescent patients and is not recommended for use in children.

Surgery:

All components, devices and instruments used during the procedure should be kept in good condition and

care should be taken to ensure that the instrumentation does not damage the implants or other components.

Following implant placement, the surgeon assesses bone quality and primary stability and determines when the implants can be loaded.

After surgery

In order to ensure a long-term treatment outcome, it is advisable to ensure regular comprehensive patient follow-up after implant treatment and to provide the necessary information about proper oral hygiene.

8. Residual Risks and Side Effects:

The clinical outcome of dental treatment can be influenced by many variables. Possible residual risks and side effects may occur during or after the operation.

Pain, swelling, phonetic difficulties, gingivitis.

Dental implants, permanent paresthesia, dysesthesia, marginal bone loss, localised or systemic infections, oroantral or oronasal fistula, disruption of adjacent teeth, irreversible damage to adjacent teeth, implant fractures in the jaw, bone or prosthesis, nerve damage, exfoliation, chronic pain associated with hyperplasia, implant failure, fractures in the neck area where the implant and abutment meet, screw loosening or fracture, abutment fracture, abutment compression into the implant.

9. Cleaning and Disinfection:

Nucleoss dental implants are delivered sterile and disposable. They should not be cleaned and disinfected. Şanlılar Tıbbi Cihazlar Med. Kim. San Tic. Ltd. Şti does not accept any responsibility for the processing of devices initially delivered as sterile, regardless of who performs the procedure or by which method.

10. Sterilisation:

Nucleoss dental implants are delivered sterile and for single use only. They must not be sterilised. Nucleoss dental implants and caps are sterilised by Gamma Radiation (sterility guaranteed for five years).

Nucleoss dental implants are wash-processed in a Class 10,000 environment and sealed in a Class 100 clean room environment. The double sterile barrier system and packaging protects the sterilised device from external factors and ensures sterility until the expiry date if the device is stored correctly. Asepsis rules must be followed when removing the device from the protective packaging and sterile barrier system. The sterile barrier system should not be opened until just before implant placement. Before opening the

sterile packaging of the devices, check for damage. Devices with damaged packaging should not be used. It is recommended to have a spare on hand. Re-sterilisation not performed by the manufacturer does not guarantee that the device is sterile. Şanlılar Tıbbi Cihazlar Med. Kim. San Tic. Ltd. Şti. does not accept any responsibility for re-sterilised devices that were originally delivered as sterile, regardless of who performed the re-sterilisation or by which method. Under no circumstances should a previously used or unsterilised implant be used.

Please refer to the abutment user manual for abutment sterilisation information.

11. MR Safety Information:

Non-clinical testing has demonstrated that the NucleOSS Dental Implant System is a "Conditional MR".

The patient can be safely scanned with this device immediately after placement under the following conditions:

- In the magnetic static field of 1.5-Tesla and 3-Tesla
- 4,000 -gauss/cm (40 T/m) dimensional gradient magnetic field
- Maximum reported MR system average specific absorption rate (SAR) for the body 2-W/kg

(Normal Operating Mode) Under the scan conditions specified above, the NucleOSS Dental Implant System is expected to produce a maximum temperature rise of less than 1.7 C° after 15 minutes of continuous scanning.

In non-clinical testing, when imaged with an artifact gradient echo pulse train and a 3.0 T MRI system, the image extends approximately 5 mm from the implant.

12. Storage Conditions:

The devices should be stored under the conditions of 18°C -28°C temperature and 40%-60% humidity range.

The devices should be stored in their original packaging in a dry place and protected from direct sunlight.

Improper storage may jeopardise the basic material and design properties and may cause the device to malfunction.

13. Disposal:

The disposal of the device must comply with local regulations and environmental requirements, taking into account the different levels of contamination.

Hazardous waste from contaminated devices or sharps must be disposed of in appropriate containers that fulfil certain technical requirements.

14. Patient Information:

The patient should be informed about contraindications, warnings, precautions, side effects and complications of Nucleoss dental implants.

There is no residue, leakage or harmful residue on the surface of the device that could harm the user or the patient.

The patient should be informed about the MRI compatibility of the Nucleoss products used.

The surgical site should be kept clean before and after the operation. The patient should be well informed about the cleanliness of the surgical site. The implanted area should not be exposed to load with chewing movement in the early period. For detailed information, please refer to the Patient Information Booklet (see <https://www.nucleoss.com/hastaya-ozel/>)

15. Procedure:

NucleOSS Dental Implants come with a tube label, tyvek label and box label. These labels allow the lot number to be checked in three stages. The diameter label shows the diameter and length of the implant. Diameter labels are colour coded for different diameters.

The table below shows the color codes representing the diameters of Nucleoss T6 and T6 Torq dental implants.

Product Group	Color	Diameter
T6 Implant	Yellow	Ø 3.5
	Green	Ø 4.1
	Purple	Ø 4.8
T6 Torq Implant	Yellow	Ø 3.5
	Brown	Ø 4.0
	Blue	Ø 4.5
	Green	Ø 5.0
	Purple	Ø 6.0

T6 Covers are provided with NucleOSS T6 and T6 Torq Dental Implants. Implant covers are also color coded in different colors according to the implant diameter to be used together. The color coding table below shows with which diameter implants the implant covers are compatible.

Color	Meaning of Diameter Label Color Code	
	T6	T6 Torq
Yellow	Ø 3.5	Ø 3.5
Brown		Ø 4.0
Blue		Ø 4.5
Green	Ø 4.1	Ø 5.0

Purple	Ø 4.8	Ø 6.0
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The implant diameter, implant type, position and number of implants should be selected individually, taking into account patient anatomy and spatial conditions. The measurements given should be considered as minimum guidelines and are detailed in the Nucleoss Surgical Manual (see <https://www.nucleoss.com/kaynaklar/download/>)

Implant bed preparation

Heat damage inhibits healing of the dental implant.

Therefore, excessive increases in temperature should be minimised by following the guidelines for the use of Nucleoss Dental Implant System Drills and instruments regarding drilling speeds, intermittent drilling and adequate cooling.

Implant placement

A Nucleoss implant is moved from the sterile tube to the surgical site with the help of the implant transport-clamping part using a ratchet, motor or screwdriver.

When moving the implant cap from the sterile tube to the surgical site, the hex key is fully inserted into the implant cap and retracted in the same axis without turning it left or right.

When placing the T6 and T6 Torq implant with a micromotor at a maximum speed of 15 rpm or with a manual hex key, it is placed by turning clockwise so that the upper surface of the implant is 0.7 mm below the bone level.

Soft tissue treatment, wound closure

Before the wound is closed, the cap, which comes out of the implant tube and is coloured according to the platform diameters, is placed on the implant with a hex key and closed by hand tightening. If it is not closed, tissue enters into the implant and creates a risk factor.

16. Expected Clinical Benefit:

Patients can expect to have one or more missing teeth replaced and/or crowns restored to restore chewing function as a benefit of treatment.

17. Summary of Safety and Clinical Performance

With the launch of the European Database for Medical Devices, a summary of safety and clinical performance for Nucleoss T6 and T6 Torq implants will be available at <https://ec.europa.eu/tools/eudamed>.

18. Notification of Serious Adverse Events

For the patient/user/third party in countries with Regulation 2017/745/EU on Medical Devices: If a serious adverse event occurs during or as a result of the use of this device, please notify the manufacturer and your national competent authority. The contact details of the manufacturer of this device for reporting a serious adverse event are as follows:

Şanlılar Tıbbi Cihazlar Med. Kim. San Tic. Ltd. Şti

E-mail: info@nucleoss.com

Web: (<https://www.nucleoss.com/iletisim/talepleriniz-onerileriniz/>)

19. Basic UDI-DI Information

The following table lists the Basic UDI-DI information for the devices described in these instructions for use.

Product Group Basic UDI-DI Code

T6 Dental Implants 869938335T67A

T6 Torq Dental Implants 869938335TRQ43

20. Implant Card

Şanlılar Med. Kim. San. Tic. Ltd. Şti. provides an Implant Card for each implant provided by the dentist. The implant card is filled in by the dentist and delivered to the patient. With this document all information about the implant is recorded and is useful for monitoring the device over time. If necessary, the patient can show the implant card to any dentist, who can act appropriately to resolve any problems and contact the manufacturer if necessary. The dentist should advise the patient to take good care of the "implant card" and bring it with him/her to every subsequent check-up.

21. Symbol Descriptions:

The symbol descriptions on all Nucleoss products are as follows.

	Product Catalogue Number		Authorised representative
	Product Lot Number		Read the operating instructions
	2nd time not used		Expiry date
	Sterilisation with Gamma Irradiation		Manufacturer
	Do not use if the packaging is damaged		Prescription use only
	Temperature range		MRI Safety Information

	Humidity range		Warnings
	Do not sterilise again.		Double sterile barrier system
	Medical device		Producer country
	Unique device identifier		Model number
	Importer		Distributor
	CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC legislation. Where applicable: The identification number of the Notified Body will follow this symbol.		

CE 2975



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Publishing Date:24.10.2025
Revision Date: -
D004/Rev000