

1. Definition:

Nucleoss Dental Implant System is an in-bone dental implant system with dental implants and related abutments, healing caps, surgical instruments. Compatible with T6 & T6 Torq Superstructures, T6 & T6 Torq Dental Implants and T6 Surgical Set. Failure situations that may occur as a result of use with different systems may harm the patient. Please refer to the product label for product code, specification and production date.

NucleOSS Dental Implant System offers dentists a wide range of superstructure options that can be used for different purposes with all bodies. These include cemented, screwed, customised, removable prosthesis, cad-cam solutions and scan bodies, as well as auxiliary prosthetic parts and temporary parts.

1.1. Bases:

Abutments are placed on dental implants to provide support for prosthetic reconstructions such as crowns or bridges. See the catalogue for superstructures compatible with the platform diameter and length of the abutments.

1.2. Screws:

The screw is used to fix the superstructure to the dental implant.

1.3. Healing Heads:

Healing caps are used in single-stage, transmucosal surgical protocols and are screwed into the dental implant, protecting the implant internal structure and not supporting a prosthetic superstructure.

1.4. General Information:

Most of their superstructures are suitable for use throughout the patient's lifetime. Temporary abutments can be shortened to the implant screw level depending on the patient's oral anatomy.

Cemented abutments of the NucleOSS Dental Implant System are manufactured from Grade-23 Titanium alloy according to ISO 5832-3 standard and are offered for sale as non-sterile. It must be sterilised before use by the end user.

Chemical Composition for Titanium Alloy:

	N	C	Al	O	Fe	V	H	Ti
max	0.05	0.08	6.75	0.20	0.30	4.50	0.015	Balance
min	0.00	0.00	5.50	0.00	0.00	3.50	0.00	Balance

Each superstructure package has a Lot number on it. There are also three Lot number labels inside each superstructure pack. For retrospective traceability of the product, it is strongly recommended that these Lot number labels are kept in the patient's file and together with the panoramic X-ray.

2. Intended Use:

Cemented abutments are intended for use with Nucleoss Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients.

3. Indications:

Nucleoss T6 and T6 Torq superstructures are prefabricated prosthetic components directly connected to endosseous dental implants and are intended to be used as an aid in prosthetic rehabilitation.

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 Abutment System products Şanlılar Med. Kim. San. Tic. Ltd. Şti. Brand usage and sale of products can only be realised by Şanlılar Tıbbi Cihazlar and its business partners.
- All models in the NucleOSS Dental Abutment system (T6, T6 TORQ) should be applied according to NucleOSS Surgical and Prosthetic protocols.
- It should be kept out of the reach of children.
- The abutment suitable for the patient's oral structure should be used with the appropriate dental implant.
- The patient should be informed before and after the surgical operation.
- Abutments with damaged packaging should not be used.
- Make sure that the patient's health condition is suitable for the operation.
- Abutments are sold as non-sterile. Before use, they must be sterilised by the user as specified in the instructions for use.
- Previously used abutments cannot be reused.

7. Points to Consider / Precautions:

If the following warnings and precautions are not observed, complications may occur, such as the part entering the windpipe or swallowing the part.

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.

For dental technicians:

- When polishing the abutments, it should be ensured that the part entering the implant is protected or this process should be performed with the abutment attached to the implant analogue.
- The abutment should be placed on the model by checking the correct orientation and make sure that it is fully seated.
- The abutment should be fixed with the abutment screw provided and tightened with the torque values given in Table 1.
- After this stage, the prosthesis suitable for the treatment should be created and the prosthesis should be removed from the model with the help of the correct hex key.

For dentists:

- The clinician should take the abutments from the laboratory and remove the temporary restorations, closure screws or healing caps from the patient's mouth.
- After cleaning, disinfecting and sterilising the prosthetic parts from the laboratory, the clinician should apply them to the patient's mouth by tightening them with a tightening piece according to the specified torques.
- If the superstructures are tightened more or less than the specified torque values, it may cause the abutments and/or implants to fail.
- The appropriate torquing values for the use of superstructures can be found in Table 1.

Table 1. Suitable torque values for Nucleoss superstructures

All Covers and Healing Heads	By Hand/Raschette (10 Ncm)
All Simante Abutment Screws	Max. 30 Ncm
Temporary (PEEK) Parts and Screws	10 Ncm
Multi Unit Bases	Max. 30 Ncm
Abutment Occlusal Screw	20 Ncm
All Cap Screws	10 Ncm
All Universal Cast Screws	Max. 30 Ncm
Knob Abutments	Max. 30 Ncm
Equator® Abutments	Max. 30 Ncm
CAD-CAM Ti-Base Abutment Screws	Max. 30 Ncm

Before Surgery:

Clinical and radiological examination of the patient should be performed preoperatively to determine whether the patient is suitable for treatment and to determine his/her 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 must be kept in good condition and care must be taken to ensure that the instrumentation does not damage implants, superstructures or other components.

Following implant placement, the surgeon's assessment of bone quality and primary stability determines when the implants can be loaded. The choice of superstructure and the time of application should be evaluated.

Nucleoss superstructures are medical devices that do not require installation. It is strongly recommended that specialists who will use Nucleoss superstructures for the first time receive training from the Şanlılar Medical Devices team. If users need more information about the product, Nucleoss dealers, representatives can be contacted or you can contact Nucleoss info@nucleoss.com via e-mail.

After surgery:

In order to ensure a long-term treatment outcome, it is recommended to ensure regular comprehensive patient follow-up after implant treatment and to provide the necessary information on 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 T6&T6 Torq superstructures are not sterile when delivered. The product must be cleaned, disinfected and sterilised before the superstructures are placed in the patient's mouth.

The steps for cleaning and disinfecting the bodies are as follows. Details of the sterilisation process can be found in chapter 10 Sterilisation.

The superstructures are washed inside and outside with a soft bristle brush under running water.

The superstructures are disinfected with a suitable disinfectant that will not damage the titanium alloy (Gr 23), PEEK and Chrome-Cobalt material.

10. Sterilisation:

All superstructures of the NucleOSS Dental Implant System are offered for sale as non-sterile. They must be sterilised before use by the end user.

Before sterilization, place the superstructures separately in sterilization bags.

Sterilisation conditions for titanium superstructures are as follows:

Method	Moist Heat Sterilisation according to ISO 17665
Ccycle	Pre-Vacuum
Temperature	132°C / 270°F
Exposure Time	4 minutes
Pressure	2.2 Bar
Pre-Vacuum	3 times < 60 mBar
Minimum Drying Time	30 minutes indoors

After sterilisation, the products must be used immediately.

A minimum valid sterilisation time and temperature is required to achieve a sterile assurance level of -10-6.

Note: The sterilisation parameters and methods shown are validated by NucleOSS Dental Implants. According to EN ISO 17665, the ultimate responsibility for the validation of sterilisation techniques and equipment is directly associated with the processor. All autoclaves/sterilisers must be maintained and validated in accordance with EN ISO.

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

11. MR Safety Information:

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

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

- 1.5-Tesla and 3-Tesla magnetic static field
- 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

12. Storage Conditions:

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

13. Disposal:

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

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

14. Patient Information:

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

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.

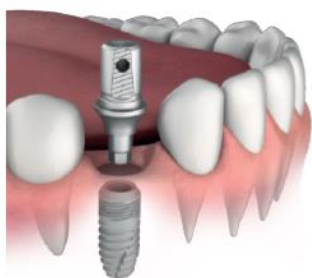
The surgical site should be kept clean before and after the operation. The patient should be well informed about the cleanliness of the surgical site. The area where the implant and superstructure are placed should not be exposed to load with chewing movement in the early period. For detailed information,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

15. Procedure:

Standard straight abutment is used in cemented restorations and is compatible with all diameters of T6 and T6 Torq implants. It has a platform switching feature that ensures soft tissue-abutment compatibility and has an internal hex connection feature.

15.1. Placement of the Standard Straight Abutment on the Implant:

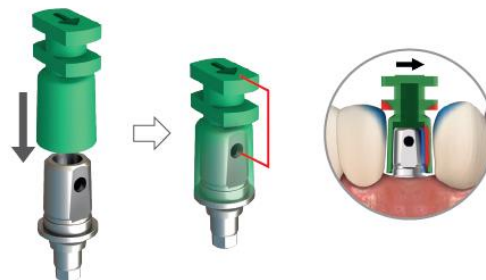
1. The healing cap is carefully removed with a manual hex key.
2. If there are blood and tissue particles in the implant, they are firstly vacuum cleaned.
3. The abutment selected according to the gingival height and platform diameter is carefully inserted into the implant with the perforated anti-rotation surface facing towards the vestibule (outside the mouth).



4. In order to fix the abutment to the implant, a yellow connection screw is used, the screw is inserted with a hex key and tightened by hand.

15.2. Taking Measurements:

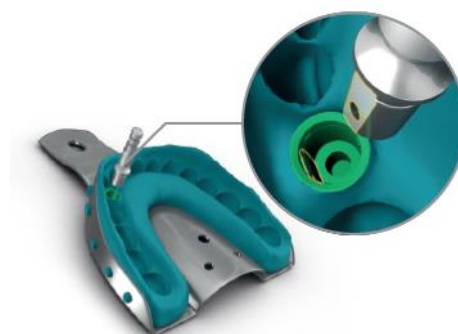
1. The impression cap, which comes out of the abutment package, is placed on the fixed abutment with the arrow direction facing the perforated surface of the abutment. Press the cap in the apical direction until it clicks into place.



The impression caps compatible with standard straight abutments with different prosthetic platform diameters are designed in different colors. The color code table below indicates with which prosthetic platform diameter standard straight abutments are compatible with different colored impression caps.

Prosthetic Platform (mm)	Color Code	Image
Ø 4,3	Yellow	
Ø 5	Green	
Ø 6	Purple	

2. Remove the mould with the measuring spoon.
3. The abutment is removed from the patient's mouth and sent to the laboratory together with the connection screw and impression tray.
4. The healing cap or temporary abutment is inserted into the patient's mouth.
5. The analogue and abutment are fastened together with the yellow connection screw and replaced in the measuring tray.



6. The assembled analogue group is pressed from behind and the flat surface of the rest is placed on the flat surface of the impression part in the tray so that it fits into the impression cap in the tray.
7. A plaster model is created with the help of a impression tray.

15.3. Prosthesis Making:

1. Abutment sent by the clinic with the impression tray is attached to the plaster model with the help of a connection screw (T6 16007).
2. A plaster model is formed on the dimensionally appropriate abutment by applying mould spacer paint (Vintage Die Spacer) to create a cement cavity in the metal prosthesis to be made.
3. After the wax patternsn is made on the abutment, the prepared wax part is sent to the casting process.
4. After the casting process, the coating process is applied on the metal prosthesis.
5. The material to be used for the coating process is prepared in accordance with the instructions given by the manufacturer and coated on the cast model.



6. The dental prosthesis is placed so that the flat surface inside it coincides with the antirotation surface of the abutment and sent to the clinic together with the plaster model to be fitted to the patient.

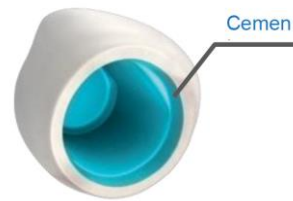
15.4. Placing the abutment in the patient's mouth:

1. The healing cap or temporary abutment is removed from the patient's mouth.
2. If there is blood, tissue or pus inside the implant, it is cleaned with vacuum.
3. Before placing the created single tooth prosthesis in the patient's mouth, the sterilised standard flat abutment is carefully placed on the implant in the patient's mouth.
4. To fix the abutment to the implant, the M.1.6 standard connection screw is tightened by hand (manually) with a hex key.
5. The connection screw should be torqued to a maximum of 30 Ncm with a NucleOSS ratchet.

15.5. Placing the prosthesis on the abutment:

1. The dental restoration is cleaned, disinfected and sterilised.
2. Before the single tooth is cemented into its place, a trial is made in the patient's mouth. If there is no problem (such as the abutment is viewable, the prosthesis is higher than needed, etc.), the single tooth is removed from the patient's mouth.

3. A material such as Gutta-percha, silicone or temporary filling material is placed in the screw hole of the abutment. It is filled with composite or a preferred material.
4. A sufficient amount of cement is applied to the inner walls of the single tooth prosthesis.



5. The single tooth prosthesis is placed in the patient's mouth so that the flat surface of the abutment inside the denture coincides with the antirotation surface.



6. Excess cement is carefully removed from the patient's mouth to prevent gingival recession.

This procedure should be considered a minimum guideline and details are detailed in the Nucleoss Surgical Manual (see: <https://www.nucleoss.com/kaynaklar/download/>)

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 Medical Devices Database, a summary of safety and clinical performance for Nucleoss T6 and T6 Torq bodies 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

19. Basic UDI-DI Information:

869938335SSA2Z: Standard Straight Abutment

20. Symbol Explanations:

	Product Catalogue Number		Authorised representative
	Product Lot Number		Read the operating instructions
	2nd time not used		Expiry date
	Do not use if the packaging is damaged		Manufacturer
	Not sterile		Prescription use only
	Medical device		Distributor
	Producer country		Warnings
	Unique device identifier		Model number
	MRI Safety Information		Importer
	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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