

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 abutment 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. Abutments

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

1.2. Screws

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

1.3. General Information

Most of their abutments are suitable for use throughout the patient's lifetime. However, Nucleoss Temporary Peek Abutments should be kept in the patient's mouth for less than 30 days and Temporary Titanium Abutments should be kept in the patient's mouth for more than 30 days.

Temporary abutments can be shortened to the implant screw level depending on the patient's oral anatomy.

All superstructures of the NucleOSS Dental Implant System are manufactured from Grade-23 Titanium alloy according to ISO 5832-3 standard and ASTM F2026-16 Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications are offered for sale as non-sterile. It must be sterilised before use by the end user.

2. Intended Use:

Nucleoss abutment and prosthesis parts are parts used to support crowns, bridges or superstructures in the lower and/or upper jaw, used with Nucleoss Dental Implant in completely edentulous or partially edentulous patients.

3. Indications:

Nucleoss T6 and T6 TORQ abutments 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:

- 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 only by hand (Pee products max. 10 Ncm, Titanium products max. 30 Ncm).
- 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 abutments are tightened more or less than the specified torque values, it may cause the abutments and/or implants to fail.

- You can find the appropriate torque values for the use of abutments in the table below:

All Covers and Healing Heads	By Hand/Raschette (10 Ncm)
All Simante Abutment Screws	Max. 30 Ncm
Temporary (PEEK) Parts and Screws	10 Ncm
Temporary (Titanium) Parts and Screws	30 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, abutments 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 abutment and the time of application should be evaluated.

Nucleoss abutments are medical devices that do not require installation. It is strongly recommended that specialists who will use Nucleoss abutments 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) and PEEK 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 abutments are as follows:

Method	Moist Heat Sterilisation according to ISO 17665
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Cycle	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 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 ISO 17665.

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.

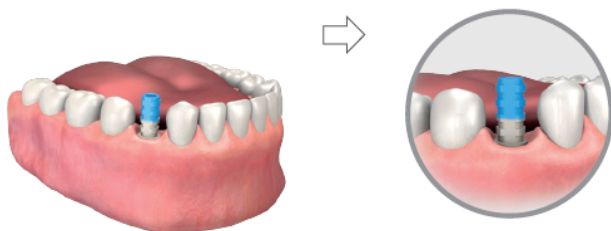
The surgical site should be kept clean before and after the operation. The patient should be well informed about the cleanliness of the surgical site. The area where the implant and superstructure are placed should not be exposed to load with chewing movement in the early period. For detailed information,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

15. Procedure:

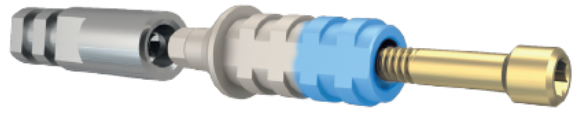
Nucleoss Temporary Abutments are used for the production of short-term temporary single tooth, bridge or total dentures held with cement. There are Peek options for short-term use and Titanium options for long-term use and can be shaped easily.

Temporary abutments can be used immediately after the surgical procedure, after the implant has healed and the cover is removed, or immediately after impression taking. The process steps are given below.

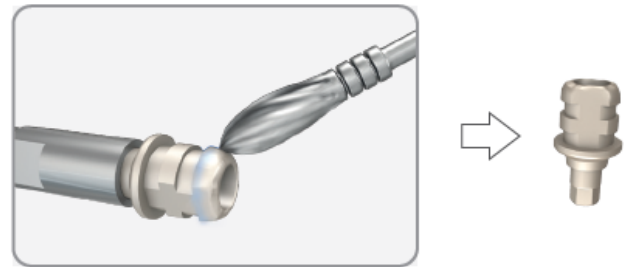
1. The healing cap attached to the implant is loosened with the carrying-tightening hex wrench (T0 2025) and taken off the implant with the help of the hex wrench (T0 25253).
2. It should be ensured that there is no bone or soft tissue on the implant platform.
3. The temporary abutment is placed on the implant and fixed to the implant with the connecting screw provided with the product. The screw must be tightened by hand.
4. Temporary abutments are marked to be shaped, taking into account the occlusal level of the bridge prosthesis to be created.



5. The marked temporary abutments are removed from the implant and fixed on the standard analog with connecting screws.



6. When temporary titanium abutments are removed from the patient's mouth for shaping, the gingiva former must be reattached to prevent soft tissue from collapsing onto the implant.
7. Temporary abutments connected to the analog are cut from the marked areas and shaped with a carbide or acrylic bur.



8. Once the shaping process is completed, the temporary abutment is placed back on the implant.
9. Before attaching the abutment, the bone and gum on the implant platform are cleaned; The internal connection area of the implant is washed and dried.
10. The sterilized abutment is placed on the implant and it is ensured that the implant-abutment connection is made properly.
11. The temporary titanium abutment is tightened with M1.6 connection screw as it cannot be disassembled again.
12. Tightening should be done with a hex wrench or a torque wrench. The tightening torque value should be set as 30 Ncm for temporary titanium abutments and 10 Ncm for temporary PEEK abutments.

Note : Applying torque higher than the recommended torque may result in failure of the abutment and/or implant. Less than the recommended torque may result in loosening of the abutment, which may result in abutment and/or implant failure.

Creating a Temporary Prosthesis (Single Tooth):

1. The screw hole of the temporary PEEK abutment is filled with a selected flexible material (gutta-percha, silicone or temporary filling material).
2. The screw channel remaining on this material is closed with composite or another selected material.
3. A bridge shell made of polycarbonate material for suitable areas is selected and placed on the temporary abutment.

4. Acrylic or another material is prepared, the bridge is placed in the shell and aligned on the temporary abutment.

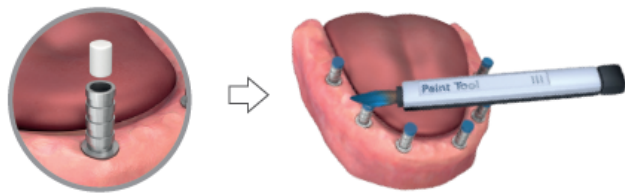


5. After the acrylic dries, the bridge shell is removed and excess acrylic is cleaned and the temporary bridge is given its final shape. After the shaping process is completed, polishing is applied.

Creating a Temporary Prosthesis (Total Tooth):

1. Acrylic dental prosthesis is prepared.

2. The screw hole of temporary titanium abutments is covered with cotton or a cotton-like material. The abutments are painted over.



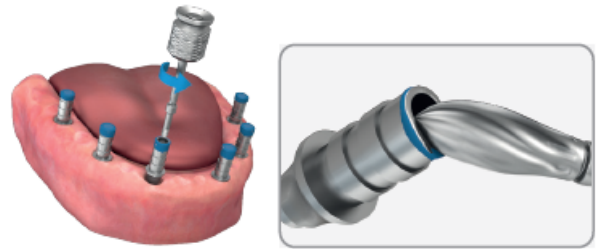
3. After the painting process, the prepared acrylic total dental prosthesis is carefully placed on the abutments. Holes are drilled in the painted marked areas of the lower part of the acrylic total dental prosthesis.



4. Acrylic total dental prosthesis is placed on the abutments, and the parts of the abutments remaining on the teeth are painted again to ensure correct shaping.

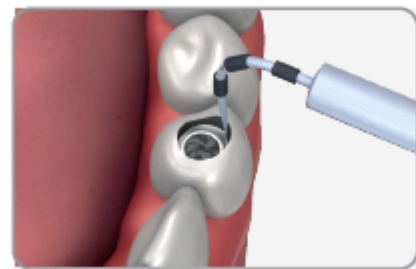


5. After painting, the acrylic thread is removed and the M1.6 connecting screws are removed. Temporary titanium abutments with painted tops are sent to the shaping process in turn.



6. The shaped temporary abutments are fixed again onto the implants in the patient's mouth with M1.6 connection screws. After the abutments are fixed, the acrylic total dental prosthesis is placed on the abutments.

7. Liquid acrylic is poured into the space between the temporary abutment and the holed tooth and waited until it cools.



Note: Before pouring acrylic, the screw hole of the abutments is covered with cotton or a cotton-like rubber material to prevent liquid from leaking into it.

8. After the temporary abutment and the acrylic total dental prosthesis are thoroughly fused together, the rubber materials in the abutment are removed, the M1.6 connection screws are removed, the prosthesis is removed and the excess acrylic on it is cleaned.

9. After going through procedures such as cleaning and polishing, the total dental prosthesis is finally placed on the implants. And M1.6 connection screws are tightened by hand with a manual hex wrench, enough to hold on to the implants.

10. Finally, the screw holes are covered with a cotton-like material. And the process is completed by filling.

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

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

19. Basic UDI-DI Information

869938335TA7W: Temporary 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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