

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.

The multi unit superstructures 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:

Multi-Unit 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. Multiunit abutments are indicated for screw-retained restorations. It offers fixed denture option in edentulous

No-hex structure of the Multiunit abutment is recommended for use in bridge, bar and hybrid treatments. No-Hex structures are used to provide desired indexing in external tooth applications. All parts of multi unit abutments used in angled or straight restorations are compatible with each other.

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
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 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 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/>)

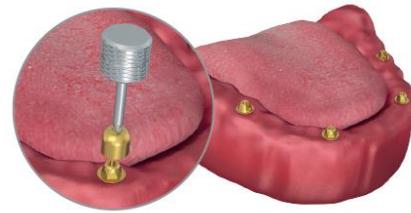
15. Procedure:

NucleOSS Multi Unit abutments have their own superstructure options for impression taking or prosthesis construction. Once the abutments are placed on the implants in the patient's mouth, they do not need to be removed again. This enables comfortable and practical treatment.

15.1. Total Dental Treatment with Temporary Titanium Caps:

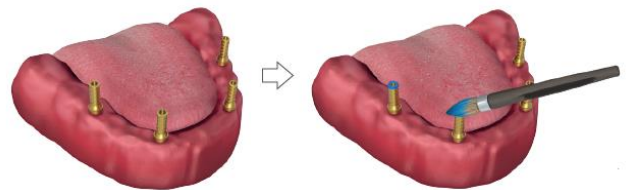
15.1.1. Placement of Temporary Titanium Caps on the Abutment:

1. The comfort caps on the multi unit abutments are carefully removed with a hex key.



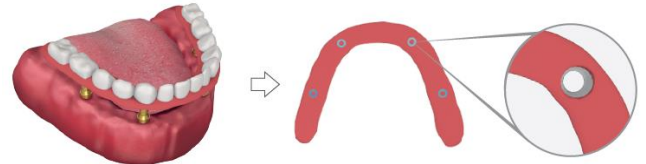
2. The temporary titanium caps are carefully placed on the multi unit abutments in the patient's mouth. The occlusal screws are inserted into the multi unit abutment by passing them over the temporary titanium caps with the help of a manual hex key.

3. After the temporary titanium caps are placed on the multi unit abutments, the caps are marked.

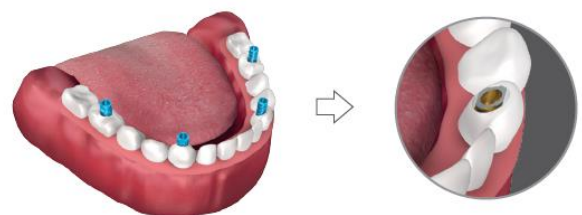


15.1.2. Preparation of Acrylic Dental Prosthesis:

1. After the caps are marked, acrylic teeth are prepared and holes are made on the marked areas of the dental prosthesis to fit the caps.



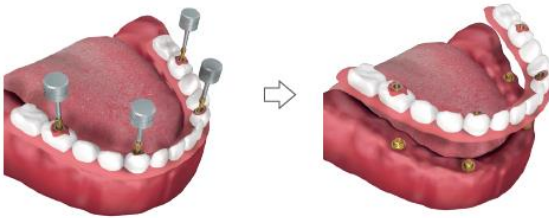
2. The acrylic total denture with holes made is placed on the temporary titanium caps in the patient's mouth. The remaining parts of the abutment on the prosthesis are marked and cut.



3. After the temporary titanium caps are shortened, they are placed on the multi unit abutments. The acrylic dental prosthesis is also placed on the caps and checked. After the necessary corrections are made, occlusal screws are inserted.

4. Pour liquid acrylic into the gap between the temporary titanium cap and the drilled acrylic dental prosthesis and left to cool.

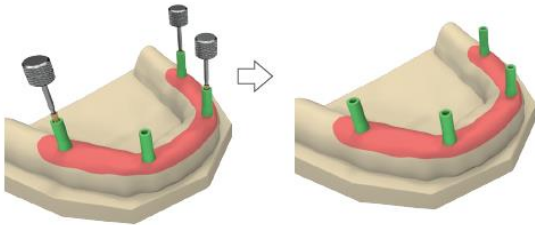
5. After the liquid acrylic has set, the occlusal screws are removed and the total prosthesis is removed from the mouth for tooth correction and the procedure is completed.



15.2. Total Dental Treatment with Burn Out Caps:

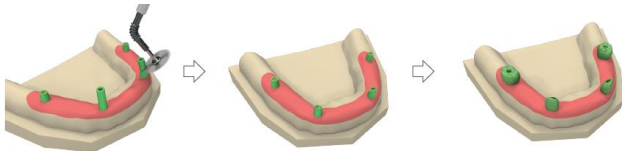
15.2.1. Placing the Burn Out Caps on the Plaster Model:

1. Before placing all burn out caps, one of the caps is placed on the multi unit analogues on the plaster model to ensure that the plaster, analogue and cap are compatible. Then, the occlusal screw is inserted into the analogue through the cap with the help of a manual hex key and make sure that it is completely seated.
2. The other burn out caps are placed on the multi unit analogues on the plaster model and make sure that they are fixed. The occlusal screws are carefully placed with the help of a manual hex key.

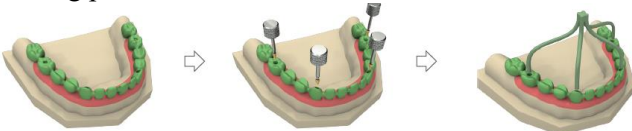


15.2.2. Preparation of the Wax Model:

1. After the burn-out caps are fixed to the analogs, cutting is performed up to the maximum occlusal screw level according to the dimensions of the dental prosthesis to be created. Prosthesis teeth model is prepared with wax on the cut burn-out caps.



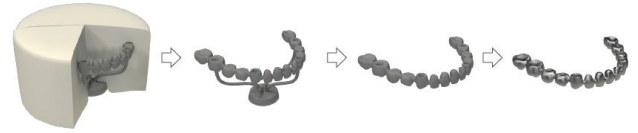
2. The occlusal screws are removed, and wax channels are placed over the formed wax model to create a casting path.



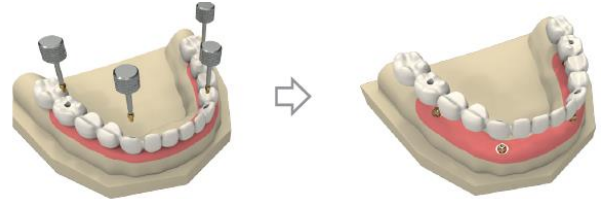
3. The wax model is removed and placed on the flask.

15.2.3. Creating the Total Tooth Prosthesis:

1. Close the wax model tightly while it is on the flask and the liquid investment is poured into the cap. After the investment have dried, investment and the molten metal are placed in the centrifugal casting device and the molten metal is injected into the mould.
2. After the molten metal has cooled down, the metal tooth model is created by breaking the investment.



3. The excess parts of the metal tooth model is cleaned, and sandblasting or polishing processes are performed.
4. The metal dental prosthesis is placed on the analogs in the plaster model and occlusal screws are attached.
5. Processes such as coating and polishing are performed on the metal dental prosthesis.
6. After the controls and corrections are performed on the total dental prosthesis, the prosthesis is removed by unscrewing the occlusal screws.



15.3. Using the Multi Unit Abutment Open/Close Top Tray Impression Part:

15.3.1. Measuring:

1. If the patient has a temporary prosthesis in his/her mouth; the temporary prosthesis is carefully removed with a manual hex key (T0 25253). If there is a comfort cap on the multi-unit abutment; the comfort is carefully removed with a manual hex key.
2. Make sure that there are no particles or soft tissue on the multi unit abutment platform.
3. Depending on the user preference and clinical situation, the impression taking parts are carefully placed on the multi unit abutment according to the impression taking technique to be applied (open tray or close tray).
4. Before the tray is placed in the patient's mouth, an elastomeric which is a dense impression material is placed in the impression tray.
5. When the material has cured and hardened, the mould is removed from the patient's mouth with the impression tray.
6. In order to prevent any substance from entering into multi-unit abutments, comfort cap is placed on it and tightened with a hex key.

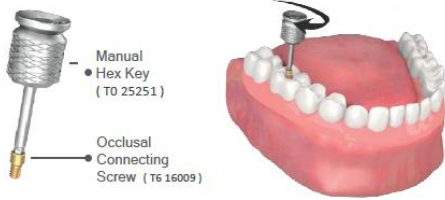
15.3.2. Creating the Plaster Model:

1. Multi unit analogue is carefully placed on the impression part in the tray and fixed with the connection screw.
2. Pour plaster into the measuring tray and wait until the plaster is cooled.
3. After the plaster has set, the impression tray is removed, the impression parts are removed and the process is completed. The burrs on the prepared plaster model can be cleaned and the prosthesis can be made.

4. The prepared total prosthesis is tested on the plaster model and the passive fitting prosthesis is sent to the clinic together with the plaster model to be placed on the patient.

15.4. Placing the Total Dental Prosthesis in the Patient's Mouth:

1. The total prosthesis is placed in the patient's mouth and occlusal screws are inserted into the abutments with the help of a manual hex key.



2. The occlusal screws should be torqued to a maximum of 20 Ncm with the help of tightening wrenches.



3. Finally, the screw hole in the tooth occlusal is covered with teflon and filling material is applied and hardened in case the total prosthesis is to be removed in the future.

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:

869938335MA79: Multi-Unit Abutment

869938335TMA2L: Temporary Multi-Unit Abutment

869938335MTA26: Multi-Unit Tibase Abutment

20. Symbol Explanations:

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



Şanlılar Tıbbi Cihazlar Medikal Kimya San. Tic. Ltd. Şti.
İTOB Organize Sanayi Bölgesi İTOB Atatürk Caddesi No:24
Tekeli/Menderes/İZMİR/TÜRKİYE
T: +90 232 799 03 04 F: +90 232 799 03 06

EU REP

SLH Microtech GmbH
Tiergartenstr. 7b ,64646 Heppenheim (Bergstr.),
Deutschland



Publishing Date: 24.10.2025

Revision Date: -

D010/Rev000