

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 & T6 Torq 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. CAD-CAM Abutments

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.

CAD-CAM abutments of the NucleOSS Dental Implant System are produced from Grade-23 Titanium alloy according to ISO 5832-3 standard and are sold non-sterile. It must be sterilized 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 body 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:

Nucleoss T6 and T6 Torq Dental Implant Systems are designed for use in dentistry. Nucleoss abutments and prosthetic parts are medical devices used to support mandibular and/or maxillary crown-bridge or superstructures in patients with total or partial prosthesis indications.

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 must be fixed with the abutment screw provided and tightened in accordance with the torque value given in the torque value table.
- 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.
- You can find the appropriate torque values for the use of superstructures 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
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:

Final prosthetic treatment with an implant can only be performed after the soft tissue has healed and is free of inflammation.

The abutment is selected by the clinician based on the patient's individual situation. Abutment choice depends on implant diameter and mucosal thickness. Great care should be taken in choosing the abutment according to the diameter and angularity of the implant, as well as the gingival height.

15.1. Digital Solutions Tibase Abutments

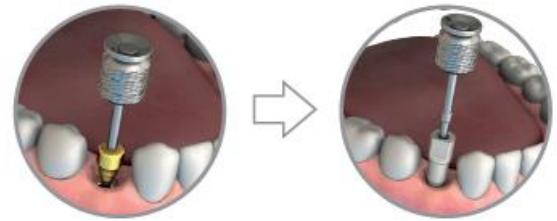
Final prosthetic treatment with an implant can only be performed after the soft tissue has healed and is free of inflammation.

The basis is chosen by the clinician based on the patient's individual situation. Abutment preference depends on implant diameter and mucosal thickness. Great care should be taken in choosing the abutment according to the diameter and angularity of the implant, as well as the gingival height.

Use by the Dentist:

1. Before placing the abutment on the implant, remove the healing cap or temporary abutment and clean the inside of the implant.
2. In digital solutions, use scanning parts to take an intraoral scan of the patient.

3. Connect the scan part to the implant with the M.1.6 connecting screw using a Hex wrench. The flat surface on the part shows the Hex direction of the implant to which it is connected.



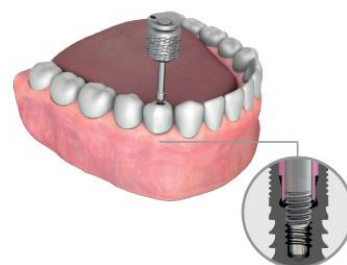
4. An intraoral scan is performed and the jaw model is transferred to the digital environment. All digital library files of NucleOSS Cad/Cam parts can be used in exocad, 3shape or dentalwings dental design programs. Note: You can download and use all updated versions of Cad/Cam files free of charge from the website www.nucleoss.com.

Use by the technician:

5. After the intraoral scan, the 3D jaw model is transferred to the digital platform. CAD/CAM Ti-base abutments are placed in place of the scanning part on the digital platform and the dental prosthesis is designed.
6. The 3D dental jaw model and dental prosthesis created on the digital platform are printed and checked.
7. The digital analog 3D jaw model is mounted on the model using the digital analog cover.
8. Coating and polishing processes of the 3D dental prosthesis are performed.
9. Cement is applied on the Ti-base abutment and adhered to the prosthesis.
10. The created dental prosthesis is mounted on the patient's 3D jaw model using a digital analog cover.

Use by the Dentist:

11. It is placed on the implant with the hex direction of the abutment facing towards the vestibule.
12. The connection screw is tightened with a manual hex wrench (by hand) until it holds the implant and the torquing process begins.



- The connection screw is tightened with a manual hex wrench (by hand) until it holds the implant and the torquing process begins. After that; The connection screw of the Ti-base abutment is torqued up to a maximum of 30 Ncm with the help of a torque rail.

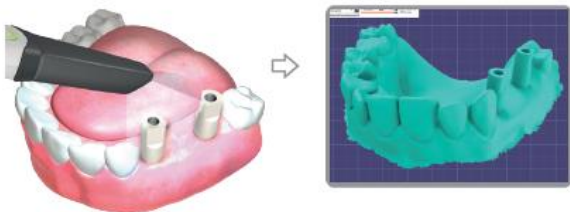
15.2. Multi Unit CAD/CAM TiBase Abutments

Intraoral Scan

- The comfort cap from the patient's mouth is removed.
- Scan posts are placed on multi unit abutments. Occlusal screws are fixed on multi unit abutments with the help of a hex driver. The screw of the scanning part is torqued with a maximum of 5 Ncm.

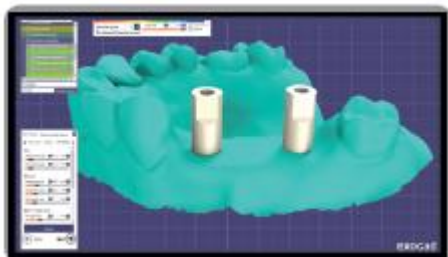


- An intraoral scan is performed and a 3D dental model of the patient's mouth is created digitally. Scanning posts or abutments designed for NucleOSS digital solutions can be used integrated with dental design programs such as exocad, 3Shape and dentalwings.

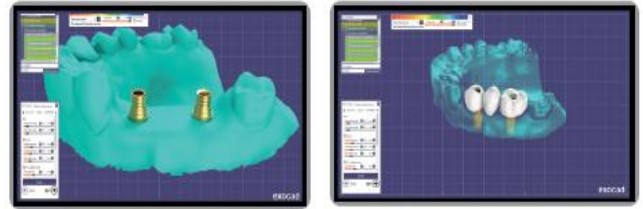


Creating a Bridge Dental Prosthesis on a Digital Platform

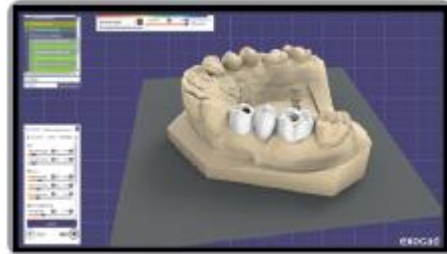
- An intraoral scan is performed and the lower jaw model is transferred to the digital platform environment. Multi unit ti-base abutments are selected from the program's library.



- A bridge dental prosthesis is made on multi-unit ti-base abutments.



- After the prosthetic teeth are created, checks are made on the patient's 3D dental model on the digital platform.



Preparation of 3D Dental Model

- Using 3D resin printers, the dental tooth model created on the digital platform is printed. Multi unit digital analogues and connection screws are prepared for mounting on the 3D dental model.



- Multi unit digital analogues are placed so that the flat surface on them and the flat surface in the 3D dental model coincide with each other.



- Green connection screws are placed on the multi unit digital analogs in the 3D dental model with the help of a manual hex driver, and the analogs are fixed to the model.



Preparation of Bridge Dental Prosthesis

1. The bridge prosthesis designed on the digital platform is tested on a 3D dental model after going through processes such as engraving and sintering.



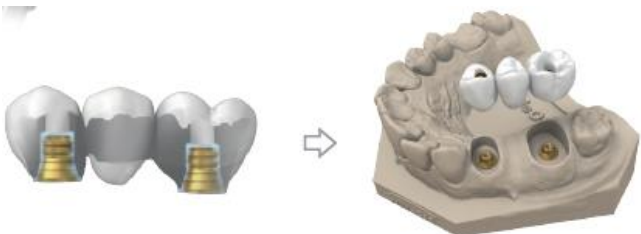
2. It is prepared to attach multi-unit tibase abutments and occlusal screws to the 3D dental model.



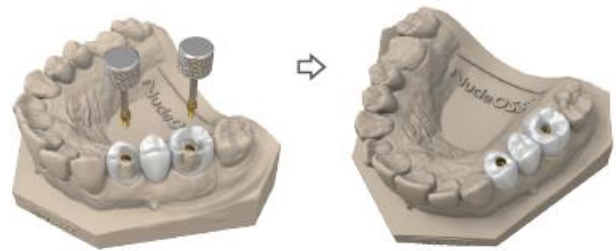
3. Multi-unit tibase abutments are placed into the created dental prosthesis and checked. After the necessary corrections are made, cement adhesive is applied into the dental prosthesis. Multi unit tibase abutments are placed and the cement is waited to set. At this stage, be careful not to let the cement get into the tibase abutment.



4. After the cement adhesive sets, the created bridge dental prosthesis is placed on the multi-unit analogues in the 3D dental model.



2. Its compatibility with the teeth on the right and left is checked. After the necessary corrections are made, the bridge dental prosthesis is sent to the clinic to be installed in the patient's mouth.



Placing the Bridge Dental Prosthesis in the Patient's Mouth

1. The created bridge dental prosthesis is placed on the multi-unit abutments in the patient's mouth. Occlusal screws are tightened using a manual hex driver until they hold on to the multi-unit abutments.



2. The occlusal screw is tightened with a torque ratchet until it reaches a maximum torque value of 20 Ncm.



Checking the Bridge Dental Prosthesis

1. After the bridge dental prosthesis is placed on the multi unit analogues, occlusal screws are also placed.

3. The screw hole in the tooth occlusal is closed with Teflon and filling material is applied and hardened. When it is desired to disassemble the total prosthesis, this material is removed and the screw is removed.

Once the Nucleoss abutment is secured to the implant with the specified torque, it should not be removed.

Caution: 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.

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/>)

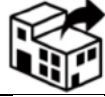
19. Basic UDI-DI Information

869938335CTAYH: Cad-Cam Ti-Base Abutment

869938335CCTATM: Cad-Cam Cerec Ti-Base 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.		

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