NucleOSS™

SLIMex

NucleOSS Dental Implant System

SURGICAL GUIDE

This manual contains recommended instructions for use for surgical applications of the NucleOSS Dental Implant system. Treatment and surgical planning should be based on clinical data and the physician's evaluation of the case.

FEBRUARY 2024 EN

Dear Clinician

Şanlılar Ltd.Şti., the manufacturer of the NucleOSS brand, was established in Izmir in 2001 and produced Turkey's first dental implant. In the light of meticulous R&D studies and knowledge, we continue to produce more innovative and user-friendly products for you with the excitement of the first day, by adopting world-class sensitive production protocols. In order to increase the quality of the operation and to enable more comfortable treatment processes, we design and develop quality and innovative products, and offer them to you.

We established the TFI (Together for Implantology) academy in order to create a platform where dentists can share their ideas, studies and information about implants within an ethical framework and thus contribute to the development of the field of implantology. As NucleOSS, we adopt reliable, quality and customer-oriented production with transparent, ethical and principled management.

We work more and more every day within the framework of our open to change and innovative approach, which is the first condition of progress and growth. We design new products, constantly change and develop with our understanding of management and production that values people.

We are growing thanks to your support... We are enchanting...

Salih ŞANLI

PRESIDENT

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NucleOSS™

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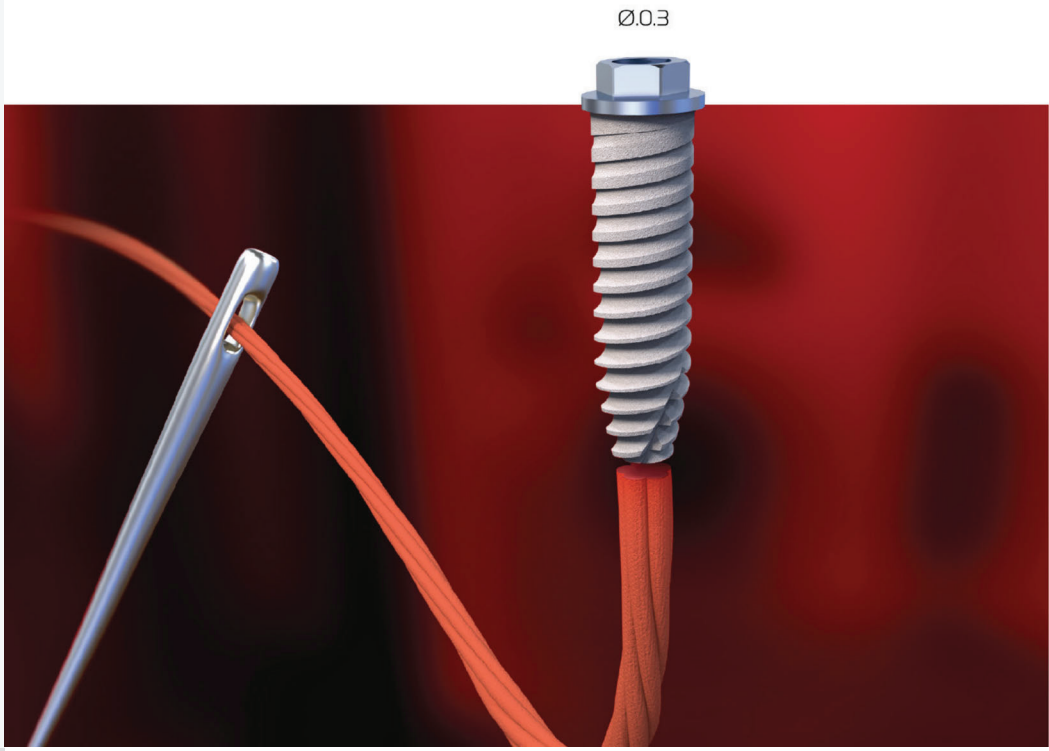
NucleOSS™

SLIMex

Offers thin and durable solutions in the crests where bone thickness is insufficient.



Bone Level Implant

extra slim **extra durable**

Different and wide prosthetic feature, gingiva height abutment option.

Slimex implant the newest member of the NucleOSS product family, offers thin and durable solutions in the crests where bone thickness is insufficient.

The certified unique Maxicell surface provides a safe and high survival rate for Slimex implants.

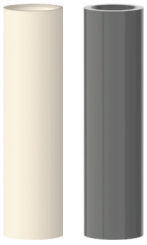
Slimex, which has a durable and reliable structure thanks to its external design, satisfies all implant treatments with its unique and wide superstructure options.

NucleOSS offers the Slimex implant, developed with 20 years of R&D experience and the support of specialist physicians, to the use of you, precious physicians.

- Cemented Solutions

- Screw-Reatined Solutions

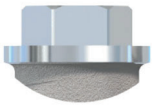
- Custom Solutions



- Overdenture Solutions

- Digital CAD/CAM Solutions

Hexagonal External Connection

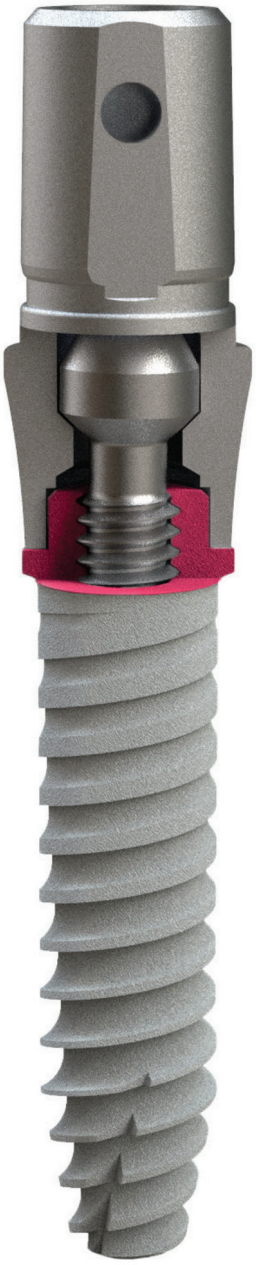


Thanks to hexagonal external connection of NucleOSS Slimex Implant, abutments can be applied with 6 different positions within 60° rotation.

Double Thread

Double Thread and reverse buttress form provide faster and easy loading. Increases contact area between bone and implant.

Strong Side Walls



Ø 3.0 Diameter

3.0 mm implant diameter for narrow crests.

Cutting Edges

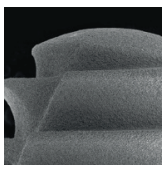
It enables the implant to move into the implant bed steadily and without damage when placing the implant.

Maxicell Surface

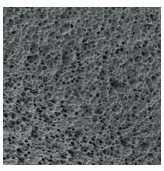
Proven and certificated clean and hydrophilic unique surface.

Certified Maxicell Surface

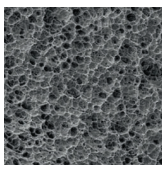
Zoom x100



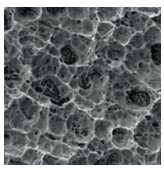
Zoom x1000



Zoom x1500



Zoom x3000

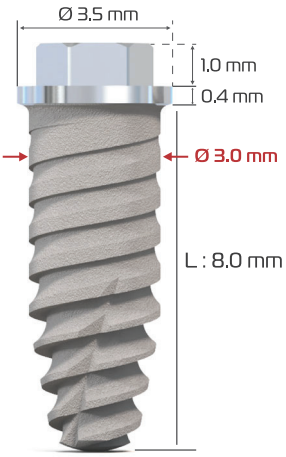


Diameter and Length Options

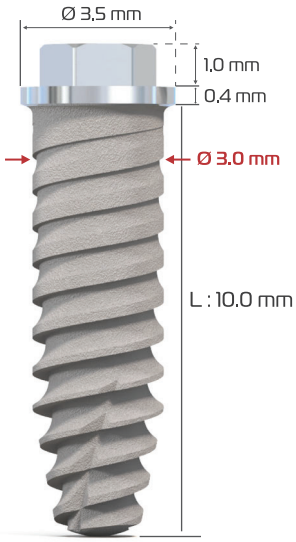
Slimex bone level narrow implant designed with modern and aesthetic details; It offers a comfortable surgical process to the physician and the patient with its safe surgical protocol. It brings bold smiles with its wide superstructure range. It refreshes your self-confidence with its smiling designs and advanced strength.

Slimex implant is provided in four different sizes.

Ø3.0



Lenght	Product No
L : 08	> TS 3008



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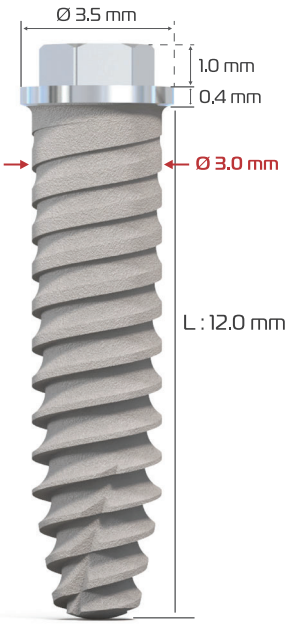
L : 10	> TS 3010



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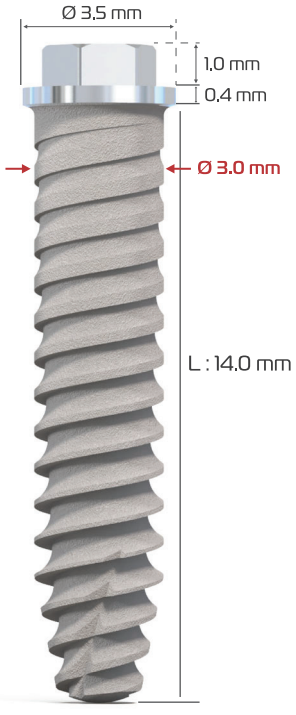
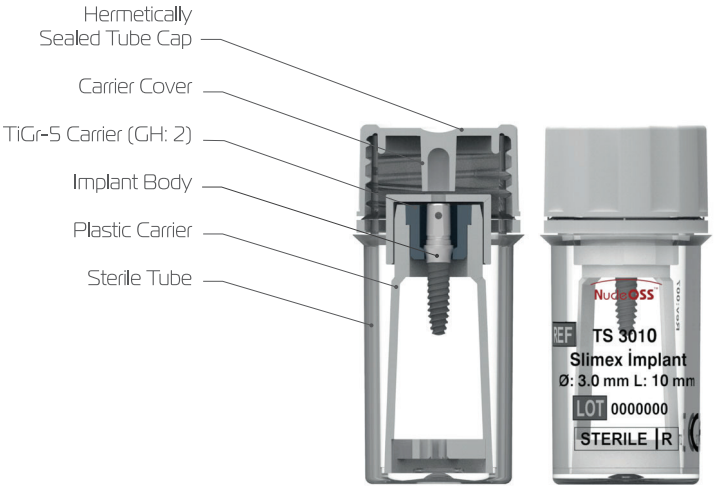


Lenght	Product No
L : 14	> TS 3014

Package Content

Slimex implant is provided in blister and sealed sterile tube. The implant package includes; comfort cap, impression post, abutment screw and standard abutment GH:2mm.

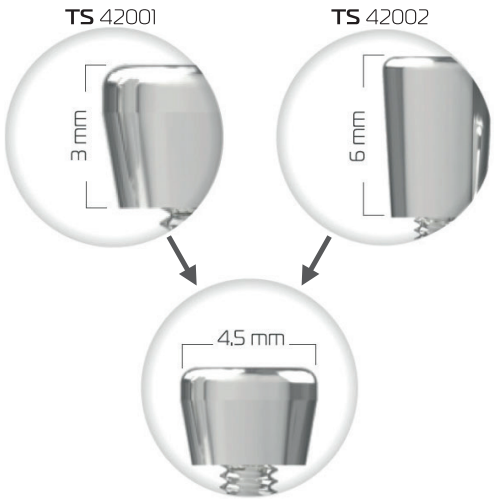


Slimex implant boxes are opened by tearing over the line that created for security purposes.

The first safety barrier of Slimex implants are thermoforms. The package is opened by holding the opening end on the edge and the tube is taken out.

Package content consists of 3 parts.

Connection Screw	Impression Cap	Comfort Cap (short)	Comfort Cap (long) (extra)
TS 18000	**TS** 32909	**TS** 42001	**TS** 42002



Product Image	Material	Prosthetic Platform Ø (mm)	Gingival Height GH (mm)	Description	Code
Standard Straight Abutments					
	Ti Gr5	4.2	0.6	Straight	TS 42003
			1.6	Straight	TS 42004
			2.6	Straight	TS 42005
			3.6	Straight	TS 42006
Angled Abutments					
	Ti Gr5	4.2	1	15°	TS 42007
			2	15°	TS 42008
			3	15°	TS 42009
			4	15°	TS 42010
Auxiliary Parts					
	Plastic	4.3		Impression Cap	TO 32909
	Ti Gr5			Abutment Screw	TS 18000
	Ti Gr5	4.2		Open Tray Impression Screw	TS 18002
			3	Open Tray Impression Post	TS 32606
			3	Close Tray Impression Post	TS 32603
	Plastic			Impression Cap for Close Tray	TO 32912
	Stainless Steel	3.5		Analog	TS 32206

The abutments are made of TiGr5 material.

The abutments are provided with a connecting screw.

The basis suitable for planning can be selected from the table.

Pack Content

Pack Content

Cemante offers solutions in different prosthetic platform diameters and gingival heights for prosthetic solutions. Angled abutments offer solutions in different prosthetic platform diameters and gingival heights for cemented angled prosthesis solutions. It has 15° angle options.

Product Image	Material	Prosthetic Platform Ø (mm)	Gingival Height GH (mm)	Description	Code
Casting Caps					
	Delrin	3.5		Burn Out Cap (NO HEX)	TS 35000
				Burn Out Cap (HEX)	TS 35001
	Ti Gr5			Abutment Screw	TS 18000
Auxiliary Parts					
	Ti Gr5	4.2		Open Tray Impression Screw	TS 18002
				Open Tray Impression Post	TS 32606
	Plastic			Close Tray Impression Post	TS 32603
				Impression Cap	T0 32912
	Stainless Steel	3.5		Analog	TS 32206
CAD-CAM Abutments					
	Ti Gr5	4.2	0.6	NO HEX	TS 42012
			2.4	NO HEX	TS 42013
			2.4	HEX	TS 42014
			0.6	HEX	TS 42015
CAD-CAM Auxiliary Parts					
	Ti Gr5	4.8		T6 Multi Unit Digital Analog	T6 32210
	Stainless Steel	3.5		Slimex Digital Analog	TS 32209
	Ti Gr5			Digital Analog Screw	T0 2015
	PEEK	3.5		Scan Post	TS 42011
	Ti Gr5			Abutment Screw	TS 18000

Pack Content

Pack Content

CAD/CAM Ti-base abutments are designed for physicians and laboratories making dental designs on digital platforms. Hex connection options are available for single tooth treatments and No Hex connection options are available for multiple tooth treatments.

Universal Casting Caps are designed for physicians and laboratories who design personalized superstructures with the casting technique. It is made of Delrin material. Hex (White) for single tooth and No-Hex (Black) for multi-tooth applications are available. Supplied with one cast cap and abutment screw.

Product Image	Material	Prosthetic Platform Ø (mm)	Gingival Height GH (mm)	Description	Code
Multi Unit Abutments (0°)					
	Ti Gr5	4.8	1.5	Straight	TS 47000
			2.5	Straight	TS 47001
			4.5	Straight	TS 47002
	Ti Gr5	4.8	4.4	Comfort Cap	T6 32915
			5.7	Comfort Cap	T6 32921
	Ti Gr5	4.8		Occlusal Screw	T6 16009
Multiple Teeth (NO HEX)					
	Ti Gr5	4.8		Impression Cap	TO 32912
				Impression Post (close)	T6 32614
				Impression Post (open)	T6 32613
	Ti Gr5	4.8		Ti-Base Abutment	T6 32813
				Temporary Titanyum Cap	T6 32916
	PEEK / Delrin / Ti Gr5	4.8		Scan Post	T6 32037
				Burn Out Cap	T6 32917
				Analog	T6 32207
Single Tooth (HEX)					
	Plastik / Ti Gr5	4.8		Impression Cap	TO 32912
				Impression Post (close)	T6 32617
				Impression Post (open)	T6 32616
	Ti Gr5	4.8		Ti-Base Abutment	T6 32814
				Temporary Titanyum Cap	T6 32919
	PEEK / Delrin / Ti Gr5	4.8		Scan Post	T6 32038
				Burn Out Cap	T6 32918
				Analog	T6 32208

Pack Content

Pack Content

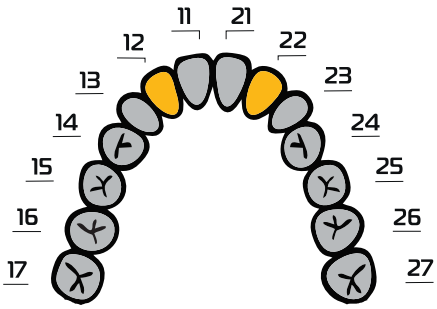
Multi unit abutments are shipped with NO HEX option, green color burn out cap and two occlusal screws. Multi unit abutments are shipped with HEX option, blue color burn out cap and two occlusal screws.

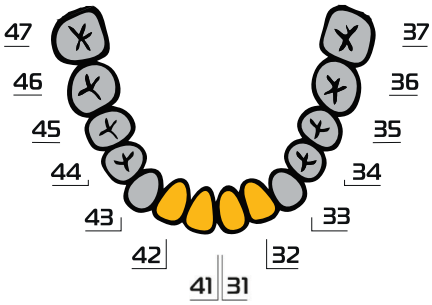
Product Image	Material	Prosthetic Platform Ø (mm)	Gingival Height GH (mm)	Description	Code
Ball Abutment					
	Ti Gr5	4.5	1.5		TS 45003
			2.5		TS 45004
			4.5		TS 45005
Ball Abutments Auxiliary Parts					
	Stainless Steel	3.5		Analog	TO 4521
	Ti Gr5			Impression Cap	TO 32615
				Metal Ring	TO 5200
	Silicon			Silicon Ring	TO 4500-3
				Silicon Ring (for impression cap)	TO 4500-18
Equator® Abutments					
	Ti Gr5		1.5		TS 45000
			2.5		TS 45001
			4.5		TS 45002
Equator® Abutments Auxiliary Parts					
	Ti Gr5	4.5		Impression Post	044 CAIN
				Analog	144 AE
	Stainless Steel			Tightening Part (Ratchet)	774 CHE
				Tightening Part (motor)	760 CE
				Cap Inserter and Exractor Tool	485 IC
	Ti Gr5			Metal Housing	CA008
	Silicon			Transparent/Standart	CN051
				Pint/Soft	CN052
				Black/Laboratory	CN068

Pack Content

Pack Content

Ball abutment solutions are offered to users with different gingival heights in removable total prosthesis treatments. It is made of TiGr5 material. Equator® abutment solutions are offered to users with different gingival heights in removable total prosthesis treatments. It is made of TiGr5 material.





While planning the superstructure in dental implant - prosthesis treatment, the positioning of the implant in the patient's mouth constitutes the basic structure.

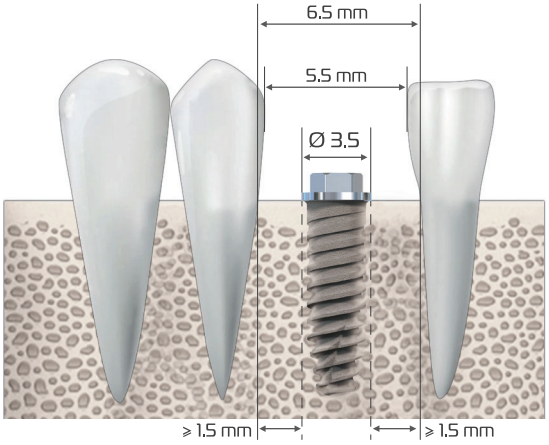
Implant abutments should always be planned axially and coaxiality should be provided with the lateral teeth. The anatomical condition of the patient should be considered when deciding on the diameter, length, model and number of implants and abutments.

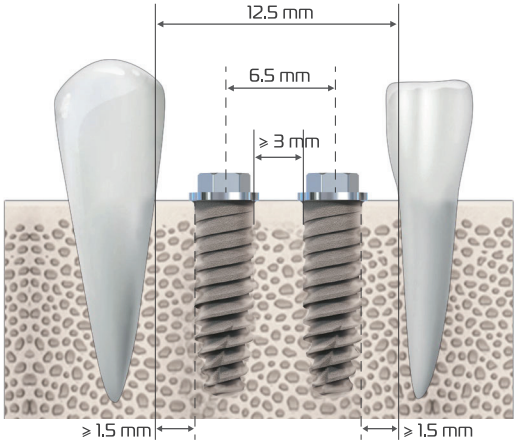
Below are the recommended minimum placement sizes when planning the Slimex implant in the patient's mouth.

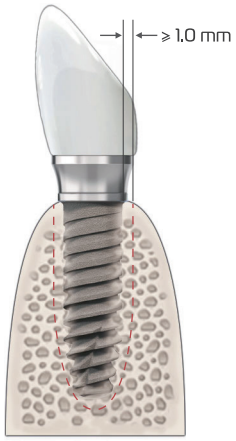
Diameter & Length Selection Suggestions :

The image shows the recommended areas of use according to the diameter of the Slimex bone level implant. For treatment and implant selection, the clinician should evaluate the patient, the case and the intended restoration. Use outside the specified regions is the choice and responsibility of the clinician.

Implant Positioning:







In order for the implant to provide primary stability in the bone, there should be a minimum of 1.0 mm bone thickness on the palatal and vestibule surfaces.

In cases where the bone thickness is below 1.0 mm, the augmentation method can be applied.

Pre-Operational Examination

General evaluation of the patient should be made with clinical and oral radiographic tests, and mucous membrane, jaw morphology, dental history, prosthetic history and oral dysfunctional signs should be carefully examined before the operation. Radiographic analyzes should be used in the examination of bone topography.

In addition to clinical examination, preliminary radiographic evaluations are a basis for determining the patient's suitability for implant treatment.

If the patient is found suitable for treatment, a more detailed clinical examination should be performed for the treatment area and the countervailing area. Any pathological condition detected in the jaw should be treated before the implant operation.

Pre-Operation Planning

While performing the planning before the operation, the final prosthetic treatment should be considered and planning should be done accordingly. First of all, the intended final prosthetic treatment should be planned, and the type and number of implants should be decided accordingly. The prosthetic material to be used should be chosed according to the region where the implant will be placed. While planning the treatment, all stages from the healing process to the final restoration should be evaluated with the intended final treatment in mind

Articulator-mounted models provide information about the connection between the tooth and the jaw. Wax modeling from the edentulous area makes an important contribution to correct planning. The most appropriate treatment planning can be achieved by examining the occlusal picture and evaluating factors such as load distribution and preferred slots for implants.

The Transparent Radiographic Implant Guide, showing the magnified dimensions of the implants at different rates, will contribute to the most appropriate selection of the point, direction and length of implant.

During the surgical operation, factors such as the primary stability of the implant, single-stage or two-stage surgery, immediate implant placement after extraction, and expected recovery time before loading should be considered as well as the intended final treatment approach.

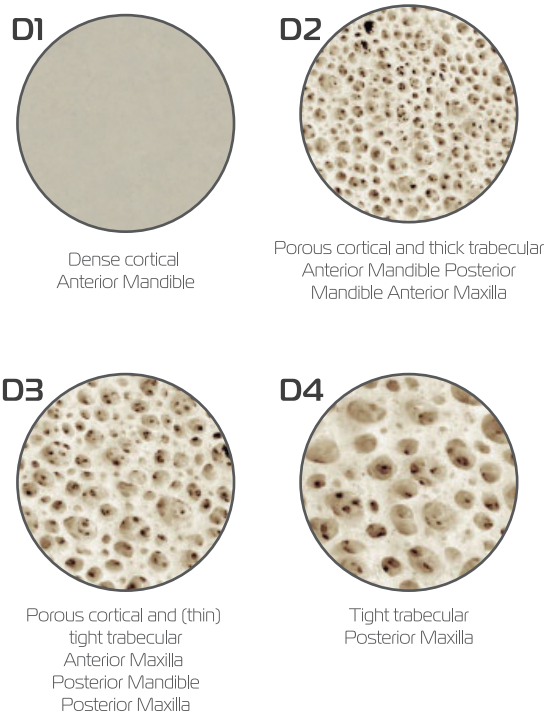
The recommended healing period before loading is 12 weeks, unless there is a different medical decision taken by the physician.

In each case, the loading time for each implant should be determined by the clinician by carefully examining bone quality, quantity, density, primary stability, restoration style, and loading conditions.

Before starting the treatment, hole process should be clearly explained to the patient by specifying the results of the examination performed before the operation, the required treatment method, the expected result after the treatment, the required care and possible risks.

Bone Classification

Since the thickness and density of the bones of every patient vary, implant placement and surgery also varies for each case. According to the case data identified at the examination, the appropriate route should be followed for loading and implant surgery. Therefore, the NucleOSS surgical set and protocol were prepared taking into account these functional needs.



D1 — Dense cortical
Anterior Mandible

D2 — Porous cortical and thick trabecular
Anterior Mandible Posterior
Mandible Anterior Maxilla

D3 — Porous cortical and (thin)
tight trabecular
Anterior Maxilla
Posterior Mandible
Posterior Maxilla

D4 — Tight trabecular
Posterior Maxilla

The NucleOSS Dental Implant System has been developed considering the natural oral anatomy and the intended final prosthetic restoration.

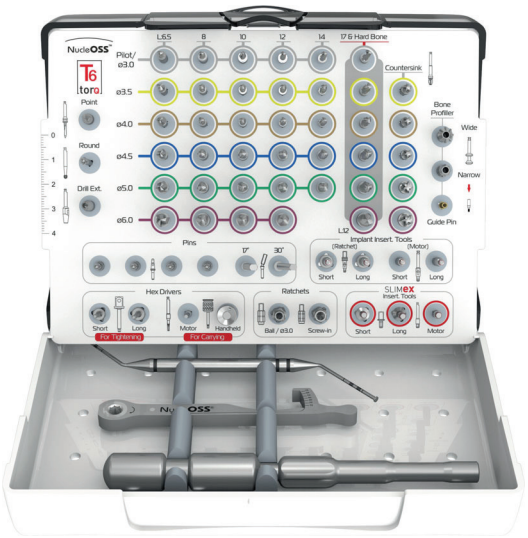
Positions of implants are recommended based on crown-implant compatibility. However, while deciding on the placement of the implant, the size and shape of the implant, soft tissue healing, support required for the intended final restoration, bone volume, and connection to the neighbor tooth should be considered.

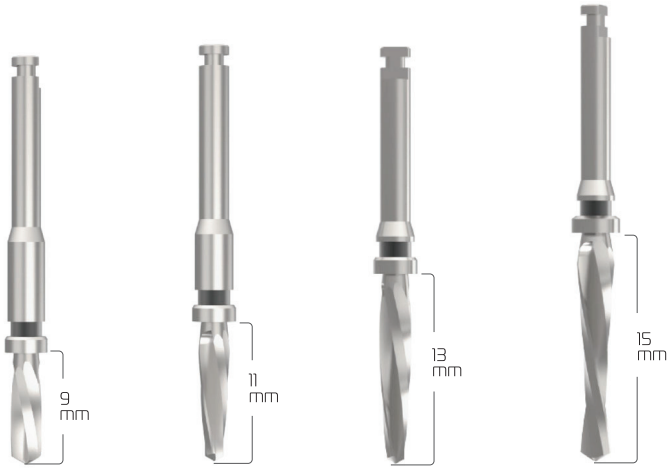
Based on mechanical considerations, it is always recommended to use the largest diameter implant possible. This recommendation should be especially taken into account for the rear areas where the loading forces are higher. In all cases, loading conditions and the intended final prosthetic restoration should be considered when planning implant surgery and determining the number of implants.

In order to place Slimex implants in the jawbone, the point and pilot drills in the T6 standard and T6 torq surgical sets should be used.

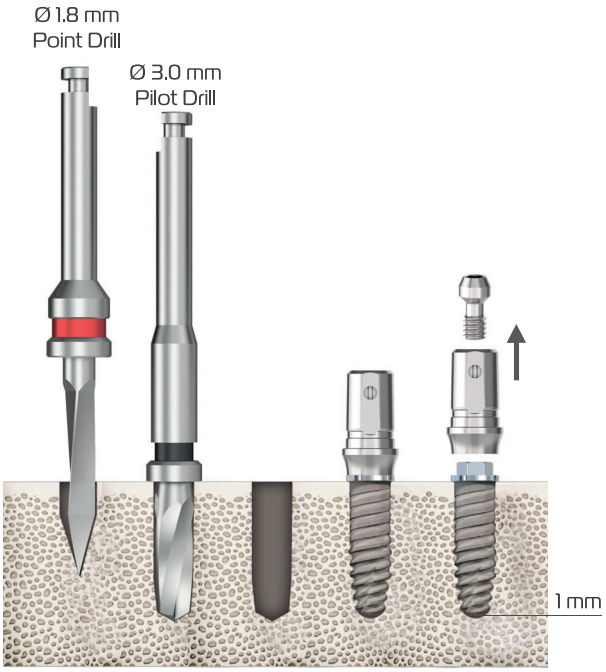
CRH-109
T6 Standard Surgical Set

CRH-115
T6 Torq Surgical Set





Lenght >	L:08	L:10	L:12	L:14
Product No >	**T0** 25043	**T0** 25044	**T0** 25045	**T0** 25046



Step 1 : Point drill is done to determine the slot location.

The final drills for Slimex implants are the standard pilot drills found in the T6 standard and T6 TorQ surgical sets. The drills are with stoppers and there are separate drills for each implant size.

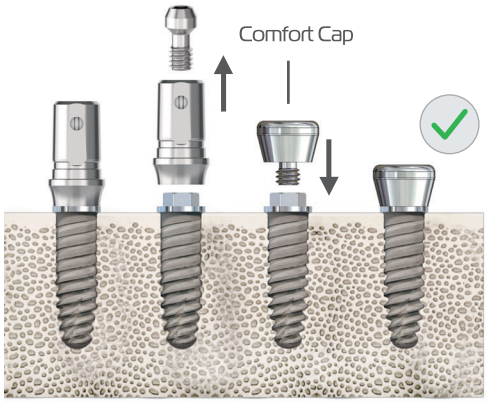
The slot preparation is completed by entering the slot opened with a point drill with the drill selected according to the implant size.

Drills should be run with coolant at max. 800 rpm.

Step 2 : The slot preparation is completed by entering the slot opened with a point bur with the bur selected according to the implant size.

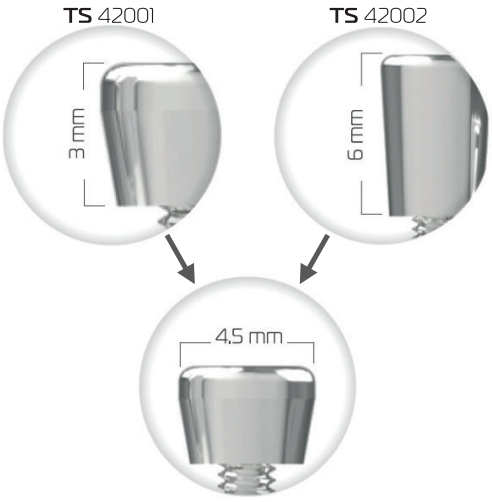
Step 3 : The implant (with the carrying part) is carefully placed in the opened slot.

Note : Drill length is 1 mm longer than implant length. This should be taken into account in surgical planning.



Step 4: Finally, the necessary healing caps are placed on the implant and left to the osseointegration process.

TS 42001 **TS** 42002

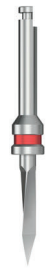


Attention ! : NucleOSS standard pilot drills should be used in the drill protocol of the implants.

The Drills are designed 1 mm longer than the implant length. Therefore, if the drill stopper comes into contact with the bone, the bur will open the implant socket 1 mm deeper than the implant length.

Drill lengths should be taken into account when planning the drill for the implants.

Drill Protocol - Auxiliary Parts



T0 25024
Point Drill

T0 0103
Round Drill

T0 2012-1
Frez Extension

T0 25320
Pilot
Parallel Pin

T0 25212
Ratchet
Adaptor

T0 2024
Hex Driver
Short (Ratchet)

T0 2025
Hex Driver
Long (Ratchet)

T0 2009
Hex Driver
(Motor)

T0 25251
Hex Driver
(Handheld)

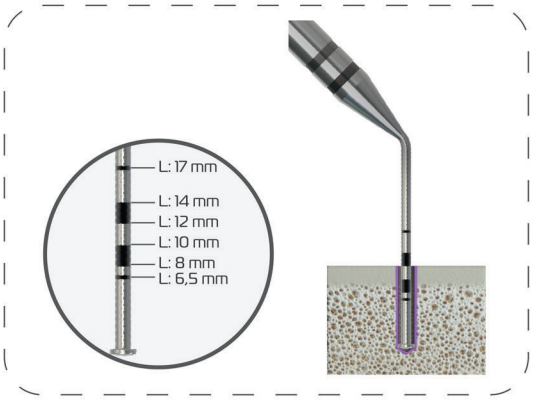
T0 25205
Ball Abutment
Tightening Parts

T0 25206
Screw-Retained
Abutment
Tightening Parts

T0 2005-1
Tightening Parts
Long (Ratchet)

T0 2006-1
Tightening Parts
Short (Ratchet)

T0 2008
Tightening Parts
(Motor)



T0 25312
Depth Gauge

T0 25900
Ratchet

T0 2022
Screwdriver

Opening the package

Slimex Implant boxes are opened by tearing over the traced line created for security purposes.

Opening the thermoform

The thermoforms, which are the first safety barrier of Slimex implants, are opened by holding the opening tip on the edge and the tube is taken out.

Opening the tube cap

The tube cover, which is another safety barrier, is opened by turning it counterclockwise. There is a security ring attached to the covers with thin nails. When the cap is turned, the tabs break off and the safety ring is separated from the cap and remains on the tube.

If this ring is separated from the cap at first use, it indicates that the tube has been opened before.

Caution : Thermoform or tube cap unlocked implants should not be used.

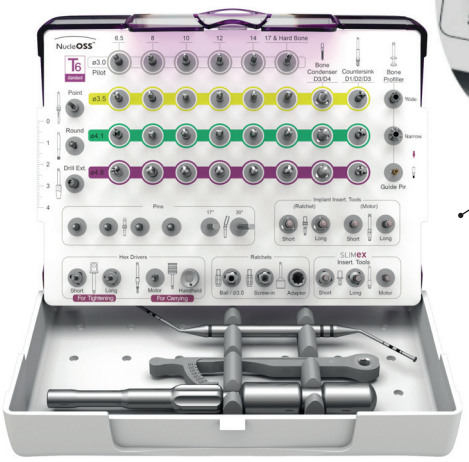
The tube is removed by turning it upside down from the closest distance on the carrier glove or sterile clean cloth in the Slimex implant with the opened cover.

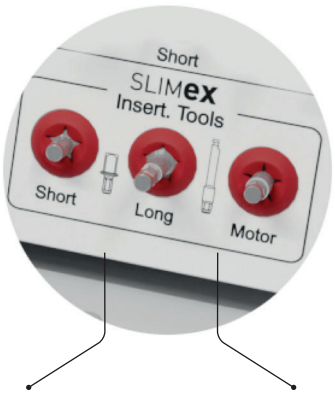
The carrier cover is held with the help of the thumb and forefinger, turning it slowly with the help of the thumb and index fingers of the other hand and pulled upwards.

Caution : Caution: Once the carrier is capped, the implant is released, so the carrier should never be tilted more than 60°. Otherwise, the implant may come off and fall.

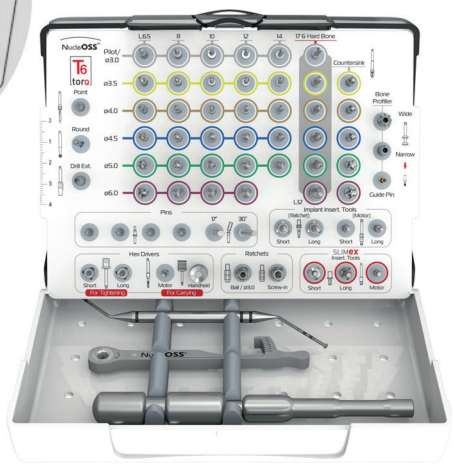
After the implant carrier cover is opened, the implant is transported and placed in the area where it will be placed with the help of Slimex carrying parts in T6 surgical kits.

CRH-109
T6 Standard Surgical Kit





CRH-115
T6 Torq Surgical Kit



TO 2005-1

TO 2008

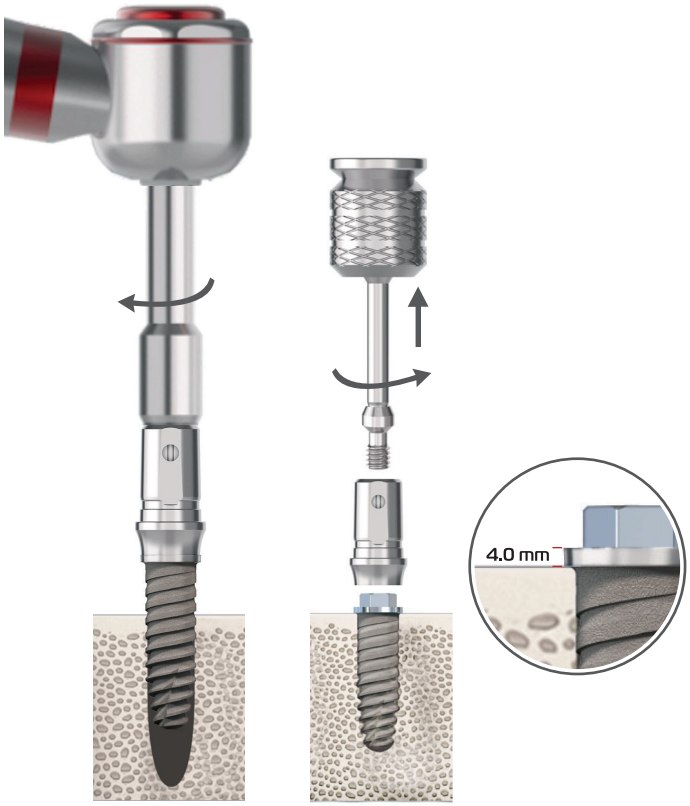
TO 2006-1

Ratchet

Screwdriver

Motor

Attention : The red silicone ring on the ends of the transport clamping parts prevents the implant from falling during transport. Therefore, make sure that the silicone ring is in place and undamaged before use.



The Slimex implant, which is removed from the carrier, is placed in the patient's mouth as soon as possible without touching anything, into the implant socket opened according to the protocol.

While placing the Slimex implant with a motor or by hand, turn it clockwise at a maximum speed of 15 rpm until the shiny platform of the implant with a diameter of Ø3.5mm comes into contact with the bone surface.

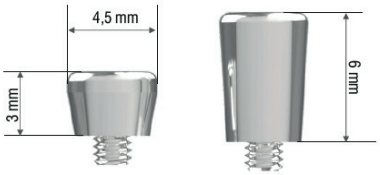
Caution : Implant placement torque is recommended as 35-40 Ncm, in order to minimize bone damage at torques higher than these values, the implant should be removed and the socket checked.

Note : The O-ring abutment clamping piece is compatible with the external hex connection of the implant and can be used after the implant is placed.

Placement of the comfort cap

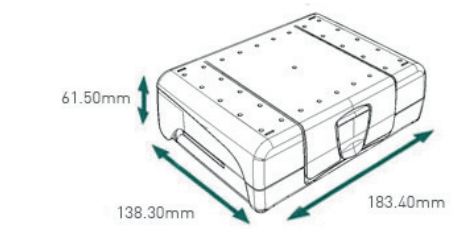
Step 1 : After making sure that the implant is placed, the carrying clamping part on the implant is removed by turning it counterclockwise with the help of a manual hex wrench.

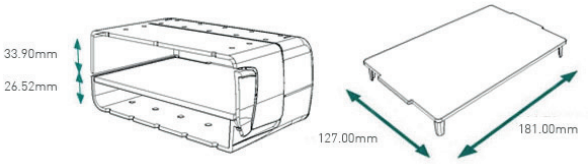
Step 2 : The healing head in the second eye of the thermoform is moved with the help of the hex key. Before inserting into the implant, the inside of the implant is cleaned with the help of a probe, then the cap is placed on the implant by turning it clockwise and tightened with a maximum torque of 10 Ncm.



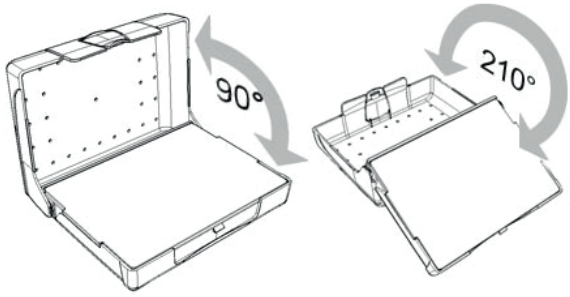
Attention: The healing head supplied with the standard package is 3 mm high. Healing head with a height of 6 mm can be selected for higher gingiva.

Dimensions





Opening Positions



NucleOSS surgical sets are designed in direct collaboration with healthcare practitioners, giving you the best possible match between the ergonomic design of the surgical tray, the surgical instruments it contains and its size.

The surgical set cover can be removed with one easy move.

Lightweight, easy to use, stackable, compact and roomy. It is easy to carry and guarantees the safety of the tools it contains, prevents them from being misplaced during transport.

The surgical set is made of highly impact resistant plastic materials suitable for autoclave sterilization. Plastic raw material can withstand more than 1000 cycles of steam sterilization.

T6 surgical sets consists of two parts, a movable middle shelf where surgical burs and tightening parts are located, and a lower section where torque ratchet and other hand tools are located.

Thanks to its compact and convenient design, it can be sterilized as one piece without having to be taken the parts inside out of the box in clinical autoclave devices.

Surgical sets are suitable for autoclave sterilization in the B134°C Prion (134°C/2.15 Bar/18 min) cycle.

Set cover can be used in two different positions by being opened 90° or 210°. When the cover is closed, the parts inside are locked automatically.

Surgical kit consists of drills, parallel pins, neck expanders, hex wrenches and hand tools.

Thanks to the flat and embedded type of silicones holding the surgical parts, they are dirt-proof and easy to clean.

Surgical drills are made of high-quality stainless steel, and after heat treatment, they have a long-lasting cutting edge with sharpening techniques.

T6 Standard Surgery Kit

T6 standard

CRH-109

T6 Torq Surgery Kit

T6 torq

CRH-115

General Info

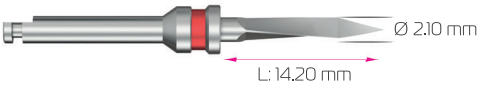
The parts in the T6 surgical sets are used with the micromotor or the NucleOSS ratchet or screwdriver in the surgical kits..

In addition, parts such as connecting screws placed on the implant, implant caps, healing caps or connecting screws placed on the abutment can also be used with the manual hex wrench included in the surgical kits.

Caution!
Drills must be correctly attached to the micromotor and should not be operated until they are properly seated.

Round Drill - T0 0103

Point Drill - T0 25024



Drill Extender - T0 2012-1

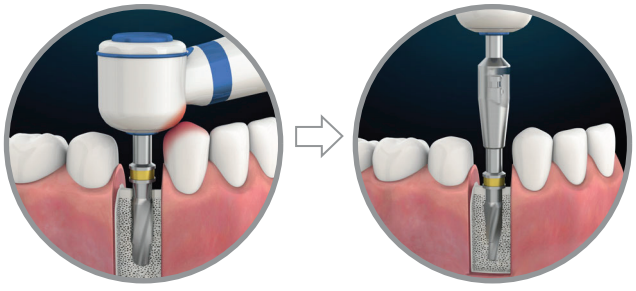
Initial drills are used to prepare the cavity during osteotomy.

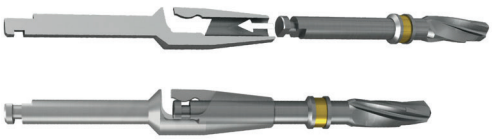
Round drill is used to make necessary corrections by filing at the beginning of the osteotomy if the bone surface in the area where the implant will be placed is damaged or irregular.

The point drill is used to determine the place where the implant will be placed on the bone and to allow the next drill to advance comfortably.

After the necessary corrections are made with the round drill , the milling is first started with the point drill according to the surgical protocol.

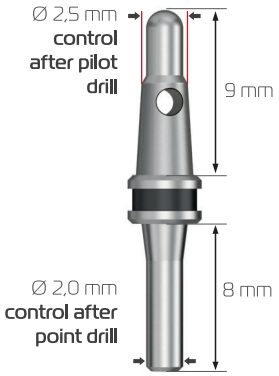
The drill extender is used to extend the drill lengths by approximately 16 mm in cases where the drill length is insufficient.





The distance is increased with drill extender in cases where the micromotor is not able to advance in the mesial or distal of the implant area.

Pilot Parallel Pins

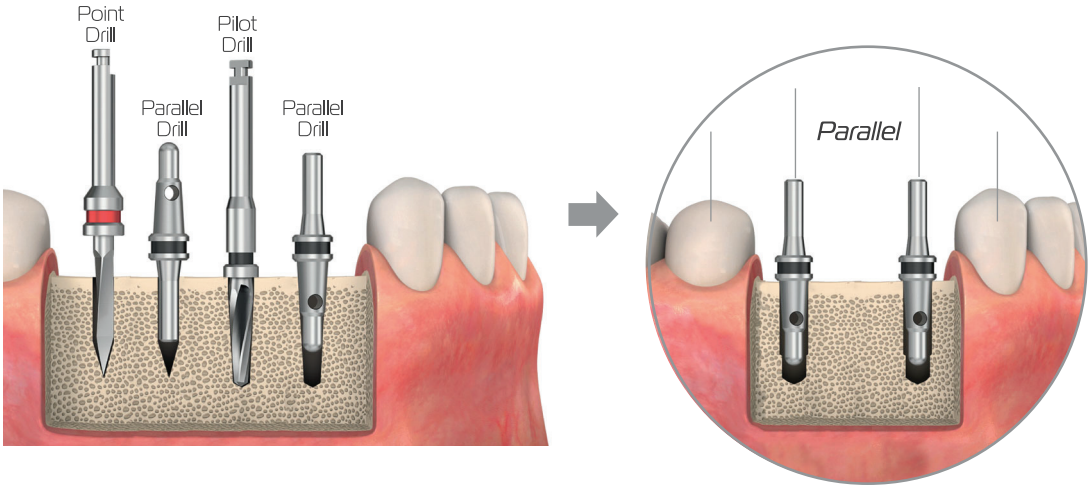


TO 25320

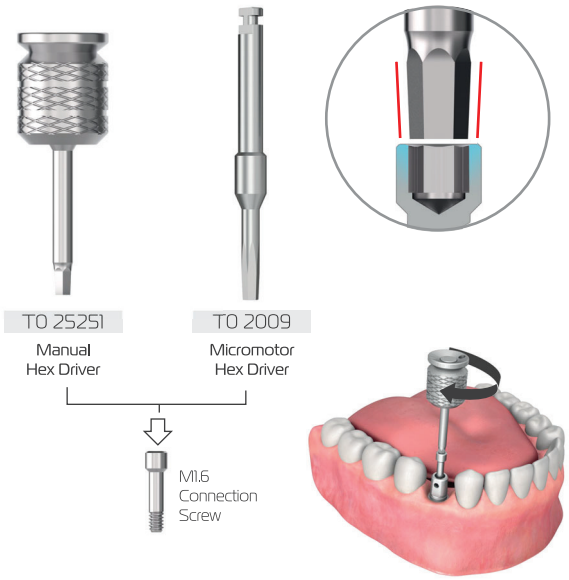
Parallel pins are used to control the parallelism with the adjacent teeth in single implant treatments, and to control the parallelism between the implant cavities during surgical intervention in multiple implant treatments

T6 surgical sets have four parallel pins.

The lower part of the parallel pin is Ø 2 mm and can be used after point drilling.



Hex Driver - Transfer



Hex wrench is used for fixing healing components, prosthetic and impression parts.

It is made of stainless-steel material.

It can be procured in a surgical set and in one piece.

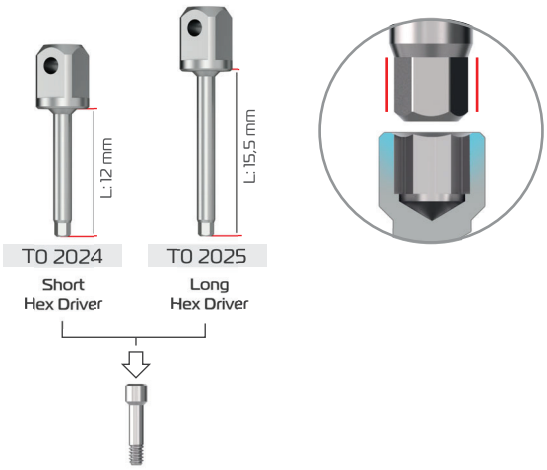
The tip of the hex wrenches used manually and with micromotor is in hex structure and conical shape.

It can be used for carrying connecting screws and healing caps and for light tightening.

Torque up to a maximum of 10 Ncm can be made with these hex driver.

Note: Final torque must never be done. Because the hex slot of the screw or the tip of the hex wrench may be damaged.

Hex Driver (torque)



The screw is held with a hex wrench and placed on the part it will be fixed to. The hex driver is gently turn clockwise to tighten the screw.

Tightening drivers are used for fixing healing components, prosthesis and impression parts.

It is used with a ratchet

It is made of stainless-steel material.

It can be procured in a surgical set and in one piece

The tip of the hex wrenches used for final torque is straight. It is only used for torque with NucleOSS ratchet. It has no retention, it is not used for carrying.

The ratchet is carefully seated on the hex driver.

The screw is tightened by turning the ratchet clockwise. By following the torque values specified at the end point, the desired torque value is set and the tightening process is completed.

O-Ring Abutment Tightening Part (ball)

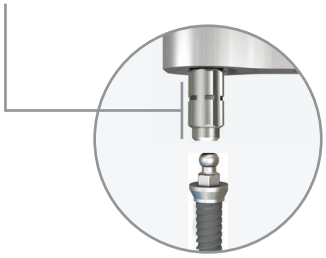
T0 25205

O-Ring abutment tightening part is used to place ball abutments on a T6 implant.

They are made of stainless steel.

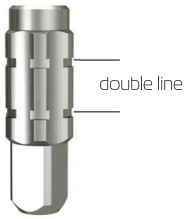
It can be used with a ratchet or screwdriver.

The ball abutment is carefully inserted into the body. The ball abutment tightening part (T0 25205) is used to fix the abutment to the body.

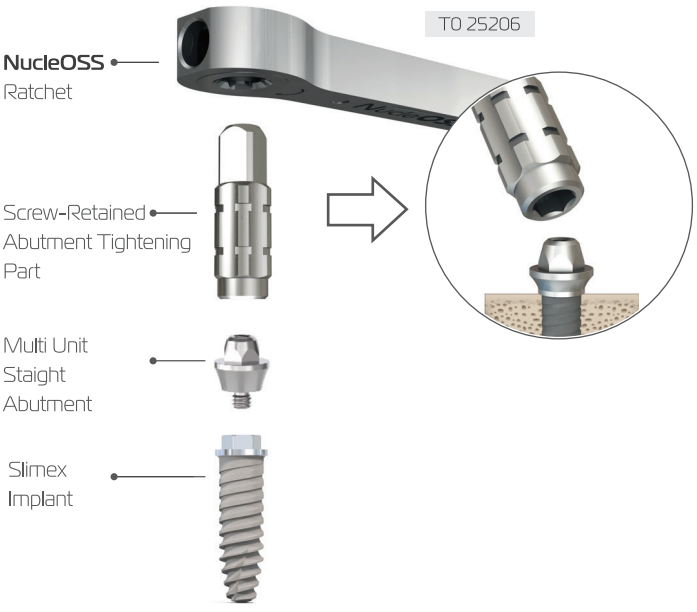


Ball abutment should be torqued to a maximum of 30 Ncm using the NucleOSS ratchet.

Screw-Retained Tightening Part



T0 25206



Threaded abutment tightening part is used to place multi-unit straight abutments on T6 implants.

It is made of stainless steel.

It can be used with a ratchet or screwdriver.

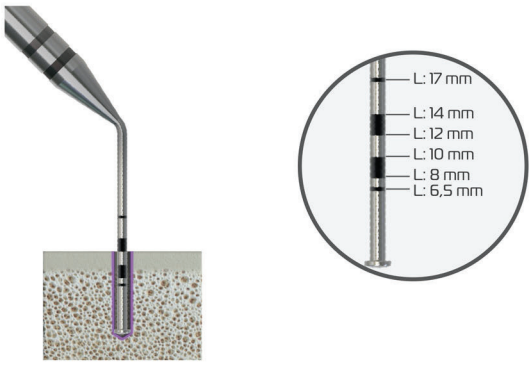
Multi-unit straight abutment has a threaded connection structure. When placing the abutment on the implant, attention should be paid to the tightening and torque values.

Caution!
Multi-unit straight abutment should be torqued to a maximum of 30 Ncm when being placed on the abutment!

If the torque value is less or more than the specified value, loosening or breakage of the abutment may occur.

Multi-unit angled abutment is carefully placed on the implant by holding the carrying part and fixed to the implant with the Connecting screw included in the package. The connecting screw should be torqued to a maximum of 30 Ncm with the help of a NucleOSS torque ratchet.

Depth Gauge - T0 25312

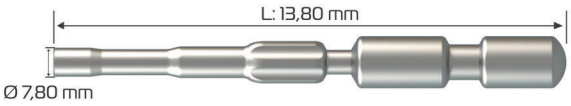


It is one of the items that are included in both the T6 Standard and T6 TorQ surgical kits.

In order to be sure of the depth of the opened slot(cavity), a control should be performed using a depth gauge.

It is one of the items that are included in both the T6 Standard and T6 TorQ surgical sets.

Screwdriver - T0 2022



It is offered as an alternative to the NucleOSS ratchet for the use of implant carrying/tightening parts, Hex wrenches, threaded abutment tightening part, ball and equator tightening parts.

Compatible with square head parts.

Torque Ratchet - T0 25900

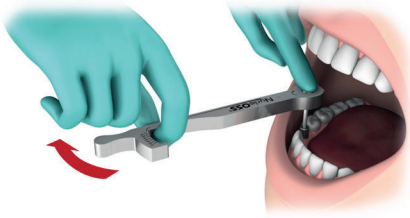
The torque value of the NucleOSS ratchet is from 0 Ncm to 70 Ncm.

When the needle is at the top, it shows about 80 Ncm.

The ratchet is used by NucleOSS to tighten all the abutments and screws at the torque values specified in the product catalogs.

It is made of stainless-steel material.

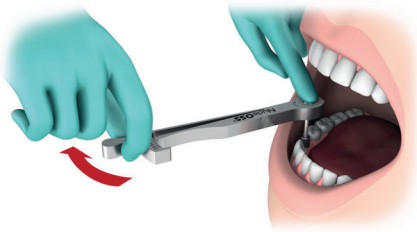
It can be procured in a surgical set and in one piece.



Using as Torqueless Ratchet;

Hold the torque arm and torque needle together. Press down on the wheel with your finger to hold the ratchet in place.

Caution! Direction arrow should point to the top during tightening and to the bottom during untightening.



Using as Torque Ratchet:

Press down on the wheel with your finger to hold the ratchet in place. Then pull the torque arm lightly in the direction of the arrow until you reach the desired torque value.

Caution! The torque arm should not be turned more than the torque values specified on the ratchet. Otherwise, the torque will be incorrect. Direction arrow should point to the top during tightening and to the bottom during untightening

Using Ratchet for Removal:

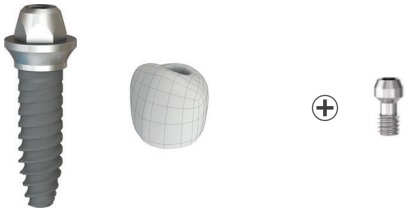
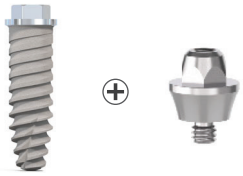
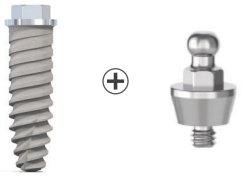
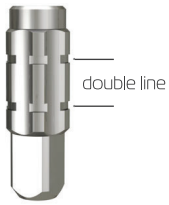
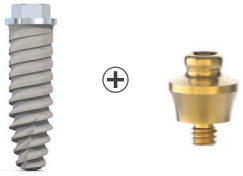
Use the ratchet with the direction arrow facing down.

T0 25900

Products	Tighten Parts	Torque Values
Comfort Caps 	 T0 25251 Manuel Hex Driver	Manuel/ Ratchet (max. 10 Ncm)
Cemented Abutment Screws 	 T6 2024 Short (ratchet)  T6 2025 Long (ratchet)	Max. 30 Ncm
Cad/Cam Ti-Base Abutment Screws 	 T6 2024 Short (ratchet)  T6 2025 Long (ratchet)	Max. 30 Ncm Scan post is torqued with max. 10 Ncm
Universal Casting Abutment Screws 	 T6 2024 Short (ratchet)  T6 2025 Long (ratchet)	Max. 10 Ncm

Tightening - Torque Values

T0 25900

Products	Tighten Parts	Torque Values
Multi Unit Abutments 	 T6 2024 Short (ratchet) T6 2025 Long (ratchet)	20 Ncm
Multi Unit Abutments (Straight/ 0°) 	 single line T0 25205	Max. 30 Ncm
Ball Abutments 	 double line T0 25206	Max. 30 Ncm
Equator® Abutments 	 774CHE Tightening Part (ratchet/screwdriver)	Max. 30 Ncm

NucleOSS Dental Implant System - Implant Prospectus

Definitions
NucleOSS Dental Implants (T1, T3, Tpure, T5 Short, T6, T6 TorQ and Slimex) are medical devices that intended to be surgically placed in the bone of maxillary and/or mandibular arches to support prosthetic restorations for restoration of the patients' chewing function. The implants are manufactured out ISO 5832-2 pure titanium Grade 4 to fulfill the requirements of 93/42/EEC medical devices directive.

NucleOSS Dental Implant is recommended for delayed loading after 12 weeks. NucleOSS Implants are non-pyrogenik. Implants are provided as sterile in a hermetic tube with a blister package and are for single use. Do not sterilize again.

Surface Specification
All NucleOSS Dental Implants have max①cell® surface. The surface is sand blasted and processed in acid baths. Following its special cleaning steps, the surface gains its hydrophilicity.

Patient Information
Surgery site must be clean before and after operation. The patient must be well informed about cleaning of the surgical area. The implant site should not be exposed with pressure due to chewing function. For a more detailed explanation please refer to Patient Information Broschure (D05.001/en).

Packaging
NucleOSS Dental Implants are protected with double barrier system as primary packaging (tube) and secondary packaging (blister). Implants are placed in blister package and are sterilized; and delivered to final packaging process as sterilizied.

Labelling
NucleOSS Dental Implants are provided with tube label, tyvek label and box label. These labels enables to control the lot number in three different stage. The diameter label that is present on the tube states the diameter and length of the implant. Diameter labels are color coded for different diameters.

Sterilization
NucleOSS Dental Implants are provided as sterile. Implants are sterile washed under Class 10.000 and packed under Class 100 clean room technology. Implants are placed in hermetically sealed tubes and sterilizied by 25-40 kGy of gamma irradiation. Gamma sterilization is protected until the best before if the packaging is not harmed. The proper storage conditions that is present on the package are 18-28^0 and %40-%60 moisture must taken seriously to protect sterilization.

⚠ **Cautions**
- NucleOSS Dental İmplant System products are produced by Şanlılar Med. Kim. San. Tic. Ltd. Şti.. Brand usage and sale of the products can be conducted only by Şanlılar and partner firms.
- NucleOSS Dental Implant system models (T1, T3, Tpure, T5 Short, T6, T6 TorQ and Slimex) should apply accordingly with NucleOSS Surgical and Prosthesis Surgical Protocols. It is adviced to wait at least 3 months (12 weeks) for osseointegration after surgery.
- Implants are in sterile packaging.
- Do not open the tube cover before use under any circumstances. Do not use the implant tubes that is opened or became deformed.
- Keep it away from the child reach.
- If the impression and transfer part is present inside the implant package, this part might broken in case of using it as tightening part. Tightening must be actualizied with tightening part.
- It is important to decide on the implant that is suitable as diameter and lenght for implementation site. Adviced implementation sites are present in the relevant product catalogs. Please refer to the relevant catalogs for further information (for T6 D01.001/en; for Tpure D01.002/en; for T3 D01.003/en; for T1 D01.004/en; for T6 TorQ D01.005/en; for Slimex D01.006/en and for T5 short D01.007/en document numbered.)
- Apply adequate number of implants with suitable diameters in an axis with compatible with the dentition.
- Use the proper drill compatible with diameter and lenght.
- Inform the patient before and after surgery.
- Adequate general state of health of the patient is necessary.
- Implant tube must removed from the blister to sterile laboratory cloth by wearing handgloves.
- Implants with broken protection ring or harmed package must not be used.
- To avoid the risk of contamination, the implant must insert to the bed in the moment of taking it out of the sterile tube without touching it or contacting anywhere.
- Bone development of the patient must be considered for the implant treatment.

Storage Conditions
Devices should be stored at 18^{0}C - 28^{0}C temperature range and 40% - 60%

Caution ! Previously used implants cannot be used again. Use only the NucleOSS Dental System components and surgical kits. Manufacturer will not take responsibility in case of using the parts other systems.

Caution ! If the tube consists of which is also colored accordingly with its platform diameters, must transfer on implant by hex driver and handtight to cover the implant. Otherwise, the tissue might fill the implant and create risk factor.

Traceability
A Lot number is written in each package. Also, each package contains three Lot number sticker, In order to trace back the product, this Lot number stickers must be attached to the patient's file and panoramic x-ray.

Indications
NucleOSS Dental Implants (T1, T3, Tpure, T5 Short, T6, T6 TorQ nad Slimex) are medical devices that intended to be surgically placed in the bone of maxillary and/or mandibular arches to support prosthetic restorations for restoration of the patient's chewing function.

Contraindications
Hypertension, cordiovascular diseases, diabetes bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, inadequate oral hygiene, serious internal medical problems,maxiallary and mandibular growth not completed, poor general state of health, uncooperative and unmotivated patient, drug/alcohol/tobacco abuse, psychoses, long term treatment resistant functional disorders, xerostomia, granulocytopenia, Ehlers Danlos syndrome, radiation theraphy, osteoradionecrosis, weak immune system, kidney failure, organ transplantation, fibrous dysplasia, crohn disease, use of steroids, corticosteroids or anticonvulsant usage, prophylactic antibiotics, creatinin, serum calsium, titanium allergy, uncontrolled endocrine disorders, anticoagulation medicines, hemorrhagic diathesis, bruxism, parafunctional habits, unfavorable anatomic bone condition, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic of jaw, changes in the oral mucosa, pregnancy, breast-feeding, osteoporotic crush fracture, respiratory disease, tyhroid or paratyhroid diseases. Active osteolytic patients, inflammatory, diagnosed malignancy, modular enlargements, tenderness, the patients with unexplained lump in the neck or head, infectious process in the implanting site, unrealistic patient expectations, unattainable prosthodontics reconstruction, lack of adequate training of pyhsician.

Risks
The risks may include inadverting perforation of the nasal and maxillary sinus, local and systemic infections, perforation the soft tissue, nerve damage, temporary bumps and pain due to implantation, speech problems nad gingivitis.

Nerve, local or systemic bacterial infections and inactive endocarditits in susceptible individuals are included as the long term problems. Inaccurate implantation migh risk the present dental axis.

Surgical Guide
Do not instert the implant in high torque or speed (15 rpm). If it feels any difficulty, the practician must step back, extract the implant and check for the implant bed and drills.

MRI Safety Information
Non-clinical testings demonstrated that the NucleOSS Dental Implant System is MR Conditional. A patient with this device can be scanned safetly, immediately after placement in an MR system meeting the following condtions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 4,000 -gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the NucleOSS Dental Implant System is expected to produce a maximum temprature rise of less that 1.7^0 after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the implant when imaged with a gradient echo pulse sequence and a 3.0 MRI system.

Superstructures
NucleOSS Dental Implant System offers dentists a rich abutment options that can be used for all bodies with different purposes. These are defined as cemented solutions, screw-in solutions, custom solutions, overdenture solutions, cad-cam solutions and scannig bodies, auxiliary prothetic parts, temporary parts. The product compability according to platform diameter and lenght of abutments can be seen in relevant catalogs of the products.

Abutments are only suitable for the bodies of NucleOSS Dental Implant System. The failure that is caused by using with other system might hurt the patient.

All Abutment belong to NucleOSS Dental Implant System are produced out ISO 5832-3 Grade-5 Titanium and ISO 5832-12 Cobalt-Chromium alloy and non-sterile and presented for sale. The must sterilize by the last user.

Sterilization
Titanium superstructures recommended sterilization condition as fllows;

Method	Moist heat sterilization according to ISO 17665
Cycle	Pre vacuum
Temperature	132^0 C / 270^0 F
Exposure time	4 minutes
Pressure	2.2 Bar
Pre-vacuum	3 times < 60 mbar
Minimum drying time	30 minutes in chamber

- Do not storage the products after sterilization.
- Minimum validated sterilization time and temprature required to achieve a -10^{-6} sterility assurance level.

Note: Sterilization parameters and methods shown are validated by NucleOSS Dental Implants. According to EN ISO 17665, the final resposibility for validation of sterilization recniques and equipment lies directly with the practician. All autoclaves/sterilizers should be validated and maintained in accordance with EN ISO 17665-1.

Indications
NucleOSS abutments and prosthetic parts are intended for use with NucleOSS Dental Implant in the maxillar and mandibular arches to privde and support for crowns, bridges or overdentures for edentulous or partially edentulous cases.

Contraindications
Allergy may be developed to submaterials of the superstructures. Titanium, Gr-5 titanium alloy (titanium-aluminium-vanadium), PEEK (Polietheretherketone), POM (Polyoxymethylen), ISO 5832-12 raw material CoCr alloy allergies must be considered.

⚠ Cautions
In case of not considering the cautions below, complications may occur as parts slipping into trachea or getting swallowed.

For dental technicians:
Make sure to protect the parts of abutments that goes inside the implant or this process must complete while abutment is connected to analog.

Abutment must be placed on the model by controling if its in the right direction and must make sure that it fits perfectly. Abutment must be stabilized by abutment screw and hadtight only (max. 10 Ncm). After this point, the accurate prosthesis fir the treatment must be formed and extracted from the model by proper hex driver.

For dental professionals:
Clinician takes the abutments comes from the laboratory, and takes the temporary restorations, cover screws or gingiva formers out of the patient's mouth. After cleaning, disinfecting and sterilizing the prosthesis parts coming from the laboratory, the application must be followed as the given appropriate torque values.

- In case of tightening abutments more or less than the adviced torque values, abutment or implant might fail.
  See below for recomended torque values;

Torque Values for NucleOSS Parts

All Covers and Gingiva Formers	Hand/Ratchet (10 Ncm)
All Cemented Abutment Screws	Max. 30 Ncm
Temporary (PEEK) Parts and Screws	10 Ncm
Multi Unit Abutments	Max. 30 Ncm
Abutment Occlusional Screw	20 Ncm
All Cap Screws	10 Ncm
All Universal Casting Abutment Screws	Max. 30 Ncm
Ball Abutments	Max. 30 Ncm
Equator® Abutments	Max. 30 Ncm
CAD-CAM Ti-Base Abutment Screws	Max. 30 Ncm

Caution: Products must be used right after sterilization. Sterilization conditions are given above.

Covering the Screw Channel:
Before inserting the crown on abutment, abutment screw channel must be covered with sealing component (teflon). This process enables to take the abutment out if that is nedeed afterwards.

Adjustment to the Patient's Anatomy:
PEEK, Titanium or Titanium Alloy abutments may shortened untill the top level of the connection screw, if needed to adjust to the patient's anatomy.

CoCr Castable Abutment Cautions:
CoCr raw material must comply with ISO 5832-12 standard.
The molten metal temperature should not exceed 1420 ^{0}C to avoid the melting of CoCr Casting Abutment.

CoCr Coefficient of Thermal Expansion (CTE) (a):
- For 20 - 100˚C, 13.2 (10-6 K-1)
- For 20 - 200˚C, 13.3 (10-6 K-1)
- For 20 - 300˚C, 13.5 (10-6 K-1)
- For 20 - 400˚C, 13.8 (10-6 K-1).

Gingiva height should not exceed 5.0 mm and abutment angle should not exceed 25^{0}.

Caution! Temporary abutments should not stay in patients' mouth more than exposure time. Exposure time for temporary abutment (Ti, PEEK) is 180 days.

-Şanlılar Tıbbi Cihazlar Med. Kim. San. Tic. Ltd. Şti. consistently gives trainings. While preparing this prospectus, it is assumed that the clinician participates in these trainings and have prior knowledge to the practise. For further information please refer to surgical manuals (for T6 D03.001/en, for Tpure D03.002/en, for T3 D03.003/en, for T1 D03.004/en, for T6 TorQ D03.005/en, for Slimex D03.006/en and for T5 Short D03.007/en document numbered) and surgical instruments instructions for use (D02.002 document numbered).

Any serious incident related to the medical device should be reported to the manufacturer and the local authority.

If the storage conditions connot be met, the product should not be used.

Warning Signs

REF Catalog number

LOT Lot number

For single use only

STERILE R Sterile by gamma irradiation (for implant)

Do not use if package is damaged

Temperature limit

Humidity limit

EC REP Authorised Representative

Consult operating instructions

Use before expiry date

Manufacturer

℞only For prescription use only

MR MRI Safety Information

Cautions

NON STERILE Non Sterile (For Abutment)

Double Sterile Barrier System

MD Medical Device

CC Country of Manufacturer

UDI Unique Device Indetifer

Model number

2 STERILIZE Do not sterilize (for implant)

NucleOSS™

SANLILAR

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