DXL Medical GMBH

USER MANUAL
DENTAL IMPLANT SYSTEMS

1. DXL DENTAL IMPLANTS

DXL Dental Implants are used in partial or total edentate maxillar or mandibullar arcs in order to support and single and/ or multiple lost teeth or total arc stabilized and/or removable prothesis. That Endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing functions.

Mechanism of action: The prosthesis needs to an intra bone support system. Bone tissue fills " The SLA roughened surface" and between the mechanical grooves of the implant. Thus, necessary implant support is provided by osseointegration for prosthetics.

Design Spesifications

Conic connection: Knowledge and experience gained in general engineering and implantology, Conical design implant-abutment connection has been observed to give better results in the medium and long term.

- The same conical design was used on the head of the abutment screw. This design allows the screw in the abutment to be tightened together without any gap.
- In the abutment, screw compatible grooves are also designed that support this conical design. Thus, the implant-abutment connection has been formed more stable and strong.

Hex Index: Determines the direction relationship of the abutment with the prosthesis in general implantology. This prevents loss of direction in the processes between the impression laboratory and the clinic.

- **DXL IMPLANT:** It is designed for higher and thinner shaped bone applications. It is prefered in the case of bones with inadequate diameter in patients.
- **DXL IMPLANT PLUS:** It is used for the patients with an adequate bone volume. It is generally designed for being used in mandibulla (compact bones). It has a Light Slope Shoulder Design.
- **DXL SMART IMPLANT:** It is designed for maxilla and soft tissue applications. It is used for the patients with an adequate bone volume. Suitable for using immediate loading. It has a Light Slope Shoulder Design. It has deeper groves, more surfaces.
- **DXL SMART SHORT IMPLANT:** It is used in patients with insufficient vertical bone level but wide enough bone. It is prefered in the case of bones with inadequate diameter in patients.
- **DXL PREMIUM HYBRID IMPLANT:** When the vertical bone size is sufficient and the bone cross-section is thin, the neck of the implant is buried 1-1.5 mm and the neck region facilitates bone deposition and increases its amount.
- **DXL IMPLANT WITH COVER:** DXL implant and cover screw are packaged with cover screw as sterile. After packaging, gamma radiation is used in order to sterilize the implants.
- **DXL IMPLANT PLUS WITH COVER:** Kapatma vidası ve DXL Implant Plus are packaged with cover screw as sterile. After packaging, gamma radiation is used in order to sterilize the implants.
- **DXL SMART IMPLANT WITH COVER:** Kapatma vidası ve DXL Smart Implant are packaged with cover screw as sterile. After packaging, gamma radiation is used in order to sterilize the implants.
- **DXL PREMIUM HYBRID IMPLANT WITH COVER:** DXL Premium Hybrid Implant are packaged with cover screw as sterile. After packaging, gamma radiation is used in order to sterilize the implants.

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Implant Diameter and Lenght Measurement Table according to DXL Implant System

Diameter\ Lenght	Ø3,3 (mm)	Ø3,5 (mm)	Ø3,75 (mm)	Ø4,0 (mm)	Ø4,1 (mm)	Ø4,5 (mm)	Ø4,8 (mm)	Ø5,0 (mm)	Ø5,5 (mm)
DXL Implant	8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		
DXL Implant Plus	8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		
DXL Smart Implant		8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0			8,0 10,0 12,5 15,0
DXL Premium Hybrid Implant		8,0 10,0 12,0 14,0		8,0 10,0 12,0 14,0		8,0 10,0 12,0 14,0		8,0 10,0 12,0 14,0	
DXL Implant with cover	8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		
DXL Implant Plus with cover	8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0		
DXL Smart Implant with cover		8,0 10,0 12,5		8,0 10,0 12,5 15,0		8,0 10,0 12,5 15,0			8,0 10,0 12,5 15,0
DXL Premium Hybrid Implant with cover		8,0 10,0 12,0 14 ,0		8,0 10,0 12,0 14,0		8,0 10,0 12,0 14,0		8,0 10,0 12,0 14,0	

Note: In the "DXL with cover" series products, the cover screws which are H0 and Ø2.6 mm supplied with the Narrow (Ø3,3) implant. In other products of this series, H0 and Ø3.1 mm covers are provided as standard.

Warning:

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These presented informations are not sufficient for immediate appliciation of DXL Dental Implant System. It is necessary that the user is capable of surgical operation legally and get informed in detail about system tools and have further education in the area of oral implantation before usage.

Declaration of Legal Liability:

The usage of this implant is only in charge of end user. Any obligation related the miss use of the product, loss and damage in the case of disobey the user manual is undertaken. This system only be used with original DXL pieces. The usage of third party pieces cancel the guarantee which is provided by DXL and neutralise the product.

Copyright and Patent:

The patents belongs to DXL® are protected and DXL Medical GmbH is the ownership of the products. It is forbidden to use the signs in any way and in the case of usage, it is indicted within Germany and International law.

Education:

Dental implant treatment includes complex surgical and restorative procedures. These kind of applications in this area should be performed by the dentist who took the required education. Lack of education causes surgical and prosthetic complications and so that failure of the implant and restoration.

Patient Population: It is used for the adult patients with completed bone development.

Material: ISO 5832-2 Unalloyed Titanium Material Content:

Implants are produced from ISO 5832-2 Grade 4 Unalloyed Titanium. DXL® surface micro structure is roughened with the methods of sandblasting and acidification (SLA) in order to obtain osseointegration optimum Ra values.

DXL Implants Usage Indications:

DXL® Dental Implants are used in partial or total edentate maxillar or mandibullar arcs in order to support and the single and/ or multiple lost teeth or total arc stabilized and/or removable prothesis. Implants are surgically placed in two phases.

- Special Indications for Ø3.3 mm and Ø3.5 mm Implants:

- Implants with a small diameter can be used when mechanically support is not required. These implants:
- Mandibullar central and lateral incisal and maxillar lateral incisal.
- With the help of the other implants in treatment of multiple edentation
- Ø3,3 implants are suitable for use with front teeth number 1 and 2 in the upper and lower jaw. It is strictly not recommended for other teeth.

It can be used in a purpose of support of the removable prothesis Ø3.3 mm and Ø3.5 mm diameter implants are not recommended for usage in molar area.

Contraindication

Although it is not limited; in the case of poor general state of health, serious internal medicine situations, uncontrolled diabetisis, uncontrolled hemorage disorders, anticoagulant treatments, coronary diseases, inadequate wound healing, connective tissue diseases, kemotheraphy and radiotheraphy, young patients who have not yet completed bone development, metabolic bone

diseases, physcological diseases, usage of drug and alcohol and allergy to titanium compounds, it is contraindicated.

Local Contraindications

Although local contraindications are not limited, contain as follows: in the case of inadequate bone volume in terms of wideness and height, oral infections, periodental illness, parafunctional habits, acute cotton mouth, bad oral hygiene and incompatible and inadequate behaviours about oral hygiene of the patient.

Possible Side Effects

– Infection
- Ache
- Neurosensory disorder
- Mandibullar fracture
- Hematom formation
- Air embolism
- Wilting of adjacent tooth
- Maxillar sinus perforation
- Absence of the primer stability
- Wound dehiscence
- Peri implanter mucositis
- Posperative soft tissue complications
- Abscess that remained from suturing

Apart from these, easing and cleavage of the pin, cleavage of the implant and easing of the abutment etc. mechanical complications might occur.

Packaging and Sterilization:

DXL® implants with cover are packaged with cover screw as sterile. The products are single use products. After packaging, gamma radiation is used in order to sterilize the implants. Due to sealed packaging, contagion from outer environment is prevented. Appropriate storage conditions are in the room temperature and sterilization is valid until the end of the expiration date which is stated on the package. The implants inside of the damaged packages should not be used. Contaminared implants can not be sterilized again. Reuse of the implants cause clinical failure, infection, disintegration of the implants, bone loss and wilting of adjacent tooth and unlimited complications. Do not touch the implants by hand, it might affect the surface properties. Other tools should be use by sterilizing based on the standard sterilization tecniques with autoclave.

Shelf Life: Expiration date is indicated on each package of the implants clearly.

Planning of the Treatment:

Extensive patient examination, screening before operation, diagnosis and treatment planning should be performed before the implant treatment. Inadequate planning and evaluation might cause implant complications, moreover implant failure.

Preparation of the Surgical Area:

Preparation of the surgical area should be performed with DXL surgical drills in the surgical sets. Decision should be made by the dentist regarding to drilling operation speed and hardness degree of

the bone. Drilling operation should be performed under the irrigation and attention should be paid about preventing the bone heating. It should be avoided that using surgical drills with loss of sharpness, yet this might cause unnecessary trauma in the bones. Alignment of the drills based on the implant diameter is available in the cover of the set and it is recommended to follow from there.

Surgical Placement of the implants:

Check the lenght and diameter of the implant from the product tag. Stick 3 tags which are placed in the package to the patient file. Open the outer cartoon package and take off the inner cover package. By opening the transparent part of the cover package, empty the sterile inner tube to the surgical area. Implant tube is composed of two parts:

1. Lower part which includes the cover screw.
2. Upper cap which includes the implant. Open the implant tube by turning the upper cap. use the implant carrier in the set in order to carry the implant to the implant shaft. In order to place the implant, torque shaft or physiodispenser in the set can be used. Cover screw should be placed with 1.25 hex screwdriver. Cover screws and healing caps should be torqued manually.

Healing Period of the DXL Implants: Generally, implants should be left for healing in a period of 2-4 months based on the bone quality, type and general health status. Immediate and early loading can be performed by only sticking up to the right case selection and literally accepted immediate loading protocols. If immediate loading is going to be performed, occlusion ambient should be controlled, if there is more than one implant, it should be splinted and in the case of total edentulism, in madibula at least 4, in maxilla 6 implants should be linked with a prothesis. Based on the bone anatomy, implants with an appropriate number, diameter and lenght should be placed.

Post-operative Maintenance:

Eager chase of the patient after the operation is crucial. Using the appropriate oral mouthwashes and proving the good oral care and disuse of the tobacco products are recommended.

2-) DXL Cover Screw Indications:

Cover screws are included in the "Implant with cover" series. Cover screws are used in two-stage implant surgery approaches to close the screw entrance of the implant. “DXL Cover Screw-NonSteril” or “DXL Cover Screw Sterile” is recommended for the doctors who prefer to purchase the screw of the implant separately.

- **DXL Cover Screw-NonSteril**: It is a non-sterile product. Autoclave sterilization is recommended before use.
- **DXL Cover Screw Sterile:** It is a sterile product. Gamma sterilization was applied after packaging.

Impact Mechanism: It protects the internal threads and around of implant during the healing phase.

Material: ISO 5832-3 Alloyed Titanium

Cover Diameter and Lenght Measurement Table according to DXL Implant System

Diameter/ H (Gingiva height)	**Ø2,6 (Narrow)**	**Ø3,1**	**Ø6,0**
DXL Cover -Steril		H0 H2	H1
DXL Narrow Cover -Steril	H0		

	H2		

Contraindications:

Contraindication

Although it is not limited; in the case of poor general state of health, serious internal medicine situations, uncontrolled diabetisis, uncontrolled hemorage disorders, anticoagulant treatments, coronary diseases, inadequate wound healing, connective tissue diseases, kemotheraphy and radiotheraphy, young patients who have not yet completed bone development, metabolic bone diseases, physcological diseases, usage of drug and alcohol and allergy to titanium compounds, it is contraindicated.

Possible Side Effects:

Possible dental implant side effects are mentioned above.

Placement:

Cover screws and healing caps are fixed manually by 1.40 mm hex screw driver.

Packaging and Sterilization:

- Dxl Implant With Cover
- Dxl Implant Plus With Cover
- Dxl Smart Implant With Cover

In the above products, Cover screw are packaged with the implant in a sterile tube. If it is not damaged, sterilization is valid until the end of the expiration date.

It is recommended: Fractionated vacuum method at 134 °C for 10 min. The packaging of the superstructure and auxiliary components is not compatible for sterilization. Please use suitable autoclave bags *according to EN 868-5* Standard for sterilization.

DXL Cover Screw Sterile product, the cover screw is packaged single and sterile.If the package is not damaged, Sterilization is valid until the expiration date on the package.

DXL Cover Screw-NonSteril products are non-sterile packaged. These products should be sterilized by autoclave method before use.

3-) DXL® Abutments, Healing Caps, Prosthetic Parts

DXL Suprastructure Components, Healing caps, Prosthetic Parts are used with screws compatible with their own particular size. All abutments are packaged with screws.

The support and connection part between the prosthesis and the implant.

Design Specifications

Conical connection: Knowledge and experience gained in general engineering and implantology, Conical design implant-abutment connection has been observed to give better results in the medium and long term.

- The same conical design was used on the head of the abutment screw. This design allows the screw in the abutment to be tightened together without any gap.

- In the abutment, screw compatible grooves are also designed that support this conical design. Thus, the implant-abutment connection has been formed more stable and strong.

Hex Index: Determines the direction relationship of the abutment with the prosthesis in general implantology. This prevents loss of direction in the processes between the impression laboratory and the clinic.

Material: ISO 5832-3 Alloyed Titanium

Intended Uses:

- **DXL Healing Cap:** After healing, the placed implant in the bone is used to guide and shape the gum. It ensures that the gum on the osseointegrated implant is shaped according to the prosthesis.

DXL Healing Cap Diameter and Gingiva Height Table

Diameter/H (Gingiva height) (mm)	Ø4,7	Ø4,8	Ø6,0	Ø8,0	Ø4,1	Ø4,8
DXL Healing Cap	H3,5 H4,5 H5,5 H6,5	H1,0 H2,0 H3,0 H4,0 H5,0 H6,0	H2,0 H3,0 H4,0 H5,0 H6,0	H3,0 H5,0		
DXL Narrow Healing Cap					H2,0 H3,0 H5,0	
Multi Unit Healing Cap						H0

3-) Abutments Indications:

- **DXL Straight Abutment**: It is a straight (0 ° angled) support connection part that is used when there is no angle difference between the implant axes and path of insertion of prothesis. It is used in the case of the dentist wants to make a screwed abutment from occlusal to the implant. Various diameter and gingiva heights are existed. It can be attached to implant and analog. Laboratory rehearsal is completed on the implant and then once the tooth is prepared, it is attached to the patient.
- **DXL Aesthetic Straight Abutment:** It is a connection between prosthesis and the implant that is placed into the bone. In the event of that if dentist places the implant in an straight position. It is fixed on the implant with the aid of an abutment screw. A tooth made of porcelain or zircon material is cemented on it. Various diameter and gingiva lenghts are exist. It is fixed on the implant with the help of an abutment screw.
- **DXL Aesthetic Angled Abutment**: It is a connection between prosthesis and the implant that is placed into the bone. In the event of that if dentist places the implant in an angular position, it is used in order to tolerate that angle. It is fixed on the implant with the aid of a screw. A tooth made of porcelain or zircon material is cemented on it. Various diameter and gingiva hight are exist.
- **DXL Multi Straight Abutment**: The DXL-multi-concept is one of prosthetic solution for immediate restoration of edentulous patients. This abutment is straight without angle.

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- **DXL Multi Angled Abutment**: The DXL-multi-concept is one of prosthetic solution for immediate restoration of edentulous patients. For better support of restoration it is possible that the posterior implants are set in 17 ° or 35 ° angles to distal. This angulation is compensated by multi angled abutments.
- **DXL Ball Abutment:** It is a connection between prosthesis and the implant that is placed into the bone. It is used in the case of the dentist wants to operate with a removable denture. Various diameter and gingiva lenghts are exist. It can be attached to implant and analog. Laboratory rehearsal is completed on the implant and then once the tooth is prepared, it is attached to the patient.
- **DXL Tibase Abutment:** It is the part that connects custom made prostheses to the implant. Ti-Base, which uses with the original scanning part. That uses for determining the direction of the implant in the 3D design in the software. The system can also be used to produce prosthetic restorations used in connection with the implant.
- **DXL Multi Abutment TiBase**: Multi Abutment Tibase are part of the DXL-multi-concept is a prosthetic restorations for immediate protocol of edentulous patients. DXL Multi Abutment Tibase in order to be used with intended scan body is used to determine the Multi abutment position for the design in the 3D soft-ware.
- **DXL Premil Abutment:** Optionally, Instead of prefabricated abutments, In order to used in the production of “customize abutment” for the patient. The part above the implant-abutment connection is shaped in CNC milling machines according to the design. It creates optimum path of insertion for a personalized, ideal prosthesis, with the priority of aesthetics, function and hygiene.
- **DXL Locator Abutment**: It is the support-connection part between the implant and the prosthesis. It is used in cases where the physician wants to apply removable prosthesis to the patient. There are different types of diameters and gingiva height.
- **DXL Short Abutment:** It is used for patients with short vertical bone distance.
- **Abutment Screws**: It is used for attachment of straight and angled abutments on the conic system dental implants.

Impact Mechanizm

It is the connection-support part between the removable prosthesis and the implant. Various diameters and gingival lengths are available. It can be attached to the implant and analog. Laboratory rehearsals are completed on the analog of implant and then screwed to the patient after the prosthesis is prepared.

Contraindications

It is not limited; in the case of poor general state of health, serious internal medicine situations, uncontrolled diabetisis, uncontrolled hemorage disorders, anticoagulant treatments, coronary diseases, inadequate wound healing, connective tissue diseases, kemotheraphy and radiotheraphy, metabolic bone diseases, physcological diseases, usage of drug and alcohol and allergy to titanium compounds, it is contraindicated.

Local contraindications:

Although local contraindications are not limited, contain as follows: in case of oral infections, periodental illness, parafunctional habits, acute cotton mouth, bad oral hygiene and incompatible and

inadequate behaviours about oral hygiene of the patient.

Sterilization and Packaging:

Caps, abutments (including with healing caps), prosthetic parts and tools are packaged in an insulated closed blister without being sterilized. Before usage in patients, it is necessary that the whole system parts to be sterilized. Sterilize the all the components with autoclave within the frame of recommended protocols. It is recommended: Fractionated vacuum method at 134 °C for 10 min.

Attention:

Please use suitable autoclave bags *according to EN 868-5 Standard* for sterilization. The Blister-tyvek package of the product is not suitable for autoclave sterilization.

Placement:

DXL® abutments related implants are placed with prosthetic abutment screw and 1,4 mm hex screwdriver. DXL ball abutments are one part abutments and they are fixed on the hex shaft over the circular part of the implant by using 1,4 hex T-Bona screwdiver. The recommended amount of torq is 27 Ncm for ball abutments. Cement should not be used in multi abutment application. Ball abutments and Locator abutments should be used for moving prosthesis for removable prosthesis accustomed patient. Angled ball and locator abutment options should be used according to the implant posture. The difference between the angle of the dental implant to the bone and the angle of the abutment to the dental implant should not exceed 25.

General MR Safety Information.

Taking into consideration that various type MRI devices are produced by various manufacturers and they are lots of parameters that can be adjusted by user, the net effect can not be dedected on the implant.

So, please note that the compatibility and safety of the DXL Implant to the MR environment has not been evaluated.

Warnings:

The implants inside of the damaged packages should not be used. Contaminated implants cannot be sterilized again. Reuse of the implants cause clinical failure, infection, disintegration of the implants, bone loss and wilting of adjacent tooth and unlimited complications. Do not touch the implants by hand, it might affect the surface properties.

Disposal:

The implants removed from the patient should not be implanted to the patient again for the reason that fatigue status of the device can not be determined visually. These devices should be accepted as biocontaminated and the process should be performed in this direction. Removed implants should processed based on biohazardness and should be disposal in accordance with country's legal regulations and hospital policies.

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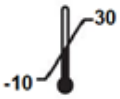
Meanings of the Symbols

	:	CE Mark	1984	:	Notified Body number
	:	Consult user manual.		:	Product code number
	:	Use of time (expiration date)		:	Lot number
	:	Production Date		:	Do not use if the packaging is damaged
	:	Manufacturer name and address		:	Disposable, do not use again
	:	Sterillized using irradiation		:	Store in dry place
	:	Recommended Storage Temperature		:	Non-sterile
	:	Do not re-sterilize		:	Caution
	:	Keep away from sunlight			

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