USER MANUAL
DENTAL IMPLANT SYSTEMS

1. MANUFACTURER AND AUTHORIZED REPRESENTATIVE INFORMATION

The legal and official registration information of the manufacturer is below:

Legal Manufacturer Title	**DXL Medical GmbH**
Registered Legal Address	NORDSTERN PARK 22, HERZOGENRATH, AACHEN, GERMANY
Unique Registration Number	DE-MF-000029142
Commercial Registry Information	Aachen HRB 29653
Official Website	www.dxlimplant.de / ifu.dxlimplant.de

2. DEVICE DESCRIPTION AND MODE OF ACTION

DXL Dental Implant System; It is a modular and multi-part system consisting of endosseous dental implants surgically placed in the mandibular and maxillary bone and prosthetic superstructure components (abutments/abutments, healing caps, cover screws and fixation screws) fixed on these implants.

Implant bodies are made of pure titanium (Grade 4) in accordance with ISO 5832-2 standard. The Endosseous surface of the implants is roughened by Sand-blasting and Acid-etching (SLA) method to support Ossteointegration. Prosthetic superstructure components (abutments, screws, etc.) are made of Ti-6Al-4V Alloy Titanium (Grade 5) in accordance with ISO 5832-3 standard to provide mechanical strength. All implant-abutment connections are designed with conical connection and hex index geometry to increase mechanical fatigue resistance and prevent microleakage.

Mode of Action and Working Principle:

Implants do not perform their main function by pharmacological, immunological or metabolic means; It performs as a mechanical carrier anchor thanks to the physical and biological connection (Ossteointegration) it establishes directly with the jawbone. The superstructure parts are supported by this anchorage and transmit chewing forces to the bone tissue in a balanced way.

Table 1: Product Groups Basic UDI-DI and Classification Matrix

Product Group	Basic UDI-DI	GMDN Code / Definition	EMDN Code / Definition
DXL Dental Implants	426066596DXLIMPJT	55849 / Endosseous dental implant	P01020101 / Dental Implants
DXL Cover Screws	426066596COVERDX	44880 / Suprastructure, temporary	P01020101 / Dental Implants
DXL Abutments	426066596ABUTMENT4E	44879 / Suprastructure, permanent	P01020101 / Dental Implants
DXL Healing Caps	426066596HEALINGCAP2H	42354 / Implant, transgingival	P01020101 / Dental Implants

3. INTENDED USE, INDICATIONS, AND TARGET USER

3.1 Intended Use

DXL Dental Implant System and its components; It is designed to support fixed and removable prosthetic restorations (crowns, bridges, overdenture prostheses, etc.) through bone integration (Ossteointegration) in cases of single tooth, partial edentulism or complete edentulism in the upper and lower jaws and to restore the patient's chewing and aesthetic functions.

3.2 Implant Clinical Indications and Model Distribution

Implants are surgically placed Endosseously in two stages into partially or completely edentulous maxillary and mandibular arches to support single- or multi-unit fixed or removable prostheses. Clinical indication details according to product models are as follows:

- **DXL Implant:**

It is indicated in the treatment of patients with high bone level but narrow crest width and limited alveolar crest diameter to preserve bone volume.

- **DXL Implant Plus:**

It is indicated in patients with adequate bone quality and optimal crest width. It can generally be used in lower jaw applications and immediate surgical placement protocols depending on the primary stability status.

- **DXL Smart Implant:**

It is indicated in cases with deep thread architecture designed to provide high primary stability in soft bone types (Types III and IV) and upper jaw (maxilla) regions where bone density is poor.

- **DXL Premium Hybrid Implant:**

It is indicated in cases where a hybrid surface transition design is needed to control micro-stresses at the cortical bone level and to maintain the marginal bone level in the neck region.

- **DXL Smart Implant Short:**

It is indicated in anatomically constrained areas (such as the maxillary sinus floor or mandibular nerve proximity) with insufficient vertical bone height but alveolar crest width that allows for standard implant placement, with the aim of tolerating vertical restrictions according to clinical evaluation and physician judgment.

- **Narrow Diameter (Ø3.3 / Ø3.5 mm) Implant Limitations:**

Narrow implants with a diameter of Ø3.3 mm and Ø3.5 mm are indicated only for the treatment of mandibular central/lateral incisors and maxillary lateral incisors where mechanical support is less needed. Their use as a single implant in posterior (molar) regions where chewing forces are high is contraindicated.

3.3 Superstructure Clinical Indications and Model Distribution

- **DXL Healing Cap**:

It is used to guide and shape the gingiva of the implant, which is embedded in the bone, in the stage after bone healing. It ensures that the gingiva on the Osseointegrated implant is shaped in accordance with the prosthesis.

- **DXL Straight Abutment:**

It is a straight (0° angled) support piece used when there is no angle difference between the implant and the prosthesis entry path. It is used when the dentist wants to make an occlusal screwed abutment on the implant. Various diameters and gingival lengths are available. It can be attached to the implant and analogue. Laboratory try-ins are completed on the implant and then the tooth is attached to the patient with a screw after it is prepared.

- **DXL Aesthetic Straight Abutment:**

It is the abutment between the prosthesis and the implant**.** In this case, if the dentist has placed the implant in a straight position, he can use this abutment. It provides a more aesthetic appearance by adapting to the gingival height. An abutment is fixed to the implant with the help of a screw. A tooth made of porcelain or zircon material is attached to it. Various diameters and gingival lengths are available.

- **DXL Aesthetic Angled Abutment:**

It is the abutment between the prosthesis and the implant embedded in the bone. If the physician places the implant at an angle, it is used to tolerate that angle. It is fixed to the implant with the help of a screw. A tooth is bonded to it from materials such as porcelain or zirconia.

- **DXL Multi Straight Abutment:**

DXL-multi-concept is one of the prosthetic solutions for the immediate restoration of edentulous patients. These abutments have no angle.

- **DXL Multi Angled Abutment:**

The DXL-multi-concept is one of the prosthetic solutions for the immediate restoration of edentulous patients. For better support of the restoration, it is possible to place the posterior implants distally at angles of 17° or 35°. This angle is compensated by multi-angle abutments.

- **DXL Ball Abutment:**

It is the external connection of the implant embedded in the bone. It is used in cases where the physician wants to apply a removable prosthesis to the patient. It is available in different diameters and gingival height. It can be attached to the implant and analogue. It is attached to the patient after laboratory try-in on the analog and tooth preparation

- **DXL Ti-Base Abutment**:

DXL Ti-Base is a non-sterile specially designed abutment, supplied with a screw. All parts are for single use only. It is the part that connects the custom-made implant prostheses to the implant. Ti-Bases used with the original scanning part are used by determining the direction of the implant in the design in the 3D software. The system can also be used in the processing of prosthetic restorations used in connection with the implant.

- **DXL Multi Ti-Base Abutment**:

It is the part that connects the custom-made implant prostheses to the implant. Ti-Bases used with the original scanning part are used by determining the direction of the implant in the design in the 3D software. The system can also be used to produce prosthetic restorations used in connection with the implant.

- **DXL Premil Abutment:**

Optionally, instead of ready-made abutments, it is used in the production of "personalized abutment" for the patient. The part above the implant-abutment connection is shaped (milling) in CNC machines according to the design. For a personalized, ideal prosthesis, it creates the optimum prosthesis entry route with the priority of aesthetics, function and hygiene.

- **DXL Locator Abutment:**

It is the support connection piece between the implant and the prosthesis. It is used in cases where the physician wants to apply a removable prosthesis to the patient. There are different types of diameter and gingival height.

- **DXL Short Abutment:**

It is used for patients with short vertical bone distance.

- **DXL Abutment Screws:**

The abutment system is used to attach straight and angled abutments to dental implants.

3.4 Target Patient Population and Target User

Target Patient Population: Adults who have completed jawbone development and skeletal growth. Its use is contraindicated in children and young people with ongoing bone growth.

Target User: Products should only be administered by licensed dentists, periodontologists, and oral and maxillofacial surgeons who are legally authorized and have received academic and clinical specialty training in dental implant surgery and prosthetic restorations.

Table 2: DXL Implant System Diameter and Length Dimensions Matrix (mm)

Implant Type / Model	Diameter Options (Ø mm)	Length Options (L mm)
DXL Implant	Ø3.3 Ø3.75 Ø4.1 Ø4.8	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	Ø3.3 Ø3.75 Ø4.1 Ø4.8	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	Ø3.5 Ø4.0 Ø4.5 Ø5.5	8.0 / 10.0 / 12.5 5.0 (Short) / 8.0 / 10.0 / 12.5 / 15.0 5.0 (Short) / 8.0 / 10.0 / 12.5 / 15.0 5.0 (Short) / 8.0 / 10.0 / 12.5 / 15.0
DXL Premium Hybrid Series	Ø3.3 Ø3.5 Ø3.75 Ø4.0 Ø4.1 Ø4.5 Ø5.0	8.0 / 10.0 / 12.0 8.0 / 10.0 / 12.0 / 14.0 8.0 / 10.0 / 12.0 / 14.0 8.0 / 10.0 / 12.0 / 14.0 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: All implants can also be ordered with cover screws.

Table 3: DXL Implant Cover Screw Diameter and Length Dimensions Matrix (mm)

Cover Type / Model	Diameter (Ø mm)	Gingival Height (H)
DXL Cover Screw	Ø3,1 mm	H0 mm / H2 mm
DXL Narrow Cover Screw	Ø2,6 mm	H0 mm / H2 mm

Note: Cover screws sold separately can also be ordered as sterile or non-sterile

Table 4: DXL Healing Cap Diameter and Length Measurements Matrix (mm)

Healing Type / Model	Diameter (Ø mm)	Gingival Height (H)
DXL Healing Cap	Ø4,7 mm Ø4,8 mm Ø6,0 mm Ø8,0 mm	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	Ø4,1 mm	H2.0 / H3.0 / H5.0
Multi-Unit Healing Cap	Ø4,8 mm	H0

Table 5: DXL Abutment Diameter and Length Measurements Matrix (mm)

Abutment Type / Model	Platform Diameter (Ø)	Gingival Height (H/GH)
DXL Straight Abutment	Ø5,0 mm Ø6,5 mm Ø3,7 mm	H1.0 / H2.0 / H3.0 / H4.0 / H5.0 / H6.0 (Size:4.0, 7.0mm) H1.0 / H2.0 / H3.0 (Size: 4.0, 7.0mm) H0 (Size: 5.0, 7.0, 9.0 mm)
DXL Narrow Straight Abutment	Ø4,0 mm	H1.0 / H2.0 / H3.0 (Size: 5.5 mm)
DXL Straight Aesthetic Abutment	Ø5,0 mm	H0.5 / H1.0 / H3.0 mm
DXL Aesthetic Angled Abutment	Ø5,0 mm	For 7°: H0.5 / H1.0 / H2.0 / H3.0 / H4.0 For 15°/25°: H0.5 / H1.5 / H2.5 / H3.5 / H5.0
DXL Narrow Aesthetic Angled	Ø4,0 mm	For 7°/15°: H0.5 / H1.0 / H2.0 / H3.0 For 25°: H0.5 / H1.0 / H2.0
DXL Multi Straight Abutment	Ø4,80 mm	H0 / H1.0 / H2.0 / H3.0
DXL Narrow Multi Straight Abutment	Ø4,80 mm	H1.0 / H2.0 / H3.0
DXL Multi Angled Abutment	Ø4,80 mm	For 17°: H0.5 / H1.5 / H3.5 (Hex & Non-Hex) For 35°: H0.5 / H1.5 / H3.5 (Hex & Non-Hex)
DXL Narrow Multi Angled Abutment	Ø4,80 mm	For 17°: H1.0 / H2.0 For 35°: H1.0 / H2.0
DXL Ball Abutment	Ø3,70 mm	H1.0 / H2.0 / H3.0 / H4.0
DXL Narrow Ball Abutment	Ø3,0 mm	H1.0 / H2.0 / H3.0
DXL Ti-Base	Ø3,8 mm Ø4,4 mm Ø4,8 mm	Ti-Base Bar H0.5 / H1.5 / H2.5 Ti-Base Cerec 4.5
DXL Multi Ti-Base	Ø4,8 mm Ø5,1 mm Ø5,4 mm	5.5mm / 12mm 10.5 mm 5.5 mm
DXL Premil Abutment	Standard / Narrow	10 mm / 14 mm
DXL Locator Abutment	Ø3,70 mm	H1.0 / H2.0 / H3.0 / H4.0 / H5.0
DXL Narrow Locator Abutment	Ø3,0 mm	H1.0 / H2.0 / H3.0 / H4.0 / H5.0
DXL Short Abutment	Ø5,0 mm	H1.0 / H2.0 / H3.0
DXL Abutment Screws	M1.4 Narrow M1.6 Regular Healing Cap Screw Short Abutment Screw	Straight / Angled / Multi / Maximus Locator Straight / Angled / Multi / Maximus Locator - -

4. CONTRAINDICATIONS

Before dental surgery and implantation, the patient's general health status and local oral structure should be evaluated in detail. The use of DXL Dental Implant System components is strictly contraindicated in the following cases:

4.1 Systemic and General Contraindications:

- Clotting Disorders: Hemophilia, active clotting disorders, or uncontrolled high-dose anticoagulant therapies.
- Metabolic and Bone Diseases: Use of high-dose intravenous bisphosphonates in the treatment of metabolic disorders, active Paget's disease, osteomalacia, or osteoporosis that directly inhibit wound healing.
- Endocrine and Hormonal Disorders: Uncontrolled Diabetes Mellitus, unregulated thyroid dysfunctions, and uncontrolled hormone disorders that interfere with surgery/bone metabolism.
- Immunodeficiency and Oncology: Recent radiotherapy to the head and neck region, active chemotherapy, or severe immunosuppressive therapies that suppress the immune system.
- Allergy and Metal Sensitivity: Known allergy or hypersensitivity to Titanium (Ti), Aluminum (Al) or Vanadium (V) elements, which are implant/abutment materials defined in ISO 5832-2 and ISO 5832-3 standards.
- Addictions: Active use of alcohol, substances, or heavy tobacco use.
- Cardiovascular and Vascular Diseases: Uncontrolled coronary artery diseases, severe cardiac failures, peripheral vascular disorders, and uncompensated internal diseases that prevent surgery.
- Connective Tissue Diseases: Active rheumatologic or autoimmune connective tissue diseases (e.g., scleroderma, lupus) that impair tissue regeneration and peri-implant soft tissue adaptation.
- Patient Complience and Psychological Status: Psychiatric or behavioral disorders that cannot comply with post-operative care instructions, prosthesis use and physician instructions.

4.2 Local and Intraoral Contraindications:

- Active Infections: Presence of periodontitis, acute gingivitis, osteomyelitis, or active intraoral lesions at the surgical site.
- Bruxism: Uncontrolled teeth clenching and grinding habits that cannot be taken with protective measures such as night plate/splint application.
- Insufficient Bone Volume: Insufficient bone width and height that is not suitable for augmentation or grafting procedures and cannot provide the stability of the implant.
- Anatomical and Prosthetic Limitations: Lack of sufficient interocclusal (vertical) distance for implant placement or fit of prosthetic parts.
- Patient Compliance, Saliva Flow, and Lack of Oral Hygiene: Chronic/incurable poor oral hygiene habits that prevent the patient from maintaining prosthetic and peri-implant care, severe dry mouth (xerostomia) and acute oral fungal infections (oral candidiasis/thrush) that increase the risk of tissue infections.

5. POSSIBLE SIDE EFFECTS

5.1 Possible Surgical and Biological Side Effects

- Local Surgical Reactions: Local swelling (edema), temporary pain, hematoma formation and bleeding in the form of leakage in the operation area after surgical intervention.
- Postoperative Infections: Wound infection, flap dehiscence, and bone loss due to Endosseous ischemic necrosis or bacterial infiltration during osteotomy preparation.
- Nerve Injuries: Temporary or permanent numbness, loss of sensation or paresthesia in the lower lip due to damage to the lower jaw canal (mandibular alveolar nerve) during the operation.
- Sinus Perforation: Perforation of the sinus floor by the implant or surgical instrument in maxillary posterior (posterior molar) operations and the development of sinusitis due to this.
- Primary Stability Loss: Rotation of the implant within the bone due to too weak bone density or inadequate bone bed preparation, and primary stability cannot be achieved.

- Early Implant Loss: Failure to achieve Osseointegration and loss of the implant as a result of bacterial infection, surgical overheating or immunological reactions.
- Late Soft Tissue Reactions: Peri-implant mucositis caused by bacterial plaque accumulation in the gingival pocket and peri-implantitis leading to bone resorption if left untreated.
- Subgingival Cement Irritation: Inflammation of the gingival tissue, apical migration and marginal bone loss development as a result of the inability to clean the adhesive cement overflowing into the subgingival area in cement-retained abutment restorations.

5.2 Prosthetic and Mechanical Possible Side Effects

- Screw Loosening and Breakage: Loosening of prosthetic screws under chewing forces or screw breakage due to excessive occlusal forces.
- Implant Fracture: Formation of metallic fatigue cracks in the implant body under bruxism or excessive mechanical stress and fracture of the implant.
- Abutment Fracture and Deformation: Metal fatigue, cracking, bending, or fracture of the abutment body as a result of excessive occlusal forces, parafunctional habits (bruxism), or improper torque applications.
- Interface Wear and Rotational Mismatch: Wear, stripping, and loss of rotational stability on the connection surfaces due to micro-movements or inadequate fit in the abutment-implant interface (hex / tapered connection).
- Cement Detachment: Dislodgement of crowns or bridges bonded to the abutment as a result of adhesive cement detachment.
- Retainer Wear: Wear, tear and loss of retention of the retainer plastic matrices and metal housings in overdenture prostheses over time.

6. SAFETY INSTRUCTIONS, WARNINGS AND PRECAUTIONS

Aspiration and Ingestion Protection:

In all surgical and prosthetic procedures performed in the patient's mouth; The physician should take appropriate safety measures according to the clinical situation in order to prevent small components such as cover screws, healing caps, abutments and screwdrivers from escaping into the trachea or being swallowed. In case of aspiration, medical imaging must be performed immediately, and appropriate medical intervention must be initiated.

Surgical Torque Limits and Overheating:

During the preparation of the bone socket, work should be done under abundant sterile saline irrigation to prevent overheating of the bone. In order to maintain the primary stability of the implant and prevent bone necrosis, the surgical placement torque should be controlled by the physician in accordance with bone quality and clinical protocols, and excessive compression should be avoided.

Angle and Prosthesis Rules:

Prosthetic restorations should be designed in accordance with the long axis of the implant. In angled abutment applications, attention should be paid to the angle limits with the implant axis and excessive non-axial forces should be avoided. Prostheses should be positioned on the abutments without tension.

Original Equipment Compatibility:

DXL dental implants and prosthetic parts should only be applied with genuine DXL surgical set hand tools, screwdrivers, and torque wrenches. The use of incompatible or worn tools may lead to deformation of the screw heads and mechanical loosening.

Clinical Disclaimer:

Since the final clinical storage conditions of the implants, the operational technical skill of the physician, patient selection, surgical preparation stages and oral care of the patient take place beyond the control of the legal manufacturer DXL Medical GmbH; the legal manufacturer does not accept responsibility for failures or implant losses resulting from these stages. All treatment and clinical responsibility rests exclusively with the treating physician.

7. RULES REGARDING SEMI-FINISHED AND SPECIAL PROCESSING COMPONENTS

The following rules must be meticulously followed to maintain the original interface and mechanical strength during CAD/CAM design, milling, and casting techniques of semi-finished (Ti-6Al-4V Alloy Titanium (Grade 5)) superstructures machined in dental laboratories:

- Manufacturer specifications and relevant laboratory guidelines must be strictly followed for minimum machining wall thickness, casting temperature limits, and geometric tolerances of materials used in laboratory processes. Improper machining may disrupt joint compatibility (Manufacturer verification required).
- The implant internal conical structure of the abutments and the sensitive connection surfaces that come into contact with the hex index area should NEVER be sandblasted, leveled or subjected to any abrasive treatment. Sandblasting these sensitive surfaces causes tolerance losses, prosthesis movement within the implant and screw loosening.

- Laboratory screws (by hand tightening) should be used to prevent wear of the original titanium screws during try-in and work on the model in the laboratory stages. When fixing the final prosthesis in the patient's mouth, only the new, original titanium fixing screw that comes in the packaging should be used.

8. SURGICAL APPLICATION, HEALING AND PROSTHETIC LOADING PROTOCOL

Surgical Preparation and Drilling:

When preparing the implant socket, the DXL Surgical Manual guidelines prepared specifically for bone quality and implant model should be followed. During guide drilling and sequential drilling processes, the maximum speed limits (Rpm) and torque limits recommended by the manufacturer should not be exceeded, and plenty of sterile irrigation should be done to prevent excessive bone heating.

Healing Time:

The standard recovery time for bone integration (Ossteointegration) of placed implants is usually between 2 and 4 months, depending on the patient's systemic condition and bone quality. Final prosthetic loading should not be performed before this process is completed.

Immediate Loading:

Immediate prosthetic loading decision; It should only be evaluated when sufficient primary stability is achieved, occlusal forces can be kept under control, clinical evaluation of the physician and patient condition allow. In the case of immediate loading, implants should be splinted and free from occlusal contacts.

Table 6: Operational Torque Limits and Screwdriver Usage Chart

Component / Operation Name	Recommended Torque Limit (Ncm)	Screwdriver / Tool Required	Clinical Instruction and Validation
Surgical Implantation	According to clinical assessment/max 50-55 Ncm should not be exceeded	DXL Mandrel / Surgical Screwdriver	Excessive surgical torque should be avoided to prevent bone compression necrosis.
Cover Screw / Healing Cap	Manual / Hand tightening	1.2 mm Hex Driver	It should be lightly tightened by hand; excessive torque can damage the threads.
Permanent Abutment Screws	25 - 30 Ncm	1.4 mm Hex Driver	It should be tightened within the specified limits with a torque prosthesis wrench.
Temporary Abutments / Laboratory Screws	Manual / Manual tightening	1.4 mm Hex Driver	In laboratory stages, only light manual tightening should be done by hand.

9. STERILIZATION & REPROCESSING INSTRUCTIONS

9.1 Sterile Products (Implants and Sterile Sets):

Implants in unopened, undamaged sterile blisters are sterilized with Gamma radiation (STERILE R) and are disposable. Never use products with open packaging, torn or expired products. Never re-sterilize implants.

9.2 Non-Sterile Offered Reusable/Non-sterile Parts:

Non-sterile cover screws, healing caps, laboratory parts, and reusable surgical instruments must be cleaned, disinfected, and sterilized in an autoclave before surgery. The reprocessing steps are:

- Pre-Cleaning: After use, coarse dirt and tissue residues on the parts should be removed by brushing under cold running tap water (without saline).

- Ultrasonic Cleaning and Disinfection: Parts should be cleaned according to hospital instructions in an ultrasonic bath containing an alkaline or enzymatic disinfectant solution.
- Rinsing and Drying: Parts should be rinsed with deionized water and dried completely in a medical drying cabinet or with clean dry compressed air.
- Packaging and Sterilization: Dried parts should be sealed in sterilization bags in accordance with EN ISO 11607 standards and sterilized with the following steam autoclave parameters:

Table 7: Steam Autoclave (Moist Heat) Validation Limits Table

Sterilization Method	Minimum Cycle Temperature	Minimum Exposure Time	Drying Time and Verification
Moist Heat (Pre-Vacuum / Dynamic Air Extraction)	134°C (273°F)	10 minutes	20 minutes
Gravity Displacement	121°C (250°F)	20 minutes	30 minutes

Note: Original plastic blister packs are not suitable for autoclave sterilization. Pre-autoclave parts must be transferred to suitable sterilization bags.

10. MRI SAFETY, STORAGE & DISPOSAL

Magnetic Resonance Imaging (MRI) Safety:

The safety of DXL Dental Implant System components in a Magnetic Resonance (MR) environment has not been evaluated for heating, displacement, or artifact formation. In patients scheduled for MRI, the physician should clinically evaluate the presence of implants and the risks of magnetic field interactions.

Storage and Storage Conditions:

Products in their original packaging; It should be stored clean, dry, out of direct sunlight and at room temperature (recommended: -10°C - +30°C and 0% - 80% relative humidity limits). Never use expired products.

Biological Waste Disposal:

Implants and components that have been removed from the patient or contaminated must never be reused, as fatigue status cannot be visually determined. These parts must be considered biologically contaminated and disposed of in accordance with the statutory medical and hazardous waste regulations of the country to which the hospital/clinic belongs.

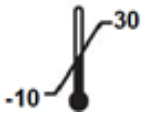
11. EU MEDICAL DEVICE REGULATION (MDR) LEGAL REQUIREMENTS

MDR Article 87 - Serious Incident Notification Process:

Any serious adverse event arising in connection with the use of this medical device (device malfunction, serious deterioration in the patient's state of health, etc.) must be reported immediately to the competent authority of the member state in which the incident took place and to the legal manufacturer DXL Medical GmbH (info@dxlimplant.de)

12. EXPLANATIONS OF LABELS AND PACKAGING SYMBOLS

Below are the meanings of the graphic symbols used on product labels and packaging:

	:	CE Marking	1984	:	Notified Body number
	:	Consult instructions for use		:	Catalogue number
	:	Use-by date		:	Batch Code
	:	Date of manufacture		:	Do not use if package is damaged and consult instructions for use
	:	Manufacturer		:	Do not reuse.
	:	Sterilized by irradiation		:	Keep dry
	:	The temperature range at which it can remain safe		:	Caution
	:	Do not resterilize.		:	Non-sterile
	:	Keep away from sunlight		:	A product that has been proven safe in an MRI environment.
	:	Medical Device		:	The humidity range in which it can remain safe
	:	Unique Device Identifier			