LEADER MEDICA

CE 0425

DENTAL IMPLANTS – INSTRUCTIONS FOR USE

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DEVICE INDICATIONS

The medical device known as 'Dental Implant':

does not contain or incorporate medicinal products;

does not contain or incorporate tissues/cells of human origin

does not contain or incorporate tissues/cells of animal origin

does not contain, incorporate or administer substances and/or combinations of substances intended to be introduced into, absorbed by and/or dispersed within the human body, and is neither haemolytic nor haemolysable;

does not process biological materials for subsequent processing and/or reuse;

does not contain or incorporate CMR substances and/or endocrine disruptors;

does not contain or incorporate phthalates;

does not contain or incorporate nanomaterials;

STORAGE AND HANDLING

The Medical Device known as "Dental Implant" must be stored in a cool, dry place, away from direct sunlight, water and sources of heat.

⚠ Do not use the Medical Device if the packaging is damaged or has been opened.
The product known as "Dental Implant" is a Medical Device that poses no risk to those handling it, but must be protected from the possibility of contamination.

⚠ When handling medical devices intended to come into contact with the patient, it is recommended that surgical gloves are always worn to protect against bacterial contamination.

It is recommended to avoid any contact between the surface of the implant and epithelial and connective tissue.

Any contact, even accidental, with the surface of the implant prior to its insertion into the surgical site would compromise the ideal surface conditions achieved through the surface treatment process, thereby jeopardising the success of the procedure.

Should it be necessary to handle the implant whilst inserting it into the prepared site, it is recommended that only clean, sterilised titanium forceps be used.

DEVICE SUPPLY

The product known as "Dental Implant" is a Medical Device that is sold (in a pack) as STERILE, with the indication that the Medical Device has been sterilised by irradiation. The product known as "Dental Implant" is a SINGLE-USE Medical Device.

'SINGLE-USE' means that each individual device must be used exclusively for a single patient.

⚠ Failure to comply with these instructions may compromise the accuracy of the devices and may lead to cross-infection. Any reuse on different patients must be considered off-label use, and in such cases, no liability is accepted.

CHEMICAL COMPOSITION OF THE MATERIAL:

Maximum composition limits		
ELEMENT	**Titanium Grade 4**	**Titanium Grade 5 ELI**
Nitrogen	0.01	0.004
Carbon	0.01	0.008
Iron	0.07	0.175
Hydrogen	0.001	0.001
Oxygen	0.31	0.097
Titanium	Equilibrium	Equilibrium

DEVICE DESCRIPTION

The product known as "Dental Implant" is a Medical Device, intended to be surgically inserted into the maxillary or mandibular bone to provide support and retention for dental prostheses, crowns, bridges and overdentures, restoring the patient's aesthetics and masticatory function. Implant systems are also indicated for immediate loading where there is good primary stability and adequate occlusal load. Implants can be used for two-stage or single-stage surgery.

For a detailed explanation of the guidelines for osteotomy preparation and implant placement, please refer to the relevant surgical manual.

When tightening dental implants, it is recommended to adhere to the following torque settings:

Manual ratchet	25–45 Ncm
Contra-angle driver	20 rpm

When tightening the surgical screw and/or transmucosal healing screw, please adhere to the following torque values:

Surgical screw (Cap screw)	By hand or at 10 Ncm
Healing screw (Transmucosal healing screw)	By hand or to 10 Ncm

⚠ Screw the implant in, taking care to ensure the thread is fully engaged (if prepared); never exceed the specified insertion torque. Over-tightening the implant may result in damage to the implant connection, fracture or necrosis of the bone site.

If the implant does not reach the desired depth, DO NOT force it, but remove it from the site and repeat the drilling and tapping procedures, checking the depth and the correct surgical sequence; in this case, the product known as the "dental implant", once removed from the oral cavity, must be disposed of in accordance with local regulations and replaced with a new, sterile one.

INTENDED USE, PATIENTS, CONTRAINDICATIONS AND WARNINGS

The product known as "Dental Implant" is a Medical Device intended for use within the patient's oral cavity to replace the tooth root in patients with single, partial or complete edentulism.

The product known as "Dental Implant" compensates for a prosthetic deficiency in the oral cavity. The product known as "Dental Implant" is a Medical Device which has no contraindications for use in patients with mental and/or physical disabilities (except where implantation is impossible due to the patient's lack of cooperation, specific malformations in the implant site, or clinical contraindications).

Given the nature of the product, it is frequently used in elderly patients. Treatment of children and adolescents is not recommended until growth is complete and the epiphyses have closed. Generally, for women who are pregnant or breastfeeding, dental implant treatment is recommended only when the clinical picture is complex or where there is a risk of infection; if there are no particular problems, it is advisable to wait until the end of pregnancy to avoid undergoing procedures that may require X-rays or the use of harmful medicines such as anti-inflammatories and certain antibiotics.

As a general rule, as in all medical disciplines, oral surgery is contraindicated when the benefits of the procedure are outweighed by the risks involved and, of course, in all patients who do not give their consent to treatment.

EXPECTED CLINICAL BENEFITS

The product known as 'Dental Implant' (implant fixture) is an implantable device (metal component) surgically inserted into the mandibular or maxillary bone, designed to support prosthetic components for the rehabilitation of patients with partial and/or total edentulism, with a view to restoring masticatory, phonetic and aesthetic function; the device is also intended to preserve bone tissue, protect adjacent teeth and improve the patient's quality of life.

LIFESPAN OF THE DEVICE

The average lifespan of an implant is generally 10 years, unless medical devices that are undersized for the implant site are used. In this case, the dentist is obliged to inform the patient that, for various reasons, it has been necessary to deviate from the guidelines set out in the surgical protocol and, consequently, of any risks to which the implant may be exposed. This is one of the conditions under which the implant's lifespan may be shorter than normal. Furthermore, the patient must be thoroughly informed of the procedures to follow for the proper care of the implants. The dentist is obliged to arrange follow-up appointments for routine check-ups and, where necessary, carry out repairs on the implants to ensure the device functions correctly.

⚠ The product known as the 'dental implant' is a medical device which, if stored in its original packaging, has a service life of 5 years. The expiry date is clearly marked on the packaging.

⚠ WARNING!!! It is recommended that you DO NOT USE the implants beyond the stated expiry date.

GENERAL RISKS

The use of these devices is restricted to professionals in the sector who have acquired adequate professional training over time. Before using a component, the professional must check the mechanical integrity of the devices and their packaging. In case of any doubts regarding the use of the device, the professional must consult the local representative or the manufacturer. The manufacturer cannot be held liable for any modifications made to the device without its approval.

GENERAL ABSOLUTE CONTRAINDICATIONS

- Severe congenital or acquired mental or neurological disorders, such that treatment and prognosis are problematic or unfeasible.
- Recurrent or chronic neurological disorders in which the patient's relationship with reality undergoes periods of instability, during which there is a risk that the patient's psychological relationship with the endosseous prosthesis may be compromised.
- Severe neoplastic diseases with an imminent fatal outcome.
- Serious diseases affecting: bones, connective tissue, the heart, blood and the haematopoietic system; the endocrine system, kidneys, liver and nervous system.

GENERAL RELATIVE CONTRAINDICATIONS

- Pregnancy and the post-partum period: it is necessary to wait until the end of pregnancy and the breastfeeding period.
- Further investigations are required in cases of osteoporosis (blood levels of acid and alkaline phosphatase).
- In cases of non-serious heart conditions, the severity of the condition must be assessed by consulting a cardiologist; it must then be ascertained whether the patient is taking anticoagulants and, where multiple implants are to be placed, the cardiologist's advice must be followed; treatment must be suspended to bring coagulation values up to at least 70 per cent. Appropriate antibiotic cover must be arranged. Alternatively, only one implant may be placed per procedure to minimise blood loss, using a suture around the neck of the implant to control bleeding.
- Acute rheumatic fever (ARF): procedures are carried out in accordance with the (antibiotic) prophylaxis prescribed by the attending doctor.
- Allergic diathesis: it is essential to ascertain whether there is a Grade 4 allergy to titanium.
- Essential trigeminal neuralgia: the severity of the syndrome must be assessed, bearing in mind that the implant could act as a 'trigger'; if it is decided to proceed with the procedure following prior authorisation from the treating neurologist, the patient must be placed on carbamazepine treatment starting ten days before the procedure and continuing for up to twenty days afterwards.
- Anxiety-related motility disorders, clenching and grinding: adhere to the principle of limiting stress on the teeth. The use of ceramic as a material for prosthetic reconstruction is absolutely contraindicated.

ABSOLUTE LOCAL CONTRAINDICATIONS

- Untreatable bone deficiency.

RELATIVE LOCAL CONTRAINDICATIONS

- Anatomical defect correctable by plastic surgery
- Acute or chronic local inflammation of the soft tissues (periodontal diseases).
- Localised acute or chronic bone inflammation.
- Presence of root remnants at the surgical site.
- Presence of impacted teeth at the surgical site.

PATIENT INFORMATION, RESIDUAL RISKS

The product known as "Dental Implant" is a Medical Device manufactured from materials specifically intended for medical use; the materials used have been selected on the basis of their properties as required for their intended purpose. The product known as "Dental Implant" is a Medical Device which, depending on the type of component, is manufactured from the following materials:

- 3.7165 – Grade 5 ELI titanium, used exclusively on implants with a diameter of Ø2.5
- 3.7065 – Grade 4 commercially pure titanium, used on all other implant diameters

⚠ An allergy to titanium is a very rare occurrence, but it is possible. Therefore, it is always necessary to check in advance with patients that they do not have an allergy to this material either.

⚠ The titanium and titanium alloy used in dental implants are not ferromagnetic metals, which means that it is safe to undergo an MRI scan whilst they are in the mouth. However, it is best to inform the doctor of the presence of dental implants. Inform the doctor of any metal fillings, crowns, orthodontic appliances or dentures.

As a precaution, following the procedure, the patient should avoid activities requiring physical exertion.

Complications that may accompany surgical procedures include temporary symptoms such as pain, swelling, speech difficulties, gingivitis, temporary localised swelling, oedema, haematomas, temporary loss of sensation, temporary impairment of chewing function, and minor post-operative bleeding within the following 12–24 hours. Following dental implant surgery, the following may occur: loss of the alveolar ridge, permanent paraesthesia, dysaesthesia, local or systemic infections, exfoliation, hyperplasia, and oroantral and oronasal fistulas. Failure in the case of implant-supported prosthetic rehabilitation may be comparable to certain complications typical of the discipline. These may be biological in nature, related to the implant to which the prosthetic component is attached (loss of integration and/or bone resorption); or mechanical in nature, such as the fracture of a component due to excessive load or the loosening of the screws securing the prosthesis to the implants and/or, more commonly, excessive play in the tooth structure. In such cases, the patient should consult their dentist as soon as possible to restore correct prosthetic function. A delay in seeking the dentist's intervention may lead to the fracture of the retaining screw or the breakage of the supporting structure of the fixed or removable prosthesis. The most common complication is the breakage or wear and tear of the supporting structure of the fixed or removable denture, particularly after ten years.

Dental intervention is required in the event of a fracture of the prosthesis.

⚠ Any procedures to remove crowns or bridges cemented with permanent cement, which may involve the transmission of impact to the implant structures, can lead to their fracture.

USERS, ENVIRONMENTS

The product known as "Dental Implant" is a Medical Device and, for this reason, its use and handling are restricted to qualified dental professionals authorised in accordance with the applicable national legislation.

⚠ The product known as the "Dental Implant" is not intended for use by lay persons.

There are no structural requirements for oral implantology that differ from those required for any other branch of dentistry.

For this reason, it is not mandatory to have a dedicated operating theatre; a dental surgery with suitable aseptic conditions (where correct hygiene, disinfection and sterilisation procedures are followed) is sufficient for its placement in the oral cavity. Implant-prosthetic treatment must be carried out using technologically suitable equipment and appropriate instruments.

⚠ It is recommended that surfaces are always covered with sterile drapes, that the dental unit and the micromotor are covered with suitable covers, that the surgical field is isolated by covering the patient with appropriate gowns, that sterile gloves are worn, and that instruments are removed from their sterile packaging immediately before use.

INFORMATION ON PREPARATORY TREATMENT

It is advisable to collect and archive comprehensive clinical, radiological and radiographic records.

The prosthesis must always be planned in advance. Prosthetic planning must be carried out in collaboration with the dental technician

PLANNING AND PRE-OPERATIVE PREPARATION

The pre-operative preparation phase involves:

- a general medical and dental history, a general medical examination, clinical tests (full blood count) and radiological examinations, a CT scan and consultation with the patient's GP;
- information for the patient (indications, contraindications, clinical picture, expectations, normal success and failure rates, and the need for periodic follow-up checks);
- a hygiene plan, including any periodontal treatment;
- adherence to the necessary medication regimens;
- pre-prosthetic surgical planning in collaboration with the dental technician;
- assessment of the risks associated with inadequate treatment of soft and hard tissues;
- prosthetic planning in collaboration with the dental technician.

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SURGICAL PROCEDURE

Surgical techniques for implants are taught at university to final-year dental students. However, the following factors must be borne in mind:

- both hard and soft tissues must be handled with the utmost care, taking all necessary precautions to ensure successful osseointegration of the implant;
- the standard biological principles of osseointegration must be observed;
- thermal trauma, which would cause necrosis and compromise the possibility of osseointegration, must be avoided. To this end, appropriate drilling speeds must be used, along with burs with cutting edges in excellent condition; the hole must be enlarged using burs with progressively larger specific diameters.
- It is essential to adhere to the recommended healing times for implant surgery and to periodically monitor the progress of osseointegration, including through radiographic checks.

WARNINGS

1. The dental implant must be placed using only the surgical instruments specified in the surgical protocol.
2. The dental implant is for single use only; it is supplied sterile and ready for use. Reusing the same dental implant results in a loss of sterility. If the dental implant is reused for the same patient, the associated risk is implant failure due to a local infection. If the dental implant is reused for another patient, the associated risk is the transmission of infectious diseases.
3. Always keep the implants in their original packaging and store them in a dry place at room temperature. Do not use the implant after the expiry date shown on the packaging. Re-sterilisation of the implants is not permitted.
4. The implant is contained in an ampoule placed inside a sterile vial, which is housed in a box made of plastic and paper suitable for this purpose. There are four labels (two for use and two spares) bearing the details required to identify the implant. The labels are removable and self-adhesive, and can therefore be removed and affixed to the patient's medical record and the implant passport.
5. The patient must be informed of the importance of cleaning and instructed on how to maintain and care for the prosthesis.
6. Patients wearing titanium dental prostheses must not use toothpastes or mouthwashes containing free fluoride.
7. If radiotherapy to the head and neck is required, metal prostheses must be removed from the mouth.
8. In the event of sudden pain or complications, advise the patient to consult their doctor, surgeon or dentist without delay.
9. It is recommended to use burs at low rotational speeds, setting the handpiece to a speed that absolutely prevents the bone from overheating. Sudden changes in speed should generally be avoided. Pressure must never be applied to the extent of forcibly stopping the instrument's rotation. This action could lead to an excessive build-up of heat in the tissues being cut, causing tissue necrosis and compromising the integrity of the instrument being used. Furthermore, the use of a suitable cooling fluid is recommended. Incorrect insertion can lead to instrument vibrations, eccentric rotation, premature wear and bending of the shank. It is recommended that only surgical micromotors suitable for this purpose be used. Leader Medica srl accepts no liability in the event of non-compliant use.
10. The success rate for the placement and retention of implants in their sockets is very high; however, there is always a risk of failure, the cause of which may be difficult to identify. There are specific situations that can lead to failure, such as: insufficient bone tissue, limited residual bone volume, inadequate surgical technique, infections and poor oral hygiene on the part of the patient. Further complications may arise, such as: chronic pain, permanent numbness, loss of bone from the upper or lower alveolar ridge, oro-maxillary or oro-nasal fistulas, adjacent or opposing teeth subjected to unfavourable loading (with possible irreversible damage), bone fractures, implant fracture, superstructure fracture, and aesthetic issues.
11. The tightening torque of the connecting screw must not exceed 35 Ncm.

SPECIAL WARNINGS

The use of an implant with a diameter of 3.5 mm or less is restricted to the incisor and premolar regions.

LIABILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS

In implant-prosthetic rehabilitation using LEADER MEDICA SRL implants, only original LEADER MEDICA SRL components must be used. The use of non-original components limits LEADER MEDICA SRL's liability and voids the product warranty. For the surgical placement of fixtures and subsequent prosthetic restoration, appropriate original surgical/prosthetic instruments manufactured by LEADER MEDICA SRL must be used.

We accept no liability for the use of non-original instruments.

Optimal patient care and attention to the patient's needs are essential for the success of implant treatment; it is therefore necessary to carefully select the patient, inform them of the inherent risks and obligations associated with the treatment, and encourage them to cooperate with the dentist to ensure the treatment's success.

The patient must therefore maintain good oral hygiene, which must be confirmed during check-ups and follow-up appointments; this must always be ensured and documented, just as the dentist's pre- and post-operative instructions and prescriptions must be followed and documented.

The instructions provided by LEADER MEDICA SRL are made available at the time of treatment and accepted by the dental practice; they must be followed and applied at all stages of care: from the patient's medical history to post-operative check-ups.

The warranty covers only proven manufacturing defects, subject to the return of the item identified by its item code and batch number, within the warranty period. The warranty terms are available on the LEADER MEDICA SRL website.

REPORTING OF INCIDENTS

Any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

DATE AND VALIDITY OF THESE INSTRUCTIONS FOR USE

These instructions for use are valid from February 2026.

IMPLANT PASSPORT

LEADER MEDICA SRL supplies, together with the Medical Device, the implant carrier card (implant passport) and the relevant information provided to patients.

Once the European Database on Medical Devices (EUDAMED) is online, the Summary of Safety and Clinical Performance (SSCP) for LEADER MEDICA SRL's dental implants will be available at https://ec.europa.eu/tools/eudamed – until EUDAMED is fully operational, the SSCP may be requested from LEADER MEDICA by email to quality@leadermedica.com

DISPOSAL

The devices are used in a hospital setting and must therefore be disposed of in accordance with the applicable legislation on waste disposal as implemented by the facility. In particular, used devices, which may be soiled and biologically contaminated, must be disposed of as special waste. As they are intended for use in facilities that normally carry out such special waste collection, it is not necessary to include these instructions on the labelling.

These instructions for use are provided in electronic form and can be viewed on the website www.leadermedica.com

KEY TO SYMBOLS USED ON PACKAGING

Warning!	UDI code, Unique Device Identifier
Refer to the instructions for use	REF Code
Do not reuse; single-use	Rx only Sale restricted to, or on the instructions of, a qualified professional
LOT Batch Number	LATEX Latex-free product
Do not use if the packaging is damaged	Sensitive to moisture
Store away from direct sunlight and sources of heat	STERILE R Sterilised by irradiation
MD Medical Device	Non-sterilisable product
Date of manufacture	CE 0425 CE marked
Manufacturer	Single-barrier sterile system with protective inner