LEADER MEDICA

CE 0425

SURGICAL INSTRUMENT SET FOR DENTAL IMPLANT SURGERY – INSTRUCTIONS FOR USE

EN

LEADER MEDICA SRL
Registered Office: Via Longhin, 11 – 35129 Padua (PD) Italy
Padua Operational Headquarters: Via dell'Industria, 13 - 35030 Bastia di Rovolon (PD) Italy - Tel. +39 049 991 3364
Turin Operational Office: Via Botteghe, 31 - 10060 Scalenghe (TO) Italy - Tel. +39 011 986 6952
website: www.leadermedica.com email: quality@leadermedica.com

DEVICE SPECIFICATIONS

Manipulation keys/micromotor keys, Micromotor tap drills, Bur bits, Stoppers, Crestal levellers, Broken screw extractors, Mucotomes, Bur extensions: Medical device Reg. 2017/745 and subsequent amendments, Class IIa.

LEADER MEDICA instruments must only be used with LEADER MEDICA dental implants.

DEVICE SUPPLY

The product known as the "Surgical Instrument Set for Implantology" is a Medical Device sold in a NON-STERILE pack. The product known as the "Surgical Instrument Set for Implantology" is a REUSABLE Medical Device. To ensure the optimal performance of the Medical Device, it is recommended that it be used no more than 30 (THIRTY) times.

STORAGE AND HANDLING

The medical device known as the "Surgical Instrument Set for Implantology" 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 "Surgical Instrument Set for Implantology" is a Medical Device that poses no risk to the user, but must be protected from the possibility of contamination. It is recommended that surgical gloves are always worn to protect against bacterial contamination. Surgical dental burs are sharp medical instruments. Take great care when handling and using these Medical Devices.

DESCRIPTION OF DEVICES

The surgical instruments designed for LEADER MEDICA implant systems are medical devices intended for use within the oral cavity, for temporary use (continuous use not exceeding 60 minutes) and reusable following cleaning and sterilisation, in order to prepare the site for the insertion of dental implants manufactured by LEADER MEDICA. All Medical Devices are identified by a product code, which is laser-marked onto the body of the Medical Device itself. Where space does not permit the code to be marked in full, the elements necessary to uniquely identify the Medical Device are marked.

For further information, please refer to the catalogues of the individual implant systems for detailed technical specifications. The surgical instruments are manufactured in accordance with the most stringent European and American standards.

SURGICAL DRILLS

These are cutting instruments used to prepare surgical sites for dental implants. They come in various shapes: lanceolate, rosette, conical, cylindrical, etc.; depending on the implant system to which they belong, they may or may not be fitted with internal irrigation, feature depth markings to allow the working depth to be determined, and may or may not be designed to attach a depth stop.

The bur is designed for use both with and without a depth stop. The use of the depth stop is at the dentist's discretion. However, its use is recommended, particularly in cases of poor intraoperative visibility.

An extension is available for use when the total length of the instruments is too short due to the presence of adjacent teeth that prevent the handpiece head from passing through.

The surgical burs are made of surgical-grade steel characterised by high resistance to corrosion and wear. They are designed for use with a contra-angle handpiece and must be used with a suitable micromotor. Lever-like movements increase the risk of burs fracturing and must therefore be avoided. Sudden changes in speed must be avoided, and pressure must never be applied to the extent of forcibly stopping the instrument's rotation, as this could cause excessive heat to build up in the tissues being cut and lead to premature wear of the instrument and micromotor. It is always recommended to work intermittently using a vertical oscillating motion, to prevent overheating and wear

of the cutting edge and a significant rise in temperature within the alveoli affected by the bur's cutting action.

The use of a suitable cooling fluid is recommended. A lack of adequate irrigation may lead to bone necrosis. The wear of the burs depends largely on the type and density of the bone being drilled: harder bone results in greater wear of the instruments.

It is important and necessary to check the wear on the burs every 30 uses.

Drills must never be resharpened before use. Never use damaged, bent or worn instruments.

Insert the pilot drill into the handpiece, screw on the stop corresponding to the height of the chosen implant and drill. The recommended rotation speed is 600 rpm (never exceed 1000 rpm).

Proceed with the preparation of the implant tunnel by progressively enlarging the hole as indicated in the surgical protocol, carefully checking the depth reached each time using the appropriate depth gauge. To avoid dangerous overheating of the bone, the rotation speed must never exceed 1,000 rpm. Duration of use in the patient's mouth: temporary.

TAPPING INSTRUMENTS

These are cutting instruments capable of preparing sockets in the bone for the threads of the implants. Their use is necessary in the presence of very dense or cortical bone to alleviate compression and the torque required for implant insertion. Duration of use in the patient's mouth: temporary.

DRIVING KEYS/MICROMOTOR DRIVING KEYS

These are devices powered by a micromotor, used to screw implants into place quickly and consistently. The device does not come into contact with the body. Time spent in the patient's mouth: temporary.

STOPPERS

These are devices that allow precise depth control, preventing excessive drilling and minimising the risk of damage to adjacent structures. Duration of use in the patient's mouth: temporary.

CREST LEVELLERS

These are devices that allow the bone crest to be levelled to facilitate better use of subsequent instruments. Duration of use in the patient's mouth: temporary.

BROKEN SCREW EXTRACTORS

These are devices used to remove damaged or broken screws from dental implants. These instruments are essential for ensuring the safety and effectiveness of dental implant maintenance and repair procedures. Time spent in the patient's mouth: temporary.

MUCOTOMES

These are instruments used to create a complete incision in the mucosal flap. Time

spent in the patient's mouth: temporary.

EXTENSION FOR DRILL BITS

This is an instrument to be used when the total length of the burs is too short. The device does not come into contact with the body. Duration of use in the patient's mouth: temporary.

INTENDED USE, PATIENTS, CONTRAINDICATIONS AND WARNINGS

The product known as the "Surgical Instrument Set for Implantology" is a Medical Device with no contraindications for use on patients with mental and/or physical disabilities (except where application 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, it is recommended that dental implant treatment be carried out 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 the pregnancy to avoid undergoing procedures that may require X-rays or the use of harmful medication such as anti-inflammatories and certain antibiotics.
The medical history is taken to identify any systemic conditions that might interfere with or influence, in any way, the diagnosis and subsequent surgical treatment. To ensure a more accurate diagnosis, certain diagnostic tests are valuable aids in oral surgery, such as intraoral X-rays, orthopantomography (OPT), computed tomography (CBCT), magnetic resonance imaging (MRI) and ultrasound. Blood tests are useful for assessing any systemic abnormalities prior to oral surgery. Pre-operatively, and only if the information from the patient's medical history makes them necessary, standard blood tests may be carried out; these should include at least a complete blood count, platelet count, erythrocyte sedimentation rate (ESR), blood urea nitrogen (BUN), blood glucose, prothrombin activity, international normalised ratio (INR), activated partial thromboplastin time (aPTT), standard urine analysis, and the markers HBsAg, HCV and HIV.
Generally speaking, as in all medical disciplines, oral surgery is contraindicated when the benefits of the procedure are outweighed by the risks and, of course, in all patients who do not give their consent to treatment. Contraindications to surgical treatment are essentially related to the patient's state of health.
The product known as the 'Surgical Instrument Set for Implantology' is a Medical Device for which the contraindications are:

- systemic conditions in the patient that constitute an absolute contraindication to any type of oral surgical procedure, to be identified on a case-by-case basis;
- incomplete skeletal growth;
- conditions reported in the patient's medical history and for which the dentist has indicated the need for appropriate modifications, in order to eliminate or reduce the risk of treatment failure (suitability for implant-prosthetic rehabilitation, such as defects in occlusion and/or articulation, as well as insufficient interocclusal space or an inadequate alveolar ridge).

Examples of such conditions include:

- poor patient motivation and/or cooperation; physical and/or psychological impairments that prevent or make it very difficult to carry out proper oral hygiene at home; severe drug or alcohol dependence and excessive smoking; the presence of infections and/or inflammation that are untreated or have been treated unsuccessfully (periodontitis, gingivitis). Metabolic or systemic disorders affecting tissue regeneration, with a particular impact on wound healing and bone regeneration; acute or chronic infectious diseases; subacute chronic maxillary osteitis; systemic diseases; endocrine disorders; diseases resulting in microvascular disorders; immunosuppressive therapies (chemotherapy and radiotherapy); haemophilia, disorders of the blood coagulation system, treatment with anticoagulants, granulocytopenia, use of steroids, diabetes mellitus, renal failure, fibrous dysplasia, cardiovascular diseases, hypertension, thyroid or parathyroid disorders, malignant tumours diagnosed within the 5 years prior to surgery, or nodular enlargements, or patients who have previously undergone organ transplants
- the presence of a residual alveolar ridge which, in terms of quantity, quality and morphology, is unsuitable for accommodating an implant of a size appropriate to the functions to be performed, where surgical procedures to correct such anatomical conditions are not feasible or are associated with high rates of failure or complications;
- insufficient space for the fabrication of a prosthesis that is morphologically and functionally suitable, where procedures to rectify this situation are not feasible or would result in an unfavourable cost-benefit ratio.

It is recommended that the rotation speeds specified in the individual catalogues or surgical manuals be used to prevent the development of bone necrosis. Lever-like movements increase the risk of instrument fracture and must therefore be avoided. In general, sudden changes in speed should be avoided. Pressure must never be applied to the extent that it forcibly stops the rotation of the instrument.

EXPECTED CLINICAL BENEFITS

The product known as the "Surgical Instrument Set for Implantology" is a Medical Device intended for use within the patient's oral cavity to prepare the site for the insertion of a dental implant and to attach the relevant prosthetic components in order to restore masticatory and/or phonetic and/or aesthetic function.

PATIENT INFORMATION, RESIDUAL RISKS

The product known as the "Surgical Instrument Set for Implantology" is a Medical Device manufactured from materials specifically designed for medical use;

The materials used have been selected on the basis of their properties as required for their intended use.

The product known as the "Surgical Instrument Set for Implantology" is a Medical Device which, depending on the type of component, is manufactured from the following materials:

• Steel 1.4542 (AISI 630)

• Steel 1.4197 (AISI 420F MOD)

• Steel 1.4123 (AISI 420 MOD)

•Grade 5 titanium ELI 3.7165

The medical device contains nickel. An allergy to titanium is very rare, but possible. Therefore, it is always necessary to check in advance with patients that they do not have an allergy to this material either.

As a precaution, following the procedure, the patient must 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 masticatory 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, desquamation, hyperplasia, and oroantral and oronasal fistulas.

The risks of implant surgery include: perforation of the labial or lingual plate, bone fractures, implant fractures, superstructure fractures, aesthetic issues, inadvertent perforation of the maxillary sinus, nerve damage, and compression of the natural dentition.

ENVIRONMENTS, USERS

There are no structural requirements for oral surgery 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 practice with suitable aseptic conditions (where correct hygiene, disinfection and sterility procedures are followed) is sufficient for the placement of implants in the oral cavity. Implant-prosthetic treatment must be carried out using technologically suitable equipment and appropriate instruments.
The product known as the 'Surgical Instrument Set for Implantology' is a Medical Device and, for this reason, its use and handling is restricted to:

- graduates in Dentistry and Dental Prosthetics;
- graduates in Medicine and Surgery who are authorised to practise and who began their university medical training on or before 28 January 1980;
- graduates in Medicine and Surgery who are authorised to practise and who commenced their university studies after 28 January 1980 and before 31 December 1984, provided they have passed the specific aptitude test referred to in Legislative Decree No. 386 of 13 October 1998;
- graduates in Medicine and Surgery who are authorised to practise and who commenced their university studies after 28 January 1980 and before 31 December 1984, and who hold one of the three-year specialisation diplomas listed in the Ministerial Decree of 18 September 2000 issued by the Ministry of Health, namely: Dentistry and Dental Prosthetics; Oral and Maxillofacial Surgery; Oral and Maxillofacial Medicine; Orthodontics.
- graduates in Medicine and Surgery who commenced their university studies after 31 December 1984 and hold a three-year specialisation diploma in the field of dentistry as referred to in the aforementioned Ministerial Decree of 2000, provided that the said specialisation course commenced by 31 December 1994.

The product known as 'Surgical Instrument Set for Implantology' is not intended for use by laypersons.

WARNINGS

It is recommended that surgical drills be used for a maximum of 30 procedures; beyond this, their suitability is no longer guaranteed.

To ensure that site preparation is carried out without causing excessive trauma to the bone and does not delay or compromise healing, it is necessary to:

- Always bear in mind that the drills over-prepare in terms of length.
- Bear in mind that all depth indications for the drills are designed to position the implant at a level predetermined during the planning phase; should placement at a lower level be necessary, this must therefore be taken into account during all stages of site preparation.
- To keep the bone temperature low and prevent necrosis of the affected cells, ensure adequate external irrigation of the drills and taps using saline solution cooled to approximately 4°C.
- Use motors with adjustable speed and power settings. Do not apply constant pressure to the handpiece until the maximum depth is reached; instead, perform the drilling using a piston-like rotation, advancing and retreating by a few millimetres at a time, so as to facilitate the flow of the saline solution and allow the removal of debris resulting from the drilling and tapping of the bone.
- If you encounter unusual resistance before reaching the intended depth, you should stop, check the direction and depth, and, if necessary, take an X-ray with the drill still in place to compare it with the reference panoramic X-ray used for the implant plan.
- Use drills and taps that are intact and have sharp cutting edges.
- Keep the flap well retracted and ensure it does not come into contact with the rotating drills.
- Ensure effective suction of blood and excess saline to keep the operating area clean and clearly visible.
- Carefully control the pressure on the handpiece to prevent sudden slippage from causing serious damage to nerve or vascular structures.
- To be used only with LEADER MEDICA components and their original product ranges.

IN_A055FE26 _ Rev02 - 03/2026

LEADER MEDICA

CE 0425

EN

CLEANING / STERILISATION AND STORAGE

Warning! All surgical instruments for implantology are sold in a NON-STERILE condition. Before use, all surgical instruments must be cleaned, disinfected and sterilised in accordance with the following procedure. These processes must be carried out before first use, or before each use for any trial procedures. Repeating the processes described in this section does not alter the characteristics of these devices.

Failure to follow these instructions may lead to cross-infection and intraoperative complications.

STERILISATION

INSTRUCTIONS FOR THE REPROCESSING OF DENTAL INSTRUMENTS			
	PROCESS	PROCESS STEP	DESCRIPTION, INSTRUCTIONS, WARNINGS
1.	Initial treatment at the point of use	**1.1** Soaking	The instrument must be soaked within a maximum of 2 hours after use. Use products containing enzymes of proven efficacy (e.g. DGHM, FDA or CE-marked), suitable for the disinfection of instruments compatible with them.
		1.2 Containment and transport	No specific requirements. It is recommended that instruments be processed as soon as reasonably practicable after use and soaking.
2.	Preparation prior to cleaning	-	No specific requirements.
3.	Cleaning, disinfection and drying Automated	Thermal	For cleaning instruments, it is advisable to use a mechanical procedure involving a thermal disinfector (a machine for washing, disinfecting and drying). The use of neutral or slightly alkaline detergents, free from critical substances (depending on concentration), is recommended. If alkaline detergents (pH 9.5–11.5) are used, colour changes may occur on metal surfaces. However, this does not compromise the functionality of the instrument. Avoid strongly alkaline detergents (pH > 11.5). The suitability of the products for effective cleaning and disinfection via a mechanical process (93°C, 10 min) using alkaline detergents and the addition of a surfactant has been verified. The manufacturer accepts no liability for the use of other types of detergent (or non-equivalent products). Use only detergents of proven efficacy that are comparable to those listed in this section. When selecting a cleaning system, ensure that: • it is, in principle, suitable for cleaning the instruments; • the chemical agents are compatible with the instruments. Adhere to the concentrations and exposure times specified by the detergent manufacturer. Immerse the unloaded instrument, with the lid open, in the cleaning and disinfection unit and follow the unit manufacturer's instructions.
4.	Manual cleaning and disinfection	-	The use of products containing enzymes and a disinfectant is recommended. Use the product in accordance with the manufacturer's instructions. Immerse the instrument with the lid facing downwards in the solution in the ultrasonic bath and use a soft brush to remove any residues left over from the procedure. After treatment, rinse the instrument under running water. Check that the instrument is clean; if any dirt and/or foreign material is still visible, repeat the procedure.
5.	Manual drying	-	Dry the instrument thoroughly using disposable alcohol-based disinfectant wipes or a sterile, lint-free cloth, and, if necessary, using compressed air. To avoid damaging the products, the air pressure must be < 3 bar. It is advisable that the air used for drying be filtered.
6.	Maintenance, inspection and testing	-	Check that the products are functioning correctly in accordance with the relevant instructions for use and ensure there is no visible damage. For moving or rotating parts, the use of instrument oil is not recommended, as certain plastics tend to expand and oils can adversely affect correct operation.
7.	Packaging	-	Before sterilisation, the instrument must be placed in a single-use, sterilisable medical-grade package (single or double packaging) and/or in a suitable sterilisation container: # compliant with standard EN 868/ISO 11607; # suitable for steam sterilisation (temperature resistance up to 134°C, sufficient steam permeability); # regularly maintained (sterilisation container) WARNING: do not sterilise the instrument inside its original transport packaging.
8.	Sterilisation	In a steam autoclave (vacuum cycle at 134°C for 4 minutes)	For sterilisation, use only the procedures indicated below; do not use any other methods. For steam sterilisation, ensure that: # the steam steriliser (vacuum type) complies with standards EN 13060 and EN 285. # the procedure is approved in accordance with ISO 17665. #Maximum sterilisation temperature: 134°C (plus tolerance in accordance with ISO 17665) #Sterilisation time: 4 minutes at 134°C. The suitability of the products for effective sterilisation using the above sterilisation times and temperatures has been verified. Do not use hot-air sterilisation.
9.	Storage	-	Once sterilised, store the products in a cool, dry and clean place, keeping them in their sterilisation packaging.
10.	Inspection and operation al testing operation	-	Before each use, carry out a visual inspection and a functional test in accordance with the instructions for use.

PREPARATORY TREATMENT INFORMATION

PRE-OPERATIVE PLANNING AND PREPARATION

The pre-operative preparation phase involves:

- a general and dental medical history, a general medical examination, clinical tests (full blood count) and radiological examinations, a CT scan and consultation with the patient's GP;
- patient information (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.

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 treated with the utmost care, taking all necessary precautions to ensure good implant integration;
- 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.

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 hospital. 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 hospitals which normally carry out such special waste collection, it is not necessary to include these instructions on the labelling.

Limitation of liability: LEADER MEDICA Srl accepts no liability for any direct, indirect and/or incidental damage arising from the use of the device, whether resulting from a failure to check its functionality, sterilisation or validity, from surgical intervention, or from failure to comply with the above Instructions for Use.

Any serious incident occurring in connection with the medical device supplied by us must be reported to the manufacturer and to the competent authority of the Member State in which you are based.

KEY TO SYMBOLS USED ON PACKAGING


Warning!


Manufacturer


Refer to the instructions for use


Keep away from moisture

Batch number

Device supplied non-sterile


Do not use if the packaging is damaged

UDI code,
Unique Device Identifier

Medical Device

Code


Date of manufacture