LEADER MEDICA

CE 0425

PROSTHETIC COMPONENTS – INSTRUCTIONS FOR USE

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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 INDICATIONS

The medical device known as 'Prosthetic Components':
does not contain or incorporate medicinal products;
does not contain or incorporate tissues or cells of human origin;
does not contain or incorporate tissues or 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;

SUPPLY OF THE DEVICE

The product known as 'Prosthetic Components' is a Medical Device supplied in NON-STERILE packaging; sterilisation is mandatory prior to use in the oral cavity. The product known as 'Prosthetic Components' is a SINGLE-USE Medical Device. 'SINGLE-USE' means that each individual device must be used exclusively for a single patient. It is common practice for a prosthetic component to be tried in the mouth several times and returned to the dental technician for final prosthetic preparation. This practice is permissible and does not alter the concept of single-use, provided that the same prosthetic component is always used solely for the same patient. In cases involving multiple prostheses, it is important that the same component is always used only in the same position and in connection with the same implant; in other words, components must not be interchanged within the same restoration.

Failure to comply with these instructions may compromise the accuracy of the restorations 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.

STORAGE AND HANDLING

The Medical Device known as "Prosthetic Components" 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 open. The product known as "Prosthetic Components" 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, both during use and during cleaning and sterilisation procedures, it is recommended that surgical gloves are always worn to protect against bacterial contamination.

DESCRIPTION OF DEVICES

For further information, please refer to the catalogues of the individual implant systems for detailed technical specifications.

The product known as 'Prosthetic Components' is a Medical Device (metal component) designed to rehabilitate patients affected by partial or total edentulism, restoring masticatory, phonetic or aesthetic function. The functions of the product known as 'Prosthetic Components' are:

- anchoring to dental implants to support dental prostheses.
- gum reconditioning

Medical Devices that can be used with "Prosthetic Components" (covered in the relevant Technical Data Sheets) are: dental implants, or fixtures, laboratory analogues, and drivers/screwdrivers

⚠ Excessively high tightening torques may weaken the mechanical structure of the screws and compromise prosthetic stability, potentially causing damage to the implant connection. It is recommended that the screws supplied with the prosthetic components be used ONLY for final screw-in placement in the oral cavity. For in-mouth trial fitting and screw-in procedures on laboratory models, it is recommended to use disposable working screws. Frequent unscrewing and re-tightening of the permanent screw may weaken its structure and cause a loss of precision, resulting in the restoration becoming loose.

1. PROSTHETIC ABUTMENTS

These are pre-formed accessories designed to support a ceramic or resin prosthesis. These abutments are fitted to the two-stage implant during surgical reopening, following the osseointegration phase. The straight abutment is aligned in a straight line with the axis of the implant. All abutments are secured to the two-stage implant using a connecting screw.

- Straight and angled abutments: titanium abutments to which the prosthetic restoration is attached; they come complete with the relevant screws for fixing to the implants, for cement-retained prostheses.
- Milling abutments: titanium abutments that allow the prosthesis to be milled; they come complete with the relevant screws for attachment to the implants, for cement-retained prostheses. They are customised by milling in the dental laboratory or using CAD-CAM techniques at milling centres.
- Castable abutments: these are abutments with a preformed alloy base, complete with the corresponding screws for securing them to the implants. They are used to produce, via overcasting in the dental laboratory, individual abutments for cement-retained prostheses, or bars for overdentures, or structures for screw-retained bridges such as the Toronto Bridge.
- Titanium bases fitted with an implant connection, featuring a standard coupling cone at the top for CAD-CAM techniques, complete with the corresponding screws for securing them to the implants.
- Abutments primarily used for screw-retained multiple dentures (Toronto-type dentures) of the traditional type (straight, direct-screw-retained) and for the MUA technique (for correcting significant misalignments), complete with the relevant screws for securing them to the implants. These abutments must be used in conjunction with the appropriate components for fabricating the superstructures.
- Locator abutments: titanium abutments for overdentures
- Temporary abutments: Temporary abutments, normally consisting of a titanium base with an upper cannula onto which the dentist or dental technician relines an acrylic prosthesis. Some versions are already made of PEEK, which can be modified by milling either in the laboratory or by the dentist directly at the chairside. PEEK cannot be relined with resin; therefore, these abutments are normally used for the restoration of single-tooth prostheses via the cementation of a crown. They are sold complete with the relevant screws for fixing them to the implants.
- MUA: The MUA is an abutment. It provides a means of ensuring retention and stability for a full denture, whilst support is shared between the implants and the underlying tissue. It consists of a transmucosal section, which can vary in height, and a cone that forms the male part of the attachment.

When tightening, it is recommended to adhere to the following torque values:

Straight and/or angled abutments	30 Ncm
Milling abutment	30 Ncm
Bonding/overcast abutment	30 Ncm
CAD/CAM abutment	30 Ncm
Straight MUA abutment	30 Ncm
Angled MUA abutment	15 Ncm
Abutment for MUA superstructures	10 Ncm
Temporary pillar	30Ncm
MUA/PAD temporary pillar	10 Ncm

2. T-BASE/ BASES/ PREMILLED/ CANNULA

The T-Base and Premilled are crown bases. The bases may also be supplied with a cannula.

3. PROSTHETIC SCREWS

These are the screws required to secure abutments and superstructures. They are supplied either as part of the relevant abutment kits or separately as spare parts. As they are used with abutments and superstructures, they are classified in the same class as the relevant device.

4. HEALING SCREWS

The healing screw is a component that replaces the cap screw and remains in place until the next prosthetic stage, allowing the gum to heal whilst preventing tissue regrowth within the implant. The maximum period of retention in the body is 180 days. BOTM healing screws are manufactured from methacrylate resins using 3D printing.
When tightening, it is recommended to adhere to the following torque values:

Healing screw	10 Ncm

RAW MATERIALS

MEDICAL DEVICES	RAW MATERIAL
Prosthetic abutments	Grade 5 ELI Titanium
T-base	Grade 5 ELI Titanium
Bases	Grade 5 ELI Titanium / Cobalt-Chrome
Premilled	Grade 5 ELI Titanium
Cannula	PMMA
Prosthetic screws	Grade 5 ELI Titanium
Healing screws	Grade 5 ELI titanium
BOTM healing screws	Methacrylate resins

CHEMICAL COMPOSITION OF THE MATERIAL

- Grade 5 ELI Titanium Ti6Al4V – ASTM F136 and ISO 5832-3:

ELEMENT	MAXIMUM COMPOSITION LIMITS MASS FRACTION PERCENTAGE %
Aluminium	5.5 to 6.75
Vanadium	3.5 to 4.5
Iron	Maximum 0.3
Oxygen	Maximum 0.2
Carbon	Maximum 0.08
Nitrogen	Maximum 0.05
Hydrogen	Maximum 0.015
Titanium	Equilibrium

- SprintRay EU Temporary Crown & Teeth methacrylate resin:

ELEMENT	MAXIMUM COMPOSITION LIMITS MASS FRACTION PERCENTAGE %
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated, and 2-methylprop-2-enoic acid	25–45 %
7,7,9 (or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	25–45 %
3,6,9-trioxaundecamethylenedimethacrylate	07–10 %
2-Propenoic acid, reaction products with pentaerythritol	< 0.2 %
Diphenyl (2,4,6-trimethylbenzoyl)phosphine oxide	< 0.2 %

- Chromium Cobalt:

ELEMENT	MAXIMUM COMPOSITION LIMITS MASS FRACTION PERCENTAGE %
Iron	Maximum 0.75
Carbon	Maximum 0.14
Nitrogen	Maximum 0.25
Silicon	Maximum 1.00
Manganese	Maximum 1.00
Chromium	From 26.00 to 30.00
Molybdenum	From 5.00 to 7.00
Nickel	Maximum 0.1
Cobalt	Balance

LIFESPAN OF THE DEVICE

The average lifespan of prosthetic components is generally 10 years, provided that medical devices that are undersized for the implant site are not used. In such cases, 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 maintenance of the implants. The dentist is obliged to arrange follow-up appointments for routine checks and, where necessary, carry out repairs on the implants to ensure the device functions correctly.

INTENDED USE, PATIENTS, CONTRAINDICATIONS AND WARNINGS

The product known as 'Prosthetic Components' is a Medical Device intended for use within the patient's oral cavity to enable the placement and fixation of dental prostheses (fixed or removable) for the restoration of masticatory and/or phonetic and/or aesthetic function.
The product known as 'Prosthetic Components' compensates for a prosthetic impairment in the oral cavity.
The product known as "Dental Prosthetic Components" is a Medical Device which has no contraindications for use on patients with mental and/or physical disabilities (except in cases 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 in 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 and, of course, in any patient who does not give their consent to treatment.
Contraindications include:

- 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 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.

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EXPECTED CLINICAL BENEFITS

The prosthetic components consist of support devices that are connected to the implant; these devices are designed and manufactured to be fitted onto dental implants so as to create, as a whole, an implant-prosthetic system capable of replacing one or more missing teeth. The prostheses manufactured are intended to restore correct masticatory, aesthetic and phonetic function in the patients using them.

PATIENT INFORMATION, RESIDUAL RISKS

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

•3.7165 – Grade 5 ELI titanium

•9.9135 – CrCoMo

•TECAPEEK CLASSIX MT

•CLEAR PMMA GS

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

Titanium and titanium alloys used in prosthetic components 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 your doctor of the presence of dental implants. Inform your doctor of any metal fillings, crowns, orthodontic appliances or dentures.
As a precaution, following the procedure, the patient should avoid activities requiring physical exertion.
Temporary complications associated with surgical procedures may include 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.
The product known as 'prosthetic components', once placed in the oral cavity without complications, has a theoretically infinite lifespan.
In reality, however, this is influenced by many factors, such as the patient's oral hygiene and the ability of the bone metabolism to continuously regenerate in order to maintain adequate conditions for osseointegration; from correct insertion and positioning during the implantology phase (correct distribution of masticatory loads) to regular checks on the prosthesis's functionality.
It can be assumed that the service life (based on clinical experience with devices of this type) in use may be 10 years.
Failure in the case of implant-supported prosthetic rehabilitation can be likened 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 osseointegration 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 attempts 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 'Prosthetic Components' 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 commenced 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 dentistry as referred to in the aforementioned Ministerial Decree of 2000, provided that the specialisation course in question commenced by 31 December 1994.

The product known as "Prosthetic Components" is not intended for use by laypersons. There are no structural requirements for prosthetic dentistry that differ from those required for any other branch of dentistry.For this reason, a dedicated operating theatre is not mandatory; a dental practice with suitable aseptic conditions (where correct hygiene, disinfection and sterilisation procedures are followed) is sufficient for placement within 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 the medical device is removed from its sterile packaging immediately before use

INFORMATION ON PREPARATORY TREATMENT

It is advisable to collect and archive a complete set of 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:

- general and dental medical history, general medical examination, clinical tests (complete blood count) and radiological examinations, CT scan and consultation with the 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.

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;
- it is essential to adhere to the recommended healing times for implant surgery and to periodically monitor, including through radiographic checks, the progressive status of osseointegration.
- thermal trauma must be avoided, as this would cause necrosis and compromise the possibility of osseointegration. 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.

CLEANING / STERILISATION / STORAGE

⚠ WARNING!!! All prosthetic components for dental implants are sold in a NON-STERILE condition. Before use, all prosthetic components must be cleaned, disinfected and sterilised in accordance with the following procedure. These processes must be carried out before first use, i.e. before each use for any trial phases and, in any case, before the final prosthetic loading. Repeating the processes described in this section does not alter the characteristics of these devices. Failure to comply with these instructions may lead to cross-infection and intraoperative complications

The product known as "Prosthetic Components" is a Medical Device that may be washed with standard bactericidal solvents used for cleaning surgical instruments. It is recommended that only neutral detergents be used. The concentration and duration of the wash must comply with the instructions as specified by the manufacturer. The use of detergents with a high hypochlorite content and household bleach is not recommended.

Automated cleaning: Use an ultrasonic bath with a suitable cleaning solution. It is recommended to use only neutral detergents. The concentration and duration of the wash cycle must comply with the manufacturer's instructions. Use demineralised water to prevent the formation of stains and marks. When draining the bath, check the recesses of the devices, the holes, etc., to ensure that all residues have been completely removed. If necessary, repeat the cycle or carry out manual cleaning. After rinsing, dry the devices thoroughly and place them in suitable sterilisation pouches.

Manual cleaning: It is recommended to use only neutral detergents. The concentration and duration of the wash must comply with the manufacturer's instructions. Brush the products with soft bristles under plenty of running water. Using the brush, apply the detergent solution to all surfaces. Rinse with distilled water for at least 4 minutes. Ensure that plenty of running water flows through the holes. After rinsing, dry the devices thoroughly and place them in suitable sterilisation pouches.

Drying: If a drying cycle is carried out as part of a washing machine cycle (e.g. disinfection), do not exceed 120°C

Packaging: Suitable sterilisation pouches

Sterilisation: Temperature: 134 °C with an autoclave cycle of 3–7 minutes. The sterilisation cycle must be validated in accordance with the UNI EN ISO 17665-1 standard

Storage: After sterilisation, the product must remain in the pouches used for sterilisation. The pouches must only be opened immediately before use. Sterilisation pouches are normally capable of maintaining sterility inside them, provided the packaging is not damaged. Care must therefore be taken not to use components if the pouches in which they were stored are damaged, and to re-sterilise them in new pouches before use. The storage period for sterilised products inside the pouches must not exceed that recommended by the pouch manufacturer. Store in a cool, dry place, away from direct sunlight, water and sources of heat.

DISPOSAL

The product known as "Prosthetic Components" is a Medical Device that does not require disposal and/or deactivation. The product known as "Prosthetic Components", once removed from the oral cavity (due to biological or mechanical failure), must be treated as biological waste for disposal, in accordance with current local regulations.

INCIDENT REPORTING

Please note that public or private healthcare professionals are required to report incidents or near-misses involving Medical Devices to the manufacturer or the competent national authorities as a matter of the utmost urgency. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any deficiency in the labelling or instructions for use which, directly or indirectly, may cause or has caused the death or a serious deterioration in the health of the patient, a user or other persons.

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 insertion of the oral implant screw 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

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

The summary of safety and clinical performance can be consulted on EUDAMED (https://ec.europa.eu/Tools/eudamed), by identifying the device using its basic UDI-DI codes; until this platform is fully operational, it can be requested by sending an email toquality@leadermedica.com .

KEY TO SYMBOLS USED ON PACKAGING

Warning!	Manufacturer
Refer to instructions for use	Latex-free
Do not reuse; this is a single-use product	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	