INSTRUCTIONS FOR USE
PROSTHETIC COMPONENTS

MANUFACTURER IDENTIFICATION
The Manufacturer and Responsible for placing on the market in the EU the Medical Devices called Prosthetic Components covered by this Instructions for Use is:

Errecieffe S.r.l.
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DEVICE IDENTIFICATION
Abutments, Healing abutments, Healing caps for MUA, MULTY UNIT ABUTMENT (MUA), Titanium cylinders for MUA, Temporary abutments on implant, Temporary PEEK abutments, Ball abutments, Locator-type abutments, Premilled abutments, Ti Base abutments, UCLA abutments, Mounters for Monophasic implants or for guided surgery, Connection screws, Easy Way Bar.

Intended use:
Prosthesis components are Medical Devices intended to be used in the oral cavity.
The functions of the prosthetic components are the anchoring to dental implants for the support of dental prostheses and the reconditioning of the gums.
designed to rehabilitate patients suffering from partial or total edentulism for the restoration of masticatory, phonetic or aesthetic function.

MATERIALS
The devices are made, according to the type of component, in:
Titanium Grade5.
gold alloy
Cobalt-Chrome alloy
Polyether ketone, abbreviation DIN - PEEK of the Classic type
Polymethyl methacrylate, abbreviation DIN - PMMA

Titanium allergy is a very rare, but possible event. Therefore, it is always necessary to check beforehand with patients that they do not have allergies to this material.
It is recommended to check with patients for any allergies to the substances used.

How to use

HEALING ABUTMENTS
Remove the cover screw of the implant. Clean the implant head with saline solution, making sure that it is perfectly free from interference of bone or gum tissue. Detect the height of the soft tissues and choose the height of the healing abutments to use. Tighten the chosen healing abutments.
Recommended durability 15-30 days.
Screw tightening torque: 15Ncm

TITANIUM ABUTMENT (straight, angled) (Class IIb - made of Titanium gr.5)
It is equipped with a locking screw with which it connects to the implant and is suitable for screw-retained prostheses (bridges and single crowns). Thanks to its anti-rotation hexagonal system and its conicity, it is used to support both single crowns and bridges. It can be shortened and rectified, then modeled directly on the implant.
Locking screw tightening torque: 32Ncm

TITANIUM ABUTMENT (STANDARD TYPE)
It consists of two pieces and is mainly used in fixed total prostheses, for the manufacture of bars or when aesthetics is not the fundamental requirement for the success of the case, as the correct

maintenance of oral hygiene is privileged. It allows screw-retained fixed prostheses to be carried out even in the presence of marked divergences.
Locking screw tightening torque: 32Ncm.

ANGLED ABUTMENT
It is composed of a single piece and is used when the inserted implants have significant disparallelisms that are difficult to correct with straight abutments.
Locking screw tightening torque: 32Ncm

BALL ATTACHMENT, Locator
Suitable for anchoring Overdenture prostheses in the event that the disparallelism of the implants does not exceed 10°. It is used with the nylon retentive cap placed in the relative steel containers easily available on the market.
Tightening Torque: 32Ncm

ABUTMENT WITH GOLD or CO-CR BASE
Castable portion made of PMMA, fixing screw in 5 grade titanium, PLATINOR N) gold alloy or Cobalt Chrome base. The concept of this abutment is similar to castable cylinders. The advantage is that the connection to the implant is already preformed and does not have to be created by casting. The gold /CO-CR base is available with two versions of connection to the implant: with hexagon (non-rotating) and without hexagon (rotating). The base is connected to the castable portion by means of a cylindrical connection with a diameter of 3.5 mm. The castable portion can be entirely modified by the technician. The hexagon version is ideal for screw-retained single teeth or for the construction of abutments. The rotating version is ideal for screw-retained bridges, for substructures directly connected to implants or for overdenture bars. Locking screw tightening torque: 32Ncm

MULTI Unit Abutment (MUA) Straight and angled
The angled abutments are equipped with a fixing screw and a screw-on rod. The Multi-unit-Abutment System is designed to provide maximum versatility and to optimize the esthetic results of multiple screw-retained dentures. The low vertical height of the straights and the 17- and 30-degree angled abutments allow for appropriate prostheses even in the most challenging cases. They also offer the possibility of managing implants with a maximum angle of 45°. The clinical solution of reference (not only) is the one called "All-on-4" and it has been developed to make the most of bone available and employ immediate loading technology. Using only four implants in fully edentulous jaws, the solution take the advantage of posterior implant inclination to provide safe and optimal prosthetic support for a bridge, even with minimal bone volume.
Torque of the locking screw of the straight Mua 32Ncm
Torque of the locking screw of the 17° and 30° angled Mua15Ncm

TITANIUM TEMPORARY ABUTMENT (type M.Abutment) for EWB
It is made of a single piece and is mainly used in fixed total prosthesis and it is provided with the grade 5 titanium locking screw. It is suitable for screw-retained prostheses and has an anti-rotation hexagonal system and a conical connection. Thanks to its external thread, it is particularly suitable for the construction of titanium Easy Way bar.
Locking screw tightening torque: 32Ncm

Package features
The devices are packaged in blisters designed to maintain the suitable degree of cleanliness for correct sterilization.

CONTRAINDICATIONS
In evaluating the patient, in addition to considering the suitability for an implant-prosthetic rehabilitation, it is generally necessary to take into account the contraindications valid for dental surgery.

Absolute contraindications
The insertion of implants and implantable prostheses is contraindicated in patients with poor general health, poor or insufficient oral hygiene, impossibility or limited possibility of controlling their general conditions, or who have previously undergone organ transplants. Patients who are mentally ill, or who

abuse alcohol, tobacco or drugs, who have serious neurological diseases, severe impairment of the immune system, chemotherapy in progress must also be discarded.
In the case of administration of bisphosphonates, numerous cases of peri-implant bone necrosis have been reported in the literature, mainly in the mandible. This problem particularly affects patients undergoing intravenous treatment.

Related contraindications
Patients with poor periodontal status must be previously treated and recovered or in the presence of infections and inflammations such as: periodontitis, gingivitis. In the event of a lack of bone substance or poor quality of the recipient bone, such that the stability of the implant may be compromised, an appropriate guided tissue regeneration must be carried out beforehand. Metabolic or systemic diseases that compromise tissue regeneration. Intolerances or allergies to the material constituting the devices in question, dialysis, osteoporosis.

WARNINGS
The risks of implant surgery include: perforation of the labial or lingual plate, bone fractures, implant fractures, fractures of the superstructures, cosmetic problems, inadvertent perforation of the nasal sinus, nerve injuries, compression of the natural dentition. The following pathophysiological problems may increase the risks: cardiovascular failure, chronic disorders, arrhythmia, chronic lung or respiratory diseases, gastrointestinal diseases, hepatitis, intestinal inflammation, chronic kidney failure, urinary system disorders, endocrine disorders, diabetes, thyroid disease, hematologic problems, anemia, leukemia, coagulation problems, osteoporosis or musculoskeletal arthritis, heart attack, neurological disorders, delays paralysis.

When tightening surgical screws, healing screws, pillar screws (prosthetic screws), it is recommended to stick to the recommended tightening torque. High tightening torques can weaken the mechanical structure of the screws and compromise the prosthetic stability, with possible damage to the implant connection.
Failure to follow these instructions may compromise the accuracy of the products.
Complications can be biological (loss of integration) or mechanical (fracture of a component due to excess load). If no complications occur, the life of the devices and of the entire prosthetic apparatus depends on the mechanical resistance as a function of the fatigue accumulated by the device. Any operations to remove crowns or bridges cemented with definitive cement, which may cause the transmission of blows to the implant structures, can lead to the fracture of the same one.

USERS
The use and handling of the medical device is reserved for medical and dental personnel with the necessary professional qualification and training.

THE CHOICE OF THE DEVICE MUST BE CONSEQUENT TO AN ACCURATE PATIENT HISTORY

PREPARATORY TREATMENT INFORMATION
Pre-operative planning and preparation
The preparation phase for the intervention includes:
general medical and dental history, general medical examination, clinical (complete haematogram) and radiological examinations, CT scan and consultation with the family doctor;
information to the patient (indications, contraindications, clinical picture, expectations, normal success and failure rates, need for periodic post-check-ups.

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SURGICAL INTERVENTION
Surgical techniques for implants are taught in universities to dental graduates.

However, the following factors should be taken into account:
tissues, both hard and soft, must be treated with extreme care, taking all the necessary precautions to obtain a good integration of the implant;
the normal biological principles of osseo-integration must be respected;
thermal trauma must be avoided as they would necrotize and compromise the possibility of osseo-integration. For this purpose, adequate drilling speeds must be used, drills with a cutting edge in excellent condition, drilling must be carried out intermittently, cooling the site with the necessary irrigation and the hole must be enlarged using drills with progressively larger specific diameters;
It is essential to respect the healing times recommended in implant surgery and to periodically check, even with X-ray checks, the progressive state of bone integration.

DEVICE ACCESSORIES

Locking screw	Where provided, it is the connection screw between the prosthetic component and the dental implant
Retentive caps	Where applicable, removable denture components

Additional devices, which can be used with dental implants (covered in the relevant Technical Files), are:

Dental Implants or Fixtures	Implantable Medical Devices
Analogues	Laboratory analogue (test executions)

Specific responsibilities
Errecieffe products for oral implantology meet the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS provided for by Regulation (EU) 2017/745-MDR. Any use of the products other than the specific one is to be considered as "improper use", relieving the manufacturer of any responsibility.

INSTRUCTIONS FOR PROPER USE AND MAINTENANCE				
Automated cleaning	Use an ultrasonic bath using a suitable cleaning solution. It is recommended to use only neutral detergents. The concentration and duration of washing must comply with the instructions of the manufacturer. Use demineralized water to prevent the formation of stains and streaks. When unloading, check the devices, the holes, etc., to verify the complete removal of residues. If necessary, repeat the cycle or perform manual cleaning. After rinsing, dry the devices completely and package them in suitable sterilization containers.			
Manual cleaning	It is recommended to use only neutral detergents. The concentration and duration of washing must comply with the instructions of the manufacturer. Brush the products with soft bristles, under running water. Using the brush, apply the cleaning solution to all surfaces. Rinse with distilled water for at least 4 minutes. Make sure that plenty of running water passes through the holes. After rinsing, dry the devices completely and place them in containers suitable for sterilization.			
Drying	In case of a drying cycle as part of the cycle of a washing and disinfection equipment, do not exceed 120°C.			
Packaging	Containers suitable for sterilization			
Sterilization	Pressure	Time	Temperature	Drying
Cycle 1	1 ATM	20 minutes	121°C	20 minutes
Cycle 2	2 ATM	3 - 7 minutes	134°C	20 minutes
Preservation	Store the device in sterilized packaging until use. Keep away from sunlight and moisture.			

Additional information	This procedure has been validated by the manufacturer by an accredited third-party laboratory.

DISPOSAL PROCEDURES
Prosthetic components, if removed from the oral cavity due to biological or mechanical failure, must be assimilated for their disposal to biological waste, according to the regulations in force at local level.

IMPLANT PASSPORT
Errecieffe S.r.l. provides, together with the Medical Device, the card for the dental implant with the related information that is provided to the patients.

SUMMARY DOCUMENT ON SAFETY AND CLINICAL PERFORMANCE
See SUMMARY document at EUDAMED website

EXPECTED CLINICAL BENEFITS
The need to apply an endoosseous implant and a prosthetic component derives from precise clinical indications that have the therapeutic objective of restoring normal masticatory function and maintain health conditions, as well as aesthetic, of natural teeth.

INCIDENT REPORTING
In accordance with SECTION 2 VIGILANCE, Article 87 Reporting of serious incidents and safety corrective actions of MDR 745/2017/EU, DL 15 November 2005 and MEDDEV guideline 2.12-1, it is recalled that public or private healthcare professionals are required to report accidents or near misses with Medical Devices to the manufacturer (Errecieffe S.r.l.) or to the National Competent Authorities as a matter of urgency.
An accident is defined as any dysfunction or deterioration in the characteristics and/or performance of a device, as well as any deficiency in labelling or instructions for use which, directly or indirectly, may cause or have caused death or a serious deterioration in the state of health of the patient or a user or other persons.

FURTHER INFORMATION
This device does not contain software.
This device must be sterilized before use (the device is supplied in NON-STERILE condition).
This device is DISPOSABLE and is not intended to be reused.
This device is not intended for use by lay users.
The device is not included in the list of product groups that do not have a medical use.

LIABILITY FOR DEFECTIVE PRODUCT AND WARRANTY TERMS
Optimal patient care and attention to his needs are necessary conditions for implantological success and it is therefore necessary to carefully select the patient, inform him of the inherent risks and duties associated with the treatment and encourage him to cooperate with the dentist for the success of the treatment itself.
It is therefore necessary that the patient maintains good hygiene, confirmed during check-ups and follow-up appointments; it must always be ensured and documented as, moreover, the indications and prescriptions of the doctor before and after surgery must be observed and documented.
The instructions provided by Errecieffe S.r.l. are available at the time of treatment and accepted by dental practice; they must be observed and applied at all stages of care: from the patient's medical history to post-operative check-ups.
The warranty covers only ascertained production defects, upon shipment of the part identified by article number and batch, within the warranty period. The warranty clauses are available on the www.errecieffe.com website.

The instructions provided above have been validated by the medical device manufacturer as ABLE to prepare a medical device for re-use. The process manager is responsible for ensuring that repeated processes are actually performed using the equipment, materials and personnel in the repeated process structure to achieve the desired result. This generally requires systematic validation and monitoring of

the process. Similarly, any deviations by the process manager from the instructions provided should be properly evaluated to assess their effectiveness and potential unintended consequences.
Proper maintenance by the patient, regular home hygiene and periodic checks related to professional hygiene sessions extend the useful life of the device.
Complications such as the unscrewing of the screws that tighten the prosthesis to the implants, or bone resorption that causes the loss of mucosal support in removable prostheses can be easily prevented with regular check-ups.
If a screw-tightening of the pillar or prosthetic screws is necessary, these operations must be carried out by the doctor using appropriate devices equipped with a tightening torque control. The calibration of such devices should be checked periodically.
There are specific products on the market for cleaning medical devices, strictly observe the instructions for use.

LEGEND OF SYMBOLS USED ON PACKAGING

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Manufacturer's Name		CE marking with identification of the Notified Body
	Date of manufacture		Batch number
	Consult instructions for use		Caution! See instruction for use
	Non-sterile device		Do not use if the packaging is damaged
	Device ID - Code		The product is a Medical Device
	Unique Device Identification - alphanumeric code that uniquely identifies a medical device		Distributor

DATE AND VALIDITY OF THESE OPERATING INSTRUCTIONS
These operating instructions are valid and effective from July 2024.