INSTRUCTIONS FOR USE:
DENTAL DRILLS AND SURGICAL INSTRUMENTS FOR ORAL IMPLANTOLOGY

MANUFACTURER IDENTIFICATION

The Manufacturer and Responsible for the placing on the market in the EU of the Medical Devices called Dental Surgical Drills and Instruments subject to this surgical procedure is:

Errecieffe S.r.l.
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DEVICE IDENTIFICATION

Drills, Taps, Countersinks, Mucotomes, Stops for Drills, Drills for guided surgery, Screwdrivers and handpiece instruments.

Intended use:

The dental drills and surgical instruments are intended for the preparation of the surgical site in which the implant is inserted, allow the extraction of the implant from the package, the transfer to the patient's mouth and the insertion of the implant itself. They also allow the correct positioning and insertion of the prosthetic components on the implant.

MATERIALS

The devices are made of 17 4PH stainless steel (AISI 630). They are subjected to a hardening heat treatment up to the H900 condition. They may have a DLC coating.
Maximum number of device usage: 20

How to use

Drills, taps and extensions must be used with the help of a handpiece (micromotor) the recommended working speed is 500 rpm maximum, except for taps and handpiece screwdrivers where the speed must be set to the minimum available of the handpiece or in any case not higher than 30 rpm.

Package features

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

WARNINGS

Failure to comply with the surgical protocol that establishes diameters, lengths and sequence can cause serious damage to the patient, especially if longer drills are used.
Check that the drills to be used are in good condition, that they have not exceeded 20 uses and that they have been cleaned and sterilized.
Before use, check that the handpiece secures the drills perfectly and that the direction of rotation is correct.
Ensure that irrigation is adequate; Abundant irrigation with sterile solution is necessary during drilling to avoid damage to bone tissue, resulting in bone necrosis.
Do not exceed the maximum RPM/min indicated on the label.
The application of lever forces during drilling could cause the drill or handpiece breakage; during drilling always apply alternating pressure, using intermittent drilling technique.
Always check that the laser marking indicating diameter and length is clearly visible.
The possible eccentricity or non-straightness of the drill could cause an oversize of the hole.
Always wear gloves when handling contaminated tools and eye protection.

Excessive torque can strip the tightening screws and/or ruin the corners of the screwdrivers, causing serious surgical or prosthetic complications.

Torque recommended for the correct use of Errecieffe DMs	
Closing screws, healing abutments, angled MUA screws	15 Ncm
Prosthetic screws	25 - 32 Ncm
Dental Implants	35 - 50 Ncm

Avoid lever movements because they increase the risk of fracture. Before screwing, make sure that you have inserted the tip of the screwdrivers firmly into the screws. Incorrect insertion can lead to the screwdriver or screw being rounded off.
It is recommended to replace the screwdrivers periodically to reduce the risks related to wear.

We recommend the use of the extension with Errecieffe drills.
All instruments must be cleaned (ultrasonic equipment is recommended) and sterilized before use, following the manufacturer's instructions for steam sterilizer.
Cleaning and sterilization must be carried out only with specific materials, in particular for cleaning is better to avoid detergents that contain:
Oxalic acid and chlorine at high concentration.
Insert the instruments into the disinfectant solution immediately after surgery and leave them for a few hours in order to avoid the formation of blood, secretions, etc.
Do not store wet or damp tools.
Do not sterilize, cleanse or disinfect instruments made of different metals in the same cycle.

For sharp instruments, steam sterilization in an autoclave is particularly recommended in order to avoid to deteriorate the sharpness of the cutting parts.

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

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

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				
WARNINGS	Dental surgical drills and instruments require special attention during cleaning so as not to damage the sharpness. Drills with internal irrigation require special care during cleaning.			
Limitation to repeated processes	Life is generally determined by wear and tear and damage due to use; Improper maintenance can affect the functionality of the device.			
Site of use	The devices provided must be cleaned and sterilized before each use.			
Containers and transport	The containers used for transport guarantee the degree of cleanliness suitable for proper sterilization but are not suitable for it. If cleaning and sterilization processes are carried out outside the facility, it is recommended to reuse the aforementioned containers so as not to damage the devices during transport.			
Manual cleaning	Remove bone/blood residues with a soft brush when using. Check that the irrigation holes are not blocked and if necessary clear them with a small needle.			
Disinfection	BIOSAN UNO disinfectant solution may be used for no more than 3 minutes (as specified by the manufacturer), or Henry Schein General Cleaner or equivalent product for cleaning dental surgical instruments			
Preparing for cleaning	All devices with moving parts must be disassembled. It is recommended to carry out preliminary cleaning and decontamination with ultrasonic equipment with a minimum of 20 minutes at a temperature not exceeding 70°, using a detergent suitable for cleaning stainless steel medical equipment.			
Automated cleaning	Carry out the washing cycle with a thermo-disinfectant washer respecting the times indicated by the manufacturer and making sure that the instruments are loaded without shaded areas (no overlapping).			
Drying	Not necessary (possibly with compressed air gun).			
Maintenance	Check that the cutter cutting edge is suitable for new use and if not, discard the device.			
Inspection and function tests	Check the cutting edge of the device for damage and signs of wear. The sharp sides must be even and not chipped. Check that any internal irrigation hole (with its outlet holes) is not clogged with any residues. Check that the assembly systems are still suitable.			
Packaging	Individually: A reference packaging material can be used. Make sure that the packaging is strong enough so that it will not be damaged by the sharp part of the device. In groups: Instruments can be loaded onto trays provided for instruments, or on general-purpose sterilization trays, without storing instruments of different materials. Make sure that the sharp parts are protected. Wrap the trays using the appropriate method.			
Sterilization	Pressure	Time	Temperature	Drying
Cycle	2 ATM	3 - 7 minutes	134°C	20 minutes
Preservation	In a clean and dry place.			
Additional information	For sterilization in a single cycle, check that you have not exceeded the maximum sterilizer load.			
Manufacturer's contact	See the brochure for the telephone number and address of the local representative.			

DISPOSAL PROCEDURES

Dental surgical drills and instruments must be assimilated to biological waste for their disposal, according to the regulations in force at local level.

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 intended for re-use.
This device is not intended for use by lay users.
The device is not listed as a product that does 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 have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for reuse. It is the responsibility of the process manager to ensure 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 the validation and systematic monitoring of the equipment used.
Incorrect or insufficient maintenance can damage the instruments in a short time.
There are specific products on the market for cleaning tools, 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.