INSTRUCTIONS FOR USE, CLEANING AND MAINTENANCE OF THE REUSABLE INSTRUMENTAL

Reusable instruments are those that are intended to maintain a direct relationship with implantable products during their use and / or placement (not remaining over time): screwdrivers, implant placement keys, parallelisers, fixation pins and stabilizers, circular scalpels, thread starters, ratchets, etc. (CE) and surgical dental drills (CE0051).

The products classified as Reusable Instruments and Dental Drills are supplied **NON-Sterile**. A cleaning, disinfection and sterilization must be carried out before use. For it, it is necessary remove them from the packaging before.

For **cleaning and disinfection** of reusable instruments and dental drills, it is recommended to use a nylon brush to remove adhered residues under running water, rotating the instruments continuously. After that, place the instruments in an appropriate container and immerse in the bath, preferably ultrasound, filled with a cleaning and disinfection solution suitable for rotating instruments and reusable instruments with proven efficacy. The concentration and the immersion time will be indicated by the manufacturer and should never be less than the recommended. The indicated immersion time does not start until the last instrument is immersed in the bath. Do not exceed the temperature of 45 ° C (risk of protein coagulation). It is recommended to pay special attention to avoid damage to the active part due to blows between them. Once the immersion time is over, rinse the instrument preferably with demineralized water. Dry the instruments preferably with compressed air and perform a visual control of their perfect condition and cleanliness. If not, repeat until you get it. Do not store wet or damp instruments.

Subsequently, a steam **sterilization** (according to ISO 17664 standard) is recommended by autoclaving 134ºC at 1 atm. pressure for 20-30 min. The steam must be free of particles to avoid stains and corrosion on the instruments. Always observe the instructions of the equipment manufacturers. For sterilization of the instrument, an appropriate packaging must be chosen, with a sufficient size to ensure that the seal is not under stress and the sterilization packaging must be placed in a suitable position in the autoclave. Instruments with limited reuse should be marked. Check instruments with signs of deterioration as these can contaminate the rest of the instruments during the sterilization process. Avoid cleaning, disinfection and sterilization in the same cycle instruments made of different material.

DENTAL DRILS

The intended purpose of use of this product is to be intended to perform the function of a surgical instrument that pierce the mandibular and/or maxillary bone, leaving the socket ready for the placement of the dental implant in patients ready to receive this treatment.

Any mayor incident related to this products has to be reported to the manufacturer and to the competent authority of the country which the patient and/or user is established.

Eckermann dental drills are available in various diameters. They present in the upper part the cutting ø of the drill marked with laser and also they are identified with a colour code on the lower part of the shank. The drills are made of surgical stainless steel.

RECOMMENDED MILLING SEQUENCES:

- ⚠ **These procedures recommended by Eckermann do not replace the judgment and professional experience of the dentist and / or surgeon.**

In all drilling processes, it shall be checked that there is abundant irrigation, and the good condition of the cutting edge of the drills.

To avoid overheating of the bone and to facilitate its cooling, drilling will be carried out making in and out vertical movements of the drill in the socket to be shaped.

In the case of guided surgeries, a **double irrigation** is recommended to avoid overheating of the bone.

A. NON-GUIDED SURGERY:

1. For All-Spiral, Triplo / Triplo Perio, Internal Hexagon (Winner), External Hexagon, Slim Narrow implants. (FLM / FSH drills)

The cutting area is marked with the different lengths according to the different intraoss lengths of the Eckermann implants.

Eckermann nomenclature	Colour	Total external diameter
ø 2	Purple	2,2 mm.
ø 2,5	Red	2,7 mm.
ø 3	Blue	3,2 mm.
ø 3,5	Green	3,7 mm.
ø 4	Black	4,2 mm.
ø 4,5	White	4,7 mm.
ø 5	Yellow	5,2 mm.

After the bone has been exposed, the drilling sequence is started with the ø 2 lanceolate drill, marking the location and direction. Deepen to the chosen intraosseous length (equal to or greater than the length of the implant to be placed). RPM: between 1.000 to 1.200 rpm.

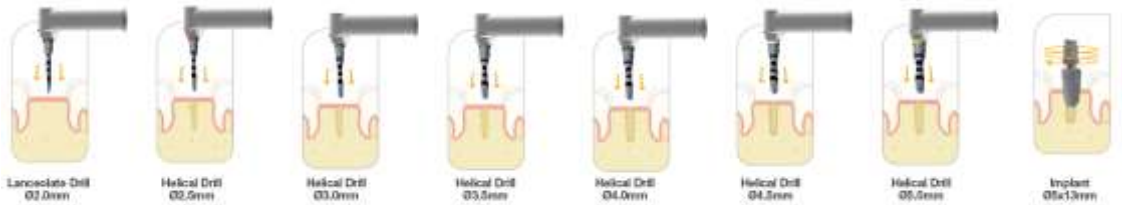
Drilled with the ø 2.5 pilot drill to the chosen depth. Allows you to modify the direction of the socket to suit the programmed insertion axis. RPM: between 1.000 to 1.200 rpm.

The different diameters of the drills are passed until reaching that of the chosen implant. Each and every one of the drills used will be deepened until reaching at least the burial length of the implant. RPM: between 400 and 600 rpm.

Eckermann provides drilling stops that make the depth to be the chosen one. These tools prevent reaching greater depths and avoid involuntary contact with the anatomical structures of the jaws.

The use of thread starters is recommended in high-density bone situations after drilling, always at the discretion of the clinician.

For bone regularization, Eckermann recommends the use of the ball drill (FBE 5). If the bone is of high density, after the surgical bed has been made, the countersink drill (FAE) can be used always under clinical criteria.



Example sequence for Triplo IKT implant 355013

2. For IHC (Easylink) implants:

After uncovering the bone, the drilling sequence is started with the ø 2 initial drill, marking the location and direction (FI00002018).

The different diameters of the conical drills (FC) are passed in increasing order, until the chosen implant diameter is reached. Each and every one of the drills used will be deepened until at least the implant burial depth is reached. RPM: between 300 and 400 rpm. In high-density bones it is advisable to slow down and increase irrigation.

FC00003511

FC00004511

For bone regularization, Eckermann recommends the use of a ball drill. If the bone is of high density, after completing the surgical bed, a countersink drill can be used, always under clinical criterion. Recommended engine speed of 500 rpm.

Sequence example for IHC 274513 implant with NON-guided surgery.

B. GUIDED SURGERIES:

Eckermann Guided Surgery users are recommended to take prior training on clinical protocols for guided surgery: radiological protocols, protocols for making surgical splints, stabilizers, etc.

If it is necessary to stabilize the surgical splint (mucosa-supported), the FI00002019 drill will be used to place the fixation pins, inserting it along its entire length (19mmm) with a speed of revolutions of 600 and 800 rpm.

1. For All-Spiral, Triplo / Triplo Perio, Internal Hexagon (Winner), External Hexagon, Slim Narrow implants.

Drills corresponding to the size of the sleeve used in the guided surgery splint must be used.

In case of opting for transmucosal surgery, we will use circular scalpels previously. As a first step, it is recommended the use of a countersink drill (FA510946 – FA430936) at a recommended speed of 400-500 rpm. After this, the 6.5 mm starting drill corresponding to the sleeve (5.1/4.3) will be used at about 500 rpm, followed by the initial drill corresponding with the implant length to be placed.

On the next step, will be passed in ascending (always according to the chosen sleeve group) order the different diameters of the tapered 6.5 mm drills until the diameter of the chosen implant is reached. Ones the implant diameter to be placed is reached, deepen with a tapered drill according to the length of the implant chosen to be placed. The drills used will be deepened until reaching at least the burial length of the implant. Revolutions between 400-500 rpm.

For D3/D4 type of bone is recommended to use as a final drill a tapered drill smaller diameter than the diameter of the implant chosen to be placed (always according to the chosen sleeve group 5.1/4.3)

2. For type IHC (Easylink) implants:

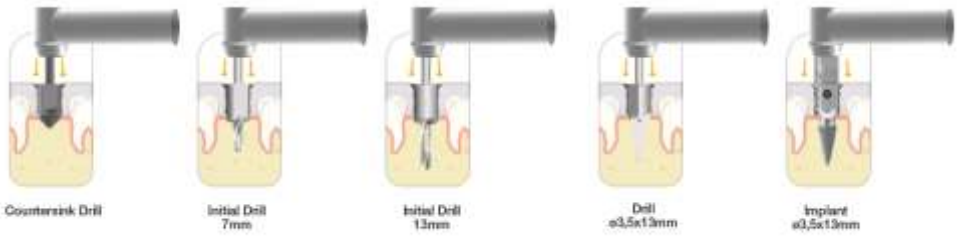
Whenever the bone needs to be regularized, the FA600960 Countersink Drill will be used. Recommended speed of 400 - 500 rpm.

- Start drill FI60092307: Recommended speed of 500 rpm.

- Initial Drill FI600923XX: Ø2.3 intermediate initial drills. The one corresponding to the length of the implant to be placed * will be used. Recommended engine speed of 500 rpm.

⚠ * *Warning: For 15 mm long implants, it will be necessary to pass an intermediate start drill (11mm FI50092311) before reaming directly with the 15mm, to ensure that the reamer is correctly guided through the surgical guide.*

- Conical drills: They will be used progressively in diameter (ø 3.5 –ø 4.5) and those of the length of the implant to be placed at the recommended speed between 300 - 400 rpm.
  FC-600935XX
  FC-600945XX
  For bones type D3-D4 it is recommended to use the 7 mm long conical drill.



Sequence example for IHC 273513 implant with guided surgery.

Planning and technique

The use of the Eckermann implant system requires on the part of the professional a prior planning and knowledge of the techniques necessary to carry out the interventions and the subsequent treatments and / or revisions that are carried out.

As an indication, prior planning should include, as a minimum:

- The general medical history.

• Complete pre-surgical and prosthetic planning.
• Information to the patient on all aspects of the treatment plan and its development, in particular about strict compliance with the doctor's instructions and in particular the need to carry out correct oral hygiene.

The technique necessary for the use, installation or implantation of this type of product requires from the doctor or professional, at least:

• Ensure that any intervention is carried out in the appropriate clinical environment and with the equipment, personnel and instruments corresponding to the chosen system.
• Maintain careful manipulation of the tissues in order to establish the optimal and necessary conditions for their correct healing around the implant.

⚠ In order to carry out the guided surgery techniques, it is necessary for the clinician to know the clinical protocols for guided surgery recommended by Eckermann, and to have the surgical splints made using 3D simulation for each patient.

GENERAL INFORMATION

Warnings

The use of these Eckermann products is authorized solely and exclusively by duly authorized professionals. (eg: dentists, stomatologists and oral or maxillofacial surgeons) duly instructed in the use of implant systems.

- Do not use any product whose recommended use deadline has been exceeded.
- Do not use products or devices that are not included in the implant system itself, or not recommended by Eckermann.
- Neither should any product that shows any type of deformation or mechanical damage, or whose packaging shows signs of deterioration or manipulation, should be used.
- A prior implant treatment planning must be carried out to detect the quality and quantity of the bone, nearby anatomical structure etc.
- The correct connection between the drills and the working contra-angle must be ensured to avoid vibrations and malfunction. Carry out maintenance according to the contra-angle manufacturer.

Eckermann recommends a maximum of 15 milling cycles to guarantee cutting quality. On some of the dental drill models the longitudinal marks becomes less visible with the use, therefore it is recommended its change. In general, during the intraoral use of these devices, the necessary measures must be taken to avoid their aspiration.

Recommendations:

- Do not use cutting instruments beyond the recommended cycles.
- Use only autoclaves that meet the requirements in EN 13060, EN 285.
- Use validated sterilization procedures according to ISO 17665.

Composition

All the products referenced here (container boxes, instruments, reusable products, dental drills, etc.), manufactured by Eckermann are made of titanium, stainless steels, and / or plastics that meet the international standards established for the manufacture of medical devices.

Contraindications

As general contraindications, the same as for the placement of implants will be attended and in particular it is not advisable to perform it when:

The patient has an allergy to titanium and / or surgical steel. The patient has a null hygienic predisposition.

Storage and maintenance:

Before use, it is recommended to store the product in a dry place in its original container. Keep in a dry place once cleaned and sterilized. Follow the manufacturer's instructions for the sterilization pouch used regarding the storage conditions and expiration date of the sterilized device.

Waste disposal

For a proper disposal of the devices, it must whereas the local regulation and the environment requirements according to the different contamination levels.

SYMBOLOGY:

CE marking 0051

CE marking

Consult instructions for use

Product Reference Code

Lot Code

Not sterile

Manufacture

Manufacturing date. (Followed by year and month: YYYY / MM)

Medical Device

Identification of the UDI code.

Do not use if package is damaged.

Maintain dry

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