

INSTRUCTIONS FOR USE

INTRAOSSIOUS IMPLANT

1. MATERIALS

IMPLANTS AND CAP SCREWS:

Titanium grade 5-Ti 6 AL 4V-ELI, as per directive ASTM F 136

Titanium grade 4, as per directive ASTM F 67

RECOVERY SCREWS, TRANSMUCOUS ABUTMENTS, MILLABLE ABUTMENTS, ANGLED ABUTMENTS, SPHERICAL ABUTMENTS:

Titanium grade 5-Ti 6 AL 4V-ELI, as per directive ASTM F 136

Titanium grade 4, as per directive ASTM F 67

SCREWS FOR ABUTMENTS:

Titanium grade 5-Ti 6 AL 4V-ELI, as per directive ASTM F 136

2. WRAP AND STERILITY

The F.M.D. s.r.l. implants are sterilized by dry heat sterilization. The implants are first sand blasted, etching and decontaminated. The package of the F.M.D. s.r.l. implants is made up of an external box with a proper label (to be attached to the patient's file so as to ensure the product traceability since the label reports the lot number of the implant.) Inside the package: blister with a glass phial containing the sterile implant. The package has to be unsealed only when the implant is being inserted. Never use the implant after the expiry date. Implants must not be re-sterilized. The remaining products are delivered in a blister or in a plastic box or in envelopes properly sealed. All devices of the F.M.D. s.r.l. system, with the exception of the implants and in some cases the cap screws, are not supplied sterile and must be sterilized before use. On the label is shown the status of the device (sterile/not sterile).

3. CHARACTERISTICS

The dental implants can be used in the upper or lower jaw to recover the mastication function. They are delivered in various lengths and diameters so as to be adapted to the different situations of the osseous tissue where they have to be implanted. For more information on the surgical procedure please consult the relative bibliography. Implant surgery is a complex and highly-specialized procedure. It requires a specialized expertise of the operator. The F.M.D. s.r.l. implants must not be used in places and situations different from those specifically indicated. The F.M.D. s.r.l. implants must be used uniquely with the surgical instruments supplied by the company itself. The sterile gloves to be used during surgery must be powder-free.

4. CONTRA-INDICATIONS

- Titanium-allergy (we suggest to perform a test before surgery).
- Osseous deficiency.
- Excessive occlusive para-function.
- Diabetes (verify the level).
- Uncontrolled blood dyscrasias.
- Pregnancy.

- Systemic diseases.
- Endocrinological diseases.
- Acute or chronic infective diseases.
- Epilepsy.
- Bad generic medical conditions of patient.
- Previous osseous radiations.
- Treatment with anti-coagulants.
- Patients with steroids treatment.
- Chronic sub-acute maxillary osteitis.
- Secondary osteoporosis.
- Valvular prosthesis.
- Patients with bad oral hygiene.
- Alcoholism.
- Drug addiction.
- Excessive use of tobacco.
- Patients with aversion to dental implants.
- The application on children, disabled and old persons is not recommended.

Attention: the device is intended for single use and if reused by mistake it could cause heavy infections with the loss of the implant and possible bone necrosis.

IMPORTANT:

A good initial stability immediately after the placement of the implant is an indispensable requirement for the final success.

5. INTERVENTION

During the intervention it is mandatory to ensure a proper level of hygiene and the use of proper tools. The area needs to be anesthetized, leave the osseous crests at sight (the incisions with bistouries shall be made according to the techniques of the surgeon). Then the surgeon performs the perforation by using a well-sharpened drill and abundant irrigation, exerting a slight pressure with sharp cutting instruments. Drilling shall always be performed intermittently. Continue with the final drills following the proper sequences with the increasing diameters. It will be necessary to use depth gauges in order to obtain the desired depth. All drills are also available with a depth-stop preset which, together with the above depth gauges, allows establishment in advance of the depth of the perforation very precisely, so as to avoid damaging the maxillary sinus or the alveolar nerve. Once completed, the perforations, according to the diameter or the required length, place the implants up to their largest diameter (submerged technique) or up to exactly 1.5 mm below their largest diameter (semi-submerged technique). Place the cap screw on the top of the implant. The suture shall be performed according to the technique followed, ensuring a good implant placement and without tensions. After a period between 6-10 days the suture can be removed. After a period between 14-22 days the surgeon can control the evolution of the implant and of the soft tissues. Once elapsed the recovery periods, it is possible to proceed with the reconstruction of the prosthesis (for the technique to be used, consult the prosthesis manual). A proper patient's motivation represents an essential element for the success of the procedure.

IMPORTANT:

A defective cutting of the surgical drill could overheat the bones, thus highly influencing its recovery. For this very reason we strongly suggest not to use the drill for a higher number of cases than recommended in the manual of the surgical procedure.

6. PROBLEMS DURING SURGERY

Some problems/complications can happen after the surgical insertion of the implants: ecchimosys, hemorrhage, hematoma, soft tissues dehiscence, delayed healing, inflammation, infection, paraesthesia, hyperaesthesia, anaesthesia, chronic pain due to the implant, maxillary sinus perforation, damage of anatomical structures (bundles of nerves and vessels), alveolar atrophy on upper or lower jaw, oroantral or oronasal fistula, damage of contiguous teeth, bone fractures, breaking of the implant or instruments. Late problems can occur in case of prosthetic overload, like fracture of the prosthetic superstructure, implant fracture, prosthetic screw loosening and loss of integration. Aesthetic imperfections and peri-implantitis represent possible complications.

7. STORAGE

Store so as to avoid packaging damage. Keep dry. Store at room temperature in a dry place. Single use. Expiry date is only referred to the product in the closed packaging. Do not use the device if the packaging is damaged.

8. PRECAUTIONS

Patients shall be subjected to a complete check in order to achieve an adequate diagnostic, clinical and radiological evaluation to detect all anatomic reference points, occlusion conditions, possible periodontitis and the status of the bone. It is suggested to carry out a lateral cephalometric radiograph and the computed tomography.

During the surgical preparation of the implant area, be careful in the bone milling phase in order to avoid bone overheating. The speed and irrigation of the drill are basically significant.

9. WARNINGS

Even though detailed information is important, it is insufficient to properly implant.

It is vital that the personnel be competent and properly instructed by the manufacturer, so as to be always updated both on the technique and on its applications. Never use the product if its package is damaged or opened. The FMD s.r.l. implants must be employed only by medical doctors specialized in dental surgery and properly trained to use these products.

FMD S.R.L. INSTRUCTIONS: in case of hard bone, after a few turns remove the implant moulder and continue with the implant driver, in order to avoid damaging the implant and the implant moulder, both the passing screw and the pick-up moulder.

IMPORTANT NOTICE

1. THE DOCTOR SHOULD INFORM THE PATIENT ON THE IMPORTANCE OF PROPER HYGIENE, CLEANING AND MAINTENANCE OF THE PROTESYS.
2. THE STERILITY IS GUARANTEED ONLY IF THE PACKING IS INTACT.
3. THE USE OF THE PRODUCT IS STRICTLY RESERVED TO MEDICAL DOCTOR ODONTOLOGISTS.
4. IN CASE THE PRODUCT IS TAMPERED, IN ANY WAY FMD S.R.L. DECLINES ANY RESPONSIBILITY.
5. FMD S.R.L. DECLINES ANY RESPONSIBILITY DERIVING FROM AN UNPROPER OR WRONG USE OF THEIR PRODUCTS OR FROM INCAPACITY OR NEGLIGENCE FROM SIDE OF THE USER AND/OR THE PATIENT.
6. FMD S.R.L. DECLINES ANY RESPONSIBILITY DERIVING FROM UTILIZATION OF THEIR OWN DEVICES TOGETHER WITH OTHER ONES NOT MANUFACTURED BY FMD S.R.L.
7. DISPOSABLE PRODUCT DO NOT USE IF THE EXTERNAL BOX OR THE INTERNAL PACKAGE ARE OPEN OR DAMAGED.
8. WHEN NOT PROVIDED STERILE, IT IS STRONGLY RECOMMENDED TO STERILIZE THE SCREW TAP FOR 15 MINUTES AT 121 °C.



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