INSTRUCTION FOR USE METE'

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Contents

The aim of the METE' implant system is to replace one or more missing teeth from a functional point of view.
The instructions relate to the following components:

- Endosseous implant: sterile, class IIb device in Ti gr.4; gr.2;
- Transmucosus neck: sterile, class IIb device in Peek;
- Mini-implant for overdenture: sterile, class IIb device in Ti gr.5;
- Cover screw: sterile, class IIa device in Ti gr.5;
- Healing cap: non sterile, class IIa device in Ti gr.5;
- Healing screw: non sterile, class IIa device in Ti gr.5 or PeeK;
- Connecting screw:: non sterile, class IIa device in Ti gr.5;
- Solid abutment: non sterile, class IIb device in Ti gr.5;
- Straight abutment with through-screw: non sterile, class IIb device in Ti gr.5;
- Angled abutment with through-screw: non sterile, class IIb device in Ti gr.5;
- Cementable (straight or angled) abutment: non sterile, class IIb device in Ti gr.5;
- Millable abutment for overfusion: non sterile, class IIb device in Ti gr.5;
- Straight or angled abutment, spherical or for cementing: non sterile, class IIb device in Ti gr.5;
- Abutment for cementing: non sterile, class IIb device in Cr-Co-Mo alloy;
- Prosthesis bracket (spherical, conical hexagonal): non sterile, class IIb device in Ti gr.5;
- T-base: non sterile, class IIb device in Ti gr.5;

Lifetime of the device

The expected lifetime of the device is normally 10 years.
If the used implants are smaller than what is normally required for the implant site, the patient should be advised that such implants are not within the surgical protocol and that their lifetime could be less than the standard one.
The lifetime of the implants depends on their maintenance by the the patient who should be accurately informed with regard to the procedures to follow. The doctor should carry our regular, scheduled control visits with the patient in order to conduct the required maintenance and controls.
To be used by qualified medical staff who know how to use the device.

General risks

The product is aimed at suitably qualified medical professionals.
Before using a component, the user must check both its mechanical integrity and the integrity of its packaging and, where applicable, its sterility.
In case of any doubt regarding the use of the product, consult local representative or the manufacturer. The manufacturer cannot be held responsible in case any changes are made to the device without its approval.

General absolute contraindications

- Serious congenital or acquired mental or nervous illnesses, making therapy and prognosis difficult or impossible.
- Recurrent of chronic nervous diseases in which the patient's relationship with reality becomes fragile and there is a possibility that the patient's relationship with the endosseous implant is compromised.
- Severe, malignant tumours.
- Serious diseases of the following: - *Bone – Connective tissue – Heart – Blood and Haematopoietic system – Endocrine system – Kidneys - Liver – Nervous system*.

General contraindications

- Pregnancy or postpartum period: you must wait until the end of the pregnancy and breastfeeding period.
- In the event of osteoporosis, you must perform further analysis (acid and alkaline phosphatase blood levels).
- In case of less serious heart diseases, you must establish the seriousness of the disease by consulting the Cardiologist. You then need to establish which, if any, anticoagulants are taken and – in the event of multiple implants and always on the basis of the Cardiologist's advice – whether the treatment may possibly be postponed to bring coagulation levels to at least 70%. You must plan for appropriate antibiotic coverage. Alternatively, you may proceed to apply a single implant per operation, in order to reduce blood loss, also by using a suture around the neck of the implant for haemostatic purposes.
- Acute articular rheumatism (AAR): operations are carried out following the prophylaxis (antibiotic) prescribed by the patient's physician.
- Allergic diatheses: you must check for a possible allergy to Ti Gr. 2, Ti Gr. 4, Ti Gr. 5.
- Essential trigeminal neuralgia: you must establish the severity of the syndrome: bearing in mind that the implant could be a "trigger"; if you decide to carry out the operation following the prior authorization of the Neurologist, the patient must be placed under therapy with Carbamazepine (Tegretol) starting from ten days prior the operation and must continue the therapy up to 20 days after the operation.
- Changes in motility due to anxiety, clenching and grinding: you must comply with the notion of limiting stress. The use of porcelain as a material for prosthetic reconstruction is absolutely contraindicated.

Local absolute contraindications

- Untreatable bone defects and lack of bone

local relative contraindications

- Anatomical defect, correctable through plastic surgery.
- Acute or chronic local inflammation of soft tissues (periodontal disease).
- Local, acute or chronic inflammatory status of the bone.
- Presence of root residue at the intervention site.
- Presence of impacted teeth at the intervention site.
- Previous tooth extaction less than 30-60 days before

Instructions

1. Keep implants stored in their original package in a dry place at room temperature. Do not use implants after the expiry date indicated on the package. Do no use implants if their package has been damaged or tampered with. IT IS NOT POSSIBLE TO RE-STERILIZE IMPLANTS WITH DAMAGED PACKAGING.
2. Dental implants are SINGLE-USE. Never re-use the same implant.
   Dental implants are supplied sterile. Re-using the same dental implant leads to LOSS OF STERILITY. If the dental implant is re-used on the same patient, there is an associated risk of implant failure due to local infection. If a dental implant is re-used on another patient, there is an associated risk of cross-infection.
3. The patient should be informed about the importance of hygiene and should be instructed regarding the maintenance and cleaning of implants.
4. Users of dental implants in Titanium should not use toothpaste or mouthwash containing free fluoride.
5. In the event that radiation therapy to the head and neck is required, metal prostheses should be removed from the mouth.
6. In the event of sudden pain or complications, advise the patient to immediately consult their doctor, surgeon or dentist.
7. The success index relating to implantation and maintenance of dental implants is very high, but a risk of failure cannot be entirely excluded, the causes of which may not be easily identified. There are specific possible causes, such as: lack of available bone tissue, small amount of residual bone, unsuitable surgical technique, infection and poor oral hygiene of the patient. Further complications may occur, such as: chronic pain, permanent anaesthesia, upper or lower alveolar ridge bone loss, oroantral or oronasal

fistulas, contiguous or antagonist teeth subject to unfavourable load (with possible irreversible damage), bone fractures, implant fracture, fracture of the overdenture, aesthetic issues.

8. The torque applied to the connection screw should not be greater than 15 Ncm (except for STR components).
9. Specific instructions for implants and prosthetic components of the STR line:
   - Secondary components (screwed solid abutment or connecting screws) should be tightened at 35 Ncm torque, which is necessary to enable the proper activation of cone metric coupling.
10. Specific instructions for implants and prosthetic components:
    - Use of implants with diameter 2.5 mm - 3.0 mm is restricted for incisors. Their use is not indicated for and premolar and molar teeth.
    - Use of implants with diameter of either 3.2 or 3.3 mm is indicated for incisors and premolars. Their use is not recommended for molar teeth.

Key to symbols

Warning, please read enclosed documents

Single-use device

Lot number

Device sterilized by ionizing radiation

NON STERILE **non sterile device**

Use by date XXXX – MM (Year – Month)

Do not re-sterilise

Do not use if packaging is damaged

Manufacturer

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