INSTRUCTIONS FOR USE

SELF-TAPPING OSTEOSYNTHESIS SCREWS

Please carefully read the instructions below to guarantee the correct use of the product with complete safety.

In compliance with Directive 93/42/EEC and the later modification to Directive 2007/47/EEC, the required information is provided for efficient and safe use of emexact® manufactured products.

DESCRIPTION

- The bone fixation screws system, manufactured by emexact®, designed for the fixation of monocortical bone grafts. They are of universal use and their designenables easy and safe fixation to the surrounding bone.
- emexact® products are designed to be used by qualified health professionals (Doctors and Dentists). The safety and efficiency of products supplied by emexact®, is only guaranteed when used by suitably trained professionals.
- The Screws are manufactured in specific Stainless Steel, for medical applications, in compliance with Standard ISO 5832-1: Implants for surgery - Metal Materials, which by their nature, avoid osseointegration. They can be extracted once the bone fixation stage has been completed.
- The fixation systems are designed for single use, unlike the multi-use accessory instruments required.
- Fixation screws are easily stored in the container provided. They should be carefully extracted and placed using appropriate instruments.

STORAGE AND HANDLING

- All products manufactured by emexact®, should be stored at temperatures of between 15-25ºC and a humidity of between 50-60%. Products should be protected from direct sunlight and any artificial ultraviolet light. They should be protected against acids and bases. The product comes perfectly packaged and heat-sealed. Any default in this packaging could lead to a loss of decontamination and disinfection properties, hence it is recommended not to be used.
- Under no circumstances should material be extracted from the original packaging and handled without being used.
- emexact® products, are not sterile. It is therefore recommended to sterilize products before use, following the methods indicated in the corresponding section.

CONTRAINDICATIONS

- The use of products is contraindicated in patients with conditions that rule out surgery to place dental implants.
- Infections or suspected infections in the site of the graft or surrounding area.
- Known allergies and/or hypersensitivity to materials used.
- Insufficient or deficient bone substance to enable safe anchorage of the graft.
- Patients with limited cooperation capacity or willingness during treatment.
- Treatment is not advisable in risk groups.

RISKS ARISING DURING THE USE OF THE PRODUCT

- There is a risk of inhalation or ingestion of products, when they are used intraorally. Therefore, appropriate measures should be taken to avoid this.
- In the majority of cases, possible complications are caused by clinical reasons and not by the product itself. These complications include the following: Loosening of screws owing to insufficient fixation, hypersensitivity to metals or allergic reactions, necrosis of bone, osteoporosis, insufficient revascularization, bone resorption and deficient bone formation, which may be caused by premature loosening of the graft, irritation of soft tissue, and/or nerve damage owing to surgical trauma, premature infection and superficial and deep delay, increased fibrous tissue reaction around the surgical field. There may also be complications during the removal of the screws, owing to insufficient preparation of the graft site.

STERLIZATION METHODS

- emexact® products are non-sterile, hence it is recommended to follow the wet, heat sterilization method (autoclave). The product should first be extracted from the packaging and inserted into a bag suitable for autoclave sterilization, to then continue with the method described below.

- This is the most commonly used method in dental clinics and laboratories. Sterilization occurs through a physical agent, damp heat, which causes denaturation, and coagulation of proteins. These effects are mainly due to two reasons:

- The water steam has a heat transfer coefficient much higher than air. Therefore, damp materials conduct heat much quicker that dry materials, owing to the energy released during condensation.

- The autoclave is the most widely used apparatus for temperatures over 100°C. A temperature of 121°C (overpressure atmosphere), with an exposure time over 15 minutes, following the recommendations of the autoclave manufacturer, is used to destroy spore-forming organisms.

Pressure [atm]	Temperature [°C]			
	Complete discharge of air	2/3 discharge of air	1/2 discharge of air	Without discharge of air
1/3	109	100	90	72
2/3	115	109	100	90
1	121	115	109	100
4/3	126	121	115	109
5/3	130	126	121	115
2	133	130	126	121

Influence of incomplete discharge of air at the temperature of the autoclave

Advantages

- Quick heating and penetration
- Quick destruction of bacteria and spores
- Leaves no toxic residues
- Low deterioration of exposed material
- Economical

Disadvantages

- Solutions which form emulsions with water cannot be sterilized
- Corrosive on certain metal instruments

SYMBOLOGY AND DESCRIPTION

Symbol	Description
	Date of manufacture
	Date of Expiry
	Single use. Do not reuse
	Batch Number
	Product reference
	Attention! See instructions for use
	Details of the manufacture
	Non-sterile product
CE 0000	MDD CE marking, including the identification number of the Notified Body which granted approval

PRECAUTION

- emexact® products are intended for use by qualified health professionals (Doctors and Dentists). Safety and efficiency of supplied emexact® products, both screws, abutments and other surgical and prosthetic dental accessories are only guaranteed when they are used by qualified professionals.
- Qualified health professionals (Doctors and Dentists) are recommended to regularly check for possible changes in the functioning of the product every 6 months.
- emexact® products are for single use before the expiry date, as indicated on the label. If the product is withdrawn from the patient, it should be disposed of, as it could have been in contact with biological materials of the patient (blood, tissue, etc.), and traces of these could pass to another patient, if it is reused without proper cleaning and disinfection.
- All components of the system have been designed and manufactured for a specific purpose, and are therefore fully adapted. They should not modify or replace any component for an instrument or product from another manufacturer, even if it is the same size or similar to the original product, or if it is exactly the same.

- Materials used by other manufacturers, the possible structural changes owing to the use of other products and/or the contamination of materials, and even minimum differences or inaccurate adjustments between the drill bit and the screw, or similar, could be a risk for the patient, users and third parties.
- Although the drill bit can be passed at the same time to the monocortical and to the bone, where the graft is to be held, it is recommended to first pass the drill bit to the monocortical outside the mouth, and then take it to the receiving bone and pass the drill bit to the bone.
- Spiral drill bits: it is recommended to drill at a maximum of 1,000 revolutions per minute, to avoid the bone from overheating. Spiral drill bits can be used a maximum of 10 times.
- Owing to the fact that the absolute stability of the monocortical is a critical aspect to the success of the bone regeneration process:
    - to select the width of the screw, the thickness of the monocortical should be considered: small, fine 1 mm screws; large, thick 1.2 mm. screws.
    - for the length, the thickness of themonocortical should be considered, along with the mm needed to be regenerated (width and height) and the deceleration depth of the receiving bone.
- The screwdriver corresponding to the size of the system should be used. Make sure that the connection between the screwdriver and the screw head is in exact vertical alignment. There is a greater risk of damage to the screw and the screwdriver tip if this is not done. Although the screw is self-tapping, when the screw is turned, take care that there is sufficient axial force between the tip of the screwdriver and the screw. However, this axial force should not exceed a certain limit to avoid damaging the bone structure.

INDICATIONS FOR CLINICAL USE

- Ensure that the seat of the screw with the spiral drill bit is correctly prepared.
- In cases of monocortical grafts, the milling depth of the receiving bone should be slightly above the length part of the screw to be inserted into the bone, and to give stability to the monocortical. Otherwise, the screw could exceed the thread; the screw head may break by shearing or become damaged.
- Use spiral drill bits of the correct dimension.
- Select the drill bit according to the screw to be used.
- If the 0.8mm drill bit has passed the monocortical several times, the 1mm screw will not hold the graft correctly, and 1.2mm screws
  will have to be used (pass the 1mm drill bit only in the receiving bone).
- The direction of rotation on inserting should be the direction of perforation (coaxiality). There should not be an excessive increase of the torque, which would cause damage to the transmission system between the screw and the screwdriver.

RECOMMENDED TORQUE GUIDE

- The insertion of the screw in the receiving bone, should not exceed 10 Ncm nor more than 100 rpm.
- A table with the recommended Torques is given below, applied to emexact® self-tapping, bone fixation screws:

Diameter of screws	Reference	Recommended torque
Ø 1.0 mm	From 11836 to 11840	Manual (< 10N·cm)
Ø 1.2 mm	From 12245 to 12249	Manual (< 10N·cm)

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