

INSTRUCTIONS FOR USE SURGICAL INSTRUMENTS FOR INTRAOSSEOUS IMPLANT SYSTEM

GENERAL WARNING:

1. These user instructions must be followed to the letter. The manufacturer has sole responsibility for its own devices, in cases where they have been used and conditioned (that is to say, cleaned, washed and sterilised) correctly. The manufacturer declines all responsibility where its own devices have been not been used in accordance with these instructions, that is to say, in combination with devices produced by other manufacturers and where no preliminary check has been carried out with their regard to their compatibility.
 2. The prosthetic components and instruments must only be used by dental surgeons, dentists and oral-maxillofacial surgeons who have been specifically trained. They can also be used by dental technicians, who have been appropriately trained, for the sole purpose of creating prosthetic items.
 3. All the prosthetic parts and instruments are supplied clean but NOT STERILE. The use of an autoclave for 15 minutes at 121°C is advisable.
 4. Do not use if the packaging appears damaged or has been opened.
 5. The detailed information is important, but it is insufficient for using the prosthetic parts and the instruments. What is required is the training and skills of individuals, who have been trained by the manufacturer, so that they are knowledgeable about the actual technique and applications.
 6. The surgical implant technique must only be performed by a medical or dental surgeon, who has been appropriately trained and has specialised accordingly; this instruction sheet contains general information and cannot replace the knowledge received from a university.
 7. The dental drill's state of wear and tear must be checked regularly - refer to the surgical procedures manual.
- a. General instructions for use: all the prosthetic parts and instruments must be correctly washed and sterilised. In order to reduce the risk of contamination to a minimum, ensure that the prosthetic parts and instruments are cleaned and sterilised using approved methods. DO NOT USE disinfectants or detergents (sodium hypochlorite-based) that contain high percentages of chlorine and/or oxalic acid to clean stainless steel components.
When using commercially available products specifically intended for cleaning instruments, always follow the instructions provided by their producers.
- b. Identifying the parts: the adhesive labels that accompany the products must be used by the implantologist to identify record and track the codes and batches of the devices and their use.
- c. Sterilisation: the prosthetic components and the instruments SUPPLIED ARE NOT STERILE. It is advisable to check the sterilisation cycle regularly and service the equipment regularly. Sterilisation in an autoclave for 15 minutes at 121°C is advisable. Be aware of those parts that cannot undergo sterilisation.
- d. Packaging and handling: The prosthetic components and instruments supplied in blister packs or bags have been washed. The outside of the packaging will have an adhesive label that provides information about the item contained. Handle all the prosthetic components and the instruments with care in order to avoid causing any damage that may undermine their efficient and correct use. Take particular care with regard to those instruments used for cutting (e.g. drills), in order to avoid damaging their cutting parts.
- e. Contraindications:
- allergy to the materials used
 - bone deficiency
 - excessive occlusal parafunction
 - diabetes
 - unchecked blood dyscrasias
 - pregnancy
 - systemic illnesses
 - endocrinological illnesses
 - acute or chronic infectious diseases
 - epilepsy
 - a patient's poor general state of health
 - previous bone radiation
 - treatment with anticoagulants
 - patients treated with steroids
 - chronic subacute maxillary osteitis
 - secondary osteoporosis
 - valvular prostheses
 - patients with poor oral hygiene
 - alcoholism
 - drug addiction
 - excessive tobacco consumption
 - patients who lack motivation with regard to the implant
 - it's use on children, the disabled and elderly individuals is inadvisable



F.M.D. s.r.l.

Via Canelli, 3 - 00166 Rome, Italy - Ph. (+39) 06.61.52.14.15 - Fax (+39) 06.62.45.123
www.fmd-dental.com - info@fmd-dental.com

