CE 0476

PERI-SET
GB: Surgical treatment for Peri-implantitis

1. PRODUCT IDENTIFICATION
The Peri-set kit consists of instruments for the mechanical decontamination of the surface micro-geometry of the implant and the modification of the macro-geometry of the same to promote optimal healing of the hard and soft peri-implant tissues after surgery for the treatment of peri-implantitis.
2. INTENDED USE AND RISK CLASS
Peri-set devices are available both within a kit, figure 01, and individually as spare parts.
The kit consists of:
- n.2 nickel-titanium brushes, with stainless steel stem tip, attachment for contra-angle, ref. 260 / 015CAXL;
- n.2 nickel-titanium brushes, with open bristles, shank in stainless steel, attachment for contra-angle, ref. 261 / 018CAXL;
- n.1 double cone diamond cutter, medium grain, turbine connection shank, ref. FG811 / 037C;
- n.1 diamond disc, medium grain, turbine stem, ref. FG824 / 037C;
- n. 1 flamed rubber, red, shank for contra-angle, ref. 9503CA;
- n. 1 flamed rubber, green, shank for contra-angle, ref. 9533CA.

These devices are NON-STERILE. They must be washed and sterilized before use.
The Peri-set kit must be used exclusively by medical and dental personnel with the necessary qualifications and qualifications and must be used only in accordance with the indications and instructions for use, according to the general rules of dental and / or surgical treatment and in compliance with the regulations accident prevention and occupational protection. Failure to comply with the instructions provided can cause surgical problems and damage to the patient's health. The use of the kit, although tested, designed to be safe and to prevent and reduce errors, is unsuitable for inexperienced or inexperienced operators.
Both the kit and the tools are medical devices. The risk class of the is defined in table 01.
3.IDENTIFICATION OF THE MANUFACTURER
The manufacturer of the Peri-Set Kit and instruments referred to in these User's Instructions is:

SWEDEN & MARTINA S.p.A.
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4. RAW MATERIAL USED
The materials used to manufacture the Peri-set medical devices were selected according to the properties indicated for their intended use in accordance to the Regulation (EU) 2017/745, Annex I – Essential Requirements, point 10.1.
The raw materials are:
- Nitinol - Nichel Titanium alloy (brushes, working part);
- 304 stailess steel (brushes, remaining part);
- Stainless steel (tray, drill and disc).

Remember to ask patients whether they are allergic to any of the raw materials. The object devices do not include materials of animal origin.
5. PRODUCT DESCRIPTION
1. Pointed brush
Fitted on a micromotor, for use at 300–600 rpm. Designed for implant surface cleaning, and in particular to clean the spaces between one thread and another, to be used with a horizontal movement along the pitch of the thread or with vertical movements in both the apicocoronal and the coronoapical directions. Single-use surgical instrument.
2. Brushes with open bristles
Fitted on a micromotor, for use at 300–600 rpm with a reduction handpiece with a red ring or on a turbine. Designed for implant surface cleaning, to be used by resting the fibres of the brush perpendicularly to the implant surface. Single-use surgical instrument.
3. Diamond drill with double cone
To be fitted on a reduction handpiece with a red ring or on a turbine to perform resection and the first phase of polishing on the surfaces and threads of the implant, in areas outside horizontal and vertical bone levels. Thanks to the sharp angulation of the working surface near the tip, this instrument makes it possible to work along the external implant profile, even in cases where it is not possible to even temporarily remove the prosthetic over-structures fixed to the implant.
4.Diamond disk
To be fitted on a reduction handpiece with a red ring or on a turbine to perform resection and the first phase of polishing on the surfaces and threads of the implant, in areas outside horizontal and vertical bone levels. Thanks to the orthogonality of the large flat working surface, this instrument makes it possible to work perpendicularly to the external implant profile, even in cases where it is not possible to even temporarily remove the prosthetic over-structures fixed to the implant.
5. Red rubber tip
To be used on a micromotor at about 1200 rpm, to polish implant surfaces in areas outside horizontal and vertical bone levels.
6. Green rubber tip
To be used on a micromotor at about 1200 rpm, to polish implant surfaces in areas outside horizontal and vertical bone levels.
6. CLEANING/DISINFECTION/STERLIZATION/STORAGE
Caution! All surgical instruments for dental implants are sold in NON-STERILE packs. Before use, they must be cleaned, disinfected and sterilized using the following procedures validated by Sweden & Martina SpA.
The correct functionality of the tools must always be checked before using them. In case of multiple use of an instrument on a single patient, it is recommended to soak the instrument in a 3% hydrogen peroxide solution and rinse with sterile saline before cleaning or using on another implant site. Failure to comply with these instructions can lead to cross infections and intraoperative complications.
Cleaning
Containers and transports to be used for washing: no special requirements. In case of automated cleaning, use an ultrasound bath with a suitable detergent solution. Use only neutral detergents. Follow the manufacturer's instructions for detergent concentrations and washing times. Use demineralized water to prevent the formation of stains and marks.
In case of manual cleaning, use a suitable neutral detergent and follow the manufacturer's instructions. Brush products with a soft-bristled brush under abundant running water. Using the brush, apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Ensure that the running water passes abundantly through any holes and other openings.
Sterilization
In vacuum autoclave and sterilize as follows:
- Configuratione: wrap
- Temperature: 134°C
- Pressure: 2.5 bar
- Exposition time: 15 minutes
- Drying time: 20 minutes

Storage
After sterilization, the product must remain in the sterilization bags. Bags must only be opened immediately before use. In normal conditions, sterilization bags are usually able to maintain the sterility of their contents, unless the wrapping is damaged. Do not therefore use components if the bags in which they were kept are damaged, and resterilize them in new bags before using again. The storage time of products sterilized in bags must not exceed the time recommended by the manufacturer of the bags.
The product must be stored in a cool and dry place, away from direct sunlight, water and heat sources.
7. CONTRAINDICATIONS
When assessing patients, in addition to considering their suitability for implant-prosthetic rehabilitation, it is usually necessary to take into account the contraindications applicable to all operations of dental surgery.
These may include:
- Clotting disorders, anticoagulant therapies in progress
- Healing or bone regeneration disorders, such as:
  - Decompensated diabetes mellitus
  - Metabolic or systemic diseases that compromise tissue regeneration, and with effects in particular on tissue healing and bone regeneration
  - Alcohol abuse, smoking and use of drugs
- Immunosuppressive therapy, such as chemotherapy and radiotherapy
- Infections and inflammations, such as periodontitis and gingivitis
- Poor oral hygiene
- Insufficient motivation
- Occlusion and/or articulation disorders, and also inadequate interocclusal space
- Inadequate alveolar process

It is contraindicated to insert implants and perform implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly, or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment. Contraindications also include: allergies to titanium, acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, granulocytopenia, use of steroids, diabetes mellitus, kidney failure and fibrous dysplasia. Implants intended to support prostheses are medical devices inserted in the oral cavity during a surgical operation, and as such are subject to further restrictions on their use, for details of which the instructions for use of the implant fixtures must be consulted.
SIDE EFFECTS
The following phenomena may accompany surgical operations:
- Temporary local swelling, oedemas, haematomas.
- Temporary alterations in sensitivity.
- Temporary limitations in masticatory functions.
- Micro-haemorrhages in the 12–24 hours after surgery.

8. METHOD OF USE
Regarding the drill with double cone it is recommended to:
- Insert the drill as much as possible into the pliers,
- Work intermittently,
- Do not use lever movements,
- Do not use damaged, bent or worn tools.

The drill cut must be periodically revived with the appropriate sharpening stones. The rubber pads must be protected from direct exposure to sunlight, too high temperatures and dry air currents for prolonged times, in order to cause excessive drying of the raw material and premature crumbling of the instrument. Since the use of rotary instruments is linked to a profound knowledge of dental techniques, Sweden & Martina has decided to limit the risks by providing users with clear indications relating to the more general aspects of their use, such as for example pressures and cutting speeds. recommended, as well as precise information on the maintenance to be performed on the products. In fact, for each instrument Sweden & Martina recommends applying working pressures within a specific range shown in the catalogs, not to make sudden speed changes and to stick to those speeds indicated in the specific tables also present in the catalogs. From a functional point of view, it is also recommended to avoid excessively high sterilization temperatures; from a biological point of view, on the other hand, the containment of heat development is one of the most important precautions regarding the use of rotary instruments on the bone.
9. WARNINGS
Sweden & Martina SpA surgical instruments are sold in NON-STERILE packs. Before use they must be cleaned, disinfected and sterilized following the instructions to be given later. Failure to follow this precaution may expose the patient to infections. Complete clinical, radiological and radiographic documentation should be collected and stored on file. Every product pack shows the product code, a description of contents and the batch number. These details are also indicated on labels included in packs and must always be cited by the practitioner in any correspondence regarding the products. Some surgical instruments must be single-use instruments that cannot be reused. Check the symbols indicated on the pack. When handling these medical devices, both during actual use and during cleaning and sterilization procedures, surgical gloves must always be worn for individual protection against bacterial contamination. Failure to follow these instructions may cause cross-infection. Packaging conforms to European standards.
10. DISPOSAL PROCEDURE
If used, dispose of the instruments as biological waste, according to the local regulations.
11. REFERENCE STANDARDS
The instruments are designed and manufactured in accordance with the most recent directives and harmonised standards regarding the materials used, production processes, information supplied and packaging.
12.RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
Optimal patient care and attention to their needs are necessary conditions for the success of a implantation procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected to the treatment and encouraged to cooperate with the practitioner in the interests of the success of the treatment itself.
The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioner's instructions and orders shall be observed.
The instructions provided by Sweden & Martina are available at the time of the treatment and are accepted as normal dental practice. They must be followed and applied in all treatment phases: from taking the patient's medical history to post-surgery check-ups.
The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.
13. DATE AND VALIDITY OF THESE USER'S INSTRUCTIONS
These user's instructions are valid and effective from July 2021.

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EXPLANATION OF SYMBOLS		
	Caution! See instruction for use	✓
LOT	Batch number	✓
REF	Code	✓
	Manufacturer	✓
IT	Country of manufacture	✓
UDI	UDI code, Unique Device Identification	✓
MD	Medical Device	✓
	Consult instruction for use www.sweden-martina.com	✓
CE	CE marking *Where applicable: The identification number of the Notified Body shall follow this symbol.*	✓
Rx Only	American federal law restricts this device to sale by or by order of a professional practitioner	✓
	Do not use if the packaging in damaged	✓
NON STERILE	Non-sterile product	✓

Table 01

Device	Classification	Classification rule	Risk Class
Diamond drill with double cone	Surgical instruments	6	IIa
Diamond disk	Surgical instruments	6	IIa
Nichel-titanium brushes	Surgical instruments	6	IIa
Rubber tips	Surgical instruments	1	I
Complete Kit	Surgical instruments	6	IIa

Fig. 01
Peri-set Kit

sweden & martina

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