CE 0476

GB - Kit of instruments for prosthetic use

SCREW KIT

1. PRODUCT IDENTIFICATION
The Screw Kit is a practical kit contained in a Radel organiser that holds all the instruments required for restoration work (drivers/screwdrivers, driver for straight P.A.D. abutments, carriers for angled abutments, locator screwdriver, titanium cap driver for ball attachments).
The instruments designed for use with the implant systems manufactured by Sweden & Martina S.p.A are reusable medical devices intended for transient use in the oral cavity (no more than 60 minutes at a time), supplied in NON-STERILE packaging. The restoration instruments are used to:
- tighten or loosen all connection screws (cap screws, transmucosal healing screws, post screws, abutment screws, direct screw-retained abutments, restoration screws, transfer screws, etc.).

The surgical instruments manufactured by Sweden & Martina S.p.A. are designed for use with dental implants manufactured by Sweden & Martina S.p.A. Use of the Screw Kit and the instruments it contains with components other than those manufactured by Sweden & Martina S.p.A. limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void (see the “Responsibility for defective products and warranty terms” section below).

2. DESCRIPTION AND USE
The information provided in these user’s instructions complements the indications provided in catalogues/ manuals. If you are not in possession of this documentation, you may ask Sweden & Martina to provide you with a copy.
Some instruments are intended for mechanical use, i.e. they have a shank with a contra-angle connection and must be used with a suitable micromotor, others are designed for manual use. Incorrect insertion of the contra-angle instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shank buckling. Suitable surgical micromotors only should be used. Micromotors should be checked regularly by their manufacturers, according to the indications given by the same, to prevent potential malfunctions (e.g. axle shifts for transmission shafts, worn or faulty forceps, etc.). Failure to follow the instructions provided may cause surgical problems and damage to the patient’s health.
Details of the instruments contained in the Screw Kit, fig. 01 are given below:

A. Drivers/ screwdrivers
These instruments are used to fasten the cap screws, transmucosal healing screws, post screws, abutments and restoration screws. The drivers for Sweden & Martina implant systems come in two different lengths; they are compatible with all components designed to be screwed onto the implants (cap screws, transmucosal healing screws, transfer screws and abutment screws). Lever movements should be avoided as they increase the risk of breakage. Before tightening, make sure the hex socket screw head on the driver tip is correctly inserted into the screws to be tightened. Incorrect insertion is likely to pare off the hexagonal connection of the screwdriver or the screw to be tightened. Drivers have a slightly conical profile, able to guarantee the hexagonal connection on the tip of the driver grips inside the hexagonal connection on the head of the screws, making it possible to carry the screw to the patient’s mouth correctly, without dropping it. Replace drivers regularly to reduce the risk of wear to the hex connection. The Kit contains a torque ratchet to be used with special screwdrivers for the final tightening of restoration components in the final rehabilitation phase.
The recommended torques are:
- Screws for fastening posts and abutments to the implants: 20-25 Ncm
- Screws for fastening restoration superstructures to the abutments: 20-25 Ncm
- Fastening of components that screw directly into the implants (e.g. ball attachments, posts or abutments that do not have passing fastening screws but form a single body with the screw): 30 Ncm
- Screws for fastening superstructures directly onto the implants (without using intermediate abutments): 20-25 Ncm

When tightening transmucosal healing screws, do not use a torque greater than 8-10 Ncm.
Excessive tightening torques can weaken the screws’ mechanical structure and compromise restoration stability, with potential damage to the implant connection.

B. Driver for straight pad abutments
Straight PAD solid one-piece abutments that form a single body with the screw, must be screwed in using the specifically designed hex screwdriver provided in the Kit. This hex screwdriver can be connected to the hand knob, which is also provided in the kit.

C. Carrier for angled pad abutments
This device acts as a carrier, making it possible to transport PAD abutments to the mouth safely.

D. Locator screwdrivers
These screwdrivers are used to screw in Locators. They are available in two versions: short and long.

E. Titanium cap driver for ball attachments
Used to tighten and re-tighten the restoration components for the titanium cap for ball attachments.

3. INTENDED USE
Sweden & Martina declares that it is the manufacturer of the “Screw Kit” and its components and identifies their risk class as follows:
- drivers/ screwdrivers, drivers for straight PAD abutments, digital handpieces, carriers for angled PAD abutments, Locator® screwdrivers, titanium cap drivers for ball attachments: Reusable surgical instruments, for temporary use (for less than 60 minutes’ at a time), supplied in NON-STERILE packs, Risk Class 1;
- Drivers/ screwdrivers for mechanical use: Reusable invasive medical devices of the surgical kind for temporary use (for less than 60 minutes’ at a time), supplied in NON-STERILE packs, Risk Class 2A;
- Screw Kit: Reusable Medical Device in NON-STERILE packaging; Risk Class 2, based on the highest risk class for the components.

The product must only be used and handled by dentists and dental technicians with the necessary qualifications and professional experience.

4. IDENTIFICATION OF THE MANUFACTURER
The manufacturer of the surgical instruments for dental implants referred to in these User’s Instructions is:
Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padova) - Italia - Tel. +39 049.91.24.300 - Fax + 39 049.91.24.290
e-mail: info@sweden-martina.com - www.sweden-martina.com

5. RAW MATERIALS USED
The materials used to manufacture the surgical instruments for Sweden & Martina dental implants were selected according to the properties indicated for their intended use in accordance with Regulation 2017/745..
The instruments are manufactured using:
- surgical stainless steel 1.4197;
- Steel AISI 316 L ASTM F899-126;
- Titanium ASTM 136.

Remember to ask patients whether they are allergic to the raw materials.

6. WARNINGS
The Sweden & Martina Screw Kit and its components are sold in NON-STERILE packaging. Before use, they must be cleaned, disinfected and sterilised according to the instructions reported below. Failure to follow these warnings may expose the patient to infection.
Each packaging indicates the code for the individual instruments, a description of the contents and the batch number. These same details are also indicated on the patient labels inside the pack and must always be provided by the practitioner in any relevant correspondence.
When handling the devices, both during use and during cleaning and sterilisation, it is recommended to use surgical gloves for personal protection against bacterial contamination. Failure to follow these instructions may cause cross-infection. The packaging conforms to European standards.

7. CONTRAINDICATIONS
The Screw Kit is designed for the fastening of implant restorations: when assessing the patient, in addition to his/her eligibility as regards implant-restoration rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:
- Clotting disorders, anticoagulant therapy
- Healing or bone regeneration disorders such as, for example:
- Decompensated diabetes mellitus
- Metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration
- Alcohol abuse, smoking and use of drugs
- Immunosuppressive therapy, such as: chemotherapy and radiotherapy
- Infections and inflammations, such as: periodontitis, gingivitis
- Poor oral hygiene
- Inadequate motivation
- Occlusion and/or articulation disorders as well as an inadequate interocclusal space
- Inadequate alveolar process

It is contraindicated to fit implants and 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: allergy to titanium, acute or chronic infective diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia. Implants designed to support restorations are medical devices that are introduced into the mouth during surgical procedures and as such they involve further restrictions to use, details of which can be found in the User’s Instructions for the implant fixtures.

8. SIDE EFFECTS
The following may present after surgical implant procedures:
- Temporary local swelling, oedema and haematoma.
- Temporary sensitivity alterations.
- Temporary masticatory limitations.
- Post-surgical micro-haemorrhages in the following 12-24 hours.

9. CLEANING / DISINFECTION / STERILISATION / STORAGE
Attention! All the instruments for dental implants are sold NON-STERILE. Before use, they must be cleaned, disinfected and sterilised according to the following procedure validated by Sweden & Martina S.p.A. These processes must be performed before use and before each subsequent reuse. Repetition of the processes described in this paragraph has a negligible effect on the devices. Instruments should always be checked before use to ensure they are in good working order. Any instruments showing signs of wear must be immediately replaced with new devices. It is particularly important to check that the drivers grip properly inside the connection wells on the heads of the screws to be lifted and tightened with the same. Failure to follow these instructions may cause cross-infection and intraoperative complications.

a. Cleaning
Containers and transport to be used for washing: there are no special requirements.
In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer’s instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks.
When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
When cleaning manually, use a suitable neutral detergent and follow the manufacturer’s user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes.
For burs with internal irrigation, use the special pins provided with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissues.
After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags.
Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation:
For sterilization, the kits must be packed inside autoclavable bags.
Sterilization can be done as follows:
- Method 1: Autoclave (Gravity Steam)
  temperature of 121-124 ° C, exposure of 20 minutes and drying of 15 minutes;
- Method 2: Autoclave (Pre-vacuum Dynamic-Air-Removal Cycles)
  temperature of 134 ° C, exposure of 4 minutes and drying of 20 minutes.

c. Storage: after sterilisation, the product must remain in the sterilisation bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilisation bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilise in new bags before using them again. The storage time of products sterilised inside the bags should not exceed that recommended by the manufacturer of the bags.
The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

10. 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.

11. DISPOSAL PROCEDURES
If used, dispose of the instruments as biological waste, according to the local regulations.

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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Fig. 01

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	✓

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Sweden & Martina S.p.A.
Via Veneto, 10 - 35020 Due Carrare (Padova) - Italy
Tel. +39.049.9124300 - Fax + 39.049.9124290
e-mail: info@sweden-martina.com
www.sweden-martina.com

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