CE 0476

GB: Surgical instruments for mechanical use

1. PRODUCT IDENTIFICATION

The surgical 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 surgical instruments are used:

- to prepare sites for Sweden & Martina implants
- to introduce the implants into the sites
- to tighten or loosen all connection screws (cap screws, transgingival healing screws, post screws, abutments, prosthetic 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 surgical instruments for implant work 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). Sweden & Martina declines all responsibility for use of any non-original instruments.

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.

All the devices are identified by an instrument code, which is laser etched onto the body of each instrument. If there is not enough space to include the full code, the elements for unequivocally identifying the device (e.g. diameter or length) are provided.

Each Sweden & Martina S.p.A. implant system comes with a colour code to identify the instrument diameters to be used depending on the implant diameter and platform size. The colour code key is illustrated in the catalogues and surgical manuals of each implant system. The instruments forming the subject matter of these user's instructions (surgical drills and drill extensions, bone taps, drivers, auxiliary mounters, drivers/screwdrivers, surgical kits) are intended for mechanical use, i.e. they have a shaft with a contra-angle connection and must be used with a suitable micromotor. Incorrect insertion of the instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shaft 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.

a. Surgical drills and Drill extensions

These sharp instruments are used to prepare the surgical sites for dental implants. They have different shapes: precision drill, crown drill, countersink, conical, cylindrical, short for distal use, bone profilers. Depending on the implant system they belong to, they may have internal irrigation or depth lines to determine the working depth, and may be designed for connection with a depth stop. Consult the catalogues of the implant system in question for detailed technical features.

The drills produce a hole that is longer than the implant insertion depth. This greater length depends on the size of the instrument tip used. The exact measurements of the depth of the holes produced by the drills are indicated in all the implant system catalogues and surgical manuals. Use the rotation speed indicated in the individual catalogues or surgical manuals to prevent the development of bone necrosis. Lever movements increase the risk of instrument breakage and should therefore be avoided. Changes in speed should be avoided in general. Never apply pressure such as to force the instrument to stop rotating. This could lead to an excessive increase in heat in the tissues being drilled, with consequent bone necrosis, and damage both the instrument and the appliance (micromotor) used. This could also lead to breakage of the instrument. Using an intermittent approach prevents overheating and wear of the instrument used and an undesirable increase in the temperature in the tissues being cut. Suitable coolant should be used. Inadequate irrigation can lead to bone necrosis. When using a drill with internal irrigation, take care to insert the head's guide needle correctly into the through hole on the drill.

Drill wear depends to a large extent on the type and density of the drilled bone: harder bone leads to greater instrument wear. For greater safety and caution, given the device's capacity for resistance to wear, drills should not be used for more than 20 work cycles and should be replaced earlier if the instruments lose their cutting ability. These recommended 20 cycles should be considered a rough guide. Always check the instrument's residual cutting capacity after each procedure.

Sweden & Martina S.p.A. decline responsibility for the use of blunt instruments. Never sharpen drills before use. Never use damaged, buckled or worn instruments.

A drill extension is also available for use when the total length of the instruments is too short given the presence of adjacent teeth that do not allow the head of the handpiece to pass through. If used, make sure the drill shaft is inserted correctly and completely. Incorrect insertion causes eccentric rotation of the drill.

N.B.: drills marked with a code starting with "2" (e.g. FFT2-…) have a 12.5 mm-long shank. This shank is shorter than standard and requires the use of special small-headed handpieces. Contact handpiece manufacturers for information on availability. The more compact design of these drills, when used with suitable handpieces, makes handling in distal sites easier. Drills marked with numbers other than "2" are standard-sized and can be used with all handpieces.

The precision drill comes with a protective silicone sheath to protect the instrument during transportation and it must be removed before first use. Since the drill is extremely sharp, special caution is required during handling.

b. Drill stops

These devices can be fitted to specially designed drills. They make it possible to restrict the working length of a drill to a pre-set height. The sizes are indicated in the catalogues and surgical manuals.

Always check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using tweezers. Always check that the retention of the stop is adequate. If retention is too weak, the instrument will fall off the drill during use. In the event of reduced retention capacity, simply tighten the tabs by hand or using tweezers.

c. Bone taps

These sharp instruments are used to prepare the bone to accommodate the implant's thread. They are normally used in the presence of very compact or cortical bone to alleviate compression and the insertion torque of the implant.

d. Drivers

These devices have two functions. They act as a carrier for taking the implants from the package without contaminating them, i.e. without touching their surface, and transporting them into the oral cavity without dropping them and they also act as screwdrivers for transmitting the rotating motion from the micromotor to the implants, allowing them to be screwed into the prepared sites. Lever movements should be avoided as they increase the risk of breakage. There are various drivers available, depending on the implant system used. The technical details for each system are provided in the surgical manuals and catalogues. Read these details carefully before use.

e. Auxiliary mounters

These are elements placed between the implant connection and insertion drivers. For some systems, the implants are pre-assembled on standard mounters. In these systems, the service mounters are longer than standard ones and can be mounted on implants to go beyond the anatomical limits that arise from, for example, the presence of adjoining teeth that obstruct the head of the handpiece. In other implant systems, the implants are not pre-assembled on a standard mounter because they require "mountless" surgical procedures. However, it may be necessary to insert the implants surgically with split-crest techniques, where the fixtures are hammered inside the site. In these cases, the service mounters are screwed to the connections to prevent them from colliding with the hammer.

f. Drivers / Screwdrivers

These instruments are needed for fastening the cap screws, transgingival healing screws, post screws, abutments and prosthetic 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, transgingival healing screws, transfer screws and abutment screws). The exception are hexagonal cap screws, which need a special driver, with a smaller hexagonal head and which are available either as part of the system's kit or individually. 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 of the hexagonal connection.

The screwdrivers used to tighten the post screws or prosthetic screws must be used under controlled tightening torque:

- Through screws for fastening posts and abutments to the implants: 20-25 Ncm
- Through screws for fastening restoration superstructures to the abutments: 20-25 Ncm
- Fastening of components that screw directly into the implants (e.g. ball connections, certain types of abutment that do not have through screws but form a single body with the screw): 30 Ncm
- Through screws for fastening superstructures directly onto the implants (without using intermediate abutments): 20-25 Ncm

When tightening transgingival 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.

g. Surgical kits

These are practical Radel trays that hold, in an ergonometric manner, all the instrumentation required for surgery and the restoration of Sweden & Martina dental implants.

Consult the various catalogues and user's manuals for detailed information on the various kits and procedures.

3. INTENDED USE

Sweden & Martina declares that it is the manufacturer of the surgical accessories for Sweden & Martina dental implants and identifies their risk class as follows:

- Surgical drills (precision drill, crown drill, conical, cylindrical, for distal use, bone profilers) and Drill extensions, Drill stops, Bone taps, Drivers, Auxiliary mounters and drivers/screwdrivers: Reusable invasive surgical medical devices for temporary use (less than 60 minutes' at a time), supplied in NON-STERILE packs, Risk Class 2A, pursuant to rule 6 of annex VIII;
- Surgical Kits: Reusable Medical Devices, supplied in NON-STERILE packs; Risk Class 2A, because they contain part or all of the above instruments needed for surgery and the restoration of Sweden & Martina dental implants;

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 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 (EU) 2017/745, Annex I – Essential Requirements, point 10.1.

They are manufactured, depending on the type of component, using:

- Titanium Grade 5 (Ti6Al4V)
- 1.4197 Steel
- 1.4542 Steel (AISI 630)
- 1.4305 Steel (AISI 303)
- 1.4108 Steel
- 1.4112 Steel

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

Go to www.sweden-martina.com for detailed data sheets for all the materials used, to check the relative chemical compositions and the physical and mechanical properties.

6. WARNINGS

Sweden & Martina S.p.A. surgical instruments are sold in NON-STERILE packs. 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.

It is recommended to collect and file all the clinical, radiological and radiographic records.

Each packaging indicates the code, description of the contents and 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

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
- Drills must be used with caution in cases of low bone density and implant sites must be adequately prepared in advance. Bone condensers should be used when possible.

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 event 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 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 surgical accessories 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 drills 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 surgical components 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 surgical accessories 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.

EXPLANATION OF SYMBOLS		
	Caution! See instruction for use	✓
	Batch number	✓
	Code	✓
	Manufacturer	✓
	Country of manufacture	✓
	UDI code, Unique Device Identification	✓
	Medical Device	✓
	Consult instruction for use www.sweden-martina.com	✓
	CE marking *Where applicable: The identification number of the Notified Body shall follow this symbol.*	✓
	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 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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