GB: Surgical instruments for hand 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, and are not designed for connection with an active medical device.

Surgical instruments are used to prepare the sites for Sweden & Martina implants.

The surgical instruments manufactured by Sweden & Martina S.p.A. are designed for use with dental im-plants 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. During surgical procedures, instruments should be secured with a safety thread to prevent patients from swallowing them.

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. Some instruments have an O-ring to allow a grip between different instruments and guarantee transportation to and use inside the mouth without the risk of them falling. As these O-rings are made of plastic, their state of wear and grip capacity should be checked regularly. We recommend replacing the O-rings whenever necessary and, in any case, no more than every 20 uses of the instruments. Worn O-rings may be removed using a simple probe. New O-rings should be fitted onto the instrument and gently pushed into place. Check that they positioned correctly and are not twisted.

Failure to follow the instructions provided may cause surgical problems and damage to the patient's health.

a. Osteotomes / Bone Expanders

These are manually-operated screwdrivers and are not connected to a micromotor or sources of energy. They are used to fasten the cap screws, transmucosal healing screws and restoration post fastening screws, etc. They are very practical during the various phases of surgery because they are ready for use and no as-sembly of the different parts is necessary, therefore, they are quick and easy to use, and are available in various lengths: short, for facilitating access to distal sectors, and long for use in the presence of anatom-ical obstructions relating, for example, to the presence of adjacent teeth.

b. Drivers / Scrwdrivers

These are manually-operated screwdrivers and are not connected to a micromotor or sources of energy. They are used to fasten the cap screws, transmucosal healing screws and restoration post fastening screws, etc. They are very practical during the various phases of surgery because they are ready for use and no assembly of the different parts is necessary, therefore, they are quick and easy to use, and are available in various lengths: short, for facilitating access to distal sectors, and long for use in the presence of anatom-ical obstructions relating, for example, to the presence of adjacent teeth.

c. Bone taps

These sharp instruments are used to prepare the bone to accommodate the implant's thread. These are manually-operated instruments and are not connected to a micromotor or sources of energy. They are normally used in the presence of very compact or cortical bone to reduce compression and the implant insertion torque.

d. Drivers

These devices have two functions. They act as a carrier for removing the implants from the package without contaminating them, i.e. without touching their surface, and transporting them into the oral cavity without touching them and they also act as screwdrivers. They are manually-operated instruments and are not connected to a micromotor or sources of energy. 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. There are also drivers that have the same function as the above mentioned ones, but they do not act as carriers. They are manually-operated instruments and are not connected to a micromotor or sources of energy. Caution is required when using to insert implants instead of mounters or special drivers, since excessive torque can pare off the edges of the hex drivers and cause irreversible deformation on the sides of the internal connections. They are usually used to unscrew implants with internal connections, when it is necessary to remove an implant. Lever movements should be avoided as they increase the risk of breakage.

e. Digital connector

Hand-held devices for facilitated use of the instruments in the surgical kits.

f. Depth gauges

Manual instruments used to verify the insertion depth obtained using burs or osteotomes.

g. Parallelism pins

Instruments normally supplied with two round-tipped cylindrical sections, one narrower and one wider, that are normally inserted into holes prepared using drills, to allow the practitioner to check that the preparations are parallel. Depending on the diameter of the hole, they can be inserted with the narrower part or wider part first.

h. Mounter stop key

Manual keys used to hold implant mounters in a stable position whilst loosening their fastening screws. They are normally used to prevent the implants coming loose when removing the screws that fasten the mounters.

i. Instrument box in radel

Radel boxes designed to hold surgical instruments. Surgical instrument trays are not merely "containers", they are also "organisers" because the instruments are arranged appropriately, according to a specific order for easy identification and use. They are designed to facilitate the identification of the instruments, guiding their use with sequences indicated on the inside of the tray. They allow easy handling and correct sterilisation and minimise cross-redox between surgical instruments made of different metals. They have holes on the bottom to allow water to flow out during washing and that allow the steam to pass through when autoclaving. They also allow the correct elimination of condensate. The osteotome trays are, on the other hand, simply sterilisable containers and not organisers.

l. Guide sleeves

They are small steel cylinders that are normally inserted into special silicon or clear resin supports manufactured by dental technicians to the dentist's orders and used to guide the insertion axis of the first drill used to prepare the implant site.

m. X-Ray templates

They are transparent templates used for the radiographic analysis of the implants. The x-ray tends to in-crease the implant's size by 20-30% and therefore, the templates can be used to determine the actual di-mensions by comparison on an x-ray viewer. They are available with scales of: 1:1 , 1:2, 1:3.

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:

- Osteotomes/Bone Expanders, Drivers/ Screwdrivers, Bone taps, Drivers, Allen keys, Digital connector, Depth gauges, Parallelism pins, Mounter stop key and Dimes: Reusable surgical instruments, for tem-porary use (less than 60 minutes' at a time), supplied in NON-STERILE packs, not designed for connection to active medical devices, Risk Class 1;
- Instrument box in Radel and x-ray templates: Reusable, non-invasive Medical Devices, in NON-STERILE packs; Risk Class 1.

4. IDENTIFICATION OF THE MANUFACTURER

The manufacturer of the surgical instruments for dental implants referred to in these User's Instructions

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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-mar-tina.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 pack indicates the code, description of the contents and batch number. The doctor must communicate these details as necessary. When handling the devices, both during use and during cleaning and sterili-sation, it is recommended to use surgical gloves for personal protection against bacterial contamination. 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
- Bone expanders should be used instead of drills when preparing sites in poor quality bone.

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 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 de-tergent 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

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the treatment itself.
The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appoint-ments, 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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