sweden & martina

CE 0476

Tray of Surgical instruments

1. PRODUCT IDENTIFICATION

The Sweden & Martina tray is container used for a secure storage and reprocessing of the surgical and auxiliary instruments of the Sweden & Martina Dental Implant System. The tray are used to store and organize the surgical instruments during both the surgical and reprocessing procedures. The trays are supplied as NON-STERILE products and are not intended to maintain sterility on their own. Each Sweden & Martina tray consists of multiples components designed to be integrated into a single unit, which protects the interior components during transportation, sterilization, and storage.

2. DESCRIPTION AND USE

The Sweden & Martina trays 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 typologies of kits and procedures.

In addition to its core functionality, the Sweden & Martina tray features a distinct color-coded workflows and instruments codes to facilitate the surgical procedures.

The colour code key is illustrated in the catalogues and surgical manuals of each Sweden & Martina implant system.

The Sweden & Martina tray is compatible with the Sweden & Martina instruments only. Please ensure that only the original Sweden & Martina instruments are used with this tray**.**

3. INTENDED USE

Sweden & Martina Surgical Tray is designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and transport the instruments between uses. Soiled-used tools should never be placed back into the tray or silicone grommets. The Sweden & Martina trays are available in two (2) formats, nominal dimensions Size M (189x140 mm h 61.5 mm) and Size L (270x150 mm h 62 mm), and the worst-case loading configuration have been validated for a maximum load of 740 grams for all device configurations. The tray is to be enclosed in an FDA cleared steam sterilizable wrap, sterilization validation was completed by:

- Method

  Autoclave (Pre-vacuum Dynamic-Air-Removal Cycles) at a temperature of 134 °C (273 °F) with an exposure of four (4) minutes and a minimum drying time of twenty (20) minutes.

4.CAUTION/PRECAUTIONS

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

- Never use potentially contaminated components, if indicated for multiple uses.
- Use only adequately reprocessed devices.
- Handling according to the basic information of the surgical and prosthetic procedure is essential.
- Assure sterile handling.
- Do not use damaged or blunt instruments.
- Always inspect instruments before use.
- The tray should be replaced if the surgical workflow is no longer visible by eye.
- Do not put the tray on its side or upside down with the lid underneath.
- The tray should be replaced if an instrument holder is broken.
- All device, including the Sweden & Martina tray, with remaining signs of damage must be replaced.

5. WARNINGS

Sweden & Martina S.p.A. surgical instruments are sold in non-sterile packs. Before use, they must be cleaned and sterilised according to the instructions reported below. Failure to follow these warnings may expose the patient to infection. The Purified Water described below is equivalent to the Critical Water as per AAMI TIR 34.

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

Each tray indicates the code, description of the contents and batch number. These same details 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.

6. NOTE

Maintain and clean your instruments according to recommended instructions. Each instrument must only be used for its intended purpose.

Combined cleaning agents/disinfectants should not be used. Always follow the manufacturer's instructions for use for cleaning agents and disinfectants.

Always follow the manufacturer's instructions for use for the automated washer-disinfector.

Always follow the operating instructions of the manufacturer for your sterilizer, especially with regard to the loading weight, the operating time and functional testing. When loading the sterilizer, place the tray on the shelf in such a way that under any circumstances it does not come in contact with the walls of the autoclave. Do not put the tray on its side or upside down with the lid underneath.

Never clean instruments and sterilization trays with metal brushes ore steel wool. Flash sterilization method is not permissible. Do not use hot-air sterilization, radiation sterilization, plasma sterilization, formaldehyde ore ethylene oxide sterilization.

7. PROCEDURE

Sweden & Martina surgical trays and components are supplied clean and not sterile. Instructions for cleaning and sterilization are included in the package insert.

Sweden & Martina surgical trays and components must be cleaned and sterilized according to the procedure validated by Sweden & Martina S.p.A. They all be reprocessed in the same way. The number of validated re-use cycles is twenty (20).

The following points describes the cleaning and sterilization of Sweden & Martina Tray step by step:

a. Point of use

Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to cleaning and sterilization. Remove excess soil and debris with disposable cloth or paper wipes. It is recommended a combination of a thorough manual and automated surgical instrument cleaning prior to sterilization. Pre-soaking is recommended prior to manual cleaning.

Note: The torque ratchet as originally intended to be part of the tray configuration was not able to be sterilized in the cycle time interval. It was subsequently removed from consideration as part of the tray system with the intent of being validated as an independently packaged device.

b. Containment and transportation

Safely store and transport the tray with the instruments in a closed container to the reprocessing area to avoid any damage and contamination to the environment. It is recommended that the instruments are reprocessed as soon as possible after usage (less than 1 hour).

c. Preparation for decontamination

Instruments should be cleaned as soon as practical to ensure ease of cleaning and according to the health care facility's infection control and hazardous waste management procedures.

Prior to soaking the instruments in an enzymatic cleaning solution, rinse the Instruments under cool running tap water and wipe off any residual soil or debris with a disposable towel. Ensure to flush out any lumens, cracks, or crevices while rinsing under running cool tap water.

Note: Disassembly & Reassembly -

1. To disassemble the Tray, remove all tools and accessories, lift out inner tray that holds all the tools
2. Reassemble after cleaning.
3. Torque ratchet, see section 8.

d. Cleaning

Repeat the cleaning steps if there is still visible soil on the product and accessories following visual inspection.

Surgical Trays contain colored instrument with which should only be cleaned using neutral pH enzymatic cleaning agents. Do not use cleaning agents containing hydrogen peroxide, chlorine or chloride, bleach or formalin they are corrosive to stainless steel. Do not use cleaning materials that will scratch instrument surfaces as oxidation may occur.

Manual Cleaning

1. Prepare an enzymatic cleaning solution, such as Neutral pH cleaning solution (such as TergaZyme or equivalent), per manufacturer's recommendations using warm tap water. Place the instruments in the solution in the open position (as appropriate) and allow to soak for a minimum of 50 seconds. While soaking, actuate the Instruments through a full range of motion (as appropriate for the specific instrument) to allow complete penetration of the cleaning solution.
2. After the 50 seconds soak time, remove the items and wipe any soil or debris using a disposable towel. Then, place them into a fresh batch of an enzymatic cleaning solution using warm tap water. Actuate the Instruments through a full range of motion. Use a sterile syringe and lumen brush to clean hard to reach areas and flush the instruments/accessories with a minimum of 60 ml/2 oz.
3. Remove the Instruments/tray/accessories from the detergent and rinse under running ambient, warm water tap water directly contacting all surfaces for at least 10 seconds, then by agitating and actuating in purified water (or equivalent) for a minimum of 30 seconds. Flush all hard to reach areas with a sterile syringe with a minimum of 60 ml/2 oz. of purified water (or equivalent).

Automated Cleaning

Recommended Equipment: Medical grade ultrasonic cleaner (Such as SharperTek XP-Pro Series Ultrasonic Cleaning System or equivalent), Enzymatic Cleaner that is compatible with stainless steel, plastics and soft metals including aluminum (Such as TergaZyme Enzymatlc Cleaner or equivalent - Neutral pH cleaning solution). Don't neglect the rinse. Use ambient, warm or hot water. A running water rinse directly contacting all surfaces for at least 10 seconds on each surface is desirable. Give medical and surgical instruments a final rinse in purified water (or equivalent).

All instruments must be manually cleaned as prescribed above prior to any automated cleaning process to ensure best possible cleanliness and removal of debris, blood and tissue prior to sterilization.

1. Use a neutral pH enzymatic cleaning solution and prepare per manufacturer's recommendations using warm tap water in a sonication unit. Allow the items to sonicate for 10 minutes. Items should be properly placed to maximize cleaning and to avoid damage or dislodgement of instruments and components.
2. Remove the instruments/tray/accessories tram the detergent and rinse under running ambient, warm water tap water directly contacting all surfaces for at least 10 seconds then by agitating and actuating in ambient purified water (or equivalent) for a minimum of 30 seconds. Actuate the Instruments through a full range of motion while rinsing and flush all hard to reach areas with a sterile syringe with a minimum of 60 ml/2 oz critical water per AAMI TIR 34.
3. Dry the Instruments using a clean non-linting cloth.

Give surgical instruments a final rinse in critical water per AAMI TIR 34.

Phase	Recirculation Time	Water temperature	Detergent Type&Concentration (if applicable)
Pre-wash	5 minutes	Cold tap water	N/A
Enzyme Wash		Warm tap water	TergaZyme, 1oz/ gallon or Equivalent (Per manufacturer's instructions)
Wash	5 minutes	60 °C / 140 °F	TergaZyme, 1oz/ gallon or Equivalent (Per manufacturer's instructions)
Tap water Rinse	10 sec per surface	Ambient	N/A
Final Pure Water Rinse	5 minutes	40 °C / 104 °F	N/A
Drying	30 minutes	Room temperature allow to air dry or use oil & water free compressed air	N/A

e. Maintenance & Inspection

Visually inspect the instruments following performance of the cleaning instructions prescribed above. Ensure there is no visual contamination of the instruments prior to proceeding with sterilization.

If possible contamination or any residue is present at visual inspection, repeat the cleaning steps above; contaminated instruments should not be used/sterilized.

f. Sterilisation

The tray is to be enclosed in separate FDA cleared steam sterilizing wrap prior to sterilization. Sterilization parameters for raped items are the following:

- Method

  Autoclave (Pre-vacuum Dynamic-Air-Removal Cycles) at a temperature of 134 °C (273 °F) with an exposure of four (4) minutes and a minimum drying time of twenty (20) minutes.

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.

The instructions provided above have been validated by Sweden & Martina as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing actually performed uses equipment, materials and personnel of the processing facility to achieve the desired result. This requires routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

The description give above are insufficient to allow immediate use of the Sweden & Martina Dental implant system instruments. Sweden & Martina Instruments must only be used by dental specialists trained in the use of the Sweden & Martina Implant System.

For further information on the Sweden & Martina instruments and the Sweden & Martina Dental Implant Systems, please consult the brochure available on www.sweden-martina.com.

The Sweden & Martina product must be used in accordance with the instruction for use provided by the manufacturer. It is practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Sweden & Martina product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Sweden & Martina and all affiliates or subsidiaries of Sweden & Martina. Use of products made by third parties, which are not distributed by Sweden & Martina, will avoid any warranty or other obligation, express or implied, of Sweden & Martina.

8. TORQUE RATCHET DISASSEMBLY & REASSEMBLY

The procedures described below must be carried out before initial use, and before every subsequent operation. Failure to comply with these instructions may result in cross infection occurring.

a. Disassembly of the torque wrench

Disassemble the spanner completely as indicated in fig.D 1-3:

> Fig. D1: Unscrew the torque adjustment screw (fig.A part.5) completely and remove the spring housed in the handle of the ratchet casing. Do not separate the spring (fig.A part.6) from the pin that acts as a stop (fig.A part.7).

> Fig. D2: With the hexagonal point (fig.A part.4) at the base of the torque adjustment screw (fig.A part.5), unscrew and completely remove the lid fixing screw (fig.A part.10) from the side marked OUT.
Exert a slight pressure to avoid damaging the hexagonal point.

> Fig. D3: Once you have removed the lid, remove the two components contained inside the ratchet head: The ratchet wheel (fig.A part.2) and pawl (fig.A part.3).

b. Assembling the torque wrench

Before proceeding with sterilisation, the pieces must be reassembled. Dry the pieces and lubricate the working

areas moderately, then reassemble the spanner as indicated in fig. E 1-4 (excessive lubricant causes it to surface on the instrument again during sterilisation). Only use the “Instrument Lubricant” supplied.

> Fig.E.1: After lubricating the parts shown in the figure, insert the two elements that make up the ratchet head in the following sequence: The ratchet wheel (fig.A part.2) and then the pawl (fig.A part.3).
> Fig. E.2: Lubricate the contact area between the ratchet wheel (fig.A part.2) and the pin of the pawl (fig.A part.3).
> Fig. E.3: Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet casing, position the lid (fig.A part. 1) and turn the ratchet casing from the OUT side. Tighten the screw (fig.A part.10) using the hexagonal point on the torque adjustment screw (fig.A part. 4).
> Fig. E.4: Lubricate the spring inside the ratchet sleeve, as shown in the figure. Assemble the torque adjustment screw (fig.A part.5) checking that the instrument works correctly and activating the nut wheel manually.

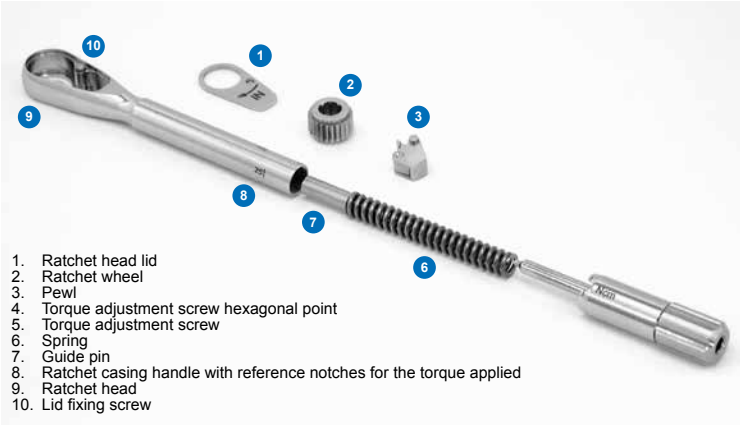
This procedure is important in order to maintain the instrument’s precision within a tolerance of ± 10% of maximum torque. Make the torque and insertion mechanism work to check that it is working properly. Remove any traces of lubricant from the external surface of the spanner. Put the device into suitable sterilisation bags.

e. Sterilisation

Before sterilisation, the wrench must be fully assembled and adjusted to its minimum torque.
The medical device must undergo steam sterilisation.

- Recommended cycle: 3 (4 for the US market) pre-vacuums, 18 minutes at 134°C / 273°F at 2 bars and drying for 20 minutes.

fig. A. Torque wrench components



1. Ratchet head lid
2. Ratchet wheel
3. Pewl
4. Torque adjustment screw hexagonal point
5. Torque adjustment screw
6. Spring
7. Guide pin
8. Ratchet casing handle with reference notches for the torque applied
9. Ratchet head
10. Lid fixing screw

fig. B. Alignment of marks for torque adjustment

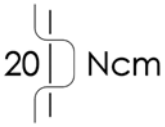


fig. C. Torque adjustment key

fig. D. Disassembly steps of the torque wrench

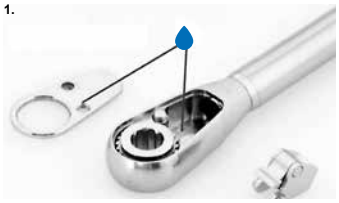
1.

2.

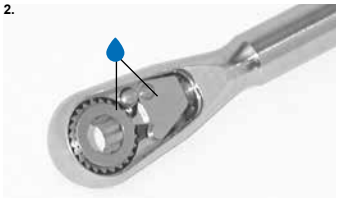
3.

fig. E. Torque wrench assembly steps and parts to be lubricated

1.

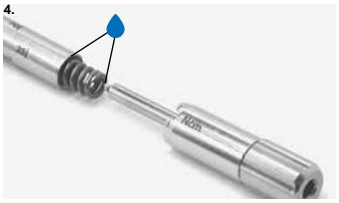


2.



3.

4.



9. REFERENCE STANDARDS

The trays and surgical components are designed and manufactured in accordance with the most recent directives and harmonized standards regarding the materials used, production processes, information supplied and packaging.

10. DISPOSAL PROCEDURES

If used, dispose of the trays and surgical accessories as biological waste, according to the local regulations.

11. DATE AND VALIDITY OF THESE USER’S INSTRUCTIONS

These user’s instructions are valid and effective from May 2023.

KEY OF THE SYMBOLS USED

The Symbols glossary is available at:
http://www.sweden-martinainc.com/en_us/ifu/

Manufacturer’s details

The Manufacturer of the medical devices is:

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