

Surgical kits

The Sweden & Martina surgical kits contain the instruments for the surgical and prosthetic procedures.

The instrument tray is made in autoclavable Radel plastic and offers simplicity and immediacy for the correct sequence of the instruments required, marked with a system of colour codes that follow the most suitable surgical procedures for the various implant systems. Descriptions of these instruments are indicated on the tray, allowing users to easily identify all instruments and to replace them in the correct position after cleansing and sterilization procedures.

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

a. Point of use

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

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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. Tray lids and grommets should not be disassembled during cleaning or damage to the device may occur.
2. To disassemble the Tray, remove all tools and accessories, lift out inner tray that holds all the tools
3. Reassemble after cleaning.

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. Instruments that are designed to be disassembled should be disassembled prior to cleaning. Instruments that do not disassemble may require additional soaking.
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 DI 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 DI 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 Enzymatic 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 deionized 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 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 ambient DI 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 DI water (or equivalent).
3. Dry the Instruments using a clean non-linting cloth.

Give medical and surgical instruments a final rinse in distilled or deionized water.

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 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 following flow chart summarizes the cleaning and sterilization steps.

