Swemac

Swemac Reprocessing Instructions

Cleaning, Sterilization, Inspection and Maintenance of Swemac re-usable medical devices

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Purpose

These instructions were developed to comply with the requirements of ISO 17664 and are intended to assist healthcare professionals in establishing a safe handling routine and an effective cleaning and sterilization process for Swemac reusable surgical instruments and non-sterile single use implants. Swemac Innovation AB has validated and demonstrated the processes described in these instructions to be effective.

Other processing methods may be equally suitable, however, they must be validated by the healthcare facility. If conflicting or more stringent national cleaning and sterilization requirements exist, particularly in respect of Creutzfeldt-Jakob disease related procedures for inactivation of prions, these shall prevail over Swemac's recommendations.

This reprocessing guide complements the instructions given in the surgical technique brochure, the instructions for use leaflet and, if applicable, the assembly/disassembly instructions for multi-component instruments.

All instructions are available electronically and can be downloaded from the Swemac resource library on http://download.swemac.com/

Hard copies are provided on request within 7 days.

Scope

This (re)processing guide provides information about the care, cleaning, disinfection, and sterilization of **reusable surgical instruments** manufactured by Swemac Innovation AB. This information is also applicable to Swemac **single-use implants which are supplied in a non-sterile condition** and must be sterilized before use.

Symbols on the product label (ISO 15223-1)

Non-sterile

Packaged devices marked as being non-sterile are supplied in a non-sterile condition and must be disinfected and sterilized before use.

Do not reuse

The device is for single use only. A device marked as single use may be re-sterilized, if it has not been used in a surgical procedure and has not been in contact with blood, bone, tissue, or other body fluids in any way (e.g. screws on a screw rack in the tray). This is also applicable to implants in sterile packaging with a broken sterile barrier, e.g. if a wrong size was selected and identified before the application so that the implant was not exposed to any of the human substances mentioned above.

Do not re-sterilize

Single-use devices that are not allowed to be re-sterilized due to product characteristics. These devices must be discarded after use or when the sterile barrier is broken.

Terms and abbreviations

Term	Description
cfu/ml	Colony forming units per millilitre
CSSD	Central Sterile Supply Department
EU/ml	Endotoxin units per millilitre
OR	Operating room

Precautions

- CSSD staff should use suitable protective clothing and equipment at all times.
- During surgery, instruments become contaminated from blood, tissue, bone fragments and marrow. The instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. All health care professionals handling these instruments should be familiar with general precautions for preventing injuries caused by sharp features and cutting edges.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers solution.
- For cleaning or disinfecting medical devices only specifically formulated cleaning agents and/or disinfectants (detergents) should be used.
- CSSD staff should strictly adhere to the instructions provided by the cleaning agent manufacturer for correct handling and use of the product. The guidance concentrations and times for device immersion in the cleaning solutions and/or disinfectants given by the detergent manufacturers shall be observed. If these concentrations and times are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.
- The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing medical devices should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes (according to the pharmacopeia's) with less than 10 CFU/ml and 0.25 EU/ml is highly recommended. Mineral residues from hard water as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination.
- Swemac trays are only intended for transport, sterilization and storage of medical devices, not for cleaning and disinfection. The devices must be removed from the tray for adequate cleaning results.

Processing Instructions

The following steps are involved in the processing of medical devices for initial use or reuse:

- Handling and care at point of use, typically the OR
- Transport to the processing area
- Manual Pre-cleaning
- Automated cleaning and disinfection in a washer/disinfector[1]
- Inspection and Maintenance
- Packaging
- Sterilization
- Storage before use
- Return of loaner kit to Swemac

[1] *Swemac has not validated and does not recommend a manual cleaning and disinfection process. The automated cleaning process is more reproducible and therefore more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used.*

Handling and care at point of use

Immediately after the surgical procedure (within a maximum of 2 hours postoperatively) remove body fluids, tissue and other gross soil from instruments with disposable, absorbing non-shedding paper wipes. Rinse under running water. Place instruments in an aldehyde-free disinfectant bath or distilled water. Alternatively, the instruments can be prevented from drying by placing them on a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions or other precleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be strictly followed.

Transport to the processing area

Used instruments should be transported to the CSSD in closed or covered containers to avoid drying of remaining soil. To prevent mechanical damage, do not mix heavy devices with delicate ones. Handle contaminated instruments with care and pay particular attention to cutting edges.

Manual Pre-cleaning

1. If applicable, disassemble multi-component instruments according to the instructions provided at http://download.swemac.com/. Take care not to lose screws, thumbwheels and other small components. Remove any gross soil that has not been wiped off in the OR right after use.

2. Rinse under running tap water and brush with soft bristle nylon brush. Brush cannulated devices with bottle brush.

3. Immerse and soak in a fresh cleaning solution using a cleaning agent with proven efficacy intended for manual cleaning with a concentration, temperature, and soaking time not less than specified in the detergent manufacturer´s instructions, but with a temperature not exceeding 50 °C. Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended.

The cleaning bath or vessel should be large enough to allow complete immersion of the instruments. Ensure that all surfaces are thoroughly wetted and that no air is trapped in hollow features. Use a syringe to inject a jet of solution into cannulations etc. Use soft and firm nylon brushes and bottle brushes. Ensure that the brush passes the whole length of each cannulation and move it back and forth several times. Pay particular attention to rough surfaces and recesses which the brush might not reach.

Brush vigorously and operate all moving parts. Make sure that moving parts such as AO/ASIF quick couplings are pulled back and that the area underneath is also cleaned. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches. Rinse under running water. Use syringes for rinsing cannulations. Inspect the instruments, repeat cleaning, allow to drain on absorbent paper or transfer immediately to cleaning in a washer/disinfector.

Caution: Never use metal brushes or steel wool for cleaning.

Automated cleaning and disinfection in a washer/disinfector

1. Load the devices into the automatic washer/disinfector. Connect any device lumens to the rinsing ports of the washer/disinfector if applicable. If no direct connection is possible, locate the cannulations on the injector jets or in the injector sleeves of the injector basket allowing water and disinfectant to drain completely.
2. Arrange the products in a way that articulating devices are open, cannulations are not in a horizontal position and blind holes incline downwards to assist drainage. Multi-component instruments should already have been disassembled for the pre-cleaning step. If they we reassembled to prevent loss of small parts, disassemble the instruments again as far as possible and place the components in the washer/disinfector.
3. Recommended cycle parameters for automated cleaning
   - 2 minutes cold prewash
   - 5 minutes[2] detergent wash
   - rinsing with cold deionized water

   Make sure that suitable water for rinsing is used (e.g. aqua purificata/aqua valde purificata) and that the air used for drying is filtered.

   [2] *Time and dosing depend on the degree of soiling, for further instructions see manufacturer's instructions for use of the detergent.*

4. A low or high level of disinfection may be used as part of the washer/disinfection cycle. However all Swemac reusable devices must be sterilized prior to use.

Note: Swemac's reusable devices are compatible with a disinfection cycle of A_0-value > 3000.

Caution: As chemical disinfection bears the risk of leaving residual disinfectant on instruments, it is not recommended. The application of rinsing aids is also not recommended, due to the danger of remnants.

5. After program is complete, remove the instruments from the washer/disinfector. Visually inspect each device for remaining soil and dryness.

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector.

A washer/disinfector with approved efficacy and validation according to ISO 15883 should be used.

When choosing cleaning agents and disinfectants, make sure that they do not contain the following:

- organic, mineral and oxidizing acids
- stronger alkaline solutions (pH > 11 not permissible, mildly alkaline detergents recommended)
- organic solvents (alcohol, acetone, etc.), benzine
- halogenated hydrocarbons, chlorine, iodine
- ammonia

Inspection and Maintenance

Before preparing for sterilization, all medical devices should be inspected for remaining soil and dryness. Visually check all parts of the devices for soil and/or corrosion. Particular attention should be paid to soil traps in recessed features such as holes and cannulations, mating surfaces, hinges, flexible shafts or under retracted AO couplings. If soil remains, repeat the cleaning process including the precleaning step.

Remaining wetness may be removed with medical grade compressed air, clean and lint-free single use wipes, if required supplemented by post-drying in a clean area for up to 2 hours, or by heating in an oven below 110°C.

Swemac does not specify the maximum number of uses appropriate for re-usable medical devices, because the useful life of these devices depends on many factors including the nature and duration of use, as well as handling, storage and transport of instruments. Careful inspection and functional testing of the device after cleaning and disinfection and before use is the best method of determining the end of serviceable life of the device. Instruments showing any signs of corrosion, damaged surfaces, chips and contamination must be discarded or returned to Swemac.

Assemble multi-component instruments for functional testing. Special attention should be paid to areas such as cutting edges, tips, joints, locks, ratchets and all movable parts. Instruments that show wear, corrosion, deformation, porosity or other damage must be replaced. Cutting edges should be checked for sharpness and mating devices for proper assembly.

Medical devices with moving parts should be operated to check correct operation. A medical grade lubricating oil suitable for steam sterilization can be applied as required. The straightness of rotating instruments such as multiple use drill bits or reamers should be verified by simply rolling them on a flat surface.

Make sure that instruments intended to be impacted are not notched to the extent that they malfunction or that burrs have been produced that could damage tissues or surgical gloves.

Packaging

The cleaned, disinfected and inspected medical devices should be placed in an assembled state in their designated brackets in each instrument tray.

The tray should be double wrapped. Ensure that the wrap is large enough to accommodate the device without stressing the seals or tearing the wrap.

The packaging for the medical devices that will be terminally sterilized should fulfil the following requirements:

- ISO 11607
- ANSI/AAMI ST79
- Suitable for steam sterilization
- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- Grade appropriate for weight of instrument and implant tray

In addition to the commonly used double wrap sterilization method, rigid sterilization containers (e.g. Aesculap containers) may be used for the same purpose to sterilize any reusable medical device supplied by Swemac. It is the hospital´s responsibility to validate the appropriate drying time with the sterilization equipment used. For the use of rigid sterilization containers please consult the instructions for use provided by the manufacturer.

The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a way that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

Sterilization

Swemac has validated the sterilization parameters to provide a 10^{-6} sterility assurance level (SAL) and recommends them for sterilization of Swemac devices.

Note: The sterile validation is only valid when all instruments are placed in their designated brackets in the instrument tray. Optional instruments or devices which are not manufactured and/or distributed by Swemac should not be added to a preconfigured instrument tray.

Moist heat/steam sterilization with fractional forced air removal is the recommended method for all Swemac reusable devices.

Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument trays in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

Caution: Neither *Gravity displacement Steam* or *Immediate Use Steam Sterilization* (Flash) cycles are recommended.

Method	Moist heat sterilization according to ISO 17665		
Cycle	Saturated steam with fractional forced air removal		
	United States Recommended Parameters		**European** Recommended Parameters
Exposure time*	min 4 minutes	or	min 3 minutes
Temperature	132°C (270°F)		134°C (273°F)
Drying time**	Recommended: minimum 30 minutes in chamber		
Stand-In time***	Recommended: minimum 30 minutes in chamber		

*) **Exposure time:** Period for which the load and entire chamber is maintained at the sterilization temperature.

) **Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases.

Because drying time varies due to load configuration, wrapping method, and wrapping material, the healthcare facility should verify the appropriate drying time, with the sterilization equipment used. The addition of a Stand-In time can be used.

***) **Stand-In time:** Period after the sterilization cycle is finished but the sterilized goods are left in the closed chamber.

Note: The validated exposure time shown above can be extended to 18 minutes (at 134°C) to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. where problem with TSE-contamination exists. Swemac medical devices are able to sustain such sterilization cycles, however instruments should be expected to have reduced functional life.

Caution: Swemac does not recommend the use of Ethylene oxide or gas plasma sterilization methods to be applied for sterilizing Swemac products.

Final responsibility for achieving sterility using the equipment and processes of the healthcare facility with the parameters recommended by Swemac lies with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

Storage before use

After sterilization, please store the medical devices in the sterilization packaging in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

The shelf life depends on the sterile barrier employed, storage manner, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by each healthcare facility.

Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized. If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set be re-sterilized.

Return of loaner kit to Swemac

Any product returns may only be sent to Swemac after completed and clearly evident disinfection/sterilization (appropriate packaging with decontamination certificate). The relevant hygiene and facility regulations must be observed. If no proof of cleaning/sterilization is included, the cost of proper cleaning will be charged to the healthcare facility.

Cleaning and Sterilization Validation Information

Detergent	Neodisher Mediclean forte
Note: The manufacturer's instructions were followed for use of the detergent **Note:** Suitability of alternative agents should be checked by the reference to the manufacturer's information and/or testing.	
Washer-Disinfector	Miele Professional G 7836 CD 5 min cleaning with 55°C and 0.5% detergent
Sterilization Accessories	Bromeda Amcor Flexibles
Steam Sterilizer	Selectomat HP 666-1HR (MMM)
Brushes	Insitumed GmbH (various sizes)

As a large variety of cleaning agents and disinfectants exists around the globe and not all products may be available everywhere, Swemac does not recommend any specific brand.

References

Identification	Title
EN 285	Sterilization - Steam sterilizers - Large sterilizers
ISO 15883-1	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
ISO 15883-2	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
EN ISO 11607-1	Packaging for terminally sterilized medical devices; Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14937	Sterilization of health care products - general criteria for characterization of a sterilizing agent and development, validation and routine control of a sterilization process
EN ISO 17664	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
EN ISO 17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
AAMI TIR 12	Designing, testing, and labelling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR 30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
AAMI TIR 34	Water for reprocessing of medical devices
ANSI/AAMI ST 79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
FDA Guidance Reprocessing	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling - Guidance for Industry and Food and Drug Administration Staff – published June 09, 2017

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