Recommendations for cleaning, disinfection and sterilization of orthopaedic instruments and devices from Swemac.

This document is intended as guidance for decontamination and sterilization for medical devices from Swemac. These instructions apply to all instruments that are sold by Swemac for reuse. These instructions also apply to single use devices that are delivered non-sterile. The methods have been developed with standard equipment and in accordance to applicable standards common for hospitals worldwide.
Recommended cleaning, disinfection and sterilization instructions

Cleaning is the single most important step in preparing a device prior to use. Effective cleaning must be carried out to achieve proper disinfection/sterilization. Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. Also, thorough rinsing is important for the removal of any residual cleaning agents from the medical devices.

The purpose of cleaning is to remove all adherent visible soil and to reduce the number of particulates, microorganisms, and pyrogens. The recommended cleaning instructions in this document include both manual and automatic washing/disinfection procedures.
Cleaning, disinfection and sterilization instructions

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The following orthopedic products are applicable:
- Re-sterilization of reusable instruments
- Implants delivered non-sterile
- Reusable instruments delivered non-sterile

To the attention of the operating doctor and surgical, cleaning personnel.

1. Cleaning and disinfection

1.1 Processing (cleaning, disinfection and sterilization)

All implants and instruments delivered non-sterile have to be cleaned, disinfected and sterilized prior to use. All non-sterile implants must be processed in a validated cleaning and disinfection process after they have been removed from the protective packaging. Use scissors to open the PE-foil packaging to avoid leavings of plastic on the product. An effective cleaning and disinfection is a vital requirement for an effective sterilization of the implants and instruments.

If implants had already been in contact with patients or they had been contaminated with blood or other bodily fluids, it is not allowed to reuse them.

The user is responsible to ensure that implants and instruments are sterile prior to use. Cleaning shall be performed in a validated cleaning process in accordance to ISO 15883. Sterilization and re-sterilization shall be performed in accordance to ISO 17665.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor’s practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions. Please pay attention to the specific product- and process requirements in case of choosing the manual cleaning and disinfection process.

2. Cleaning and disinfection

If possible, an automated procedure (disinfector) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of a ultrasonic bath – should only be used if an automated procedure is not available. In this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered. If a manual cleaning and disinfection process is used a vital that a thorough inspection is conducted to ensure that suitable result have been achieved. The process shall be validated.

2.1 Pre-treatment for instruments

Remove coarse impurities of the instruments directly after application (within a maximum of 2 h after use). For this use only running water or a disinfector solution. The disinfector should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA approval or CE marking), be suitable for the disinfection of instruments and be compatible with the instruments (see chapter Material resistance). Lay instruments down with care to avoid damages. Do not put instruments in physiological saline solution as a longer contact could create corrosion. For manual removal of impurities only a soft brush or a clean soft cloth has to be used, in no case metal brushes or steel wool.

Please consider, that the disinfectant used in the pre-treatment step serves only the personal’s safety and cannot under any circumstances replace the disinfection step in the validated cleaning process.

Pre-treatment for implants

Implants which already had contact with patients should not be re-used.

2.2. Automated cleaning and disinfection (Disinfector/Washer-Disinfector)

Pay attention to following points during selection of the disinfector:
- Fundamentally approved efficiency of the disinfector (for example CE marking according to EN ISO 15883 or DGHM or FDA approval).
- Possibility for an approved program for thermal disinfection (Av: value > 3000 or – in case of older devices - at least 5 min at 90 °C, in case of chemical disinfection danger of remnents of the disinfectant on the instruments).
- Fundamental suitability of the program for instruments as well a sufficient rinsing steps in the program.
- Postrinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water.
- Only use of filtered air for drying.
- Periodical maintenance and check/calibration of the disinfector.
- Instruments with joints shall be layed down in open state.
- Instruments with hollows or cannulated instruments have to be thoroughly rinsed inside.

Standard 134 | Prion 134 | Standard 121
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134°C (273°F) for 3 minutes* | 134°C (273°F) for 18 minutes* | 121°C (250°F) for 20 minutes*

*These times does not include the air removal, penetration or drying times.

Consult the manufacturer of the sterilization equipment for instruction on loading and configuration parameters. Flash sterilization is not recommended. Flash sterilization is only allowed in a case of emergency and shall be preformed in accordance to ANSI/AAMI ST37: 1996 Flash Sterilization- Steam Sterilization of Patient Care Items for Immediate Use.
Cleaning, disinfection and sterilization instructions

Pay attention to following points during selection of the cleaning detergent:
- Fundamental suitability for the cleaning of implants to be made of metal or plastic material and of instruments to be made of steel or plastic material.
- Additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA approval or CE marking) compatible to the used cleaning detergent.
- Compatibility of the used detergents with the instruments (see chapter Material resistance).

Pay attention to the instructions of the detergent manufacturers regarding concentration and soaking time.

2.3 Procedure for implants:

   Note! Implants which have had contact with patient are not allowed to be re-sterilized.

   1. Place the implants in the disinfector. Make sure that the implants do not have contact with each other.
   2. Start the program.
   3. Remove the implants from the disinfector after end of the program.
   4. Check and package the implants immediately after the removal (see chapters Control, Maintenance and Packaging if necessary after additional post-drying at a clean place).

Procedure for instruments:

   1. Disassemble the instruments as far as possible.
   2. Transfer the disassembled instruments in the disinfector. Make sure that the implants do not have contact with each other.
   3. Start the program.
   4. Remove the instruments of the disinfector after end of the program.
   5. Canulated instruments must be controlled thoroughly to ensure sufficient cleaning has been achieved.
   6. Check and package the implants immediately after the removal (see chapters Control, Maintenance and Packaging if necessary after additional post-drying at a clean place).

3. Manual cleaning and disinfection

Pay attention to following points during selection of the cleaning and disinfection detergents:
- Fundamental suitability for cleaning and disinfection of metal implants and instruments made of metal or plastic material.
- In case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development).
- Application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA approval or CE marking) compatible with the used cleaning detergent.
- Compatibility of the used detergents with the implants and instruments (see chapter Material resistance).

Combined cleaning/disinfection detergents should not be used.

Pay attention to the instructions of the detergent manufacturers regarding concentration and soaking time. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and filtered air for drying, respectively.

Manual cleaning:

   1. Disassemble the instruments as far as possible.
   2. Soak the disassembled instruments for the given soaking time in the cleaning solution so that the instruments are sufficiently covered.
   3. Clean by ultrasonic treatment (3.1) or careful brushing with a soft brush.
   4. If the instrument is cannulated, clean it thoroughly with a soft brush.
   5. Remove the instruments of the cleaning solution and postrinse them at least three times with water.

   6. Dry and pack the instruments immediately after the removal.
   7. Check the instruments.

3.1 Ultrasonic – cleaning

Ultrasonic cleaning is part of the manual cleaning process as a mechanical help to remove existing contamination before or after the automatic process.

   1. Disassemble the instruments as far as possible.
   2. Soak the disassembled instruments for the given soaking time in the cleaning solution so that the instruments are sufficiently covered.
   3. Remove the instruments of the cleaning solution and postrinse them at least three times with water.

Basics for use of an ultrasonic-bath:
- The bath shall be filled in respect of the manufacturer codes.
- A suited detergent or combined cleaning/disinfection solution shall be added to the bath.
- Concentration, temperatures and exposure time in respect of the manufacturers codes shall be adapted to the cleaning detergent.
- Temperatures between 40 and 50°C help the cleaning effects, higher temperatures (> 50°C) may create blood traces.
- Instruments with hinges shall be treated in open state.

Post rinse the instruments carefully after the ultrasonic bath. You may use clean water (if possible de-salted), to remove traces of cleaning and disinfection detergents.

Manual disinfection

   1. Soak the disassembled instruments for the given soaking time in the disinfectant solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.
   2. Then, remove the instruments of the cleaning solution and post-rinse them at least three times with water.
   3. Dry and pack the instruments immediately after the removal (see 6 Packaging) if necessary after additional post-drying at a clean place).

For instruments with cannulations and inner spaces make sure that they are free inside and in full contact with the solution. Make sure that air bubbles can arise by moving and holding the instruments so that a complete contact of all surfaces is provided. Check the inner room of the instruments after cleaning and make sure that nothing blocks inside.

Instruments with blocking residues have to be treated again.

When a second treatment failed, exchange the instruments.

In case of higher contamination, a frequent changing of the solution is recommended to avoid corrosion.

The implementation of the manual cleaning process

   - Put dirty implants and instruments in (fully de-salted) water by adding a blood-chasing additive for at least 10 min.
   - Submerge and wash by hand in water with added neutralizing additive.
   - Brush with a soft nylon-brush under attention to hinges, threads, hollow parts and other hardly to attempt zones
   - Is the instrument perforated, brush the inside with a soft nylon-brush
   - Afterwards rinse carefully under clean, rinsing water
   - Dry carefully the inner- and outsideride to avoid corrosion. Use a clean, soft tissue. A clean air pression could be used to try inner holes.

4. Control

Check all implants and instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged implants or instruments (limitation of the numbers of re-use cycles see 9 Reusability). Still dirty instruments are to be cleaned and disinfected again.

After completion of washing and disinfection program remove all products from the machine so that by residual moisture no corrosion can attack

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5. Maintenance and remounting of instruments
Assemble disassembled instruments again (see specific instructions). If possible do not use instrument oils. In case of application use only instrument oils (white oil) admitted to steam sterilization considering the maximum possible sterilization temperature and with approved biocompatibility.

6. Packaging
Please insert the cleaned and disinfected instruments in the corresponding sterilization trays and pack them in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements:
- EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (temperature resistance up to at least 137 °C (279 °F), sufficient steam permeability),
- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage,
- Regular maintenance according to the instructions of the manufacturer (sterilization container).

7. Sterilization
The sterilization process shall be validated in accordance to ISO 17665. Do not use any other sterilization process than the one described in this document.

Steam sterilization
- Fractionated vacuum procedure or gravity procedure (with sufficient product drying),
- Steam sterilizer according EN 13080/EN 285,
- Validated according to EN ISO 17665
- Maximum sterilization temperature 134 °C (273 °F); plus tolerance according to EN ISO 17665,
- Sterilization time (exposure time at the sterilization temperature) at least 20 min at 121 °C (250 °F) or 3 min at 134 °C (273 °F).

The flash sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

8. Storage
Please store the instruments after sterilization in the sterilization packagings at a dry and dust-free place. Avoid direct sunlight. The products of Swemac Innovation AB are not restricted to a certain durability. The products shall not be stored for long periods as the package could be damaged. In these cases the safety of the products cannot be guaranteed.

9. Material resistance
Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:
- Organic, mineral, and oxidizing acids (minimum admitted pHValue5.5)
- Strong lyes (maximum admitted pH-value 8.5, neutral/enzymatic cleaner recommended)
- Organic solvents (for example: acetone, ether, alcohol, benzine)
- Oxidizing agents (for example: peroxide)
- Halogens (chlorine, jodine, bromine)
- Aromated, halogenated hydrocarbons

Please do not clean any instruments, sterilization trays, and sterilization containers by use of metal brushes or steel wool. Please do not expose any instruments, sterilization trays, and sterilization containers to temperatures higher than 137 °C (273 °F).

10. Reusability
Implants are single use products - once they had contact to patients or they had been contaminated, it is not allowed to reuse them. The Instruments can be reused – in case of adequate care and if they are undamaged. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

11. Handling returning products
Medical products are considered as "returns" – independent from their use or disuse – when they are sent back to the supplier.

Possible reasons for returns are: repairs, returns of borrowed instrument sets or product quality claims. All persons who have contact to these products during the returning process face a possible or real risk to get in contact to contaminated products and therefore a higher risk of infections. Swemac will only process returned products that has been cleaned and disinfected in a validated cleaning process. A completed Decontamination report which states that the product is disinfected shall accompany the returned product. Any product returned to Swemac without or with uncompleted Decontamination report will be considered as contaminated and will not be processed. Inability to present a completed Decontamination report up on the return of borrowed intruments or/and implants will result in a decontamination fee for cleaning and disinfection of the products. The Decontamination report can be requested from Swemac free of charge.

12. Warnings and precaution actions
- The correct choice of the implants is of initial importance. The therapeutic success is depending on the choice of the right implant. bone size and tissue situation limit the sizes and thickness of the implants. Please request the latest developments and improvements to your supplier.
- Implants are not regarded as full substitutes for the damaged bone functions. The operating doctor has to consider the nature and comprehensions of the medical capacity after the operation.
- For exact instruction how to place the implant please read the concerned op-instruction.
- Please use for clavicula fractures only our special clavicula plates.
- Please be carefully when anatomically preforming reco plates: all pressure on the plates and in different directions can maybe later cause a break of the plate as the material was stressed.
- Please avoid drilling on metal, this may cause a damage to the drill that cannot be repaired.

Implants which already had contact to patients are not allowed to be reused. Please dispose used implants correctly. Even when it seems undamaged, small defects or internal disturbances traces may occur, which could cause technical fatigues of the material.