Medacta International

RECOMMENDATIONS FOR CLEANING, DECONTAMINATION, AND STERILIZATION OF MEDACTA INTERNATIONAL ORTHOPEDIC DEVICES



This document provides cleaning, decontamination, and sterilization guidelines for medical devices of Medacta International SA provided nonsterile, based on the state-of-the-art for global healthcare facilities.

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1 PURPOSE

This guidance is intended to support healthcare facilities in the cleaning, decontamination, and sterilization of Medacta devices which are provided nonsterile. It is intended to be applied together with local processes validated by each healthcare facility and with methodologies and supporting equipment approved by local competent authorities.

2 DESCRIPTION

Medacta provides instrument cases which are perforated to enable effective processing. Cases do not provide a sterile barrier and must be used in conjunction with a supplementary sterilization wrap or mechanism to maintain sterility.

These parameters have been validated as being capable of preparing Medacta devices for use. It is the responsibility of each healthcare facility to ensure that processing is performed using appropriate equipment, materials, and trained personnel, with validation and monitoring conducting as appropriate. Any deviations from these guidelines should be evaluated for effectiveness and potential adverse effects. Locally sourced sterilization cases/containers, which are approved by the applicable competent authority and the responsible functions of the healthcare facility, may also be used. Should you require any further information, please contact your local Medacta sales representative.

3 WARNING

- Follow the instructions and warnings issued by the supplier of any cleaning agents and equipment used.
- Do not exceed 140°C [284°F] during processing steps.
- Detergents with a pH range between 6.0 and 11.9 may be used based on the users validated process; technical sheets and material resistance verification should be considered. Enzymatic detergents aid in the removal of organic soil such as blood. Detergents should be used at the concentration level recommended by the detergent manufacturer.
- The quality of water should be carefully considered for use in cleaning devices. Water hardness is a concern because deposits left on medical devices may result in ineffective processing. The use of deionized water will reduce the mineral deposits on the devices.
- Complex devices, such as those with tubes, hinges, retractable features, muted surfaces and textured surface finishes, require special attention during cleaning. Manual pre-cleaning of such a device is recommended before an automated cleaning process.
- Avoid exposure to hypochlorite solutions, as these will promote oxidation. Scratches or dents can result in breakage.
- Care should be taken to remove any debris, tissue, or bone fragments that may collect on the instrument.
- Devices supplied nonsterile must be cleaned and sterilized prior to each use.
- Implants or other devices supplied sterile should not be re-sterilized.
- Before cleaning, remove from original packaging.
- Clean, decontaminate and sterilize devices (providing evidence of the cycles) before returning to Medacta for replacement.
- It is the responsibility of the healthcare facility to ensure the efficacy of all processing, utilizing properly validated, calibrated, and maintained equipment/processes, together with documented training of involved personnel.

- NEVER USE ABRASIVE DEVICES for cleaning, such as steel wool/abrasive cleaning agents.
- If available, the use of cleaning tools (washing systems) in accordance with the most current version of ISO 15883 is recommended.
- Always avoid overloading ultrasonic cleaning tanks trays, washers, and autoclaves.
- Anodized aluminum, titanium and titanium alloys have a high resistance to corrosion but contact with some washing/disinfecting agents, with iodine-based solutions, may chemically damage surfaces.
- Most human body fluids and tissues present chlorine ions which may contribute to oxidation when adhered to device surfaces. Iodine and chlorine ions present in some disinfecting solutions is a common use cause of pitting corrosion. Minimize the contact with these ions and rinse out immediately using distilled water (advised conductivity < 0,5µS).
- Cleaning agents with a pH beyond the levels recommended above, may damage the passivation layer of metallic materials, contributing to corrosion, causing discoloration, or change other surface properties.
- If a device contacts other devices with damaged surfaces, and is wet via an electrolyte, corrosion may occur at the contact point. Oxidation products created by this process may easily be transferred to other devices in through the electrolyte.
- The sterilization processing of devices composed of different materials should ensure no physical contact between devices to avoid any galvanic corrosion. Devices presenting any signs of corrosion must be immediately isolated and replaced.
- Avoid prolonged exposure to saline to minimize the potential of corrosion.
- Diligently ensure the removal any detergent residue before proceeding with sterilization. The residuals may result in cross-contamination which could potentially affect patient safety.
- The reconditioning and/or reuse of devices identified as single use may cause adverse effects and must be avoided.
- Repeated processing has minimal effect on instruments intended to be reusable. In this case the end-of-life is normally determined by progressive wear due to normal use.
- Devices must be removed from metal/polymer trays before performing the manual and/or automated cleaning procedures. Instrument trays, cases and lids must be cleaned without any devices placed on them.
- Instruments intended to be reusable must be carefully inspected between uses to ensure proper functioning.
- Damaged instruments should be immediately replaced to prevent potential patient harm.
- Polymers used in Medacta instruments can be steam sterilized, but if polymer surfaces turn discolored, show signs of surface damage or delamination, or become distorted or visibly warped, they should be replaced.
- Polymers are particularly subject to potential damage in washer/sterilizers that operate at temperatures equal to or greater than 140°C [284°F] and/or use direct high-pressure water jets.
- Use conditioning and sterilization systems in accordance with the most current version of ISO 11607.

NOTE: Local competent authorities may impose specific sterilization cycles to minimize the risk of transmission of Creutzfeldt-Jakob disease, especially for devices which may come into direct contact with the Central Nervous System.

4 INSTRUCTIONS

4.1 POINT OF USE

- Follow recommended hospital point-of-use practices. Remove residual body fluids and tissue from instruments. Particular care should be taken with hollow instruments: they should be rinsed with cold water (avoid saline solutions) immediately after use. These practices include keeping devices moist after use to prevent soil from drying, as well as removing heavy soil from the surfaces, crevices, connecting surfaces, cannulas, joints and all other hard-to-clean design features.

4.2 CONTAINMENT AND TRANSPORTATION

- Exercise universal precautions when handling contaminated devices.
- Used devices must be transported to the central processing center in closed or covered containers to prevent the risk of unnecessary contamination.

4.3 PREPARATION FOR CLEANING

For instruments that require disassembly prior to cleaning, perform the disassembly as shown in the applicable instructions for that instrument and/or as advised by the local sales representative.

4.4 INSTRUCTION TO THOROUGHLY CLEAN THE DEVICE

Recommended cleaning methods have been validated by Medacta to current international guidelines, developed using standard equipment and practices common to healthcare facilities. Failure to thoroughly clean the device may prevent adequate sterilization which poses a risk of infection to patients and/or device malfunction.
Manual Cleaning specified in §4.4.2 should be performed if Automated Cleaning equipment is not available and is not possible carry out the operations described in point 2 of §4.4.1.

4.4.1 Automated Cleaning

1 - Prepare the **enzymatic detergent** according to the manufacturer's recommendations:

- Fully immerse the device in the prepared detergent and allow to soak for a minimum of five (5) minutes. Actuate any moveable components, such as hinged joints or spring-loaded features, to free trapped blood and debris. For moveable parts, actuate while cleaning the area. For devices with flexible shafts, bend or flex the instrument under the cleaning solution while brushing the flexible areas.
- Using an appropriate size soft-bristled brush, scrub the devices paying particular attention to crevices and other hard-to-reach areas. **Use a syringe or water jet to flush if needed**.
- Rinse the devices with deionized water at ambient temperature to rinse the detergent. Actuate any movable parts while rinsing and flush holes and hard-to-reach areas using a syringe or water jet.
- The above-described preliminary steps could be substituted with a different validated procedure (e.g. ultrasonic cleaning).

2 - Transfer the devices, disassembled and/or configured as specified by Medacta, into the washer's mesh baskets:

- Load the instruments so that hinges are open and cannulations and holes can drain; if possible, connect a water flush nozzle to cannulations.
- Place heavier instruments at the bottom of containers. Do not place heavy instruments on top of delicate instruments.
- For instruments with concave surfaces, such as curettes, place the concave surface facing downward to facilitate draining
- Set the processing cycle according to the parameters in Table 1 below:

Phase	Recirculation time (min.)	Water Temperature	Detergent type and concentration (if applicable)
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme wash	02:00	Hot tap water	Neutral pH Enzymatic detergent
Wash 1	02:00	65.0°C [150°F] (Set point)	Neutral pH Enzymatic detergent
Rinse 1	02:00	Hot tap water	N/A
Thermal Rinse	01:00	82.2°C [180°F]	N/A
Purified water	00:10	Hot critical water	N/A
Dry time*	07:00*	115°C [240°F]	N/A

*until dry

Table 1 - Instrument Cycle

- Start the processing cycle.

3 - Check the devices for visible soil. If soil is present, repeat cleaning from step 1 and inspect again.

4.4.2 Manual Cleaning

1 - Perform the preliminary step with enzymatic detergent, according to point 1 of § 4.4.1.

2 - Prepare an alkaline detergent according to the manufacturer's recommendations:

- Fully immerse the device in the prepared detergent and allow the device to soak for a minimum of five (5) minutes. Actuate any moveable mechanisms, such as hinged joints or spring-loaded features, to free trapped blood and debris. For moveable parts, actuate while cleaning the area. For devices with flexible shafts, bend or flex the instrument under the cleaning solution while brushing the flexible areas.
- Using an appropriate size soft-bristled brush, scrub the devices paying particular attention to crevices and other hard-to-reach areas. Use a syringe or water jet to flush if needed.
- Rinse the device with deionized water at ambient temperature to remove all detergent. Actuate any movable parts while rinsing and flush the holes and hard-to-reach areas using a syringe or water jet. Dry the device using a clean, non-linting soft cloth and/or filtered compressed air.

3 - Check the devices for visible soil (see § 4.4.3 Cleaning Inspection). If soil is present, repeat cleaning from step 1 and inspect again.

4.4.3 Cleaning Inspection

- Visually inspect each device under normal lighting, paying close attention to hard-to-reach areas.
- If visible soil remains, repeat cleaning procedure again.

4.5 DISINFECTION

- **Devices must be terminally sterilized prior to surgical use (See § 4.10 Sterilization).**

4.6 DRYING

- Dry internal areas with filtered compressed air until all devices and features are fully dry.
- Verify that instruments are completely dry after the cleaning step.

4.7 MAINTENANCE

- Between uses, lubricate moving parts with a water-soluble, medical grade, lubricant in accordance with the manufacturer's instructions.
- Do not use silicon-based lubricants.

4.8 INSPECTION AND FUNCTIONAL TESTING

- Visually inspect each device and check for damage and wear.
- Cutting edges should be free of nicks and have a continuous edge.
- Jaws and teeth should align properly.
- Moveable parts should have a smooth movement consistent with the intended use.
- Locking mechanisms should fasten securely and close easily.
- Long, thin devices should be free of bending and distortion.

4.9 STERILIZATION PREPARATION

- Devices should be dry before they proceed for sterilization.
- If desired, use trays to contain devices that are provided in sets.
- Single devices should be contained in an appropriate size medical grade sterilization pouch or wrap, ensuring not to stress or damage the seal.
- Biological or Chemical Indicators (BI or CI) used for monitoring the performance of sterilization processes should be placed in the middle racks within the trays, and utilized according to the BI or CI manufacturer's directions.
- Configuration 1 (see § 4.10 Sterilization): double wrap devices in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79 in force.
- Configuration 2 (see § 4.10 Sterilization): Medacta recommends Aesculap® rigid containers, distributed by Medacta, with non-reusable filters. Alternative rigid containers may be used if approved by local competent authorities, the responsible functions of the healthcare facility, and under locally validated conditions.
- Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.

4.10 STERILIZATION

- Use a validated, properly maintained, and calibrated steam sterilizer.
- **Do not directly stack trays during sterilization.**
- Effective steam sterilization can be achieved using the following minimum cycles that have been validated by Medacta® International SA under laboratory conditions:

Sterilizer Type	Pre-Vacuum	Gravity
Temperature	132°C [270°F]	Gravity Not Recommended
Full Cycle Time	4 minutes	
Minimum Dry Time	50 minutes	
Configuration 1	Double wrapped with 1-ply polypropylene wrap[i] and towel placed between tray and wrap	
Configuration 2	Aesculap® rigid containers, distributed by Medacta, with non-reusable filters (or alternative containers under local validation and competent authority approval)	

[i] Kimguard KC600 was used in the validation studies

The use of an alternative configuration is allowed; however, the materials utilized for the sterile barrier system must be FDA-cleared for the intended use and suitable for use in the specified sterilization processes, cycle parameters, and process limits.

- Sterilization validation to a sterility assurance level (SAL) of 10^{-6} was carried out using the biological indicator (BI) overkill method.

4.11 STORAGE

- Device cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture.
- Care must be taken in the handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped device cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer.
- The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the wrapping method.

5 HOSPITAL RESPONSIBILITIES FOR LOANED SETS

- Mishandling or inadequate protection of devices can diminish their life expectancy. Devices which no longer perform properly due to wear or damage should be returned to Medacta for replacement. Notify your Medacta representative of any device problem immediately.
- Loaned sets should undergo all steps of decontamination, cleaning, disinfection, inspection and terminal sterilization before being returned to Medacta. Documentation of decontamination should be provided with devices being returned.
- Missing or damaged devices from loaned sets should be brought to the attention of the operating room supervisor or the central processing department and to your Medacta representative to ensure that the next hospital will receive a complete set of devices in proper working condition.

6 REFERENCES

- AAMI TIR12, Designing, testing, and labeling reusable medical devices for re processing in health care facilities: A guide for medical device manufacturers.
- ANSI/AAMI ST108, Water for the processing of medical devices
- ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ANSI/AAMI ST77 Containment devices for reusable medical device sterilization - Annex A - Medical device integration with rigid sterilization container system.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and FDA Staff.
- ANSI/AAMI/ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.
- ANSI/AAMI/ISO 17665, Sterilization of Health Care Products - Moist Heat - Requirements for the development, validation and routine control of a sterilization process for medical devices.

Revision in force of the above-mentioned standards at time of process validation must be considered.

7 HOW TO CONTACT THE MANUFACTURER

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