Medacta International

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

This document was prepared to provide cleaning, decontaminating and sterilising instructions for the medical devices produced by Medacta® International SA and supplied unsterile. These instructions were developed using standard equipment and practices common to global health care facilities.

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1 PURPOSE

These instructions apply to the cleaning, decontaminating and sterilising of Medacta® International SA orthopaedic devices which are supplied in an unsterile conditon. These instructions are not applicable for any electronic devices. **These instructions do not apply to any Medacta® International SA orthopaedic devices that are supplied in a sterile condition.**

2 DESCRIPTION

Medacta® International SA's unsterile devices and cases are generally composed of metal alloys and/or polymeric materials. The cases may be multi-layered with various inserts to hold devices in place during handling and storage. The inserts may consist of trays, holders and silicone mats. The cases are perforated to allow steam to penetrate the various materials and components. The cases will allow sterilization of the contents to occur in a steam autoclave utilising a sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the users facility. **Cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.**

2.1 MATERIALS

Stainless Steels	Titanium Alloys	Cobalt-Chromium Alloys	Polymeric Materials

These instructions have been validated as being capable of preparing Medacta® International SA devices for use. It is the responsibility of the facility to ensure that the cleaning, decontaminating and sterilising is performed using appropriate equipment, materials and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviations by the facility from these instructions should be evaluated for effectiveness and potential adverse consequences. 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 8.0 should be used. The use of detergents with a pH outside this range, but not higher than 11, must be evaluated by means of technical sheets and material resistancy verification by the final user. 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 decontamination/sterilization. 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 required before an automated cleaning process.
- Avoid exposure to hypochlorite solutions, as these will promote oxidation.
- Scratches or dents can result in breakage.
- For instruments produced by another manufacturer, please refer to the manufacturer's instructions for use.
- Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.
- Devices supplied unsterile must be cleaned and sterilised prior to first use.
- Implants or other devices supplied sterile should not be resterilised.

- The devices provided unsterile must be cleaned and sterilized before use. Before cleaning, remove from original packaging. Clean devices before use and always when reconditioning (always following the prescriptions for single use devices). Clean, decontaminate and sterilize the devices (providing evidence of the cycles) when returning to Medacta® International SA for replacement. **It is the direct responsibility of the person that performs the conditioning to guarantee: the efficacy of the cycles, following a validation process respecting the guidelines in force (standard loads included); that the implants are properly validated, calibrated and preserved; relevant 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) following ISO 15883 in force is recommended.
- Always avoid overloading the ultrasound-tanks trays/washers/autoclave.
- Anodized aluminium, c. p. titanium and titanium alloys have a high resistance to corrosion but, contact with strong washing/disinfecting agents, with iodine-based solutions, may chemically damage antioxidant surfaces. Most of human body fluids and tissues present chlorine ions which may attract/favour oxidation, once adhered and dried on the devices surface. Iodine and chlorine ions present in some disinfecting solutions in common use cause pitting corrosion. Minimize the contact with these ions and rinse out immediately using distilled water (advised conductivity < 0,5µS). Excessive concentration of highly acid/alkaline cleaning agents may damage the passivation layer of metallic materials, favoring corrosion, causing discoloring of anodized particulars or changes to the surface properties. If a device comes into contact for with other devices whose surfaces are damaged and it becomes wet via an electrolyte, corrosion may occur on the surface parts of the contact point. Oxidation products created by this process may easily be transferred to other devices in contact through electrolites. If possible, the sterilization process of devices composed of different materials has to be carried on separately, in order to avoid any galvanic corrosion phenomenon. Devices presenting any signs of corrosion must be immediately isolated and replaced.
- Avoid prolonged exposure to saline to minimise the chance of corrosion.
- Pay the utmost attention to remove any detergent residue before packaging for sterilization. The residuals may move from the wrap to the device and vice versa causing possible reactions to the patient.

3.1 PROCESSING LIMITATIONS

- The reconditioning and/or clinical reuse of devices identified as single use may cause the failure of the implant and/or lethal consequences for the patient. For this reason single use devices **must not be reconditioned if they present blood or organic material/fluids pollution.**
- Repeated processing has minimal effect on instruments intended to be reusable. In this case the end-of-life is normally determined by wear and tear due to normal use.
- Devices must be removed from metal/polymer trays or any other packaging for manual and/or automated cleaning procedures. Do not clean devices while in polymer or metal trays. Instrument trays, cases and lids must be cleaned separately from devices.
- If instruments are intended to be reusable carefully inspect them between uses to ensure proper functioning.
- Damaged instruments should be notified to Medacta® immediately to prevent potential patient injury.
- Polymers used in Medacta® instrument sets can be sterilised using steam/moist heat. Polymeric materials have a limited life. If polymer surfaces turn “chalky”, show excessive surface damage (e.g. crazing or delamination), or if polymeric devices show excessive distortion or are visibly warped, they should be replaced. Notify your Medacta® representative if polymeric devices need to be replaced.
- The latest available polymers will not withstand conditions in washer/sterilisers that operate at temperatures equal to or greater than 140°C [284°F], and use live-stream jets as cleaning features. Severe surface damage to polymeric devices will occur under these conditions.
- Use conditioning and sterilization systems following ISO 11607 in force.

NOTE: Due to the number of different sterilization processes, the final user must validate the sterilization process parameters (e.g.: time, temperature) used on the equipment. Some countries impose sterilization cycles to minimise 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. These practices include keeping devices moist after use to prevent soil from drying and removing heavy soil from the surfaces, crevices, connecting surfaces, cannulas, joints and all other hard-to-clean design features. The latest available polymers will not withstand conditions in washer/sterilisers that operate at temperatures equal to or greater than 140°C [284°F], and use live-stream jets as cleaning features. Severe surface damage to polymeric devices will occur under these conditions.

4.2 CONTAINMENT AND TRANSPORTATION

- Exercise universal precautions when handling contaminated devices.
  For reusable instruments:
- Instruments should be cleaned within 30 minutes after use to minimise the potential of drying prior to cleaning.
- Used devices must be transported to the central supply in closed or covered containers to prevent the risk of unnecessary contamination.

4.3 PREPARATION FOR CLEANING

For instruments that require disassembling prior to cleaning, perform the disassembly as shown in the applicable disassembly instructions for that instrument.

4.4 CLEANING INSTRUCTIONS

Recommended cleaning methods have been validated by Medacta® International SA to current international guidelines for cleaning. These methods were developed using standard equipment and practices common to healthcare facilities.

4.4.1 Manual 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 mechanisms, such as hinged joints, box locks or spring-loaded features to free trapped blood and debris. If the components of the instrument can be retracted, retract or open the part 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 the holes and any difficult to reach areas.
- Rinse the devices with deionized water (DI) at ambient temperature to rinse the detergent. Actuate any movable parts while rinsing and flush the holes and difficult to reach areas using a syringe or water jet.

2 - Prepare a safe 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, box locks, or spring-leaded features, to free trapped blood and debris. If the components of the device can be retracted, retract or open that part whilst 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 the holes and any difficult to reach areas.**
- Rinse the device with deionized water (DI) at ambient temperature to rinse the detergent. Actuate any movable parts while rinsing and flush the holes and difficult to reach areas using a syringe or water jet.
- Dry the device using a clean soft cloth.

3 - Check device for visible soil (see § 4.4.3 Cleaning Inspection). Repeat cleaning from 1 if soil is visible and inspect again.

4.4.2 Automated Cleaning

1 - Prepare the enzymatic 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, box locks, or spring-loaded features, to free trapped blood and debris. If the components of the device can be retracted, retract or open that part 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 the holes and any difficult to reach areas.**
- Rinse the devices with deionized water (DI) at ambient temperature to rinse the detergent. Actuate any movable parts while rinsing and flush the holes and difficult to reach areas using a syringe or water jet.

2 - Transfer the device, disassembled and/or configured as specified by Medacta® International SA, into mesh baskets:

- Load instruments so that hinges are open and cannulations and holes can drain; possibly connect the nozzle of the water flush to the cannulation.
- 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 instrument with the concave surface facing downward to facilitate draining.
- Avoid contact between devices.
- Select the instrument cycle and ensure the following set of cycle parameters are correctly programmed:

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	Treated water	N/A
Dry time*	07:00*	115°C [240°F]	N/A

*until dry

Table 1 - Instrument Cycle

- Start the instrument cycle.

3 - Check devices for visible soil (see § 4.4.3 Cleaning Inspection). Repeat cleaning from 1 if soil is visible and inspect again.

4.4.3 Cleaning Inspection

- Visually inspect each device under normal lighting paying close attention to hard to reach areas.
- For difficult to view design features, apply 3% hydrogen peroxide. (Bubbling is indicative of the presence of blood).
  NOTE: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing.
- If visible soil remains, repeat cleaning procedure again.

4.5 DISINFECTION

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

4.6 DRYING

- Dry internal areas with filtered compressed air.
- Check that instruments are completely dry after the cleaning step.

4.7 MAINTENANCE

- Between uses, lubricate instruments moving parts with a water-soluble, medical grade, lubricant in accordance with the manufacturer's instructions.

- Do not use siliconic lubricants because:
  - They can cover bacteria.
  - They can prevent and/or avoid contact between steam and bacteria.
  - They are hard to be removed.
- Never lubricate implants.

4.8 INSPECTION AND FUNCTION TESTING

- Visually inspect the 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 smooth movement without excessive play.
- Locking mechanisms should fasten securely and close easily.
- Long, thin devices should be free of bending and distortion.

4.9 PACKAGING

- Devices should be dry before they are packaged for sterilization.
- If desired, use device trays to contain devices that are provided in sets.
- Single devices should be packaged in an appropriate size medical grade sterilization pouch or wrapped paying attention 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. They should be tested 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): use Aesculap® rigid containers, distributed by Medacta®, equipped with non-reusable filters.
- 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 steriliser.
- **Do not 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 **FDA cleared** 1-ply polypropylene wrap[i] and towel placed between tray and wrap	
Configuration 2	Aesculap® rigid containers, distributed by Medacta®, equipped with non-reusable filters	

[i] Kimguard KC600 was used in the validation studies

- 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 packaging method.

5 HOSPITAL RESPONSIBILITIES FOR MEDACTA® LOAN SETS

- Orthopaedic surgical devices generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Devices which no longer perform properly due to length of use, mishandling or improper care should be returned to Medacta® to be discarded. Notify your Medacta® representative of any device problem immediately.
- Loan 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 to Medacta®.
- Missing or damaged devices from loan sets should be brought to the attention of the operating room supervisor, to the director of the central supply department and to your Medacta® representative to ensure that the next hospital will receive a complete set of devices in perfect 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 ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ANSI/AAMI ST77:2013 - Containment devices for reusable medical device sterilization - Annex A - Medical device integration with rigid sterilization container system.
- FDA's 1996 "Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: FDA Reviewer Guidance" Office Of Device Evaluation
- ISO 17664, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilisable medical devices.
- ANSI/AAMI/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.

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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