Instructions for the disinfection, sterilization and maintenance of Adler Ortho® surgical instruments

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1. PURPOSE

The risk arising from exposure to biological agents has been an emerging phenomenon of interest in recent years, particularly in health care facilities where there is a concentration of infected individuals and contaminated materials that result in a high frequency of exposure to biological agents, both caregivers and patients.

The purpose of this document is to provide instructions for proper decontamination, cleaning and sterilization of reusable surgical instruments manufactured and/or distributed by Adler Ortho®.
This manual also provides instructions for proper maintenance and disassembly of the instruments to verify proper functionality.

The effectiveness of procedures depends on the interaction between equipment, operators, cleaning agents and procedures. The healthcare facility should ensure that the selected treatment procedures are safe and effective.

Other treatment methods, not outlined in this document, may also be suitable for reprocessing; however, these methods must be validated by the end user. In the event of conflict with national regulations regarding cleaning and sterilization, the latter will take precedence over these recommendations.

2. GLOSSARY

- ***Chemical***: a formulation of compounds for use in processing.
  Note: Reference is made to detergents, surfactants, rinsing agents, disinfectants, enzymatic cleaners, and sterilizers.

- ***Contaminated***: the state of an instrument that has been in contact with microorganisms.

- ***Decontamination***: the use of physical tools or chemicals to remove, inactivate, or destroy bloodborne pathogens present on a surface making the instrument safe for handling or disposal.

- ***Disinfection***: a process used to reduce the number of viable microorganisms on a surface to a previously specified level that is considered adequate to allow further handling or use.
  Note: Cleaning and disinfection are often performed in the same step.

- ***Processing/reprocessing***: an activity involving cleaning, disinfection, and sterilization that is necessary to prepare a medical device for its intended use.

- ***Cleaning***: the removal of contamination from an instrument to make it suitable for further processing.

- ***Manual cleaning***: cleaning without the use of an automated washing system or a washing/disinfecting system.

- ***Washer/disinfector system***: a machine that washes and disinfects medical devices and other items used in medical, dental, pharmaceutical, and veterinary practice.

- ***Sterile***: free of all living microorganisms.

- ***Sterilization***: validated process used to eliminate all forms of viable microorganisms from a device.
  Note: In a sterilization process, the nature of microbiological death is described by an exponential function.
  Therefore, the presence of microorganisms on a single item can be expressed in terms of probability. Although this probability can be reduced to a very small number, it can never be reduced to zero. This probability can be guaranteed for validated processes.

3. WARNINGS AND PRECAUTIONS

All personnel involved in handling contaminated or potentially contaminated medical devices should observe universal precautions. Use particular care when handling sharp or pointed instruments.

When handling contaminated or potentially contaminated materials, devices, and equipment, you must wear Personal Protective Equipment (PPE), which includes lab coat, face mask, goggles, gloves, and shoe covers.

Do not use metal brushes or abrasive sponges in manual cleaning procedures. These materials damage the surface and finish of instruments. Use nylon brushes and pipe cleaners with soft bristles.
During manual cleaning procedures, use cleaning agents with surfactants that are not excessively foamy to ensure that the instruments are visible in the cleaning solution. Manual brushing of instruments should be performed so that the brush and instrument are submerged in the cleaning solution to prevent the formation of aerosols and splashes that can spread contaminants. Cleaning agents should be rinsed completely and easily from device surfaces to prevent accumulation of cleaning agent residue.

Do not use saline and cleaning/disinfecting agents that contain aldehydes, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide, **as** they are corrosive.

Instruments **should not** be placed or immersed in **Ringer's solution.**

Do not use mineral oils or silicone lubricants because:
1. They coat microorganisms.
2. Prevent direct contact of the surface with steam.
3. Are difficult to remove.

Anti-scale agents containing morpholine should not be used in steam sterilization systems. These agents leave residues that can damage polymer instruments over time.

Decontamination procedures with very aggressive cleaning agents [e.g. sodium hydroxide (NaOH) or sodium hypochlorite (NaClO)] are not necessary and are not recommended for normal processing as they pose a risk of product deterioration. The sterilization parameters recommended in this document are not intended and are not indicated for prion inactivation.

4. PROCESSING INSTRUCTIONS

The preparation of medical devices for sterilization includes cleaning, and is broken down into several steps:

- **Decontamination**
- **Cleaning and rinsing**
- **Drying**
- **Inspection**
- **Packaging**
- **Sterilization**

4.1 Decontamination

It is an operation that precedes the actual cleaning of the device and has the purpose of removing most of the organic material present on its surface. The decontamination is carried out by immersing the devices in a solution containing chemical agents so that the organic material and its possible microbial load is reduced before the subsequent manipulation of the irons.

For the decontamination procedure to be effective, it is necessary that more complex instruments be disassembled or opened as far as possible prior to immersion, ensuring that the hollow structures are pervious.

After decontamination, the medical devices must be rinsed.

4.2 Cleaning and rinsing

The actual cleaning of medical devices aims to reduce by more than 90% the extent of microbial contamination and to remove residual organic material.
The latest scientific evidence shows that a good cleaning action leads to a significant reduction of the bacterial load, which is the key to successful sterilization.
The cleaning of medical devices is a very important procedure, since residues of organic substances, after an incorrect cleaning procedure, create a barrier against the sterilizing agent and prevent its action.

Following the decontamination step, proceed with the cleaning of surgical instruments. A manual cleaning step may be required prior to automated scrubbing using an iron washer.
When possible, use the **automated method**. The automated cleaning process is more reproducible and, therefore, more reliable and reduces staff exposure to contaminated devices and the cleaning agents used.

In the manual phase, use soft-bristled brushes to remove organic material.
It is necessary to renew the solution with each use.
Rinsing, following manual cleaning, mechanically removes residual organic material and all traces of detergent that may interact with sterilizing agents.

4.3 Drying

After rinsing, medical devices must be dried to avoid corrosion and because residual water may compromise the subsequent sterilization process.
If only manual cleansing and cleaning is used, absorbent paper should be used for drying.

4.4 Inspection

Inspect all reusable instruments before preparing them for sterilization. A visual inspection with the naked eye performed in good light is usually sufficient.
Visually inspect all parts of the devices for residues and/or signs of corrosion.
Particular attention should be paid to the following:

- Places where debris may become trapped, such as mating surfaces, hinges, flexible reamer stems.
- Elements with cavities.
- Components where debris may be fouled on the device, such as grooves on a drill bit near cutting edges and tooth sides on broaches and rasps.
- In addition, check that the cutting edges are sharp and not damaged.
- For devices that may be affected, check for damage that would cause malfunction or for burrs that would damage tissue or surgical gloves.

Functional checks must be performed in all cases:

- Check for proper mounting of devices to be coupled.
- Test instruments with moving components for proper function (medical lubricating oil suitable for steam sterilization may be used as needed).
- Ensure that rotating instruments, such as multi-purpose drill bits and reamers, are straight. To do this, simply try rolling the instrument on a flat surface.
- Check the integrity of the spiral element of flexible “instruments”.

4.5 Packaging

The purpose of packaging is to ensure that, after sterilization, the devices maintain that condition and are protected from contamination.

The adequacy of a packaging system lies not only in its characteristics but also in the way each package is sealed so that it can guarantee sterile conditions.

The material to be used for packaging must meet the following requirements:

- Allow the passage of air and steam.
- Provide an effective barrier against microorganisms in the surrounding environment.
- Surrounding environment to maintain sterility of the load until use.
- Resist bending and tearing due to handling of the load during and after the process.
- Conform to the shape of the device to be sterilized and not release fibers and particles.
- Provide a sterile presentation of the contents upon opening.

The instruments manufactured and distributed by Adler Ortho® must be placed in the appropriate baskets and positioned on the designated stands and spaces.

The baskets must then be packaged in the manner intended for sterilization.

4.6 Sterilization

The type of sterilization most commonly used in health care facilities is through moist heat in the form of steam, as steam is the safest, quickest, most economical and non-polluting sterilizing medium. If the steam is subjected to pressure, you can reach temperatures above 100 °C (212 °F), which are the sterilizing conditions of penetrable materials and surfaces exposed to the agent.
Steam sterilization is obtained through the combined intervention of three factors: PRESSURE, TEMPERATURE, TIME.

We recommend sterilization in steam autoclave (humid heat) with a pre-vacuum cycle (forced air removal).

The following are the recommended steam sterilization parameters:

USA

Steam Sterilization	
Temperature	132 °C (269.6 °F)
Exposure time	4 mins
Minimum Drying Time	60 mins
Cooling Time	45 mins

EU

Steam Sterilization	
Temperature	121 °C (249.8 °F)
Exposure Time	15-20 mins
Minimum Drying Time	30 mins
Cooling Time	30 mins

Autoclaves must be properly validated and maintained in accordance with applicable regulations.
The manufacturers' instructions on the operation and load configuration of the sterilization system must be strictly adhered to.

After sterilization, reusable instruments should be stored in the sterilization package in a dry place away from dust. The shelf life varies depending on the sterile barrier used, storage methods, environmental conditions, and handling methods. The maximum shelf life for reusable instruments sterilized before use should be defined by each healthcare facility.

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