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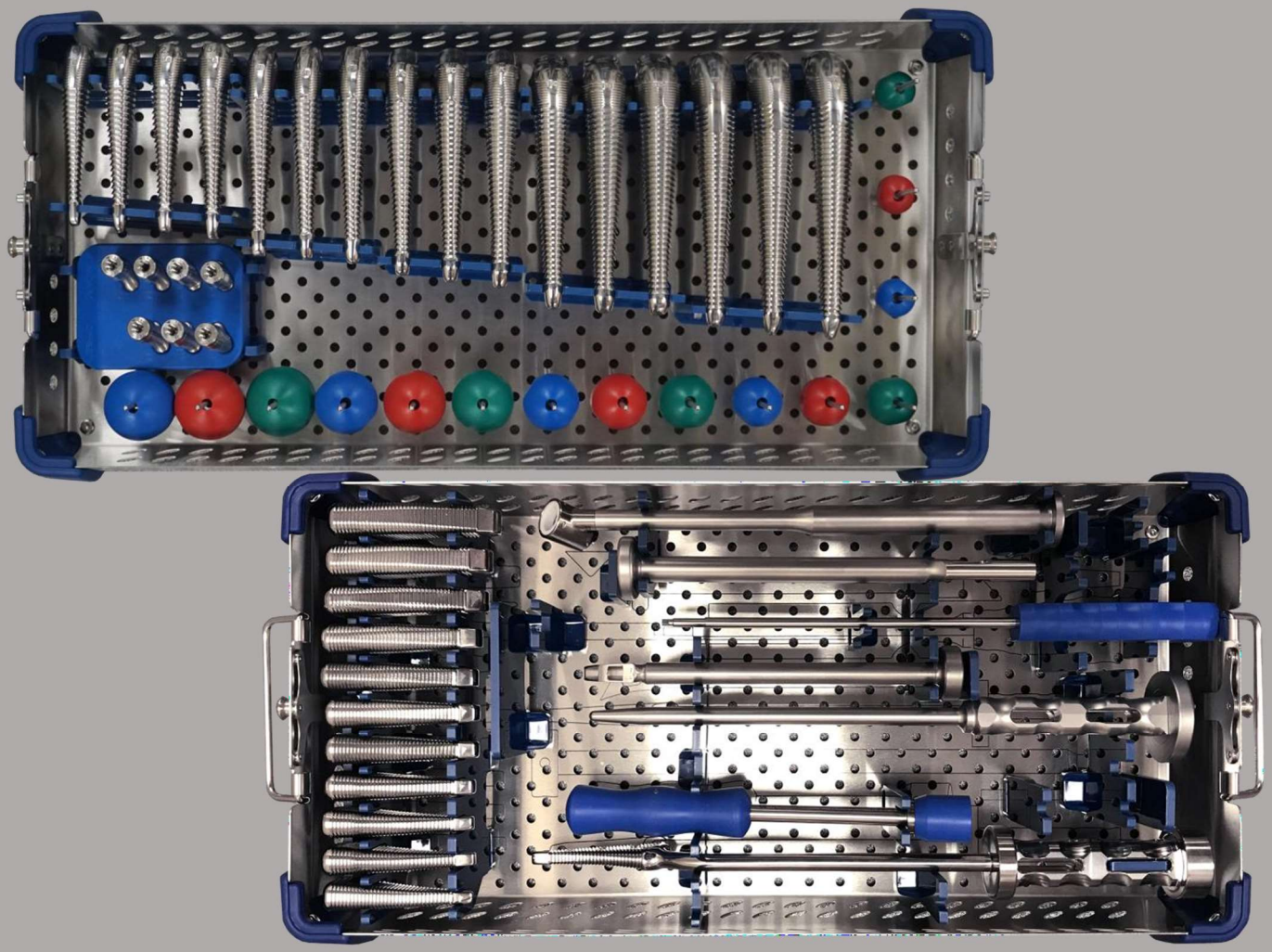
ORTHO



Manual for the disinfection, sterilisation and maintenance of Adler Ortho surgical instruments ®

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1. PURPOSE

Over the last few years, the risk deriving from exposure to biological agents has been the subject of growing interest, particularly in health care facilities where there is a concentration of infected individuals and contaminated materials leading to a high frequency of exposure to biological agents involving both care staff and patients.

The purpose of this document is to provide instructions for the correct decontamination, cleaning and sterilisation of reusable surgical instruments manufactured and/or distributed by Adler Ortho®.
This manual also provides instructions for the correct maintenance and disassembly of the instruments in order to make sure they are functioning properly. This set of activities is necessary in order to prepare medical devices (new or used) for surgical use.

1.1 Scope

Adler Ortho instrumentation includes devices conforming to the following classifications:

- class I and class IIa (in accordance with Legislative Decree no. 46 dated 24 February 1997 "Implementation of Directive 93/42/EEC concerning medical devices") used in Adler Ortho prosthesis implant procedures (Not applicable for the United States)

- class I, Ir and Class IIa (in accordance with Regulation (EU) 2017/745, not applicable for the United States)

- class I and class II medical devices (in accordance with US Federal Law).

The transport and distribution of instruments (new or used) to hospital facilities and users does not include checking and maintaining the sterilised or decontaminated condition, therefore users MUST perform the entire reprocessing procedure again.

Please follow these instructions during all stages of transport, cleaning, disinfection, sterilisation, use and storage in order to keep the instruments in good condition.

Alternative cleaning methods are not considered validated by the manufacturer. Alternative cleaning methods must be validated by users. The user must ensure that cleaning and disinfection processes are carried out in accordance with the instructions provided in this document.

2. GLOSSARY

- ***Chemicals***: a formulation of compounds to be used in processing.
  Note: reference is made to detergents, surfactants, rinsing substances, disinfectants, enzymatic cleaners and sterilisers.

- ***Contaminated***: the condition of an instrument which has been in contact with micro-organisms.

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

- ***Disinfection***: a process used to reduce the number of viable micro-organisms on a surface to a level specified in advance and regarded as adequate for further handling or use.
  Note: cleaning and disinfection are often performed during the same phase.

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

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

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

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

- ***Sterile***: devoid of any viable micro-organisms.

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

3. CAUTIONS AND PRECAUTIONS

All personnel involved in handling contaminated or potentially contaminated medical devices must observe universal precautions. Special care must be taken when handling sharp or pointed instruments.

When handling contaminated or potentially contaminated materials, devices and equipment, Personal Protective Equipment (PPE) must be worn, which includes gown, 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 the 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 instruments are visible in the cleaning solution. Manual brushing of instruments should be performed so that the brush and instrument are immersed in the cleaning solution to prevent the formation of aerosols and splashes that could spread contaminants. Cleaning agents must be fully and easily rinsed off from device surfaces to prevent the build-up of detergent residues.

Do not use saline solution and cleaning/disinfection agents containing aldehydes, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide, as they are corrosive.

The instruments **must not** be arranged or soaked in **Ringer solution.**

Do not use mineral oils or silicone lubricants because:
1. they are coated with micro-organisms;
2. they prevent direct contact of the surface with the steam
3. they are hard to remove.

Anti-scaling agents containing morpholine must not be used in steam sterilisation 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 carry the risk of product deterioration. The sterilisation parameters recommended in this document are not intended and are not indicated for prion inactivation.

4. TREATMENT INSTRUCTIONS

Instruments should be washed and disinfected as soon as possible after use to minimise the risk of infection (for medical personnel) and corrosion (for instruments).

Repeated reprocessing of instruments according to the instructions included in this document has a minimal impact on the life cycle of the instrument. The life cycle of the instrument is mainly influenced by wear and damage caused by surgical use.

Adler Ortho instruments are shipped clean, but NOT sterile. Clean, disinfect and sterilise the instruments. Adler Ortho does not recommend sterilisation of instruments with ethylene oxide (EtO), plasma gas or dry heat. Steam sterilisation (in an autoclave) is suitable for sterilisation of Adler Ortho instruments.

The preparation of medical devices for sterilisation includes cleaning in several steps:

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

4.1 Decontamination

This is an operation that precedes the actual cleaning of the device and aims to remove most of the organic material present on its surface. Decontamination is carried out by immersing the devices in a solution containing chemical agents so that the organic material and any microbial load is reduced before subsequent handling of the instruments.

For the decontamination procedure to be effective, more complex instruments must be disassembled or opened, as far as possible, before being immersed, making sure that the hollow structures are permeable.

After decontamination, the medical devices must be rinsed.

4.2 Cleaning and rinsing

The actual cleaning, or cleansing, of medical devices aims to reduce the extent of microbial contamination by more than 90% and to remove residual organic material.
The latest scientific evidence shows that good cleaning results in a significant reduction in bacterial load, which is the key to successful sterilisation.
The cleaning of medical devices is a very important procedure, since residual organic substances, after an incorrect cleaning procedure, will create a barrier to the sterilising agent and prevent it from functioning properly.

To clean Adler Ortho reusable devices, we recommend the use of enzymatic/disinfectant agents and detergents with a neutral pH or between 4.5 and 8.5.

Following the decontamination phase, proceed with the cleaning of surgical instruments. A manual cleaning phase may be necessary prior to automated cleaning by means of an instrument washer.
In the manual phase, use soft-bristle brushes to remove organic material.
It is necessary to renew the solution after each use.

Rinsing, following manual cleaning, mechanically removes residues of organic material and all traces of the detergent that could interact with the sterilising agents.
Softened tap water can be used for rinsing. For the final rinse, use purified water (obtained by ultra-filtration (UF), reverse osmosis (RO), deionisation (DI) (or equivalent methods) according to AAMI TIR 34) to remove mineral deposits on the instruments.
Boxes and instruments must be washed separately; instrument boxes must be cleaned, disinfected and sterilised following the same procedures used for the instruments themselves.

Whenever possible, use the **automatic method**. The automatic cleaning process is, to a greater extent, reproducible and therefore more reliable and reduces the exposure of personnel to the contaminated devices and detergents used.

Disinfection procedures must be carried out using an automated washer-disinfector validated according to the ISO 15883 series of standards with a standard cleaning cycle.

Only automated disinfection must be considered a validated method. No manual method has been validated by Adler Ortho. The disinfection phase must be performed using automated equipment.

4.3 Drying

After rinsing, the medical devices must be dried to avoid corrosion and because water residues can compromise the subsequent sterilisation process.
The drying phase can be performed in a hot air oven (between 120° and 140°) for 15 minutes.
In case of only manual cleansing and cleaning, use paper towels for drying.

4.4 Inspection

Before preparing them for sterilisation, inspect all reusable instruments. A visual inspection with the naked eye 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 can become trapped, such as coupled surfaces, hinges, flexible reamer stems.
- Parts with cavities or cannulated parts.
- Components where residues could be encrusted on the device, e.g. grooves of a drill bit near the cutting edges and tooth sides on broaches and rasps.
- Also check that the cutting edges are sharp and not damaged.
- For devices that may be affected, check for damage that may cause malfunction or for burrs that may damage tissue or surgical gloves.

Functional checks must be performed in all cases:

- Make sure the devices to be coupled are correctly fitted.
- Test instruments with moving parts to check that they function properly (water-soluble lubricating oil can be used - e.g.: Dr. Weigert neodisher - IP spray or equivalent lubricant - for medical use suitable for steam sterilisation as required).
- Make sure that rotating tools, such as multi-purpose drill bits and reamers, are straight. To do this, simply try rolling the tool on a flat surface.
- Check the integrity of the spiral element of "flexible" instruments.

It is also useful to check that the couplings between the instruments are working and that the movements are smooth. Check that there are no cracks or damage to the instruments that could affect their operation.

If cleaned instruments are not immediately sterilised, make sure that the components are perfectly dry and stored in a way that ensures microbial load limitation.
Instruments must be stored in their own dedicated containers, in a designated area with limited access, well ventilated and providing protection from dust, humidity, insects, vermin and temperature/humidity extremes Inadequate storage of instruments prior to sterilisation could result in recontamination and the exceeding of microbial load limits, rendering subsequent sterilisation ineffective.

4.5 Packaging

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

The adequacy of a packaging system lies not only in its characteristics but also in the way in which each package is sealed so that sterility conditions can be met.

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

- permit the flow of air and steam;
- form an effective barrier against microorganisms in the surrounding environment to keep the load sterile until use;
- resist bending and tearing due to load handling during and after the process;
- adapt to the shape of the device to be sterilised and not release fibres and particles;
- provide a sterile presentation of the contents when opened.

Prepare the packaging using the double-wrap method in accordance with the AAMI standard or an equivalent method.
Commercially available medical grade pouches or wrappers for steam sterilisation must be used to package individual instruments: check that the inner pouch is large enough to hold the instrument (without forcing the seals or damaging the packaging) and small enough to fit into a second pouch.

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

For the sterilisation process, trays and lidded containers must be wrapped according to the following alternatives in accordance with ISO 11607-1:

- standard wrappings for medical applications, adopting the double-wrap method in accordance with the AAMI standard or an equivalent method;
- approved sterilisation containers with lids featuring sterilisation seals.

Follow the sterilisation container manufacturer's instructions regarding the insertion and replacement of sterilisation container filters.

4.6 Sterilisation

Instruments supplied by Adler Ortho must be sterilised by steam sterilisation (autoclaving) validated according to the requirements of EN 285, the European Pharmacopoeia or ISO 17665-1/-2/-
3. Should the user choose another sterilisation method, the individual and/or the hospital department are responsible for the effectiveness of sterilisation and possible damage to Adler Ortho instruments. Ensure that your sterilisation facility is properly maintained and the process is validated.

Steam sterilisation is achieved through the combined intervention of three factors: PRESSURE, TEMPERATURE, TIME.

Steam autoclave sterilisation (moist heat) with a pre-vacuum cycle (forced air removal) is recommended.

Below are the minimum steam sterilisation parameters that have been validated to obtain a guaranteed level of sterility (SAL) 10^{-6}

Certified Cycle	
Cycle type	Pre-vacuum
Temperature	132 °C
Exposure temperature	4 minutes
Minimum drying time	60 minutes

4.7 Storage

After sterilisation, reusable instruments must be stored in the sterilisation package in a dry place and away from dust. Shelf life varies depending on the sterile barrier used, the method of storage, environmental conditions and handling. The maximum shelf life for reusable instruments sterilised before use must be defined by each healthcare facility.

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