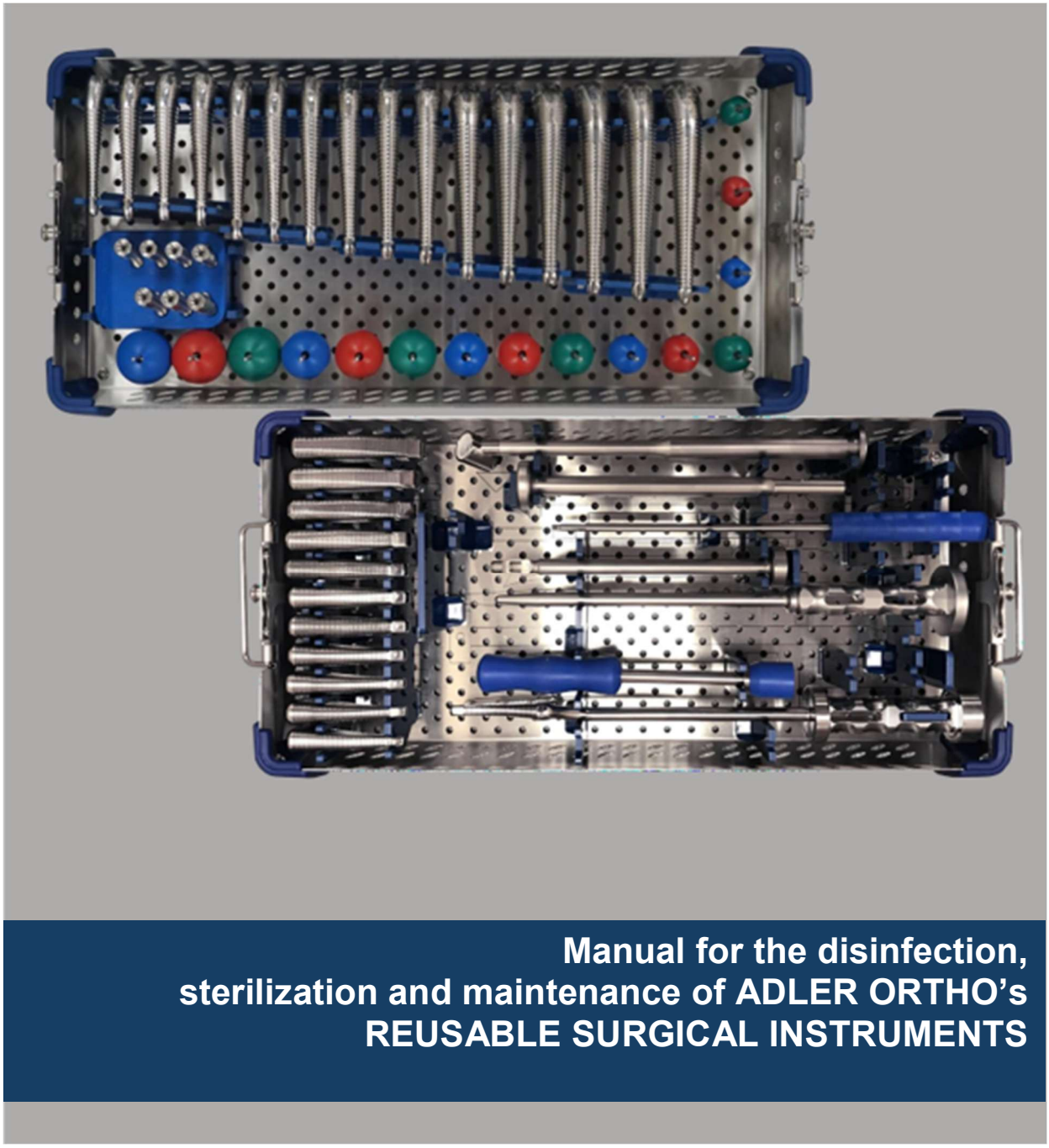
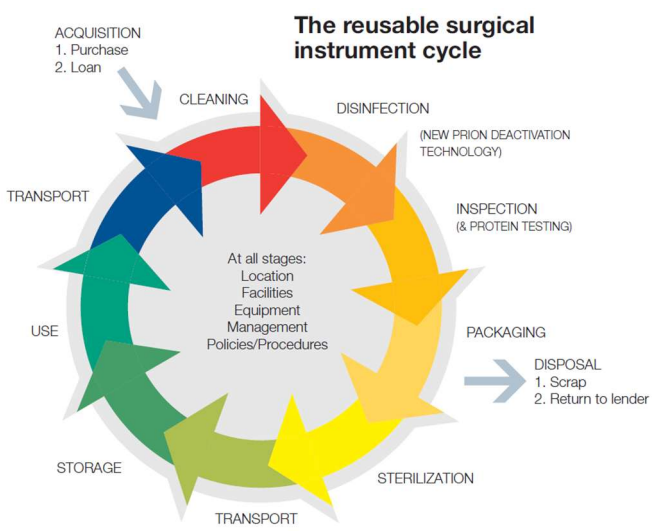


# Manual for the disinfection, sterilization and maintenance of ADLER ORTHO's REUSABLE SURGICAL INSTRUMENTS

# CONTENTS

# 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 decontamination, cleaning and sterilisation of reusable surgical instruments manufactured and/or distributed by Adler Ortho® as foressen in the **ISO 17664-1:2021**.

This manual also provides instructions for the correct maintenance and care of the instruments in order to make sure they are functioning properly.

Hospital staff, sterilisation centre operators and operating theatre personnel involved in the handling of reusable surgical instruments must be familiar with these instructions in order to ensure a safe and effective execution of the reprocessing procedures and in order to prevent possible damage or incorrect use/handling of the surgical instruments supplied by Adler Ortho.

As foreseen in the standard **ISO 17664-1:2021**, the treatment consists of the following steps:

1) Pre-treatment at the point of use prior to processing and preparation prior to cleaning;
2) Cleaning - Disinfection - Drying;
3) Inspection, maintenance;
4) Packaging;
5) Sterilization;
6) Storage;
7) Transport.

This set of activities is necessary in order to prepare medical devices (new or used) for surgical use and to improve outcomes in terms of:

- patient safety (minimizing risks to patients)
- clinical effectiveness improving instrument integrity
- infection and protein contamination prevention (reducing the risk of cross-infection and cross contamination).

Treatment of a medical device that requires cleaning followed by disinfection and/or sterilization ensures that the device is safe and effective for its intended use.

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

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.

**These instructions apply only to reusable surgical instruments supplied by Adler Ortho. Do not apply these instructions to sterile single-use medical devices.**

The instruments in the kit are not intended to be implanted.

Reusable instruments supplied non-sterile must be reprocessed following the guidelines provided in this document prior to use to ensure cleanliness, disinfection and sterility.

During orthopaedic surgery, instruments are in direct contact with body fluids and tissues. Instruments may become contaminated due to direct contact with body fluids and tissue. All reusable surgical instruments supplied by Adler Ortho can be effectively and safely decontaminated, cleaned, sterilized by applying the procedures described in this document.

This document is intended to assist health care professionals in the safe and effective handling of Adler Ortho reusable devices in order to prevent damage or misuse of reusable devices.

Effective handling ensures that the risk of transmission of infectious agents is minimized. Effective handling minimizes the risk of other negative effects on medical devices, e.g. corrosion or loss of functionality.

Cleaning is the first and most important step in making a used medical device safe for re-use. Failure to remove contaminants (e.g. residues, blood, tissue, microorganisms, detergents and lubricants) from the internal and external surfaces of medical devices may compromise any subsequent disinfection and/or sterilization process or the proper functioning of the medical device.

After cleaning, other factors may influence the safe and effective use of a medical device. For example, inspection and functional testing are necessary to ensure that a medical device does not pose a safety risk when in use.

The materials constituting the strumentation are known to withstand routine cleaning and sterilization. The materials have a proven resistance to multiple autoclaving and the most common chemical agents used as detergents/disinfectants.

It is prohibited to modify or alter the instruments. Instruments must not be used for practices other than those indicated by Adler Ortho. Surgical instruments subjected to excessive loading may be damaged.

Updated instructions for use on care, cleaning, disinfection and sterilization of the instrument kit and previous revisions are available on the website www.adlerortho.com.

If necessary, a hard copy of the instructions for use can be requested by sending an e-mail to info@adlerortho.com or novagenit@adlerortho.com or by making the request explicit at the time of ordering.

## 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).

# 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*.

- **Cleaning**: the removal of contamination (adherent soil e.g. blood, protein substances and other debris) from an instrument (surfaces, crevices, serrations, joints and lumen of a medical device) by a manual or authomated process to make it suitable for subsequent processing and safe handing.

- **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.

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

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

- **Sterile:** free from 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.*

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

# 3. CAUTIONS AND PRECAUTIONS

In order to avoid, minimise risks of infection, corrosion, loss of functionality, prior to and after each use the hospital is instructed in the following order to clean, disinfect, dry, inspect, sterilise the instruments using validated processes, cycles.

**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. Use latex free gloves during all instrument handling steps.

**Cleaning** (performed with detergent and water) is the first and most important step in making a used medical device safe for re-use. Failure to remove contaminants (e.g. residues, blood, tissue, microorganisms, detergents and lubricants) from the internal and external surfaces of medical devices may compromise any subsequent disinfection and/or sterilisation process or the proper functioning of the medical device.

Choose cleaning and disinfection products ensuring:

- that they are generally suitable for cleaning and disinfecting surgical instruments,
- that the detergents (and any disinfectants used) are suitable for ultrasonic application (no foaming),
- that the detergent and disinfectant are of proven effectiveness (e.g. DGHM or FDA certification, CE mark).

Only select detergents and disinfectants that do not contain the substances listed below:

- organic acids and oxidants
- strong bases (avoid using products with a pH value > 10.5; neutral or slightly alkaline detergents are recommended)
- do not use alkaline detergents for polishing points
- alcohols, ether, ketones, petrols
- oxidisers.

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 use of disinfectants and cleaning agents containing one or more of the following substances is not recommended for stainless steel: chlorine, oxalic acid, hydrogen peroxide ($H_2O_2$).

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. Potentially they are contaminated with micro-organisms;
2. they prevent direct contact of the surface with the steam
3. they are hard to remove leaving residues that can damage polymer instruments over time.

Avoid contact with objects or corrosive substances (e.g. strong acids, bases, solvents) that may alter the materials. Rinse with deionised/ultrapure water.

During cleaning, disinfection and automatic neutralisation, the dosage, temperature and duration of washing/disinfection instructions given by the manufacturer of the equipment used must be carefully and strictly followed.

After cleaning and disinfection it is recommended to **inspect (in terms of cleanliness and integrity)** the devices to ensure the safety and effectiveness of the medical device.

Prolonged use, misuse and neglect are the main causes of damage to surgical instruments.

To avoid impairing their proper functioning, they must be used with care.

There are no limitations or restrictions to consecutive cleaning, disinfection and sterilisation cycles if properly performed. **Repeated cleaning with appropriate products and repeated autoclaving do not compromise the characteristics, functionality and safety of the instruments. Instruments can be damaged if not used and handled correctly**.

If specific instrument has damaged tip on inspection, ask the manufacturer for a replacement. A damaged instrument could damage the associated implants and compromise the operation with which the instrument is used.

Use the instrument only for its intended purpose.

Adler Ortho disclaims any responsibility for this instrument or any part of it on which repairs and/or modifications have been performed or attempted.

# 4. TREATMENT INSTRUCTIONS

## 4.1. Pre-treatment

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).

Pre-treatment at the point of use before processing and preparation before cleaning.

Potential exposure of operators to biological agents starts with the collection of materials used as contaminated or potentially contaminated.

Procedure:

- Wear latex free gloves
- Place instruments in a rigid container preferably with side handles.

After use, the instruments should be immediately immersed for approximately 2 minutes in a chemical disinfectant of recognized efficacy before cleaning to prepare for sterilization.

Do not allow blood or debris to dry on the instruments.

Use running water or a disinfectant solution for this purpose. The disinfectant must have the following characteristics aldehyde-free (otherwise blood residues will be fixed), proven to be effective (e.g. DGHM or FDA certification, CE mark), suitable for disinfecting instruments and compatible with the material.

The aim of this pre-treatment is to reduce the presence of micro-organisms on the material to be treated both to guarantee greater protection for the operator and to facilitate cleaning operations as it prevents dirt from attaching to the surfaces of the device to be sterilized.

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 before and after each use. Adler Ortho does not recommend sterilisation of instruments with ethylene oxide (EtO), plasma gas or dry heat. **Steam sterilisation (in an autoclave) has been validated and is therefore considered suitable for sterilisation of Adler Ortho instruments.**

### 4.2. Decontamination

To ensure compliance with HTM 01-01[1] and ISO 15883 standards, decontamination processes must be carried out using validated washer-disinfectors.
For decontamination to align with ISO 15883 standards, ensure complex instruments are disassembled where feasible (by following the assembly procedure backwards before use taking care not to damage them, compromizing their functioning) and immerse them to allow full chemical penetration into hollow parts. The use of validated washer-disinfectors is recommended for consistent and reproducible results.

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.

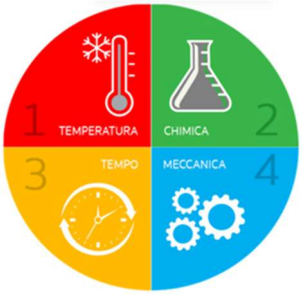
After decontamination, the medical devices must be rinsed.

### 4.3. 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 (HTM 01-01).

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.




**Reusable instruments must be treated with automated washing and washed with cycles defined within the healthcare facilities in relation to the 'Sinner' cycle (definining the proper four basic factors for cleaning: time , temperature, chemicals, mechanical agents) and regulated by the European standard UNI EN ISO 15883.**

**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.**

The use of disinfectants and cleaning agents containing one or more of the following substances is not recommended for stainless steel: chlorine, oxalic acid, hydrogen peroxide ($H_2O_2$).

pH-neutral detergents, enzymatic detergents and alkaline (pH>12) cleaning agents with low-foaming surfactants are recommended. If alkaline agents are used, the cleaning process requires a subsequent neutralization step or thorough rinsing.

When defining the correct concentration, temperature and contact time of the selected cleaning agent, please refer to the instructions, data sheets of the respective manufacturer.

The automatic cleaning procedure can be carried out by means of an iron cleaner, glass cleaner or other cleaning or decontamination equipment.

There are many types of automatic cleaning systems, each with specific instructions.

[1] Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care (Part A, B, C, D) – (documens are available from website at www.gov.uk/government/collections/health-building-notes-core-elements)

These machines normally perform an initial rinse in cold water followed by a wash cycle with a low foaming detergent (pH 7.0-10.0, neutral to slightly basic).

The detergent is removed with an initial rinse followed by a final rinse with deionized or reverse osmosis water. The cycle may also include a drying phase for the washed items.

The automatic cleaner can be equipped with a decontamination function.

Ultrasonic cleaners can be used with hot water at temperatures recommended by the manufacturer (usually 32-60 ºC) and specially formulated detergents. For specific cleaning solutions for ultrasonic cleaners, follow the manufacturer's recommendations.

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. The disinfection phase must be performed using automated equipment.

Typical European/U.S. pre-cleaning and Automated Washer/Disinfector Cycle for Surgical Instruments validate by Adler Ortho:

| Step | Description | main phase |
|---|---|---|
| 1 | Rinse with cold tap water | Pre-Cleaning procedure |
| 2 | Soak for 2 minutes in a detergent bath - Enzymatic Cleaner pH 7-9 according to the dilution conditions indicated by the manufacturer (such for example Valsure* enzimatic cleaner 2ml/L) using warm tap water (31-40°C/88-104°F)<br><br>**Valsure enzymatic cleaner is a classic example of a low foaming, specific and effective cleaner for cleaning surgical instruments* | |
| 3 | Brush the instruments with soft bristled brush | |
| 4 | Rinse with cold tap water | |
| 5 | Transfer the instruments inside the washer and select the cycle as listed below | |
| 6 | **pre-wash** _ 2 minute rinse with cold tap water | Authomated cleaning |
| 7 | **wash** _ 1 minute wash with detergent - Enzymatic Cleaner pH 7-9 according to the dilution conditions indicated by the manufacturer (such for example Valsure* enzimatic cleaner 2ml/L)) and warm tap water (43°C /109°F) | |
| 8 | **Neutralization wash** _ 2 minute wash with detergent - Neutral Cleaner according to the dilution conditions indicated by the manufacturer (*such for example Valsure neutral detergent 2ml/L*) and warm tap water (43°C /109°F) | |
| 9 | **Rinse** _ 1 minute rinse with tap water | |
| 10 | **Drying** _ 7 minute hot air dry (90°C/194°F) | |

No manual method has been validated by Adler Ortho.

**Manual pre-cleaning is allowed, but instruments must always undergo automated cleaning as the validated method. For final rinsing, use deionised or ultrapure water to prevent mineral deposits that may interfere with sterilisation efficacy.**

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, **do not use metal brushes or abrasive sponges**. These materials damage the surface and finish of the instruments**.** Use nylon brushes and pipe cleaners with soft bristles to remove organic material. This precaution in order to not damage the surface and finishes of instruments and so as not to remove laser marking.

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.

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.

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.

### 4.4. Drying

Drying is critical for HTM 01-01 and ISO 17665. After rinsing, the medical devices must be dried to avoid corrosion and because water residues can compromise the subsequent sterilisation process.
Ensure all instruments are thoroughly dried using hot air (i.e 120°C–140°C for 15 minutes) or appropriate drying equipment to avoid moisture that could compromise sterilisation.
In case of only manual cleansing and cleaning, use paper towels for drying.

### 4.5. Inspection

Prolonged use, misuse and neglect are the main causes of damage to surgical instruments.

To avoid compromising their proper functioning, they must be used with care. To minimize damage, proceed as follows:

- Examine instruments for integrity at the time of delivery and after each use and cleaning. Instruments that are not completely clean should be cleaned again, and those that need repair/replacement should be set aside pending service or returned to Adler Ortho.
- After cleaning, any instruments that have been disassembled (in the case of instruments with interchangeable universal metal handles) must be reassembled and placed in their cases/bags to prevent recontamination.
- Use the instrument only for its intended purpose.

Incompletely cleaned instruments must be cleaned again.

Damaged instruments in need of repair/replacement must be set aside pending service or returned to Adler Ortho.

Instruments that after repeated washing and sterilization cycles have a laser marking (and therefore the product identification information marked thereon) that is no longer clearly legible must be returned to the manufacturer and/or disposed of.

Functional checks for HTM 01-01 and ISO 17665 must include ensuring the integrity of all mechanical parts. Test the operation of movable components and inspect for corrosion or residuals that might compromise sterilisation.

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 and aging.**

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.
- Also check the presence and legibility of laser marked information (that can be removed after repeated

**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.

Adler Ortho accepts no liability for instruments or any parts thereof on which repairs and/or modifications have been carried out or attempted.

## 4.6. 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 (contents should occupy approximately ¾ of the potential volume of the bag).

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 (stainless steel containers suitable for steam sterilisation).

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.

### 4.7. Sterilisation

**Instruments supplied by Adler Ortho must be sterilised by steam sterilisation (moist heat autoclave using pre-vacuum phases) with cycles 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.

As required by ISO 17665, validated steam sterilisation cycles should be applied as follows:

- Standard cycle: 121°C for 15–30 minutes.
- Rapid cycle: 134°C for 3–5 minutes.

Ensure sterilisation facilities comply with ISO 17665 validation requirements to achieve sterility assurance level (SAL) $10^{-6}$.

The sterilisation processes must be validated and monitored, with recording of parameters (HTM 01-01).

The validation testing performed on Adler Ortho reusable surgical instruments satisfies the overkill validation methodology requirements of ISO 17665-1.

Below are the minimum steam sterilisation parameters that have been validated on worst case product placed in a stainless steel container for autoclaving wrapped in a double layer of autoclavable towel to obtain a guaranteed level of sterility (SAL) $10^{-6}$ and therefore a sterile product.:

| **Validated Cycle** | |
|---|---|
| Sterilization Type: | Prevacuum |
| Preconditioning pulse | 4 |
| Temperature: | 132°C |
| Exposure Time: | 4 minutes |
| Minimum Drying Time: | 30-60 minutes |
| Cool-Down Time: | 45 minutes |

The following sterilisation cycles have been also validated on a family of surgical instruments made of stainless steel and polypropylene handles:

Validated sterilisation parameters for instruments wrapped in a double layer of autoclavable towel or placed in a rigid container:

| | |
|---|---|
| temperature | 134°C |
| Exposure time | 3 min |

Validated sterilisation parameters for instruments packed in double medical paper bags:

| | |
|---|---|
| temperature | 121°C |
| Exposure time | 15-20 min |

The minimum recommended conditions for steam sterilisation of reusable Adler Ortho instruments are as follows:

Sterilization time (exposure time at sterilization temperature) at least 15-20 min at 121°C (250°F) or 3-5 min at 132°C (270°F)/134°C (273°F)

Cycles at 134 °C (134 °F) up to 18 minutes do not cause any deformation or deterioration of plastic and metal instruments as declared by the manufacturers of the materials from which these instruments are made.

It is recommended not to exceed the maximum load of the validated autoclave.

The drying cycle varies according to the type of packaging used.

The drying cycle varies according to the type of packaging used.
The drying time is important to not compromise the efficacy of the SBS (Sterile Barrier System) or the packaging system and the quality of the product, resulting in microbial recontamination and a non-sterile load during the storage. Drying stage ensure that residual moisture is reduced to a level which will not compromise the SBS or product characteristics upon removal from the sterilizer.

It is under the responsibility of the user to choose:
- other sterilisation parameters,
- to redure the drying time.

In these two cases, the user may ensure that the sterilisation facility is properly maintained and the process is validated in order to garantee the effectiveness of sterilisation and the preservation of SBS.
if the user decides to use a shorter drying time, make sure that the instruments are used as soon as possible”

The sterilisation parameters recommended in this document are not intended and are not indicated for prion inactivation.

### 4.8. Use, Storage and Transport

After sterilisation, instruments is ready to be used ensuring they are at room temperature. Remove the components from the packaging using validated sterile technique and powder-free gloves.

Alternatively instruments after sterilization must be stored in conditions that prevent contamination and maintain sterility. ISO 17665 highlights the importance of environmental controls, including limiting humidity and ensuring dust-free areas.

In addition, after sterilisation, reusable instruments must be stored in the sterilisation package in a dry place and away from dust (HTM 01-01).

The shelf life after each sterilisation varies depending on the sterile barrier used, the storage methods, the environmental conditions and the handling methods at the hospital. The maximum shelf life for reusable instruments sterilised before use must be defined by each healthcare facility. However, it is recommended to use the instruments immediately after sterilisation.

In the event that the packaging in which the instruments are packed after cleaning and sterilization is torn, perforated, or shows signs of tampering, the instrument set must be cleaned, repackaged and sterilized.

Surgical instruments that are not expected to be used in the near future and are not immediately returned to Adler Ortho must be stored clean, decontaminated, sterilized and completely dry.

All instruments returned to Adler Ortho must be cleaned and decontaminated before shipment and must be packaged in such a way that the instruments are not damaged during transport. Rigid containers and bubble wrap protection prevent damage.

## 5. CLINICAL BENEFIT

When properly used, checked, cleaned and sterilized as recommended, the instrumentation kit is particularly useful for performing the surgical technique. The instrumentation kit supports implant to achieve its intended purpose, without having a direct therapeutic or diagnostic function.
The surgical instruments used have an indirect clinical benefit. The instruments facilitate the implantation procedure of the implant.
The positive impact of the instrumentation (as part of the surgical procedure in association with implantation) on an individual's health or public health is considered in these terms

- the instrumentation guarantee the implantation of the associated implant optimizing surgery time and surgical procedure.

## 6. MONITORING

(ex European Directive 93/42/EEC and Regulation (EU) 2017/745)

Users are stakeholders in the application of the monitoring system after the medical device has been placed on the market. Indeed, they are required by law to report to the competent authorities and manufacturers any incident related to the medical device that has resulted or may result in a serious risk to the health status of the patient or a user.

| # | SYMBOLS | Symbol Ref. | Definition | Définition | Definition | Definición | Definizione | Definição | ορισμοί |
|---|---|---|---|---|---|---|---|---|---|
| |  | *Ref. 1641 § ref.5.4.3 | Consult instruction for use or consult electronic instruction for use | Consultez le mode d'emploi ou consultez le mode d'emploi électronique. | Gebrauchsanweisung konsultieren oder elektronische Gebrauchsanweisung konsultieren | Consulte las instrucciones de uso o consulte las instrucciones electrónicas de uso | Consultare le istruzioni per l'uso o consultare le istruzioni elettroniche per l'uso. | Consultar instruções de uso ou consultar instruções eletrônicas de uso | Ανατρέξτε στις οδηγίες λειτουργίας ή συμβουλευτείτε τις ηλεκτρονικές οδηγίες λειτουργίας. |
| |  | *Ref. 0434A § ref. 5.4.4 | caution | attention | Vorsicht | precaución | cautela | advertência | Προσοχή |
| |  | *Ref. 3082 § ref 5.1.1 | Manufacturer | Fabricant | Hertseller | Fabricante | Fabbricante | Fabricante | κατασκευαστής |
| |  | *Ref. 2492 § ref 5.1.5 | Batch code | Code du lot | Chargennummer | Código | Numero di lotto | Código do lote | αριθμός παρτίδας |
| |  | *Ref. 2493 § ref 5.1.6 | Catalogue number | Référence de catalogue | Bestellnummer | Número de catálogo | Numero di catalogo | Número do catálogo | Αριθμός καταλόγου |
| |  | *Ref. 2609 § ref 5.2.7 | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | μη αποστειρωμένο |
| |  | | Caution: U.S. federal law restricts this device to sale by or on the order of a physician | Attention: La loi fédérale des États-Units limite la vente de ce dispositif aux médécins ou sur prescription médicale | Vorsicht: Nach US-Bundesgesetz darf dieses Produkt nur von einem Arzt oder auf dessen Anordnung verkauft werden | Precautión: La legislación fede- ral de Estados Unidos restringe la venta de este dispositivo a médicos o por prescripción | Attenzione: Conformemente alla normativa federale statunitense, la vendita del presente dispositivo è consentita esclusivamente ai medici o su prescrizione medica | Atenção: A lei federal dos EUA limita a venda deste dispositivo a médicos ou mediante a prescrição de um médico | Προσοχή: Σύμφωνα με τους ομοσπονδιακούς κανονισμούς των ΗΠΑ, η πώληση αυτής της συσκευής επιτρέπεται μόνο σε γιατρούς ή με ιατρική συνταγή. |
| |  | MDR annex V | CE Marking xxxx: Notified Body ID number | Marquage CE xxxx: Numéro d'identification de l'organisme notifié | CE Kennzeichnung xxxx: Identifikationsnummer der benannten Stelle | Marcado CE xxxx: Número de identificación del cuerpo notificado | Marcatura CE xxxx: Numero identificativo di organismo notificato | Marcação CE xxxx Número de identificação do organismo notificado | Σήμανση CE xxxx: Αριθμός αναγνώρισης κοινοποιημένου οργανισμού |

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|---|---|---|---|---|---|---|---|---|---|
| | MD | N/A<br>§ ref 5.7.7 | Medical device | Dispositif médical | Medizinisches Gerät | Dispositivo médico | Dispositivo medico | Dispositivo médico | ιατρική συσκευή |
| | UDI | n/a<br>§ ref 5.7.10 | Unique device identifier | Identifiant unique du dispositif | Eindeutige Kennung des Geräts | Identificador único del dispositivo | Identificativo univoco del dispositivo | Identificador exclusivo do dispositivo | Μοναδικό αναγνωριστικό συσκευής |

Notes

1. * Symbol ISO 7000: Graphical Symbols For Use On Equipment - Registered Symbols

2. § in accordance with ISO 15223-1

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