Instructions For Reprocessing Ortho Solutions Non-Sterile Devices

All Ortho Solutions devices that are supplied non-sterile **MUST** first be reprocessed prior to use. Ortho Solutions devices have been designed to facilitate their safe cleaning, disinfection, and re-sterilisation per EU MDR Annex I, Chapter II, Section 11.2. The cleaning and sterilisation methods recommended in this IFU have been validated. It is the responsibility of the user to ensure that appropriate cleaning and sterilisation methods are used where Ortho Solutions recommendations are not followed. Reprocessing must also comply with applicable national guidelines and hospital procedures (e.g., HTM 01-01 in the UK), particularly if said guidelines impose stricter requirements than those listed in this document.

These instructions are to be utilised with Ortho Solutions Non-Sterile Devices manufactured by Ortho Solutions UK Ltd West Station Business Park, Spital Road, Maldon, CM9 6FF, United Kingdom, Phone: +44(0)1621 843599, Fax: +44(0)1621 858953, www.orthosol.com. All instructions provided in this document must be followed.

Ortho Solutions UK Limited West Station
Business Park, Spital Road
Maldon, Essex, UK CM9 6FF

Tel: +44(0)1621 843 599
Fax: +44(0)1621 858 953
Email: sales@orthosol.com
Website: www.orthosol.com

This document is subject to change. Users are advised to consult the latest version available at www.orthosol.com/eifu or contact Ortho Solutions directly to confirm that they are using the most up-to-date Instructions for Use.

Please verify that the current printed version is identical to the one at www.orthosol.com/eifu

EC REP

Authorised representative in EU
Advena Ltd
Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013 Malta.

'Reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.

IMPORTANT INFORMATION – Please Read Before Use
These instructions apply to all devices supplied by Otho Solutions non-sterile that require processing to prepare them for clinical use.

1. INTRODUCTION / PURPOSE

All Ortho Solutions reusable devices supplied to users non-sterile are classified as critical medical devices. These devices **MUST** be thoroughly cleaned, inspected, and sterilised prior to clinical use.

The instructions provided have been validated by Ortho Solutions as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

2. INTENDED USE

These devices are intended for use in orthopaedic surgery to enable implantation of the associated Ortho Solutions implant(s) when used in accordance with the surgical technique. These devices are supplied non-sterile and are intended for reprocessing in a healthcare facility setting prior to use.

3. INDICATIONS / CONTRAINDICATIONS / PATIENT POPULATION

For information relating to indications, contraindications, clinical benefits, and intended patient populations refer to the Ortho Solutions implant system instructions for use.

4. EXPECTED CLINICAL BENEFIT

No direct clinical benefit is expected from these devices as this benefit is expected to be derived from the associated Ortho Solutions implant.

5. INTENDED USERS

These instructions are intended for use only by qualified personnel with the appropriate specialist knowledge and have documented competency and training in the handling and reprocessing of reusable medical devices in a healthcare facility setting. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.

6. MATERIALS

The Otho Solutions non-sterile devices are made from the following materials :

Material
Stainless steel
Silicone
Aluminium
Acteal
PEEK
Titanium alloy
Tufnol
Cobalt-chrome

7. WARNINGS & PRECAUTIONS

- All devices that are supplied non-sterile must be thoroughly cleaned, inspected and sterilised prior to clinical use.
- The use of non-validated processes for cleaning or sterilization may render the devices unsuitable for their intended use.
- Incorrect or omitted manual pre-cleaning and/or automated cleaning may not remove all biological soil, rendering the devices unsuitable for their intended use.
- Cleaning alone does not render the devices sterile, they must be sterilised as per the recommendations in these instructions prior to being introduced into a sterile surgical field.
- Incorrect or omitted inspection, maintenance and/or handling may render the devices unsuitable for their intended use.
- Automated cleaning using a washer-disinfector alone may not be effective in cleaning soiled devices, especially those with complex features such as lumens, cannulations, blind / threaded holes, and mated surfaces. Manual pre-cleaning is recommended to be performed, prior to automated cleaning.
- Automated equipment, including washer-disinfectors, ultrasonics and steam sterilisers must be installed, maintained and operated in accordance with equipment manufacturer's instructions.
- Automated cleaning must be performed in a validated washer-disinfector according to relevant ISO / HTM 01-01 standards.
- Steam sterilisation must be performed in a validated steam sterilisation process according to relevant AAMI/ASTM/ISO standards.
- When reprocessing these devices, handle with care to prevent damage or loss of function, and wear the appropriate personal protective equipment (PPE).
- Dry heavily soiled devices are more difficult to clean and may reduce the effectiveness of the cleaning processes documented in these instructions.
- Where applicable, devices must be disassembled as much as possible, and those which articulate opened as much as possible, prior to the manual pre-cleaning and/or automated cleaning process.
- For correct disassembly/assembly of the applicable Ortho Solution devices, refer to *OS TD 00081_25*, which can be accessed on the Ortho Solutions website at the following address: https://www.orthosol.com/eifu/
- Devices with complex features such as long, narrow cannulations/lumens, blind/threaded holes or mated surfaces require particular attention during the cleaning process.
- Ortho Solutions recommend the use of pH neutral enzymatic detergents. The use of highly alkaline or highly acidic cleaning detergents are not recommended to be used, as they may cause damage to materials such as stainless steel, aluminium and polymer plastics.
- Cleaning detergents should be prepared and used as per the manufacturers' instructions.
- In the manual pre-cleaning process it is recommended the cleaning detergent is changed before it becomes heavily soiled, to ensure effective ultrasonic cleaning is not inhibited.
- Cleaning detergents with chlorine or chloride as the active ingredient are damaging to stainless steel and are not recommended for use.

- Cleaning detergents must be completely rinsed from device surfaces to prevent accumulation of detergent residue that may cause harm to a patient.
- Purified or deionised water (or equivalent) is recommended to be used for the final rinse and thermal disinfection of devices in the cleaning process as part of reprocessing, as this helps prevent ineffective cleaning, contamination and staining associated with mineral residues found in tap water.
- Do not use cleaning aids that can damage the internal or external surface and finish of the devices such as metal wool, metal/wire brushes and scouring pads. Soft bristled, nylon brushes are recommended.
- All devices must be thoroughly cleaned and inspected to ensure all visible soiling (e.g. blood, tissue, and/or bone) in or on the surface of the devices has been removed prior to sterilisation. If soiling is still observed, repeat the cleaning process until removed.
- Ensure devices, especially those with lumens, are positioned within the washer-disinfector and/or drying oven chamber in a way that prevents the retention of water residue to allow for effective drying.
- Ensure devices are dry following the automated cleaning program to prevent residual moisture allowing possible microbial contamination.
- The sterilisation parameters in these instructions are only valid for devices that are adequately cleaned via validated methods.
- All devices should be located in their specific position as identified by the labelling within the instrument tray to ensure effective sterilisation and protection during transportation.
- Devices must be carefully inspected before each use to ensure that they are functional and free from damage. Incorrect assembly, surface damage, excessive wear, corrosion, deformation and dull cutting features can result in instrument misfunction.
- Only lubricants that are intended for use with medical devices and compatible with steam sterilisation are recommended to be used.
- The use of devices, other than those supplied by Ortho Solutions, may cause damage to the implants, handling issues, or other complications. Only use Ortho Solutions devices for implantation of the Ortho Solutions implants to avoid compatibility issues.

8. LIMITATIONS ON PROCESSING

Repeated reprocessing cycles as described in these instructions that includes ultrasonic cleaning, automated cleaning in a washer-disinfector and steam sterilisation have negligible effects on Ortho Solutions reusable devices.

Ortho Solutions defines no maximum number of reuses for reusable devices, as this is dependent on multiple parameters from each individual use. End of life of these devices is normally determined by damage, wear and loss of function due to surgical use, reprocessing and/or handling. Careful Inspections and functionality tests of the reusable devices before each usage are the best methods to identify damage and wear and identify if a device has reached the end of life, refer to **Section 9.5** for further information.

Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged and excessively worn devices should not be used.

Single-use devices that are supplied in a non-sterile condition must be cleaned and sterilised before initial use. Following clinical use these devices must not be reprocessed and used clinically for a second time. Following initial clinical use discard these devices as per hospital policy/procedure and disposal provisions.

9. CLEANING INSTRUCTIONS

This IFU provides validated instructions for cleaning, disinfection, and sterilisation of reusable surgical instruments to meet EU MDR Annex I Chapter III §23.4(i, m, n). Further information is available upon request.

These instructions detail a cleaning method comprised of two elements: manual pre-cleaning (including the use of an ultra-sonic bath) followed by automated cleaning to be performed in a washer-disinfector. Both manual pre-cleaning and automated cleaning are recommended to be performed as part of the reprocessing of Ortho Solutions reusable devices.

Thorough cleaning and disinfection are vital to reprocessing reuseable medical devices and ensuring effective sterilisation. Cleaning should be performed in a manner designed to minimise exposure to blood borne pathogens. Reusable medical devices should be kept moist immediately after use until cleaning. Thorough cleaning and rinsing should be carried out as soon as possible.

The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates and microorganisms. Furthermore, thorough rinsing is necessary to remove any residual cleaning agents from the medical device. Cleaning primarily removes rather than kills microorganisms.

A device is considered successfully cleaned when all visible soil, debris, and moisture are removed from external and internal surfaces, including joints, cannulations, and textured areas. Visual inspection under adequate lighting must be performed after each cleaning cycle. Devices failing visual inspection must be re-cleaned before sterilisation.

Water quality should be carefully considered for use in preparing enzymatic detergents and for rinsing in the cleaning procedure. Water hardness is a concern because deposits left on the device may result in ineffective cleaning and decontamination. Deionised and/or purified water is recommended and helps prevent discolouration and staining associated with mineral residues found in tap water.

The cleaning agents described in this IFU have been validated for material compatibility. All instruments are made from surgical-

grade stainless steel or equivalent materials designed to withstand enzymatic cleaning at the recommended parameters.

The detergents should be prepared and used as per the manufacturers' instructions. Always follow the manufacturer's instructions for cleaning agents and equipment. The detergent listed in **Table 1** was used for the cleaning validation performed by Ortho Solutions. Ortho Solutions does not recommend specific cleaning detergents.

Cleaning	Manufacturer	Product
Manual pre-clean	Serchem Ltd.	Triple-Zyme
Automated		

Table 1: *Detergent used for cleaning validations.*

After rinsing, the devices should be dried thoroughly. Residual moisture can compromise sterilisation efficacy and must be completely removed prior to packaging.

9.1. INITIAL TREATMENT AT THE POINT OF USE

Processing begins at the point of use and prompt initial cleaning steps and/or measures to prevent the drying of soil on the device surface prior to cleaning should be taken to facilitate subsequent cleaning steps. Reprocessing procedures should minimise or eliminate delays between steps. Delays may create conditions favourable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and sterilisation.

Soiled devices should be removed from their instrument tray and separated from non-soiled devices to avoid cross contamination.

9.2. TRANSPORT TO REPROCESSING

Used instruments must be transported to the reprocessing area in closed or covered containers to prevent unnecessary contamination risk. Soiled devices should be transported separately from non-soiled devices to avoid cross-contamination. During transportation handle with care and do not drop the devices.

9.3. MANUAL PRE-CLEANING

Automated cleaning using a washer-disinfector alone may not be effective for complex and significantly soiled devices with complex features such as lumens, cannulations, blind holes and mated surface. Soiled devices are recommended to be manually pre-cleaned prior to the automated cleaning process.

Recommended equipment:

- Ultrasonic cleaning bath.
- Freshly prepared enzymatic cleaning detergent.
- Syringes – various sizes dependant on cannulation / hole sizes.
- Brushes – soft-bristled nylon, various sizes dependant on cannulation / hole sizes.
- Appropriate Personal Protective Equipment (PPE).

Reprocess all soiled devices as soon as it is reasonably practical following use.

Refer to the Non-Sterile Device Disassembly Instructions, *OS TD 00081_25* for guidance on the correct disassembly method for the applicable devices, which can be accessed at the following address: https://www.orthosol.com/eifu/.

The following recommended manual pre-cleaning program was utilized by Otho Solutions during the validation of these instructions:

Stage	Description
Preparation	Disassemble device(s) as much as possible prior to cleaning and open any articulated device(s) as much as possible. Ensure detergents are prepared as per the manufacturer's instructions such as for concentration and temperature.
Rinse	Rinse the device(s) under running cold tap water for a minimum of one (1) minute to remove gross soil and debris. Pay close attention to textured areas, lumens, cannulations, crevices, blind / threaded holes, hinges and mated surfaces.
Wash	Completely submerge the device(s) in freshly prepared detergent and while immersed ensure the following is performed: • All surfaces are thoroughly wetted. • Use a soft-bristled nylon brush to thoroughly scrub the surfaces of the device to remove all gross soil and debris. Pay close attention to textured areas, crevices, hinges and joints. • Lumens, cannula and blind holes are thoroughly brushed through their entire length using an appropriate diameter and length bristle size. Insert the brush and pass up and down the whole length, with a twisting motion at least three times. • Actuate moving parts at least three times, ensuring all concealed areas are exposed to the detergent and thoroughly cleaned.
Ultrasonic Wash	Prepare an ultrasonic cleaning bath with freshly prepared detergent. Completely submerge the devices and ensure all surfaces are thoroughly wetted. Ultrasonic clean at a frequency of 40 (+/-5) kHz for a minimum of ten (10) minutes. The enzymatic detergent should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited.
Rinse	Remove the device(s) from the ultrasonic bath and thoroughly rinse using with purified water for a minimum of one (1) minute. Use syringes to flush difficult to wet areas such as lumens, cannulations, crevices and mated surfaces at least three times or until the water runs clear.

Table 2: *Information on water type, duration and temperature for automated cleaning.*

9.4. AUTOMATED CLEANING

Disassemble devices as much as possible and open any articulated devices as much as possible prior to automated cleaning in a washer-disinfector. Refer to the Non-Sterile Device Disassembly Instructions, *OS TD 00081_25* for guidance on the correct disassembly method for the applicable devices, which can be accessed at the following address: https://www.orthosol.com/eifu/.

Place disassembled devices directly on to the washer trays, connecting lumens/cannulations to rinsing ports where possible, and ensuring that devices are positioned in a way to prevent the retention of water residue.

The following recommended automated cleaning program was utilized by Otho Solutions during the validation of these instructions, using an appropriately qualified washer-disinfector:

Cycle	Minimum Time (mins)	Temperature	Water	Detergent
Pre-rinse	3	≥ 20⁰C	Cold tap water	N/A
Wash	10	≥ 40⁰C	Warm tap water	Enzymatic detergent
Rinse 1	2	≥ 40⁰C	Warm tap water	N/A
Rinse 2	1	≥ 20⁰C	Cold tap water	N/A
Thermal Disinfection (Ao value > 600)	1	≥ 90⁰C	Purified Water	Purified Water
Drying (air dry)	30	110⁰C	N/A	N/A

Table 3: *Information on water type, duration and temperature for automated cleaning.*

Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil and moisture. Repeat the full automated cleaning program if soil is still visible. If moisture is still visible wipe away with a lint free cloth or put through drying cycle again; otherwise, proceed to Inspection, testing & maintenance.

The drying cycle as part of the automated cleaning process can be performed within a washer disinfector or a separate drying oven that utilises an air drying method. Ensure medical-grade air is used to prevent possible contamination of the devices.

9.5. INSPECTION, TESTING & MAINTENANCE,

Prior to sterilisation all devices should be inspected and functionally tested to check for end of life indicators that identify that the device should no longer be reused. Refer to the Non-Sterile Device Lifetime Manual, *OS TD 00334_25* for further information on end of life indicators, which can be accessed at the following address: https://www.orthosol.com/eifu/.

Generally, visual inspection with the naked eye under good lighting conditions will suffice. The following inspections and functionality tests should be performed at minimum:

- Visually inspect each device and instrument tray to ensure all soil, blood, debris, cleaning detergent and moisture has been completely removed from all surfaces and features. If contamination is still present repeat the cleaning process.
- Visually inspect each device and instrument trays for completeness, correct assembly, damage, deformation, bending, fractures, cracks, excessive scratches, severe discoloration (minor water marks to be expected as part of repeated reprocessing), blunt cutting edges, excessive wear, corrosion and completeness of direct part markings. If damage or wear is observed that might compromise the safety and function of the device, do not process them further and contact Ortho Solutions Customer Services or your Sales Representative for a replacement.
- Check the functionality of all devices containing moving parts to verify correct device function and smooth operation throughout the intended range of motion. If loss of functionality is observed do not process them further and contact Ortho Solutions Customer Services or your Sales Representative for a replacement.
- If necessary, hinged or articulating instruments can be lubricated with an instrument product (e.g. instrument milk or equivalent product) specifically intended to be used with medical devices and is compatible with steam sterilisation.

10. PACKAGING

Only devices manufactured by Ortho Solutions should be included in Ortho Solutions instrument trays. These validated reprocessing instructions are not applicable to Ortho Solutions trays that include devices that are not manufactured by Ortho Solutions.

To ensure devices are arranged for maximum steam penetration within their dedicated instrument tray, ensure positions allocated for specific devices only contain the devices specifically intended for them.

Instrument trays are recommended to be double wrapped following AAMI or equivalent guidelines, using a wrap made from an appropriate material (e.g. complaint to ISO 11607-1) and is intended to be used for steam sterilisation within a healthcare facility.

11. STERILISATION INSTRUCTIONS

Ortho Solutions reusable devices are supplied non-sterile unless it is clearly and explicitly labelled as sterile. Non-sterile devices must be sterilised prior to being introduced into a sterile surgical field. The sterilisation parameters detailed in these instructions are only valid for devices that have been thoroughly cleaned using a validated process. Moist heat / steam sterilization is the preferred and recommended method for Ortho Solutions reusable devices.

'The sterilisation parameters recommended in these instructions have been validated by Ortho Solutions to provide a sterility assurance level (SAL) of 10^{-6}. The sterilisation parameters have been validated by Otho Solutions according to ISO 17664 and 17665 using the half-cycle method.

The sterilisation conditions described in this IFU have been validated for material compatibility. All instruments are made from surgical-grade stainless steel or equivalent materials designed to withstand repeated steam sterilisation at the recommended parameters.

The recommended steam sterilisation parameters for Ortho Solutions non-sterile devices are as follows:

Market	Cycle Type	Exposure Time	Cycle Temperature	Drying Time
US	Dynamic air removal (pre-vacuum)	4 minutes	132°C (270°F)	20 to 30 minutes[1]
EU / GB	Dynamic air removal (pre-vacuum)	3 minutes	134 – 137°C (273 – 279°F)	20 to 30 minutes[1]

Table 4: Recommended steam sterilisation parameters.

12. STORAGE

Sterilised devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes in accordance with local hospital protocols.

Sterile packages must be inspected before use, and any with signs of damage or moisture must be reprocessed. For long-term loan sets and consignment stock under the control of the hospital, instruments must be inspected after each use. Any device showing signs of damage, corrosion, or wear should be removed from and replacement request made to Ortho Solutions as necessary.

Ortho Solutions has not established a maximum number of validated reprocessing cycles. Instruments may be reprocessed and reused provided they remain undamaged and continue to meet their intended performance specifications.

13. USER RESPONSIBILITY FOR STERILISATION CONDITIONS

It is the responsibility of the healthcare facility to ensure that instruments are appropriately cleaned, disinfected and sterilised prior to use. To support this, Ortho Solutions has conducted validation of the cleaning, disinfection and sterilisation processes in accordance with ISO 17664 and ISO 17665-1 using clinically representative equipment, packaging, and load configurations.

These validated parameters are provided to support users in reprocessing the devices. However, Ortho Solutions does not assume responsibility for achieving sterility at the point of use, as this is dependent on numerous site-specific factors beyond our control including:

- The performance, maintenance, and calibration of sterilisation equipment,
- The load configuration and wrapping technique used by the facility,
- Compliance with cleaning and packaging steps prior to sterilisation,
- Adherence to local hospital protocols and national sterilisation guidelines.

Therefore, it is the responsibility of the hospital or reprocessing facility to ensure that:

- The sterilisation equipment used (including washer-disinfectors and steam sterilisers) is validated, maintained, and routinely monitored according to local protocols and national regulations.
- The load configuration, packaging materials and method, and instrument layout arrangement are equivalent to or less challenging than those used in the Ortho Solutions Kits.
- Deviations from the validated parameters described herein (e.g., alternative sterilisation methods, different wrapping systems, or denser instrument loads) are independently validated by the user to ensure sterility and device safety are not compromised.

Based on our validation results, if the user follows the recommended sterilisation conditions provided in this document, the devices should achieve a sterility assurance level (SAL) of 10^{-6}. It remains the responsibility of the hospital or reprocessing facility to ensure these conditions are correctly implemented and that effective sterilisation is achieved. Reprocessing should only be performed by personnel trained in medical device decontamination procedures. Improper handling, cleaning, or sterilisation may result in non-sterile devices and increased patient risk.

Failure to adhere to these validated conditions may result in ineffective sterilisation and increased risk of patient harm. Ortho Solutions does not assume responsibility for the performance of sterilisation processes conducted outside of these validated parameters. The use of alternative sterilisation methods (e.g., ethylene oxide, low-temperature hydrogen peroxide plasma, or dry heat) has not been validated by Ortho Solutions and is not recommended. Use of such methods is at the discretion and risk of the healthcare facility and must be independently validated.

14. REUSE OF SINGLE USE DEVICES

Devices labelled as single use may not perform as intended if reused. Reuse of these devices may cause irreversible changes to the micro and macro structure of the material; consequently, performance characteristics of the device will be sub-optimal if reused. Reuse of a single use device may lead to an increased risk of infection, failure of the device to perform as intended, material degradation, and / or endotoxic reactions.

15. USE ORTHO SOLUTIONS INSTRUMENTS ONLY

The use of surgical instruments, other than those supplied by Ortho Solutions, may cause damage to the implants, handing issues, or other complications. Only use Ortho Solutions instruments for implantation of the Ortho Solutions implants to avoiding compatibility issues.

[1] Refer to the individual IFU of the device system for drying times for a specific Kit.

16. SYMBOL GLOSSARY

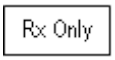
Symbol	Title of Symbol
	Non-Sterile
	Medical Device - Sterile and non-sterile
	Batch Number
	Catalogue Number
	Consult instructions for use
	Caution – surgeon must be fully trained in the surgical technique or IFU.
	Manufacturer
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
CE 2797	Applied per part number as appears on the device packaging, or the device.
CE	Applied per part number as appears on the device packaging, or the device.
UK CA 0086	Applied per part number as appears on the device packaging, or the device.
UK CA	Applied per part number as appears on the device packaging, or the device.

Table 5: *Symbol glossary.*

17. COMPLAINTS / FEEDBACK

Any adverse event or incident arising from the use of Ortho Solutions devices in any country must be reported to regulatory@orthosol.com upon discovery or awareness of event without undue delay. Any feedback related to the use of Ortho Solutions devices must be reported via https://orthosol.com/customer-feedback/ or sales@orthosol.com.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.