

# Preparation instructions for surgical instruments

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## Recommendations for care, cleaning, maintenance and sterilisation

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## 1. Purpose

These instructions are recommended for the care, cleaning, maintenance and sterilisation of reusable, hand-held HumanTech instruments for orthopaedic surgery. This document is intended to provide nurses and sterilisation assistants with safe handling practices and useful information on the effective reprocessing and maintenance of reusable HumanTech instruments. These instructions are intended to assist hospital management and hygiene officers in establishing procedures for the safe and effective preparation of HumanTech instrument sets. The responsibility for the safe handling and clinical use of loaned and consignment HumanTech instruments often lies in the hands of central sterilisation and supply departments or facilities. In order to ensure safe and effective reprocessing by the responsible members of staff and to prevent any damage to or abuse of the environment, persons or materials, hospital management and the heads of each department should be familiar with these instructions and recommendations.

## 2. Scope

These instructions discuss the care, cleaning, disinfection, sterilisation and maintenance of hand-held instruments for orthopaedic surgery and apply to all reusable medical products that have been manufactured and/or distributed by HumanTech. This information also applies to disposable medical instruments which are manufactured by HumanTech and supplied in a non-sterile state, but which are sterilised for use. These products are intended for single use, but may be recycled provided they have not been used (e.g. screws).

**Note: The term “unused” means that said components have not come into contact with blood, bone, tissue or body fluids. Any as of yet unused disposable products that come into contact with blood, bone, tissue or body fluids may not be reprocessed or re-sterilised and must be disposed of.**

Products that cannot be reused can be labelled with the following symbol:  
DIN EN ISO 980, 5.2 **Intended for single use only.**



Products that cannot be re-sterilised can be labelled with the following symbol:  
DIN EN ISO 980, 5.22 **This product must not be re-sterilised!**



## 3. Glossary

**Preparation/reprocessing:** Activity which comprises cleaning, disinfection and sterilisation, and which is necessary to prepare a new or used medical device for its intended use.

**Chemical:** Composition of substances for use during reprocessing.

**Note: These include washing agents, surfactants, detergents, disinfectants, enzymatic detergents and sterilising agents.**

**Decontamination:** The use of physical or chemical agents to remove, inactivate or destroy pathogens on surfaces or objects which have been transmitted through blood and body secretions until they are no longer capable of transmitting infectious particles and the safe handling and disposal of the surface or object is ensured.

**Disinfection:** A process for reducing the number of viable microorganisms on a product to a level that has been previously set as appropriate for further handling or use.

**Note: Cleaning and disinfection are frequently carried out in a single step.**

**Contaminated:** State after actual or potential contact with microorganisms.

**Manual cleaning:** Cleaning by hand without the use of a washer or washer/disinfection machine.

**Cleaning:** Removal of dirt deposits from an object to the extent necessary for further processing.

**Sterile:** Free from all viable microorganisms.

**Sterilisation:** Validated process for ridding a product from all forms of viable microorganisms.

**Note:** In a sterilisation process, the degree of microbiological destruction is expressed as an exponential function. Therefore, the presence of microorganisms on an object may be expressed as a probability. Although this probability can be reduced to a very low number, it cannot be reduced to zero. This probability can only be guaranteed in the case of a validated sterilisation process.


**Washer/disinfection machine:** Machine for the cleaning and disinfection of medical devices and other articles that are used within the context of medical, dental, pharmaceutical and veterinary practice.


## 4. Acronyms and abbreviations


|             |                                           |
|-------------|-------------------------------------------|
| <b>BI</b>   | = Biological Indicator                    |
| <b>CJD</b>  | = Creutzfeldt-Jakob Disease               |
| <b>OR</b>   | = Operating Room                          |
| <b>PPA</b>  | = Personal Protective Equipment           |
| <b>SAL</b>  | = Sterility Assurance Level               |
| <b>TSE</b>  | = Transmissible Spongiform Encephalopathy |
| <b>CSSD</b> | = Central Sterile Supply Department       |

## 5. Symbols

 **DIN EN ISO 980, 5.2 “INTENDED FOR SINGLE USE ONLY”**  
Should be used only once.

 **DIN EN ISO 980, 5.18 Symbol for “OBSERVE INSTRUCTIONS FOR USE”**  
Consult instructions.

 **DIN EN ISO 980, 5.22 Symbol for “DO NOT RE-STERILISE”**  
This product must not be re-sterilised.

 **DIN EN ISO 980, 5.11 Symbol for “CAUTION”**  
Warning or instructions for use.

## 6. Notes

This manual applies to all reusable surgical instruments manufactured by HumanTech and should be read carefully.

The user should adhere to the local laws and regulations in countries with stricter recycling requirements than those set out in this manual. New and used instruments **must** be thoroughly prepared in accordance with these instructions prior to use. In the case of operations on the musculoskeletal system, instruments will become contaminated with blood, tissue, bone chips and bone marrow. The instruments could also become contaminated with body fluids containing the hepatitis virus, HIV or other etiological pathogens. All nursing staff should be familiar with the necessary, generally recognised safety precautions for avoiding injury from sharp instruments when handling these during and after surgery and during reprocessing. It should be noted that, during surgical procedures, large amounts of irrigation fluids and other saline solutions are often used which have a corrosive effect on instruments. In orthopaedic surgery, heavy instruments with multiple components, joints or rotating mechanisms, removable handles and plastic parts in different sizes are required. These instruments are usually supplied in sets and divided into trays and containers in which the products can be arranged according to size or in the order required for a particular surgical procedure. **Hospitals are responsible for the cleaning, disinfection, packaging and sterilisation of all loaned instrument sets before returning these to HumanTech.** The next user must also inspect the set upon receipt, however, and verify that the instruments have in fact been adequately cleaned and decontaminated before repeating the reprocessing procedure for

preparing loaned sets for subsequent reuse. HumanTech cannot guarantee that sterility has been achieved by the previous user and maintained during transport. HumanTech employees regularly open and inspect instrument sets being passed from one user to the next; a process which causes the instruments to lose their sterility and requires them to be completely reprocessed before subsequent reuse. All HumanTech instruments can be safely and effectively reprocessed in accordance with the instructions for manual or machine cleaning in this manual. Necessary orthopaedic main instrument sets must be complete and in good condition in order to ensure correct usage. Optional instruments may be available from your HumanTech contact person upon request. For the proper care of instruments, it is important to consider the following information and processing instructions:

- Warnings and safety precautions
- Completeness and functionality of the instrument set
- Reprocessing limitations
- Preparation for reprocessing at the job location
- Preparation for cleaning (including assembly and disassembly, if necessary)
- Cleaning, disinfection and drying
- Maintenance, inspection, testing and handling of lubricants
- Sterile packaging
- Sterilisation
- Storage

## 7. Preparation categories

HumanTech recommends recycling all reusable instruments in accordance with the instructions for manual or combined manual/machine cleaning in this manual.

### **Steel/metal instruments *without* cannulated holes**

Steel/metal instruments without cannulated holes/lumen or non-metal/polymer handles or other components (e.g. compressors, distractors, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. In the presence of rust or corrosion, these instruments can be cleaned using rust remover approved for use on surgical instruments.

### **Steel/metal instruments *with* cannulated holes**

Steel/metal instruments with cannulated holes/lumen, but without non-metal/polymer handles or other components (e.g. polyaxial screwdriver, approximator, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. In the presence of rust or corrosion, these instruments can be cleaned using rust remover approved for use on surgical instruments.

**Cannulas and cavities must be cleaned by hand.**

### **Instruments made from or using polymers without cannulated holes**

Instruments made from polymers or metal instruments with polymer components (e.g. awl, pedicle probe, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing.

### **Instruments made from or using polymers with cannulated holes**

Instruments with cannulated holes made from polymers or metal instruments with polymer components (e.g. T-handle, straight handle, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. **Cannulas and cavities must be cleaned by hand.**

### **Instruments made from titanium or aluminium alloys**

Instruments made from titanium or aluminium alloys for assembly or disassembly or with other reprocessing aids (e.g. instrument containers, trays and sterilisation containers). These instruments should be cleaned in

accordance with the manual or combined manual/automated cleaning procedures in this manual. **These instruments should not be exposed to alkaline cleaning agents.**

## 8. Processing instructions

These processing instructions are intended to assist hospital management and the heads of the sterilisation and reprocessing department in the development of procedures for realising the above objectives for the hospital's own and loaned instrument sets.

**Note: These instructions describe the necessary processing steps which new and used instruments must undergo in order to achieve sterility.**

### A. Warnings and safety precautions

- Hospital staff who come into contact with contaminated or potentially contaminated medical instruments **must take generally recognised precautions**. Instruments with points or sharp edges should be handled with caution.
- When dealing with contaminated or potentially contaminated materials, instruments and products, **appropriate personal protective equipment should be worn**. This includes a gown, a mask, goggles or visors, gloves and shoe covers.
- In the case of manual cleaning, no **metal brushes or abrasive cleaning materials are permitted**. These materials result in damage to the surface and coating of the instruments. It is advisable to use nylon brush with soft bristles.
- During the manual cleaning process, detergent with low-foaming surfactants should be used to ensure that the instruments are visible in the detergent solution. When scrubbing by hand using brushes, the instruments should always remain below the surface of the cleaning solution, so as to avoid creating particulate material and spray, thereby potentially spreading contaminating substances. Cleaning agents must be gently yet thoroughly rinsed off from the product surfaces to prevent the accumulation of detergent residues.
- **Heavy objects should not be placed on sensitive products.**
- **Do not allow contaminated instruments to dry prior to reprocessing.** All of the steps for cleaning and sterilisation described below are facilitated if blood, body fluids, bone and tissue residues, saline solution and disinfectants are not allowed to dry on used instruments.
- Saline solutions, cleaning agents and disinfectants which contain aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and **must not** be used. Instruments **must not** be immersed or placed in **Ringer's solution**.
- Mineral oil and silicone lubricant **should not** be used as they:
  - 1) coat microorganisms;
  - 2) prevent the direct contact of steam with the surface and
  - 3) are difficult to remove.
- Only instruments manufactured and/or distributed by HumanTech should be placed in HumanTech instrument trays or containers. These reprocessing instructions **do not apply** to HumanTech trays and containers which contain devices that are not manufactured and/or distributed by HumanTech.
- No descaling agents containing morpholine should be used in steam sterilisers. This agent leaves residues that may cause damage to instruments made from polymer over time.

### B. Inspection upon receipt – check of the contents and functionality of the instrument set

- Upon receipt in the hospital, instrument sets should be checked for completeness. Thumbscrews, wing nuts, adjusting screws or other types of screws, screw-on or other removable handles and interchangeable attachments should all be inspected. Many containers have schematic diagrams and instrument numbers or sizes, which have been printed on the container or tray.
- The marks on the instruments used for estimating anatomical dimensions must be legible. These may include length markings, angles, internal or external diameters, length, or depth calibrations and view from left/right. Notify your HumanTech contact partner if scales or other markings are illegible.



## C. Limitations

- Enzymatic and other cleaning agents with a neutral pH-value are recommended and preferred for the cleaning of reusable HumanTech instruments. Alkaline agents with a pH of 12 or less can be used for cleaning stainless steel and certain polymer instruments in countries where the laws or local regulations require it, or if there is suspected contamination by prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt-Jacob disease (CJD). **It is of the utmost importance that alkaline cleaning agents are completely and thoroughly neutralised and rinsed from the instruments.**  
**Note: Cutting instruments of all kinds should be carefully examined after treatment with alkaline cleaners to ensure that the cutting edges are sharp enough to use.**  
**Note: It is important to choose enzyme solutions which are intended for the decomposition of blood, body fluids and tissues. Some enzyme solutions are specifically designed for the decomposition of faecal or other organic contaminants and may not be suitable for use on orthopaedic instruments.**
- Repeated reprocessing has a minimal impact on reusable, hand-held HumanTech instruments if the guidelines below are followed, unless otherwise indicated. The service life of surgical instruments made of stainless steel or other metals is generally determined by wear and damage due to the intended surgical use of the instrument, and not due to reprocessing.
- Machine cleaning with only a washer/sterilising machine **may not** be thorough enough in the case of orthopaedic instruments with lumens, cannulas, cavities, precise cooperating surfaces and other complex design features. Rather, thorough manual cleaning or a combination of manual/machine cleaning is recommended.
- Where applicable, instruments consisting of several components should be disassembled for cleaning. It is generally readily apparent if disassembly is required. It must be ensured that no small parts are lost. If a part is lost, please notify your HumanTech contact partner when returning the instrument.
- Instruments **must** be removed from the metal or polymer tray for manual and/or machine cleaning. Instruments **should not** be cleaned in polymer or metal trays. Instrument trays, containers and lids must be cleaned separately from the instruments. Non-sterile disposable implants are exempt from this rule. Plates and screws may remain in the tray or caddy during reprocessing.
- The polymers used in HumanTech instrument sets can be sterilised using steam/moist heat. Polymer materials have a limited service life. If polymer surfaces become “chalky” and show signs of excessive wear (e.g. whitening due to micro-cracks, spalling), or if the polymer instruments undergo an extreme change in shape or become visibly bent, they should be replaced. Consult your HumanTech contact partner if polymer instruments need to be replaced.
- Most polymers currently available cannot withstand the conditions in washers/sterilising machines, which operate at temperatures of at least 141°C and use steam nozzles as cleaning aids. Under these conditions, the surfaces of the polymer instruments are badly damaged.
- Soaking in disinfectant may be a necessary step in the control of certain viruses. However, these agents may cause discoloration or corrode the instruments (bleaches for household use contain or form chlorine and chloride in the solution and have a similar corrosive effect to saline solution). Disinfectants contain glutaraldehyde or other aldehydes and can denature protein-containing contaminants, making them harden and more difficult to remove. Soaking in the disinfectant should be avoided if possible.
- Steam sterilisation is the recommended method for the sterilisation of HumanTech instruments.
- Ethylene oxide (EO), gas plasma and dry heat sterilisation are not recommended as sterilisation methods for HumanTech instruments.
- Instruments with removable polymer covers **must** be disassembled for sterilisation.
- Products made from titanium and titanium alloys tend to discolour due to steam impurities and detergent residues that form multi-coloured surface layers of oxide deposits. These oxide layers, which are not harmful to the patient, can be so dark as a result of repeated sterilisation that they may hide tick marks, catalogue and lot numbers and other stamped or engraved information. This discoloration can be removed with acidic corrosion inhibitors. Frequent use of these inhibitors is not recommended.
- The use of hard water should be avoided. Soft tap water is suitable for the initial rinse. Clean water should be used for the final rinse, however, in order to eliminate the deposition of minerals on the instruments.

Clean water can be obtained via one of the following processes: ultrafiltration (UF), reverse osmosis, deionisation or equivalent methods.

#### D. Note on preparation during and directly after use

- Wipe excess body fluids and tissue from the instruments using a lint-free, disposable cloth. Place instruments in a bowl of distilled water or cover with a damp cloth. Do not allow saline solution, blood, body fluids, tissue, bone remains or other organic particles to dry on instruments prior to cleaning.  
**Note: Soaking in proteolytic enzyme solutions facilitates cleaning, particularly in the case of instruments with complex designs and difficult to access areas (e.g. cannulated and tubular designs, etc.). These enzyme solutions decompose protein-containing substances and prevent blood and protein-containing materials from drying on instruments. The manufacturer's instructions for the preparation and use of these solutions should be followed exactly.**
- The instruments **should** be cleaned within 30 minutes of use in order to minimise the risk of drying before cleaning.
- Used instruments **must** be brought to the main supply department in sealed or covered containers in order to prevent an unnecessary risk of contamination.

#### E. Preparation for cleaning

- Engraved symbols or specific instructions on instruments or instrument trays and containers should be closely followed.
- Where applicable, instruments consisting of several components should be disassembled for adequate cleaning. It should be ensured here that no small screws or components are lost. If a part is lost, please notify your HumanTech contact partner when returning the instrument.
- Published instructions for use and surgical methods and/or procedures may serve as a further source of information to illustrate the instructions for the assembly/disassembly of certain HumanTech instruments.

#### F. Preparation of the cleaning agent

- Enzyme cleaners and detergents with a neutral pH-value and low-foaming surfactants are preferred and recommended by HumanTech. Alkaline agents with a pH of 12 or less can be used in countries where the laws or local regulations require it. Treatment with alkaline agents should be followed by a neutralising agent and thorough rinsing.
- All detergents should be prepared in the required dilution and at the temperature recommended by the manufacturer. Soft tap water can be used to prepare the detergent. In order to achieve optimal detergent performance, the recommended temperatures must be observed.
- Dry powder detergents should be completely dissolved prior to use in order to prevent discolouration or corrosion of the instruments.
- Fresh cleaning solutions should be prepared when existing solutions become heavily contaminated (blood and/or turbidity).

**Table 1 Cleaning/disinfection options**

| Method                                            | Description                                                                        | Section |
|---------------------------------------------------|------------------------------------------------------------------------------------|---------|
| Manual cleaning                                   | Soak and scrub in an enzyme solution followed by ultrasonic cleaning               | G       |
| Combined manual/machine cleaning                  | Soak and scrub in enzyme solution followed by an automatic wash/disinfection cycle | H       |
| Mechanical cleaning (washer/disinfection machine) | Wash/disinfection cycle – <b>not recommended without manual pre-cleaning</b>       | I       |

## G. Instructions for manual cleaning/disinfection

1. Immerse the instruments completely in an enzyme solution and soak for 20 minutes. Carefully scrub the instruments using a nylon brush with soft bristles until all visible dirt has been removed. Particular care must be taken when it comes to cleaning cavities, lumens, mated surfaces, joints and other hard to reach areas. Lumens should be cleaned using a long, narrow nylon brush with soft bristles.
2. Remove the instrument from the enzyme solution and rinse with tap water for at least 3 minutes. Rinse lumens, openings and other hard to reach areas thoroughly.
3. Provide prepared cleaning agent in an ultrasonic cleaner. Immerse the instrument completely in the cleaning solution for 10 minutes and clean using ultrasound at 45-50 kHz.
4. Rinse the instrument with clean water for at least 3 minutes, or until there are no more visible signs of blood or dirt on the instrument. Rinse lumens, openings and other hard to reach areas thoroughly.
5. Repeat the steps for ultrasonic cleaning and rinsing above.
6. Wipe off excess moisture with a clean, absorbent, lint-free, disposable cloth.

**Note: In the case of discoloured or corroded stainless steel instruments, an acidic corrosion inhibitor in an ultrasonic cleaner may be sufficient to remove deposits on the surface. It must be ensured that the acid is thoroughly rinsed from the instruments. Acidic corrosion inhibitors should only be used when required.**

## H. Instructions for combined manual/machine cleaning and disinfection

1. Immerse the instruments completely in an enzyme solution and soak for 10 minutes. Gently scrub the instruments using a nylon brush with soft bristles until all visible dirt has been removed. Particular care must be taken when it comes to cleaning cavities, lumens, mated surfaces, joints and other hard to reach areas. Lumens should be cleaned using a long, narrow nylon brush with soft bristles.

**Note: The use of an ultrasonic cleaner at 45-50 kHz promotes the thorough cleaning of the products.**

**Note: Difficult to reach areas or mated surfaces can be better rinsed with a syringe or water jet.**

2. Remove the instruments from the enzyme solution and rinse with clean water for at least 1 minute. Rinse lumens, blind holes and other hard to reach areas thoroughly.
3. Place instruments in a suitable basket in the washer/disinfection machine and run a standard instrument cycle. The following minimum parameters are crucial for thorough cleaning and disinfection.

**Table 2 Typical machine wash/disinfection cycle for the surgical instruments**

| Step | Description                                                            |
|------|------------------------------------------------------------------------|
| 1    | prewash with cold tap water for 2 minutes                              |
| 2    | spray with enzyme solution and hot tap water for 20 seconds            |
| 3    | soak in enzyme solution for 1 minute                                   |
| 4    | rinse with cold tap water for 15 seconds (X2)                          |
| 5    | wash for 2 minutes with detergent and hot tap water                    |
| 6    | rinse with hot tap water for 15 seconds                                |
| 7    | rinse with warm water (90°C) for 5 minutes (A <sub>0</sub> 3000)       |
| 8    | rinse with clean water and optional lubricant (64-66°C) for 10 seconds |
| 9    | dry with hot air for 7 to 30 minutes (116°C)                           |

Note: The washer/disinfection machine manufacturer's instructions should be strictly adhered to.

## I. Instructions for machine cleaning/disinfection

1. Exclusive cleaning with machine washer/disinfection systems is not recommended for surgical instruments. Orthopaedic instruments should be cleaned according to the manual or combined manual/machine cleaning procedures outlined in these instructions, unless otherwise specified.
2. In addition to the manual cleaning procedure described above, a washer/disinfection machine can also be used, although this is not required.
3. Simple instruments without multiple components, lumen/cannulas, blind holes, mated surfaces, joints and internal mechanisms or other complex design features can be successfully cleaned and disinfected by a typical wash/disinfection cycle for surgical instruments, as set out in Table 2 of these instructions. Products should be inspected thoroughly prior to sterilisation to ensure effective cleaning.



## J. Inspection, maintenance, testing and handling of lubricants

1. Inspect each instrument carefully to ensure that all visible dirt has been removed. If dirt build-up is found, repeat the cleaning/disinfection process.
2. Carry out a visual inspection for completeness, damage and/or wear.

**Note:**

- **If damage or wear is discovered which could affect the function of the instrument, please contact your HumanTech contact partner for a replacement.**
  - **If instruments are damaged, reprocessing may be negatively influenced.**
3. Check the mobility of movable parts (e.g. hinge joints, locks, connectors, sliding parts, etc.) to ensure smooth operation through the intended range of motion.
  4. Instruments with a hinge, rotating or joint mechanism should be treated with an oil-free product (e.g. instrument care lotion or an equivalent lubricant) which is intended for use on sterilised surgical instruments. Some oil-free instrument lubricants contain bacteriostatic agents that are useful. The expiration date specified by the manufacturer should be observed for concentrations which are stored and diluted for use in order to ensure effectiveness.

**Note: Mineral oil and silicone lubricant should not be used as they:**

- 1) coat microorganisms;
- 2) prevent the direct contact of steam with the surface and
- 3) are difficult to remove.

Note: These instructions for handling lubricants do not apply to compressed air-driven and electric instruments. Other requirements apply for these types of instruments and they should be treated with lubricant in accordance with the manufacturer's instructions.

5. Check long and narrow instruments (in particular rotatable instruments) for bends.
6. In the case of instruments which are assembled into larger units, check whether the single parts can be put together easily.

## K. Sterile packaging

### Packaging of individual instruments

- A commercially available, medical steam sterilisation bag (made from paper, Tyvek™ or an equivalent material) of a corresponding size can be used to double-pack individual instruments. Make sure that the inner bag is large enough to completely contain the instrument without damaging the seal or packaging, but small enough to fit inside a second bag without compromising the integrity of the entire package.
- Individual instruments can be packed in medical steam sterilisation fabric. Packaging should be prepared with a double layer of fabric in accordance with AAMI standards, or using an equivalent method.

**Note: If sterilisation fabric is used, it must be free of detergent residues. Reusable fabric is not recommended.**

### Packaging of instrument sets in fixed trays and containers with lids

**Safety measure:** The total weight of the coated instrument tray or container should not exceed 11.4 kg. When placed in a sterilisation container with a sealed lid, the total weight of the package should not exceed 16 kg. If maximum weights other than those described herein are used as standard, the total weight described here shall apply as the upper limit accordingly.

- Trays and containers with lids may be wrapped with a double-layer of medical steam sterilisation fabric in accordance with AAMI rules or using an equivalent method.
- Trays and containers with lids can also be placed in an approved sterilisation container with a sealed lid for sterilisation.

**Note: The installation and replacement of the sterilisation filters in the sterilisation containers should comply with the sterilisation container manufacturer's instructions Instrument trays and containers with marked, preconfigured layouts**

- Areas designated for certain instruments should contain only the instruments specifically designed for these areas.

- Optional HumanTech instruments should only be added to preconfigured instrument trays or containers which are designed with a dedicated universal area or dedicated universal compartment and to which the following guidelines for trays and containers without marked layouts or universal areas can be applied.
- Only instruments manufactured and/or distributed by HumanTech should be placed in HumanTech instrument trays. These validated reprocessing instructions **do not apply** to HumanTech trays which contain devices that are not manufactured and/or distributed by HumanTech.

**Universal instrument trays and containers without marked, preconfigured layouts or with unmarked, universal areas or compartments should only be used under the following conditions:**

- The total weight of the coated instrument tray or container should not exceed 11.4 kg. If maximum weights other than those described herein are used as standard, the total weight described here shall apply as the upper limit accordingly. When placed in a sterilisation container with a sealed lid, the total weight of the sterilisation package should not exceed 16 kg.
- All dismountable instruments must be disassembled before being placed in the container.
- All instruments should be arranged so that the steam can reach all instrument surfaces. Instruments should not be stacked on top of or touching one another.
- The user must ensure that the instrument container is not tilted and that the contents are not shifted once the instruments have been arranged in the container. Silicone mats can be used to keep the instruments in place.
- Only instruments manufactured and/or distributed by HumanTech should be placed in HumanTech instrument trays. These reprocessing instructions **do not apply** to HumanTech trays which contain devices that are not manufactured and/or distributed by HumanTech.

### L. Sterilisation instructions

- Table 3 lists the recommended minimum sterilisation parameters using which a Sterility Assurance Level (SAL) of 10<sup>-6</sup> can be achieved.
- The hospital is responsible for internal audit procedures with regard to the assembly, inspection and packaging of instruments after they have been subjected to a thorough cleaning, which provides for full penetration of the sterilisation steam and adequate drying. In addition, the hospital should recommend measures to protect against sharp or potentially dangerous parts of the instruments.
- Sterilisation using moist heat/steam is the preferred and recommended method for orthopaedic instrument sets.
- The recommendations of the sterilisation equipment's manufacturer should **always** be observed. If several instruments are being sterilised in a single sterilisation cycle, ensure that the maximum permissible number of devices as specified by the manufacturer is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or containers that allow for the distribution and penetration of steam, thereby ensuring that it comes into contact with all surfaces.

**Table 3 Recommended steam sterilisation parameters**

| Cycle type | Temperature | Duration of sterilisation | Minimum drying time |
|------------|-------------|---------------------------|---------------------|
| Pre-vacuum | 132-135°C   | ≥ 5 minutes               | 30 minutes          |
| Pre-vacuum | 121°C       | 30 minutes                | 30 minutes          |

### M. Storage instructions

- Sterile, packaged instruments should be stored in a place that is only accessible to certain designated members of staff, and that is well-ventilated and protected from dust, moisture, insects, vermin, extreme temperatures and extreme humidity.
- The sterile packaging of the instruments should be checked carefully prior to opening in order to ensure the integrity of the packaging.

**Note: If the sterile nonwoven fabric is torn or punctured, has been visibly damaged or gets wet, the instrument set must be re-packaged and re-sterilised.**

**Note: If there are signs that the cover gasket or filter on the sterilisation container have been opened or damaged, the sterile filter must be changed the instrument set must be re-sterilised (in the case of reusable filters, perform a detailed visual inspection).**

## 9. Hospital responsibilities for HumanTech loaned instrument sets

- Orthopaedic surgical instruments are generally characterised by a long service life. Their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments that do not work properly due to wear and tear, abuse or improper care should be returned to HumanTech for disposal. Please inform your HumanTech contact partner of any instrument problems.
- Loaned sets should be subject to cleaning, disinfection, inspection and final sterilisation and returned to HumanTech only once all of these decontamination steps have been carried out. Instruments returned to HumanTech should be accompanied by documentation of their decontamination.
- The responsible parties from the OR or the central sterilisation and reprocessing department, as well as your HumanTech contact partner, should be made aware of missing or damaged instruments from loaned sets in order to ensure that the next hospital receives a full set of instruments in working condition.
- These instructions have been created so that HumanTech surgical instruments can be recycled for reuse. It is the responsibility of the hospital to ensure that suitable equipment and materials are used during reprocessing and that the personnel involved have been trained accordingly. Only in this way can the desired results be achieved. This generally requires validation and routine monitoring of equipment and processes. Any deviation from the procedure described here should be tested for efficacy in order to prevent any undesirable consequences.

## 10. Customer service information

|                                                                                                                                                                                                                  |                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                         |
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## Annex: Cleaning/disinfection procedure

**Table 4 Manual cleaning/disinfection procedure**

|        |                                                                                                                                                                                                           |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1 | Immerse the instruments completely in an enzyme solution and soak for 20 minutes. Gently scrub using a nylon brush with soft bristles until all visible dirt has been removed.                            |
| Step 2 | Remove the instrument from the enzyme solution and rinse with tap water for at least 3 minutes. Rinse lumens, openings and other hard to reach areas thoroughly.                                          |
| Step 3 | Provide prepared cleaning agent in an ultrasonic cleaning device. Immerse the instrument completely in the cleaning solution for 10 minutes and clean using ultrasound at 45-50 kHz.                      |
| Step 4 | Rinse the instrument in clean water for at least 3 minutes, or until there are no more visible signs of blood or dirt on the instrument. Rinse lumens, openings and other hard to reach areas thoroughly. |
| Step 5 | Repeat the steps for ultrasonic cleaning and rinsing above.                                                                                                                                               |
| Step 6 | Dry off excess moisture with a clean, absorbent, lint-free, disposable cloth.                                                                                                                             |

**Table 5 Combined manual/machine cleaning/disinfection procedure**

|        |                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1 | Immerse the instruments completely in the enzyme solution and soak for 10 minutes. Gently scrub the instruments using a nylon brush with soft bristles until all visible dirt has been removed. Particular care must be taken when it comes to cleaning cavities, lumens, mated surfaces, joints and other hard to reach areas. Lumens should be cleaned using a long, narrow nylon brush with soft bristles. |
| Step 2 | Remove the instruments from the enzyme solution and rinse with clean water for at least 1 minute. Rinse lumens, openings and other hard to reach areas thoroughly.                                                                                                                                                                                                                                            |
| Step 3 | Place the instruments in a suitable basket in the washer/disinfection machine and run a standard instrument cycle.                                                                                                                                                                                                                                                                                            |

**Table 6 Typical machine wash/disinfection cycle for the cleaning/disinfection of surgical instruments**

|        |                                                                  |
|--------|------------------------------------------------------------------|
| Step 1 | Prewash in cold, soft tap water, 2 minutes                       |
| Step 2 | Spray with enzyme solution and hot tap water, 20 seconds         |
| Step 3 | Soak in enzyme solution, 1 minute                                |
| Step 4 | Rinse (X2) with cold, soft tap water, 15 seconds                 |
| Step 5 | Wash with detergent and hot, soft tap water (64-66°C), 2 minutes |
| Step 6 | Rinse (X2) with hot, soft tap water, 15 seconds                  |
| Step 7 | Warm rinse with hot, soft tap water (90°C), 5 minutes            |
| Step 8 | Rinse with clean water (64-66°C), 10 seconds                     |
| Step 9 | Dry with hot air (116°C), 7 to 30 minutes                        |

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