

Reprocessing instructions for surgical instruments -spinal surgery-

Recommendations for care, cleaning, disinfection, maintenance and sterilization

1. Purpose

This instruction manual describes the necessary reprocessing steps to which newly delivered and used instruments must be subjected.

The instruction manual is recommend for care, cleaning, disinfection, maintenance and sterilization of reusable surgical instruments - spinal surgery - by HumanTech and must be read carefully. This information also applies to disposable medical instruments which are manufactured by HumanTech and supply in a non-sterile state, but which must be sterilized before use. These products are intended for single use, but must be reprocessed before use, as long as they have not been used yet.

Note: The designation "not used" means that such components have not come into contact with blood, bone, tissue or body fluids. Any not used single-use (disposable) instruments that have come into contact with blood, bone, tissue or body fluids should not be reprocessed or re-sterilized and should be discarded.

The purpose of the Instruction is to provide Nursing and Sterilization Assistants with safe handling practices and helpful information in the effective reprocessing and maintenance of HumanTech reusable instruments. The hospital management and the management of the individual departments should have knowledge of these instructions and recommendations to ensure safe and effective reprocessing by the entrusted employees and to prevent harm or misuse to the environment, human and material.

The user should comply with local laws and regulations in countries where stricter reprocessing requirements apply than those defined in this manual.

2. Symbols

	DIN EN ISO 15223-1, 5.4.2 Symbol for „INTENDED FOR SINGLE USE ONLY“ Only for single use.
	DIN EN ISO 15223-1, 5.4.3 Symbol for „OBSERVE INSTRUCTIONS FOR USE“ Read the manual.
	DIN EN ISO 15223-1, 5.2.6 Symbol for „DO NOT RE-STERILIZE“ The product must not be sterilized again.
	DIN EN ISO 15223-1, 5.4.4 Symbol for „ATTENTION“ Review the instructions for use for important safety-related information.

3. Inspection at entrance and delivery of the sets

The instruments are usually supplied in sets and divided into sieve and containers. Individual shipments/ replacement shipments are usually delivered individually packaged.

When entering the hospital, instrument sets should be checked for completeness:

- thumb, wing, adjusting or other types of screws, screw or other removable handles and exchangeable accessories are to inspect.
- Many containers have schematic diagrams, instrument names or sizes imprinted on the tray or sieve.

The markings on the instruments used to estimate anatomical dimensions have to be readable. These may include length marks, angles, inside or outside diameters, length or depth calibrations, and right / left indicators. Inform your HumanTech representative if scales or other markings are non-readable.

Note: Hospitals are responsible for the cleaning, disinfection, packaging and sterilization of all loaned instrument kits before returning them to HumanTech. The enclosed form "Decontamination verification_for_returns_of_medical_products" have to fill out with the return of the medical devices.

4. Warnings and preventive measures

- Operations in spinal surgery contaminates instruments with blood, tissue, etc. All nursing should be familiar with the necessary generally recognized precautions to avoid injuries caused by sharp instruments during handling during and after surgery and during reprocessing. Thus, care should be taken when handling instruments with sharp points or sharp edges.
- Appropriate personal protective equipment should be worn when handling contaminated or potentially contaminated materials, instruments and products.
- For manual cleaning procedures, do not use metal brushes or swab. These materials cause damage to the surface and coating of the instruments. It is advised to use nylon brushes with soft bristles.
- It must be pointed out that large amounts of saline and other rinsing fluids are commonly used during a surgery and have a corrosive effect on instruments. Before cleaning, these solutions/ liquids and contaminated instruments must be cleaned as soon as possible after use, so that they do not dry on the instrument.
- During manual cleaning procedures, detergents with low-foaming surfactants should be used to ensure that the instruments are visible in the detergent solution. When manually scrubbing with a soft brush, the instrument should always be below the surface of the cleaning solution to prevent the formation of aerosols and to avoid splashes, which may spread contaminants. Detergents have to be easily and completely rinsed off the product surfaces to prevent buildup of detergent residue.
- Do not place heavy objects on sensitive products.
- Only instruments manufactured by HumanTech may be placed in the HumanTech sieves.
- Do not use descaling agents in the steam sterilizers which containing morpholine. These medium leaves residues, which may with time damage polymer instruments

5. Restrictions

- Repeated reprocessing will have minimal effect on reusable surgical instruments –spinal surgery- by HumanTech if performed according to the instructions below. The life cycle of surgical instruments made of stainless steel or other metals is usually results from wear and use damage because of the intended surgical use and not because of the reprocessing.

Note: Cutting instruments of all types should be carefully inspected after processing with alkaline cleaners to ensure that the cut surfaces are sufficiently sharp for use.

Note: It is important to choose enzyme solutions that are destined for the decomposition of blood, body fluids and tissues. Some enzyme solutions are specifically destined to decompose faeces or other organic contaminants and may not be suitable for use with orthopedic instruments.

- **The following solutions may not be used for cleaning: saline, Ringer's solutions and detergents/ disinfectants containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide.**
- Machine-only cleaning with a single washer/ sterilizer **may not** be thorough enough for orthopedic instruments with lumens, cannulae, cavities, precisely co-operating surfaces, and other complex design features. Rather, a thorough manual or combined manual/ machine cleaning procedure is recommended.
- Instruments **must** be removed from the metal or polymer sieves for manual and/ or mechanical cleaning procedures. Instruments **must not** be cleaned in polymer or metal sieves. Instrument sieves, containers and lids must be cleaned separately from the instruments.
- Polymers used in instrument sets from HumanTech can be sterilized with saturated steam / damp heat. Polymer materials have a limited life cycle. If polymer surfaces become "calcareous" and have excessive damages (e.g.

whitening by micro cracks, surface flaking) or if the polymer instruments have excessive changes of form or are visibly bent, they should be replaced. Contact your HumanTech representative if polymer instruments need to be replaced.

- **Soaking in disinfectant have to be avoid if possible.** These agents can lead to discoloration or corrosion of the instruments. Disinfectants contain glutaraldehyde or other aldehydes and can denature protein-containing contaminants, causing them to harden and are difficult to remove.
- The use of hard water have to be avoid. For the initial rinse soft tap water is suitable. However, for the final rinse, pure water have to be used to eliminate any buildup of minerals on the instruments.

6. Reprocessing categories

HumanTech recommends reprocessing of all reusable surgical instruments, as well as non-sterile disposable surgical instruments that have not been used yet, in accordance with the manual or combined manual/ mechanical cleaning instructions in this manual.

Alkaline cleaners can be used on cannulated and non-cannulated steel / metal instruments, polymers or plastics, as well as metal instruments with polymer components. In this case, a subsequent neutralization with acid, as well as a thorough rinse have to be carried out.

The cleaning of cannulated instruments and cavities have to be done manually, using a soft brush.

Note: In the case of rust, it must be ensured that the rust remover is compatible with the respective instruments and that no damage is caused to the instrument function. In this case, the manufacturer's instructions of the rust remover have to be observed.

A. Instructions for reprocessing during and immediately after use

- Wipe excess body fluids and tissues off the instruments with a lint-free disposable cloth. Place the instruments in a bowl of distilled water or cover with damp cloths. It is important to ensure that saline, blood, body fluids, tissue, or other organic particles are not allowed to dry on instruments before cleaning.

Note: Soaking in proteolytic enzyme solutions facilitates cleaning, especially for instruments with complex designs and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzyme solutions degrade proteinaceous substances and prevent blood and proteinaceous materials from drying on instruments. The manufacturer's instructions for preparing and using these solutions have to be followed carefully.

- The instruments have to be cleaned immediately after use to minimize the risk of surface drying before cleaning.
- Used Instruments have to be brought to the primary care department in closed or covered containers to prevent unnecessary contamination.

B. Preparation of detergents

- Enzyme cleaners and detergents with a neutral pH and low-foaming surfactants are preferred and recommended by HumanTech (e.g. neodisher® medizym). Alkaline agents with a pH of 12 or less may be used in countries where regulatory or local regulation so requires or where prion diseases such as transmissible spongiform encephalopathy (TSE) and Creuzfeldt-Jacob-Disease (CJD) are suspected. It is of the utmost importance that alkaline detergents be completely and thoroughly neutralized and rinsed off the instruments.
- All detergents should be prepared at the required dilution and at the manufacturer's recommended temperature.
- Dry powdered detergents have to be completely dissolved before use to avoid discoloring or corrosion of the instruments.
- Fresh cleaning solutions should be prepared when existing solutions become heavily contaminated (blood and/or cloudiness).

C. Cleaning preparation & disassembly

- If appropriate, multi-component instruments should be disassembled for proper cleaning. It have to be ensured that no small screws and components are lost. If any part is lost, please inform your HumanTech representative when returning the instrument.

- Published instructions for use and surgical techniques and/ or procedures may serve as a further source of information to illustrate instructions for assembling/ disassembling of certain HumanTech instruments.

D. Instructions for a manual cleaning / disinfection

Manual cleaning:

- Immerse the instruments completely into an enzyme solution (e.g. 0.5% (v/ v) neodisher® medizym dissolved in demineralized water) until no more air bubbles appear and soak for 10 minutes. Clean carefully the instrument with a soft bristled nylon brush until all visible dirt is removed. Particular attention have to be paid to cavities, lumens, precisely interacting surfaces, connecting parts and other hard to reach areas. Clean the lumen/ cannulization with a long, narrow nylon brush with soft bristles.
- 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.

Note: Hard to reach areas or precisely interacting surfaces can be better rinsed out with a syringe or a water nozzle.

- Put the prepared cleaning agent into an ultrasonic cleaner. Immerse the instrument completely in the cleaning solution and sonicate for 10 minutes at 45-50 kHz at a temperature of 30 °C to 40 °C.

Note: The use of an ultrasonic cleaner at 45-50 kHz and a temperature of 30°C to 40° C support a thorough cleaning.

- 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.
- Wipe off excess moisture with a clean, absorbent, lint-free disposable cloth.
- Lumens, openings, and other hard-to-reach areas have to be dried thoroughly with medically clean compressed air.

Manual disinfection:

- Immerse the instrument completely in a disinfectant solution (e.g.: 1.0% (v/v) Bomix® PLUS dissolved in demineralized water) until no more air bubbles appear and leave in the solution at a temperature of 20 ± 2 °C for 15 minutes.
- Rinse the instrument with pure water for at least 3 minutes
- Pay attention to a sufficient drying.

Inspect carefully each instrument to ensure that all visible contaminants have been removed. If dirt buildup is detected, repeat the cleaning/ disinfecting procedure.

E. Instructions for a combined manual/ mechanical cleaning and disinfection

- Perform steps 1-6 in chapter D (Manual Cleaning).
Place instruments in a suitable basket of the washer/ disinfecter. The instruments should not touch each other. If instruments with narrow lumens/ cavities are not connectable, they must be placed in the washer/ disinfecter so that the water and detergents can drain off completely.
Run the instruments through a standard instrument cycle of the washer/ disinfecter. The disinfection must be carried out at 90 °C - 100 °C for 5 minutes with demineralized water. The instructions for use of the washer-disinfecter manufacturer have to be followed. The following minimum parameters are essential for thorough cleaning and disinfection

Table 1 Typical machine-wash/ disinfect cycle for surgical instruments

Step	Description
1	1 minute prewash with cold tap water
2	10 minutes cleaning with cleaning medium (e.g. 0.4 % (v/v) neodisher® mediclean forte at 55°C
3	Rinse with cold water for 2 Minutes
4	Rinse 5 minutes for thermal disinfection at 93°C (AO >3000)
5	20-60 minutes drying at 100°C

Note: The instructions of the washer-disinfecter manufacturer should be strictly adhered to.

Note: Exclusive cleaning with machine wash/ disinfectant systems is not recommended for surgical instruments.

2. Pay attention to a sufficient drying.
3. Check and pack the instruments as soon as possible after removal from the washer/ disinfector. If necessary, do a final drying of the instruments. For that purpose use medically pure compressed air.

F. Inspection, maintenance, testing

1. Inspect each instrument carefully to ensure that all visible contaminants have been removed. If dirt buildup is detected, repeat the cleaning/ disinfecting procedure.
2. Make a visual inspection for completeness, corrosion, damage and/ or wear. Separate out damaged instruments.
3. Long and narrow instruments (especially rotatable instruments) have to be checked for bending.

Note: If any damage or deterioration is detected that could affect the function of the instrument, please contact your HumanTech representative for replacement.

Note: Damaged instruments may affect the reprocessing success.

4. Check the movement of moving parts (e.g. hinge joints, locks, connectors, sliding parts, etc.) to ensure that the intended movement can be performed.
5. Instruments provided with a hinge mechanism, rotating or joint mechanism should be treated with an oil-free product (such as instrument care milk or an equivalent lubricant) intended for surgical instruments which can be sterilized. Some oil-free instrumental lubricants contain bacteriostatic agents that are useful. To be effective, the expiry date given by the manufacturer of the product should be observed at stored and diluted concentrations.

Note: Mineral oil or silicone lubricant may not be used.

6. Fit all disassembled instruments. For instruments assembled into larger units, check that the individual components are easy to assemble.

G. Sterile packaging and sterilization instructions

The hospital is responsible for the assembly, inspection and packaging of the instruments after thorough cleaning to ensure complete penetration of the sterilization steam and proper drying. In addition, the hospital should recommend arrangements to protect against sharp or potentially dangerous parts of the instruments.

The recommendations of the manufacturer of the sterilizer should **always** be followed.

The sterilization should be carried out with the included containers and instrument sieves.

- Only instruments manufactured by HumanTech may be placed in the HumanTech sieves.
- Instruments with removable polymer sleeves **must** be disassembled for sterilization.
- Sterilization have to be carried out using saturated steam in accordance with the specifications of EN ISO 17665-1.
- Instrument sets should be properly prepared and packaged in instrument sieves and containers.
- The recommended minimum sterilization parameters, that have been validated to achieve a Sterility Assurance Level (SAL) of 10^{-6} , are as follows:

Sterilization medium	Sterilization method	Sterilization temperature	Holding time
Saturated steam	Pre-vacuum	134°C	5 minutes
Saturated steam	Pre-vacuum	121°C	30 minutes

H. Instructions for storage

- Sterile, packaged instruments should be kept in a designated place, that is well ventilated and protected from dust, moisture, insects, vermin, extremes of temperature and extreme humidity. It's only accessible for specific personnel.
- The sterile packaging of the instruments have to be inspected before opening to ensure they are undamaged.

7. Creutzfeldt-Jakob-Disease (CJD) and HIV infection

If you know about a contact of the medical device(s) with Creutzfeldt-Jakob-pathogens, please do a packaging of the device(s) for protection of third person, sign the device(s) with „Creutzfeldt-Jakob infected“ and inform HumanTech Spine

GmbH in a written form. Please note the enclosed form "Decontamination certificate for return deliveries of medical devices".

The instruments can also be contaminated with body fluids containing the hepatitis virus, HIV or other etiologic pathogens. All nursing staff should be familiar with the necessary generally accepted precautions to avoid injuries caused by sharp instruments during handling, during and after surgery and while reprocessing.

8. Responsibilities of the hospital for instrument sets from HumanTech

- Orthopedic surgical instruments are generally characterized by a long life cycle. However, their life expectancy may quickly decrease in the event of abuse or inadequate protection. Instruments that do not work properly due to wear, abuse, or improper care should be returned to HumanTech for disposal. Report all problems with the instruments to your HumanTech representative.
- Borrowed instrument kits may only be returned to HumanTech after completion of the cleaning, disinfection, inspection and final sterilization. The instruments returned to HumanTech should enclosed the documentation of decontamination. If no proof of cleaning/ sterilization is included, the cost of proper cleaning may be charged.
- The responsible person in the OR or the central sterilization and reprocessing department and your HumanTech representative should be aware of any missing or damaged instruments from loaned sets.
- The instructions have been prepared so that surgical instruments from HumanTech can be reprocessed before use. It's the responsibility of the hospital to ensure that suitable equipment and materials are used for reprocessing and that the personnel have been trained to achieve the desired results. This usually requires a validation and regular monitoring of the equipment and the processes. Any deviation from the procedure described here have to be checked for its effectiveness in order to exclude any potential undesirable consequences.

