HumanTech Spine GmbH

Processing Instruction for implants

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PROCESSING INSTRUCTIONS FOR IMPLANTS

These recommendations are for processing non-sterile HumanTech Spine implants.

The information provided applies to HumanTech Spine implants only.

Explanted implants must never be reprocessed and should be handled according to hospital protocol upon removal. Details on disposal please refer to IFU.

Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer to implant's product insert for any specific processing, cleaning, and sterilization instructions for that implant.

CAUTIONS

- The implants must be cleaned, disinfected and sterilised before use on the patient
- Effective cleaning and disinfection is an indispensable requirement for effective sterilisation
- We do not recommend processing used implants. A used implant is an implant that has come into direct contact with a patient, even though it has not been implanted
- Implants should not be lubricated
- Do not use implant if the surface has been damaged
- Do not use steel wool or abrasive cleaners on implants
- Implants are critical devices and must be terminally sterilized prior to use
- The sterilization parameters are only valid for devices that are adequately cleaned
- Do not disassemble unsterile pre-mounted implants for reprocessing
- Non-sterile delivered implants are delivered either in equipped trays within sterilisation containers or packaged individually. The individual packaging must be intact at the time of delivery. The sterilisation containers, trays and associated covers must not be damaged
- If implants are still in the original individual packaging, these are to be taken from the packaging before processing

LIMITS ON REPROCESSING

- Repeated processing cycles with mechanical or manual methods, as well as sterilization have minimal effects on implants
- Implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue. Any implant with corrosion, scratches, notches, residue, or debris should be discarded

PROCESSING INSTRUCTIONS

Point of Use Care

- Implants should remain covered until needed to avoid becoming soiled or contaminated with blood, tissue, and/or bodily fluids/matter. Only those implants to be implanted should be handled.
- Minimal handling of implants is necessary to prevent damage to the surface.

CONTAINMENT AND TRANSPORTATION

- Avoid cross contamination of implants with soiled instruments during transport.

Preparation for Processing

- We do not recommend processing used implants. A used implant is an implant that has come into direct contact with a patient.

PROCESSING - MANUAL METHOD

Manual cleaning (max. 2 hours after application)

- Completely immerse the products for 10 minutes in the cleaning medium (0.5 % (v/v) Neodisher® MediClean forte dissolved in demineralised water at a temperature of 30 ± 2 °C). At the beginning of the immersion time, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- After the immersion time, the entire accessible surface of the products, in particular the hard-to-access areas (cavities, gaps and recesses), must be cleaned with a soft non-metallic brush (medium hard toothbrush) in the cleaning medium until residues are no longer visible (for at least 30 seconds per product).
- Rinse the products 1 minute with demineralised water at room temperature.
- Transfer the products to an ultrasonic bath and clean for 10 minutes at a frequency of 35 kHz at an initial temperature of 25°C to 30°C. A mixture of 0.5 % (v/v) neodisher® MediClean forte dissolved in demineralised water is used as a cleaning agent for the ultrasonic bath.
- Rinse the products under demineralised water at room temperature for 3 minutes after ultrasonic cleaning.

Manual disinfection

- Completely immerse the products in a disinfectant solution (3.0 % (v/v) neodisher® Septo Fin dissolved in demineralised water) at a temperature of 20 ± 2 °C for 15 minutes. At the beginning of the immersion time, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- Dip the products after the disinfection bath for 1 minute in cold demineralised water and then an extensive rinsing must be ensured to remove remaining disinfectant residues from the products.
- Ensure complete drying.

Basic note

Proof of the basic suitability for effective manual cleaning and disinfection was provided by an independent accredited test laboratory, taking into account the procedure described in the previous chapter. Neodisher® MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg) was used as a detergent and as a disinfectant neodisher® Septo Fin (Dr. Weigert GmbH & Co. KG, Hamburg). In addition, an ultrasonic tank RK 510H (manufacturer: Bandelin electronic GmbH & Co. KG, Berlin) and a medium hard Dr. Best toothbrush (manufacturer: GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Munich) was used.

PROCESSING - COMBINED MANUAL/AUTO METHOD

Manual pre-cleaning (max. 2 hours after application)

- Completely immerse the products for 10 minutes in the cleaning medium (0.5 % (v/v) neodisher® MediClean forte dissolved in demineralised water at a temperature of 30 ± 2 °C). At the beginning of the immersion period, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- After the immersion time, the entire accessible surface of the products, in particular the hard-to-access areas (cavities, gaps and recesses), must be cleaned with a soft non-metallic brush (medium hard toothbrush) in the cleaning medium until residues are no longer visible (for at least 30 seconds per product).
- Rinse the products 1 minute with demineralised water at room temperature.

Automatic cleaning and thermal disinfection

Information on the selection of the cleaning and disinfectant device

When selecting the cleaning and disinfectant device, care must be taken to ensure that:

- the cleaning and disinfection device complies with the EN ISO 15883 standard and is legally CE marketed.
- a tested program for thermal disinfection is used (A0-value >3000).
- the cleaning and disinfection device is regularly maintained and checked.
- the program used meets the minimum requirements set in table 1 below

The instructions of the manufacturer of the cleaning and disinfection equipment must be complied with.

Steps for automatic cleaning and thermal disinfection

Following steps have to be followed for automatic cleaning and thermal disinfection

- Place the products in a screen basket for automatic cleaning and disinfection. The products must not touch each other. Then place the equipped screen basket in a load carrier of the cleaning and disinfection device and insert it in the cleaning and disinfection device.
- Start the program – the program must be executed according to the process sequence described in table 1.
- At the end of the program, remove the products from the device.
- Ensure complete drying.
- Allow products to cool to room temperature.

Process for automatic cleaning and thermal disinfection	**Description**
1	Rinse 1 minute with water at a water temperature of 25 ± 2 °C
2	Clean for 5 minutes at 55 °C ± 2 °C with cleaning medium consisting of a mixture of 0.5 % (v/v) neodisher® MediClean forte dissolved in water
3	Neutralise 1 minute at 42 ± 2 °C with neutralisation medium consisting of a mixture of 0.1 % neodisher® Z dissolved in water
4	Rinse 1 minute with water at 42 ± 2 °C
5	5 minutes thermal disinfection at 90 °C (A0 >3000) with demineralised water

INSPECTION

- Implants should be inspected after processing, prior to sterilization.
- Any implant with corrosion, discoloration, scratches, flaws, residue or debris should be discarded.
- Sort and replace damaged and defective products.
- Products containing residues from the previously described cleaning and disinfection process shall be cleaned and disinfected again.

PACKAGING

Only legally CE marketed and cleared sterilization barriers (e.g. wraps, pouches, or containers) should be used by the end-user for packaging terminally sterilized devices.

Place the products at the appropriate position in the intended trays and, if provided, close the trays with a cover. Then wrap the trays for the implant systems twice with sterilisation fleece/sterilisation paper (1) and then position them in the sterilisation container and close the cover of the sterilisation container. The sterilisation containers, trays and associated covers must not be damaged.

When using sterilisation containers with a filter system, care must be taken to ensure that the corresponding filter is correctly used before closing the container. Care must be taken to ensure that the filter can only be used once.

(1) For sterilisation validation, the trays were double wrapped in sterilisation paper/sterilisation fleece (company Brömeda Sterisheet 100+ green/woven heavy quality/66 g/m² item number 68170912) according to ANSI/AAMI ST79: 2006 – Fig.4 Sequential double-wrapping: envelope fold, which meets the requirements of ISO 11607-1. The chosen folding methodology corresponds to that in ANSI/AAMI ST79: 2017 – Fig.5 Sequential wrapping: envelope fold presented methodology.

Rigid Sterilization Container Use Instructions and Considerations

In order to ensure proper sterilization of the devices when using a rigid sterilization container, the following must be taken into consideration:

- Only legally CE marketed and cleared rigid sterilization containers may be used with the devices
- The rigid sterilization container manufacturer's instructions for use are to be followed. If questions arise regarding the use of the rigid sterilization container, HumanTech recommends contacting the manufacturer of that specific container for guidance.
- For any questions related to the volume to vent ratio, please contact the container manufacturer.

STERILIZATION

The following are the recommendations for the sterilization of HumanTech implants:

Parameters

Implant group:
VENUS® Posterior Spinal Implant System
VENUSnano® Posterior/Anterior Spinal Implant System
ADONIS® Lumbar Interbody Fusion
TRISTAN® Cervical Interbody Fusion
HERO® Cervical Plate System

Sterilisation medium	Sterilisation procedure	Pressure for venting processes	Pressure for sterilisation phase (saturated vapour pressure)	Sterilisation temperature	Time to hold	Drying time
Saturated steam	3x fractionated prevacuum	15 kPa	287 kPa ± 9 kPa(1)	132 °C ± 1 °C	5 minutes	10 minutes
Saturated steam	3x fractionated prevacuum	15 kPa	205,5 kPa± 6,5 kPa(1)	121 °C ±1 °C	30 minutes	10 minutes

Implant group: SAMSON® Vertebral Body Replacement						
Sterilisation medium	**Sterilisation procedure**	**Pressure for venting processes**	**Pressure for sterilisation phase (saturated vapour pressure)**	**Sterilisation temperature**	**Time to hold**	**Drying time**
Saturated steam	3x fractionated prevacuum	15 kPa	304 kPa± 9 kPa(1)	134 °C± 1 °C	5 minutes	10 minutes
Note: Due to the different loading configurations (including the type and extent of additional loads) as well as the density/total weight, as well as the performance characteristics of the steam steriliser (including its equipment), drying times generally vary greatly.The specified drying time must not be exceeded. (1) Since the sterilisation is carried out with saturated steam, the pressure for the sterilisation phase (saturated steam pressure) is directly dependent on the sterilisation temperature.The given values were taken from Table C.1 of DIN ISO/TS 17665-2.						

The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must show a tested efficiency, be properly installed, maintained, and calibrated. Procedures from ISO 17665 should be followed. Only legally CE marketed and cleared sterilization barriers (e.g. wraps, pouches, or containers) should be used by the end-user for packaging terminally sterilized devices.

SYMBOL GLOSSARY

	Manufacturer
	Date of manufacture
	Do not re-use
	Batch number
	Reference number
	Quantity
	Medical device
	Unique Device Identification
	Read the documentation
	Keep dry

	Unsterile
	sterilized by irradiation
	Do not resterilize
	Date of expiry
	Do not use when packaging is damaged.
	Attention
	MR conditional

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