Processing Instructions

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INFORMATION ON THE PREPARATION OR REPROCESSING OF PRODUCTS

PLEASE READ THIS MANUAL CAREFULLY AND FOLLOW THE INSTRUCTIONS.

INTRODUCTION

This part is valid for the following products:

- Implants NON STERILE
- Instruments
- Storage systems/trays

In case of different handling, the subgroups are explicitly mentioned.
This information is intended to assist clinical staff in the safe handling and reprocessing of reusable products. The parameters listed apply only to properly installed, maintained and calibrated reprocessing systems that meet the requirements of ISO 15883 and ISO 17665.

GENERAL INFORMATION

Delivery

All products from Hofer Medical Solutions which are delivered NON STERILE must be cleaned, disinfected and sterilised before each use. This also applies to the first use after delivery. The delivery packaging of the implants is NOT suitable for sterilisation. It is only used for transport purposes and must be removed before cleaning, disinfection and sterilisation. Products must be checked for damage before reprocessing. In case of damage after delivery, the manufacturer must be contacted.

Re-usability of Products

Disposable products: Medical products intended for single use are marked on the label with the following symbol: 
These products are intended for single patient use. However, they must be reprocessed before use if they are delivered UNSTERILE. Reprocessing of an implant is not permitted if it has already been in patient contact or contaminated with blood or other body fluids. Direct sterilisation of the products in the transport packaging without prior unpacking and cleaning is not permitted

Reusable products: Products that are not marked with the above symbol may be reused. These are instruments and trays.
A prerequisite for reuse is that the products are undamaged and uncontaminated. The reusable products must be reprocessed before each use. In case of disregard, the manufacturer excludes any liability.
Hofer Medical Solutions does not specify a maximum number for the use of reusable products. The life of the products depends on many factors, such as the manner and duration of each use, and/or handling, treatment between uses. Careful inspection and functional testing of the products before use are the best ways to determine the useful life of the product. The legibility of the labelling and, if available, the legibility of the UDI should also be checked during the inspection. In case of non-readability, the product should be replaced.

Materials used

Knowledge of the materials used and their properties is essential to ensure expert reprocessing and maintenance of the instruments.

- EN ISO 5832-1 Implant steel
- EN ISO 5832-2 Pure titanium grade 2
- EN ISO 5832-3 Titanium alloy grade 5
- EN ISO 7153-1 Instrument steel
- PEEK (polyetheretherketone)
- POM (polyoxymethylene)
- Anodised aluminium (storage systems, trays)

The materials used can be seen on the product label.

Basics of cleaning, disinfection and sterilisation

The basic principles described in this section must be observed in all reprocessing steps! Effective cleaning and disinfection are an indispensable prerequisite for effective sterilisation.
To ensure hygienic safety, Hofer Medical Solutions products may only be reprocessed by means of mechanical cleaning and disinfection. **Manual cleaning and disinfection are excluded!**

As part of your responsibility for the cleaning, disinfection and sterility of the individual components, please always observe the following during use:

- Use only approved agents (RKI, DGHM/VHA, FDA, etc.), preferably (mildly) alkaline cleaners.
- Only use washer-disinfectors that comply with EN ISO 15883 Part 1 and Part 2.
- The validated and/or manufacturer-recommended parameters must be adhered to for each cycle.
- Use fully demineralised water and/or water quality according to DIN EN 285 or EN 13060.
- In addition, observe the legal/hygiene regulations applicable in your country.
- Products with cavities (lumens, cannulations) must also be completely rinsed on the inside. Suitable inserts with rinsing devices must be used for these products.

Patients deemed to be at risk for prion diseases (such as Creutzfeldt-Jakob Disease) and associated infections must be operated on using disposable instruments. Instruments used to operate on a patient with suspected CJD or proven disease must be discarded after surgery or currently valid national recommendations must be followed. The sterilization procedure specified in this manual is not suitable for the inactivation of prions.

Warnings

- Reprocessing must be carried out as soon as possible after use. Soiling must not be allowed to cake on.
- Special attention must be paid to hard-to-reach areas such as hollow bodies, long and narrow cannulas, blind holes and joints. Clean cannulated products with tools such as cleaning wire, syringes and cannulas.
- Always disassemble instruments that can be disassembled before reprocessing.
- Always keep joints and locks in the open position.
- Do not clean instruments in the trays provided.
- Storage in metal containers (except stainless steel and aluminium containers) is not permitted.
- Always handle the instruments with the necessary care.
- Take measures to protect against damage during transport, cleaning and storage.

Tools for pre-cleaning

Never clean the products with metal brushes or steel wool. Noncompliance may damage the material.
Use clean, lint-free cloths and/or soft brushes as tools. For reprocessing cannulated products and / or products with cavities, you need cleaning pins, bottle brushes and / or disposable syringes with associated cannulas as an attachment.

Drying tools

Use lint-free disposable cloths or medical compressed air for drying.

Care products

Only use silicone-free care products that are suitable for the subsequent sterilisation process.

Information on preparation according to table A.1 of EN ISO 17664

<table>
<tr><td>Initial treatment at the point of use</td><td>Remove coarse soiling immediately after each application. Avoid caking on of tissue and blood, e.g. by wiping surfaces or rinsing cannulas, hollow bodies or blind holes with sterile or distilled water. Blood and tissue residues can lead to corrosion, for example. Take care to avoid fixation and adhesion of residues and germs (e.g.: aldehyde-free chemicals, cold water).
Do not return contaminated or used instruments to the screen basket or tray. Contaminated products must be reprocessed separately from the screen basket or tray. Contaminated instruments must not be transported or stored together with implants or other disposable products. Instruments can be damaged when being deposited, so care must be taken to ensure that instruments are deposited properly and that the instrument trays are not overfilled.</td></tr>
<tr><td>Preparation before cleaning</td><td>Clean the disassembled and opened instruments under running water. Tissue debris and other visible residues should be completely removed before machine cleaning. In the case of hollow bodies/cannulations, soft brushes or cannulas and disposable syringes should be used for this purpose. It is important that the brushes are of the correct diameter because cleaning will not be effective if the diameter is too small or too large.</td></tr>
<tr><td>Pre-treatment with ultrasound</td><td>If required. For pre-cleaning with ultrasound, prepare a fresh and clean cleaning solution. Observe the concentration/dilution, exposure time, temperature and water quality recommended by the manufacturer of the cleaning agent. Afterwards, the products must be thoroughly rinsed with fully demineralised water.</td></tr>
<tr><td>Cleaning & disinfection, drying</td><td>The manufacturer's instructions regarding exposure time, concentration and temperature of the detergent/disinfectant used must be observed.
To ensure hygienic safety, Hofer Medical Solutions products may only be reprocessed by means of mechanical cleaning and disinfection.
The following procedure has been validated by Hofer Medical Solutions:
<table>
<tr><td>Phase</td><td>Temperature</td><td>Duration</td><td>Medium</td></tr>
<tr><td>Rinsing</td><td>≤ 30°C</td><td>min. 1 min</td><td>Cold water</td></tr>
<tr><td>Cleaning</td><td>≥ 55°C</td><td>min. 10 min</td><td>0.5% neodisher Mediclean forte</td></tr>
<tr><td>Rinsing</td><td>10°C</td><td>min. 1 min</td><td>AD* or VE water</td></tr>
<tr><td>Thermal disinfection</td><td>≥ 93°C</td><td>5 min</td><td>AD* or VE water</td></tr>
<tr><td>Drying</td><td>110°C</td><td>20 min</td><td></td></tr>
</table>
* AD = Aqua Destillata / demineralised water</td></tr>
<tr><td>Inspection</td><td>Visually inspect the items to be rinsed, especially critical areas (e.g. blind holes, cannulations, joints, etc.), carefully for visible dirt residues and moisture residues. If necessary, repeat the process immediately.
Important: Avoid renewed contamination of the cleaned medical device. Sufficient cleanliness is a basic requirement for successful sterilisation!</td></tr>
<tr><td>Maintenance</td><td>Check instruments after reprocessing and before sterilisation for signs of end of product life, e.g. residues, damage, deformation, wear, corrosion and legibility of labelling. In case of damage, the instruments must be replaced!
After a successful visual inspection, instruments must be assembled in a cooled-down state. If not expressly indicated, do not assemble parts with force!
Check moving parts and articulated instruments for ease of movement, if necessary, use a small amount of validated, medically approved, silicone-free care products suitable for sterilisation.</td></tr>
<tr><td>Packaging</td><td>Before sterilisation, all products must be placed in the appropriate sieve.
For sterilisation, additionally use a suitable packaging system, such as a sterile barrier system according to ISO 11607-x (e.g.: sterilisation paper, sterilisation containers).
Protect the packaging and contents from mechanical damage.</td></tr>
<tr><td>Sterilisation</td><td>All NON-STERILE products can be sterilised with steam in an autoclave. The autoclaves must comply with EN 285 or EN 13060 with regard to validation, maintenance and inspection. The specifications of the manufacturer concerning loading and operation of the sterilizer must be followed exactly
The following procedure has been validated by Hofer Medical Solutions:
<table>
<tr><td>Procedures</td><td>Fractionated pre-vacuum process</td></tr>
<tr><td>Temperature</td><td>134°C</td></tr>
<tr><td>Exposure duration</td><td>≥ 5 min</td></tr>
<tr><td>Drying time</td><td>≥ 20 min</td></tr>
</table>
If other procedures are used by the user, these must be validated by the user in accordance with EN ISO 17665-1. Ultimate responsibility for validation of sterilisation techniques and sterilisation equipment lies with the user.</td></tr>
<tr><td>Storage</td><td>Storage area with limited access that is climate-controlled, well ventilated, and dry and provides protection from dust, moisture, insects and parasites, as well as direct sun exposure. The maximum storage time depends on various factors such as packaging, storage methods, environmental conditions and handling. Users must define a maximum storage time for sterile products until use. Within this time, the products must be used or, if necessary, reprocessed (sterilised).</td></tr>
<tr><td>Transport</td><td>Implants should not be transported or stored together with contaminated instruments, materials and / or equipment. Always handle the products with the necessary care. Take measures to protect against damage during transport. Carefully handle packaging and sterilization containers and protect them from damage or negative influences, e.g., mechanical or climatic type of effects.</td></tr>
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