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The processing and cleaning of instruments provided by the company Weber Instrumente GmbH & Co. KG

SOP

Contents

1 Preface

Please read this instruction on processing and cleaning of instruments provided by the company Weber Instrumente GmbH & Co. KG thoroughly before you start with the processing/sterilization of instruments. In the event that questions arise referring these instructions, you may contact Weber GmbH & Co. KG or the respective manufacturer of cleaning/disinfection equipment, sterilizer and ultrasonic bath or the manufacturer of cleaning, neutralization and disinfection agents. All instruments must undergo a visual inspection between each operational treatment. Here, instruments should be checked with regard to damages of surfaces or indication of corrosion (rust formation). Besides, the functioning of movable parts should be inspected upon cleaning. Damaged, corroded or inoperable instruments must not be reused. You may contact Weber Instrumente GmbH & Co. KG if you have further questions.

2 Further applicable norms, directives and additional information

In this chapter, a short overview of further applicable norms, directives and additional information will be given which are needful for the processing and disinfection of instruments. No responsibility is taken for the completeness of this information. For general technical as well as regulatory information and hints about processing/sterilization of instruments you may consider applicable legislation, literature and recommendations by the Robert Koch Institute.

- Please consider instructions of the disinfection/cleaning agent manufacturer for instruments with regard to concentration, dwell time and temperature. Disinfection agents without chlorine, ammonia and aldehyde with proven efficacy against HBV, HCV und HIV must be used only. They must correspond to the applicable national law for disinfection agents (e.g. FDA-admission, DDGHM (2002)/VAH (2011)-Listing, CE-marking etc.). Due to the protein-fixing effect of disinfection agents containing aldehyde, a disinfection should be carried out with agents free of aldehyde.
- Always consider the specification of the manufacturer of cleaning and disinfection equipments, ultrasonic bath and sterilizers.
- With regard to sterile packages (e.g. sterilization container) you should consider manufacturer instructions.
- Please consider the specification DIN EN ISO 17664 sterilization of medical devices - information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004); German version EN ISO 17664:2004
- Please consider the specification of the RKI directive 2001: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (Bundesgesundheitsblatt 44: 1115-1126)
- Please consider the specification of the directive by the DGKH, DGSV and AKI for validation and routine monitoring of mechanical cleaning and thermic disinfection processes for medical devices and for principles of equipment selection (3rd edition 2008).
- Please consider the specifications of the Draft Guidance for Industry and FDA Staff / Processing/ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling 2May 2011
- Please consider the specifications of ANSI/AAMI TIR12 September 2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- Please consider the specifications of DIN EN ISO 15883-1 (2006-09) Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (ISO 15883-1:2006); Deutsche Fassung EN ISO 15883-1:2006

3 General requirements for the processing of medical devices

To execute an adequate processing of instruments, you should consider the national applicable legislation and hygiene regulations of medical practice and/or hospitals. This applies foremost for specifications regarding to an effective inactivation of prions (e.g. Creutzfeldt-Jakob-disease).

Targeted preventive measures during treatment minimize permanent existing risks of contamination and infection. Including:

- The assessment of dangers connected to medical activities and definition of appropriate preventive measures
- Systematic proceeding of processing and work sequences with the primary target of prevention of contamination and injuries
- Thorough anamnesis, which registers all infection risks based on a patient

Instruments are contaminated when they have been used or opened (even unused!). They must then be hygienically processed without exception. The personnel has to wear an appropriate protective clothing, foremost gloves, for its own safety.

Instruments should not be kept longer than necessary in physiological saline solution as the contact can cause corrosion (rust formation). The moistening of instruments should be effected thoroughly in an adequate container.

After disinfection, subsequent flushing should be carried out only with demineralized water. This proceeding minimizes the generation of water spots and other deposits which may influence the following sterilization process negatively.

In order to achieve the necessary safety upon sterilization of instruments, the staff member in charge for processing of instruments must apply validated procedures for cleaning, disinfection and sterilization only. Regular maintenance, monitoring and compliance with pre-defined parameters for each cycle of processing are also mandatory. Processing is accomplished upon release for application by the staff member in charge. The respective SOP of the equipment lists modalities of the sterile-package (e.g. sterile-container). A sterilization indicator and indication of the date of sterilization must be marked in general.

Basically, it is distinguished between manual and mechanical procedures for processing. Mechanical procedures for processing should be preferably deployed, as the process parameter and procedures can be reproduced. The following chapters describe the instruction for manual and mechanical processing and sterilization.

4 Manual pre-cleaning

Touch dry contamination can make the processing of instruments difficult. Removable parts must be disassembled. Hence, pre-cleaning should be carried out promptly after deployment of instruments. For prevention of touch-dry contamination and for the protection of the personnel, all instruments should be put into an adequate disinfection solution with bactericide, fungicide, sporocide und antiviral effect. This must be thoroughly swayed. Rough contaminations, as blood, and residues from tissues and bones must be removed subsequently. For this purpose, the instruments must be taken from the bowl and all visible residues and contaminations must be washed up with fluent cold water. Alternatively, instruments may be cleaned in a disinfection solution with a soft nylon brush or a clean soft cloth which will be used for the purpose of this cleaning only. The instruments must not be treated with metal brushes, steel wool or other similar abrasive tools. Mechanical cleaning should be followed within the subsequent 2 hours.

Attention:

Danger of protein coagulation exists upon temperatures from 40°C, connected with an impeded removal of organic residues. The optimal working temperature for a disinfection bath is around room temperature. The initial disinfection is not a replacement for the subsequent sterilization of instruments!

4.1 Pre-cleaning of instruments with a through hole

Due to the small diameter of through holes, for e.g. guide wires, requirements for re-processing are high. To assure a reliable processing of such instruments, these relatively small lumens must be manually pre-cleaned as well. Thereby, the following listing is decisive:

- The instrument must be put into cold water for soaking of the contaminations promptly after its deployment. Thereby, the instrument has to be fully wetted with water.
- The through holes must be released by rough contaminations by using a water-cleaning gun (at least 15 seconds, pressure 4.2 bar). Passability has to be checked.
- Instruments can be cleaned mechanically afterwards.

4.2 Ultra sonic cleaning

Ultra sonic cleaning should be effected if instruments are strongly contaminated or if rough contaminations cannot be removed easily through manual pre-cleaning (see chapter 4.1). Application time and concentration of the cleaning agents must be considered and complied with manufacturer information. Beside, manufacturer information referring to the amount of water in the ultra sonic bath and compatibility of cleaning agent and instruments must be considered. In case of doubt, the manufacturer of the cleaning agent should be contacted.

5 Mechanical cleaning

Adequate and qualified cleaning and disinfection equipment should be used for mechanical cleaning. They must allow the pre-defined and validated cleaning processes and inspections by the user. Manufacturer information of cleaning and disinfection equipment must be complied. This also applies for manufacturer information of cleaning and neutralization agents, especially dosing. The preferable water quality for cleaning, notably for the subsequent flush-phase, is fully desalinated water or water which meets the required purity degree. Cleaning programs are regarded as optimal if they achieve thermic disinfection and a best possible removing of blood. In case of doubt, the manufacturer of cleaning and disinfection equipment as well as cleaning and neutralization agents should be contacted. The company Weber Instrumente recommends the following cleaning method (or an equivalent validated procedure):

- Machine/program: Vario TD Program by the company Miele Professional with cleaning agent: neodischer MediClean, disinfection agent: Getinge 88.
- Pre-cleaning with cold water for 4 min.
- Cleaning with alkaline cleaner, max 55°C 10 min.
- Neutralization 6 min.
- Inbetween-cleaning 3 min.
- Disinfection 5 min.
- Drying 30 min.

5.1 Drying before maintenance and sterilization

Usually the drying of instruments will be effected automatically in the drying cycle of the cleaning and disinfection equipment. Residue-free compressed air can be used for the drying of lumens. Afterwards, all cleaned and disinfected instruments must be checked once again with regard to damages of surfaces and corrosion.

6 Maintenance of instruments

Disassembled components of instruments can be reassembled before maintenance. To ensure efficiency of removable parts, notably the coupling and ratchets, they must always be lubricated after mechanical cleaning and before steam pressure sterilization. The components of the instruments should never dry run, i.e. deployed without lubricants as this may cause increasing wear-out failure and rapid failure of the entire instrument. The company Weber Instrumente recommends the care spray for instruments by the manufacturer Dr. Schuhmacher GmbH (D-34323 Malsfeld). For lubrication, equivalent care spray-lubricants for medical devices may also be used. Before each sterilization, a function check of removable parts must be carried out. If instruments are damaged, they must not be redeployed.

6.1 Application with Forcipes and similar instruments

Forcipes and similar instruments with swivel joints or prismatic joints and threads have to be lubricated at the bearing surfaces. The user has to take care that the instrument is half opened and a thin oil film is sprayed on (Figure 1 - example of forcipes). Generally a distance of the spray to the instrument of approximately 25 cm should be kept and approx. 1 second should be sprayed. Excessive oil should be removed with a clean lint free cloth (please follow the instructions of the manufacturer). The instrument is ready for sterilization.

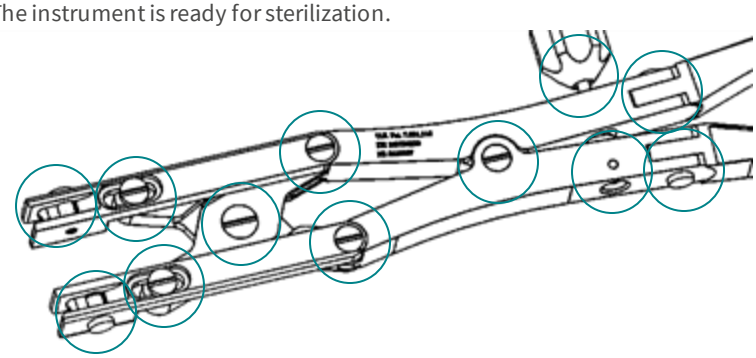

Figure 1: Example of forcipes (compressor) with bearing surfaces that have to be lubricated (circuited areas)

6.2 Application with couplings and ratchets

Important for the maintenance of couplings and ratchets is the lubrication of the inner functional parts. The following points have to be followed to achieve a sufficient lubrication:

- The spray has to be moved with the nozzle pipe to the limit stop into the drilling which is counterpart to the push button (if this is present). Spray for approx. 1 sec (Figure 2).

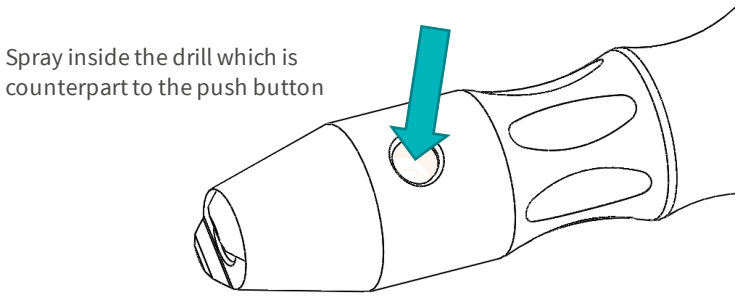

Figure 2: Spray into the drill

- Spray with nozzle pipe to the limit stop inside the main through hole of the coupling and the ratchet (that is valid for all designs). Spray for approx. 1 sec.
- Spray inside the gap between push button (if this is present) for one second (Figure 3).
  Push the push button (if this is present) 3 times (Figure 3).

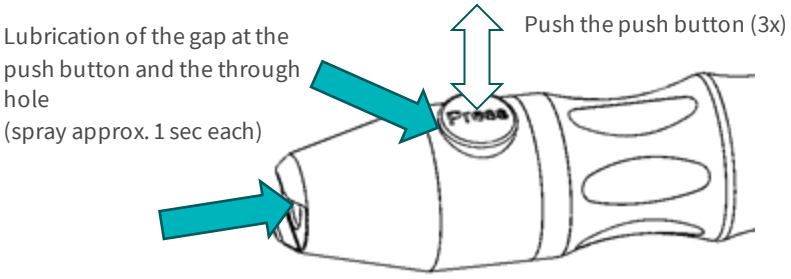

Figure 3: Lubricate the gap and through hole, push the push button 3 times

- The gap between the coupling body and the housing has to be lubricated (spray for approx. 1 sec). Move the sliding sleeve (if this is present) 3 times (Figure 4).

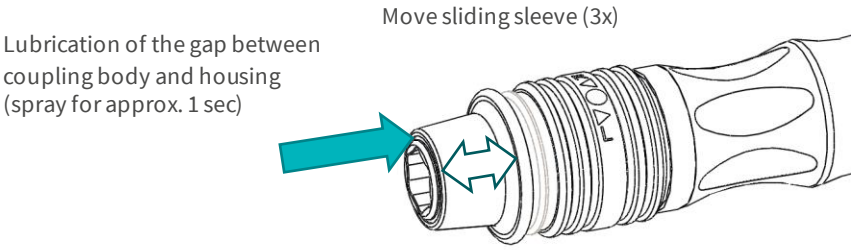

Figure 4: Lubrication of gap between coupling body and housing, move sliding sleeve 3 times

- To achieve a homogeneous lubrication of the inner functional parts the regulation sleeve has to be placed at a limit stop (right or left). Spray between the gap of the regulation sleeve and housing at the surface that is free. Take care that the nozzle pipe is at the level of the screw / labeling. Spray for approx. 1 sec (Figure 5).

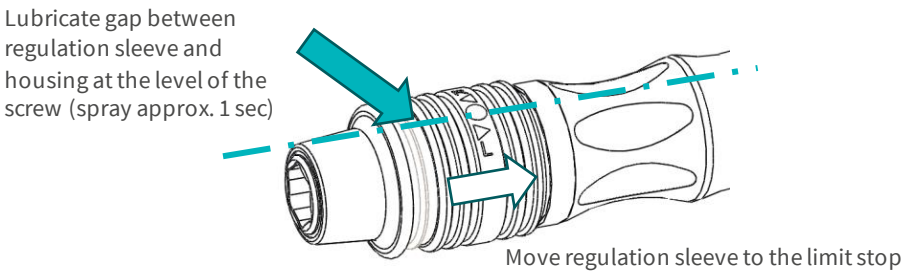

Figure 5: Lubricate the gap between the regulation sleeve and housing

- Move the regulation sleeve to the opposite limit stop. Spray between the gap of the regulation sleeve and housing at the surface that is free. Take care that the nozzle pipe is at the level of the screw / labeling. Spray for approx. 1 sec (Figure 6).

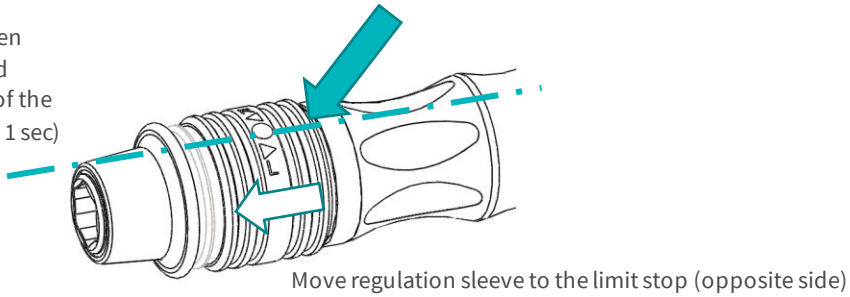

Figure 6: Lubricate the gap between the regulation sleeve and housing (opposite side)

- Move the ratchet with your fingers at least one complete turn in the free direction of rotation. Move the regulation sleeve in the opposite direction. Move the ratchet with your fingers at least one complete turn in the free direction of rotation (Figure 7).

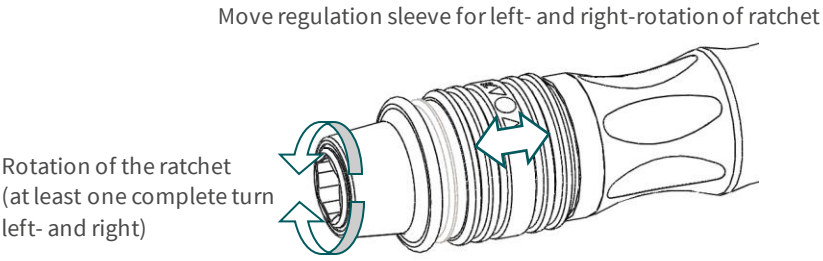

Figure 7: Left and right rotation of the ratchet, movement of regulation sleeve

- Move regulation sleeve to ratchet fixed position (centric position).
- Remove excessive oil with a clean and lint free cloth (follow the instructions of the manufacturer).
- The instrument is ready for sterilization.

7 Sterilization

The instruments can be sterilized individually. However, it is recommended to sort them to the designated sterilizable tray. Afterwards, the instruments or trays must be packed into single-use-sterilization packages suitable for steam pressure sterilization (single or double packing) and /or must be packed into a sterilization -container. All packages for steam pressure sterilization must adhere to the requirements according to DIN EN ISO 11607 / ANSI/AAMI ST79/ AAMI TIR12:2010, e.g. single-use-sterilization package (single or double package) with a temperature resistance until at least 137 °C (279 °F) and a sufficient vapor permeability. It must have sufficient protection against mechanical damages. Sterilization container must be maintained according to manufacturer information. Sterilization must be effected in autoclaves with the following parameters:

- Fractional pre-vacuum (threefold)
- Sterilization temperature at least 132°C
- Dwell time for at least 6 min.
- Drying time at least for 10 min.

Release for anew deployment of instruments must be effected by the staff member in charge upon evaluation of the recorded sterilization parameters.

8 Storage

Store sterile packaged instruments dry and dust-free at room temperature. Further notes may be listed in the manufacturer information of the respective packages.

9 Marking of products

This SOP applies only for products provided by Weber Instrumente GmbH & Co. KG, which are marked by the company Weber Instrumente GmbH & Co. KG. Identically constructed products, which are marked user-specifically by customers of the company Weber Instrumente GmbH & Co. KG, require a separate user-specific modified instruction for cleaning and processing.

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02				
03				
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