Non-Sterile Instruments and Implants For Spinal Surgery:

Instructions for Care, Cleaning, Maintenance, Sterilization.

CLARIANCE
innovation for spine surgery

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CLARIANCE reusable surgical instruments requiring disassembly before cleaning or sterilization procedure are listed in the appendix file, including the assembly-disassembly instructions.

1 INTRODUCTION

CLARIANCE non-sterile instruments and implants must be cleaned and sterilized to prepare them for use. This document provides detailed instructions on the cleaning, disinfection, maintenance, and sterilization of all non-sterile instruments and implants manufactured by Clariance.
This document also provides:

- The inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.
- The Disassembling and assembling of instruments before cleaning and the sterilization when the instruments are made up of several components.

The effectiveness of processes which are provided in these instructions has been validated by CLARIANCE. The efficacy of the reprocessing depends on:

- Equipment,
- Operators,
- Cleaning agents
- Procedures.

The healthcare facility should ensure that the selected processing steps are safe and effective. The reprocessing methods which are not in the scope of the instructions given by CLARIANCE must be validated by the Healthcare facility. These reprocessing methods shall prevail over CLARIANCE recommendations in the event of conflicting with the national cleaning and sterilization requirements.

Clariance instruments are reusable. Clariance implants must not be reprocessed for re-use. When single use devices are supplied non-sterile and require sterilization before use, the appropriate sections of these instructions may be applied unless other specific instructions are provided in the package insert. Single use devices must not be reused.

2 WARNINGS AND PRECAUTIONS

Single use devices are not designed to perform as intended after the initial use; they should not be reused. Please refer to the device label to identify single or multiple use devices and components. Under repeated uses, some instruments can have changes of their mechanical, chemical and physical characteristics. These changes may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications.

The reusable instruments of CLARIANCE are not normally used in surgical procedures where they are in contact with TSE infective tissue (Transmissible Spongiform Encephalophaties) as defined by the World Health Organization (WHO). Therefore, decontamination procedures with highly aggressive agents (i.e. sodium hydroxide NaOH or sodium hypochloride NaOCl) are not routinely recommended.

3 LIMITS OF REPROCESSING

CLARIANCE has demonstrated the instruments and implants can be reprocessed 200 times. The useful life of these devices depends on many factors (method and duration of each use, handling…). Careful inspection and functional tests of the instruments and implants before use is the best method of determining the end of serviceable life. Once 200 (re)cycling are achieved or when defects are detected please contact CLARIANCE. We will inform users on further actions to implement.

4 REPROCESSING INSTRUCTIONS

The chart Fig.1 describes the sequence of steps to prepare non-sterile instruments and implants and to prepare new devices for initial use. The detailed instructions are given on the following pages.

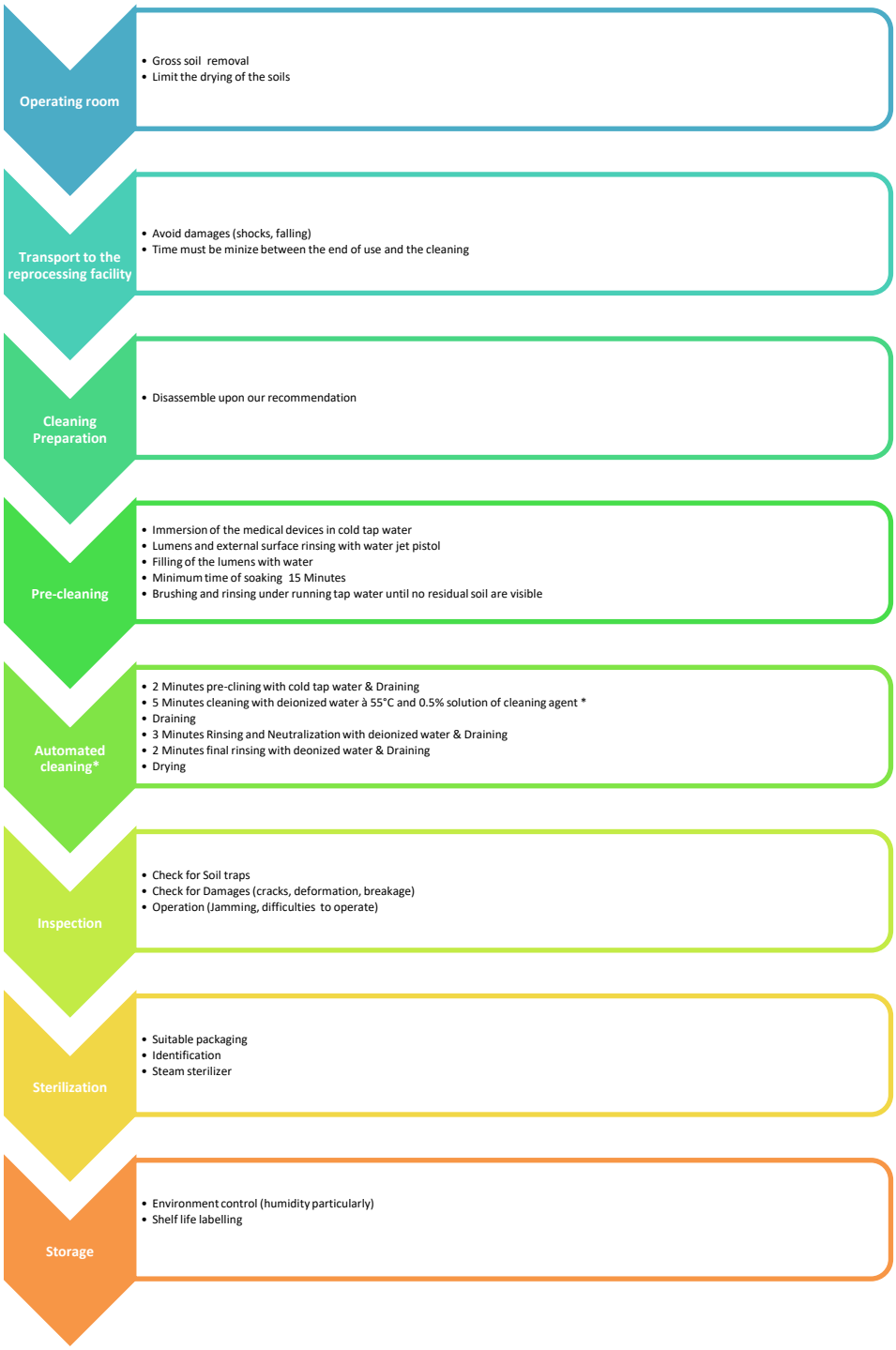

Fig. 1

** Cleaning agent used by Clariance for the validation of the cleaning process for non-sterile medical devices (implants and instruments) is Neodisher MediClean (Dr Weigert, Hambourg). The automated cleaning has been performed using a washer/disinfector Miele G7735CD.*

5 CLEANING

The method of cleaning CLARIANCE non-sterile instruments and implants is provided in these instructions; this method is a manual method. First, the reprocessing staff should use suitable protective clothing and equipment at all times. In particular, the instructions provided by the cleaning agent manufacturer for correct handling and use of the product must be followed. The guidance provided by the manufacturer of the detergent concerning the concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur for some devices. These discoloration or corrosion could also occur when the rinsing after cleaning and/or disinfecting is not enough. Specifically, formulated cleaning agents and/or disinfectants should be used for the cleaning or the disinfection of instruments and implants. Cleaning agent used by Clariance for the validation of the cleaning process for instruments and implants is Neodisher MediClean (Dr Weigert, Hambourg). It is an enzymatic, alkaline detergent. Equivalent product should be used for the cleaning of instruments and implants.

Mineral residues as well as contamination with micro-organisms and endotoxins from hard water can result in staining of the device or prevent an effective cleaning and decontamination. The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing instruments and implants should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes with less than 100 CFU/ml and 0.5 EU/ml is highly recommended.

Caution: CLARIANCE trays and cases are intended for transport and storage of instruments and implants. They are not designed for cleaning and disinfection in the fully assembled state. The instruments and implants must be removed from the tray for adequate cleaning results.

5.1 Operating room

Gross soil using absorbent paper wipes must be removed after use (within a maximum of 2 hours post-operatively). Intensive rinsing of the instruments and implants with fluent water or transfer of the medical devices into a bath with an aldehyde- free disinfectant solution is highly recommended.

5.2 Transport to reprocessing facility

Avoid the mixing of heavy devices with delicate devices to prevent any mechanical damages. Pay attention to cutting edges, both to avoid personal injury and prevent damage to the reusable instrument and non-sterile medical devices in general. Transport the reusable instruments and non-sterile medical devices to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the medical devices with a damp cloth to avoid drying of soil.

5.3 Cleaning preparation

Disassemble instruments as required. Specific instructions for instruments that require disassembly are provided in the Appendix of these instructions.

5.4 Manual pre-Cleaning

The following equipment is highly required:

- Personal must be equipped with the protective equipment as recommended by the cleaning agent supplier,
- Cleaning bath or vessel must be large enough to allow complete immersion of the all non-sterile medical devices,
- Cleaning wires for cannulated instruments and implants, soft and firm brushes and bottle brushes must be selected in accordance with the type of device to be cleaned,
- Water pistol connected to the tap water distribution network
- Remove gross soil using wipes and solution of cleaning agent.
- Immerse instruments and implants in the tap water.
- Ensure that all surfaces are thoroughly wetted.
- Ensure that air is not trapped within features of the device when immersing in the solution.
- Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches.
- Use a water jet pistol to ensure that the water reaches all parts of cannulated devices or lumens.
- A particular attention has to be taken for the instruments and implants with rough surfaces and features where soil may be impacted or shielded from the cleaning process. These devices must be cleaned with suitable soft bristle brushes.
- Use a bottle brush of appropriate diameter and length for cannulated devices. Ensure that the brush passes the whole length of each cannulated devices.
- Operate articulating devices and those with moving parts.
- Respect the 15 Minutes recommended minimum time for soaking.
- Rinse in running tap water until no residual test soil are visible.
- Pay particular attention to cannulated devices, threaded and blind holes, as well as hinges and joints, between mating parts.
- Visually inspect for any remaining soil and repeat the steps above if necessary.
- Transfer immediately to cleaning step.

Caution: Never use steel wool or metal brushes for cleaning, because they degrade the protective layer of the metallic surface of the device.

5.5 Automated cleaning and disinfection using washer disinfector

Equipment required:

- Washer-disinfector with approved efficiency (e.g. CE mark or FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing.
- An approved thermal disinfection program with sufficient rinsing steps
- Cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.

5.5.1 Procedure:

- Load the non-sterile instruments and implants into the washer-disinfector. Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.
- Avoid contact between devices as movement during washing could cause damage and washing action could be obstructed.
- Arrange reusable instruments and implants so that cannulations are not horizontal and blind holes incline downwards to assist drainage.
- Articulating devices should be in the open position.
- Operate the washer-disinfector cycle.
- Upon completion, unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process. Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.

5.5.2 Cleaning cycle:

- 2 Minutes pre-cleaning with cold tap water
- Drain
- 5 Minutes cleaning with deionized water at 55°C in a 0.5% solution of cleaning agent
- Drain
- 3 Minutes intermediate rinsing with deionized water.
- Drain
- 2 Minutes final rinsing with deionized water.
- Drain
- Drying
- If additional drying is required, arrange all non-sterile medical devices in a clean area or heat in an oven below 110°C.

Caution: Chemical disinfection programs are not recommended due to the potential for chemical residues to remain on the instruments and implants. These residues could interfere with sterilization efficacy.

5.6 Inspection

Before preparing for sterilization, all non-sterile instruments and implants should be inspected. Generally un-magnified visual inspection under good light conditions is enough.
All parts of the devices should be checked. Evidence of damage and wear on an instrument may include, but is not limited to, corrosion, discoloration, excessive scratches, flaking, wear, and cracks.

Particular attention should be paid to:

- Recessed features (holes, cannulations).
- Soil “traps” such as mating surfaces, forceps hinges.
- Cutting edges should be checked for sharpness and damage.
- For devices that may be impacted, check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Functional checks should always be performed:

- Mating devices should be checked for proper assembly.
- Instruments and implants with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
- Rotating medical devices should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface.

6 PACKAGING

Where appropriate, the cleaned, disinfected, and checked non-sterile instruments and implants should be assembled into the dedicated trays provided by CLARIANCE. Cases/trays should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized non-sterile instruments and implants should be suitable for steam sterilization at must meet the following requirements:

- ISO 11607-1
- CE Mark or FDA clearance

7 STERILIZATION

Steam autoclave sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of and be validated and maintained in accordance with EN 285, EN 13060, EN ISO 17665.

CLARIANCE has validated an autoclave cycle for sterilization of complete set including implants, reusable instrument cases & trays. Instruments shall be sterilized in the assembled state as stored on the tray (i.e.: there is no need to disassemble these instruments for sterilization, if the brackets in the tray are designed to accommodate multi-component instruments in their assembled state).

7.1 USA

Cycle	Temperature	Exposure Time[1]	Drying Time[2]
Dynamic Air removal	270°F (132°C)	4 Minutes	20 Minutes
Gravity	270°F (132°C)	15 Minutes	30 Minutes

<u>Caution:</u> CLARIANCE does not recommend the use of 'flash' sterilization for instruments and implants.

<u>Warning:</u> Single-use implants and instruments should not be re-used.

7.2 Outside USA

Cycle	Temperature	Exposure Time[1]	Drying Time[2]
Dynamic Air removal	270°F (132°C)	4 Minutes minimum	20 Minutes minimum
Gravity	270°F (132°C)	15 Minutes Minimum	30 Minutes Minimum
Dynamic Air removal[3]	273°F (134°C)	18 Minutes minimum	30 Minutes Minimum

[1] <u>Exposure time:</u> Period of maintain of the load at the sterilization temperature in the autoclave.

[2] <u>Drying time:</u> Period during which steam is removed from the autoclave and the autoclave pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material.

[3] Some Healthcare Authorities recommend sterilization according to these parameters to minimize the potential risk of transmission of Creutzfeldt-Jacob disease.

8 ADDITIONAL REPROCESSING ADVICES FOR THE HANDLES

For the reprocessing of CLARIANCE handles, follow the recommendations described previously. Additionally, particular attention should be paid to the following points:

- The surgical ratcheting handle must be disassembled from the shaft instruments before reprocessing. Specific advices for disassembly are provided in the Appendix of these instructions.
- The handle must be cleaned within 30 minutes of use to minimize the potential for drying inside inaccessible parts before cleaning procedure. To avoid the drying of soil, soak the handle into cold water.
- Cleaning of small holes, interstices and cannulations requires special attention. Use a syringe to flush all hard to reach areas. A soft bristle brush with the appropriate diameter should be used to remove debris.
- To avoid water residues inside holes and cannulations, the use of sterile compressed air is recommended.

9 STORAGE BEFORE USE

After sterilization, non-sterile instruments and implants should be stored in the sterilization wrap in a dust-free and dry place. The shelf life is depending on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized instruments and implants before use should be defined by each health care facility. This information must be labeled on the sterilization wrap.

10 DISPOSAL OF DEVICES

All disposable devices are considered as a biomedical waste and should be handled according to the health waste management internal procedure applied by the hospital.

11 REFERENCES

- ✓ ISO 17665-1 Sterilization of health care products, moist heat.
- ✓ ISO 11607 Packaging for terminally sterilized medical devices.
- ✓ ISO 17664-1 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

12 CUSTOMER SERVICE INFORMATION

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