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I. Introduction, general information, and warnings

1. Introduction

This document is intended to give general guidance on how reusable medical devices supplied by SPINEVISION may be processed to prepare them for use. It also gives instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

This document provides detailed instructions on the cleaning, disinfection, maintenance, and sterilization of **surgical instruments and is applicable to all non-sterile medical devices** manufactured by SPINEVISION.

SPINEVISION surgical instruments' must be cleaned and sterilized prior to use. This document is provided in conjunction with the assembly and disassembly instructions for multi-component instruments (handling instruction cards) which must be disassembled prior to cleaning and the instructions for use which come with the products.

SPINEVISION 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, as they are not designed to perform as intended after 1st usage but can be resterilized if not used[1] (e.g. screws, plates, etc…).

The changes in mechanical, physical, or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use and/or cleaning and re-sterilization release.

Single use devices bear the following symbol according to ISO 15223-1 on their labels:

Do not reuse

This information is not applicable to **single-use devices that are sold sterile** and cannot be resterilized.
Those devices bear the following symbol according to ISO 15223-1 on their labels:

Do not resterilize

One validated method of cleaning, using automatic washer and sterilization SPINEVISION reusable medical devices is provided in this document. The automated method is more reproducible and allows staff to be less exposed to contaminated devices. SPINEVISION has demonstrated the processes described in these instructions to be capable of being effective.

Note: Alternative methods of processing outside the scope of this document may be suitable for reprocessing. In the event of conflicting national cleaning and sterilization requirements, these shall prevail over SPINEVISION

[1] Not used means any device that has never been in contact with blood, bone fragments, tissue, and any body fluids.

recommendations. It is the user responsibility to qualify any deviations from the recommended methods of processing and inform SPINEVISION if there are deviations.

2. General information

The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

New and used reusable devices must be thoroughly processed according to these instructions prior to use.

Hospitals must assume responsibility for cleaning, disinfection, and sterilization of all instrument sets before returning them to SPINEVISION.
However, the next user must also inspect the set upon receipt to verify via documentation and visual control that devices have, in fact, been adequately cleaned and decontaminated before repeating procedures to prepare the set for subsequent reuse.

Surgery requires complex instruments which have multiple components, articulating or rotating parts, removable handles. Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure.
Instrument sets must be complete according to the Set Composition to be used correctly. The Set Compositions have been provided with the containers.

Please refer to assembly and disassembly instructions for multi-component instruments (handling instruction cards) provided along with the products.

3. Warnings and precautions

During surgery, instruments become contaminated from blood, tissue, and bone fragments and in some cases marrow. They may also become contaminated with body fluids containing hepatitis virus, HIV, or other pathogens. All care workers should become familiar with the necessary precautions of preventing injuries caused by sharp instruments when handled during utilization or reprocessing.

Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.

Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes mask, goggles or face shield, gloves, overall and shoe covers.

Metal brushes or scouring pads must NOT be used during cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

Cleaning agents must be thoroughly rinsed from the device to prevent accumulation of detergent residue.

Do not stack instruments or place heavy instruments on top of delicate devices.

Dry soiled surgical instruments are more difficult to clean. **Do not allow contaminated devices to dry** prior to reprocessing.

Do not use fixing products which would cause the binding of residues and affect the outcome of soaking, cleaning and rinsing.

Do not clean soiled instruments in trays.
Instrument trays, cases and lids must be **cleaned separately** from soiled instruments.

Devices must always be checked before use (visual and functional general state). Some instruments need lubrication before sterilization, please refer to assembly and disassembly instructions for multi-component instruments (handling instruction cards) provided along with the products.

SPINEVISION advises the disposal of all infectious wastes in accordance with applicable national and local regulations and the medical waste protocol of the medical center, and not endanger the security or the health of patient, user, or another person until its complete disposal (including cleaning, decontamination, and waste).

4. Limits of reprocessing

A thorough inspection and functional check of the device has to be implemented before each use. Repeated reprocessing of reusable medical devices has minimal effect on the devices. SPINEVISION has demonstrated the devices can be reprocessed 200 times. The usefull life of these devices depends on many factors (method and duration of each use, handling…). Carefull inspection and functionnal tests of the instrument 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 SPINEVISION. We will inform users on further actions to implement. Please refer to assembly and disassembly instructions for multi-component instruments (handling instruction cards) provided along with the products.

II. Equipment required

1. Summary

- Personal protective equipment as recommended by the cleaning agent supplier
- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Non-shedding wipe
- Tap water[2]
- Freshly prepared purified water/ highly purified water[3]
- Freshly prepared cleaning solution using a cleaning agent according to healthcare organization
- Syringe
- Soft bristle brushes and bottle brushes for cannulations lumens and other blind areas (ensure that the brushes have the appropriate shape and size) - Never use metal brushes or steel wool
- Absorbent paper
- 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
- Cleaning agent for the washer (i.e.: Neodisher SeptoClean - Dr. Weigert)
- Neutralizer for the washer (i.e.: Neodisher Z - Dr. Weigert)
- Lubricant for the washer (i.e.: Neodisher MediKlar - Dr. Weigert)
- Steam autoclave

2. Indications for the cleaning agent

Only agents whose efficacy has been proven (FDA cleared, EC marked, …) should be used. It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues which are suitable for use with orthopaedic instruments.

SPINEVISION's cleaning protocol has been validated using the cleaning agent: Neodisher SeptoClean.

Saline and cleaning/disinfection agents containing **bleach, formaldehyde,** or **sodium hydroxide (NaOH)** can damage specific components and **should not be used**.

As **aldehydes** may hold TSE agents steady, solutions containing aldehydes **should not be used**.

Cleaning agents should be prepared at the concentration and temperature recommended by the manufacturer.

If cleaning step is performed using an acidic or very alkaline agent, a neutralization step using a neutralizer must be performed immediately after the automatic cleaning cycle.

SPINEVISION devices are not normally used in surgical procedures where they contact low or high-risk TSE (Transmissible Spongiform Encephalopathies) infective tissue. Therefore, decontamination procedures with extremely aggressive agents are not necessary and, for normal processing, are not recommended because material degradation may occur.

When the instruments have been used in surgery with a risk of contamination by **TSE agents (prions), a specific cleaning procedure** may be necessary.

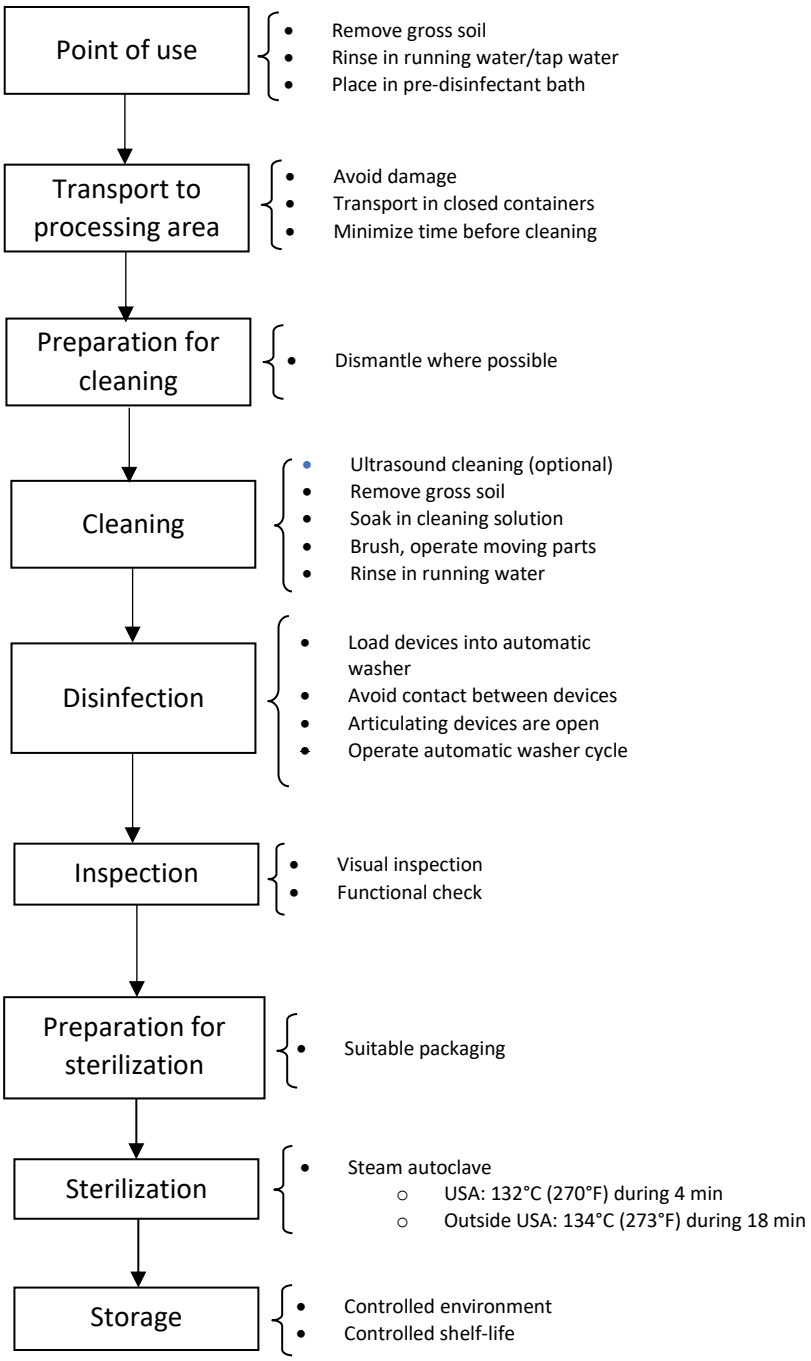
[2] Avoid use of hard water. Hot water would cause the binding of proteins and other residues that could affect the efficacy of the cleaning process.

[3] Purified water can be considered as critical water as described in ANSI/AAMI ST108:2023 "Water for the processing of medical devices" for final rinsing

III. Processing Instructions

To maintain reusable devices properly, it is important to consider the following instruction.

1. Flowchart



2. Preparation for cleaning

The cleaning process starts at the point of use to the sterilization step and consist of the washing and the disinfection of the reusable devices.
SPINEVISION trays are intended for transport, storage and sterilization of reusable instruments and unused implants. They are not designed for cleaning and disinfection in the fully equipped state. **The instruments must be removed from the trays and disassembled following specific instructions for adequate cleaning results**. Pay attention to small items as they might get lost.

a) Point of Use

Immediately after use:

- Remove soiled devices from trays.
- Remove gross soil present on the devices with a disposable, non-shedding wipe.
- Soak devices according to healthcare organization
- For devices with cavities, it is mandatory to irrigate every channels or voided parts. Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc…).
- These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on devices. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.
- Carefully rinse, using tap water (softened tap water may be used), the devices before cleaning to avoid any interaction between the disinfectant solution used in the pre-cleaning and the solutions used during cleaning.
- For optimal results, devices should be cleaned within 30 minutes after use.

b) Transport to Processing Area

- Avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones. Pay particular attention to cutting edges, both to avoid injury and damage to the medical device.
- Used devices **must be transported** to the processing area **in closed containers** to avoid unnecessary contamination risk and drying of soil.
- If transfer to the processing area is to be **delayed**, consider covering the reusable instruments with a **damp cloth to avoid drying of soil.**

c) Preparation before Cleaning

- When applicable, multi-components instruments should be dismantled for appropriate cleaning following specific instructions (handling instruction cards) provided with the products.
- Attention should be paid to avoid losing small screws and components.

3. Cleaning

a) Cleaning

The pre-cleaning step is obligatory. If the devices contain cannulated parts, prewash them in an ultrasonic bath after the soaking step.

- **Remove gross soil** using **wipes** and solution of cleaning agent.
- **Immerse** reusable devices in solution of cleaning agent.

- Ensure that **all surfaces are thoroughly wet**. **Use a syringe** to ensure that the cleaning solution reaches all cannulated parts.
- **Ensure that air is not trapped** within cannulas or voids of the device when immersed in the solution.
- **Soak for minimum recommended time** by the detergent manufacturer's instructions.
- Using suitable **soft bristle brush**, **clean the instrument thoroughly**, paying particular attention to rough surfaces as threads, cannulated parts, joints, and difficult access areas where soil may be impacted or shielded from the cleaning process.
- **Use a bottle brush** of appropriate diameter and length for cannulation. Ensure that the brush passes the whole length of each cannulation. Otherwise, the device does not conform and not reusable; please contact your SPINEVISION representative for an exchange.
- **Rinse** in running water / tap water for at least **2 minutes**, and until all traces of cleaning solution are removed.
- Visually **inspect** for any remaining soil and repeat the steps above if necessary.
- Allow to drain on absorbent paper or transfer immediately to cleaning step.

b) Disinfection

- **Load** the reusable instruments into the automatic washer.
- **Avoid contact between devices** as it could diminish the efficacy of cleaning process.
- Arrange reusable devices so that **cannulations are not horizontal** and **blind holes inclined downwards** to help drainage.
- **Articulating devices** should be opened.
- **Operate the washer-disinfector cycle**, using a neutral pH cleanser. See the following table "Automatic Disinfection Steps and Parameters"
- 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.

Automatic Disinfection Steps and Parameters:

Cycle	Minimum Time (minutes)	Water/Detergent Type	Minimum Temperature
Cleaning/Disinfection	10	Cold Purified Water Septoclean Dr Weigert	55°C (131°F)
Rinse I	2	Cold Purified Water Neutralizer	N/A
Rinse II	6 sec	Cold Purified Water	N/A
Final Rinse[4]	1	Cold Purified Water Rinse aid	55°C (131°F)
Thermal Rinse	5	De-ionized water	90°C (194°F)
Dry Hot Air	30	N/A	100°C (212°F)

[4] Final rinse needs to be performed with purified water according to definition of critical water as described in ANSI/AAMI ST108:2023 "Water for the processing of medical devices". The Endotoxin limits correspond to critical water with an endotoxin limit <10EU/mL.

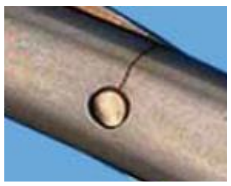
4. Inspection

- Before preparing for sterilization, all reusable devices should be inspected, under good light conditions.
- All parts of the devices should be checked for remaining soil, particularly in the **cannulations,** mating surfaces, hinges, and holes.
- Check that the engraving is still readable.
- Check for damage and excessive wear such as distortion, deformation, cracks, corrosion (Cf. defect library below).
- Check for any discoloration which lead to a misidentification or a misinterpretation (Cf. defect library below).
- In case of any doubts, do not hesitate to contact your SPINEVISION representative to ask for confirmation.

If any of the above occur to you, contact your SPINEVISION representative for exchange and fill in a complaint form.

Multicomponent instruments disassembled for the cleaning should be reassembled following the specific instructions (handling instruction cards) provided with the products.
If a part is lost during the process, notify your SPINEVISION representative to return the device or to get spare parts.
Once reassembled, check if the instruments are functional and do not seize up.

Here is a library which can be used to identify **potential defects**:

INTEGRITY			
			
Breakage	*Deformation*	*Stress cracks*	*Wear*
CORROSION			
			
Surface Corrosion	*Pitting corrosion*	*Fretting corrosion*	*Rust Film*
SURFACE CHANGE			
			
Discoloration	*Water Spots*	*Stains*	

5. Packaging

Where appropriate the cleaned, disinfected, and checked medical devices should be assembled into the dedicated trays provided. SPINEVISION cases/trays should be double wrapped and the packaging for terminally sterilized medical devices should:
- comply with EN ISO 11607-1 standard
- be suitable for steam sterilization (temperature resistance up to at least 141 °C, sufficient steam permeability)
- provide sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

SPINEVISION ® instrumentations should be packed before sterilization:

- Single instruments: a standard polyethylene/Tyvek (or equivalent, like double wrap) sterilization pouch with appropriate size may be used for single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging.
- Instruments in Sets: sets of instruments may be loaded into dedicated instrument trays provided for sterilization. Use standard medical grade steam sterilization wrap following the AAMI double wrap method (ANSI/AAMI ST46).

6. Sterilization

Before use, the SPINEVISION® components must be steam-sterilized by using a sterilization process according to the international standard for moist heat ISO 17665-1, in compliance with country-specific regulations. The sterilization of SPINEVISION® instrumentations and implants has been validated using the following parameters. However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should validate the process that they use, employing the actual equipment and operators that routinely process the devices.

	Outside USA	USA
Method	Steam Sterilization	Steam Sterilization
Cycle	Prevacuum	Prevacuum
Temperature	134°C (273°F)	132°C (270°F)
Minimum Exposure Time	18 minutes *See Note 1*	4 minutes
Dry Time (Minimum)	30 minutes	30 minutes

Note 1: This steam sterilization cycle is not considered by the Food and Drug Administration to be standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Note: Where there is a concern about TSE contamination (prions), the World Health Organization recommends processing through a prevacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/APH/ 2000.3, "WHO Infection Control Guidelines for TSE").

Additional information about sterilization validation:

Studies demonstrated that steam-sterilization provide a Sterility Assurance Level (SAL) of at least 10^{-6}.

Additional instruments, that are not intended to be contained in kits (according to the standard set composition), packaged singly in double wrap.

When several devices are sterilized during the same sterilization operation, it is necessary to check that the permissible maximum load of equipment is not exceeded.

Please note that according EN ISO 17664-1, It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

7. Storage

After sterilization, please store the medical devices in the sterilization packaging in a dry and dust-free place. Storage conditions must be in compliance with good practices in health care facilities, with a controlled environment free of dust, insects, moisture and vermin and protected from humidity and temperature extremes.

IV. References

The reprocessing instructions have been written in accordance with standards:

- AAMI TIR 12 – Designing, testing, and labelling reusable medical devices for reprocessing in Health Care Facilities: A guide for medical device manufacturers.
- ANSI/AAMI ST108:2023 "Water for the processing of medical devices"
- AAMI TIR 30 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- ANSI/AAMI ST77 – Containment devices for reusable medical device sterilization
- ANSI/AAMI ST 79 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ASTM F565 – Standard Practice for Care and Handling of Orthopaedic Implants and Instruments
- ISO 11607-1 – Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 15223-1 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: general requirements
- ISO 15883-1 – Washer-disinfectors - Part 1: general requirements, terms and definitions and tests
- ISO 15883-2 – Washer-disinfectors - Part 2: requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- ISO 17664 – Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17665-1 – Sterilization of health care products - Moist heat - Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices
- Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling.
- World Health Organization (WHO): WHO/CDS/CSR/APH/2000.3. *WHO Infection Control Guidelines for TSE.*

Refer to data on file for further information on the validation studies.

V. Contact information

Refer to the Instructions for Use of the system or contact:
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92160 Antony France
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