enovis™

External Fixation System
Instrumentation

Instructions for Use for Proper Maintenance of Surgical Instruments

Please read before use.

1. PACKAGING
Single, in blister or pouch. Product identification is given on external label.

2. PROCESSING INSTRUCTIONS
The sequence of steps required to prepare re-usable instruments for re-use or to prepare new devices for initial use, are summarized below. More detailed instructions for each step are given after.

- Point of use. Remove gross soil.
- Transport to processing area. Avoid damage, minimize time before cleaning.
- Preparation for cleaning. Disassemble as required.
- Manual pre-cleaning. Soak in enzymatic solution (15 minutes minimum), rinse using agitation under the water level.
- Inspection. Check soil “traps”, operation, straightness, and damage.
- Sterilization. Suitable packaging, steam sterilizer.
- Storage. Control environment and storage time.

3. PREPARATION FOR CLEANING AND DISINFECTING
Brand-new instruments must be removed from their transportation packaging before storing and/or before the instrument usage and processing cycle. Any protective caps or foils must be removed. Before using brand-new instruments, they must be sent through the entire processing cycle in the same manner as used instruments. The cleaning step should never be skipped because residues, as picking materials or care agents, could lead to the formation of stains or deposits during sterilization. Always check cleaning results by visual inspection. The instruments should be visibly clean after the cleaning stage.

Point of Use
After use (within a maximum of 2 hours post-operatively) remove gross soil using absorbent paper wipes. Intensive rinsing of the re-usable instruments with fluent water or transfer of the medical devices into a bath with an aldehyde free disinfectant solution is highly recommended.

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 personal injury and prevent damage to the re-usable instrument. Transport the re-usable instruments 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 re-usable instruments with a damp cloth to avoid drying of soil.

Preparation for Cleaning
Disassemble instruments as required. Specific instructions for instruments that require disassembly are provided in Annex together with the instrument set.

Pre-Cleaning
The pre-cleaning step can be omitted in case of direct subsequent manual cleaning and disinfection. In the event that highly contaminated re-usable instruments are to be subjected to an automatic cleaning process, pre-cleaning in an ultrasonic bath is recommended.

⚠ Never use metal brushes or steel wool for cleaning.

4. PRE-CLEANING

- Remove gross soil using wipes and solution of cleaning agent.
- Immerse re-usable instrument in solution of cleaning agent.
- Ensure that all surfaces are thoroughly wetted.
- Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
- Ensure that air is not trapped within features of the device when immersing in the solution.
- Soak for minimum recommended time by the detergent manufacturer's instructions.
- Using suitable soft bristle brushes, clean the re-useable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
- Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes, and the teeth of broaches.
- Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.
- Operate articulating devices and those with moving parts.
- Rinse in running water until all traces of cleaning solutions are removed.
- Pay particular attention to cannulations 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.
- Allow to drain on absorbent paper or transfer immediately to cleaning step.

5. MANUAL CLEANING AND DISINFECTION
If powdery cleaning agents or disinfectants are used, make sure you dissolve the powder completely in water before immersing the instruments. Undissolved particles may cause surface damage.

Following manual cleaning or disinfection, make sure to rinse instruments adequately and thoroughly with clear running water. This procedure removes dirt residues that may still adhere to the surfaces of the instruments. To prevent water spots, a final rinse using fully demineralized water is recommended. After this, the instruments must be dried carefully, immediately.

Compressed air drying is the drying method of choice because it is not only a very gentle but also highly effective technique. When using machine-based cleaning and disinfecting process, all trays, inserts, holders, etc., must be correctly loaded. To ensure effective cleaning of all articulated instruments (scissors, clamps, etc.) they must be placed into the washer in open position. The trays, racks, holders and supports must be such that subsequent cleaning in ultrasound basins or washer disinfectors will not be hampered by areas inaccessible to ultrasound or water. The items should be removed from the machine immediately upon completion of the program. If they are left in the closed machine, the residual moisture may cause corrosion.

Here is the recommended procedure for manual cleaning and disinfection:

- Prepare an ultrasonic bath with a cleaning solution using the concentration and temperature specified by the detergent manufacturer.
- Immerse the device completely and activate the bath for minimum of 15 minutes.
- Using suitable brushes or cleaning wires, clean the device, paying particular attention to rough surfaces and features that may be shielded from the brushing action.
- Rinse for at least one minute in running water until all traces of cleaning solutions are removed. Pay particular attention to cannulations, blind holes, hinges, and joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml).
- If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.
- Prepare a bath with a disinfectant solution using the concentration and temperature specified in the detergent manufacturer's instructions.
- Immerse the device completely for at least the time specified in the detergent manufacturer's instructions.
- Rinse cannulations at least three times with a syringe. Rinse for at least 1 minute in running water of the specified quality until all traces of disinfectant solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse at least five times with a syringe (volume 1-50ml). Dry the re-useable instruments using filtered, compressed air, or clean, lint-free wipes.
- If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C.
- Visually inspect and repeat complete manual cleaning and disinfection if necessary.

6. STERILIZATION

Every surgical instrument is supplied in NOT STERILE packaging and needs to be sterilized in steam autoclave (max 140°C) before use, avoiding any form of

chemical sterilization. Sterilization has to be performed using suitable packaging materials checked in the contest of sterilization process validation.

Steam autoclave (moist heat) 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, and ANSI/AAMI ST79.

Instruments shall be disassembled before sterilization as described in the Annex provided together with the instrument set.

⚠ Single use instruments should not be re-sterilized. See below for recommended minimum sterilization parameters that have been validated to provide a 10^{-6} sterility assurance level (SAL).

- **Method:** Moist heat sterilization according to ANSI/AAMI ST 7.
- **Cycle type:** pre-vacuum (Pre-Vac).
- **Minimum temperature:** 132°C (270°F)
- **Minimum exposure time (1):** 10 minutes
- **Minimum dry time (2):** 30 minutes.

(1) **Exposure time:** period for which the load and entire chamber is maintained at the sterilization temperature.

(2) **Drying time:** period during which steam is removed from the chamber and the chamber 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.

⚠ The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

⚠ Refer to Sterilization Containers instructions for use to have more information.

7. STORAGE

Instruments may corrode as a result of adverse storage conditions. To prevent this, they should be stored in dry and dust-free conditions. Major temperature fluctuations should be avoided in order to prevent accumulation of condensate on instrument surfaces. Never store instruments near chemicals which may

destroy metals when in direct contact with them, or may emit corrosive vapors. Brand new instruments and those returned from repair may only be stored at room temperature in dry rooms or cabinets. Otherwise, condensate may build up inside plastic packages as a result of temperate fluctuations. This may cause subsequent corrosion damage.

To guarantee instrument sterility up to the time of use on the patient, Citieffe provides a Sterilized Container that is indicated for use by hospitals and by health care facilities to:

- Organize and protect stainless steel, aluminum, and titanium general surgical instruments that will be sterilized.
- Allow sterilization of the contained instruments (both surfaces and lumens) by pre-vacuum steam sterilization.
- Maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been compromised.

Please refer to the Sterilization Container Instructions for Use for more details.

8. INSPECTION, MAINTENANCE, TESTING, AND LUBRICATIONS

Before each surgery, check the instrument functionality. As the duration, in good conditions of the instrument set is not foreseeable, before each surgery, check the instrument integrity also faking the movement which will be performed during the surgery intervention. In the event you notice a malfunctioning or a decrease in prevision, contact Citieffe which will control or eventually repair the instrument.

⚠ Citieffe does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection progress.
- Visually inspect for completeness, damage, and/or excessive wear.

⚠ If damage or wear is noted that may compromise the function of the instrument, contact your Citieffe representative for a replacement.

- Check the action of moving parts (E.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Hinged, rotating or articulating instruments should be lubricated with a water-soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized.

Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

⚠ Mineral oil or silicone lubricants should not be used because they

1. Coat microorganisms.
2. Prevent direct contact of the surface with steam and are difficult to remove.

⚠ These lubrication instructions are not applicable to air powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

9. POSSIBLE UNDESIRED EFFECTS

- Colored and anodized aluminum parts may fade as a result of machine based cleaning, thereby losing their coding function.
- Stainless steel instruments could have corrosion attack if water chloride concentration is too high. The probability of pitting is low, as long as the chloride content does not exceed a level of approximately 120 mg/l (equivalent to 200 mg/l NaCl) at room temperature. With increasing chloride concentrations, however; the risk of pitting will increase rapidly, too.

10. SUGGESTIONS

- Never immerse stainless steel instruments in a physiological solution (NaCl) because prolonged instrument contact with saline solution leads to pitting and stress corrosion cracking.
- Because of corrosion risk, long intervals between instrument cleaning and sterilization (e.g. overnight or over the weekend) should be avoided.
- The cleaning and disinfecting solutions used should be freshly prepared on a daily basis. If solutions are used for too long, corrosion risk may occur due to contamination levels, increased concentration of cleaning solutions as a result of evaporations, or insufficient disinfection.
- Instruments with rotative components such as drill bits, cutters, burrs, or abrasive tools, are only conditionally suitable for machine treatment. As a rule, ultrasonic bath treatment is preferable.
- To prevent excessive chloride concentrations and subsequent pitting, it is recommended to use fully demineralized water for the final rinse.
- The use of fully demineralized water in the final rinse is not only recommended for the reasons described above, preventing chloride induced corrosion, but also because it helps to keep the surfaces of the

instruments free from stains and discolorations, and stabilizes anodized aluminum surfaces.

- To prevent damage and consequential corrosion due to metal abrasion, never use metal brushes or metal sponges for removing stains.
- Allow the instruments to cool down to room temperature to avoid thermal shock that may damage coating and coupling.
- To avoid damage, always put your instruments down carefully after use. Careless dropping can damage instruments.

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Printed in USA.
MK-10406 Rev 00. CRO-2023-0165.