Manufacturer:
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INSTRUCTION FOR USE (IFU)
English

- Please read this document carefully before using the product
- Follow the safety instructions to avoid injuries

Device: Sterilization Cassettes for the TRAUMA, RECONSTRUCTION & QUICK FIX series

Introduction
Before using this device, it is important to study the following recommendations, warnings and instructions carefully, as well as the product-specific information. Fixus BV does not accept liability in the case of non-compliance with this instructions.

1. Product Descriptions / Materials
The Fixus Sterilization Cassette consists of stainless-steel mesh baskets with custom made silicone brackets to hold Fixus fixators and instruments during transport, storage, cleaning, disinfection and sterilization.

This IFU is valid for the following devices:
• TRAUMA Cassettes;
• RECONSTRUCTION Cassettes;
• QUICK FIX Cassettes.

2. Application
The Fixus Sterilization Cassettes are used to facilitate the cleaning, disinfection and sterilization of Fixus products. The fixation of fixators and instruments into the mesh baskets protects the devices against damage that may occur.

3. Precautions
Examination
Fixus products must always be examined pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that no components were lost. Never use Fixus products with obvious signs of excessive wear, damage, or that are incomplete or otherwise non-functional.

The mesh baskets must be examined prior to use. Examination should be thorough and must include a visual and functional inspection. Examination must also ensure mesh baskets are complete. Do not use damaged mesh baskets.

Visual Inspection
As applicable, ensure the following:
• Laser markings, engravings, and other markings are legible.
• No cracks, deformation, or distortion are present.
• No cracks are present in devices handled.
• No discoloration, corrosion, stains, or rust are present.
• No cuts or gouges in the silicone of the brackets are present.
• All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose, or damaged include set screws, pins and other small parts.
• Cannulated instruments with a guide wire or other insertion tool are visually checked.

Functional Inspection
As applicable, ensure the following:
• Moving parts move freely, without sticking, binding, or grinding.
• Springs function.
• All appropriate mating parts fit together.

If the device passes the visual and functional inspection as described in the IFU, the devices can be expected to perform as intended for the perioperative period.

Cleaning Agents and Cleaning Tools
Mesh Baskets: use of alkaline cleaning agents (8.0–11.0pH) to avoid the surface of the metal parts to erode, soft bristled brushes, water jet guns, and soft pipe cleaners is recommended. High alkaline cleaning agents (>11.0pH) should not be used.

Note: alkaline cleaning agents may require neutralization following cleaning. It is critical alkaline cleaning agents be properly neutralized and rinsed from instruments and fixators if contact was made.

The following solutions or tools should not be used:
• Saline solution.
• Solutions containing chlorine (e.g. bleach) or aldehydes (e.g. glutaraldehyde).
• Formalin, mercury, chlorides, bromides, iodides, or Ringer's solution.
• Metal brushes or scouring pads.

Cleaning and Rinsing Water
If available, softened tap water should be used. Critical water should be used for the final rinse step to prevent mineral deposits on surfaces (de-ionized water is recommended). One or more of the following processes may be used to treat water defined as critical water: ultra-filter (UF), reverse osmosis (RO), de-ionized (DI), or equivalent. Use of hard water should be avoided.

Use of Mineral Oil or Silicone-Based Lubricants Mineral oil or silicone-based lubricants should not be used as they may not be removed by these cleaning instructions. These types of lubricants may coat microorganisms, prevent direct contact of steam with instrument surfaces, and hinder sterilization.

Processing Warnings/Cautions
• Universal precautions should be observed by health care facility personnel that work with contaminated or potentially contaminated devices. Caution should be exercised when handling devices with sharp points or cutting edges.
• Appropriate PPE should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes gowns, masks, goggles, face shields, gloves, and shoe covers.
• Do not allow soiled devices to dry after use and prior to cleaning.
• Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling.

Limitations on Processing
• Repeated processing has minimal effect on the Sterilization Cassette.
• End of life is determined by excessive wear and damage

from normal use.
• See the Examination section of this document to determine if the device is at the end of its useful life.

4. Cleaning instructions
Bringing a new Fixus Sterilization Cassette into service
• The Sterilization Cassette is provided non-sterile and must be thoroughly cleaned and sterilized before first use and any reuse.
• Remove packaging material prior to cleaning and sterilization.
• Fold away handles, if any, to prevent damage during internal transport.
• Avoid placing sharp/cutting parts in the silicone strip.

Point of use
• Remove visible soil from the cassette using non-shedding wipes.
• The cassette should be thoroughly cleaned immediately after use to minimize drying.
• If the cassette cannot be processed immediately, keep them moist during transport.
• Use softened tap water on soiled cassette, if available, or cover with damp towels.

Containment and transportation
• Immediately transport the cassette to a work area dedicated to further processing.

Preparation for cleaning
• Cassette lids must be removed and cleaned separately.
• Cassettes may be safely and effectively processed for cleaning using both manual and automated washer-disinfector in combination outlined in this document.

Manual pre-cleaning
1. Soak seperated parts of the cassette, fixator and instruments (devices) prior to cleaning in cold tap water for a minimum of 5 minutes.
2. Rinse, flush and scrub the devices with appropriately sized, soft bristle brushes under cold tap water for a minimum of 30 seconds.
3. Using a water jet gun, flush all applicable devices for a minimum of 60 seconds.
4. If applicable, devices are to be cleaned in an ultrasonic cleaning device using for a minimum of 15 minutes, following hospital protocol.

Note: ultrasonic cleaning is only effective if the surface to be cleaned is immersed in cleaning agent. Air pockets decrease efficacy of ultrasonic cleaning. Minimize air pockets or bubble formation with cleaning agents while the instrument is immersed in the ultrasonic cleaning device.

5. Using a water jet gun, again flush all applicable devices for a minimum of 60 seconds.
6. If applicable, devices are to be cleaned again in an ultrasonic cleaning device using for a minimum of 15 minutes, following hospital protocol.
7. Using a water jet gun, again flush all applicable devices for a minimum of 60 seconds.
8. Rinse, flush and Scrub devices with appropriately-sized, soft bristle brushes for a minimum of 30 seconds.
9. Rinse devices for a minimum of 10 seconds under cold water.
10. Visually inspect devices for cleanliness. If unclean, repeat the process.

Automated cleaning/disinfection: alkaline
1. Transfer devices to the automated washer-disinfector and program the washer-disinfector with cycle parameters in Table 1. Ensure devices are positioned in the washer-disinfector to allow proper drainage and cycle parameters in Table 1 are properly programmed.
2. It is advised to remove devices from the Sterilization Cassette and place them on top of the cassette in such a position to allow an effective drain during the decontamination process.
3. If applicable, small components must be placed back in their respective mini basket within the Sterilization Cassette.
4. Upon unloading, inspect devices to ensure visible soil is removed. If soil is still present, repeat the manual pre-cleaning process or arrange disposal.

Drying
• Upon completion of washer-disinfector cycle, perform visual inspection for dryness.
• If moisture is observed on devices, dry devices using clean, absorbent, non-shedding wipes and/or forced (medical grade) air.
• Perform a visual inspection for dryness and repeat if necessary.

Note: cycle validated using Neodisher Mediclean forte Dr. Weigert, Hamburg™.

Note: due to many variables involved with washer-disinfectors, health care facilities should properly install, calibrate, and verify the process (e.g. temperatures, times) used for their equipment. Washer-disinfector manufacturer recommendations should always be followed. When cleaning multiple devices in one cleaning cycle, ensure the manufacturer's maximum load is not exceeded. Cleaning validation was conducted using a full chamber load.

Inspection, reloading, and reassembly (if applicable)
• Inspect devices for damage by performing a thorough examination as referred to the Examination instructions in the "Precautions before use" section.
• If Sterilization Cassettes are damaged, dispose.
• If applicable, reassemble devices that required disassembly prior to cleaning with following their respective Instructions For Use.
• Load the Sterilization Cassettes with their applicable devices. Observe and place instruments according to defined layout.
• Proceed to the Sterilization section.

5. Sterilization
1. The autoclave must be installed, maintained, validated and calibrated according to the requirements of the health institution and must comply with the requirements of the ISO 17665 standard and EN285.
2. Double wrap, if applicable, individual devices with non-woven/moisture resistant surgical sterilization wrap.
3. Inspect, if applicable, packaging to ensure no rips, punctures, or seal failures are present in or on packaging prior to loading into the sterilizer.
4. Load devices into the sterilizer by following sterilizer manufacturer's recommended loading procedures and load configurations.
5. Follow the sterilizer manufacturer's recommended procedures to program the sterilizer with any one of the sets of sterilization cycle parameters in Table 2.

Note: The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations. Chamber size and chamber load differences may exist between industrial and health care facility sterilizer models. Because of many variables involved in sterilization, health care facilities should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Note: steam for sterilization should be generated from

water treated to remove total dissolved solids and non-condensable gases, filtered to remove contaminates and water droplets, and supplied via piping without dead legs or other stagnant zones where contamination may collect.

Caution: ethylene oxide (EO), gas plasma, gamma irradiation, chemical vapor, or dry heat sterilization methods are not recommended for sterilization of these devices. Steam/moist heat is the recommended method of sterilization.

6. Additional information

- Equipment for cleaning, disinfection, sterilization and drying must comply with ISO 17664, ISO 15883, EN285 and ISO 17665. Packaging materials must comply with ISO 11607.
- Any medical device that has been in contact with a patient known to have or suspected to have a prion or prion-related disease, such as Creutzfeldt-Jakob disease, should not be returned to Fixus BV and should be quarantined and processed per guidelines for processing devices contaminated with high risk tissue at the health care facility.

7. Handling and storage

- The Sterilization Cassettes are not designed to be reprocessed, transported and or stored upside down or on their side.
- Packaged products must be stored in a clean and dry environment and protected against pests, extreme temperatures, and extreme humidity.
- Follow hospital protocol for sterilized mesh baskets or sets.
- Transportation of the baskets with devices must comply with national standards.

8. Warnings

- The Sterilization Cassettes are supplied NON STERILE.
- Due care must always be observed when fixing devices in and removing them from the cassettes.
- Configurations of the cassette may only be used in combination with the basket, components and devices for which this basket was designed.

9. Incidents

In case of serious incidents which occur in relation to this device, directly contact Fixus BV by mail at info@fixus.nl and the competent authority of the country in which the medical facility and/or patient is established.

10. Symbols


Symbol for «Manufacturer»


Symbol for «Date of Manufacturing»


Symbol for «Consult instructions for use»


Symbol for «Caution»

Symbol for «Non-Sterile»


Symbol for «Do not use if package is damaged»

Symbol for «Catalogue number»

Symbol for «Batch code»

Symbol for «Unique Device Identifier»


Symbol for «Declaration of conformity according to the applicable European directive»

Symbol for «Medical Device»

Symbol for «Declaration of conformity according to the applicable UK directive»

Table 1, Alkaline Cleaning Agent

Cycle	Temperature Set Points	Minimum Time (min:sec)	Concentration
Pre-wash	10°C - 25°C	2:00	N/A
Main wash (Alkaline agent)	60°C	15:00	2ml-6ml/liter
Rinse	10°C - 25°C	15:00	N/A
Thermal (disinfection) rinse (deionized)	≥90°C	5:00	N/A
Dry	98,8°C	≥30:00	N/A

Table 2, Sterilization Cycle Parameters

Cycle	Temperature Set Points	Minimum Exposure Time (min:sec)	Minimum Dry Time (min:sec)
Dynamic air removal	134°C	3:00	30:00
Dynamic air removal	134°C	18:00	30:00