Handling instruction for SURGICAL INSTRUMENTS intended for re-sterilization

Manufacturer: LfC Sp. z o. o.
ul. Kożuchowska 41, 65-364 Zielona Góra, tel. +48 68 321 92 00, fax. +48 68 320 47 18
e-mail: lfc@lfc.com.pl, www.lfc.com.pl

Device

Following instruction refers to reusable surgical instruments, produced and supplied by LfC Sp. z o.o. supplied with sterilization trays and clamping systems. The information complies with the requirements of EN ISO 17664. The instruments are made of the following materials:
- Corrosion resistant stainless steel, including AISI 316L steel consistent with EN 10088;
- Titanium and surgical titanium alloy/implantable alloy consistent with the requirements of ISO 5832, part 3, ASTM F136, ASTM F 3001;
- Silicon and other plastics;
- Materials and plastics for instruments' trays.

The guidelines of this manual should be used before the sterilization process. The executor is responsible for ensuring that the reprocessing of products is carried out by qualified and trained personnel using the recommended equipment and materials. These activities are related to validation and routine monitoring of the ongoing process. The medical center must ensure adequate processing for cleaning, disinfecting, packaging and sterilizing devices.

Explanations of symbols given on the label of devices manufactured by LfC Sp. z o.o. (symbols consistent with EN ISO 15223-1):

MD	„MEDICAL DEVICE"		„KEEP AWAY FROM SUNLIGHT"
UDI	„UNIQUE DEVICE IDENTIFIER"		„KEEP DRY"
	„CAUTION"	NON STERILE	„NON STERILE"
	„DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE"	STERILE	„STERILIZED USING STEAM"
2	„SINGLE USE ONLY"	STERILE R	„STERILIZED USING IRRADIATION"
2 STERILIZE	„DO NOT RESTERILIZE"		„PATIENT INFORMATION WEBSITE"
	„DOUBLE STERILE BARRIER SYSTEM"		„CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE"

WARNINGS

- Each instrument made of stainless steel is subjected to corrosion, covering with spots or damage, in case of not treating it with proper care and recommendations;
- Surgical instruments should only be used according to their intended purpose. Do not repair tools on your own.
- Do not use worn, damaged instruments or repaired by unauthorized units;
- Do not allow strong contamination of instruments. Intensive contaminations must be removed immediately, because they may cause unwanted surface effects (discoloration) which influences proper functioning of the instrument during surgical procedure.

Limitations in repeated proceedings

- Repeatedly following these instructions will affect the normal wear and tear of the tool. Performing instrument preparation for reuse in accordance with these instructions should only have a slight impact on the reuse and life cycle of the instrumentation;
- **There is no maximum number of uses specific to reusable surgical instruments. The validity period of these tools depends on many factors, including the manner and duration of each use and the handling between applications**;
- **The suitability of surgical instruments for use is limited by their wear and tear and/or damage resulting in malfunction. After each cycle of preparing the instrument for reuse, it must be inspected (See "Inspection");**
- **A thorough check and function test of the tools before use are the best way to determine the end validity period;**
- **The LfC instrument processing facility is responsible for ensuring that the desired results are achieved. Validation and routine process control are required.**

PROCEEDINGS

Preparation at the place of use

- **The instruments should be preliminary-cleaned immediately after use; as soon as possible to facilitate subsequent cleaning processes;**
- Before handing contaminated instruments for cleaning, disinfection and sterilization, wipe them off to remove visible dirt: secretions, blood and other adherent surface contaminants. Remove dirt and residues with disposable cloths or paper towels. Do not use metal brushes or other sharp devices that could damage the instruments;
- If instruments cannot be cleaned directly after surgical procedure, they must be placed in a container with distilled water to avoid strong adherence and drying of contaminations;
- After initial preparation, instruments must be placed in transport containers protecting from mechanical damage and movements.

Note: Placing devices in a detergent solution for washing medical devices, prepared in accordance with the detergent manufacturer's instructions, facilitates subsequent cleaning. This applies especially to products with complex shapes, having small holes, cannulas or contact/hinged operation during use.

Preparation before cleaning

- **LfC recommends the use of combined manual and automatic cleaning or the use of automatic cleaning due to the higher efficiency and repeatability of these processes compared to using only manual cleaning;**
- **Whenever an automatic procedure is available, do not use only manual cleaning and disinfection;**
- **Tools that consist of components must be disassembled for cleaning and disinfection.** For this instrumentation, follow the additional instructions for disassembly and reassembly of LfC. Protect all disconnected tool components from loss, in particular small components, e.g. screws, bolts, springs;
- **Before soaking the instrumentation in the cleaning solution, rinse with running water and wipe with a disposable towel** to remove any dirt or residue. Rinse all cannulas, holes, or slots with running cool tap water;

Note:
During initial cleaning you should:
- ***Pay particular attention to cleaning difficult to reach and difficult to clean places such as joints, cannulas, sleeves, gears, blades, etc. (see section 'Manual cleaning and disinfection');;***
- ***For quick couplings, move the moving parts several times during pre-cleaning to clean difficult to reach places. Then carefully check the flushing for any operational contamination;***
- ***Handles and grips containing quick couplings should be washed manually or ultrasound before the automatic washing with the following parameters: temp. 50°C, time 15 min .;***

- The user of the medical device (medical center) is responsible for strict compliance with all washing and disinfection parameters.

Manual cleaning and disinfection

- **A separate process of cleaning and disinfection have to be conducted:**
- **Particular attention should be paid to cleaning places that are difficult to reach and difficult to clean, such as joints, cannulas, sleeves, racks, blades, etc. After inserting the tools into the washing solution, press all moving parts several times and/or turn the knobs, joints (if applicable);**
- **To clean difficult to reach places and internal cannulas use special cleaners of different sizes, adapted to the cleaned places and surfaces;**
- **Perform cleaning and disinfection using agents approved for medical devices in a way that prevents shape changes, damage and scratches on the surface;**
- **Wash in a multienzymatic medium. Disinfect using a mean of a spectrum of action (bacteria, fungi, mycobacteria, viruses);**
- Use fresh demineralized or distilled water;
- Use only newly prepared solution of cleaning agent, disinfectant;
- Follow the manufacturer indications of cleaning and disinfection agent in terms of dosage, concentration, temperature, compatibility of materials and time.

* **An example of the recommended procedure for manual cleaning and disinfection with the use of Neodisher® MultiZym, Neodisher® Septo Active, Neodisher® Septo MED**

Step	Time [min.]	Step	Time [min.]	Step
I CLEANING				
Manual cleaning	5-10	5-10 ml/l	DEMI	Neodisher® MultiZym, pH ca. 8,4-8,6
		10g/l (1%)		Neodisher® Septo Active, pH ca. 7,6-7,9
Intermediate rinse	5	-	DEMI	-
II DISINFECTION				
Chemical disinfection	15	30 ml/l (3%)	DEMI	Neodisher® Septo MED, pH ca. 8,5
	15	20 g/l (2%)		Neodisher® Septo Active, pH ca. 7,6-7,9
Final rinse	5	-	DEMI	-
Drying	Compressed medical air			

**Note:*
1) *DEMI water used in process should comply with the following standards: EN 285 and ISO 17665, (conductivity (at 25 °C)* ≤ 5µS/cm);*
2) *In case of use of any other cleaning-disinfectant agent, follow it's manufacturer guidelines.*

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Automatic cleaning and thermal disinfection

- **For automatic cleaning and disinfection tools have to be taken out of the trays;**
- **Cleaning and disinfection is performed with the use of substances approved for medical devices, in a manner that prevents changes in shape, damages and scratches on the surface;**
- **It is recommended that thermal disinfection should be performed with the use of devices complying with EN ISO 15883-1, that are used with alkaline cleaning agents of pH max.12.** Use of alkaline agents may slightly change the hue of titanium alloy devices, this however does not affect technical and utility properties;
- Follow the indication of the manufacturer of cleaning and disinfection agent in terms of dosage, concentration, temperature, material compatibility and time;
- Load the implants, start cleaning, rinsing and drying cycle. Follow the instruction, proper procedures and programs specified by the manufacturer of used equipment.

***An example of the recommended procedure for automatic cleaning and thermal disinfection with use of Neodisher® MediClean Forte, Neodisher® MediKlar**

Step	Temperature T [°C]	Time t [min.]	Concentration [%]	Water quality	Chemical agent
Initial rinse	25	2	-	Water softening	Total hardness:<3°d (<0,5 mmol CaO/L)
Basic cleaning	55	10	7 ml/l	DEMI	Neodisher® MediClean Forte, pH ca. 10,4-10,8
Intermediate rinse	>10	2	-	DEMI	-
Thermal disinfection	90	5	0,5 ml/l	DEMI	Neodisher® MediKlar, pH ca.5,7
	**or until the parameter A_0=3000				
Drying	110	15	-	-	-

Note:

1) ***According to Standard EN ISO 15883-1 annex B, term A_0, is used as an amount of microorganisms killed in the process with the use of moist heat, boiling water. Value A_0 equal or greater than 3000 should be achieved for the medical products which are or may be contaminated with heat resistant viruses like hepatitis B. It is possible to achieve it in temperature 90°C for 5 minutes. Automatic decontamination should be performed when the value A_0 equals 3000, type and number of microorganisms contaminating the medical devices is unknown and prone to suddenly change its numbers and when the medical devices will be sterilised after. Robert Koch Institute recommends the thermal disinfection with the value A_0 at least 3000 for so called critical equipment.*
2) *DEMI water used in process should comply with the following standards: EN 285 and ISO 17665, (conductivity (at 25 °C)* ≤ 5µS/cm);*
3) *In case of use of any other cleaning-disinfectant agent, follow it's manufacturer guidelines.*

Manual drying, automatic drying

Provide dry, clean, compressed air. Dry devices on the out- and inside with air, till no marks of water drops are visible.

Automatic drying is a part of cleaning and disinfection cycle in thermal disinfector, do not exceed the temperature of 130°C.

Inspection

Before sterilization, all instruments should be inspected visually in good lighting, magnifying glasses can be used. Disposable gloves should be worn for inspection.

CLEANLINESS:

- All tool components should be checked for visible dirt and corrosion. Particular attention should be paid to:
  - difficult to reach places where dirt may accumulate (e.g. joints, hinges, cannulas, sleeves, gears, blades, joined surfaces, etc.);
  - narrow holes, channels, depressions;
  - places where dirt can be pressed in when working with tools: (e.g. quick couplings, grooves);
  - places with markings on the tools.
- The tools must not have residues of operational impurities, residue from washing and disinfection (e.g. stains, stains, discoloration, corrosion, deposits, flakes, etc.).

GENERAL STATUS:

- Tools must not be incomplete, damaged (e.g., cracked, bent, deformed, blocked, etc.) and worn (e.g., blunt, twisted, chipped, etc.)
- The markings on the tool must be clearly visible and undamaged (the occurring damages are e.g. partially illegible, invisible markings).

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<table>
<tr><td rowspan="2">Inspection</td><td>OPERATION TESTS:</td></tr>
<tr><td>
– Tools requiring assembly must be assembled in accordance with LfC instructions. After assembly, always check that the tool is complete and works correctly;
– In tools with hinges, check the smoothness of hinge movement. Tool hinges after each washing and drying, and before storage should be lubricated with paraffin-based oil approved for medical applications, eg Neodisher® IP Spray;
– In instruments with moving parts, these elements should be moved to check their function (if necessary, use medical grade lubricating oil that is suitable for steam sterilization). In this case, quick couplings should be moved several times to check the smoothness of movement, and then check the correct connection with the working tool (the working tool should easily slide into the socket of the quick coupler and may not slide out after locking);
– In rotating tools (e.g. cutters, drills, guide elements), check that they are straight (checking by rolling the tool on a flat surface);
– In tools with cutting edges, check these edges for sharpness and damage (e.g. blunt tip, blunt cutting grooves, chipped cutting grooves, distorted work surfaces);
– In mallet instruments, check that they are not damaged to such an extent that they cause improper operation or burrs that could damage the tissue or surgical gloves;
– In screwdriving tools with a working tip cooperating with an implant, e.g. a star working tip, check the condition of the working tip for possible damage, e.g. deformation of the working tip (twisting, rounding, bent or damaged edges);
– Check the expiration date printed on the tool on torque tools. Do not use torque tools beyond the expiration date.
</td></tr>
<tr><td></td><td>ASSESSMENT:</td></tr>
<tr><td></td><td>
– Various types of damage can be caused by the expiration date of a tool, improper use or improper maintenance
– In the event of indelible dirt, malfunction, damage or wear, exceeding the expiration date, the tool must be withdrawn from use. Such an instrument should be replaced and not used.
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<tr><td>Packaging</td><td>
– It is acceptable to repack devices in medical facilities only in accordance with legal provisions, including EN ISO 11607-1: “Packaging for terminally sterilized medical devices”;
– Packaging should be performed in a room where the micro bacterial environment is strictly controlled, minimal air class “C” – ISO-Class 7 in compliance with the norm EN ISO 14644-1;
– Ensure that the package is big enough for the instrument so it does not create any pressure on the sews;
– Products should be placed in the packaging in such a way that its sharp shapes do not damage the packaging.
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<tr><td>Sterilization</td><td>
– Only cleaned and disinfected devices can be sterilized. Instruments must be dry before sterilization;
– Devices can only be steam sterilized (over pressured steam). Sterilization process must be planned, conducted and validated according to EN 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”;
– It is recommended to sterilize in steam sterilization device (autoclave) according to EN 13060/ISO 17665-1. It is absolutely necessary to use fractional pre-vacuum processes to ensure proper steam penetration;
– Sterilization control must be up to date and periodically.
<table>
<tr><th>Sterilisation device type</th><th>Process temperature</th><th>Minimal exposition time</th><th>Drying time</th></tr>
<tr><td>with fractional vacuum</td><td>sterilization temperature at least 132 °C, max. 137 °C</td><td>shortest time of maintenance of sterilization parameters 4 min.</td><td>*at least 10 min.</td></tr>
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*Recommended drying time is 20 min. The drying time of sterilized products in sterilization containers or packed medically may differ based on the type of packaging, product type, sterilization device and the sterilization load.
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<tr><td>Storage</td><td>
– Store the products in a separated and ventilated room, away from the main communication routes;
– Limit the personnel access to the warehouse (room entrance, access to shelves, cabinets, drawers etc.);
– Products ought to be stored in the so-called room temperature, in a clean and dry place;
– in storage rooms, protection against sudden temperature and humidity changes, against contamination with, e.g. dust, pests solar radiation, mechanical damage, and any other factors threatening the secondary contamination of the product must be provided;
– Products have to be stored in the original, and undamaged protective packaging;
– Damage to the product in transit and/or in storage eliminates it from further use.
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