Handling instruction for SURGICAL IMPLANTS intended for re-/multiple sterilization

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Device

This instruction applies to surgical implants of the DERO Spinal System for single use, produced by the company LfC Sp. z o. o.. The information complies with the requirements of EN ISO 17664. Implants are made of the following materials:
- titanium and its surgical/implant alloys in accordance with the requirements of ISO 5832 Part 3, ASTM F136, ASTM F3001. These implants can be coated with a layer of oxides of different color;
- PEEK polymer (Polyetheretherketone) in accordance with the requirements of ASTM F2026.

Material which the device is made of, is specified on the label and on the device.

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):

	**WARNING (check the instruction manual, safety pictograms)**		**DO NOT STERILIZE THE PRODUCT AGAIN**
	**DO NOT USE THE PRODUCT AGAIN**		**DO NOT USE IF THE PACKAGING IS DAMAGED**
	**AVOID CONTACT WITH SUN LIGHT**		**READ THE INSTRUCTION MANUAL**
	**PROTECT THE PRODUCT FROM WETTING**		**NOT STERILE PRODUCT**
	**PRODUCT STERILIZED BY STEAM**		**PRODUCT STERILIZED BY RADIATION**

WARNINGS

- **Implants of the Spinal System DERO are intended for single use only. It is not allowed to reuse previously used devices. Do not use damaged or previously surgically removed implants or their components;**
- **Implants that have been used and removed or tried on during surgical procedure must be immediately utilized according to the local requirements. They cannot be prepared for reuse;**
- Re-use of single-use devices may affect the structural integrity of the implants, may result in loss of usability as an implant, as well as increase the risk of malfunction, which may lead to unwanted injury to the patient. In addition, the re-use of single-use devices creates the risk of infection, e.g. by transferring pathogens from patient to patient. This may result in injury and / or illness to the patient and/or user.

Limitations in repeated proceedings

- **Re-sterilization may only be carried out for products delivered in a non-sterile or steam-sterilized condition which have not had any contact with the patient (not fitted, not used, placed on sterilization trays or in packaging);**
- **It is absolutely not possible to re-sterilize radiation sterilized products supplied by LfC;**
- **Repeatedly following these instructions may affect the product and its life cycle. After each cycle of preparing the product for reuse, it must be evaluated. Usability is limited by the occurrence of wear and tear during reprocessing of the product (see section "Inspection")**;
- **The body conducting LfC implants processing is responsible for ensuring that desired results will be achieved. It is required to validate and routine control of the process.**

PROCEEDINGS

Preparation at the place of use

Before use implants should be cleaned and disinfected and then repacked in room with supervised microbiological cleanness. Then the implants should be sterilized. Perform these activities according to the instruction.

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;**
- User of medical device (medical center) is responsible for strict observance of all parameters of cleaning and disinfection.

Manual cleaning and disinfection

- **Two separate processes of cleaning and disinfection have to be conducted;**
- **Special attention should be paid to cleaning places that are difficult to access and difficult to clean, such as joints, cannulas, sleeves, racks, blades, etc. After inserting the implants into the cleaning solution, press all moving parts several times and/or turn the knobs and joints several times (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 inside 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.*

Automatic cleaning and thermal disinfection

- **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 packing and sterilizing, all implants should be inspected visually in good lighting, magnifying glasses can be used. Disposable gloves should be worn for inspection.

CLEANLINESS:

- All implant surfaces should be checked for visible dirt and residues from the cleaning and disinfection process. Particular attention should be paid to:
  - difficult to reach places where dirt can accumulate (e.g. hinges, joined surfaces, etc.);
  - narrow holes, channels, depressions;
  - places where dirt can be pressed in;
  - places where markings are placed on implants.
- Implants must not have residues after washing and disinfection (e.g. damp patches, stains, discoloration, deposits, flakes, etc.)

GENERAL STATUS:

- Implants must not be incomplete, damaged (e.g., cracked, bent, deformed, blocked, etc.) and worn (e.g. discoloration of colored surfaces, scratches, etc.);
- The markings placed on the implant must be clearly visible and undamaged (the occurring damages are e.g. partially illegible, invisible markings).

ASSESSMENT:

- **If the above mentioned abnormalities still occur after the process has been carried out, repeat washing and disinfection;**
- **In case of incorrect operation, lack of completeness, damage or wear, the product should be withdrawn from further preparation of the product for use. Such a product can no longer be used;**
- **In case of any doubts regarding the handling of the implant, please contact the manufacturer.**

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Packaging

- 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.

Sterilization

- 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.**

Sterilisation device type	Process temperature	Minimal exposition time	Drying time
with fractional vacuum	sterilization temperature at least 132 °C, max. 137 °C	shortest time of maintenance of sterilization parameters 4 min.	*at least 10 min.

*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.

Storage

- Storage place in which sterilized medical equipment is stored has to be clean, dry, protected from the sun, with constant temperature and ventilated;
- Storage rooms should be free from insects, dust, inaccessible to the public, away from the main communication routes ;
- Products should be stored in undamaged packaging;
- When stored on shelves, the distance from the floor should be at least 30 cm;
- Standard environment: storage temperature 15-25ºC, relative humidity in between 25%-65%;
- Damaged packaging and/or equipment during transport or storage eliminates the product from further use;
- For sterile equipment an expiration date of sterilization should be given on a separate label.