Instruction for use
Reprocessing

LBL379
Care, Maintenance, and Sterilization Procedures for Non-sterile Implants and Instruments

Important Information – please read before use!

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The following instructions are strongly recommended for the care, cleaning, maintenance and sterilization of Silony Spine non-sterile implants and instruments prior to use and before returning to Silony Spine.

Non-sterile implants and instruments have been delivered cleaned and decontaminated. They must be treated as decontaminated only as indicated on the Manufacturers Certificate of Equipment Contamination Status. On receipt of the implants and instruments and prior to using the implants and/or instruments, follow section 3. On completion in operating room, follow sections 1 to 6.

When using reusable instruments, the indications and contraindications within the applicable Instruction for use of the implant systems must be observed. Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study indications/contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) incident related to the device to the manufacturer and to the state competent authority.

The system-specific product information can be viewed at the following links:

- https://elabeling.silony-medical.com
- www.silonyspine.com

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's product information.

Caution: Federal Law (USA) restricts these devices to be sold by or on the order of a physician.

1 Cleaning Contaminated Implants and Instruments

1.1 It is important that the instruments are disassembled prior to cleaning and decontamination, if applicable. Do not use saline solution as this has a corrosive effect on stainless steel. Remove visible debris and soak for 15 minutes in a warm Comtrex EZ enzymatic or equivalent solution. Scrub with soft bristle brushes including any lumens. Rinse and flush with warm tap water. Place in clear warm water bath and scrub again. Rinse and flush until all water is clear, and no visible traces of contaminants remain.
Place the instruments in a clean ultrasonic bath and sonicate for 15 minutes. Perform final rinsing with DI or clean tap water. Dry thoroughly with a soft, clean cloth and use 70% IPA or clean compressed air to dry any lumens. Check to ensure no moisture is present.
After cleaning, reassemble instruments, as applicable, and check functionality. Items must be cleaned as soon as possible after use to minimize drying of blood and body fluids onto the item. Disassembly instructions STALIF C Implant Introducers for IN235/1 and IN532, are provided per LBL030. All other instruments must be cleaned in the state shown per the relevant surgical technique guide.

1.2 Thoroughly clean contaminated items to remove all body fluids and tissues in which a transmissible agent may be present is critical in ensuring effectiveness of the decontamination regime. Manual handling of contaminated implants and instruments must be kept to a minimum and automated decontamination process as described below, must be used wherever possible.

1.3 Contaminated implants and instruments are recommended to be processed by/via a covered ultrasonic cleaner and then must be cleaned by an automated thermal washer/disinfector in which no other implants or instruments are being cleaned. Strictly adhere to the Ultrasonic Cleaner and Automated Washer Manufacturers' written instructions. Neutral or enzymatic detergent suitable for use with this processing must be used to prevent pitting and tarnishing of implants and instruments and must be completely rinsed.

1.4 **WARNING** – Aluminum trays and instruments with aluminum parts (these will be specified specifically on the set) must NOT be cleaned with the detergent SprayDry 2000. Use warm (room temperature) purified water for washing and rinsing. Wash with a pH-neutral or mild detergent. Do not use acidic or alkaline solution for washing. ALWAYS refer to the detergent suppliers / manufacturer's data sheet to ensure that the detergent is suitable for aluminum instruments/trays.

1.5 Staff carrying out the cleaning and subsequent processing of implants, instruments, and equipment must follow standard basic precautions for avoiding exposure to infectious material.

1.6 It is important that the implants and instruments are visually inspected, and no visual contamination remains prior to disassembly.

2 Decontaminating the Cleaning Equipment

- Following the processing of implants and instruments, the ultrasonic bath and automated washer/disinfector must be run through an empty cycle.
- Any solid waste/tissue must be disposed of by incineration, including cleaning aids such as brushes.
- Liquid waste must be disposed of safely either by normal direct discharge from automated washers or by collection and inactivation from equipment such as ultrasonic baths.

3 Autoclaving/Steam Sterilization

3.1 After decontamination, process in a porous (high vacuum) steam sterilizer using one of the following cycles. Downward or upward displacement vacuum must not be used. Manufacturers' written instructions must be strictly adhered to.

3.2 The implants and instruments must be prepared for sterilization so all surfaces have direct contact with steam.

Place implants and instruments within the perforated sterilization case provided or a generic perforated sterilization case best suited for proper sterilization.

3.3 Steam sterilization is the preferred method for implants and instruments (using deionized water).

3.3.1 Autoclaving for a minimum exposure time of 4 minutes at 132°C pre-vacuum and 30-31 PSIG autoclave cycle as described in ANSI/AAMI ST79 for wrapped implants and instruments, is recommended. The dry time per this standard is 20-30 minutes. Maintain sterility after processing using an FDA-cleared wrap or other FDA-cleared validated accessory.

3.3.2 Alternately, autoclaving wrapped implants and instruments at 135°C for a minimum holding time of 3 minutes and drying time of 16 minutes, also per ANSI/AAMI ST79, is acceptable. Maintain sterility after processing using an FDA-cleared wrap or other FDA-cleared validated accessory.

3.3.3 Per ANSI/AAMI ST79, the above steam sterilization methods have been validated to achieve a sterility assurance level of SAL 10^{-6} for Silony Spine implants and instruments with an overkill/half-cycle method.

3.4 Any instrument in contact with Creutzfeldt-Jakob disease (CJD) must be destroyed and must not be used again.

3.5 For outside the US audiences only, any implants and instruments in contact with known or suspect patients with CJD or any transmissible agent, the following cycles must be carried out:
- A single cycle of 134-137°C for a minimum holding time of 18 minutes or:
- 6 successive cycles of 134-137°C for a minimum holding time of 3 minutes for each cycle.

4 Product Use /Life

- There are no restrictions on the number of re-uses of non-sterile implants and instruments.
- Routinely inspect devices for wear and tear, to provide an endpoint for that inspection (e.g., an applicable valid endpoint such as corrosion, pitting, discoloration, cracked seals, etc.), and a directive to adequately dispose of devices that do not meet that endpoint.

5 User's Certification after Use

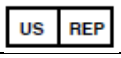
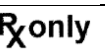
- A copy of the User's Certificate of Contamination Status or a suitable decontamination certificate must be returned with the implants and instruments or given to a representative in person in such a way that the form can be examined without the handling of the implants and instruments.
- Failure to observe these provisions may lead to adverse legal consequences, such as criminal breach of Health and Safety or Medical Device Regulations or exposure to product liability or insurance consequences.
- Implants and instruments which are returned without a certificate, will be assumed to be contaminated and additional expense may be charged as a result of the manufacturer decontaminating the equipment/item. Contaminated or partially contaminated equipment/items must not be returned to us by mail or courier.

6 Adverse Incident

- If the equipment has been involved in a suspected adverse incident, DO NOT clean or decontaminate it prior to discussion with the manufacturer and/or appropriate regulatory authority as this may hinder investigation of the incident.
- DO NOT return the equipment/item without first consulting the manufacturer or supplier to discuss arrangements for its safe handling.

7 Labeling and Symbols

Symbols according to ISO 15223-1 and 21 CFR 801 Labeling.

Symbol	Explanatory Text
	Manufacturer
	US Representative
	Federal law in the USA restricts this device to sale by or on the order of a physician.
	Article number
	Lot number
	Number of items
	Medical device
	Unique device identification
	Consult instruction for use
	Caution
	Non-sterile
	Do not use if the packaging is damaged
	Keep dry
	Keep away from sunlight
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)

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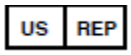

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