Care, Maintenance, and Sterilization Procedures for Non-sterile Implants and Instrumentation

The following instructions are strongly recommended for the care, cleaning, maintenance and sterilization of the Centinel Spine Non-sterile Implants and Instrumentation, prior to using non-sterile implants and instruments, and before returning equipment to Centinel Spine. There are no restrictions on the number of re-uses of these non-sterile implants and instrumentation.

This equipment has been delivered to you cleaned and decontaminated. This equipment must be treated as decontaminated only as indicated on the Manufacturers Certificate of Equipment Contamination Status.

ON RECEIPT OF THE EQUIPMENT AND PRIOR TO USING THE IMPLANTS AND/OR INSTRUMENTS, FOLLOW SECTION 3. ON COMPLETION IN OPERATING ROOM, FOLLOW SECTIONS 1, 2, 3, 4, 5, AND 6.

Section 1: Cleaning Contaminated 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 rinse 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.

1.1.1. Disassembly instructions for IN235/1 and IN532, STALIF C® Implant Introducers, are provided per LBL030. Disassembly instructions for IN359/3R, MIDLINE II™ Implant Inserter Distracter, are provided per LBL163. 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

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possible.

1.3. Contaminated implants and instruments are recommended to be processed thorough 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 instrument 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 neutral pH 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.

Section 2: Decontaminating the Cleaning Equipment

Following 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.

Section 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. Manufacturer's written instructions must be strictly adhered to.

3.2 The instrument 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 the 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, Table 5 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, Table 5, 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 Centinel 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.

Section 4: Product Use /Life

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.

Section 5: User's Certification after Use

5.1 A copy of the User's Certificate of Contamination Status or a suitable decontamination certificate must be returned with the equipment / item or given to a representative in person in such a way that the form can be examined without the handling of the equipment.

5.2 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.

Equipment/items, which are returned without a certificate, will be assumed to be contaminated and additional expense may be charged as a result of Centinel Spine decontaminating the equipment/item. Contaminated or partially contaminated equipment/items must not be returned to us by mail or courier.

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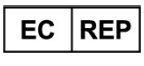
Section 6: Adverse Incident

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.

Section 7: Symbols

	Manufacturer
	Catalog Number
	Batch Code
	Consult Instructions for Use
	CE Logo
	Authorized representative in the European community
	Do not use if pack is opened or damaged

Section 8: Contact Information

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