Care and Sterilization Procedures for Disposable prodisc Components

The following instructions are strongly recommended for the care and sterilization of the Centinel Spine non-sterile prodisc disposable components, prior to using non-sterile components, and before returning components to Centinel Spine. These non-sterile components are all single-use items.

This IFU is to be used for the following item #s:

Inserter Tips	03.820.130	Inserter Tip M & MD - 5MM
	03.820.131	Inserter Tip M & MD - 6MM
	03.820.132	Inserter Tip M & MD - 7MM
	03.820.133	Inserter Tip L & LD - 5MM
	03.820.134	Inserter Tip L & LD - 6MM
	03.820.135	Inserter Tip L & LD - 7MM
	03.820.140	Inserter Tip XL & XLD - 5MM
	03.820.141	Inserter Tip XL & XLD - 6MM
	03.820.142	Inserter Tip XL & XLD - 7MM
Milling Bits	03.820.157	MILLING BIT - CYLINDRIC
	03.820.167	MILLING BIT - CYLINDRIC
	03.820.153	MILLING BIT - 1.8
	03.820.163	MILLING BIT - 2.0
	03.820.159	Milling Bit Flat Coupling
	03.820.169	Milling Bit 2 w/ Flat Coupling
	03.820.117	Milling Bit Synthes-Coupl
	03.820.161	Milling Bit 2 Synthes-Coupl
Retainer Screws	03.820.102-CS	Retaining Screw 3.5x12
	03.820.103-CS	Retaining Screw 3.5x14
	03.820.104-CS	Retaining Screw 3.5x16
	03.820.105-CS	Retaining Screw 3.5x18
Rescue Screws	03.820.106-CS	Retaining Screw 4.5x13
	03.820.107-CS	Retaining Screw 4.5x15
	03.820.108-CS	Retaining Screw 4.5x17
	03.820.109-CS	Retaining Screw 4.5x19

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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 1. ON COMPLETION IN OPERATING ROOM, FOLLOW SECTIONS 1, 2, 3, 4, 5, AND 6.

Section 1: Manual Cleaning

1.1 Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.

1.2. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.

1.3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.

1.4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.

1.5. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.

1.6. Visually inspect device. Repeat the manual cleaning procedure (steps 1 - 5) until no visible soil remains on device.

1.7. Perform a final rinse on device using DI or PURW water.

1.8. Dry device using a clean, soft, lint-free cloth or clean compressed air.

Section 2: Thermal Disinfection

2.1 For automated cleaning, thermal disinfect at 93°C for a minimum of 2 minutes and 30 seconds.

2.2 The below automated cleaning may also be utilized:

Automated Cleaning:

Phase	Recirculation Time (minutes)	Water Temperature and Type	Detergent Type and Concentration (if applicable)
Pre-wash 1	2:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzymatic Detergent - Equivalent to Enzol (1 oz. per gallon)
Wash 1	2:00	80°C Tap Water (Set Point)	Neutral pH Detergent - Equivalent to Valsure Neutral (0.25 oz. per gallon)
Rinse 1	0:15	43°C Tap Water (Set Point)	N/A
Rinse 2	1:00	43°C Tap Water (Set Point)	N/A
Pure Water Rinse	1:00	43°C RO/DI Water (RO) Reverse Osmosis (DI) Deionized (Set Point)	N/A
Heated Dry	7:00	115°C (Set Point)	N/A

Section 3: Drying

3.1 If a dry cycle is not included in the mechanical washer or if the device is not processed in a mechanical washer:

Dry each device thoroughly inside and out to prevent rusting and malfunction. Use a clean, soft, lint-free cloth to avoid damage to the surface. Pay special attention to areas where fluid can accumulate.

Section 4: Autoclaving/Steam Sterilization

4.1 The following are the recommendations for the sterilization of Centinel Spine devices:

*When applying dry times to Centinel Spine cases and their accessories, dry times outside the standard healthcare pre-vacuum parameters may be required. This is especially important for polymer-based (plastic) cases/trays used in conjunction with heavy duty nonwoven sterilization wraps. The current recommended dry times for Centinel Spine cases can range from a standard 20 minutes to an extended time of 60 minutes. The dry time is most often influenced by the presence of polymer based (plastic) materials; therefore, changes such as elimination of silicone mats and/or change in sterile barrier system (e.g. heavy grade to light grade wrap or the use of rigid sterilization containers) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches or containers) should be used by the end-user for packaging terminally sterilized devices.

The following are the recommendations for the sterilization of Centinel Spine devices:

Sterilizer Type	Preconditioning Pulses	Temperature	Full Cycle Time	Dry Time
Prevacuum	4	132°C	4 minutes	30 minutes

Section 5: Limits on Reprocessing

5.1 Repeated processing cycles that include mechanical washing and sterilization have minimal effects on Centinel Spine surgical instrumentation.

5.2 End of life of a device is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.

Section 6: User's Certification after Use

6.1 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.

6.2 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.

Section 7: 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.

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