

STRATOFUSE™ Cervical Allograft Instrumentation Recommended Decontamination and Sterilization



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STRATOFUSE Cervical Allograft Instrumentation must be cleaned and sterilized prior to use. It is recommended that the inserter instrument be disassembled for cleaning and re-assembled prior to sterilization. The instructions for disassembly are listed below.

1. Press the button on the inserter handle to release the combined inner and outer shaft sub-assembly (Fig. 1 and Fig. 2).

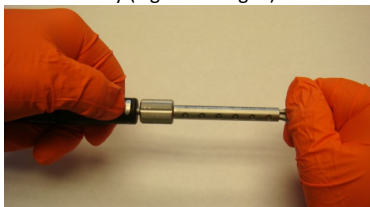


Figure 1: Button on handle is being pressed.



Figure 2: Sub-assembly has been released from inserter handle.

2. Holding the inner shaft fixed, turn the outer shaft counterclockwise until it separates from the inner shaft (Fig. 3). The instrument is now disassembled and ready for cleaning (Fig. 4).

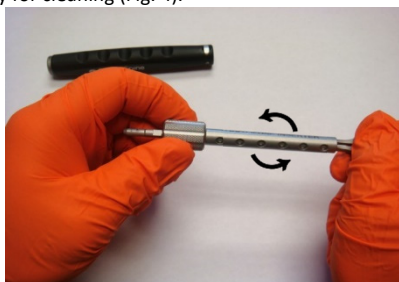


Figure 3: Outer shaft is being rotated counterclockwise while inner shaft is being held fixed.



Figure 4: Assembly has been completely disassembled.

3. Follow the cleaning guidelines listed in this document.
4. After cleaning, reverse steps 1 and 2 to reassemble the inserter. Take care to thread the outer shaft onto the inner shaft such that the top of the knob on the outer shaft rests just below the laser mark line on the inner shaft (Fig. 5). Correct assembly can be verified by pulling on the inner shaft while holding the handle to confirm that the assembly does not separate (Fig. 6).



Figure 5: The top of the knob on the outer shaft is resting just below the laser mark line on the inner shaft.



Figure 6: Inserter has been fully assembled.

5. Follow the sterilization guidelines listed in this document.

Cleaning and Decontamination:

All instruments are supplied to the health care facility clean but non-sterile. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field.

Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected, and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling. When appropriate, disassemble instruments prior to cleaning.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush (M-16) as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer and visually inspect for soil. Repeat if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush (M-16) as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and rinse with cool tap water (< 35°C) for

at least one (1) minute.

7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner and sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner and thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel and filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth and filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Sterilization:

ChoiceSpine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters:

Steam Sterilizer Type: Pre-vacuum

Temperature: 132°C

Duration: 4 minutes

Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature).

Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures.

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials, and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these ChoiceSpine instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Surgical Technique Manual:

The STRATOFUSE Cervical Allograft Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Product Complaints:

The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the instruments "malfunction" (i.e., do not meet any of their performance

specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Caution:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:



ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:

ChoiceSpine, LLC
Sales Support Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333 or fax: 865-588-4045
salessupport@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community
	MR Conditional

	Unique Device Identification
	Medical Device