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Processing Non-Sterile KLS Martin Group® Implants

The Symbol Glossary is located on the last page of this IFU.

These recommendations are for processing non-sterile KLS Martin® implants that are sold in the United States and Canada. The information provided applies to unused and non-contaminated KLS Martin® implants only. Explanted KLS Martin® implants must never be reprocessed and must be handled according to hospital protocol upon removal. Any implant that has not been used, but has become contaminated, must be handled according to hospital protocol. KLS Martin® does not recommend the reprocessing of contaminated implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

Please follow the validated hospital processing procedure (handling, cleaning, disinfecting, sterilization) for KLS Martin® surgical items.

PROCESSING INSTRUCTIONS

Caution	• Any implant that has not been used, but has become contaminated should be handled according to hospital protocol. KLS Martin® does not recommend the reprocessing of contaminated implants. • KLS Martin® implants should not be lubricated. • Do not use a KLS Martin® implant if the surface is damaged or if other implant properties are impaired. • Do not use steel wool or abrasive cleaners on KLS Martin® implants. • KLS Martin® implants must not be processed or transported with any type of contaminated materials. • In accordance with AAMI guidelines, KLS Martin® does not recommend or support the Immediate Use sterilization method for implants. • KLS Martin® implants are critical devices and must be terminally sterilized prior to use. • The sterilization parameters are only valid for devices that are adequately cleaned. • The following parameters are only valid for properly installed, maintained, calibrated, and compliant reprocessing equipment.
Limits On Reprocessing	• Repeated processing cycles (ultrasonic, mechanical washing, and sterilization) have minimal effect on KLS Martin® implants. • KLS Martin® implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration, or residue. Damaged implants must not be implanted.
Point of Use Care	• Implants should remain covered until needed to avoid contamination. Only those intended to be implanted should be handled. • Handling prior to implantation should be kept minimal to prevent damage to the surface.
Containment and Transportation	• Implants should not come in contact with contaminated devices and/or equipment. • To avoid contamination, implants should be transported separate from soiled devices. • During transportation, ensure that no material or abrasion will be transferred to the implant.
Preparation for Processing	Any implant contaminated with blood, tissue, and or bodily fluids/matter must be discarded using appropriate measures. KLS Martin® does not recommend the reprocessing of contaminated implants.
Cleaning-Manual Method	Equipment: soft-bristled brushes, enzymatic cleaner & neutral detergent, sterile syringes/pipettes, and/or water jet, clean lint-free cloths, and filtered pressurized air. 1. Prepare an enzymatic cleaner, such as Enzol®, per manufacturer's recommendations at 1 oz/gallon using lukewarm tap water. 2. Fully immerse the devices in the prepared solution. Allow the devices to soak for a minimum of 10 minutes. 3. Remove the devices from the solution and rinse under cool running tap water for a minimum of 2 minutes. 3.1. While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard to reach areas. 3.2. Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed. 4. Prepare a neutral detergent, such as Valsure® Neutral, per manufacturer's recommendations at 1/4 oz/gal using lukewarm tap water. 5. Fully immerse the devices in the detergent solution. Thoroughly brush the devices for a minimum of 5 minutes using a soft-bristled brush and/or lumen brush. Ensure to thoroughly brush all lumens, channels, and hard to reach areas. 5.1. Actuate all movable device features through their full range of motion to ensure all areas of the devices are exposed to the detergent solution. 6. Thoroughly rinse the devices using reverse osmosis/deionized (RO/DI) water for a minimum of 2 minutes. 6.1. While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard to reach areas. 6.2. Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed. 7. Perform a final rinse on devices using RO/DI water. 8. Dry devices using a clean, soft, lint-free cloth and filtered pressurized air. 9. Visually inspect each device. Repeat the cleaning process if visible soil remains.

Cleaning-Mechanical Method

Equipment: ultrasonic cleaner, FDA-cleared washer, sterile syringes/pipettes, and/or water jet, enzymatic cleaner & neutral detergent, clean lint-free cloths.

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

1. Prepare an enzymatic cleaner, such as Enzol®, per manufacturer's recommendations at 1 oz/gallon using lukewarm tap water.
2. Fully immerse the devices in the prepared solution. Allow the devices to soak for a minimum of 2 minutes. While fully immersed, thoroughly brush the devices with a soft-bristled brush. Actuate all movable device features through their full range of motion to ensure all areas are exposed to the detergent.
3. Remove the devices from the solution and rinse under cool running tap water for a minimum of 1 minute.
   3.1. While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard to reach areas.
   3.2. Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed.
4. Prepare a neutral detergent, such as Valsure® Neutral, per manufacturer's recommendations at 1/4 oz/gal using lukewarm tap water in an ultrasonic cleaner.
5. Fully immerse the devices in the ultrasonic cleaner and sonicate for 15 minutes.
6. Thoroughly rinse the devices using RO/DI water for a minimum of 2 minutes. While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard to reach areas.
7. Transfer the devices into the washer for processing.

The following cycles, times, temperatures, and detergents are **for reference only** due to the differences in manufacturer's equipment. The parameters must be in accordance with the hospitals validated procedure for the equipment used.

Phase	Minimum Time (minutes)	Minimum Temperature/ Water	Detergent Type and Concentration
Pre-wash I	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Enzol® 1 oz/gal
Wash I	05:00	43°C	Valsure® Neutral ¼ oz/gal
RO/DI Rinse	02:00	43°C	N/A
Drying	10:00	90°C	N/A

8. Remove devices from the washer.
9. Dry the devices using a clean lint-free cloth.
10. Visually inspect each device. Repeat the cleaning process if visible soil remains.

Detergents/ Cleaning Agents Used

Enzol® and Valsure® Neutral were the cleaning agents used to validate the parameters in these instructions.
KLS Martin® does not recommend any specific detergent or cleaning agent.

Inspection

KLS Martin® implants must be inspected after processing, prior to sterilization. Any implant with corrosion, discoloration, scratches, flaws, residue, or debris should be discarded.

Packaging

The devices must be packed in a sterilization packaging material which meets the requirements of ISO 11607. We recommend the use of an FDA-cleared wrap.

Sterilization

Sterilization must be performed in a validated steam sterilization process according to relevant AAMI/ASTM/ISO standards. Validation was performed in accordance with ISO 17665-1:2006 and ISO 17665-2:2009 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method.

The following recommendations are for the sterilization of KLS Martin® implants:

Cycle Type	Sterilization Exposure Time (minutes) at 132°C (270°F)	Minimum Dry Time*
Dynamic Air Removal	4	20 minutes

* Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven 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.

Additional Information	The cleaning and sterilization information is provided in accordance with ANSI/AAMI ST81:2004/(R2010), ISO 17664:2004, AAMI TIR30:2011, AAMI TIR12:2010, and ANSI/AAMI ST79:2017. • The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile KLS Martin® medical implant. It remains the responsibility of the processor and/or hospital to ensure that the processing is actually performed, when using equipment, materials and personnel in the processing facility, in order to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor and/or hospital from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences. • All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards. • Users must wear appropriate protective equipment (PPE) when processing implants.
Manufacturer Contact	For further information, contact the KLS Martin® Customer Service Department at 904.641.7746 or 800.625.1557.

SYMBOL GLOSSARY

ISO 15223-1: 2016 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements			
SYMBOL	**SYMBOL REF. NO.**	**SYMBOL TITLE**	**EXPLANATORY TEXT**
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.

OTHER SYMBOL(S) – NOT FROM STANDARDS				
SYMBOL	**REFERENCE**	**TITLE**	**SYMBOL TITLE**	**EXPLANATORY TEXT**
Rx ONLY	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only	Requires prescription in the United States.
	21 CFR 801.109(b)(1)	Labeling-Prescription devices.		

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