Recommendations for Decontamination and Sterilization of StarLipo Reusable Device

This document was prepared to provide decontamination and sterilization instructions for StarLipo reusable device produced by Inomedica.

StarLipo can be sterilized using Ethylene Oxide Sterilization or Plasma Sterilization.

StarLipo is non-autoclavable.

These methods were developed using standard equipment and practices common to global healthcare facilities.

These instructions were developed using the guidance given in AAMI TIR 12 (Designing, Testing, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers), ISO 17664:2004 (Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices) and Health Technical Memorandum (HTM) 2030.

General Information for Recommended Disinfection of StarLipo Device

Cleaning is the single most important step in preparing a device for reuse. Proper cleaning must be carried out to achieve effective decontamination/sterilization.

Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates, microorganisms, and pyrogens. Also, thorough rinsing is important for removing any residual cleaning agents from the medical devices.

The recommended cleaning instructions in this document include manual washing/disinfection procedures. Automatic washing procedures are not recommended for StarLipo.

Cleaning Agents/ Equipment	Important Information/Recommendations for Use
Detergents	Enzymatic detergents with a neutral pH range (typically between 6.0 and 8.0) are recommended. Detergents with a pH outside this range (i.e., neodisher® MediClean forte) pH 10.5–10.9 have been approved for use with StarLipo. Enzymatic detergents aid in the removal of organic soil such as blood. Detergents should be used at the concentration level recommended by the detergent manufacturer.
Water	The quality of water should be considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective decontamination.
Disinfection Solutions	Solutions such as glutaraldehyde are sometimes used in healthcare facilities for disinfection of devices. These types of disinfectants are not recommended as sterilants for StarLipo.
Ultrasonic Cleaner	Ultrasonic cleaning should not be used for StarLipo.

Automatic Washer/ Disinfector	The automatic washer/disinfector equipment should not be used for StarLipo.
Manual Cleaning Aids/ Instruments	Manual cleaning procedures are recommended for StarLipo. General purpose cleaning brushes and low-linting, non-abrasive soft cloths are recommended. Sharp instruments should not be used for StarLipo cleaning.

Recommended Cleaning Methods for StarLipo Reusable Device

Efforts have been made by Inomedica to validate reusable device cleaning methods to current international guidelines. These methods were developed using standard equipment and practices common to healthcare facilities. Other methods of cleaning may be suitable, but must be validated by the user of the StarLipo device.

Warnings	**All cleaning should be performed in a manner designed to minimize exposure to blood-borne pathogens. Manual cleaning should be performed with the instrument immersed.**
	It is the responsibility of the user to ensure that the cleaning process, as it is actually performed, achieves the desired result.
Point of Use	Follow recommended “point of use” practices. These practices should include keeping the devices moist after use to prevent soil from drying, and removing gross soil from surfaces as soon as possible after use.

Manual Cleaning	1. StarLipo requires gentle handling/cleaning to preserve its electrical insulation. 2. The most distal end of the StarLipo cable includes an electrical connector. This electrical connector should not be immersed during the cleaning process. This connector can be cleaned with a damp gauze as needed. 3. Soak StarLipo for a minimum of one (1) minute in enzymatic detergent. 4. Use a soft cleaning brush or cloth to remove visible soil. 5. Rinse thoroughly with warm water. 6. Check the instrument for visible soil. Repeat cleaning if soil is visible.

Cleaning Verification	1. After cleaning, visually inspect device under normal lighting for the removal of visible soil. 2. For difficult-to-view design features, apply 3% hydrogen peroxide (bubbling is evidence of the presence of blood). Note: Rinse device throughly with warm water following hydrogen peroxide testing. 3. Repeat cleaning if not visibly clean and reinspect.

Storage	StarLipo that will be stored between cleaning and sterilization should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments. **StarLipo should ALWAYS be throughly cleaned prior to storage.**

Recommended Sterilization Instructions

The following recommended sterilization methods have been validated to sterility assurance levels (SAL) in compliance with federal and international guidance/ standards. Other sterilization cycles may also be suitable, however the validation of cycles not included here is the responsibility of the individual user.

Warning	**StarLipo device is sold non-sterile. It is critical to properly clean StarLipo prior to sterilization.**
Preparation for Sterilization	• It is important that adequate cleaning be performed prior to sterilization.
	• StarLipo must be placed in a suitable packaging for the sterilization process.

Recommended Sterilization Parameters for StarLipo	100% Ethylene Oxide Cycle (A)
	• Exposure temperature 50–60° C (122–140° F) • Exposure time: 60 minutes • EO concentration ~730 mg/litre • Relative humidity 35–70% • Aeration time: 12 hours
	90/10 Ethylene Oxide Cycle
	• Exposure temperature 50–60° C (122–140° F) • Exposure time: 120 minutes • EO concentration ~600 mg/litre • Relative humidity 50–70% • Aeration time: 12 hours.
	100% Ethylene Oxide Cycle (B)
	• Exposure temperature 50–60° C (122–140° F) • Exposure time: 60 minutes • EO concentration ~883 mg/litre • Relative humidity 30–70% • Aeration time: 12 hours
	100% Ethylene Oxide Cycle (C)
	• Exposure temperature 52–60° C (125–140° F) • Exposure time: 180 minutes • EO concentration ~700–750 mg/litre • Relative humidity 30–70% • Aeration time: 12 hours

Recommended Sterilization Parameters for StarLipo (continued)	STERIS System 1®
	• Sterilize as instructed in the STERIS System 1 User Manual (the standard cycle contains no user variables)
	STERRAD® 100
	• Sterilize as instructed in the STERRAD 100 User Manual (the standard cycle contains no user variables)
	STERRAD® 100S
	• Sterilize as instructed in the STERRAD 100S User Manual (the standard cycle contains no user variables)

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