Reprocessing Guide

stryker®

Laparoscope Sterilization Tray

REF 0233032108

CE Rx ONLY

Contents

Introduction

This reprocessing guide provides instructions for the proper cleaning and sterilization of the following sterilization tray:

233-032-108 Laparoscope Sterilization Tray

This sterilization tray is intended for use **only** with the devices listed below. For tray/device configuration, see the "Sterilization Tray Setup" section of this guide.

HD Autoclavable Laparoscopes	
502-539-010	5.0mm 0° 30cm
502-539-030	5.0mm 30° 30cm
502-539-045	5.0mm 45° 30cm
502-859-010	10.0mm 0° 30cm
502-859-030	10.0mm 30° 30cm
502-859-045	10.0mm 45° 30cm
502-503-010	5.5mm 0° 30cm
502-503-030	5.5mm 30° 30cm
502-503-045	5.5mm 45° 30cm
502-103-010	10.0mm 0° 33cm
502-103-030	10.0mm 30° 33cm
502-103-045	10.0mm 45° 33cm
502-329-010	2.9mm 0° 30cm
502-329-030	2.9mm 30° 30cm
Auoclavable Laparoscopes	
502-555-010	5.0mm 0° 30cm
502-555-030	5.0mm 30° 30cm
502-555-045	5.0mm 45° 30cm
502-457-010	10.0mm 0° 30cm
502-457-030	10.0mm 30° 30cm
502-457-045	10.0mm 45° 30cm
Laparoscopes	
502-585-010	5.0mm 0° 30cm
502-585-030	5.0mm 30° 30cm
502-585-045	5.0mm 45° 30cm

Infrared Laparoscopes	
502-540-010	5.0mm 0° 30cm
502-540-030	5.0mm 30° 30cm
502-540-045	5.0mm 45° 30cm
502-860-010	10.0mm 0° 30cm
502-860-030	10.0mm 30° 30cm
502-860-045	10.0mm 45° 30cm

While these instructions have been validated by the manufacturer as being capable of preparing the tray for re-use, it remains the responsibility of the processor to ensure that the reprocessing (as actually performed, using equipment, materials, and personnel in the reprocessing facility) achieves the desired result. This normally requires validation and routine monitoring of the process.

Intended Use of Sterilization Trays

Sterilization trays are plastic and/or metal containers used to hold and protect surgical devices during the sterilization process. They consist of an interlocking tray and lid, which are both perforated to allow the passage of sterilizing agent from outside the tray to the devices placed inside.
Sterilization trays typically feature a silicon finger mat or group of device holders that secure devices during the sterilization process. Some models feature stacking internal trays to allow the segregation of devices.

Warnings

- These instructions are validated only for sterilization of the tray and device(s) identified herein. Using combinations or parameters not described in this manual may result in incomplete sterilization.
- These instructions do not replace the cleaning instructions provided with individual devices. Prior to sterilization, clean all devices as specified in their respective user manuals.
- Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.
- Both the device and the tray must be cleaned prior to sterilization, or incomplete sterilization will result.
- The sterilization tray, its lid, and any internal components have been designed and validated for use as a single system. Do not separate components from the system, for use individually or in combination, or incomplete sterilization may result.
- Inspect the tray and its components for visible damage, such as cracking or chipping, prior to use. Do not use the tray if it is damaged.

Cautions

- Before lifting the tray assembly, verify that the latches connecting the lid to the tray are secure.
- The tray is not designed for use as a shipping container. To avoid damage, remove all devices and pack them separately.

Limitations on Reprocessing	• Proper processing has a minimal effect on the tray. End of life is normally determined by wear and damage due to use. • Do not cross-sterilize the tray. Using multiple sterilization methods may significantly reduce the performance of the tray. • Do not leave the tray in solutions longer than necessary. This may accelerate normal product aging. • Damage incurred by improper processing will not be covered by the warranty.

Instructions

Instructions apply to the **sterilization tray only.** For instructions on how to reprocess the devices, consult their respective instructions for use.

Point of Use	• Wipe excess soil from the tray using disposable paper towels. • If an automated cleaning method will be used, rinse the tray in sterile distilled water immediately after use.
Containment and Transportation	Reprocess device(s) / tray as soon as reasonably practical following use.
Preparation for Manual Cleaning Cleaning was validated using Enzol® at 1 oz/gal. at 35-40°C.	1 Disassemble the tray into its individual components: base, lid, and (if applicable) silicon mat. 2 Prepare an enzymatic detergent[1] according to the manufacturer's recommendations. 3 Wipe the entire tray with a clean cloth dipped in detergent. 4 Immerse the tray in the detergent. 5 Soak the tray in the detergent for 15 minutes.

Manual Cleaning	
	1 Brush • Thoroughly brush the exterior of the tray with a soft-bristled brush, focusing on any mated or rough surfaces. • Using a pipe cleaner and brush, brush and flush the hard-to-reach areas of the tray. • Actuate the tray, brushing any movable parts in their extreme open and closed positions.
	2 Rinse • Rinse the tray with reverse osmosis/deionized (RO/DI) water at ambient temperature to remove all detergent residues. After all detergent residues have been removed, continue to rinse for a minimum of 30 seconds. • Drain excess water from the tray and dry it using a clean cloth and filtered pressurized air (40 psi). • Visually inspect the tray for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1 and 2.
	3 Soak • Prepare a non-enzymatic detergent[2] according to the manufacturer's recommendations. • Fully immerse the tray and inject any mated surfaces with at least 50mL of the detergent. • Soak the tray for a minimum of 15 minutes.
	4 Brush • Thoroughly brush the exterior of the tray using a soft-bristled brush. • Inject the prepared detergent into any mated surfaces a minimum of five times. • Actuate the tray, brushing any movable parts in their extreme open and closed positions. • Using a pipe cleaner and syringe, brush and flush the hard-to-reach areas of the tray.

[2] Cleaning was validated using Renu-Klenz™ at ¼ oz/ gal. at 35-40°C.	**5 Rinse** • Thoroughly rinse the tray with ambient RO/DI water until all detergent residue is removed. Flush any crevices five times with a syringe. After the detergent residue is removed, continue rinsing for a minimum of 30 seconds. • Drain the excess water from the tray and dry it with a clean cloth and filtered pressurized air (40 psi). • Visually inspect the tray for cleanliness, paying close attention to hard-to-reach areas.
Automated Cleaning	**1 Rinse** • Disassemble the tray into its individual components: the base, lid, and (if applicable) silicon mat. • Rinse the tray with RO/DI water at ambient temperature until there is no visible detergent residue. Use a syringe to assist in rinsing. After all detergent residues have been removed, continue to rinse for a minimum of 30 seconds. • Place the tray in the washer on an incline to facilitate drainage.

2 Automated wash

- Program the washer using the settings below.

	Recirculation Time	Water Temperature	Detergent (type and concentration)
Pre Wash	2 min.	Cold tap water	—
Enzyme Wash	2 min.	Hot tap water	Enzymatic Detergent[3]
Wash 1	2 min.	Set point 60°C (140°F)	Non-enzymatic Detergent[4]
Rinse 1	2 min.	Heated 60°C (140°F)	—
Dry Phase	7 min.	**Drying Temperature** 115°C (239°F)	—

3 Drying

- Remove the tray from the washer after the completion of the dry phase.
- Dry the tray using a clean soft cloth. Use filtered pressurized air (40 psi) to assist in drying.
- Visually inspect the tray for cleanliness, paying close attention to hard-to-reach areas.

[3] Cleaning was validated using Enzol® at 1 oz/gal.

[4] Cleaning was validated using Renu-Klenz™ at ¼ oz/gal.

Maintenance

- No routine maintenance is required for the sterilization tray.

Inspection and Testing

- Inspect the tray for dents and cracks. If a problem is observed or suspected, the tray should be returned for repair.
- Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.

Packaging for Sterilization

- Double-wrap the tray unless otherwise noted below.

Sterilization

Caution: Only devices marked "autoclavable" are compatible with steam sterilization methods. Using steam sterilization on devices that do not bear this marking can cause permanent product damage.

- Prepare the device(s) and the sterilization tray as indicated in the "Sterilization Tray Setup" section below.
- Sterilize the device(s) inside the tray according to the parameters indicated below.

Ethylene oxide (EtO)

	Preconditioning	Sterilization	Aeration
Temperature	55°C (131°F)	55°C (131°F)	55 ± 4°C (131 ± 7°F)
Relative Humidity	70%	70%	—
Vacuum Set Points	1.30 psia	—	—
EtO Concentration	—	725 mg/L (100% EtO)	—
Time	30 minutes	60 minutes	12 hours

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Sterlize the devices and tray using the **STERRAD® 100S** system.

Autoclave (Steam)

	Gravity	Prevacuum		"Flash" Prevacuum
		U.S.	E.U.	
Wrapping	double	double	double	—
Temperature	132°C (270°F)	132°C (270°F)	134°C (273°F)	132°C (270°F)
Time	15 minutes	4 minutes	3 minutes	4 minutes
Dry Time	35 minutes	30 minutes	30 minutes	—

⚠ Warning: Drying time depends on several variables, including: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Users must verify that drying time set in their autoclave yields dry surgical equipment.

⚠ Warning: These instructions were developed using the guidance from AAMI TIR 12, ISO 17665 and AAMI ST79 and Stryker recommends users observe these standards.

Storage	Trays with non-absorbent liners (such as plastic or silicone-fingered organizing mats) can cause condensate to pool. To preserve sterility, remove devices from standing solution.
Additional Information	N/A

Manufacturer Contact	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 USA 1-800-624-4422 U.S. Patents: www.stryker.com/patents

Sterilization Tray Setup

Maximum Weight Load (devices and tray combined)	**0.82 kg (1.8 lbs)**
Internal Stacking	No internal stacking is permitted with this tray.
External Stacking	Do not stack other trays or devices on or below this tray.
Accessories	There are no accessories available for use with this tray.
Device Distribution	Devices should be placed in the tray as illustrated below.
Chemical Indicator* 	Place the chemical indicator () in the bottom-right corner of the tray as illustrated in the following picture.
Biological Indicator* 	Place the biological indicator () on any scope tip as illustrated in the following picture.

*Note: Placement of the biological or chemical indicator is not required during sterilization of this tray. If, per hospital procedure, placement of an indicator is desired, the recommended placement sites are as follows.

References

- **ISO 17664—**Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices
- **ISO 17665-1—**Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- **ANSI/AAMI ST77—**Containment devices for reusable medical device sterilization
- **ANSI/AAMI ST79—**A comprehensive guide to steam sterilization and sterility assurances in health care facilities
- **ANSI/AAMI ST81—**Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices
- **AAMI TIR12—**Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers

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