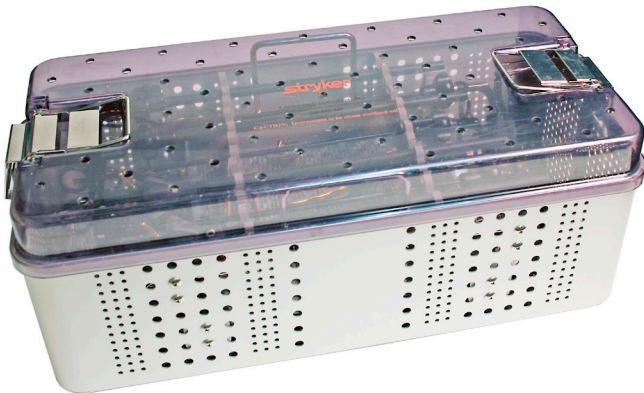


Reprocessing Guide

stryker[®]

Laparoscopic Instruments Sterilization Tray

REF 0250015500



CE Rx ONLY

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Introduction

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

250-015-500 Laparoscopic Instruments 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.

Top Tier Instruments

Place any **12** of these instruments in the top tier of the sterilization tray.

Monopolar-Handle Laparoscopic instruments

250-282-045	3mm PEEK MONOPOLAR HANDLE
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250-080-617	5mm PEEK MONOPOLAR HANDLE
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250-080-618	10mm PEEK MONOPOLAR HANDLE
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Multifunction-Handle Laparoscopic instruments

250-282-046	3mm PEEK MULTI-FUNCTION HANDLE
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250-181-106	5mm MULTI-FUNCTION PEEK HANDLE
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250-181-107	10mm MULTI-FUNCTION PEEK HANDLE
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Ratcheting-Handle Laparoscopic Instruments

250-080-230	ROTATING HANDLE, W/RATCHET, INSULATED SHAFT
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250-080-231	ROTATING HANDLE, RATCHET, INSULATED SHAFT
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250-080-233	ROTATING HANDLE, RATCHET, INSULATED SHAFT
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250-080-234	ROTATING HANDLE, W/RATCHET, INSULATED SHAFT
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Instruments

250-080-130	5mm FIXATION CLAMP
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250-080-558	10mm CLIP-APPLYING FORCEPS
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250-080-765	5mm, 33cm Single Action Sliding Lock Atraumatic Grasper
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250-080-767	5mm, 33cm Double Action Sliding Lock Atraumatic Grasper
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250-010-310	Multicut Scissors, Straight
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250-010-311	Multicut Scissors, Curved
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250-080-130	5mm FIXATION CLAMP
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250-080-558	10mm CLIP-APPLYING FORCEPS, ETHICON ML(LC300 OR LT300 COMP)
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Middle Tier Instruments

Place a maximum of **5** of these instruments in the middle tier of the sterilization tray.

Needleholder Handle

250-080-235	5mm, 33cm NEEDLEHOLDER HANDLE
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Bipolar Handle

250-080-236	5mm, 33cm BIPOLAR RING HANDLE
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250-080-237	5mm, 33cm BIPOLAR SPRING HANDLE
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Middle Tier Instruments

Place a maximum of **5** of these instruments in the middle tier of the sterilization tray.

Trocars, Pyramidal Tip

250-080-692	TROCAR, PYRAMIDAL TIP, 3.5mm (105mm LENGTH)
250-080-730	TROCAR, PYRAMIDAL TIP, 3.5mm (145mm LENGTH)
250-080-154	TROCAR, PYRAMIDAL TIP, 5.5mm
250-080-155	TROCAR, PYRAMIDAL TIP, 8mm
250-080-156	TROCAR, PYRAMIDAL TIP, 11mm
250-080-422	TROCAR, PYRAMIDAL TIP, 12.5mm

Cannulas

250-080-634	3.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK, W/OUT TROCAR(55mm)
250-080-171	5.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK WITHOUT TROCAR
250-080-174	11.0mm CANNULA, AUTOMATIC VALVE, STOPCOCK WITHOUT TROCAR
250-080-175	5.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK, OBTURATOR, FIXABLE CONE
250-080-176	5.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK
250-080-178	11mm CANNULA, AUTOMATIC VALVE, STOPCOCK, OBTURATOR, FIXABLE CONE
250-080-179	11.0mm HASSON CANNULA, AUTOMATIC VALVE, STOPCOCK
250-080-436	12.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK

Obturers

250-080-157	5.5MM OBTURATOR FOR HASSON CANNULA
250-080-158	11.0MM OBTURATOR FOR HASSON CANNULA

Instruments

250-080-181	2.9mm, 120mm NEEDLE/CANNULA
250-080-182	2.9mm, 120mm NEEDLE
250-080-183	2.9mm, 120mm CANNULA, W/2 STOPCOCKS
250-080-201	11mm FASCIA SCREW
250-080-206	11mm, 5.5mm REDUCER SLEEVE
250-080-212	120mm NEEDLE, BODY ONLY
250-080-436	12.5mm CANNULA, AUTOMATIC VALVE, STOPCOCK
250-080-619	SEALING CAP
250-080-200	5.5mm FASCIA SCREW
250-080-139	PORTIO ACORN, SMALL ONLY
250-080-140	PORTIO ACORN, LARGE ONLY

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

Single-Action Graspers

250-282-099	3mm SINGLE ACTION ATRAUMATIC GRASPER, 29cm
250-080-310	5mm, 33cm SINGLE ACTION ATRAUMATIC GRASPER

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

250-080-325	5mm, 33cm MICRO GRASPER
250-080-244	10mm, 33cm SINGLE ACTION CLAW
250-080-246	10mm, 33cm BIOPSY SPOON
Double-Action Graspers	
250-282-003	3mm INSERT, FUNDUS GRASPER 20cm
250-282-050	3mm INSERT FUNDUS GRASPER 29cm
250-282-004	3mm INSERT ALLIGATOR GRASPER 20cm
250-282-051	3mm INSERT ALLIGATOR GRASPER 29cm
250-282-006	3mm INSERT FENESTRATED SCHERTL GRASPER 20cm
250-282-053	3mm FENESTRATED SCHERTL GRASPER INSERT, 29cm
250-282-007	3mm INSERT COBRA GRASPER 20cm
250-282-054	3mm INSERT, COBRA GRASPER
250-282-009	3mm INSERT BLUNT GRASPER 20cm
250-080-008	OPERATING SCISSORS, SERRATED
250-282-055	3mm INSERT WITH SPOON GRASPER 29cm
250-282-056	3mm INSERT BLUNT GRASPER 29cm
250-282-096	3mm INSERT DORSEY GRASPER 20cm
250-282-097	3mm INSERT DORSEY GRASPER 29cm
250-282-100	3mm DOUBLE ACTION ATRAUMATIC GRASPER, 20cm
250-282-052	3mm INSERT NEEDLE NOSE DISSECTORS 29cm
250-080-101	NEEDLE HOLDER, STRAIGHT
250-282-103	3mm BABCOCK GRASPER 29cm
250-080-084	5mm BOWEL GRASPER FORCEPS
250-080-286	5mm, 33cm SERRATED GRASPER
250-080-287	5mm, 33cm NARROW JAW GRASPER
250-080-311	5mm, 33cm DOUBLE ACTION ATRAUMATIC GRASPER
250-080-312	5mm, 33cm FENESTRATED SCHERTL GRASPER
250-080-313	5mm, 33cm BLUNT GRASPER WITH SPOON
250-080-314	5mm, 33cm DEBAKEY GRASPER
250-080-315	5mm, 33cm FUNDUS GRASPER
250-080-316	5mm, 33cm ALLIGATOR GRASPER
250-080-317	5mm, 33cm COBRA GRASPER
250-080-318	5mm, 33cm SERRATED FENESTRATED GRASPER
250-080-319	5mm, 33cm DORSEY GRASPER
250-080-320	5mm, 33cm STRONG GRASPER (FENESTRATED)
250-080-321	5mm, 33cm BABCOCK GRASPER
250-080-322	5mm, 33cm GRASPER, DELICATE, FENESTRATED

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

250-080-591	5mm, 33cm ALLIS GRASPER (SINGLE ROW OF TEETH)
250-080-592	5mm, 33cm ALLIS GRASPER (DOUBLE ROW OF TEETH)
250-080-697	5mm, 33cm, RETENTION GRASPER
250-080-699	5mm, 33cm, ENDO GRASPER
250-080-700	5mm, 33cm, PADDLE BABCOCK GRASPER
250-080-755	5mm, 33cm FENESTRATED GRASPER
250-080-240	10mm, 33cm ALLIS GRASPER
250-080-241	10mm, 33cm BABCOCK GRASPER
250-080-242	10mm, 33cm PENNINGTON GRASPER
250-080-245	10mm, 33cm DOUBLE ACTION CLAW

Double-Action Dissectors

250-282-104	3mm INSERT RIGHT ANGLE DISSECTORS, 20cm
250-282-105	3MM INSERT RIGHT ANGLE DISSECTORS 29CM
250-282-005	3MM INSERT NEEDLE NOSE DISSECTORS 20CM
250-282-052	3MM INSERT NEEDLE NOSE DISSECTORS 29CM
250-282-109	3MM DISSECTING FORCEPS 20CM
250-282-110	3MM DISSECTING FORCEPS 29CM
250-282-010	3MM INSERT TAPERED BULLET 20CM
250-282-057	3MM INSERT TAPERED BULLET 29CM
250-282-011	3MM INSERT MARYLAND DISSECTORS 20CM
250-282-058	3MM INSERT MARYLAND DISSECTORS 29CM
250-080-280	5MM, 33CM DOLPHIN WITH SPOON DISSECTOR
250-080-281	5MM, 33CM TAPERED BULLET DISSECTOR
250-080-282	5MM, 33CM MARYLAND DISSECTOR
250-080-283	5MM, 33CM CURVED KELLY DISSECTOR
250-080-284	5MM, 33CM TISSUE GRASPER DISSECTOR (45°)
250-080-288	5MM, 33CM NEEDLE NOSE DISSECTOR
250-080-320	5MM, 33CM STRONG GRASPER (FENESTRATED)
250-080-694	5MM, 33CM RIGHT ANGLE DISSECTOR
250-080-757	5MM, 33CM RIGHT ANGLE (LONG JAW)
250-080-760	5MM, 33CM DISSECTING FORCEPS
250-080-248	10MM, 33CM MARYLAND DISSECTOR
250-080-249	10MM, 33CM MIXTER
250-080-250	10MM PADDLE BABCOCK GRASPER

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

Single-Action Scissors

250-282-001	3MM INSERT PERITONEAL SCISSORS 20CM
250-282-016	3mm PEEK PERITONEAL SCISSORS 20cm
250-282-048	3MM INSERT, PERITONEAL SCISSORS 29CM
250-282-002	3MM HOOK SCISSORS
250-282-049	3MM HOOK SCISSORS INSERT 29CM
250-080-260	5MM, 33CM HOOK SCISSORS
250-080-262	5MM, 33CM PERITONEAL SCISSORS
250-080-269	5MM, 33CM MICRO SCISSORS (STRAIGHT)
250-080-247	10MM, 33CM OPERATING SCISSORS, SERRATED

Double-Action Scissors

250-282-047	3mm INSERT, METZENBAUM, CURVED, LONG SCISSORS, 29CM
250-080-261	MINI HOOK SCISSORS
250-080-263	METZENBAUM SCISSORS, STRAIGHT, LONG
250-080-264	METZENBAUM SCISSORS, STRAIGHT
250-080-265	METZENBAUM SCISSORS, CURVED, LONG
250-080-266	MINI METZENBAUM SCISSORS, CURVED
250-080-267	METZENBAUM SCISSORS, CURVED
250-080-268	BABY METZENBAUM SCISSORS, CURVED
250-080-270	MICRO SCISSORS, CURVED
250-282-015	3mm PEEK METZENBAUM, CURVED, LONG SCISSORS, 20CM

Single-Action Biopsy

250-282-013	3MM BIOPSY PUNCH 20CM
250-282-060	3MM INSERT BIOPSY PUNCH 29CM
250-080-290	5MM, 33CM BIOPSY PUNCH
250-080-292	5MM, 33CM BLAKESLY BIOPSY
250-080-293	5MM, 33CM SINGLE ACTION BIOPSY SPOON WITH PIN

Double-Action Biopsy

250-282-012	3MM INSERT BIOPSY FORCEPS 20CM
250-282-059	3MM INSERT BIOPSY FORCEPS 29CM
250-080-291	5MM, 33CM DOUBLE ACTION BIOPSY SPOON WITH PIN

Double-Action Forceps

250-080-084	5.0mm BOWEL GRASPER FORCEPS
250-282-018	3mm PEEK FUNDUS FORCEPS 20cm
250-282-020	3mm PEEK NEEDLE NOSE FORCEPS 20cm
250-282-022	3mm PEEK COBRA FORCEPS 20cm
250-282-026	3mm PEEK MARYLAND FORCEPS 20cm

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

250-282-102	3mm INSERT BABCOCK FORCEPS 20cm
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250-080-285	MIXTER FORCEPS
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250-080-243	KOELN FORCEPS
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250-080-323	5MM, 33CM MESO-OVARIAN FORCEPS
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250-080-324	5MM, 33CM OVIDUCT FORCEPS
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250-080-698	5mm INSERT, TENACULUM 33cm
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250-080-733	5MM, 33CM, PARK FORCEPS
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250-080-763	5MM, 33CM JOHANN FORCEPS
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Needleholder Handle

250-080-235	5MM, 33CM NEEDLEHOLDER HANDLE
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Needleholder Instruments

250-282-014	3MM, 20CM INSERT STRAIGHT NEEDLEHOLDER
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250-282-061	3MM, 29CM INSERT STRAIGHT NEEDLEHOLDER
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250-080-340	5MM, 33CM STRAIGHT NEEDLEHOLDER
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250-080-341	5MM, 33CM CURVED LEFT NEEDLEHOLDER
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250-080-342	5MM, 33CM CURVED RIGHT NEEDLEHOLDER
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Monopolar Electrosurgical Probes

250-040-111	5MM, 33CM SPATULA TIP ELECTROSURGICAL PROBE (3BX)
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250-040-112	5MM, 33CM L-TIP ELECTROSURGICAL PROBE (3BX)
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250-040-113	5MM, 33CM J-TIP ELECTROSURGICAL PROBE (3BX)
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33cm Bipolar Instrumentation

250-080-120	5MM, 33CM BIPOLAR FENESTRATED FORCEPS WITH RING HANDLE
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250-080-123	5MM, 33CM BIPOLAR FENESTRATED FORCEPS WITH SPRING HANDLE
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250-080-121	5MM, 33CM BIPOLAR PADDLE FORCEPS WITH RING HANDLE
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250-080-124	5MM, 33CM BIPOLAR PADDLE FORCEPS WITH SPRING HANDLE
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Bipolar Instrumentation

250-080-360	5MM, 33CM BIPOLAR FENESTRATED FORCEPS (INSERT)
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250-080-361	5MM, 33CM BIPOLAR PADDLE FORCEPS (INSERT)
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250-080-362	5MM, 33CM BIPOLAR MICRO TIP FORCEPS (INSERT)
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250-080-371	5MM, 33CM BIPOLAR SHAFT
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Bipolar Handle

250-080-236	5MM, 33CM BIPOLAR RING HANDLE
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250-080-237	5MM, 33CM BIPOLAR SPRING HANDLE
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Bipolar Accessories

250-040-016	REUSABLE BIPOLAR CABLE (VALLEY LABS)
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250-080-693	BIPOLAR HANDLE SEALING CAP
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Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

Trocars, Pyramidal Tip

250-080-692	Trocar, Pyramidal Tip, 3.5mm (105mm length)
250-080-730	Trocar, Pyramidal Tip, 3.5mm (145mm length)
250-080-154	Trocar, Pyramidal Tip, 5.5mm
250-080-155	Trocar, Pyramidal Tip, 8mm
250-080-156	Trocar, Pyramidal Tip, 11mm
250-080-422	Trocar, Pyramidal Tip, 12.5mm

Cannulas

250-080-634	3.5mm Cannula, Automatic Valve, Stopcock, Without Trocar(55mm)
250-080-137	Cohen Intrauterine Cannula, Complete
250-080-171	5.5mm Cannula, Automatic Valve, Stopcock Without Trocar
250-080-174	11.0mm Cannula, Automatic Valve, Stopcock Without Trocar
250-080-179	11.0mm Hasson Cannula, Automatic Valve, Stopcock

Obturator

250-080-157	5.5mm Obturator For Hasson Cannula
250-080-158	11.0mm Obturator For Hasson Cannula

Reducers

250-080-202	Reducer, 5.5mm - 3.0mm
250-080-203	Reducer, 8.0mm - 5.5mm
250-080-204	Reducer, 12.5mm/11mm-5.5mm
250-080-472	Reducer, 12.5mm - 10.0mm

Cones

250-080-177	5.5mm Fixable Cone For Hasson Cannula (Obsolete)
250-080-180	11.0mm Fixable Cone For Hasson Cannula

Instrument Accessories

250-080-205	5mm-11mm Dilation Set
250-080-207	Male Luer Lock For 6mm Tubing
250-080-208	Female Luer-Lock For 6mm Tubing
250-080-701	5mm Endoloop Applicator
250-080-702	5mm Aspiration Needle, 33cm Long, 17 Gauge Needle
250-080-131	3.0mm Knot Pusher
250-080-132	5.0mm Knot Pusher
250-080-133	5.0mm Myoma Drill
250-080-134	10.0mm Myoma Drill
250-080-135	5mm Palpation Probe, 33cm Long
250-080-138	Cohen Cannula (Cannula Only)
250-080-139	Small Acorn

Bottom Tier Instruments

Place any combination of these instruments in the bottom tier of the sterilization tray, provided the total weight of the loaded tray does not exceed **5.99 kg (13.20 lbs)**.

250-080-140

Large Acorn

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

¹ 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 detergent¹ 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

² Cleaning was validated using Renu-Klenz™ at ¼ oz/gal. at 35-40°C.

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 detergent² 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.

	<p>4 Brush</p> <ul style="list-style-type: none"> • 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. <p>5 Rinse</p> <ul style="list-style-type: none"> • 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.
<p>Automated Cleaning</p>	<p>1 Rinse</p> <ul style="list-style-type: none"> • 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	Detergent (type and concentration)
Pre Wash	2 min.	—
Enzyme Wash	2 min.	Enzymatic Detergent ³
Wash 1	2 min.	Non-enzymatic Detergent ⁴
Rinse 1	2 min.	—
Dry Phase	7 min.	—

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

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

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.

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

⚠ Warning: Do not place inserts, cannulas, or instrument accessories in the top tier of the sterilization tray or incomplete sterilization may result.

⚠ Warning: Assembled instruments will not sterilize completely. Disassemble all instruments prior to placement in the tray for sterilization.

⚠ Warning: Place the stopcock of the devices (where applicable) in the open position prior to sterilization; otherwise, non-sterile products may result.

- 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	Aeration
Temperature	55°C (131°F)	55 ± 4°C (131 ± 7°F)
Relative Humidity	70%	—
Vacuum Set Points	1.30 psia	—
EtO Concentration	—	—
Time	30 minutes	12 hours

		Autoclave (Steam)	
		Gravity	Prevacuum
Wrapping		double	double
Temperature		132°C (270°F)	132°C (270°F)
Time		36 minutes	4 minutes
Dry Time		60 minutes	60 minutes
		<p>⚠ 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.</p> <p>⚠ Warning: These instructions were developed using the guidance from AAMI TIR 12, ISO 17665 and AAMI ST79 and Stryker recommends users observe these standards.</p>	
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	<p>Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 +1.800.624.2244, +1.408.754.2000 www.stryker.com</p>
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Sterilization Tray Setup

Maximum Weight Load (devices and tray combined)	5.99 kg (13.20 lbs)
Internal Stacking	Up to three tiers may be stacked inside the tray. Do not stack instruments on top of each other within individual tiers.
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 () between the jaws of any grasper as illustrated in the following picture.

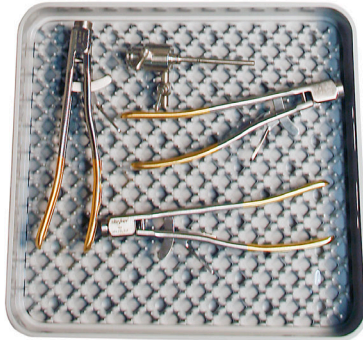
*Note: Placement of the biological or chemical indicator is not required during sterilization of this tray. If, per hospital procedure, placement of an indicator is desired, the recommended placement sites are as follows.

Bottom Tier
combination of any
“bottom tier”
instruments
(identified in this
guide)



Top Tier
combination
of any 12 “top
tier” instruments
(identified in this
guide)

Middle Tier
combination of any 4 - 5
“middle tier” instruments
(identified in this guide)



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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