General Reprocessing Instructions for KARL STORZ Products (USA)

Important information for users of KARL STORZ instruments

Please read this entire instructions-for-use carefully before using the KARL STORZ instruments. Failure to follow the instructions, cautions and warnings presented in this manual may result in serious consequences to the patient.

Procedures for proper handling and care of KARL STORZ instruments are described in this instructions-for-use. KARL STORZ endoscopes and accessories are delicate surgical instruments and should be handled with care. Improper use during surgical procedures will result in damage, breakage or patient injury. KARL STORZ Endoscopy-America, Inc. assumes no liability if the instruments are misused, mishandled or otherwise abused. Proper handling and care, as described in this instructions-for-use, will prolong the life of these instruments

Contents

Note: This document is updated frequently. Please check for latest update.

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WHY IS WATER QUALITY IMPORTANT?

The quality of water used for instrument processing has a considerable influence on the proper function and longevity of an instrument. A hard layer (lime deposits, scale) can form on instruments depending on water hardness and temperature that can be very difficult to dissolve. Excessive concentrations of chlorides can also cause pitting. Cleaning solutions made up with tap water will leave mineral residues on instruments that will not wash off fully even with de-ionized water. Over time, these residues will build and could affect instrument function.

The quality of the final rinsing water is a part of the hygienic standards for reprocessing of medical devices. Rinsing water for final manual cleaning and disinfection of medical devices without following sterilization has to be absolutely free of pathogenic microorganisms. When an instrument is rinsed in tap water recontamination can occur.

To recap: Water quality impacts on the following:

1. Medical Devices –
   - Damage: pitting and corrosion with eventual loss of device function
   - Reduction in cleaning efficacy
   - Interference with high level disinfection/sterilization efficacy

2. Patient –
   - Infection transmission
   - Adverse reaction such as inflammation and fever

General characteristics to be considered for reprocessing medical device:

1. Microbiological content of the water
2. Inorganic and organic content of the water

Distilled or demineralized water is recommended for cleaning and rinsing of all instruments.

Table 1

	Products ☑ * REFER TO REPROCESSING SECTIONS FOR DETAILED INSTRUCTIONS * Refer to page number listed in matrix box	STERILIZATION							High Level Disinfection				
				STERRAD®			STERIS®		Automated		Manual		
		Steam	Ethylene oxide gas	100S	NX	100NX		Amsco V-PRO	STERIS Reliance EPS	Medivators AER	Cidex 14 Day	Cidex OPA	Resert XL HLD (2.0% H_2O_2)
1	Hopkins Telescopes	A	X	X	X	X					X	X	
2	Hopkins Telescopes with Instrument Channels	A	X	15*	X	X					X	X	
3	Semi Rigid Telescopes	A	X	X	X	X					X	X	
4	Semi Rigid Telescopes with Instrument channels	A	X		14*	13*					X	X	
5	Bonfils Intubation scopes including DCI (no channel)		X	X	X	X					X	X	
6	C-MAC 8401AX/BX/HX/AXC/BXC/KXC Intubation Laryngoscopes		X	X	X	X		X			X	X	
7	V-MAC 8401A/B/C/D/E/G Intubation Laryngoscopes # *Blade only*		X	X	X#						X	X*	
8	LED Bright Blades	A	X	X	X	X					X	X	
9	Flexible Fiberscopes		X		X	X			X	X	X	X	
10	Flexible Fiberscopes w/ no channels, ureteral stents		X	X	X	X			X	X	X	X	
11	Flexible Video Endoscopes		X								X	X	
12	Flexible Video Endoscopes w/ no channels		X	X							X	X	
13	Insulated/Non-insulated one piece surgical instruments	X	X	X	X	X					X	X	
14	CLICK*line* (insulated) or CLICK*line* (non-insulated) + Take-Apart Instruments (insulated) disassembled	X	X										
15	Trocars/Cannulas/Sheaths/Obturators/Laryngoscopes	X	X	15*	15*	15*					X	X	
16	Fiber optic light cables	X	X	X	X	X					X	X	
17	Cameras (See Table 2, page 4)	A	X	X	4*	4*		4*			X		X
18	Powered instruments	10*	X										
19	Resectoscope Working Element	X	X								18*	18*	
20	High Frequency cords	A	X	X	X	X							
21	Bronchoscope/Esophagoscope Tubes (light carrier off)	X	X								X	X	
21	Light Carriers	A	X	X	X	X					X	X	
22	Direct Laryngoscope Handles (light carrier removed)	X	X								X	X	
23	Bronchoscope/Laryngoscope Suction Tubes	X	X								X	X	
24	Prismatic Light Deflectors	A	X	X	X	X					X	X	
25	Metal instrument + Lubricant + Flexible Forceps	X											

X Approved method

A: Telescopes, Prismatic Light Deflectors, and Cameras marked "AUTOCLAV" may be steam sterilized in <u>pre-vacuum only</u>, NO Flash.

Table 2

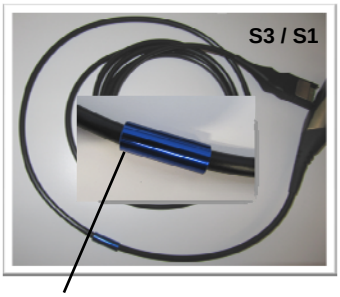
CAMERA HEADS	STERILIZATION							HIGH LEVEL DISINFECTION		Sterile Drape
	EtO Gas	STERRAD® (Vaporized H_2O_2, Plasma)				STERIS®		CIDEX (Glutaraldehyde, 2.4%)	Resert XL HLD (2.0% H_2O_2)	
		100S (US)	100S "Short" Cycle (Int'l)	NX "Standard" Cycle	100NX "Standard" Cycle	Amsco V-PRO 1 / V-PRO 1 Plus (Vaporized H_2O_2)				
Non-Autoclavable										
H3-Z (with blue cable nut)	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3-ZI (with blue cable nut)	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3-P (with blue cable nut)	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3 (with blue cable nut)	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3 (with black cable nut)	✓	✓	✓					✓	✓	✓
S3 / S1 (with blue cable cylindrical ring)	✓	✓	✓	✓	✓	✓		✓	✓	✓
S3 / S1	✓	✓	✓					✓	✓	✓
P3 / P1	✓	✓	✓	✓	✓			✓	✓	✓
F3	✓	✓	✓	✓	✓			✓	✓	✓
D1	✓	✓	✓	✓	✓			✓	✓	✓
Telecam	✓	✓	✓					✓	✓	✓
DCI-1/DCI-2	✓	✓	✓					✓	✓	✓
Tricam	✓	✓	✓					✓	✓	✓
Autoclavable										
A3 /A1	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3-ZA	✓	✓	✓	✓	✓	✓		✓	✓	✓
H3-FA	✓	✓	✓	✓	✓	✓		✓	✓	✓
Telecam A/C	✓	✓	✓					✓	✓	✓
Tricam A/C	✓	✓	✓					✓	✓	✓

✓ = Approved method

Note: Non-soakable Cameras (22220154-3 - H3-M HD Microscope Head) Surface Disinfection Only

Red cable back nut

Blue cable back nut



Blue cable cylindrical slide ring

Red Cable Nut (H3-FA, H3-ZA) Camera heads are Autoclavable.

Blue Cable Back Nut (H3/H3Z HD Cameras) or Cylindrical Slide Ring (S3/S1 SD Cameras) indicates validation for STERRAD NX/100NX and/or STERIS Amsco V-PRO Vapor Hydrogen Peroxide Sterilizers.

WARNING: KARL STORZ instruments should be thoroughly cleaned and high level disinfected or sterilized according to validated infection control procedures prior to use and subsequent reuse.

CAUTION: Any deviations from the recommended parameters for cleaning and sterilization should be validated by the user.

Pre-Cleaning Preparation:

Place the instruments in containers and soak no longer than one hour with a neutral pH (pH 6.0 to 8.0) enzymatic cleaning solution (e.g., Enzol, Metrizyme, or equivalent, diluted to proper concentration per manufacturer's instructions) immediately after use to prevent blood, protein, and other contaminants from drying onto the instruments. Wipe the instruments thoroughly with a lint-free, disposable cloth, preferably moistened with an enzymatic cleaning solution.

CAUTION: DO NOT soak the telescope in any solution (including water) for longer than 60 minutes.

CAUTION: DO NOT use alcohol for wipe-down of the flexible endoscope shaft. DO NOT use pushing and pulling movements to avoid damage.

Water Quality Requirements:

Distilled or demineralized water is recommended for cleaning and rinsing of all instruments.

Cleaning Instructions for Instruments:

CAUTION: WEAR PROTECTIVE GLOVES, CLOTHING, AND A FACE MASK FOR CLEANING OF CONTAMINATED INSTRUMENTS.

Caution: Do not process sheaths with ceramic beaks or optical devices such as flexible endoscopes, telescopes, cameras, and light cables in an ultrasonicator.

Caution: Do not soak or immerse in a liquid/chemical solution for the following instruments:

- Telescopes with HAMOU eyepiece drive mechanism
- Magnifying lenses with drive mechanism
- IMPERATOR handpieces

Caution: Remove pressure compensation cap from flexible endoscopes before cleaning.

1. All instruments with removable parts should be disassembled. All moving parts should be in the open position.
2. Thoroughly rinse the instruments to remove all gross debris prior to cleaning.
3. Manual cleaning is recommended. Instruments (except the aforementioned devices) with difficult to reach areas such as joints, lumens and stopcocks can be processed using an ultrasonicator. It is important to follow the manufacturer's instructions for operating the ultrasonicator.
4. Completely immerse the instruments, with instrument jaws open, in a neutral pH enzymatic cleaning solution (e.g. Enzol, Metrizyme or equivalent diluted to proper concentration per manufacturer's instructions). Use distilled or demineralized water to prepare cleaning solution

to proper concentration. KARL STORZ does not recommend the use of detergents alone, as they contain high concentrations of surfactants, which can leave a film on the instruments.

5. Remove any residual blood, protein material and contaminants from the instrument with brushes, sponges, soft clothes or cotton tip applicator. Cleaning accessories are available from KSEA.

Table 3

Cleaning Brushes

Product #	Length	Diameter	Suggested Use
27648A/3	58cm	16mm	Laryngoscopes, Adult Bronchoscopy/Esophagoscopy.
27650A/3	35cm	11mm	Pediatric Bronchoscopy/Esophagoscopy, Adult Cystoscopy, Hysteroscopy
27650B/3	35cm	7mm	Pediatric Cystoscopy, Arthroscopy, Adult Cystoscopy
27650C/3	35cm	2.5mm	Small Joint Arthroscopy, Instrument Channels, Suction tubes
27650D/3	50cm	11mm	Medium Diameter Bronchoscopy and Esophagoscopy Tubes
27650E/3	50cm	7mm	Extended Length Resectoscope and Cystoscopy Sheaths
27650G/5	50cm	2.5mm	Clickline Tubes
27651A	150cm	1mm	Flexible scopes with instrument channels <1.2mm, suction tubes
24651AK	75cm		Flexible scopes with instrument channels of 1-1.5mm
27651AL	150cm	1.5mm	Flexible Intubation Telescopes
27651B	100cm	2mm	Flexible Intubation Telescopes, Flexible Cystoscopes
27651C	230cm	2mm	Flexible Intubation Telescopes
27651G	180cm	2.5mm	Pediatric Gastroscope
27651H	230cm	5mm	Gastroscopes, Colonoscopes
27651I	270cm	5mm	Gastroscopes, Colonoscopes
27651K1	40cm	0.4 - 0.6mm	Sialendoscopes and other miniature endoscopes
27651K2	40cm	0.6 - 0.8mm	Sialendoscopes and other miniature endoscopes
27651K3	40cm	0.8 - 1.4mm	Sialendoscopes and other miniature endoscopes
27651K4	40cm	0.2 - 0.4mm	Sialendoscopes and other miniature endoscopes
27651UA	60cm	2mm	Semi-rigid ureteroscopes
27651UB	60cm	2.2mm	Semi-rigid ureteroscopes
27652/3			Cleaning brush for jaws Click*line*/Take-Apart Instruments, 3/pkg
11275CS/10	10cm		Short cleaning brush: Stopcocks, T Fittings, 10/pkg, single use, non-sterile
11275CL2/10	70cm	3-5mm	Tapered, Flexible Cystoscopes,5mm flexible hysteroscopes 10/pkg, single use, non-sterile
11276CL/10	110cm	1mm	Channels up to 1.2mm (3.6Fr), 10/pkg, single use, non-sterile

Note: Always choose an appropriately sized cleaning brush for a particular instrument or telescope. Using the wrong cleaning brush may result in damage to the instrument or telescope. Please refer to the instruction manual for specific cleaning instructions.

6. While immersed, clean the inside of the instrument channel ports with a short cleaning brush. Clean the inside of the sheaths and outer tubes with the appropriate size cleaning brushes. For instruments that have cleaning ports, the ports should be cleaned using a short brush and flushed with a large syringe. All visible organic debris should be removed while submerged in cleaning solution.
7. Cleaning brushes should be cleaned and high level disinfected or steam sterilized after each use.
8. Triple rinse all instruments with distilled/demineralized water, for a minimum of one minute for each rinse. The rinse water should be discarded at the end of each rinse, as it will be contaminated with the cleaning solution. Thorough rinsing of the instruments is necessary for removing any debris or detergent, which could interfere with sterilization. Cleaning pistols (KSEA part number 27660) with the smallest attachments are useful for rinsing the instruments.
9. Dry the instrument with a lint free soft cloth or filtered compressed air (<5psi). To insure that all debris and water are removed from the instrument channels of sheaths, flush all instrument channels several times with water and filtered compressed air (<5psi). Cleaning pistols (KSEA part number 27660) with the smallest attachments are useful for drying the instruments with compressed air.
10. After cleaning, inspect the instruments for cleanliness and damage.
11. Do not use any instruments or accessories that show visible signs of damage or that are difficult to use. Any malfunction of an accessory or instrument during a procedure could result in injury to the patient and further damage to the instrument.
12. Before sterilization, lubricate all moving parts of the instrument with a non-silicone water soluble instrument milk or lubricant (e.g. Codman Preserve per manufacturer's instructions). Silicone or oil based lubricants are not recommended for use because sterilants cannot penetrate the silicone or oil.

Sterilization Instructions*:*

Routine sterilization is recommended for initial and subsequent sterilization of all instruments. Instruments may be sterilized in ethylene oxide (EtO), steam, STERIS® Amsco V-PRO® Sterilization Systems or STERRAD® Sterilization Systems. To achieve the desired sterility assurance level (SAL) of 10^{-6}, KARL STORZ approves the following EtO, steam, STERIS® Amsco V-PRO® Sterilization Systems and approved STERRAD® Sterilization Systems sterilization methods.

WARNING: Before sterilization, the instruments must be thoroughly cleaned and all visible organic material, blood and cleaning solution completely removed.

WARNING: KARL STORZ recommends that, in order to assure sterility, all instruments should be sterilized disassembled and then reassembled in a sterile field.

WARNING: **Sterilization is recommended for "critical" instruments to be used for Hysteroscopy, Neuroendoscopy, Arthroscopy, or Laparoscopy.**

High level disinfection (minimum requirement) is recommended for "semi-critical" instruments which come into contact only with intact mucous membranes or non-intact skin.

WARNING: **Only endoscopes specially designated to be STERRAD® 100S/NX/100NX compatible are to be processed by these methods.**

CAUTION: The approved sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

CAUTION: Any deviations from the recommended parameters for sterilization should be validated by the user.

CAUTION: KARL STORZ recommends the use of one cleaning agent and one sterilization method to prevent the unknown rate of material degradation due to material-chemical interactions from various cleaning and sterilization processes.

CAUTION: Do NOT mix peracetic acid-based solutions with hydrogen peroxide agents for reprocessing flexible endoscopes.

Ethylene Oxide (EtO) Gas Sterilization:

WARNING: KARL STORZ recommends that instruments be sterilized with ethylene oxide disassembled and then reassembled in a sterile field.

WARNING: Sterility of KARL STORZ instruments sterilized with ethylene oxide cannot be assured if the instruments are sterilized assembled.

CAUTION: For flexible endoscopes, place pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before EtO gas sterilization. Do not use the yellow transport cap (#Z03553), which maybe present on refurbished endoscopes.

1. Place the instruments in the sterilization tray.
2. Wrap with two layers of FDA cleared polypropylene wrap or equivalent material.
3. KARL STORZ has validated Ethylene Oxide (EtO) sterilization for instruments using the following parameters:

Table 4

100% Ethylene Oxide			
CONDITIONING PARAMETERS (In-Chamber)			
Temperature (set point) :	55°C (131 °F)		
Humidity :	≥ 70% RH		
Vacuum (set point) :	1.3 psia		
Conditioning Dwell Time :	30 minutes		
STERILIZATION PARAMETERS			
Sterilant :	100% Ethylene oxide		
Temperature (set point) :	55 °C (131 °F)		
Humidity :	≥ 70% RH		
Humidity Dwell Time:	30-45 minutes		
Product Load Configuration	**1**	**2**	**3**
EO Gas Concentration :	725 ± 30 mg/L	725 ± 30 mg/L	735 ± 30 mg/L
EO Gas Exposure Time :	60 minutes	120 minutes	180 minutes
AERATION PARAMETERS			
Aeration Time :	12 hours		
Aeration Temperature :	51 - 59°C (124° - 138°F) set point: 55°C		

Product Load Configuration Descriptions:

1. Load Configuration 1

Product Load Configuration **1**	
EO Gas Concentration:	725 ± 30 mg/L
EO Gas Exposure Time:	60 minutes

The 60-minute EO cycle parameter is recommended for the following:

- Surface sterilization of non-lumen instruments (without sterilization tray) wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.
- Flexible endoscopes with or without channel in sterilization tray wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.

2. Load Configuration 2

Product Load Configuration **2**	
EO Gas Concentration:	725 ± 30 mg/L
EO Gas Exposure Time:	120 minutes

The 120-minute EO cycle parameter is recommended for the following:

- Instruments (lumen or non-lumen devices) placed in sterilization tray wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.
- Instruments with lumen and without sterilization tray wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.

3. Load Configuration 3

Product Load Configuration **3**	
EO Gas Concentration:	735 ± 30 mg/L
EO Gas Exposure Time:	180 minutes

The 180-minute EO cycle parameter is recommended for Camera Heads product family. The Camera Head (with or without sterilization tray) is wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.

Steam Sterilization:

WARNING: STEAM STERILIZE ONLY KARL STORZ TELESCOPES MARKED – 'AUTOCLAV'!

NON-AUTOCLAVABLE TELESCOPES WILL SUFFER IRREPARABLE DAMAGE.

WARNING: Do not "FLASH" sterilize any KARL STORZ telescopes, light carriers, or light deflectors.

WARNING: Do not steam sterilize (autoclave) any KARL STORZ flexible endoscopes.

CAUTION: During sterilization, telescopes should not come into direct contact with metal.

WARNING: KARL STORZ recommends that, in order to assure sterility, all instruments be sterilized disassembled and then reassembled in a sterile field.
All sterilization methods recommended by KARL STORZ require that the instruments be disassembled prior to sterilization.

1. Place the instruments in a sterilization tray.
2. Wrap with two layers of FDA-cleared polypropylene wrap or equivalent material.
3. KARL STORZ has validated the following steam sterilization methods:

- **Pre-vacuum:**

  Pre-vacuum or high vacuum sterilization consists of four basic phases: a conditioning phase, an exposure phase, an exhaust phase and a drying phase. The conditioning phase removes air from the chamber by pulling a vacuum and then warms the instruments by injecting steam. Sterilization occurs during the exposure phase when the chamber reaches a temperature of 270°F (132°C) and pressure of 27 psi. The exposure phase in a pre-vacuum type of sterilizer is 4.0 minutes and minimum dry time of 20 minutes. The exhaust phase removes the steam from the chamber. The following conditions have been used to validate sterilization procedures for instruments in a pre-vacuum sterilizer.

  Note: Two and three piece Click*line* instruments may be sterilized assembled ONLY in a 4 minute prevacuum steam cycle with luer port cap open.

Temperature:	270 - 272°F (132-133°C)
Pressure:	27 psi
Exposure Time:	4 minutes for all instruments

  Note: The following conditions have been used to validate sterilization procedures for the Powershaver SL Multifunction hand pieces and its accessories:

Temperature:	270 - 272°F (132-133°C)
Pressure:	27 psi
Exposure Time:	16 minutes

- **Gravity Displacement:**

  Gravity displacement sterilization also consists of four basic phases, which are similar to the pre-vacuum type of sterilization. During the conditioning phase, steam is injected into the chamber and the air is forced out through the drain. Sterilization occurs when the temperature in the chamber reaches 250 to 254°F (121-123° C) and the pressure reaches 15 psi. The steam is removed from the chamber during the exhaust phase by allowing the steam to escape down the drain. The sterilized items remain in the chamber at atmospheric pressure to dry by the heat given off by the autoclave jacket. The following conditions have been used to validate sterilization procedures for instruments using a gravity displacement sterilizer:

Temperature:	250 - 252°F (121-122° C)
Pressure:	15 psi
Exposure Time:	45 minutes

  Note: The following conditions have been used to validate sterilization procedures for the Powershaver SL Multifunction hand pieces and its accessories:

Temperature:	270 - 272° F (132-133°C)
Pressure:	15 psi
Exposure Time:	35 minutes

  Caution: Please note increased temperature and time exposure for this item in Gravity Displacement.

- **Flash Sterilization:**

  Flash sterilization can be accomplished in either a pre-vacuum or gravity displacement type of sterilization unit. Flash sterilization has three phases 1) conditioning 2) exposure 3) exhaust, no dry-time. KARL STORZ has validated flash sterilization using a pre-vacuum and gravity displacement units for disassembled Clickline™ instruments with the following conditions:

	Gravity-Displacement:	Pre-Vacuum:
Temperature:	270 - 272°F (132-133°C)	270 - 272°F (132-133°C)
Pressure:	27 psi	27 psi
Exposure Time:	15 minutes	4 minutes

  Note: It is important to remember that Flash sterilization is not recommended for powered instruments, **unless specifically validated.**

4. Instruments should be positioned in the sterilizer so that there is adequate circulation and penetration of steam, air removal and condensate drainage. A loosely loaded sterilizer allows the best penetration of sterilant.
5. At the completion of the steam sterilization cycle, all instruments should remain untouched until adequately cooled.

STERRAD® Sterilization Systems (STERRAD 100S, NX, and 100NX):

The STERRAD® Sterilization Systems, manufactured by Advanced Sterilization Products (ASP), utilize a synergism between hydrogen peroxide and low temperature gas plasma to produce a rapid, low temperature, low moisture inactivation of microorganisms. It is intended for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices.

STERRAD® NX is a table top sterilizer with rectangular chamber size of 51.3L / 26L (usable). It utilizes the same sterilant (vapor hydrogen peroxide) as the STERRAD® 100S. The major difference is the vaporization system that renders the hydrogen peroxide sterilant more concentrated and improves diffusion into lumens. This combined with a shorter cycle time results in a similar exposure to the sterilant. The STERRAD® NX is capable of sterilizing a single channel flexible endoscope in the Advanced Cycle without a STERRAD® Booster.

The **STERRAD® 100NX™ System** is very similar to the current STERRAD® NX Systems. The STERRAD® 100NX™ System is a large sterilizer with rectangular chamber size of 51.3L / 26L (usable) and two cycles – a ***Standard*** cycle at approximately 47 minutes and a ***Flex*** cycle at approximately 42 minutes.

WARNING: **Only endoscopes specially designated to be STERRAD® 100S/NX/100NX compatible are to be processed by these methods.**

WARNING: **Do not process KARL STORZ flexible endoscopes with lumens in STERRAD® 100S sterilization system.**

NOTE: **KARL STORZ flexible endoscopes without lumens may be processed in STERRAD® 100S sterilization system.**

CAUTION: For flexible endoscopes, place pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before STERRAD sterilization. Do not use the yellow transport cap (#Z03553), which maybe present on refurbished endoscopes.

CAUTION: STERRAD® sterilization may cause cosmetic changes to the devices that do not necessarily impact the functionality of the device.

WARNING: KARL STORZ recommends that instruments sterilized in STERRAD® Systems be disassembled prior to the sterilization cycle and then reassembled in a sterile field. (Example: stopcocks)

WARNING: Sterility of KARL STORZ instruments sterilized with STERRAD® cannot be assured if the instruments are sterilized assembled.

CAUTION: All instruments must be thoroughly DRIED before loading into the STERRAD® sterilizer. Loads containing moisture may cause a cycle cancellation.

WARNING: Please note that there are restrictions as to what may be sterilized in the STERRAD® Sterilization Systems based on lumen size and materials. For appropriate lumen restrictions, please refer to the specific STERRAD® Sterilization Systems User's Guides.

- Stainless steel and Titanium materials are compatible with STERRAD® Systems. Refer to the STERRAD Sterilization Systems User's Guides for other compatible materials.

CAUTION: KARL STORZ recommends the use of one cleaning agent and one sterilization method to prevent the unknown rate of material degradation due to material-chemical interactions from various cleaning and sterilization processes.

CAUTION: Do NOT mix peracetic acid-based solutions with hydrogen peroxide agents for reprocessing flexible endoscopes.

CAUTION: Use only STERRAD® compatible instrument trays in the sterilization chamber. These trays are specially designed for vapor hydrogen peroxide sterilization. (See page 16).

CAUTION: Use only FDA-cleared polypropylene sterilization wraps and/or polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

NOTE: Instruments that KARL STORZ has determined to be compatible with the STERRAD® sterilization process have been validated with at least one hundred STERRAD® cycles.

NOTE: The following may be sterilized in <u>STERRAD® 100NX "Standard" Cycle</u>:

- KARL STORZ hand instruments compatible with STERRAD® 100S/NX sterilization
- Rigid/semi-rigid telescopes/instruments with stainless steel channels with inside diameter:
  - 0.7mm or larger whose total channel length is 500mm or shorter. *
    - * ASP conducted validation testing for this lumen size using a maximum of 10 lumens per load.
- KARL STORZ has conducted additional sterilization validation studies for the 27010L/K Semi-Rigid Uretero-Renoscopes at ASP. KARL STORZ recommends sterilization of this device in the validated STERRAD® 100NX "Standard" Cycle sterilization process.

NOTE: The following may be sterilized in STERRAD® 100NX "Flex" Cycle:

- Flexible endoscopes, no lumens, as well as with channels 1mm or larger with total channel length of 850 mm or shorter.
  - 1-2 endoscopes per cycle, 1 fiber optic light cable per tray per cycle, no additional load.

NOTE: The following may be sterilized in STERRAD® NX "Standard" Cycle:

- KARL STORZ hand instruments compatible with STERRAD® 100S sterilization
- Rigid/semi-rigid telescopes/instruments with stainless steel channels with inside diameter:
  - 1mm or larger whose total channel length is 150mm or shorter. **
  - 2mm or larger whose total channel length is 400mm or shorter. **

NOTE: The following may be sterilized in STERRAD® NX "Advanced" Cycle:

- Semi-rigid endoscopes/instruments with stainless steel channels with inside diameter 1mm or larger whose total channel length is 500 mm or shorter. **

  ** ASP conducted validation testing for this lumen size using a maximum of 10 lumens per load.

- Flexible endoscopes without lumens as well as with channels 1mm or larger with total channel length 850 mm or shorter.
  - One (1) endoscope per cycle and 1 fiber optic light cable per tray per cycle, no additional load.

NOTE: KARL STORZ flexible endoscopes compatible with STERRAD® NX/100NX sterilization have the following:

1) **A silver, stainless steel focusing ring, (not applicable to flexible DCI intubation endoscopes)**
2) **Polymer handle,**
3) **Serial numbers that begin with the number "2", and**
4) **Meet the lumen restrictions detailed above.**

NOTE: KARL STORZ Video endoscopes are NOT STERRAD® 100NX or STERRAD® NX compatible.

CAUTION: Use only STERRAD® compatible instrument trays in the sterilization chamber. These trays are specially designed for vapor hydrogen peroxide sterilization. (See page 15).

CAUTION: Use only FDA-cleared polypropylene sterilization wraps and/or polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

NOTE: Instruments that KARL STORZ has determined to be compatible with the STERRAD® sterilization process have been validated with at least one hundred STERRAD® cycles.

1. Clean and thoroughly dry all instruments.
2. Place the instruments in STERRAD® instrument trays, wrap in FDA-cleared polypropylene sterilization wrap or enclose in polyolefin pouches. Place STERRAD® indicator strips in all trays and pouches.
3. Load the STERRAD® sterilizer, arranging the items such that the hydrogen peroxide plasma can surround them. Do not allow any items to touch the wall of the sterilizer.
4. Please consult the STERRAD® Sterilization Systems User Guides for detailed instructions for use of any STERRAD® unit.
5. Please contact KARL STORZ Endoscopy-America, Inc. for questions about STERRAD® SYSTEMS compatibility.

Table 5
STERRAD Sterilization Systems Lumen Claims

STERRAD 100S (US CLAIMS)

Claims (US)	Inside Diameter	Length	Special Requirements
Plastics	6 mm or larger	310 mm or shorter	
Stainless Steel Lumens	1 mm or larger#	125 mm or shorter	
	2 mm or larger#	250 mm or shorter	
	3 mm or larger#	400 mm or shorter	

100S = 10 stainless steel lumens max per load

STERRAD NX and 100NX Systems (WORLDWIDE CLAIMS)

Worldwide Claims	Inside Diameter	Length	Special Requirements
PE/PTFE tubing	1 mm or larger	350 mm or shorter	NX Only: Process in Standard Cycle
	1 mm or larger	1000 mm or shorter	For NX: process in Advanced Cycle
Flexible Endoscopes with PE/PTFE lumen	1 mm or larger	850 mm or shorter	Single channel flexible endoscopes only (NX=Advance Cycle; 100NX=FLEX Cycle)
Stainless Steel Lumens	1 mm or larger	150 mm or shorter	NX Only: Process in Standard Cycle
	2 mm or larger	400 mm or shorter	NX Only: Process in Standard Cycle
	1 mm or larger	500 mm or shorter	NX Only: Process in Advanced Cycle
	0.7 mm or larger	500 mm or shorter	100NX Only: Process in Standard Cycle

NX/100NX = 10 stainless steel lumens max per load

Note: Data provided by ASP

Table 6
STERRAD® Tray Compatibility and Maximum Load

Tray Name	Intended Content	STERRAD® 100S	STERRAD® NX		STERRAD® 100NX		Max. Product Load Per Tray
			Standard Cycle	Advanced Cycle	Standard Cycle	Flex Cycle	
Flexible Endoscope Tray, P/N 39402AS	Flexible Endoscope	✓		✓		✓	1 flexible fiberscope 1 fiber optic cable
Flexible Endoscope Tray, P/N 39401AS	Flexible Endoscope			**Note: tray does not fit chamber**		✓	1 flexible fiberscope 1 fiber optic cable
Flexible Video Endoscope Tray, P/N 39403AS	Flexible Video Endoscope	✓		✓		✓	1 flexible video endoscope
Camera Trays, P/N 39301HCTS, P/N 39301ACTS, P/N 39301BCTS P/N 393123TS (EUR)	Camera Head	✓	✓		✓		1 camera head
Telescope Tray, P/N 39301AS	**Scopes to 4mmx18cm** Rigid Telescopes	✓	✓		✓		2 rigid telescopes
Telescope Tray, P/N 39301BS	**Scopes to 5.5mmx33cm** Rigid Telescopes	✓	✓		✓		2 rigid telescopes
Telescope Tray, P/N 39301CS, P/N 39301C1S	**Scopes to 10mmx33cm** Rigid Telescopes	✓	✓		✓		39301CS: 2 rigid telescopes 39301C1S: 1 rigid telescope
Telescope Tray, P/N 39301DS	**Scopes to 5.5mmx53cm** Rigid Telescope	✓	✓		✓		2 rigid telescopes
Basket Style Telescope Trays, P/N 39305C1S, P/N 39305C2S, P/N 39305L1S, P/N 39305L2S	**Scopes to 4mmx30cm** Rigid Telescopes **Scopes to 10mmx33cm**	✓	✓		✓		39305C1S/L1S: 1 rigid telescope 39305C2S/L2S: 2 rigid telescopes

STERIS SYSTEM 1 - Removed

"The STERIS System 1 (SS1) is not a legally marketed device"

(Reference: "Letter to Endoscope Manufacturers: Possible Misbranding of Reusable Devices Labeled for Reprocessing by the STERIS System 1 Processor", FDA 2-22-10)

STERIS® Amsco V-PRO™ Sterilization Systems

The STERIS Amsco V-PRO™ Low Temperature Sterilization Systems (i.e. V-PRO 1 and V-PRO 1 Plus) from STERIS® utilizes vaporized hydrogen peroxide (no gas plasma) to inactivate microorganisms. The STERIS Amsco V-PRO™ Systems are large sterilizers with rectangular chamber size of 136L. They are intended for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices.

CAUTION: STERIS® Amsco V-PRO™ sterilization may cause cosmetic changes to the camera head assembly that does not necessarily impact the camera's functionality.

CAUTION: KARL STORZ recommends the use of one cleaning agent and one sterilization method to prevent the unknown rate of material degradation due to material-chemical interactions from various cleaning and sterilization processes.

CAUTION: Instruments must be thoroughly dried before loading into the Amsco V-PRO™ sterilization chamber. Loads containing moisture may cause a cycle cancellation.

CAUTION: For flexible endoscopes, place pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before Amsco V-PRO sterilization. Do not use the yellow transport cap (#Z03553), which maybe present on refurbished endoscopes.

CAUTION: Use only STERIS® Amsco V-PRO™ compatible instrument trays in the sterilization chamber. These trays are specially designed for vapor hydrogen peroxide sterilization.

CAUTION: Use only FDA-cleared polypropylene sterilization wrap and polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

1. Clean and prepare instruments as recommended in the cleaning section of this instructions-for-use. Be sure that instruments are completely dry.
2. Place the instruments in V-PRO compatible instrument trays, wrap in FDA-cleared polypropylene sterilization wrap or enclose in polyolefin pouches. Place V-PRO indicator strips in all trays and pouches.
3. Load instruments tray into the STERIS® Amsco V-PRO™ sterilizer, arranging it so that the hydrogen peroxide vapor can surround it. Do not allow tray to touch the wall of the sterilizer.
4. Please consult the STERIS® Amsco V-PRO™ Sterilization System Operator's Manual for detailed instructions for use.
5. Please contact STERIS® for the most up to date information regarding sterilization with the STERIS® Amsco V-PRO™ Sterilization Systems.

High Level Disinfection (HLD) Instructions for KARL STORZ Instruments:

WARNING: **High level disinfection (minimum requirement) is recommended ONLY for "semi-critical" instruments which come into contact only with intact mucous membranes or non-intact skin.**

High level disinfection is NOT recommended for "critical" instruments to be used for Hysteroscopy, Neuroendoscopy, Arthroscopy, or Laparoscopy.

WARNING: **Refer to CIDEX OPA labeling for important contraindications regarding the use of CIDEX OPA on instruments that will be used for patients with bladder cancer.**

CAUTION: Any deviations from the recommended disinfection parameters must be validated by the user.

CAUTION: Before disinfection, the instruments must be thoroughly cleaned, rinsed, and dried if applicable.

CAUTION: To avoid damage to the instruments, do not immerse the devices in disinfectant solution for longer than one hour.

CAUTION: To avoid damage, ensure that resectoscope working elements are completely dry after disinfection and before use in the surgical field.

CAUTION: For flexible endoscopes, remove pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before immersion in liquid.

CAUTION: Do not immerse eyepiece section of HAMOU rigid telescopes.

CAUTION: KARL STORZ recommends the use of one cleaning agent and one sterilization method to prevent the unknown rate of material degradation due to material-chemical interactions from various cleaning and sterilization processes.

CAUTION: Do NOT mix peracetic acid-based solutions with hydrogen peroxide agents for reprocessing flexible endoscopes.

Manual HLD

KARL STORZ instruments may be chemically disinfected (manual) using high-level disinfectant solutions containing a 2.4% concentration of glutaraldehyde (e.g. CIDEX®, a 14-day glutaraldehyde solution) or 0.55% *ortho*-phthalaldehyde (e.g. CIDEX OPA, a 14-day solution) or 2.0% concentration of hydrogen peroxide (e.g. Resert XL HLD).

KARL STORZ does not recommend the use of CIDEX® PLUS or other 28-day room temperature glutaraldehyde solutions for manual high level disinfection, as they contain high concentrations of surfactants, which may dry and crystallize on the endoscopes if they are not thoroughly rinsed. The crystalline form of the surfactant can become conductive to electricity providing a pathway for arcing. Glutaraldehyde solutions with concentrations greater than 2.4% should be avoided, as a higher percentage of glutaraldehyde may damage the instruments.

1. Place the instruments into approved plastic containers. Approved plastic containers should be used to avoid scratching of the instruments and to eliminate electrolytic corrosion, which may occur when dissimilar metals are soaked in the same solution. Do not soak endoscopes with other instruments to prevent potential damage.

2. Prepare the disinfecting solution for use:

   2. 4% Glutaraldehyde Solution (e.g. CIDEX®)

   - Activate the glutaraldehyde solution by adding the entire contents of activator vile to the solution in the container. Shake well. Activated solution immediately changes color to green, thereby indicating the solution is ready to use. Use CIDEX (Activated Dialdehyde) Solution Test Strips to verify the solution is above the minimum effective concentration (MEC). Test the solution prior to each use. Do not use activated solution beyond stated 14 day reuse life. Record the date of activation and the expiration date on the container.

   0.55% *ortho*-Phthalaldehyde (e.g. CIDEX OPA)

   - No activation is necessary. Use CIDEX (Activated Dialdehyde) Solution Test Strips to verify the solution is above the minimum effective concentration (MEC). Test the solution prior to each use. Record the date the solution was poured out of the original container.

   Resert XL HLD (2. 0% Hydrogen Peroxide Concentration Solution)

   - No activation is necessary. Use Verify® Chemical Monitoring Strip for Resert XL HLD Solution to confirm hydrogen peroxide concentration before each use. Record the date the solution was poured out of the original container.

3. Completely immerse the device; care must be taken to remove any air bubbles adhered onto the surface of the immersed device. Fill the instrument and irrigation channels with disinfectant solution; a large luer tip syringe is useful for drawing disinfectant solution into the instrument channel.

4. Utilize the following disinfection conditions to achieve manual high-level disinfection:

   2.4% Glutaraldehyde Solution (e.g. CIDEX®)

   - Completely immerse the flexible endoscope in the undiluted 2.4% glutaraldehyde solution for a minimum of **45 minutes at 25°C (77°F)**, not to exceed 1 hour.

   0.55% *ortho*-Phthalaldehyde (e.g. CIDEX OPA)

   - Completely immerse the flexible endoscope in the undiluted solution for a minimum of **12 minutes at 20°C (68°F)** or higher, not to exceed 1 hour.

Resert XL HLD (2. 0% Hydrogen Peroxide Concentration Solution)

- Completely immerse the camera head assembly in the undiluted 2.0% hydrogen peroxide solution for a minimum of 8 minutes at 20°C (68°F).

5. After disinfection is completed, remove the instruments from the disinfectant solution and rinse the instruments by completely immersing it completely in a large volume of sterile water (e.g. two gallons). Keep the instruments totally immersed for a minimum of one (1) minute in duration. Flush a minimum of 500 mL of water through all lumens during each separate rinse. Repeat this procedure for a total of three (3) immersion rinses. Discard the water after each rinse, as it will be contaminated with the disinfectant. Use fresh sterile water for each immersion rinse. Thorough rinsing of the endoscopes is essential for preventing the toxic effects of any residual disinfectant solution.

   Note: Please refer to the disinfectant manufacturer's Instructions-for-Use for more detailed information regarding the use of the disinfectant solution, including proper rinsing techniques.

6. Dry the instruments with a lint-free sterile cloth or filtered compressed air (<5psi). To thoroughly dry the instrument and irrigation channels, flush the channels with 70% isopropyl alcohol. Then flush dry channel with 50cc syringe or filtered compressed air (<5psi).

CAUTION: Light transmission could be considerably impaired due to incomplete rinsing. Any disinfectant or cleaning solution residues on the light post could burn into the light post when the fiber optic light cable is connected.

Automated HLD

STERIS Reliance EPS® (High Level Disinfection)

CAUTION: For flexible endoscopes, remove pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before processing.

Please consult the STERIS® Endoscope Quick Reference Guide for the Reliance EPS Endoscope Processing System for proper Flow Unit or contact STERIS Customer Service at 1(800) 548-4873.

MEDIVATORS AER Systems (High Level Disinfection)

Please refer to the Medivators' Reprocessing Systems Hookup Application Guide or contact Medivators Technical Support at 1(800) 444-4729.

CAUTION: For flexible endoscopes, remove the pressure compensation cap (#11025E, #11025XE, #Z10455, #Z10456, or #Z11457) on vent port before processing.

NOTE 1: For flexible endoscopes, use only with KARL STORZ approved High Level Disinfection agents, CIDEX®, CIDEX® OPA, or Rapicide.

NOTE 2: For Flexible GI Videoscopes, use only with KARL STORZ approved High Level Disinfection agents, CIDEX®, CIDEX® OPA, Rapicide, or Rapicide PA.