KARL STORZ — ENDOSKOPE

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. **Refer to PI-000092 included with your product to identify the appropriate reprocessing methods for your KARL STORZ instruments. For Flexible Endoscopes, please refer to the Instructions-for-use (IFU) included with your device.**

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.

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 subsequent sterilization has to be absolutely free of pathogenic micro-organisms. 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

Water Quality Requirements:

Distilled or demineralized water is recommended for cleaning and rinsing of all instruments. If the customer elects to use tap/potable water, refer to the water quality requirements as described below. Check with your institution's policies on water quality.

1. Pre-cleaning:

Potable water may be used for pre-cleaning and rinsing a device immediately after patient use to remove gross contamination. Water temperature should not exceed 113˚F (45˚C) to prevent coagulation blood and other proteins.

2. Cleaning

Potable water is adequate for rinsing and removing debris loosened by the cleaning process. For “critical” and “semi-critical” devices, high-purity water (processed water) is recommended for final rinsing.

If high-purity water is not available, fresh filtered potable/tap water at the point of use may be used for final rinsing of critical and semi-critical devices.

3. High Level Disinfection:

Follow the high level disinfectant manufacturer’s water quality recommendation for dilution of liquid chemical high level disinfectant (as applicable). Sterile or bacteria-free water should be used for final rinsing after manual high level disinfection of “semi-critical” devices.

If sterile or bacteria-free water is not available, high-purity water (processed water) or fresh filtered potable/tap water at the point of use may be used for final rinsing of the endoscope’s external surfaces and inner channel(s). Flush the channel(s) with filtered alcohol (70% isopropyl alcohol) followed by purging the channel(s) with dry, oil-free compressed air (<5psi). Dry the external surfaces of the instruments with a lint-free sterile cloth or dry, oil-free compressed air (<5psi).

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.

Pre-Cleaning Preparation:

1. Immediately after a procedure, at the point of use (e.g. operating room), wipe the instruments with a soft, lint-free, disposable cloth, moistened with water to remove all heavy soiling.
2. Contain and transport the contaminated instruments with a soft, lint-free, disposable cloth, moistened with water or cleaning detergent to remove all heavy soiling.
3. If immediate cleaning is not feasible, place the instruments in a container and soak for no longer than 30 minutes with a neutral/mild pH enzymatic cleaning solution (e.g. Enzol), diluted with water to proper concentration per manufacturer's instructions.

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

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 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

Note: Refer to the “Water Quality Requirements” Section.

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.

Note: HOPKINS® Rigid Telescopes without lumens may be processed in automated washing units using KARL STORZ sterilization basket trays #39305C1S/39305C2S/39305L1S/39305L2S with endoscopic instrument cycles. The Telescopes must not be processed in an ultrasonic cycle or damage will result to the Telescope.

4. Completely immerse the instruments, with instrument jaws open, in a neutral /mild pH enzymatic cleaning solution (e.g. Enzol), diluted to proper concentration per manufacturer's instructions. If applicable, be sure that the lumens of all instruments are filled with cleaning solution. Keep the instruments immersed for 10 minutes.
5. While the instruments are immersed, and using the appropriate cleaning brush, brush the surface of all instruments. In addition, brush the inside of all lumens with the appropriate size brush provided for your device.

Cleaning Instructions for Instruments (Continued):

6. After the immersion period, remove the instruments from the cleaning solution and completely immerse in a large volume of water (e.g. 2 gallons). Be sure to flush all lumens with water to remove the cleaning solution. Discard the water and repeat with fresh water for a total of three immersion rinses.
7. Dry the instruments with a lint free soft cloth or clean, dry, oil-free compressed air (<5 psi). To dry out instruments with lumens, flush the lumen with clean, dry, oil-free compressed air (<5 psi). Cleaning pistols (KSEA part number 27660) with the smallest attachments are useful for drying the instruments with compressed air.
8. After cleaning, inspect the instruments for cleanliness and damage.
9. 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.
10. Before steam 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. Refer to the KARL STORZ Sterilization and High-Level Disinfection Chart (PI-000092) provided with your product to identify the appropriate sterilization method for your product.

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.

Sterilization Instructions (Continued):

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

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.

Ethylene Oxide (EtO) Gas Sterilization

WARNING: Sterilize the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

1. Place the instruments in an FDA-cleared sterilization tray or pouch.
   a. Double wrap the tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
   b. Double pouch the instrument using two sequentially sized disposable FDA-cleared pouches. The sealed inner pouch should fit inside the other pouch without folding.

Packaging of the instrument must be prepared in a manner that pouches should be positioned so that plastic faces plastic and breathable side faces breathable side.

2. Load the sterilization pouch or wrapped tray into the sterilizer.
3. Use the following KARL STORZ validated parameters for Ethylene Oxide gas sterilization.

Product Load Configuration Descriptions:

1. Load Configuration **1**:

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

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

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

2. Load Configuration **2**:

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

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

EtO Sterilization (Continued)

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

- 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**:

The 180-minute EO cycle parameter is recommended for the following:

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

- Camera Heads product family. The Camera Head (with or without sterilization tray) wrapped in two (2) layers of 1-ply FDA-cleared polypropylene wrap or equivalent material.

  WARNING: Sterilize the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

- Sialendoscope with lumen placed in sterilization tray 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 use immediate-use (FLASH) steam sterilization for any KARL STORZ telescopes, light carriers, or light deflectors.

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

1. Place the instruments in an FDA-cleared sterilization tray or pouch.
    a. Double wrap the tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
    b. Double pouch the instrument using two sequentially sized disposable, paper- plastic peel FDA-cleared pouches. The sealed inner pouch should fit inside the other pouch without folding. Packaging of the instrument must be prepared in a manner that pouches should be positioned so that plastic faces plastic and paper faces paper. Do not place the pouched instrument within a wrapped sets or containment devices.

2. Load the sterilization pouch or wrapped tray in the sterilizer. The tray or pouch should be positioned so that there is adequate circulation and penetration of steam, air removal, and condensate drainage.
3. Use the following KARL STORZ validated parameters for steam sterilization.

- **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 phase occurs during the exposure phase when the chamber reaches the set-point temperature of 270˚F (132˚C). The sterilization exposure phase in a pre-vacuum type of sterilizer is 4 minutes and minimum dry time of 20 minutes (refer to the specific product instruction manual for the validated dry time, if applicable). The exhaust phase removes the steam from the chamber. The following conditions have been used to validate sterilization procedures for instruments in a prevacuum sterilizer.

Temperature:	270˚F (132˚C)
Exposure Time:	4 minutes

Steam Sterilization (Continued)

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˚F (132˚C)

Exposure Time: 4 minutes for all instruments

Note: The following conditions have been used to validate sterilization procedures for the Powershaver SL Multifunction (32K) hand pieces and its accessories:

Temperature: 270˚F (132˚C)

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 phase occurs when the temperature in the chamber reaches the set-point temperature. 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˚F (121˚C)

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˚F (132˚C)
Exposure Time:	35 minutes

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

- **Immediate-Use (Flash) Steam Sterilization:**

Note: Immediate-use sterilization is only recommended for non-patient contact products.

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

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

Gravity Displacement

Temperature:	270˚F (132˚C)
Exposure Time:	15 minutes

Steam Sterilization (Continued)

Pre-vacuum

Temperature:	270˚F (132˚C)
Exposure Time:	4 minutes

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.

The **STERRAD® NX System** 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. The STERRAD NX System offers two cycles – ***Standard*** cycle at approximately 28 minutes and ***Advanced*** cycle at approximately 38 minutes. The STERRAD® NX is capable of sterilizing a single channel flexible endoscope in the Advanced Cycle.

The **STERRAD® 100NX™ System** is very similar to the current STERRAD® NX System. The STERRAD® 100NX™ System is a large sterilizer with rectangular chamber size of 152L / 93.4L (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: Sterilize the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

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

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.

STERRAD® Sterilization (Continued)

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

CAUTION: Use only STERRAD® compatible instrument trays in the sterilization chamber. These trays are specially designed for vapor hydrogen peroxide sterilization. Refer to the instrument tray instruction manual for compatibility information.

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

- KARL STORZ hand instruments that are 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 and 27011L/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® NX "Standard" Cycle:

- KARL STORZ hand instruments that are 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 1 mm 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.

STERRAD® Sterilization (Continued)

- **KARL STORZ has conducted additional sterilization validation studies for the 27011L/K Semi-Rigid Uretero-Renoscopes at ASP. KARL STORZ recommends sterilization of these devices in the validated STERRAD® NX "Advanced" Cycle sterilization process.**

1. Place the instruments in a STERRAD® compatible instrument tray or enclose in polyolefin pouches.
2. Place a STERRAD® indicator strip in each tray and pouch.
3. Double wrap the sterilization tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
4. 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.
5. Please refer to the STERRAD® Sterilization Systems User Guides for detailed instructions for use of any STERRAD® unit, ASP's STERRAD® Sterility Guide (SSG) at www.sterradsterilityguide.com, or contact ASP Customer service at (888) 783-7723.
6. Please contact KARL STORZ Endoscopy-America, Inc. for questions about STERRAD® SYSTEMS compatibility.

Table 2 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 System (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 = Advanced 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.

STERIS® Amsco V-PRO™ Sterilization Systems

The STERIS® Amsco V-PRO™ Low Temperature Sterilization Systems 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.

The Amsco **V-PRO** 1 Low Temperature Sterilization System performs one (1) pre-programmed sterilization cycle. The cycle parameters are equivalent to V-PRO 1 Plus "Lumen" Cycle. The VPRO 1 Cycle can sterilize devices, including rigid endoscopes, with single-stainless steel lumen with:

- An inside diameter of 3 mm or larger and a length of 400 mm or shorter
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter
- An inside diameter of 1 mm or larger and a length of 125 mm or shorter

The Amsco **V-PRO 1** Plus Low Temperature Sterilization System performs two (2) pre-programmed sterilization cycles.

- Lumen Cycle -- The Lumen Cycle is identical to the Amsco V-PRO 1 sterilization cycle.
- Non Lumen Cycle

STERIS® Sterilization (Continued)

The Amsco **V-PRO maX** Low Temperature Sterilization System performs three (3) pre-programmed sterilization cycles.

- Lumen Cycle
- Non Lumen Cycle
- Flexible Cycle

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

WARNING: Sterilize the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

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: 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. Place the instruments in V-PRO compatible instrument trays or enclose in polyolefin pouches.
2. Double wrap the sterilization tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
3. Place V-PRO indicator strips in all trays and pouches.
4. Load trays or pouches into the STERIS® Amsco V-PRO™ sterilizer, arranging them so that the hydrogen peroxide vapor can surround it. Do not allow any items to touch the wall of the sterilizer.
5. Please consult the STERIS® Amsco V-PRO™ Sterilization System Operator's Manual for detailed instructions for use or contact STERIS® Customer Service at (800) 548-4873.
6. Please contact STERIS® for the most up to date information regarding sterilization with the STERIS® Amsco V-PRO™ Sterilization Systems.

STERIS® Sterilization (Continued)

STERIS® SYSTEM 1E Liquid Chemical Sterilant Processing System

WARNING: The STERIS® SYSTEM 1E System is only approved for liquid chemical sterilization of cleaned, immersible, and reusable critical and semi-critical heat-sensitive medical devices.

WARNING: Sterilize the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

Please consult the STERIS® SYSTEM 1E Operator Manual and specific Quick Connect Processing Instructions for proper liquid chemical sterilization processing and use of the Quick Connect kit and compatible STERIS® trays. Endoscopes with channels may only be sterilized using the proper Quick Connect Kit. Endoscopes without channels may be sterilized using STERIS® SYSTEM 1E.

Refer to the STERIS® Corporation's website for SYSTEM 1E Device & Quick Connect Finder.

http://www.steris.com/products/quickconnects/

Please consult the appropriate KARL STORZ manual or contact STERIS® customer service at (800) 548-4873 to identify the appropriate Quick Connect Kit for an endoscope. Various flexible and semi-rigid endoscopes have SPECIFIC Quick Connect Kits.

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.

WARNING: Process the KARL STORZ Pendulum Camera Heads with the slide-lock mechanism in the open position.

High Level Disinfection (Continued)

CAUTION: Resert XL HLD is NOT compatible with Brass, Chrome-Plated Brass, Copper, Monel S, Nickel-Plated Steel, Silver, and Tungsten Carbide.

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: 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.

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.

Note: Refer to the "Water Quality Requirements" Section.

1. Prepare the disinfecting solution for use:

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

   - Activate the glutaraldehyde solution by adding the entire contents of activator vial to the solution in the container. Shake well. Activated

High Level Disinfection (Continued)

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.

2.0% Hydrogen Peroxide
(e.g. Resert XL HLD)

- 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.

2. Place the instruments into a plastic container containing the HLD solution. Ensure that the instruments are fully immersed and remove any air bubbles adhered onto the surfaces of instruments. Fill any lumen with the HLD solution.

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

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

   - Immerse in the solution for **45 minutes at 25˚C (77˚F)**.

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

   - Immerse in the solution for **12 minutes at 20˚C (68˚F)**.

   2.0% Hydrogen Peroxide
   (e.g. Resert XL HLD)

   - Immerse in the solution for **8 minutes at 20°C (68°F)**.

4. After disinfection is completed, remove the instruments from the disinfectant solution and rinse the instruments by completely immersing it 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 to remove the cleaning solution. Discard the water and repeat with fresh water for a total of three immersion rinses.

High Level Disinfection (Continued)

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.

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

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):

The Reliance EPS is intended for high level disinfection of cleaned, immersible, reusable, heat-sensitive, semi-critical medical devices.

Please consult the STERIS® Operator Manual and Endoscope Quick Reference Guide for the Reliance EPS Endoscope Processing System for proper Flow Unit, listing of safety precautions, warnings and cautions, or contact STERIS Customer Service at (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 (800) 444-4729. Refer to the Minntech Corporation's website to identify the correct Medivators AERs Hookup(s) for reprocessing of the specific KARL STORZ Endoscopes.

http://www.minntech.com/products-and-services/endoscope-reprocessing/hookups

http://www.minntech.com/medivators/hookuplookup/

CAUTION: Do not mix reprocessing methods using peracetic-based high level disinfection agents with hydrogen peroxide-based agents.

The Medivators AER Systems are intended for high level disinfection of cleaned, immersible, reusable, heat-sensitive, semi-critical medical devices.

Mediavators AERs						
Description	**CER-1 (MV-1)**	**CER-1 (MV-2)**	**DSD / SSD**	**Advantage Multi-Use**	**DSD Edge**	**Advantage Plus**
Recommended HLD Agents	CIDEX®, CIDEX® OPA or Rapicide				Rapicide PA	

KARL STORZ — ENDOSKOPE

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a Physician.

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