

**STORZ**  
**KARL STORZ—ENDOSKOPE**

HOPKINS®

***Telescopes***

HOPKINS®

***II Telescopes***

**Instruction Manual**



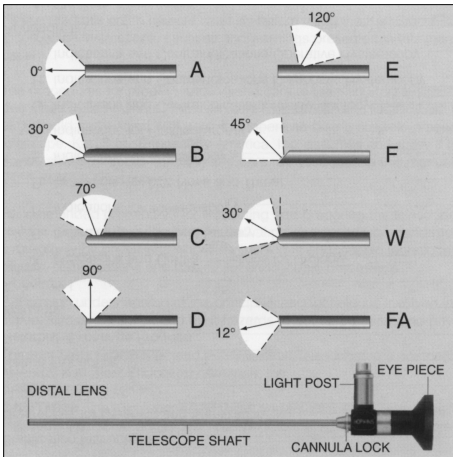
## **Important information for users of KARL STORZ instruments**

Thank you for placing confidence in the name of KARL STORZ. As with all our other products, we have invested years of experience and much care in production of this telescope. You, and your organization, have chosen a modern high-quality KARL STORZ instrument.

These instructions are designed to assist you in cleaning, sterilizing, disinfecting, caring for and storing your KARL STORZ telescopes. Please read them carefully.

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

## Illustrated Description



## Specifications:

### Letter code

### Direction of View

A	0°-10° Straight Forward
B	30° Forward-Oblique
C	70° Lateral
D	90° Lateral
E	120° Retrospective
F	45°
W	30° Wide Angle
FA	12° Telescopes

**KARL STORZ HOPKINS® and HOPKINS® II Telescopes are provided both auto-clavable and non-autoclavable. To identify the difference please note "AUTOCLAV" marked on the eyepiece.**

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## **Important Information for users of KARL STORZ instruments**

### **IMPORTANT**

Please read this entire manual carefully before using KARL STORZ HOPKINS® and HOPKINS® II Telescopes. Failure to follow the instructions, cautions and warnings presented in this manual may result in serious consequences to the patient.

The procedures for proper handling and care of KARL STORZ HOPKINS® and HOPKINS® II Telescopes are described in this manual. The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are delicate optical instruments and should be handled with care. Improper use during surgical procedures will result in damage or breakage of the telescope. KARL STORZ Endoscopy-America, Inc. assumes no liability if the telescopes are misused, mishandled or otherwise abused. Proper handling and care, as described in this manual, will prolong the life of the KARL STORZ HOPKINS® and HOPKINS® II Telescopes.

Recommended procedures for inspecting and preparing the telescopes for use are described in this manual. The manual does not describe how the actual procedure is to be performed. Endoscopic procedures should be performed only by physicians who have training in endoscopic techniques. Consult medical literature relative to techniques, complications and hazards of endoscopic procedures.

A thorough understanding of the principles and techniques involved in endoscopic and electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and physician.

The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are compatible with any light sources and light cables marketed by KARL STORZ Endoscopy America, Inc.

**CAUTION:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are provided NON-STERILE, and must be cleaned, disinfected and/or sterilized prior to the initial use and before each subsequent use.

## General Information for the Safe Use of KARL STORZ Telescopes

### User qualifications

These instruments may only be used by licensed physicians and qualified medical personnel who have been trained in their use.

### Warnings and precautions

Please read this manual carefully. It is very important that the user be thoroughly familiar with the operation of the instrument prior to use on a patient. The terms “Warning,” “Caution” and “Note” are intended to draw your attention to important parts of the instruction manual. All warnings, precautions and notes should be thoroughly reviewed prior to use of the instrument. Close attention to all warnings, precautions and notes is necessary for safe and effective operation of the device.

### Definitions

**WARNING:** A warning indicates that the personal safety of the patient or physician may be compromised. Disregarding the warning may result in serious injury to the patient or the physician.

**Caution:** A caution indicates that the device may be damaged if the caution is disregarded.

**Note:** A note provides additional information regarding the safe operation of the device.

### Description of Device

The KARL STORZ HOPKINS® and HOPKINS® II telescopes are reusable rod lens endoscopes consisting of an eyepiece lens, a light post connection for fiber optic light cables with screw-on adapters which will accommodate light cables from other manufacturers.

## **General Information for the Safe Use of KARL STORZ Telescopes (Continued)**

A shaft made of non-corrosive material encloses the rod-lens system and a built-in fiber optic light carrier. See page 4 for identification of parts.

### **Indications**

KARL STORZ HOPKINS® and HOPKINS® II telescopes are to be used for visualization of the surgical site during diagnostic and therapeutic endoscopic procedures. See Appendix I for specific indications for use.

### **Contraindications**

KARL STORZ HOPKINS® and HOPKINS® II telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient. See Appendix I for specific contraindications.

**WARNING:** KARL STORZ HOPKINS® and HOPKINS® II telescopes are provided NON-STERILE and must be thoroughly cleaned and sterilized according to validated infection control procedures prior to use and subsequent reuse.

**WARNING:** High level disinfection is recommended ONLY for telescopes which come into contact with intact mucous membranes or minor skin breaches. Disinfection is NOT recommended for telescopes to be used for laparoscopic, arthroscopic, hysteroscopic, Ob/Gyn, plastic, reconstructive, aesthetic, or neurology surgery procedures.

**WARNING:** Always adjust the light source to the minimum illumination intensity necessary to achieve optimum illumination of the endoscopic scene, either by direct vision or coupled to a video camera. The higher the light intensity setting of the light source, the greater the heat energy that will be generated at the distal end of the telescope.



**WARNING:** Never place the end of a fiber optic cable or telescope connected to a light cable on or under a surgical drape while the light source is activated. The intensity of the light may cause burns to the patient and/or the surgical drape. Turn the light source to standby or initial mode when the telescope is not in use. Never attach cable or cable connector to patient or drape.

**WARNING:** Do not use telescopes with visible signs of damage.

**Caution:** Steam sterilize only KARL STORZ telescopes marked 'AUTOCLAV'! Non-autoclavable telescopes will suffer irreparable damage.

**Caution:** Do not use Immediate-Use Steam (FLASH) sterilization for any KARL STORZ HOPKINS® or HOPKINS® II telescopes.

## Inspection

**Inspection of the HOPKINS® and HOPKINS® II Telescopes:** Inspection of the KARL STORZ HOPKINS® and HOPKINS® II Telescopes for signs of damage should be performed before and after every surgical procedure.

## Working Shaft

Inspect the entire surface of the working shaft of the telescope for any signs of damage such as dents, bends or scratches.

## Objective lens and Eyepiece

Inspect the objective lens (distal tip) and eyepiece for scratches, chips, fingerprints or residual debris by observing the reflected light on the surfaces of the eyepiece and objective lens. These surfaces should be smooth and shiny. To check for clarity of view slowly rotate the telescope while looking through the eyepiece. A partially or completely obstructed view may be the result of a damaged lens within the eyepiece or within the telescope shaft. Foggy images may result from moisture entering a damaged seal around the lens.

## Inspection (Continued)

**CAUTION:** Do not use telescopes if signs of damage are present.

**CAUTION:** The telescope must be replaced if the image is clouded, distorted or there is no image.

**CAUTION:** The telescopes are provided NON-STERILE and must be cleaned, disinfected and/or sterilized prior to initial use and subsequent reuse.

**CAUTION: Steam sterilize only KARL STORZ telescopes marked 'AUTOCLAV'! Non-autoclavable telescopes will suffer irreparable damage.**

**CAUTION:** Do not use Immediate-Use Steam (FLASH) sterilization for any KARL STORZ HOPKINS® and HOPKINS® II telescopes.

If there is any doubt about whether the telescopes are safe to use, please contact your sales representative or the Technical Support Staff directly at KSEA (1-800-421-0837).

## Handling of HOPKINS® and HOPKINS® II Telescopes

KARL STORZ HOPKINS® and HOPKINS® II Telescopes are delicate instruments. To ensure the long lasting quality of the telescope, please follow the handling instructions described below.

1. To prevent breakage, telescopes should be supported by firmly grasping the eyepiece end. Never handle the telescope by the distal end alone.
2. Never bend the stainless steel shaft. This could lead to breaks or cracks in the rod-lens system.

3. Handle the telescope with care. Mishandling of the telescope, particularly at the distal end, may result in damage or cracks in the telescope. Damage to the telescope may allow liquid and other materials to penetrate causing unclear images.
4. When cleaning, disinfecting and sterilizing telescopes, KARL STORZ recommends that they be handled separately from other instruments.
5. Protective cases, which are suitable for storage, transport and sterilization, are available in various lengths for KARL STORZ HOPKINS® and HOPKINS® II Telescopes.

## Operating Instructions

1. Be sure that the telescopes have been properly cleaned, disinfected and/or sterilized prior to use. (See Cleaning, Disinfection and Sterilization section for detailed procedures).
2. Inspect the telescope for damage and proper function as described above.
3. Operate all video and light source equipment in accordance with manufacturer's instructions.

**WARNING:** Always adjust the light source to the minimum illumination intensity necessary to achieve optimum illumination of the endoscopic scene, either by direct vision or coupled to a video camera. The higher the light intensity setting of the light source, the greater the heat energy that will be generated at the distal end of the telescope.

**WARNING:** Never place the end of a fiber optic light cable or a telescope connected to a light cable on or under a surgical drape while the light source is activated. The intensity of the light may cause burns to the patient and/or the surgical drape. Turn the light source to standby or initial mode when the telescope is not in use.

4. Prepare the surgery entry site in accordance with proper endoscopic surgical techniques. Consult the appropriate medical literature.
5. Attach the light cable to the fiber optic light post on the telescope. KARL STORZ recommends that the appropriate size light cable be used to minimize the heat energy generated from the light source. Use of the appropriate size light cable will reduce the risk of patient burns, as well as the risk of igniting flammable material.

Telescope Diameter	Light Cable Diameter
4.0 mm and less	2.5 mm
6.0 mm and less	3.5 mm
Larger than 6.0 mm	4.8 mm

## Cleaning , Disinfection and Sterilization Instructions

**WARNING: The KARL STORZ HOPKINS® and HOPKINS® II Telescopes should be thoroughly cleaned, disinfected and/or sterilized according to validated infection control procedures prior to use and subsequent reuse.**

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

## Preparation for Cleaning and Sterilization

- ~~1. Disconnect the light cable from the telescope.~~
- ~~2. Remove the light cable adapters.~~

- ~~3. Place telescope in a plastic container and soak with a neutral pH (pH 6.0 to 8.0) enzymatic cleaning solution (e.g., Enzol, Metrizyme or the equivalent diluted to proper concentration per manufacturer's instructions) immediately after use to prevent blood, protein and other contaminants from drying onto the telescope. Do not soak telescopes with other instruments to prevent damage to the telescope.~~

## Water Quality Requirements

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



## Cleaning Instructions for HOPKINS® AND HOPKINS® II Telescopes

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

**CAUTION:** DO NOT clean the KARL STORZ HOPKINS® and HOPKINS® II Telescopes in an ultrasonic bath.

**CAUTION:** Manual cleaning of the KARL STORZ HOPKINS® and HOPKINS® II Telescopes is recommended. However, HOPKINS® Telescopes without lumens may be cleaned in automated washing units using KARL STORZ sterilization basket trays #39305C1S/39305C2S/39305L1S/39305L2S with endoscopic instrument cycles. The basket telescope trays and its intended content(s) should be processed through the cleaning phase cycle only, NOT through disinfection cycle of automated washing units.

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

**Cleaning , Disinfection and Sterilization Instructions (Continued)**

1. Remove light cable adapters before cleaning ~~and sterilization~~. Do not clean or rinse telescopes with other instruments to prevent damage to the telescope.
2. Remove any residual blood, protein material and contaminants with sponges, soft cloths or a cotton cloth applicator using 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) and distilled water~~. KARL STORZ does not recommend the use of detergents alone, as they contain high concentrations of surfactants which can leave a film on the telescopes. See Appendix II for available KARL STORZ cleaning accessories.
3. Clean the lenses and fiber optic inlet post with alcohol wipes or sterile cotton tip applicators with 70% alcohol to remove any residue or film left after cleaning.
4. Triple-rinse all telescopes with distilled 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 telescope is necessary for removing any debris or detergent which could interfere with sterilization.
5. Dry the telescope with a lint-free soft cloth or filtered compressed air.
6. Special Instructions for cleaning autoclaveable telescopes: Telescopes that have been autoclaved many times may develop deposits on the glass surfaces. To remove the deposits, clean the telescope with KARL STORZ cleaning paste (27661). Put a small amount of cleaning paste on a moist cotton swab and lightly spread it on the glass surface. Rub gently to remove any stubborn deposits.

7. After polishing with the cleaning paste, thoroughly rinse the glass surfaces with water. Clean the surfaces with 70% alcohol or alcohol wipes to remove all traces of the cleaning paste. It may be necessary to repeat steps 2 to 5 above to ensure all of the cleaning paste is removed.

**Caution:** Cleaning with the cleaning paste should only be done if the image is cloudy (after approximately 10 to 20 sterilizations) and not as part of the routine cleaning.

8. After cleaning, inspect the telescope for cleanliness and damage as described above. (See Inspection Section).

## Disinfection Instructions for KARL STORZ Telescopes

**WARNING:** High level disinfection is recommended **ONLY** for telescopes which come into contact with mucous membranes or minor skin breaches. Disinfection is **NOT** recommended for telescopes to be used in any laparoscopic, arthroscopic, OB/GYN, plastic, reconstructive, aesthetic, or neurology surgical procedures.

**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.

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

KARL STORZ HOPKINS® and HOPKINS® II Telescopes may be chemically disinfected 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).

## **Cleaning , Disinfection and Sterilization Instructions (Continued)**

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 telescopes 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 telescopes.

1. Place the telescopes into separate plastic containers. 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 telescopes 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 vial 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.

3. Completely immerse the device. Care must be taken to remove any air bubbles adhered onto the surface of the immersed telescopes. 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 high-level disinfection:

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

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

5. After disinfection is completed, remove the telescope from the disinfectant solution and completely immerse in a large volume of sterile water. 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 rinse.

## Cleaning , Disinfection and Sterilization Instructions (Continued)

Thorough rinsing of the telescope 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 telescope with a lint-free sterile cloth or filtered compressed air. To thoroughly dry the instrument and irrigation channels, flush the channels with 70% isopropyl alcohol.

**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.

## Sterilization Instructions for Telescopes

Routine ethylene oxide (EtO) sterilization is recommended for initial and subsequent sterilization of all HOPKINS® and HOPKINS® II Telescopes. To achieve the desired sterility assurance level (SAL) of  $10^{-6}$ , KARL STORZ recommends the following EtO, steam, STERRAD® sterilization methods.

**CAUTION:** Steam sterilize only KARL STORZ telescopes marked 'AUTOCLAV'! Non-autoclavable telescopes will suffer irreparable damage.

**CAUTION:** Do not use Immediate-Use Steam (FLASH) sterilization for any KARL STORZ HOPKINS® or HOPKINS® II telescopes.

**CAUTION:** Before sterilization, the HOPKINS® and HOPKINS® II Telescopes must be thoroughly cleaned and all organic material, blood and cleaning solution completely removed.

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

**CAUTION:** The recommended 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.

## Ethylene Oxide (EtO) Gas Sterilization

1. Place the HOPKINS® and HOPKINS® II Telescopes in a 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 the telescopes using the following parameters:

### Validated Parameters for Ethylene Oxide (EtO) Gas Sterilization

100% Ethylene Oxide	
CONDITIONING PARAMETERS	
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
EO Gas Concentration*:	725 ± 30 mg/L
EO Gas Exposure Time*:	120 min. (full cycle)
Aeration Time:	12 hrs. (full cycle)
Aeration Temperature:	51 – 59 °C (124° – 138°F)

## **Cleaning , Disinfection and Sterilization Instructions (Continued)**

### **STERRAD® System**

KARL STORZ telescopes are compatible with the STERRAD® 100S, NX and 100NX sterilization systems. The STERRAD® System utilizes a synerism between hydrogen peroxide and low temperature gas plasma to produce a rapid, low temperature, low moisture inactivation of microorganisms.

**WARNING: Consult STERRAD® labeling for lumen size restrictions.**

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

**CAUTION:** All telescopes must be thoroughly DRIED before loading into the STERRAD® System chamber. Loads containing moisture may cause a cycle cancellation.

**CAUTION:** Use only STERRAD® Instrument trays in the sterilization chamber. These trays are specially designed to allow the plasma to surround the items.

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

**CAUTION:** Any deviations from the recommended STERRAD® System sterilization parameters must be validated by the user.

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

1. Clean and thoroughly dry all instruments.
2. Place the telescopes in STERRAD® instrument trays, wrap in 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® System Operators Manual for detailed instructions for use.

## Steam Sterilization

**WARNING: ONLY KARL STORZ HOPKINS® and HOPKINS® II TELESCOPES marked “AUTOCLAV” can be steam sterilized.**

**WARNING: Do not use Immediate-Use Steam (FLASH) sterilization for any KARL STORZ HOPKINS® and HOPKINS® II TELESCOPES.**

**CAUTION:** Sudden changes in temperature may fracture the glass components of telescopes. Do not immediately expose telescopes to air after removal from the autoclave.

**CAUTION:** Never attempt to cool telescopes by pouring cool, sterile liquid over the telescope. Forced cooling will cause severe damage to the telescope.

**CAUTION:** Before steam sterilization all telescopes must be thoroughly cleaned and any organic material, blood and cleaning solution completely removed.

1. Place the HOPKINS® or HOPKINS® II Telescopes marked “autoclav” 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 parameters:

## **Cleaning , Disinfection and Sterilization Instructions (Continued)**

### **• 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 132°C (270°F) ~~and pressure of 27 psi.~~ The exposure phase in a pre-vacuum type of sterilizer is 4.0 minutes. The exhaust phase removes the steam from the chamber. The drying phase is accomplished by pulling an additional vacuum and allowing the instruments to dry under vacuum for approximately 20 minutes. The following conditions have been used to validate sterilization procedures in a pre-vacuum sterilizer:

Temperature: 132-133°C (270-275°F)

~~Pressure: 27 psi~~

Exposure Time: 4 minutes for all instruments

3. Trays 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.
4. At the completion of the steam sterilization cycle, all telescopes should remain untouched until adequately cooled.

## **References for Cleaning and Sterilization**

1. The Difficulty of Reprocessing Reusable Rigid Laparoscopic Forceps and Other Endoscopic Accessories: Are Disposables the Answer? *Health Devices*, Vol. 23, Nos.1-2, pp. 57-58, 1994.
2. Descoteaux, J-G, Poulin, E.C., Julein, M. And Guidoin, R. Residual Organic Debris on Processed Surgical Instruments. *AORN Journal* Vol. 62, No. 1, pp. 23 - 29, 1995.
3. Gruendemann, B.J. and Meeker, M.H. *Alexander's Care of the Patient in Surgery*, 12th edition. The C.V. Mosby Company, St. Louis, Mo. 2003.
4. Association for the Advancement of Medical Instrumentation. *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*. AAMI TIR No. 12-2010.

## **Inspection Upon Receipt**

THOROUGHLY INSPECT SHIPMENT IMMEDIATELY UPON ARRIVAL.

Although KARL STORZ products are carefully packed to minimize in-transit damage, all shipments should be carefully examined upon receipt and if a product is damaged, Customer must document the nature and extent of the damage and immediately contact KSEA. If concealed loss or damage is discovered, Customer must retain all packing materials and immediately notify KSEA, requesting an inspection. If shipments are received short, Customer must contact KSEA's Customer Support Department at once. KSEA reserves the right to make partial shipments on any Order. Invoices for partial shipments are payable upon receipt. KSEA is not liable for any damages caused by or attributable to delays and/or non-delivery due to any cause whatsoever.

## **Maintenance and Repair**

KARL STORZ recommends that the instruments be checked once a year by KARL STORZ Endoscopy-America, Inc. or by an authorized agent. All services such as modifications, repairs, calibrations, etc., may only be performed by KARL STORZ Endoscopy-America, Inc. or by an authorized agent.

## **Return Policy**

A return merchandise authorization (RMA), must be obtained from KSEA's Customer Support Department prior to returning any products. When phoning or writing KSEA, for an RMA, the Customer Support Representative must be provided with:

- (1) Customer name and number, as it appears on the invoice;
- (2) the telephone number and the person to contact;



- (3) the applicable P.O. number;
- (4) the KARL STORZ catalog number and, if applicable, the serial number for each product; and,
- (5) the reason for the return.

KSEA reserves the right to refuse or return any products sent back to KSEA without prior authorization of its Customer Support Department. Returns must be carefully packed and shipped pre-paid to KSEA, attn: RMA number. KSEA's Customer Support Department will provide the return address and the RMA number. Shipping charges will be reimbursed if the return was due to an error on the part of KSEA. When returning products, Customer should include a copy of the original invoice or packing slip to ensure prompt issuing of credit. Full credit will only be issued for products that are returned within 30 days of invoice date, and so long as such items are unused, in resalable condition and in their original product container. All products returned after 30 days from the date of invoice are subject to a 15% restocking fee.

The following products may not be returned for credit or exchanged:

- (1) products held longer than 90 days from invoice date;
- (2) sterile packaged products where the package is opened and/or damaged;
- (3) discontinued products;
- (4) instruments that are etched or engraved by Customer;
- (5) products damaged by the Customer;
- (6) products purchased "as is" or as demo products; and,
- (7) used products.

In order to prevent the transmission of disease to the medical facilities' and/or KSEA's personnel, all products must be cleaned and then sterilized and/or disinfected before sending such products back to KSEA, who reserves the right to return unclean and contaminated products to the Customer. Additionally, if any product becomes damaged and is not immediately returned, KSEA assumes no responsibility or liability for Customer's continued use of that damaged product. KSEA does not guarantee the performance, and may decline to repair or accept for repair/exchange, any product that has been repaired, modified and/or altered by any person or entity other than KSEA or an authorized repair facility of KSEA.

## **Repair Program**

If repairs become necessary, for other than damages incurred during initial shipment, the Customer must follow the RMA procedure set forth in the "Return Policy", above. Warranty repairs will be made without charge (see "Warranty Policy," below, for covered repairs). All other repairs are subject to KSEA's applicable standard repair or exchange charges. If requested, Customer will be advised of the estimated cost of the repair work or a product exchange before it is undertaken. All repairs carry a 90 day warranty.

Exchange products carry the applicable KARL STORZ product warranty. If the damaged product is not returned within thirty (30) days of receipt of the replacement product, Customer will be invoiced for the full list price of the replacement. KSEA reserves the right to refuse or return any product sent back without prior authorization of KSEA's Customer Support Department.

## Warranty Policy

Except as otherwise provided herein and/or by the applicable warranty information for a specific product or type of product, all KARL STORZ-branded products are generally warranted to be in good working order at the date of delivery and free from defects in workmanship and materials for one (1) year from date of delivery. However, since some products carry a shorter or a longer warranty period, Customer should check with KSEA's Customer Support Department or product specific literature, instruction manual and/or labeling for the exact warranty period. Any such product(s) with a defect occurring during the applicable warranty period will be promptly replaced or, at the sole discretion of KSEA, repaired at no charge to Customer.

**THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, WITH RESPECT TO ALL KARL STORZ PRODUCTS OR SERVICES. ANY AND ALL OTHER WARRANTIES, REPRESENTATIONS AND/OR GUARANTEES, OF ANY TYPE, NATURE OR EXTENT, BE IT IMPLIED, EXPRESS AND/OR WHETHER ARISING UNDER OR AS A RESULT OF ANY STATUTE, LAW, COMMERCIAL USAGE, CUSTOM, TRADE OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED AND DISCLAIMED.**

Any contrary course of performance by and between the parties will not modify any representations and/or warranties set forth herein. KSEA neither assumes nor authorizes any person to assume for it any other liabilities in conjunction with and/or related to the sale and/or use of its products. To ensure proper use, handling and care of KARL STORZ products, Customer should consult the product specific literature, instruction manual,

and/or labeling included with the product or otherwise available. Repairs, modifications or alterations of KARL STORZ products, performed by any person or entity, other than by KSEA or an authorized repair facility of KSEA, nullifies and otherwise voids all applicable KARL STORZ warranties. Repair or replacement of a KARL STORZ product shall not extend the term of any applicable warranty. The remedies provided herein are Customer's exclusive remedies under this Warranty Policy.

## **Limitation of Liability**

KSEA is not liable, directly or by way of indemnity, either expressly or impliedly, for: (1) any damages which might arise or be caused, whether by the Customer or by any of the users of the products provided by KSEA, as a result of, in connection with, or otherwise attributable to: (a) misuse, abuse, mishandling and/or improper operation and/or storage; (b) repairs, servicing, modifications and/or alterations performed by any person or entity, other than KSEA or an authorized repair facility of KSEA; (c) use in combination with adaptors, accessories and/or equipment from other manufacturers unless authorized or recommended by KSEA or, (d) use in any manner other than those for which such products are designed and are otherwise intended to be used; and, (2) any special, incidental, consequential, punitive, exemplary or indirect damages, including but not limited to alleged damages for delayed shipment, non-delivery, product failure, product design or production, inability to use such products or services, loss of future business (lost profits), or from any other cause, whatsoever, in connection with or arising from the purchase, sale, lease, rental, installation or use of such KARL STORZ products, even if Customer has been advised of the possibility of such damages.



**KARL STORZ—ENDOSKOPE**

**SOME JURISDICTIONS DO NOT ALLOW EXCLUSIONS AND DISCLAIMERS OF CERTAIN WARRANTIES OR LIMITATIONS OF LIABILITY, SO THE LIMITATIONS AND/OR EXCLUSIONS, SET FORTH IN THESE TERMS AND CONDITIONS, MAY NOT APPLY. IN THAT EVENT, KSEA'S LIABILITY WILL BE LIMITED TO THE GREATEST EXTENT PERMITTED BY LAW IN THE SUBJECT JURISDICTION.**

## Appendix I

### Urology

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are to be used for visualization of the surgical site during diagnostic and therapeutic urology procedures.

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

### General Surgery

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use during general endoscopic and laparoscopic surgical procedures (diagnostic and therapeutic).

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

### Thoracoscopy

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use to view the thoracic cavity during diagnostic and operative endoscopic procedures.

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

## Ear, Nose and Throat

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use to view the nasal, sinus and/or pharyngeal cavities during diagnostic and operative endoscopic procedures.

The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use to view the bronchi, trachea and esophagus during diagnostic and operative endoscopic procedures.

The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use to view the tympanic membrane and middle ear during diagnostic and operative endoscopic procedures.

The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use to view the larynx during diagnostic and operative endoscopic procedures.

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

## Arthroscopy

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use during diagnostic and therapeutic arthroscopic surgical procedures in the knee, shoulder, elbow, wrist, ankle, jaw and hip.

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

## Plastic Surgery

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are for use during endoscopic plastic, reconstructive and aesthetic surgical procedures.

**Contraindications:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

**Appendix I (Continued)****Gynecology (Laparoscopy)****Indications for Use:**

- unexplained pelvic pain (acute, chronic)
- infertility work-up
- tubal sterilization
- unexplained primary or secondary amenorrhea
- diagnosis and/or treatment of ectopic pregnancy
- evaluation, diagnosis and/or treatment of small pelvic tumors, including myomata
- evaluation of congenital anomalies of the pelvic organs
- retrieval of small foreign bodies
- determination of the presence and extent of pelvic endometriosis
- determination of the presence and extent of pelvic inflammatory disease
- laparoscopic assisted vaginal hysterectomy
- evaluation of ovarian endocrinopathy
- visualization, diagnosis and/or treatment of perforate abdominal organs

**Strong Relative Contraindications:**

- Class IV cardiac decompensation
- infection with acute peritonitis
- bowel obstruction
- ileus
- intraperitoneal hemorrhage
- diaphragmatic hernia

**Other Relative Contraindications:**

- cardiac disease
- diaphragmatic hernia
- previous abdominal surgery
- obesity
- thin nulliparous patient
- pregnancy greater than 16 week size or abdominal mass of comparable size
- chronic obstructive lung disease
- liver failure with established collateral vessels
- invasive carcinoma of the cervix
- medical contraindication
- intolerance to anesthesia

**WARNINGS:**

For use only by clinicians trained in laparoscopy



## Precautions:

- Ultrasonography prior to laparoscopy may identify clinical conditions that will alter patient management.
- Abdominal puncture sites 10 mm or greater (for the introduction of auxiliary instrumentation) may be a source of herniation.
- Lasers and electrosurgical probes should not be activated simultaneously. Further, when one is activated, the tip of the other should be completely retracted. This avoids deflection of the energy to the other tip.
- Electrosurgical Safety: Inadvertent burns can occur when the appropriate patient return path is obstructed. Inadvertent burns may also occur as a result of capacitive coupling.

**WARNING:** Although not reported in the current literature with the use of monopolar resectoscopes when used with non-electrolytic distending media, **air/gas emboli have been reported with the use of bipolar resectoscopes and laser when used in saline for uterine surgery.** Proper monitoring of end-tidal CO<sub>2</sub>, oxygen saturation and possibly Doppler TE echo should be monitored during the procedures by the operating team. Removal of the weighed speculum and use of a modified Trendelenberg and monitoring of intrauterine pressure are also recommended to reduce intravasation of uterine contents into the vascular system.

## Diagnostic Hysteroscopy

### Indications for Use:

- abnormal uterine bleeding
- infertility and pregnancy wastage
- evaluation of abnormal hysterosalpingogram
- intrauterine foreign body
- pelvic pain
- evaluation of abnormalities of the endometrium
- monitoring IUD status

**Appendix I (Continued)****Absolute Contraindications for use:**

- acute Pelvic Inflammatory Disease (PID)

**Relative Contraindications for use:**

- inability to distend uterus
- cervical/vaginal infection
- uterine bleeding or menses
- known pregnancy
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication
- intolerance to anesthesia

**Warnings**

Suspicion of pregnancy should suggest a pregnancy test prior to the performance of diagnostic hysteroscopy.

**Precautions**

Vaginal ultrasonography prior to hysteroscopy may identify clinical conditions that will alter patient management.

**Operative Hysteroscopy****Indications for Use:**

- directed biopsy
- removal of submucous fibroids and large polyps
- submucous myomectomy
- transection of intrauterine adhesions
- transection of intrauterine septa
- endometrial ablation

**Absolute Contraindications for use:**

- acute Pelvic Inflammatory Disease (PID)

**Relative Contraindications for use:**

- inability to distend uterus
- cervical/vaginal infection
- uterine bleeding or menses
- known pregnancy
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication
- intolerance to anesthesia

## **Relative Contraindications to Endometrial Ablation**

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken before adequate training, preceptorship and clinical experience. Additionally, tissue sampling is required prior to destruction of the endometrium. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

- adenomatous endometrial hyperplasia
- severe adenomyosis
- pelvic pain (subtle PID)
- uterine anomalies

## **Relative Contraindications to Hysteroscopic Myomectomy**

Hysteroscopic myomectomy, whether by laser or electrosurgery, should not be undertaken before adequate training, preceptorship and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- severe anemia
- inability to circumnavigate the myoma

## **Warnings**

If a liquid distention medium is used (continuous flow hysteroscopy), strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 2 liters should be followed with great care to avoid the possibility of fluid overload.

## **Complications**

- hyponatremia
- hypothermia
- uterine perforation, resulting in possible injury to the bowel, bladder, major blood vessels and ureter
- pulmonary edema
- cerebral edema
- air or gas embolization

**Appendix I (Continued)****Neurology****Indications for use:**

KARL STORZ Neuroendoscopes are indicated for use during neuroendoscopic surgical procedures for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

**Contraindications:**

- Use of KARL STORZ Neuroendoscopes are contraindicated whenever neuroendoscopy is contraindicated.
- Use of KARL STORZ Neuroendoscopes are contraindicated in patients suspected of being infected with Creutzfeldt-Jakob disease.

**Warnings:**

- Infusion of fluids into the cranial cavity without proper venting can lead to intracranial hypertension. Introduction and evacuation of fluids should be regulated by using the inflow and outflow stopcocks.
- During infusion of fluids when irrigating, make sure that the outflow path does not become obstructed. Increased intracranial pressure may result.
- Use of a camera is recommended with the neuroendoscope to ensure optimal viewing and to maintain sterility of the system. If direct viewing is desired, make sure your eye does not contact the eyepiece of the neuroendoscope. Sterility will be compromised.
- Insufficient cleaning may compromise the sterility of the neuroendoscope.
- The neuroendoscope must be sterilized after each use.
- Disinfection does not sterilize neuroendoscopes.
- The use of the neuroendoscope with cables and accessories may produce tension and torquing forces on the neuroendoscope during use. To prevent pressure on, or injury to, the brain tissue, always be sure that the body of the neuroendoscope is supported adequately.

- Do not allow the tip of the neuroendoscope to remain in contact with brain tissue for prolonged periods of time.

## **Cautions:**

- Do not use the neuroendoscopes without the operating sheath.
- Immobilize the neuroendoscope using your hospital's standard stabilization system to ensure proper stabilization of the neuroendoscope during use.
- Irrigation fluids should be warmed to body temperature prior to infusion.
- When handling the neuroendoscope, always hold it by the eyepiece assembly.
- Avoid actions that might flex or bend the neuroendoscope shaft.
- Do not drop the neuroendoscope, or allow it to strike any hard surface.
- Do not place any object on top of the neuroendoscope.
- Do not touch the lenses at either end of the neuroendoscope.
- Do not introduce or withdraw surgical instruments through the neuroendoscope instrument channel while the instrument jaws are open; damage to the neuroendoscope and instruments may occur.

## **Precautions:**

All procedures using KARL STORZ Neuroendoscopes should be performed by a qualified neurosurgeon with neuroendoscopic experience.

## **Dentistry**

**Indications for Use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are to be used whenever magnification is desirable and/or access is restricted during dental, endodontic, and periodontic procedures.

**Contraindications for use:** The KARL STORZ HOPKINS® and HOPKINS® II Telescopes are contraindicated for use when, in the opinion of a qualified dentist, endodontist, or periodontist, such use would create a condition that would be dangerous for the patient.

## **Appendix II**

### **Cleaning Accessories available from KSEA**

#### **Cleaning Brushes:**

- 27648 A     Cleaning brush. Length: 50 cm  
27650 A     Same. Length: 35 cm. Large size  
27662       Grasping forceps for careful handling of instruments

#### **Metal Sterilizing Cases:**

- 27640 A     Metal case with cover for telescopes with holes for sterilization, 400 x 75 x 50 mm  
27640 B     Same, 260 x 75 x 50 mm  
27640 C     Same, 615 x 75 x 50 mm  
27641 A     Same, 640 x 140 x 50 mm  
27641 C     Same, 500 x 200 x 50 mm  
27641 E     Same, 400 x 150 x 50 mm

#### **Protective tubes for Hopkins telescopes:**

- 723750 A     Length, 11.9 cm  
723750 B     Length, 19.7 cm  
723750 E     Length, 31.9 cm  
723750 H     Length, 46.8 cm

#### **Cleaning pistol and attachments:**

- 27660

## Quick Reference for Sterilization of KARL STORZ Telescopes:

<u>Products</u>	Steam	Ethylene oxide gas	STERRAD			
			100S	NX	100NX	
			X	X	X	X
			X	X	X	X

**\*WARNING:** High level disinfection is NOT recommended for telescopes to be used for laparoscopy, arthroscopy, hysteroscopy, plastic, reconstructive, aesthetic, or neurology surgery procedures.

### DISTRIBUTED AND SERVICED BY:

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