STERIS SYSTEM 1E STERILIZATION (SS1E)

PURPOSE:
To provide guidelines for sterilization of heat-sensitive items in the Steris System 1E. Steris SS1E is “just in time” technology. When used for the sterilization of critical items, sterilized items are used immediately and not shelved for later use. When used for the sterilization of semi-critical items, these items are dried thoroughly and stored in a manner that protects them from recontamination in accordance with department specific guidelines. (See Spaulding Classification.)

SPAULDING CLASSIFICATION
Critical: Critical items confer a high risk for infection if they are contaminated with any microorganism. A device that enters sterile tissue or the vascular system must be sterile, which is defined as the destruction of all microbial life. This category includes cardiac and urinary catheters, arthroscopes, laparoscopes, surgical instruments, and ultrasound probes used in sterile body cavities.

Semicritical: A device that comes into contact with intact mucous membranes or non intact skin. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and GI tract, generally are resistant to infection by common bacterial spores, but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. These devices minimally require high-level disinfection. Examples: respiratory therapy and anesthesia equipment, colonoscopes, gastrointestinal scopes, laryngoscope blades.

POLICY
Responsibility:
The department manager is responsible for assuring that proper training is conducted with all employees responsible for operating the Steris System 1E Processor and all accessories in compliance with the Operator’s Manual, labeling and instructions for use.

The department manager is responsible for developing and/or adapting this work instruction in accordance with device manufacturer’s recommendations, recommended infection control and other practices, and regulatory standards.

The department manager is responsible for maintaining documentation of competency training and testing for personnel who operate the Steris System 1E.

Service and maintenance of this machine is the responsibility of the Biomedical Engineering Department. The cleaning of the outside surface is the responsibility of the department where the machine is located.

Locations approved for Steris System 1E:
The 2K Operating Room, 3K Operating Room, Central Medical Supply, Women’s Health Clinic, The Endoscopy Clinic, Urology Clinic, and Feist-Weiller Cancer Center are the only areas approved for Steris System 1E Sterilizers.

Personnel authorized to operate the Steris System 1E:
Only personnel who have been trained and competency tested are allowed to sterile instruments in the Steris System 1E. Competency Testing is performed on an annual basis.

Notes:
1. Diagnostic testing is done each day and after changing water filter to insure the sterilizer is working properly.
2. Instruments are cleaned and decontaminated according to department specific guidelines prior to placing in the Steris System 1E.
3. Chemical indicator strips are used with each load as a check on the sterilization process. Record the results in the log book.
4. Only heat sensitive instruments that are validated by Steris or by the instrument manufacturer are processed in the Steris System 1E. (Refer to SS1E Miscellaneous Device Matrix, SS1E Quick Connect Availability Matrix)

**For Diagnostic Testing Failure:**
1. Re-run the cycle. If second failure occurs, remove the machine from service.

**Chemical Indicator Failure:**
1. If chemical indicator shows a processor failure, re-run the load with a new strip.
2. If a second failure occurs, remove the machine from operation and call the BioMed department.
3. Do not use instruments if the chemical indicator fails. Re-process in a different SS1E or other approved sterilizer.

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**PREPARATION OF INSTRUMENTS FOR GENERAL PROCESSING**

**A.** Barrier gowns, gloves, mask and goggles should be worn.

**B.** Wash instruments with instrument cleaner thoroughly according to department specification and/or manual instructions. Be sure to read and follow the instructions on the label for diluting and using instrument/enzyme cleaner. Measure and mix the instrument enzyme cleaner and water accurately according to label instructions. Dry instruments before placing in SS1E.

**C.** Perform leak test on all scopes with channels.

**D.** Written departmental guidelines and/or manufacturer's written instructions regarding the care and cleaning of medical devices must be available and followed.

**E.** Colonoscope/Sigmoidoscope

1. Insert the reusable black stopper into the air/water channel port.
2. Cover the suction port with the reusable black plastic cap.
3. Attach the adapted all-channel irrigator.
4. Place the biopsy cap (Olympus CW-2) over the biopsy channel port.
5. Attach the adapted auxiliary water irrigator.
6. Place the scope in the tray. Caution: Failure to ensure flexible endoscope is correctly positioned in the tray may result in damage to the scope and/or create processor spills.
7. Attach quick connects to the fluid ports of the flexible tray. **Right port:** all-channel irrigator. **Left-port:** auxiliary water channel irrigator. Assure that connectors are the appropriate ones approved by steris.
8. Place biopsy forceps in holding rack.
9. Place valves, semi-disposable biopsy cap in mesh bag.
10. Place mesh bag on rack. Caution: Damage to small parts and/or blockage of the drain may occur if small parts are not contained.
F. Gastroscope
1. Wipe scope down with pre-cleaning solution.
2. Leak test scope.
3. Attach the adapted all-channel irrigator.
4. Place the biopsy cap (Olympus CW-2) over the biopsy port channel.
5. Attach the adapted auxiliary water channel irrigator (if the gastroscope is equipped with an auxiliary water channel, i.e., double channel scope). Assure that connectors are the appropriate ones approved by steris for SS1E.
6. Place the scope in the tray. Caution: Failure to ensure flexible endoscope is correctly positioned in the channels of the sterilizer may result in damage to the scope and/or create processor spills. Failure to properly position instruments so that all surfaces will be exposed to the liquid sterilant or over-looking the container may result in an ineffective sterilization process and/or damage to the instruments.
7. Attach quick connects to the fluid ports of the flexible tray. Right port: auxiliary water channel irrigator. Left port: all-channel irrigator. In gastroscopes without auxiliary water channel, right port: all channel irrigator.
8. Place valves and semi-disposable biopsy cap in mesh bag.
9. Place mesh bag on rack. Caution: Damage to small ports and/or blockage of the drain may occur if small ports are not contained.

Note: For scopes with elevator wire channel (i.e., ERCP scope), attach 3 cc syringe and cleaning tube. Flush with instrument cleaner, clear water, and then instill Cidex and place in SS1E. Following sterilization, remove Cidex, flush with sterile water, empty channel.

G. Bronchoscope/Flexible Cystoscope/Nasopharyngoscope
1. Attach the fifteen (15) inch tubing with quick connect (Steris 200088) to the metal suction port.
2. Place the biopsy cap (Olympus MB-358) over the biopsy channel port. Do not close cap.
3. Place scope in tray. Caution: Failure to ensure flexible endoscope is correctly positioned in the tray may result in damage to the scope and/or create processor spills.
4. Attach quick connect to the fluid ports of the flexible tray. Right port: fifteen inch tubing. Assure that connectors are the appropriate ones approved by steris for SS1E.
5. For Pediatric Bronchoscopes:
   a. Irrigate channels with enzyme cleaner after manually cleaning outside scope; rinse.
   b. Leak test scope.
   c. Place adapted channel irrigation on scope and place in right port of Steris sterilization.
6. For Rigid Cystoscopes
   a. Instruments should be laid in the processing tray with all stopcocks in open position.
   b. Place chemical indicator strip in orange angled clip in tray.
   c. Place cover on processing tray assuring proper closure with no crowding of instruments within tray.

H. Dilators
1. Wipe outside of dilators with enzyme solution.
2. Brush through dilators and irrigate with enzyme solution using a 60 cc syringe.
3. Place dilators in Steris tray, attach a quick connect to dilators and begin sterilization process.
I. Beside Pre-cleaning Cleaning of Endoscopes

Immediately after completing an endoscopic procedure, pre-clean the endoscope. Ensure that the endoscope is wiped down thoroughly. After wiping down, place the sponge and cleaning brush with the endoscope, place in a cinch pad, and return to the endoscope processing area.

OPERATION OF THE PROCESSOR

1. Ensure that the UV light is on and warm (typically 5 minutes).
2. Add S 40 Sterilant Concentrate to the chamber located in the lower right hand corner of the processing tray. Gently push cup down until the lid is flush with the tray. Check to be sure the S 40 Sterilant box for damage or expiration date. **Do Not Use Steris 20 Sterilant or any other chemistry with the SS1E.**
3. Insert aspirating probe into the sterilant cup by lining up the tip of the aspirating probe over the cross cuts located in the center of the lid. Insert probe in a downward motion until the top of the aspirator is resting on the lid of the sterilant cup. The correct position of the aspirator probe assembly with the connected flexible tube is the 5 o’clock position when the probe is placed into the sterilant cup. Ensure tubing is not kinked.
4. Place chemical indicator strip in orange angled clip into processor chamber.
5. Close lid. If resistance is met, stop and inspect positioning of tray/container or endoscope and aspirate assembly. **Do not force lid closed.**
6. Press start. If “wait for UV Lamp” appears, allow the lamp to warm up for 5 minutes, then press start. If “change Max Pure filter” appears, contact Physical Plant.
7. When sterilization cycle is complete, there will be an audible tone (5 one second beeps).
8. Press cancel; inflatable seal will deflate. Do not open the lid until the display shows “Cycle complete Open Lid”.
9. Lift handle; open lid.
10. Remove aspirator probe from sterilant.
11. Remove empty sterilant container and discard. Always verify that the sterilant cup is empty.
12. Remove sterilized items - disconnect all-channel irrigator and auxiliary water channel irrigator from fluid port in flexible processing tray. Deliver sterile items immediately to the sterile field.
13. For Endoscopes, use compressed air to flush retained moisture from scope. Flush scopes with 70% Isopropyl alcohol to aid in moisture evaporation. Repeat the compressed air. Dry and hang in cabinet. Hang caps and valves unattached to the endoscope.

CANCELLED CYCLE

1. The cancel function will be initiated automatically by the processor if one or more of the parameters for liquid sterilization have not been achieved or maintained. When cancel occurs, the devices will not be sterile and/or adequately rinsed. If a “CANCEL” occurs, all items must be carefully removed and thoroughly rinsed, re-cleaned, and reprocessed for use. If cancellation was initiated by the processor, troubleshoot the problem; refer to the owner’s manual.
2. To cancel a cycle, refer to the SS1E operator’s manual.

DAILY CLEANING AND MAINTENANCE OF THE PROCESSOR

1. Wipe external surface, inside lid and flexible endoscopic tray, aspirator probe
assembler and sterilant compartment with a soft cloth dampened with 70% isopropyl alcohol.

2. Check aspirator probe and assembly to make sure the lumen is clean with no cracks or chips. (Replace aspirator probe assembly if any damage/breakage is noted).

3. Check drain screen. Remove any debris and/or lint from screen.

4. Remove tray from chamber and clean chamber using a soft cloth dampened with 70% isopropyl alcohol.

5. Open control panel and check printer paper.

6. Sterile air filters are changed every six months. Date to change filter is found on the filter.

7. The processor will print out when the sterile water filter and pre-filters are to be changed. (The filters can also be changed if they appear to need changing by the processor operator).

**STERIS S40 STERILANT**

1. Do not use Steris 40 after the expiration date indicated on the label.

2. A new cup of Steris 40 is used with each load.

3. Do not use leaking or damaged containers. To discard leaking or damaged containers:
   a. Increase ventilation to remove any strong vapors.
   b. Shut off ignition sources.
   c. Put on protective attire to include water proof gloves, apron, and chemical goggles. Wear the protective attire during the entire procedure.
   d. Remove individual box and cup and submerge in a sink filled with at least 12 inches of water.
   e. While box is submerged, remove cup from the box, rinse box in water and drain. Discard box following procedures for clean paper waste.
   f. Open the submerged cup manually to dilute the remaining acid. Using a pair of scissors, insert in the cross section in the top center of the cup (aspiration probe insertion point) and cut both the inner and outer cup in half. **Avoid splashing or spraying.** Dilute both liquid (peracetic acid and powders) in water.
   g. Drain sink and rinse residual powders away.
   h. Rinse inner and outer cups with copious amounts of running water (at least one gallon per cup).
   i. Thoroughly drain the cup, empty cup and discard following procedures for clean plastic/paper waste.

4. If it is necessary to remove a cup which has been opened but not diluted, follow the disposal instructions for leaking/damaged cups.

5. If Steris 40 cup has solution in it when cycle is complete, follow disposal instructions.

6. In case of spillage of Steris 40, use dilution:
   a. Press cancel button.
   b. When cancellation is complete, unplug the processor.
   c. Increase ventilation to remove any strong tear-producing vapors.
   d. Put on protective attire to include water proof gloves, apron, and protective eyewear. Wear protective attire for the entire procedure.
   e. Rinse to a non-blocked (clear) floor drain if available or wipe liquid up with absorbent towels, sponges, or mops. Thoroughly rinse the area and dry. Towels, sponges or mops (whether reusable or disposable) used to clean up spillage, must be thoroughly rinsed before disposal into the appropriate receptacles (i.e. trash or soiled linen).

**CHEMICAL MONITORING OF STERIS STERILIZER**
Purpose:
   a. To check the sterilizer to ensure the concentration of sterilant is adequate for sterilization. The Verify Chemical Indicator for the system IE Processor is blue when unprocessed. It changes from blue through an intermediate beige and then to the end point pink when exposed to adequate levels of per acetic acid.

Policy:
   a. Performed with each instrument load run.

Equipment:
   a. Orange angled handling clip.
   b. Chemical indicator strip.

PROCEDURE
1. Check for expiration date on the bottle. If a new bottle is opened record the date it was first opened and the new 3 month expiration date on the bottle.
2. Use a new strip each time. Remove a strip and compare it with the START reference color on the bottle. DO NOT USE THE STRIP IF THE COLORS DO NOT MATCH.
3. Place one strip into the clip provided, then into the Processor Chamber.
4. Start the processing cycle.
5. Within 30 minutes of cycle completion, retrieve the strip and compare the color with the reference color blocks on the bottle.
   a. If the indicator is the same as, or more pink than, the PASS reference on the bottle, the processed items may be used.
   b. If the indicator does not meet the PASS criteria, re-run the load with a new indicator strip. If the second load fails, the instrument cannot be use. Remove and reprocess in another sterilizer. Take the failed sterilizer out of service and notify Biomed.
6. Store all unused indicator strips tightly closed in their original container away from direct light.
7. Exposed indicators cannot be maintained as a permanent record.
8. Expiration date is 3 months after first opening the bottle, or the manufacturer’s printed expiration, whichever is shortest. DO NOT USE AFTER THE EXPIRATION DATE.

References:
2. FDA. Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, 2003.

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