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**APPENDIX C  
STERILIZATION PROCEDURES**

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A: **STEAM STERILIZATION:** Follow manufacturers' operational manuals during steam sterilizer operation.

1. Steam Sterilizer Process Records


- a. Records must contain the following:
  - 1) Sterilizer number
  - 2) Sterilization date
  - 3) List or lot number
  - 4) List of contents of each load run
  - 5) Initials of operator who ran the sterilizer
  - 6) Daily Air Removal Test (Dart) results, where applicable
  - 7) Record of all items recalled when evidence of sterilizer failure is noted.
- b. Storage of Records
  - 1) All sterilizer records must be retained for at least 7 years.

2. Steam Sterilizer Process Monitors

- a. For Manufacturing Area (*Wilmer OR, Weinberg Processing Area, JHOC CSD, Central Sterile Processing, GOR Processing Area*), the following will take place:
  - 1) Before any load is released, the operator must verify by external chemical indicator that the sterilizer parameters have been met.
  - 2) Run a chemical integrator with each load and read it before releasing the load. Place this integrator on the bottom rack closest to the drain.
- b. All areas
  - 1) Biological Indicators (BI)
    - Test each sterilizer using a biological spore test containing *Bacillus stearothermophilus* at least weekly (see frequencies below) and incubate according to manufacturers' instructions.
    - Read the results according to manufacturer's instruction and record the results in the sterilizer process records.
    - Perform routine biological monitoring sterilizers with fully loaded chambers (except for gravity displacement or flash sterilization).
    - To verify the reliability of the biological test spores and proper incubation of the biological indicator, each week:
      - Leave one biological indicator from each of the lots used for testing unexposed to the sterilant; incubate it, and treat it as a control to verify the presterilization viability of the test spores.
      - If the control from a lot fails to grow, assume that the test biological indicators from that lot are non-viable or that improper incubation occurred and consider the test results invalid and repeat the test.
      - If the second test fails to grow, alert Central Sterile and repeat the test using a different lot.
- c. Biological Indicator Testing for Hospital Manufacturing Areas is required as follows:

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- 1) Central Sterile Processing and JHOPC Processing: daily, when in use
- 2) General Operating Rooms
  - High-vacuum sterilizers: daily, when in use
  - Gravity displacement sterilizers: daily, when in use
- 3) Wilmer OR
  - High-vacuum sterilizers: daily, when in use
  - Gravity displacement sterilizers: daily, when in use
- 4) JHOPC OR sterilizers: daily, Monday through Friday
- 5) Dental Clinic: weekly
- 6) Weinberg OR
  - High-vacuum sterilizers: daily, when in use
- 7) Sterrad: daily, when in use.
- 8) Other areas: weekly
- d. Prior to use, validate proper functioning of sterilizers after major repairs have been performed:
  - 1) Gravity displacement sterilizers:
    - Following major repairs, include anything that affects the temperature control device or the printer circuit board, perform a biological indicator test and read results to assure proper functioning prior to the use of the machine.
- e. High vacuum sterilizers
  - 1) Following repairs on the printer circuit board or temperature control device of a high vacuum sterilizer, a biological indicator test and a Daily Air Remover Test (DART) must be performed and read to assure proper functioning prior to use of the sterilizer. Perform a test for air removal during the pre vac stage.
  - 2) Following repairs listed below that can affect sterilizer performance, a DART must be performed and read to assure proper functioning prior to use of the sterilizer.
    - vacuum adjustments
    - door gaskets
    - door adjustment
    - steam to chamber valve
    - drain valve
- f. Chemical Integrators
  - 1) Use an internal chemical integrator within each package sterilized.
  - 2) Place chemical integrators face up in the middle of every package.
  - 3) Place sterilizer indicator tape on the outside of every package.
- g. Mechanical Control Monitors
  - 1) Maintain a time/temperature pressure chart on each sterilizer.
  - 2) Indicate load numbers of each cycle recorded on the chart.
  - 3) If the sterilizer has no permanent graphing device, record actual exposure time, temperature and pressure gauge readings and on the load sheet.
- h. Perform a DART to determine adequacy of air removal during the pre-vacuum stage in each pre-vacuum sterilizer during the first cycle each day.

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### 3. Steam Sterilization Times

Sterilizer Type	Penetration Time (PT)	+	Kill Time (KT)	+	Safety Time (ST)	=	Sterilization time	Biological Indicator Used
Gravity Sterilizers								1 hour rapid readout
Wrapped, 121 C (250 F)	12 min	+	12 min	+	6 min	=	30 min.	
Unwrapped, 133C (272F) (metal and glass only) b	...		2 min	+	1 min	=	3 min. (flash)	
Unwrapped, 133C (272F) (includes towels, rubber, bovie cord, etc.) b	7 min	+	2 min	+	1 min	=	10 min. (flash)	
High-speed vacuum sterilizer								3 hour rapid read out
Wrapped and unwrapped, 133C (272F)	1 min	+	2 min	+	1 min	=	4 min.	

- a. Sterilization times do not include the time to reach the required temperature or the exhaust and drying time; therefore, **it is shorter than the total cycle time.**

### 4. Sterilization of Implantable items (see Appendix A)


- a. Flash sterilization must be:
- 1) Limited to emergent situations only (no routine between case preparation of trays)
  - 2) Used only when there is insufficient time to sterilize an item by the preferred prepackaged method
  - 3) Audited on a regular basis to trend reasons for use
  - 4) If use is due to insufficient inventory of instruments and support is needed by the department to obtain more, this should be brought to the HEIC Committee.

### 5. Packaging of Items for Steam Sterilization

- a. All packaging for steam sterilization must provide the following:
- 1) Adequate air removal from and steam penetration into package contents
  - 2) Adequate barrier to microorganisms or their vehicles
  - 3) Resistance to tearing or puncture
  - 4) Proven seal integrity (that is, will not de-laminate upon opening and will not reseal after opening)
  - 5) Ease of aseptic presentation
  - 6) Absence of toxic ingredients and non-fast dyes
  - 7) Low lint quantities
  - 8) Cost-effectiveness
- b. Arrangement on the Sterilizer Cart
- 1) Place items close to each other with a finger breath gap
  - 2) Do not stack sterile containers on top of each other
  - 3) Do not place rigid instrument containers on their side

### 6. Handling of Sterilized Items


- a. Leave items removed from sterilizers on the sterilizer cart until they are completely cooled.
- b. Consider items that are wet unsterile.
- c. Minimize handling of all sterile items.

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- d. Consider items that are dropped or touched by any wet object contaminated and reprocess.
  - e. Do not place hot items on cool shelves.
  - f. Do not place rigid containers on top of wrapped trays.
7. Cleaning of Sterilizers
- a. Follow manufacturers' recommendations for cleaning.
  - b. Clean whenever soiled and per departmental cleaning schedule.

## B. ETHYLENE OXIDE GAS STERILIZATION

1. Ethylene oxide gas sterilization procedures must meet or surpass the standards of practice, must follow manufacturers' instructions, and must be approved by the Office of Health, Safety and Environment.
2. Ethylene Oxide Gas Sterilizer Process Monitors
  - a. Ethylene Oxide Gas Sterilizer Process Records must contain the following:
    - 1) Sterilizer number
    - 2) Sterilization date
    - 3) Load or lot number
    - 4) List of contents in each of load run
    - 5) Initials of operator who ran the sterilizer
    - 6) Record of biological indicator test results
    - 7) Record of time-temperature readings
    - 8) Aeration completion time
    - 9) Record of repairs and preventive maintenance
    - 10) Record of items recalled when evidence of sterilizer failure is noted
    - 11) Store records for at least 7 years
3. Ethylene Oxide Gas Sterilizer Process Monitors
  - a. Biological Indicators
    - 1) Run a biological spore test containing *Bacillus subtilis* in each load.
    - 2) Incubate the test according to manufacturers' instructions.
    - 3) Read the test results at 4 hours and record on the sterilizer record.
    - 4) One BI from the same lot is to be left unexposed, incubated and treated as a control to verify pre-sterilization viability of the test spores.
  - b. Procedures for Positive Biological Indicator Test Results
    - 1) When biological indicator test results are positive, HEIC must be notified.
    - 2) The following steps must be taken:
      - Pull the load record sheet and inspect the sterilizer chart to ascertain if time and temperature parameters were met.
      - If the parameters were met, retest the sterilizer with another biological indicator during the next load.
      - Hold the load pending results of the biological indicator test.
      - If the second test is positive, tag the sterilizer as "out of service" until repairs are completed and the sterilizer is placed back into service, following satisfactory testing with a biological indicator.
      - Recall processed items in accordance with the written recall procedures of each hospital area.
      - Notify HEIC, Risk Management and the operator of the recall.
  - c. Chemical Integrators
    - 1) Use an internal chemical integrator with each package sterilized.
    - 2) Chemical integrators must be placed face up and in the middle of every package.
    - 3) Place sterilizer indicator on the outside of every package.
  - d. Mechanical Control Monitors
    - 1) Maintain a mechanical recording chart indicating time and temperature for each sterilizer.

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- 2) Attach this chart to each day's sterilizer records.
- 3) Pre-set Automatic Control Monitors.
- 4) Follow manufacturers' operational guidelines for machines with pre-set controls that do not have mechanical recording charts.


4. Packaging Items for Ethylene Oxide Gas Sterilizer Packaging

- a. Provide the following for all ethylene oxide gas sterilization packaging:
  - 1) Adequate humidification and ethylene oxide gas penetration into the package contents
  - 2) Adequate aeration of the package contents
  - 3) Adequate barrier to microorganisms or their vehicles
  - 4) Resistance to tearing or puncture
  - 5) Proven seal integrity (that is, will not de-laminate upon opening and will not reseal after opening)
  - 6) Ease of aseptic presentation
  - 7) Absence of toxic ingredients and non-fast dyes
  - 8) Low lint quantities
  - 9) Cost effectiveness
- b. Examples of acceptable wraps:
  - 1) Woven, double thickness
  - 2) Non-woven
  - 3) Paper/plastic peel type pouches
  - 4) Polyethylene
- c. Examples of unacceptable wraps:
  - 1) Aluminum foil
  - 2) Nylon film
  - 3) Cellophane
  - 4) Polyester

5. Ethylene Oxide Gas Aeration: Adequate aeration following ethylene oxide gas sterilization is absolutely essential. Properly aerate materials prior to dispensing. Follow manufacturers' operational instructions and recommended aeration times for mechanical chamber aeration. Maintain aeration load records with the aeration chamber. DO NOT retrieve items from the aerator until the aeration time has been completed.

C. **PLASMA STERILIZER**

1. The Plasma Sterilizer (Sterrad) sterilizes instruments and other medical equipment within the process chamber. This system uses 1.8 milliliters of hydrogen peroxide transferred from the cassette into the vaporizer cap and vaporized into the chamber. The operating temperature is controlled at 42° to 50°
2. Plasma Sterilizer Process Record
  - a. Content of Records
    - 1) Sterilizer cycle and date
    - 2) Example (070197001)
    - 3) List of contents in each load run (recorded in the computer)
    - 4) Initials of operator who ran the sterilizer
    - 5) Results of the biological indicator test (are recorded in the computer in CSP)
3. Plasma Sterilizer Process Monitors
  - a. Biological Indicator
    - 1) Run a biological spore test containing *Bacillus subtilis* daily when in use.
    - 2) Incubate according to manufacturers' instructions.
    - 3) Record the test results in the computer at 72 hours.
  - b. Procedure for incubation of the biological test.
    - 1) Place the BI on the shelf close to the rear of the sterilizer.
    - 2) Incubate the BI ampule at 55C to 66C for 48 hours.

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- 3) Record results in the computer at 48 hours.
  - 4) One BI from the same lot is to be left unexposed, incubated and treat as a control to verify the presterilization viability of the test spores.
  - 5) If the control from a lot fails to grow, assume the test BI's from that lot are non viable, consider the test results invalid and repeat the test.
- c. Procedure for Positive Biological Indicator Test Results
- 1) Notify Hospital Epidemiology and Infection Control Department.
  - 2) Pull the load record and inspect the sterilizer printout to ascertain if time and temperature parameters were met.
  - 3) If the parameters were met, retest the sterilizer with another biological indicator during the next load.
  - 4) Hold the load pending results of the biological indicator test.
  - 5) If the second test is positive, tag the sterilizer "out of service" until repairs are completed.
  - 6) Retest the sterilizer with a biological indicator before placing the sterilizer back into service.
  - 7) Notify Hospital Epidemiology and Infection Control Department, Risk Management and the operator.
  - 8) Recall processed items in accordance with the written recall procedures of each hospital area.
- d. Chemical Indicator
- 1) Use a chemical indicator with each package sterilized.
  - 2) Place chemical indicator tape on the outside of the packaged items and an indicator inside the package.
- e. Mechanical Control Monitor
- 1) Keep the mechanical recording printout indicating time and temperature with the daily sterilization records.

4. Packaging Items for Sterrad Sterilizer


- a. Provide the following for all packaging:
  - 1) Adequate barrier to microorganisms
  - 2) Resistance to tearing or puncture
  - 3) Proven seal integrity (that is, will not delaminate upon opening and will not reseal after opening)
  - 4) Ease of aseptic presentation
  - 5) Low lint quantities
  - 6) Cost-effectiveness
- b. Acceptable wraps:
  - 1) Non-woven wrap
  - 2) Tyvek pouches
- c. **Note:** Paper and paper products may not be used inside or outside of the package.

**D. COLD CHEMICAL HIGH LEVEL DISINFECTION**

3. DO NOT use Cidex OPA® for cold chemical sterilization, as OPA's reliability in killing spores has not been proven. Immerse items in Cidex OPA® for 12 minutes to accomplish high level disinfection. Use cold chemical high-level disinfection only for items that do not require sterilization and which cannot be sterilized by plasma, steam, or ethylene oxide gas sterilization. Consult Central Sterile Services for assistance in determining optimal sterilization methods.
4. Precautions: Gloves and eyewear must be worn when coming in contact with the high-level disinfectant. Direct contact may cause tearing and irritation to mucous membranes. The concentrate is corrosive and irritating to the skin and mucous membranes.

**E. PERACETIC ACID**

5. The Steris System is used to high-level disinfect endoscopic and other heat sensitive instruments by immersion in a chemical sterilant at low temperatures (50°-55° C, 122°-131.91° F). Although the Steris System does render the item sterile, the processed instrument/equipment is wet and unprotected when it is removed from the

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machine. Therefore, the equipment is considered as not sterile, but high-level disinfected by HEIC. ONLY THOSE PERSONS PROPERLY INSERVICED CAN OPERATE THE PROCESSOR.

6. Microbial Destruction

- a. The Steris system utilizes 35% peracetic acid as its active ingredient. It is sporicidal, bactericidal, fungicidal, tuberculocidal, and virucidal. Peracetic acid interferes with cells metabolism by caustically attacking the cell walls.
- b. Principles
  - 1) Activation: The chemical sterilant is individually packaged in 1-cup containers. Each container is good for one use only. If any sterilant is remaining in the container after the cycle is complete, submerge it in 12 inches of water to completely dilute it before discarding the container in the trash receptacle.
  - 2) Time: The processing cycle takes 20-25 minutes; the disinfection cycle takes 12 minutes, including 4 one-minute rinses, and an air purge. Complete the entire cycle to assure proper disinfection of the instrument.
  - 3) Penetration: Free instruments of all organic material (blood, tissue, etc.) before placing in the Steris. The sterilant must contact all surfaces, therefore open all channels and box locks and remove valves and place into a mesh bag before placing loosely in the appropriate tray (flexible or rigid).
  - 4) Precautions: Wear gloves and eyewear when coming into contact with the sterilant. Indirect contact may cause tearing and irritation to mucous membranes. The concentrate is corrosive and irritating to the skin and mucous membranes.

3. Unloading

- a. Don eyewear and sterile gowns.
- b. Cover a table with sterile sheets.
- c. Disconnect channel irrigator from flexible scope.
- d. Remove tray by the handles and place them on sterile table leaving lid intact.
- e. Transport table to OR, remove the lid. The scrub person will remove instruments from the container.

4. Quality Control Measures

- a. These measures are performed with every cycle.
  - 1) The chemical monitor indicates that the proper amount of sterilant has entered the processor during each cycle. Run the appropriate indicator with each load. Negative results are indicated by a color change from purple to white or light gray. If results are positive, run a diagnostic cycle to identify the problem. Run a second diagnostic cycle after corrective action has been taken to ensure proper functioning of the processor.
  - 2) Run a diagnostic cycle each evening and after each filter change. The diagnostic cycle checks the processor for proper functioning. The printout indicates all malfunctions. Run the diagnostic cycle without the chemical sterilant. Record and initial the cycle results.
  - 3) Monitor computer printouts after each load to ensure that proper time, temperature, and optimum sterilant concentration has been achieved. The person running the load must initial the printout. Save the last 100 printouts for 7 years.
  - 4) Refer to the Clinical Practice Manual for "print-out paper change" instructions.
  - 5) Clean the processor each evening using 70% isopropyl alcohol. Refer to Clinical Practice Manual "cleaning instructions for the Steris Processor".