

UC Riverside, School of Medicine Policies and Procedures**Policy Title:** Autoclave Sterilization, Spore Testing and Cleaning**Policy Number:** 950-03-004

Responsible Officer:	Clinical Manager
Responsible Office:	Clinical Operations
Origination Date:	02/23/2016
Date of Revision:	04/2021; 06/2023; 10/2023
Scope:	UCR SOM Owned and Managed Faculty Practice Clinics

I. Policy Summary

To set forth the requirements to ensure proper use, maintenance, and performance of the autoclave through proper daily operations and weekly cleaning and spore testing.

II. Policy Text

A. Sterilization procedures should be monitored through a combination of mechanical, chemical, and biological techniques designed to evaluate the sterilizing conditions and the autoclave's effectiveness.

1. **Mechanical** techniques for monitoring sterilization include assessing the cycle time, temperature, and pressure of sterilization equipment by observing the gauges or displays on the sterilizer. Correct readings do not ensure sterilization, but incorrect readings could be the first indication that a problem has occurred with the sterilization cycle.
2. **Chemical** indicators, internal and external, use sensitive chemicals to assess physical conditions such as temperature during the sterilization process. Chemical indicators such as heat sensitive tape change color rapidly when a given parameter is reached. An internal chemical indicator should be placed in every sterilization package to ensure the sterilization agent has penetrated the packaging material and actually reached the instruments inside. An external indicator should be used when the internal indicator cannot be seen from outside the package. Multi-parameter internal indicators measure 2–3 parameters and can provide a more reliable indication that sterilization conditions have been met. Refer to manufacturer instructions for proper use and placement of chemical indicators.

Indicator test results are shown immediately after the sterilization cycle is complete and could provide an early indication of a problem and where the problem occurred in the process. If the internal or external indicator suggests inadequate processing, the item that has been processed should not be used. Because chemical indicators do not prove sterilization has been achieved, a biological indicator (i.e., spore test) is required.

3. **Biological** indicators (BIs) are the most accepted means of monitoring the sterilization process because they directly determine whether the most resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species) are present rather than merely determine whether the physical and chemical conditions necessary for sterilization are met. Because spores used in BIs are more resistant and present in greater numbers than are the common microbial contaminants found on patient care equipment, an inactivated BI indicates that other potential pathogens in the load have also been killed.

Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic (at least weekly) use of BIs. Users should follow the manufacturer's directions concerning the appropriate placement of the BI in the sterilizer. A control BI (not processed through the sterilizer) from the same lot as the test indicator should be incubated with the test BI. The control BI should

yield positive results for bacterial growth. In addition to conducting routine biological monitoring, equipment users should perform biological monitoring:

- a. Whenever a new type of packaging material or tray is used.
- b. After training new sterilization personnel.
- c. After a sterilizer has been repaired.
- d. After any change in the sterilizer loading procedures.

III. Procedures

A. Mechanical and Chemical sterilization should be documented with each load processed through the autoclave on the Autoclave Sterilization Log (Attachment A). The following information will be documented:

1. Date
2. Sterilizer #
3. Temperature
4. Load #
5. Pressure
6. Cycle Time
7. Operator
8. Instruments Sterilized & Quantity of Instruments (referrer to Attachment C for Instrument Preparation before Autoclave Sterilization)
9. Steam Integrator Lot Number & Expiration Date

B. Cleaning reusable instruments/equipment prior to sterilization

1. Enzymatic cleanser instructions are different based on the brand your clinic purchased. Always follow the manufacturer and/or product instructions from the multi-enzymatic cleanser you use.
2. Always follow the manufacturer's storage and disposal instructions on the multi- enzymatic cleaner. Ensure product is not expired.
3. All staff performing cleaning/sterilization of instruments/equipment are required to have documented training on the use of multi-enzymatic cleaner for instruments/equipment prior to sterilization.

C. Perform the following steps to document the Steam Integrator:

1. Place a Steam Chemical Integrator inside each load to be autoclaved. Use autoclave tape to attach the steam chemical integrator to the inside of an autoclave bag.
2. Process the load according to established procedures.
3. After processing, remove the Steam Chemical Integrator from the autoclave bag and interpret the results.
4. After processing, the dark color should have entered anywhere into the ACCEPT area window of the Steam Chemical Integrator. This means that all the critical parameters of steam sterilization have been met.
5. If the dark color is in the REJECT area window (has not entered the ACCEPT area window), this indicates a REJECT result which means that the items in the load were not exposed to sufficient steam sterilization conditions. The load should be returned for reprocessing and the cause of the sterilization process failure should be investigated.
6. Record the Steam Chemical Integrator test result in the Autoclave Sterilization Log (ACCEPT or REJECT).

7. After use, the Steam Chemical Integrator will not change visually within 6 months when stored in conditions stated below in “Storage and Shelf Life” section.

- D. Weekly, an Autoclave Spore test will be conducted and documented on the Autoclave Spore Testing and Cleaning Log. (Refer to Manufacture’s guidelines for machine cleaning procedures)
- E. If the mechanical (e.g., time, temperature, pressure) and chemical (internal or external) indicators suggest that the sterilizer is functioning properly, a single positive spore test result probably does not indicate sterilizer malfunction. Sterilizer operators should repeat the spore test immediately using the same cycle that produced the positive BI. The sterilizer should be removed from service and sterilization operating procedures reviewed to determine whether operator error could be responsible. Place “Out of Service” tag on sterilizer.
- F. If the result of the repeat spore test is negative and operating procedures were correct, then the sterilizer can be returned to service. If the repeat spore test result is positive, do not use the sterilizer until it has been inspected or repaired and re-challenged with BI tests in three consecutive empty-chamber sterilization cycles. When possible, items from suspect loads dating back to the last negative BI should be recalled, rewrapped, and re-sterilized. Results of biological monitoring and sterilization monitoring reports should be recorded.
- G. Weekly maintenance and cleaning will be performed in accordance with the manufactures guidelines located with the autoclave. Weekly maintenance and cleaning will be recorded with the weekly Biological Indicator test results on the Autoclave Spore Testing and Cleaning Log (Attachment B).
- H. Monthly maintenance and cleaning will also be performed in accordance with the manufactures guidelines and will be recorded on a separate line on the Autoclave Spore Testing and Cleaning Log.
- I. Logs will be maintained in accordance with the Record Retention Policy and Procedure.

IV. Forms/Instructions

Attachment A: Autoclave Sterilization Log

Attachment B: Autoclave Spore Testing and Cleaning Log

Attachment C: Instrument Preparation before Autoclave Sterilization

V. Revision History

New 2/2016

Review 04/2021

Revised 06/2023

Revised 10/2023

APPROVALS:

DocuSigned by:
Paul Hackman
B2E956F153CF4EE...

12/14/2023 | 11:07 PM PST

PAUL HACKMAN, J.D., L.L.M.
CHIEF COMPLIANCE AND PRIVACY OFFICER,
SCHOOL OF MEDICINE

DATE

DocuSigned by:
Deborah Deas
870C12B416E84CB...

12/15/2023 | 8:10 AM PST

DEBORAH DEAS, M.D., M.P.H
VICE CHANCELLOR, HEALTH SCIENCES
DEAN, SCHOOL OF MEDICINE

DATE

Attachment A
Autoclave Sterilization Log

Practice Location:

Month / Year:

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

STERILIZER #	LOAD #	INSTRUMENTS STERILIZED & QUANTITY:
DATE:		MANUFACTURER:
TEMPERATURE:		PART NUMBER:
PRESSURE:		STEAM INTEGRATOR LOT #:
CYCLE TIME:		STEAM INTEGRATOR EXPIRATION DATE:
OPERATOR:		

*Attach corresponding receipts to form.

Attachment C

Instrument Preparation before Autoclave Sterilization

The purpose of packaging and wrapping items for sterilization is to provide an effective barrier against contamination during storage once the items have been sterilized.

Instruments to be sterilized must be free from all residual matter, such as blood or organic tissue. Instruments must also be dry and free from mineral deposits. Such substances may damage the instruments or sterilizer.

1. Clean instruments after use to remove residual matter. It is recommended that all instruments be ultrasonically cleaned using enzymatic cleaning tablets or other suitable solution.
2. After cleaning, rinse instruments under tap water for 30 seconds and pat or air dry. If water has high mineral content, rinse in distilled water.
3. Be sure that instruments are separated and bagged and not directly on stainless steel trays which will result in oxidation.
4. Do not place materials to be sterilized against the chamber's wall. Place only on the tray. When using plastic bag, the plastic side should always be down.
5. Items must always be sterilized in an open position. Surfaces that are hidden because the item is in a closed position will not be exposed to the steam and will not be sterilized.
6. Place a chemical sterilization indicator in each tray or inside each wrapped pack.
7. To allow for easy retrieval without impacting instruments, chemical or biological indicators should be placed in a tray or wrapped pack, separate from instruments, to replicate true conditions.
8. At least once a week use a biological spore test in any load to insure proper sterilization.
9. Do not overload the Sterilizer trays. Overloading will cause inadequate sterilization and drying.
10. Allow a distance of 1 inch between trays to permit steam circulation.
11. Wrapped instruments should be placed in material which will allow steam penetration and promote drying, such as autoclave bag or muslin towels
12. Do not stack pouches.
13. Tubing should be rinsed after cleaning. When placed in the tray make sure both ends are open and there are no sharp bends.
14. If instruments exhibit discoloration, this can be due to the mixing of carbon steel and stainless steel. When these two metals come into contact with each other and electrolysis occurs that breaks down the metal. The best solution is to separately wrap the carbon steel to insulate it from other instruments.