



ON THE WEB

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Sterilization Process Failure Checklist

In the event that a chemical indicator, a biological indicator or sterilization cycle data alert you to a possible process failure, you must immediately:

- ☐ Quarantine the items reprocessed in that load.
- ☐ Discontinue use of the sterilizer until the issue is resolved.
- ☐ Notify involved personnel, including:
 - sterile processing department manager
 - maintenance staff or manufacturer's service representative
 - infection control and quality assurance practitioners
 - OR director
 - administrators and risk manager
 - any other sterile processing departments that use the steam
- ☐ If a positive biological indicator triggered the alert, send the vial to the lab for bacterial identification.
- ☐ Document the suspected failure and corrective actions taken.



Determine the scope of the failure:

- ☐ Review the history of physical monitoring data and biological and chemical indicators for the sterilizer and reprocessed items.
- ☐ Was the failure limited to 1 load or to 1 item in the load?
- ☐ If so, identify and correct the cause of the failure (see below), then reprocess the item or load again.
- ☐ Did the failure extend beyond the quarantined load?
- ☐ If so, recall all items reprocessed in the sterilizer at issue since its most recent successful tests.
- ☐ Notify any physicians who may have used items reprocessed in suspect loads. They may need to notify and conduct follow-up surveillance of patients.
- ☐ Reprocess all recalled items again before using.
- ☐ Identify and correct the cause of the failure (see below).

Identify and resolve the cause of the failure:

- ☐ Review the incident and available information with your sterile processing staff.
- ☐ Troubleshoot the equipment with your maintenance personnel or the manufacturer's service representative.
- ☐ Did the failure result from the incorrect use of, improper load preparation for or inappropriate item processing in operational equipment?
- ☐ If so, confirm that the sterilizer meets the manufacturer's specifications and cycle parameters.
- ☐ Return the equipment to service and reprocess the affected loads again.
- ☐ Educate your staff on correct practices.
- ☐ Otherwise, investigate for the possibility of a mechanical malfunction in the sterilizer or an issue involving the equipment's source of water or steam.
- ☐ Correct the cause of the failure.
- ☐ Test the sterilizer by processing 3 biological indicators consecutively. For sterilizers that employ the dynamic air removal method, process 3 Bowie-Dick tests as well. Ensure that proper cycle parameters are met.
- ☐ If tests are successful, return the equipment to service.

