Steam Sterilization Failure and Recall Checklist

Retain completed checklist with sterilization records.

Facility/office: _____

Date: _____ Person issuing recall: _____

☐ **Step 1: Review the steps necessary for recall based on the type of sterilization failure.**

Type of sterilization failure	Steps for recall
☐ Failed biological indicator	Recall and quarantine all sterilized packages in all loads back to the last negative biological indicator
☐ Failed internal indicator	Recall and reprocess package with failed internal indicator
☐ Multiple failed internal indicators	Recall and reprocess all packages in the same load as those with failed indicators
☐ Non-sterile medical devices are released for use	Recall and reprocess all packages with unchanged chemical indicators
☐ Wet load after cooling	Recall and reprocess all wet packages

☐ **Step 2: Review load records to determine how many sterilized packages need to be recalled.**

☐ **Step 3: Locate sterilized packages by date and load number on package.**

List all packages recalled and reprocessed:

☐ **Step 4: Document any sterilized packages which were not able to be recalled and may have been used.**

List all packages not able to be recalled:

☐ **Step 5: Notify medical director and/or manager of any sterilized packages which could not be recalled and reprocessed.**

Persons notified:_____

☐ **Step 6: Medical director/manager will decide if patients need to be notified that a potentially unsterile device was used.**

☐ **Step 7: Review the steps necessary after recall based on the type of sterilization failure.**

Type of sterilization failure	Steps after recall
☐ Failed biological indicator	• Retest the sterilizer with a biological indicator test • If it fails again, do not use sterilizer until it is repaired • If the biological indicator retest is negative, continue to use the sterilizer and review the procedures for performing a biological indicator test to determine if failure could have been operator
☐ Failed internal indicator	• Review packaging and loading procedures to determine cause
☐ Multiple failed internal indicators	• Review biological indicator test result for the load involved • Review loading procedures to determine cause
☐ Non-sterile medical devices are released for use	• Check all medical device storage areas for any packages which have not been sterilized • Look for packages which have chemical indicators which have not changed colour • Review sterilizer loading and documentation procedures to determine cause of release
☐ Wet load after cooling	• Review loading procedures to determine cause • If wet loads persist, contain repair technician

☐ **Step 8: Consider how to prevent recurrence.**

List actions taken to prevent recurrence:

Sign off

Name: _____ Signature: _____