

Biological Monitoring of Sterilizer (Spore Test)



Biological Indicator (BI)/Spore Test

Must be done for any one of the following:

- in a process challenge device (PCD) each day the sterilizer is used and with each type of cycle used that day
- in a PCD in every load containing implantable devices
- to test a new or back-up sterilizer*
- after repairs to an existing sterilizer*
- after relocation of sterilizer*

- after construction in the sterilizer area*
- after unexplained sterility failures*
- after changes in steam supply or delivery*

Note: Follow manufacturer's/laboratory instructions on proper use of BI/spore test. A control BI from the same lot number as the test BI must be incubated each day that a routine BI is incubated.



FAIL

Immediately STOP use of the sterilizer

- Record all equipment/devices in each processed load to enable tracking in the event of a recall.
- Repeat the BI/spore test. Do not release any items that were processed since the last negative (pass) test. If the repeat BI is negative (pass), all physical parameters (time, temperature, pressure) are met and there is no indication of a system malfunction, the sterilizer may be put back into service and continue as normal.

- If the repeated process indicates a failure:
 - Document the time, date, load description and results of physical, chemical and BI monitoring.
 - Contact the sterilizer manufacturer. After repair and maintenance, re-challenge the sterilizer with the BI.
 - Re-sterilize the recalled items once the results of the sterilizer indicators are acceptable.
 - Assess the risk to patients.
- Establish a procedure for notification of physicians, patients, other facilities and/ or regulatory bodies and the Health Department (required for PSS facilities).

PASS

Continue use of sterilizer

* sterilizers must pass at least 3 consecutive BI/spore tests in these events.