BIOLOGICAL INDICATORS

# BI Checklist: Troubleshoot a Positive Biological Indicator in Steam Sterilization

STERIS Life Sciences

Biological indicators, or BIs, play an important role in steam sterilization validation. BIs contain microorganisms proven to resist sterilization. Using BIs in the steam sterilization process helps validate that the conditions to kill microorganisms, such as bacterial spores, were met.

**But what if a positive culture results after processing the BI in a validated steam sterilization cycle? Use this checklist to uncover errors in operator experience, load preparation and sterilizer conditions.**

## STEAM STERILIZATION CYCLE(S)

### Review Records of Cycles with Positive Results

- [ ] Assess charts of physical parameters monitored and recorded during the cycle for irregularities
- [ ] Compare cycle parameters to the parameters of validated cycles to ensure adequate temperatures, exposure times or accumulated F0
- [ ] Verify that a positive control BI was not inadvertently exchanged for an exposed one by re-evaluating all BI and culture media control test results from the relevant interval
- [ ] Review available chemical indicator records

### Review Cycle Procedures

- [ ] Review the assembly and materials of the test pack or device
- [ ] Ensure load storage prior to the cycle was at the temperature set by standard operating procedures (SOPs)
- [ ] Confirm load placement within the sterilizer met SOPs
- [ ] Evaluate all routine and unscheduled maintenance
- [ ] Review the incident log book
- [ ] Discuss the relevant cycles with the sterilization technician

## BIOLOGICAL INDICATORS

### Review Biological Indicator Procedures

- [ ] Verify that the biological indicator has the correct spore count and D-value for the application
- [ ] Confirm the BI was stored in manufacturer-recommended conditions prior to testing
- [ ] Validate the location of the BI in the chamber, test pack or device meets SOPs
- [ ] Ensure strict aseptic techniques were used during the culturing
- [ ] Use negative controls to test and verify the sterility of the culture media
- [ ] Identify if a spore suspension was directly inoculated on the product or simulated product, which can cause clumping and affect the resistance of the inoculated material
- [ ] Ensure the temperature and humidity at all locations within the incubator met SOPs
- [ ] Make sure the incubator and fan received routine cleaning to eliminate particulates which can cause contamination
- [ ] If Verify™ Self-Contained Biological Indicators (SCBI) were used, make sure the Verify™ cap wasn't sealed until after it was exposed to the sterilization cycle
- [ ] Verify the sterilizer cycle parameters if the SCBI experiences "caramelization," or an amber color change, due to heat overexposure

### Repeat the Biological Indicator Test

- [ ] Discontinue use of the sterilizer until satisfactory results are obtained from a repeat biological indicator test and all applicable quality assurance guidelines are met

## STEAM STERILIZER EQUIPMENT

### Inspect Sterilizer Functionality for Abnormalities

- [ ] Verify condensate traps on the jacket and chamber are clean and functional
- [ ] Ensure that the strainers on steam supply and condensate piping are clean
- [ ] Inspect the chamber strainer to make sure it's clean
- [ ] Use load probes or thermocouples to verify temperature distribution in the sterilizer chamber is within proper parameters during exposure
- [ ] Ensure that the sterilizer cycle timer accurately meets factory specifications
- [ ] Run a Bowie-Dick and/or a leak test on prevacuum steam sterilizers to detect inadequate air removal from the chamber or air in the steam supply
- [ ] If available, perform a built-in chamber leak test cycle and compare the results to previous tests to ensure the leak rate meets

### Verify the Calibration

- [ ] Review the calibration documentation
- [ ] Calibrate the sterilizer temperature and pressure channels using National Institute of Standards and Technology (NIST) traceable measurements

### Ensure that Utilities Meet Sterilizer Requirements

- [ ] Check for water priming at the boiler, faulty traps, or a faulty steam condensate return system, which can create excessive condensate in the steam
- [ ] Ensure steam isn't super-heated by verifying the pressure and temperature in the sterilizer jacket is lower than in the sterilizer chamber
- [ ] Verify there aren't considerable amounts of non-condensable gases in the sterilizer steam supply due to inadequate deaeration of the steam generator feedwater

## MICROORGANISMS

### Review Environmental Monitoring Data for Airborne Microorganisms and/or Particulate Matter

- [ ] Ensure environment is free of microscopic dust and soil, which can contain common laboratory contaminants and endospores
- [ ] Verify floors, walls, ceilings and work surfaces are cleaned and disinfected regularly
- [ ] Ensure the laminar flow clean bench work surface is cleaned with 70% isopropanol (or equivalent) and dry before use
- [ ] Review maintenance records of the HEPA filters

### Perform Identification Testing on Subcultures

- [ ] Conduct a basic identification test to determine if the positive biological indicator culture is a BI organism

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Mentor, OH | sterislifesciences.com | Phone 1-440-354-2600 | lifesciences@steris.com

LSFC-BR4165.F-IT-E 09/2018