

THE UNIVERSITY OF TOLEDO MEDICAL CENTER STERILE PROCESSING DEPARTMENT PROCEDURE

**SUBJECT: POSITIVE CULTURE AND
RECALL OF HOSPITAL ITEMS**

PROCEDURE NO: SP3-7

PROCEDURE STATEMENT

Sterile Processing and the O.R. will follow a specific protocol in the event of a positive biological in a sterilization cycle in accordance with AAMI ST79:2017.

PURPOSE OF PROCEDURE

To provide a logical, effective, measured and correct response in the event of a positive biological in a sterilization cycle.

PROCEDURE

Positive biological spore tests can occur sporadically. They may occur for reasons such as slight variations in the resistance of spores, improper use of the sterilizer or improper handling of the biological. In rare circumstances a positive biological may occur if the sterilizer or sterilization cycle is defective. This occurrence is uncommon because automatic sterilizers are designed to abort if the cycle is faulty.

In the event of an aborted/incomplete cycle, the sterilizer load will not be released and the biological spore test will not be incubated because the cycle printout will indicate that the cycle is complete and has not met all parameters. The load will be considered a failed cycle, rewrapped and resterilized.

Procedure In the event of a positive biological spore test

A determination must be made whether the biological is an actual positive biological or a false positive and whether it is due to operator error, product fault, Incubator fault or mechanical fault.

Steps to be taken are as follows:

Step 1

Notify the SPD Operations Supervisor and Surgical Tech on duty (if any.)

The Positive BI load is quarantined within the department. *Find and keep all paperwork.*

****Do NOT remove the positive BI from the incubator.****

Step 2

Verify the sterilizer Printout Tape shows correct cycle parameters.

PreVac Cycle = 270°F minimum 4 minutes

250 Cycle = 250° minimum and 30 minutes

If parameters have not been met, tear down and rewrap all sets run in the load. Resterilize in another sterilizer.

Tag the failed sterilizer "Do not use." Call Biomed for service during weekday hours.

No further action is necessary.

Otherwise go to step 3.

Step 3

Verify that all Chemical Indicators have passed

Class 2 challenge device has (steam tape) turned black.

For 270°F Prevac and 250°F Gravity Cycles, Class 5 indicator passes (Black ink passes the “accept” point.)

If chemical indicators do not pass inspection, tear down and rewrap all sets run in the load. Resterilize in another sterilizer.

Tag the failed sterilizer “Do not use.” Call Biomed for service during weekday hours.

No further action is necessary.

Otherwise go to step 4.

Step 4

Biological Indicator

Verify that external chemical indicator on BI has turned brown. If it is pink, the BI was not run. *Non implants may be released but implants must be torn down and re-run.*

No further action is necessary.

If BI indicator has turned brown go to step 5.

Step 5

Control BI

Check the Control BI. If it has not turned yellow, the BI lot may be faulty.

Steps 1 through 4 must all be completed before you do this step.

Go to step 6.

Step 6

Obtain a new lot number BI. Activate 2 controls and place them in separate incubators. (3M incubators can be dually used for steam and sterrad. Run both challenge packs in an empty load from the same lot # as the controls. Place BI's in the incubator.

*If only one BI in either incubator turns positive, there is most likely a problem with the incubator. *turn off the incubator and take it out of use. Utilizing the 1 incubator for both. *NOTIFY SUPERVISOR*

*If both pass, the problem was either with handling the BI or with the BI itself. * The sterilizer can be put back in to use.

*If they both fail, shut down the sterilizer. Call Biomed during the week and Operations supervisor on all instances.

Go to step 7.

All items from the load must be rewrapped. If an item was released prematurely it must be recovered. All unrecoverable items must be noted and reported to Infection Control.

Step 7

Remove the positive BI from the incubator. Place it and all paperwork in a plastic bag and give to the operations supervisor.

Reviewed/Revised

1996 2002 2005 2007 2008 2010

2014, 11/2016, 10/2018

1/2020