THE UNIVERSITY OF TOLEDO MEDICAL CENTER
STERILE PROCESSING DEPARTMENT PROCEDURE

SUBJECT: ROUTINE BIOLOGICAL SPORE TEST IN THE O.R.

PROCEDURE NO: SP7-2

PROCEDURE STATEMENT

The OR in conjunction with Sterile Processing will perform a biological spore test (BI) on each sterilizer in the O.R. at least weekly and preferably each day that a sterilizer is in use. Reference: AAMI ST 79:2010

PURPOSE OF PROCEDURE

To ensure and to document the effectiveness of the sterilization process.

PROCEDURE

The BI is to be run as soon after midnight as possible, after the DART Test in each tray configuration in routine use.

Tray configurations and Schedule:

**Odd days of the month:**
(Open tray 5 minute gravity cycle using an approved BI for Flash Sterilization.)

**Even days of the month:**
(“Flashpak” 5 minute gravity cycle using and approved BI for Flash Sterilization.)

**1 time per week, (Sundays)**
(“Flashpak” 5 minute Pre-Vac cycle) - SPD staff will run a 5 minute Express, Pre-Vac cycle using an approved BI for pre-Vac sterilization. Incubation and recordkeeping will take place in SPD. Refer to SPD policy # SP 6-24 starting at (PROCEDURE,) line #5 for processing instructions.

*For Flash Gravity cycles*

A CONTROL Biological must be pulled from the same lot as the BI’s used for the daily sterilizer tests. It is activated and placed in the incubator for 24 hours. Write a “C” on the label of the vial and the current date.

In the Steam Sterilizer Daily Biological Test Form enter the date and the time it was placed in the incubator with your initials. Place the Control in the incubator. A biological with the same lot number as the CONTROL is placed in a tray on the bottom shelf near the drain of the sterilizer or in the bottom front of the “Flashpak.” or open tray.

A class 5 Integrator must be placed in the tray, next to the BI.

Close the sterilizer door and start the cycle.
Initial the top of the sterilizer tape at the beginning of the cycle. (Operator__________). When cycle is complete, remove tape from sterilizer, verify correct parameters of sterilizer load and if correct, initial at bottom of tape: (Printout checked by:__________).

Attach tape to the front page of the Steam Sterilizer Record Keeping Log, 3M #1266S.
Open the chamber door for 5 minutes. After 5 minutes, using protective gloves or towel, remove the biological indicator and integrator. Allow BI to cool for 10 minutes.

After 10 minutes remove the BI and Integrator. Check the BI label to make sure that it turned brown.

Read the Integrator. It must show a “Pass” to continue. If the Integrator shows Failure, the cycle has failed and another BI and Integrator must be run. If the Integrator fails a 2nd time, tag the sterilizers “Do Not Operate” and contact Sterile Processing and Clinical Engineering.

Press the cap of the Biological Indicator down then crush the ampoule in the crusher well of the Auto-Reader. (Do not crush the ampoule between your fingers.

In the Steam Sterilizer Daily Biological Test Form enter the Load number (it should be #2)

The incubator constantly reads any BI in its wells. If at any time the incubator detects growth in a BI, the incubator will alarm and register a positive reading on its lighted panel. At the end of one hour, if the BI is negative, the incubator will register a negative reading on its lighted panel.

After 1 hour check the reader and visually check the ampoule to assure that the reading is negative. The BI will remain purple if negative and will turn yellow if positive.

If the reading is positive, tag the sterilizer “Do not operate” and contact Biomedical Engineering for a repair.

If the reading is negative, check the minus sign next to “Biological Results.” At 1 hour. Enter the time and your initials under “Time out/Initials.” Remove the BI from the incubator and visually check the BI. If the BI is negative circle the minus sign under “Visual Color Change.” Remove the label from the BI and place it on in the log book under “Load Contents.” Appropriately Discard the BI.

Check the Control BI after 1 hour and 24 hours. It should be positive. In the log sheet under “Control Results” check the plus sign. Remove the Control from the Incubator; Remove the Label from the Control. Place the Label in the Log on the “Control” line. Discard the positive BI in a sharps container. If the control BI is negative remove all BI’s with the same lot number from service obtain Biologicals with a different lot number. If a 2nd Control shows a negative, contact the SPD supervisor as the lot may be bad and will need to be replaced.

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