STERILE PROCESSING PROCEDURE
STERILIZATION

Procedure SP3-9: **BI test for gas plasma sterilizers (STERRAD)**

Policy Number Superseded:

Responsibility: Operations Manager, Sterile Processing

Effective Date:
December 2025

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1996

Purpose of Procedure: To challenge the efficiency of the sterilizer to attain a maximum level of sterility assurance. To follow the IFU of the STERRAD 100NX.

Procedure:

The sterile processing department will perform a biological test on the STERRAD sterilizers each morning on the standard cycle, and the first cycle of any of the following cycles: express, flex or duo.

(A) Each box of BI test vials contains 30 vials of test media. One vial is to be used as the control each day for the two sterilizers.

(B) Each cycle can use the same control from the corresponding lot number.

(C) Biological testing is to be done for the standard cycle, run after midnight in each sterilizer.

(D) Biological testing is done with the first cycle of the day for express, flex or duo as needed.

(E) Remove vials from box. Label 1 vial C-5, 1 vial C-6 on the label for control, with date and cycle number. Press top of vial down, crush and place in incubator for control.

(F) Prepare test vials labeled S-5, S-6 with date and cycle number and place each vial inside STERRAD peel pouch with an indicator.

(G) Label F for Flex, E for Express and D for Duo with the cycle number and date.

(H) Enter all pertinent information in the SPM computer system.

(I) Place the bio-test pack on the bottom shelf near the back of the sterilizer.

(J) Run load cycle.

(K) Upon completion of cycle, remove processed pack. Crush vials and place in the designated incubator.

(L) If the cycle cancels, the BI test pack should be discarded and a new pack used when starting the next cycle.

(M) Rewrap and re-sterilize any other items which were processed in the cancelled cycle.

(N) If a true positive result is observed, repeat the biological test procedure on a second vial that has been processed in the sterilizer. If a positive result is again obtained, have the sterilizer checked by bio-med personnel. Follow the item recall procedure.

(O) Use one control vial of the same lot number per day.

(P) Read and record results at 24 hours.

(Q) Scan the cycle printout and enter biological test information and results in the computerized sterilization management system.

Approved by:
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