BIOLOGICAL MONITORING OF WRAPPED GOODS STEAM STERILIZATION CYCLES

Quick Reference Guide

Clinical Education Services

STERIS®

For Internal Use Only

BIOLOGICAL MONITORING OF WRAPPED GOODS STEAM STERILIZATION CYCLES

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Quick Reference Guide

This paper is intended to be a quick reference on the topic of biological monitoring of wrapped goods steam sterilization cycles. It is designed specifically for internal use by STERIS employees. The information has been gathered from the recommended practices indicated in the text. It is important that our customers/clients be encouraged to purchase the full documents, for their continual reference, from the organizations indicated. Providing a copy of this information to our customers is not permitted because it would put us in violation of our agreement with AAMI, who authorized STERIS to quote and illustrate their material for our convenience.

Biological monitoring products include the

- ***Conventional*** product configuration using bacterial spores and media for growth.

- ***Biological indicators with enzyme-based early-readout capability*** which may serve as the basis for release of sterilized items, including implantable devices, without the need for full incubation. AAMI ST46 indicates that proper application of this monitoring product requires that the sterilization process be periodically verified by either (a) allowing continued incubation per manufacturer instructions to ensure any surviving microorganisms will grow out or (b) perform a test using the ***conventional*** biological test product, at least weekly, but preferably every day that the sterilizer is in use. At the time of this publication AAMI ST46 does not permit the use of this type of product for initial installation testing, after relocation, after sterilizer malfunction, after process failures or major repairs (this may change in future AAMI documents).

- ***Multi- enzymatic products without biological indicator*** results would have to backed up by conventional biological testing at least weekly, preferably every day the sterilizer is used.

See also current STERIS information provided regarding the use of the Class 5 integrator challenge test pack – Verify C5, for monitoring steam sterilization loads. AAMI ST46 indicates that the results of Class 5 of integrating indicators may serve as the basis for release of processed items, excluding implants. The Class 5 integrator must be used in an appropriate test pack. Using the Class 5 integrating indicator for this purpose does not replace the need for the use of AAMI ST46 recommended biological monitoring.

The Association for the Advancement of Medical Instrumentation (AAMI) has published standards and recommended practices for biological monitoring of wrapped goods steam sterilization cycles. The document **Steam Sterilization and Sterility Assurance in Health Care Facilities ANSI/ AAMI ST46** is an American National Standard that carefully details the steps to be taken. Essential information regarding biological monitoring will be presented here in an abbreviated form.

AAMI is accredited by the American National Standards Institute (ANSI) and is well known as one of the principal voluntary standards organizations in the United States. AAMI provides a forum for over 60 technical committees, subcommittees, and working groups that write consensus voluntary

standards for medical devices, technical information reports, and recommended practices. These documents are respected around the world and are used as models and references nationally and internationally. STERIS, as an active corporate member, takes part in writing documents regarding decontamination and sterilization processing.

The PURPOSE of biological monitoring is to determine the efficacy of a particular sterilization cycle (the ability to kill microorganisms). Performing this test does not prove that anything in the load is sterile, however. If a medical device is improperly prepared and/or loaded for sterilization, the sterilant may not be able to make contact with the surface you intend to sterilize. The test does determine whether the items in the load have been subjected to the appropriate conditions for sterilization.

Biological indicators consisting of *Geobacillus stearothermophilus* are used to conduct the test. It is important that the customer/client obtain information from the manufacturer of the biological test indicator regarding the reliability, safety, performance, storage, and handling conditions for their product. Instructions for proper application and use, as well as data on the microbiological testing of their product, are also needed. It is important to use the type of biological indicator specifically designed for monitoring the wrapped goods steam sterilization process.

FREQUENCY OF BIOLOGICAL MONITORING is often a question. The AAMI document indicates that biological test packs should be used to monitor sterilizers:

- **UPON INSTALLATION, RELOCATION, STERILIZATION PROCESS FAILURES & AFTER MAJOR REPAIR** - run three consecutive biological test packs in an otherwise empty chamber and release the sterilizer for use upon three negative results. A major repair is one that could directly affect the efficacy of the sterilization cycle; a repair not only to the sterilizer but also the steam source. A major repair is defined in AAMI ST46 as one that is "outside the scope of normal maintenance, such as weld repairs of the pressure vessel, replacement of the chamber door or a major piping assembly, or rebuilds or upgrades of controls." Preventative maintenance such as rebuilding a solenoid valve is not considered a major repair.

- **ROUTINELY** in a full load, that means at least weekly, but preferably every day the sterilizer is in use.

- **Any load containing IMPLANTABLE devices.**

TEST PACK CONSTRUCTION the AAMI challenge test pack is specifically designed to perform this test. The pack that will be described here was validated as equivalent for use by AAMI in a sequence of round robin testing. A report on the development of the pack and the testing, "Development and Qualification of the 16-Towel Biological Indicator Challenge Test Pack" can be found in the AAMI document **Steam Sterilization and Sterility Assurance in Health Care Facilities**.

This 16-Towel test pack is the only approved pack for the performance of this test, except for those

commercially prepared test packs that have shown equivalency. Performing this biologic test with any other type of test pack is unacceptable/invalid.

THE TEST PACK CONTAINS:

- 16 freshly laundered, but not ironed, absorbent reusable surgical towels, in good condition. Each towel should be approximately 16" x 26" (41 x 66 cm).

- Fold towels lengthwise into thirds and then in half (Figure 1).

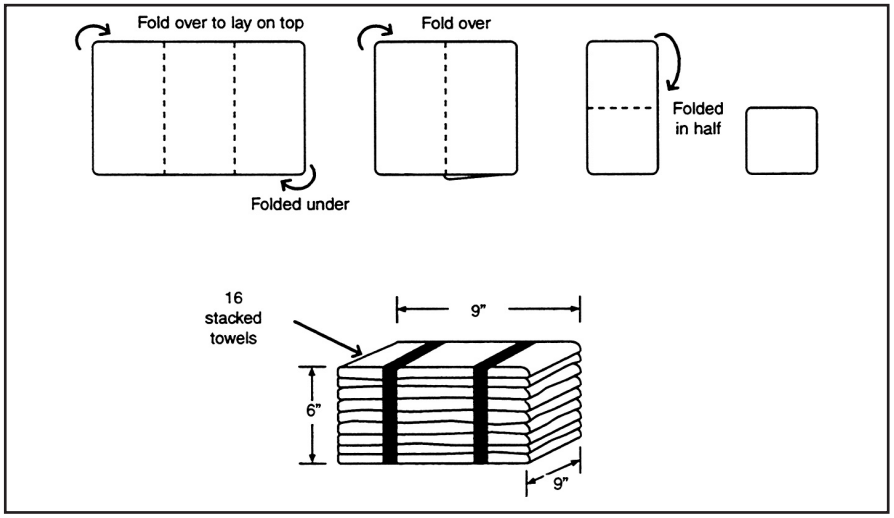

Figure 1. Construction of the 16-towel biological indicator test pack.

- Place towels one upon the other, alternating folded side left to right to form a uniform stack that measures approximately 9" long x 9" wide x 6" high (23 x 23 x 15 cm).

- Place one or more biological indicators between the 8th and 9th towels in the approximate center of the pack. (One biological indicator is usually used.)

- If a chemical indicator is used, it should be placed next to the biological indicator.

- No wrapper is applied.

- Secure the stack using steam chemical indicator tape, being careful to maintain the size of the pack indicated earlier (Figure 1). The pack should weigh approximately 3 pounds.

POSITIONING THE PACK IN THE STERILIZER:

- **AFTER INSTALLATION, RELOCATION, STERILIZATION PROCESS FAILURE & AFTER MAJOR REPAIR** - Place the pack on the sterilizer shelf in an <u>otherwise empty chamber</u>, over the sterilizer drain. Position the pack so that the layers of the towels are sitting flat,

one upon the other, for a greater challenge. (Textile packs are normally positioned with the layers of towels perpendicular to the shelf they sit on) (Figure 2).

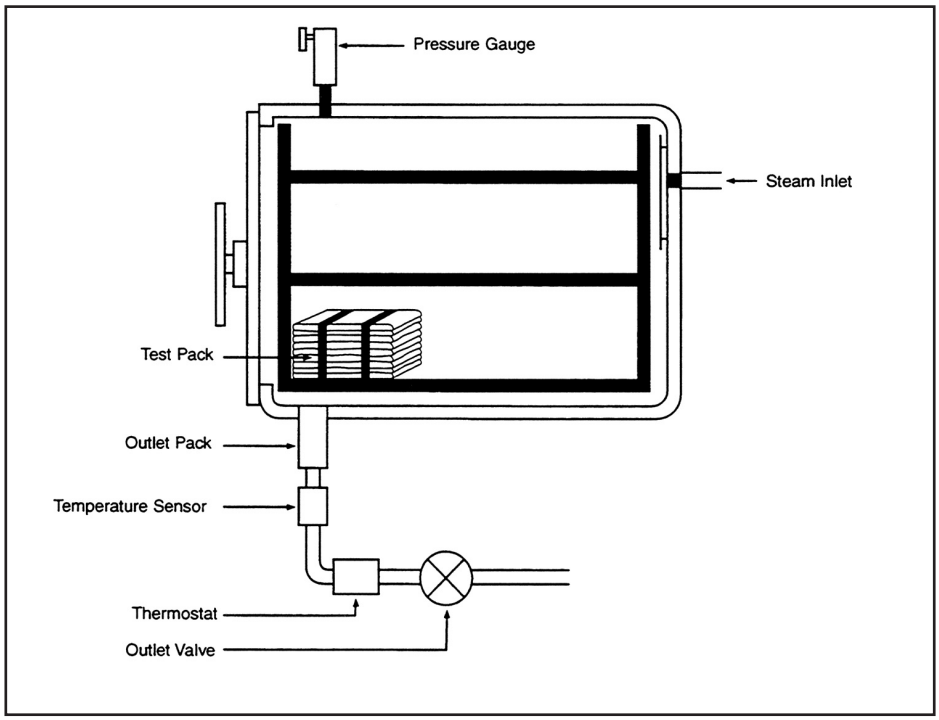

Figure 2. Positioning of the 16-towel biological indicator test pack for installation testing.

- **ROUTINE TESTING AND LOADS WITH IMPLANTABLES** - Place the pack on the sterilizer shelf in a fully loaded chamber, over the drain. Position the pack so that the layers of towels are sitting flat, one upon the other, for a greater challenge (Figure 3).

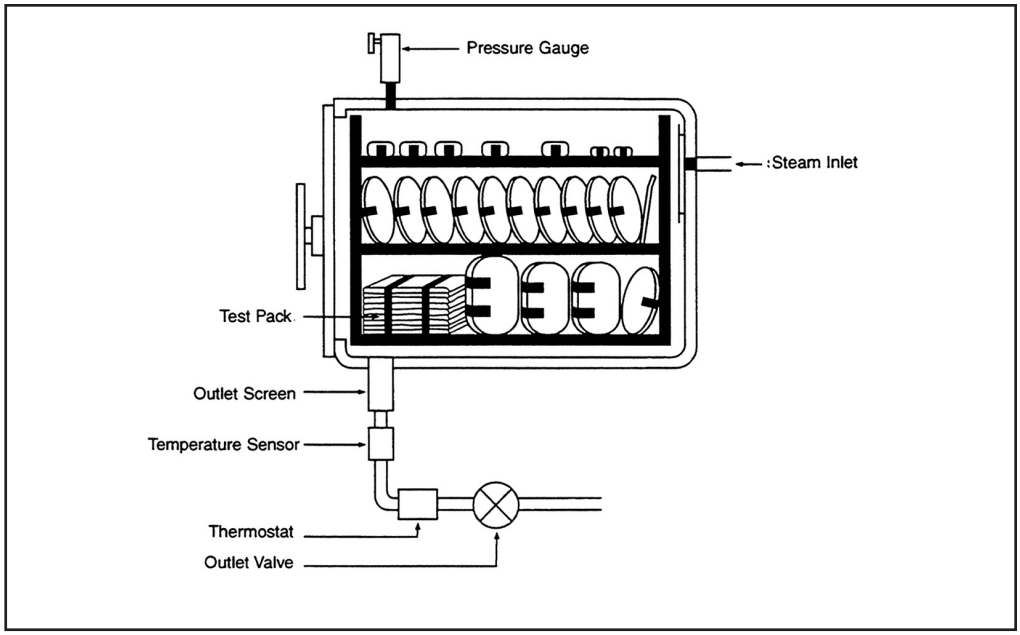

Figure 3. Positioning of the 16-towel biological indicator test pack for routine biological monitoring.

TEST CYCLE PARAMETERS:

A normal cycle is run in each circumstance depending on the type of cycle being monitored, Gravity displacement SFPP, or Prevacuum. The client should consult the Operators manual for appropriate cycle times. Generally speaking, the following would apply for STERIS steam sterilizers:

- **GRAVITY DISPLACEMENT CYCLES -**
  250º F (121º C).....30 minute Exposure Time / use minimum pre-programmed dry time
  270º F (132º C).....15 minute Exposure Time / use minimum pre-programmed dry time

- **PREVACUUM CYCLES -**
  270º F (132º C).....4 minute Exposure Time / use minimum pre-programmed dry time

ACCEPTANCE CRITERIA:

If a POSITIVE biological indicator test result is reported, indicating that the *Geobacillus stearothermophilus* was presumably not killed during sterilization, the manager/supervisor must be notified, who will in turn notify the entire infection control department. A written report should be prepared by the department, which details the following:

- Date and time of the questionable sterilization cycle.

- Description of the load and load control number.

- Cycle results recorded on chart recorders and computer printouts.

- Results of internal chemical indicator within the test pack.

- Any other information that would help to determine if the report was valid or questionable due to human error.

The supervisor should further:

- Ask the laboratory to perform a presumptive identification of the biological specimen to assure that it is *Geobacillus stearothermophilus* that is growing and not a contaminant.

- The supervisor, along with facility maintenance and sterilizer service personnel, will attempt to determine the cause of the POSITIVE result.

- All sterilized items having been processed in the questionable sterilizer since the last good

biological test must be considered unsterile, be retrieved if possible, and then reprocessed. Some might hold the items in quarantine until confirming results on the presumptive lab test.

- Once the cause for the failure has been found and corrected, the sterilizer must be retested and not be released for use until satisfactory biological results are obtained.

- Results of the DAILY AIR REMOVAL TEST should also be examined.

RECORD KEEPING:

The recommended practices from both AAMI and AORN indicate that sterilization records shall be maintained for as long as is required by state and local statutes. It is suggested that the persons involved in setting policy for same include the OR and CS managers, Risk Management, Infection Control, and the healthcare facility's legal counsel and insurance carrier.

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Adapted with permission from the Association for the Advancement of Medical Instrumentation (AAMI) American National Standard, ANSI/AAMI ST46, Steam Sterilization and Sterility Assurance in Health Care Facilities, Arlington, VA.

References:

- Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST46.
  AAMI - 1110 North Glebe Road., Suite 220, Arlington, VA 22201- 4795
  Phone 703-525-4890, 800-332-2264, FAX 703 276-0793

- RECOMMENDED PRACTICES for Sterilization in the Practice Setting.
  AORN - 2170 South Parker Road, Suite 300, Denver, CO 80231-5711
  Phone 800-755-2676

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