Designation: E1766 – 15

Standard Test Method for Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices[1]

This standard is issued under the fixed designation E1766; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers a reproducible procedure for testing processes used to sterilize reusable medical devices (instruments). This test method is not designed to validate a sterilization process, but tests an established sterilization cycle or process. It is a practical test of the effectiveness of a sterilization process applied to reusable medical devices. Bacterial spores more resistant to the test sterilant than the natural bioburden of the instrument are used as the test organisms. Commercially available liquid suspensions of bacterial spores are used to inoculate the instruments.

1.2 This test method is intended for reusable medical devices cleaned in accordance with the device manufacturer's instructions and prepared for sterilization in accordance with the instructions for the sterilization process being used.

1.3 This test method assumes that cleaned, reusable medical devices will be free of visible soil but may have remaining adherent bioburden. A worst-case bioburden can be represented by suspensions of bacterial endospores, which are commercially available for monitoring chemical or physical sterilization processes. These endospores should have a verifiable resistance (D value) to the specific process and sterilant being evaluated.[2]

1.4 It is impractical to test for the sterility of some devices by immersion in growth medium because of their complexity, size, and availability (for long-term incubation) or adverse effects on the devices from long-term immersion. Therefore, elution, rinsing, or swabbing techniques are used to recover test organisms from inoculated devices.

1.5 A recovery control will be included by inoculation of a test device and use of the elution methods without applying the sterilization process being tested. A minimal recovery of 10^6 colony-forming unit (CFU)/mL per device is required for the recovery control.

1.6 Results of the recovery control and process test cycle are compared to determine the effectiveness of the sterilization process.

1.7 Results of the recovery control and applied inoculum are compared to determine the recovery efficiency, if desired.

1.8 The procedure should reveal that tested devices are free of recoverable microorganisms when five or more consecutive tests are conducted.

1.9 A knowledge of microbiological techniques is required to conduct these procedures.

1.10 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

D1193 Specification for Reagent Water

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

2.2 *Other:*

ASTM Poster Presentation : "Use Verification of a Proposed Draft ASTM Standard to Determine the Efficacy of Sterilization Techniques for Reusable Medical Instruments" Presented at the E35.15 Subcommittee meeting in Montreal, Canada

3. Terminology

3.1 *Definitions:*

[1] This test method is under the jurisdiction of ASTM Committee E35 on Pesticides, Antimicrobials, and Alternative Control Agents and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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[2] Oxborrow, G. S., and Berube, R., "Sterility Testing—Validation of Sterilization Processes, and Sporicide Testing," *Disinfection, Sterilization, and Preservation*, Block, S. S., 4th Edition, Lea and Febiger, Philadelphia, PA, 1991, pp. 1047–1058.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3.1.1 *bioburden*—the number and types of viable microorganisms that contaminate a device.

3.1.2 *CFU*—colony-forming unit.

3.1.3 *inoculum*—the number (usually specified as CFUs) and type (genus and species) of viable microorganisms used to contaminate a given sample or device.

3.1.4 *sporicidal agent*—any chemical or physical agent that kills spores.

3.1.5 *sterilant*—any sterilizing agent.

3.1.6 *sterile*—a state of being free of living organisms.

3.1.7 *sterilization cycle or process*—a physical or chemical process that has been demonstrated to meet applicable criteria for sterilization as defined by AAMI.[4]

3.1.8 *sterilizer*—any device using a chemical or physical process that produces sterile materials.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *applied inoculum*—the estimated count of the suspension of bacterial spores expressed as CFU/mL used to inoculate the test devices. This value may be used if the efficiencies of the recovery methods are determined.

3.2.2 *process test cycle*—a complete sterilization cycle that uses all parameters of the sterilization process as dictated by the manufacturer.

3.2.3 *recovery control*—the CFU recoverable from a device following inoculation and optional drying of the spore suspension in or on the unprocessed device. The recovery of $\geq 10^6$ CFUs per device is required.

3.2.4 *recovery efficiency*—a measure of the recovery of inoculated organisms from a device may be determined when necessary. The recovery efficiency may be expressed as the ratio of the CFU from the recovery control compared to the CFU of the applied inoculum. This value is multiplied by 100 to express efficiency as a percent. It is recommended that a minimum of three tests be performed when estimating recovery efficiency.

3.2.5 *reusable medical devices*—any medical device that is claimed to be usable after reprocessing.

3.2.6 *spore*—a bacterial endospore. (Strain identification and the means used to identify whether the vegetative or spore state is present should be indicated.)

3.2.7 *worst-case*—the intentional exaggeration of one or more parameters of a test compared to normal clinical conditions.

4. Summary of Test Method

4.1 Percent recovery of inoculum may be used to ensure reproducible inoculation and recovery techniques.

4.2 The test method is performed by contaminating the cleaned reusable medical device with a bacterial endospore suspension.

4.3 After inoculation, and drying, if required, the device is prepared and processed according to the sterilant or sterilizer manufacturer's instructions.

4.4 Following the sterilization process, the test devices are sampled using specified elution techniques to recover any surviving spores.

5. Significance and Use

5.1 The test method is designed to demonstrate that all accessible surfaces and internal recesses or lumina of previously cleaned, reusable medical devices can be rendered free of recoverable microorganisms when processed in a specified sterilizer cycle.

5.2 Surviving spores are recovered by swabbing, brushing, or irrigating with an elution fluid. Recovery methods may be enhanced by mechanical action, sonication, and repeated flushing with elution fluid.

NOTE 1—The spore inoculation technique described in this test method is only one of the available procedures for testing the sterilization of devices. Spores on paper strips (biological indocators) are a traditional tool used to develop and monitor sterilization cycles and are also appropriate for the evaluation of sterilization of medical devices.[5]

6. Apparatus

6.1 *Syringes,* 10 to 50 mL, sterile.

6.2 *Sterile Cotton Swabs.*

6.3 *Sterile Petri Dishes.*

6.4 *Sterile Test Tubes,* to hold 10 mL.

6.5 *Sterile Glass Bottles,* to hold 50 mL.

6.6 *Steam Sterilizer.*

6.7 *Water Bath,* 48 ± 2°C.

6.8 *Incubator(s),* 35 ± 2°C and 55 ± 2°C.

6.9 *Colony Counter.*

6.10 *Medical Device,* precleaned in accordance with the manufacturer's instructions.

6.11 *Disposable or Reusable Membrane Filter Apparatus,* sterile, 0.45-µm pore size.

6.12 *Micropipette,* calibrated to dispense 5 to 20 µL.

6.13 Other devices or apparatus specified by the sterilant, medical device, or sterilizer manufacturer.

7. Reagents

7.1 *Purity of Reagents*—Reagent grade chemicals shall be used in all tests. Unless otherwise indicated, it is intended that all reagents conform to the specifications of the Committee on Analytical Reagents of the American Chemical Society where

[4] See "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices" (ST27), AAMI, Arlington, VA, 1992, for typical criteria.

[5] *United States Pharmacopeia*, XXIII, or current edition, Rand McNally, Taunton, MA, 1995, pp. 200–206.