This sample policy and procedure is being provided to help you write your own policy and procedure for the use of this product in your facility. This sample should be edited as needed to comply with each facility's policy, procedures and compliance needs. It is the responsibility of each health care facility to develop policies and procedures that comply with its unique needs and allapplicable laws**,** rules, regulations, standards and industry recommended practices. For more information on the recommended use of this product, refer to the Instructions for Use provided with the product.

**Sterile Processing Department**

**Section:** Sterilization

**Title:** Routine Sterilizer Efficacy Monitoring of 4 minute 270°F/132°C and 3 minute 275°F/135°C Pre-vacuum Steam Sterilization Cycles in Sterilizers >2 ft3

**Frequency:** Every load

**Date:** 11/17/2017

**POLICY: Evidence of effective steam sterilization processes will be documented. A commercially available Biological Indicator Process Challenge Device (BI PCD) equivalent in challenge to the AAMI 16 towel PCD is used to monitor every 4 minute 270°F/132°C and 3 minute 275°F/135°C pre-vacuum steam sterilization cycle.**

*Rationale: Per AAMI ST79, all steam sterilizers should be routinely tested using Biological Indicator Process Challenge Devices (BI PCDs). Biological indicators are test systems containing viable microorganisms providing a defined resistance to a specified sterilization process. Biological indicators containing spores of* Geobacillus stearothermophilus *provide a direct measure of the lethality of the steam sterilization process. A quality control program that includes a biological indicator that has tested negative in combination with physical monitors (i.e., sterilizer printouts) that confirm specific time/temperature parameters and external and internal chemical indicators with acceptable end-point responses provide an assurance that the sterilization process was effective. They do not, however, guarantee the sterility of each individual product within the load.*

**Procedure**

1. A 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V is labeled with the appropriate sterilizer load information (sterilizer ID, load number, and processing date).
2. The 1496V challenge pack is placed flat, label side up, on the bottom shelf of the sterilizer over the drain, in each load.
3. The sterilization cycle is run.
4. When the cycle is complete, the 1496V challenge pack is retrieved and opened and the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (1492V BI or test BI) contained within the challenge pack is allowed to cool for 10 minutes. The test BI is then activated and incubated in a 3M™ Attest™ Auto-reader 490 according to the instructions provided in the IFU.
5. A positive control (i.e., unprocessed) 1492V BI having the same lot # as the test BI is incubated each day in the 3M™ Attest™ Auto-reader 490.
6. The result of the control BI is recorded. The Control BI must show a fluorescent positive result (+ symbol on the Auto-reader 490 LCD display) within 1 hour to ensure the test BI result is valid.
7. The final negative reading (- symbol on the Auto-reader 490 LCD display) of the test BI is made at 1 hour and indicates a successful sterilization process. Record the result and discard the test BI. Whenever possible, the load contents are not distributed until the BI result is available.
8. Any positive result for a test BI must be reported to the Manager of the SPD immediately for further investigation and/or action.

**References**

1. ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.*  Section 13.7.
2. 3M™ Attest™ Super Rapid Readout Steam Challenge Device 1496V – manufacturer’s written IFU.