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 (IFU) 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 Dynamic-Air-Removal Steam Sterilization Cycles in Sterilizers >2 ft3

**Frequency**: Daily + Loads Containing Implants

**Date:** 4/13/2020

**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 daily and in all loads containing implants to conduct routine efficacy monitoring of 4 minute 270°F/132°C and 3 minute 275°F/135°C dynamic-air-removal steam sterilization cycles.**

*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 Steam-Plus Challenge Pack 41482V is labeled with the appropriate sterilizer load information (sterilizer ID, load number, and processing date).
2. The 41482V challenge pack is placed flat, label side up, on the bottom shelf of the sterilizer over the drain, in the first full load of the day and in any load containing an implantable device.
3. The sterilization cycle is run.
4. When the cycle is complete, the 41482V 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 removed and allowed to cool for 10 minutes.
5. The 3M™ Attest™ Steam Chemical Integrator contained within the challenge pack is checked. The dark color should have entered the green ACCEPT window. If the dark color has not entered the green ACCEPT window, this indicates a REJECT result which means the load was not exposed to sufficient steam sterilization conditions and should not be released for use. The integrator result is recorded.
6. The test BI is activated and incubated in a 3M™ Attest™ Auto-reader 490, or in a 490H Auto-reader having software version 4.2.7 or greater, or in a 3M™ Attest™ Mini Auto-reader 490M according to the instructions provided in the IFU.
7. A control (i.e., unprocessed) 1492V BI having the same lot # as the test BI is incubated each day in the 3M™ Attest™ Auto-reader.
8. The lot number and result of the control BI are recorded. The Control BI must show a fluorescent positive result (+ symbol on the Auto-reader display) to ensure the test BI result is valid. After incubation, the control BI is steam sterilized and disposed per facility policy.
9. The final negative reading (- symbol on the Auto-reader display) of the test BI indicates a successful sterilization process. Record the lot number and result and discard the test BI.
10. Each load containing implantable medical devices is quarantined until the BI result is negative.
11. Any positive result for a test BI and/or failing chemical integrator result 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.*  Sections 13.6 and 13.7
2. 3M™ Attest™ Super Rapid Readout Steam Challenge Device 41482V – manufacturer’s written IFU.