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 all applicable laws**,** rules, regulations, standards and industry recommended practices. For more information on the recommended use of this product, refer to the package insert that is provided with the product.

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Sterile Processing Department

Section: Sterilization

Title: Load Control for the 270°F/132°C, ≥ 4 minute, Vacuum Assisted or 250°F/121°C, ≥ 30 minute, Gravity Steam Sterilization Process using 3M™ Attest™ Rapid 5 Steam Plus Test Pack, Cat. No. 41382 – Every Load

Date:

POLICY: Evidence of an effective steam sterilization processes will be documented.

Rationale:

1. *Load control is the process by which a load is monitored and released based on the result of a biological indicator. Biological indicators (BI) are designed to equal or exceed the resistance of highly resistant, naturally occurring microorganism on clean medical devices. Biological indicators play a key role in sterilization process monitoring because they respond to sterilization conditions much like "natural" microorganisms. A biological indicator that has tested negative in combination with equipment control (i.e., mechanical readings) that confirm a specific time/temperature profile and exposure and pack control (i.e., 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.*
2. *To Comply with the newest ANSI/AAMI ST79:*2006 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities document, all loads containing implants should be monitored with "a PCD containing a BI and a Class 5 Integrating Indicator or a PCD containing a BI and an enzyme-only indicator."*

Procedure

1**.** Routine biological indicator (BI) monitoring is performed in a fully-loaded sterilizer.

2. A 3M™ Attest™ 41382 Rapid 5 Steam Plus Test Pack is used to monitor the 270°F/132°C, ≥ 4 minute, vacuum assisted or 250°F/121°C, ≥ 30 minute, gravity steam sterilization process.
   [Note: AAMI ST79 states to run with all loads containing implants. It may also be used for routine load monitoring (e.g. daily or every load).]

3. The Attest Rapid 5 Steam Plus Test Pack is identified with the appropriate sterilizer load information.

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4. The Attest Rapid 5 Steam Plus Test Pack is placed on the bottom shelf, over the drain.

5. The frequency of testing with the Rapid 5 Steam Plus Test Pack is every load and quarantine the load until the indicator result is negative at 3 hours. In a documented emergency situation*, the implantable devices may be released from quarantine if the results of the processed 3M™ Comply™ Sterigage™ Chemical Integrator (CI) are within the "Accept" range.

6. The cycle specified by the sterilizer manufacturer is selected and initiated.

7. The Attest Rapid 5 Steam Plus Test Pack is retrieved and:
    a. The 3M™ Attest™ 1292 Rapid Readout Biological Indicator incubated and read according to instructions of the manufacturer of the BI.
    b. The 3M Comply Sterigage CI is taken out of the test pack and the result is read.

8. The result of the BI is recorded (i.e., record keeping control).

9. The result of the CI is recorded and retained as a permanent record (i.e. record keeping control).

10. All positive/reject test results must be reported to the Manager of the SPD immediately for further investigation and/or action.

* Release of implants before the results of the BI are known should be a rare exception. AAMI provides examples of an implant log and an exception form for the premature release of implants.