

Approximately 27,000,000 surgical procedures and an even larger number of invasive medical procedures occur each year in the United States. Each procedure can introduce infection if careful sterilization protocols are not followed.

# HIDA

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## BEST PRACTICES FOR STEAM STERILIZATION PROCESSES

With every surgical procedure performed, instruments and medical devices come into contact with a patient's internal tissue, and can introduce infection if careful sterilization process protocols are not followed.

Biological indicators (BIs), chemical indicators (CIs), and physical monitors are used to routinely monitor and improve the outcome of the steam sterilization process. It is the goal of those working in the sterilization process area to ensure that medical devices are properly sterilized before they contact a patient, thus eliminating the chance of an infection related to the use of a non-sterile medical device.

To ensure that this goal is met, establish policies and procedures for monitoring the sterilization process based on the most stringent laws and regulations, recommended practices and current scientific knowledge. The Association for the Advancement of Medical Instrumentation (AAMI) recommended practice *Steam sterilization and Sterility Assurance in Health Care Facilities*, ANSI/AAMI ST46, 2002 ([www.aami.org](http://www.aami.org)), should be used as a reference. Here are some frequently asked questions on how to ensure the medical devices are properly sterilized.

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### HOW DO I KNOW THAT THE STERILIZER IS WORKING BEFORE I PUT IT INTO ROUTINE USE?

Run a Bowie-Dick test each day in each 272 F vacuum-assisted steam sterilizer. This test is not necessary for gravity steam sterilizers. Follow the ANSI/AAMI ST46 instructions on how to run this test to ensure that the test is done correctly. If the Bowie-Dick test fails, do not use the sterilizer until the problem is corrected. Do not put the sterilizer back into use until three consecutive empty cycles containing Bowie-Dick test packs show the required uniform color change.

### HOW DO I KNOW THAT THE STERILIZER CYCLE IS SET PROPERLY AND THE PARAMETERS ARE BEING MET FOR THE LOAD BEING PROCESSED?

Determine appropriate sterilizer cycle conditions for the load being processed and set the sterilizer for those parameters. Next, monitor each sterilizer load with physical monitors. Check to see that the displays, digital printouts, and gauges that display time, temperature, and pressure are functional prior to running the sterilization cycle. Ensure the correct date and sterilizer cycle identification number are on the physical monitor. At the end of the cycle, read the results and verify the cycle information is correct by recording the operator initials. Sterilizers without these monitors should not be used. Do not use the load if the sterilization cycle information is not correct. Do not use the sterilizer until the problem is identified, corrected, and the sterilizer is re-tested (see additional testing recommended).

### HOW DO I KNOW THAT THE PACKAGES WENT THROUGH THE STERILIZATION PROCESS?

Use externally visible CIs with each package to show that the package went through the sterilization process. External CIs include indicator tape, CIs printed on the outside of peel pouches, and internal CIs that are visible inside peel pouches and unwrapped trays. During the unloading process, check the external CI on each package to ensure that it reached its end point response. If it did not, do not use the package.

Before releasing a package from the sterilization process department for use, recheck the external CI to ensure that the package did go through the sterilization process. When receiving and opening the package at its end use, also check the external CI. Do not issue or use the package if the external CI has not changed.

### HOW DO I KNOW THAT THE STERILANT PENETRATED INTO EACH PROCESSED PACKAGE?

Place a CI inside each package in the area least accessible to the sterilant to know that the sterilant or critical parameters of the sterilization process penetrated into each package and contacted the medical device. Train the person opening the package to determine if the package can be used or should be returned for reprocessing. Do not use a package if the internal CI has not changed.

### HOW DO I KNOW THAT THE STERILIZATION PROCESS IS CAPABLE OF KILLING MICROORGANISMS?

Run a BI containing a known population of microorganisms in a process control device (PCD) or test package that is representative of the load and creates the greatest challenge to the sterilization process to determine if the process killed microorganisms. A self-contained BI with an enzyme-based early readout (i.e., 1 or 3 hours) or a visual color change (i.e., 24 or 48 hours) can be used. Monitoring and releasing the load based on the result of a BI PCD is the most reliable way of testing the ability of the sterilization process to kill microorganisms.

The most stringent recommended practices state that a BI should be run daily in a steam sterilizer, preferably in each load that contains critical items, e.g., instrument sets, individual surgical instruments, or an item that comes into contact with sterile tissue (American Society for Healthcare Central Service Professionals of the American Hospital Association, *Recommended Practice for Central Service, Section Six: Sterilization*, 2001), and every load that contains an implantable medical device. Loads containing implantable medical devices must be quarantined until the BI is negative.

Choose the appropriate BI and PCD for the load being processed. Follow the BI PCD manufacturers' for use and placement of the BI PCD in the load and incubation instructions. ANSI/AAMI ST46, states that each day the test BI is incubated, incubate a positive control BI to confirm that the correct incubation conditions are present, the spores are still viable, and the media was capable of maintaining growth.

If a BI is positive, recall all medical devices from loads processed since the last negative BI. Label each package with a lot control identifier or number that designates the sterilizer identification number or code, date of sterilization, cycle number, and the expiration date/statement. This information is used to retrieve the packages.

Maintain sterilization records where the information from each sterilization cycle is recorded. The records should include lot number, contents of the load, exposure time and temperature, name or initials of the operator, leak test/Bowie-Dick test results for vacuum-assisted steam sterilizers, BI results, response of the internal CI from the BI PCD, and any reports of inconclusive CIs that did not reach their end point response.

### IS THERE ANY ADDITIONAL TESTING RECOMMENDED?

Yes, all steam sterilizers are tested with BIs upon installation, after relocation, malfunctions, major repair, and sterilization process failures. Run three consecutive empty sterilizer cycles with a BI PCD. Test each type of steam cycle used for sterilization separately (e.g., gravity, prevacuum, steam-flush pressure-pulse, "flash"). For 272 vacuum-assisted sterilizer also run the Bowie-Dick test in three separate consecutive cycles. All monitoring results must be acceptable before the sterilizer can be put back into use.

BI and CI testing is also required whenever a change is made that affects any part of the sterilization process (e.g., packaging, loading, type of materials sterilizing). This is called product testing and involves placing BIs and CIs in products, processing the load as usual and determining that the monitoring results are acceptable before the change is made.

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