3M™ Attest™ Rapid Readout
Biological Indicators

Living
Sterility
Assurance
The concept of sterilization was born in the mid 18th century when Lazzaro Spallanzani demonstrated that sealed flasks boiled for a few minutes had living "animalcules," but those boiled for an hour did not.

About a century later, Robert Koch became the first to use bacterial spores as biological indicators (BIs), as they are known today. Koch conducted a series of experiments in which a roll of flannel contaminated with spores was exposed to dry heat. When exposed at 140-150°C for four hours, the spores survived and germinated. When exposed to moist heat at 120°C for 30 minutes, they did not.

The role of spores and the basic science of BIs as a tried and trusted measure of lethality continues today.

Evolution of BIs.

Early BIs, primarily spore strips with a known population of spores, had a readout time of 7 days, which made it difficult to act on the results. What’s more, use of spore strips required the operator to be well trained in aseptic technique. Accidental contamination during the transfer of spore strips into media could cause a false positive result.

The problem was alleviated in the early 1970s, when 3M first introduced self-contained biological indicators (SCBIs) which had the spore strip and nutrient medium within a single container, requiring minimal handling by the end user. In addition, the readout time was reduced to 24-48 hours, which made the results more actionable.

Increased demand for even faster instrument turnaround time in the latter half of the 20th century led to the introduction of rapid readout BIs which provided results in 1, 3 or 4 hours. Today, this technology continues to provide the end user with a direct measurement of cycle lethality.

The monitoring value provided by BIs continues to be unparalleled. Several studies involving a side-by-side comparison of different types of monitors for sterilization effectiveness, have demonstrated the superiority of spores in being able to detect failures such as superheated steam, inability to reach temperature, and inadequate air removal that are often missed by other monitors.

The bottom line

BIs possess a unique ability to identify sterilization process failures which are not picked up by other monitoring technologies.
As a direct measure of lethality, the BI has become the “Gold Standard” for use in identifying sterilization process failures. Even marginal failures caused by the inability to reach temperature, inadequate air removal, or superheated steam can be detected by BIs. For these reasons, and more, many facilities are choosing to follow standards closely and in some cases taking standard practice to the next level when it comes to monitoring with BIs.

The Cost basis for increasing the frequency of use of BIs.

- Statistics from the Centers for Disease Control and Prevention (CDC) show that an estimated 1.7 million Healthcare-Associated Infections (HAIs) occurred in 2002 and were associated with approximately 99,000 deaths. To put this into perspective the loss of life is roughly equivalent to that of a fully loaded Boeing 747-400 series going down every other day for one year. According to the CDC, HAIs are now the sixth leading cause of death in the U.S., killing almost twice as many people as breast cancer and HIV/AIDS combined.
- The costs associated with HAIs can be a crushing burden on hospital budgets. Effective October 2008, the Centers for Medicare and Medicaid Services no longer reimburses healthcare facilities for costs related to certain HAIs that could reasonably have been prevented through the use of evidence-based guidelines.
- Approximately one in ten hospitalized patients will acquire an infection after admission. The CDC estimates the annual cost of dealing with these infections to be $60.7 billion, further contributing to the mounting costs of healthcare within the United States.

CDC (Centers for Disease Control) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

“If a sterilizer is used frequently (e.g., several loads per day), daily use of biological indicators (BIs) allows earlier discovery of equipment malfunctions or procedural errors and thus minimizes the extent of patient surveillance and product recall needed in the event of a positive biological indicator. Each load should be monitored if it contains implantable objects. If feasible, implantable items should not be used until the results of spore tests are known to be negative.”

“Biological indicators are recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e., Bacillus spores), and not by merely testing the physical and chemical conditions necessary for sterilization.”

AAMI (Association for the Advancement of Medical Instrumentation) ST79

“Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization.” “BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.” (10.5.3.1) AAMI recommends weekly, but preferably daily, routine sterilizer efficacy monitoring and sterilizer qualification testing with a biological indicator process challenge device (BI PCD). BIs within PCDs should be used to monitor every load containing implants. BIs should also be used for periodic quality assurance testing. (10.5.3.2)

For loads containing an implantable device, AAMI states that, “Patient safety could be adversely affected by the implantation of a nonsterile device. The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results.” (10.6.3)

AORN (Association of periOperative Registered Nurses) Perioperative Standards and Recommended Practices, 2009

“XVI.h.2. Steam sterilizers: Geobacillus stearothermophilus BIs should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing and periodic product quality assurance testing. Routine sterilizer efficacy monitoring should be done weekly, preferably daily, as follows:
- each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available, and
- one BI PCD should be run in three consecutive empty cycles for sterilizer qualification testing.

If a steam sterilizer is intended to be used for multiple types of cycles (e.g., gravity-displacement, dynamic air-removal, flash), each sterilization mode should be tested.”

Taking best practices to the next level.

The concept of every load monitoring.

Healthcare facilities realize the benefits of monitoring with BIs as a best-in-class solution. Many have taken their monitoring efforts to the next level by moving from standards practice to a BI in every load. Rationale for this change includes improving patient safety with one high standard of care and monitoring, as well as reducing the cost and impact of recalls should a sterilization failure occur. (To learn more about this, ask your 3M representative for information on Every Load Monitoring.)
Living Organisms That Provide A Reliable Test Of Lethality.

How a self-contained BI works.
A self-contained biological indicator (BI) consists of a known population of bacterial spores of a high resistance to the mode of sterilization being monitored. For example, *Geobacillus stearothermophilus* is the most resistant spore for steam, hydrogen peroxide gas plasma, and ozone sterilization. *Bacillus atrophaeus* is the most resistant spore for ethylene oxide (EO) and dry heat sterilization.

The self-contained 3M™ Attest™ BIs consist of a spore strip (spores that are coated on a paper strip) enclosed in a plastic vial along with growth medium contained in a crushable glass ampoule. The cap is designed to allow sterilant to penetrate into the plastic vial, killing the spores and demonstrating that sterilization conditions were met.

How an Attest Rapid Readout BI works.
3M™ Attest™ Rapid Readout Biological Indicators are similar to conventional self-contained BIs. 3M Attest rapid readout BIs for steam detect the presence of *G. stearothermophilus* by detecting the activity of alpha-glucosidase, an enzyme present within *G. stearothermophilus*. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. This fluorescence is detected by the 3M™ Attest™ Auto-reader/incubator. A fluorescence change indicates a steam sterilization process failure. Non-fluorescence indicates inactivation of the enzyme and an effective sterilization process. 3M Attest rapid readout BIs also indicate the presence of viable *G. stearothermophilus* organisms by a visible color change reaction formed by acidic by-products.

Defining Sterility Assurance Level (SAL).
Sterility is defined as being free from all living organisms. Since it is not practical to test every device for the absence of microorganisms, the concept of sterility is expressed as a statistical probability. The sterility assurance level, or SAL, defines the probability of a non-sterile unit for a validated sterilization process. Often this is expressed as a probability of $10^{-6}$, or one chance in one million that a device is not sterile. Biological indicators are used to develop and validate sterilization processes, and thus estimate SAL. A negative BI result indicates that sufficient lethality has been achieved to kill a large population of highly resistant spores whose resistance is far greater than the routine microbial bioburden on reprocessed medical devices.

It’s not just about time.
Both Medical Device Manufacturers and Sterilizer Manufacturers use this concept of SAL to do validation of the sterilization cycle. The typical procedure is to find out the time required to kill a million spores and then double it. Given this, at the beginning of the process all spores are expected to be alive or survive. By the middle of the process all spores should be killed. Based on this rationale, it is perfectly normal for a BI to be inactivated at half the stipulated full cycle time. A negative BI result indicates that sufficient lethality has been achieved to inactivate a large population of highly resistant spores. BIs can also be depended upon to detect if there was a gross or even marginal failure due to, for example, inadequate air removal, failure to reach temperature or superheated steam.

Biological Indicators: Living Organisms That Provide A Reliable Test Of Lethality.
References:
2. Sailaja Chandrapati and Martha Young. To Kill or Not to Kill – A biological indicator story. Managing Infection Control, November, 2008.

Biological Indicator Load Control for The Steam Process.

Process Monitoring

Load Control

The sterilization assurance that Biological Indicators can deliver

<table>
<thead>
<tr>
<th>Biological Indicator (BI) usage:</th>
<th>Frequency of Use*</th>
<th>With What</th>
<th>3M Product Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonimplant loads – Within a PCD, may be used to monitor nonimplant loads.</td>
<td><strong>Nonimplant loads</strong> – May use a BI within PCD.</td>
<td>3M® Attest® Rapid Readout Biological Indicators and Test Packs (results in 1 to 3 hours)</td>
<td></td>
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<tr>
<td>Implant loads – Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 Integrating Indicator.</td>
<td><strong>Implant loads</strong> – A PCD containing a BI and Class 5 integrating indicator in every load</td>
<td>• 1291/1292</td>
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<td>Routine sterilizer efficacy testing – (Within a PCD, should be used weekly, preferably daily each day the sterilizer is used) for routine sterilizer efficacy testing.</td>
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<td>• 1296 PCD</td>
<td></td>
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<td>Sterilizer qualification testing – (Within a PCD, should be used for sterilizer qualification testing after sterilizer installation, relocation, malfunction, major repair or sterilizer configuration in routine use should be tested separately.</td>
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<td>• 1296 PCD for (implant loads)</td>
<td></td>
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<td>3M® Attest® Biological Indicators and Test Packs</td>
<td></td>
</tr>
<tr>
<td>- BIOLOGICAL INDICATOR</td>
<td>Biological Indicator Load Control</td>
<td>3M® Attest® Biological Indicators and Test Packs (results in 24 to 48 hours)</td>
<td>• 1261/1262</td>
</tr>
<tr>
<td>- LOAD CONTROL</td>
<td>• 1276 PCD</td>
<td>3M®™ Comply™ SteriGage™</td>
<td>• 41300 PCD (for loads not monitored with BI Test Pack or PCD)</td>
</tr>
<tr>
<td>- PROCESS MONITORING FREQUENCY OF USE</td>
<td>3M®™ Comply™ SteriGage™ Chemical Integrator Test Pack</td>
<td>3M®™ Comply™ SteriGage™</td>
<td></td>
</tr>
</tbody>
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* Association for the Advancement of Medical Instrumentation, Types and applications for use of sterilization monitoring devices; Table II, ANSI/AAMI ST79:2006/A1:2008

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