Much more about sterilization process monitoring than you ever thought possible
Welcome to your official guide to sterilization process monitoring.

Shrinking health care budgets and growing concerns about health care liability have made a complete and successful monitoring program more important than ever. So you couldn’t have ordered this guide at a better time. Within these pages you’ll find all you need to create a sterility assurance program that’s not only effective, but easy to follow. And for easy reference, we’ve put a chart in the back that includes the various categories of sterilization process monitoring. So, without further delay, we offer you much more about sterilization process monitoring than you ever thought possible.
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Introduction
There are five basic steps in the sterilization process itself: Clean, Prep/Pack, Sterilize, Store and Issue/Use. Sterilization process monitoring impacts just two of these steps, Sterilize and Issue/Use. Monitoring tools verify the outcome of “Sterilize” and supply safeguards to the “Issue/Use” step so that no nonsterile medical devices can go beyond this point. The threat of postoperative infections caused by nonsterile medical devices makes sterilization process monitoring extremely important.
An undetected sterilization process failure can put patients, staff and the financial health of your facility at risk. Additional costs associated with postoperative infections and other health care liabilities, make the implementation of a sterilization process monitoring program an extremely critical practice for all health care facilities.

The 3M Sterilization Assurance Program is a comprehensive and practical approach to sterilization monitoring procedures and methods that you can count on to reduce your risk of undetected sterilization process failure. The 3M Sterilization Assurance Program helps you control and monitor sterilization procedures. It provides you with an easy-to-follow set of guidelines to help ensure safety and product sterility throughout your facility. The 3M Sterilization Assurance Program consists of five separate, but interrelated steps: Load Control, Pack Control, Equipment Control, Exposure Control and Record Keeping. These five
steps monitor every aspect of the sterilization process and help you establish, manage and maintain a consistent protocol for sterilization in your facility.

Health care professionals worldwide have come to trust the complete line of 3M sterilization monitoring products to help them monitor all stages of the sterilization process. 3M sets today’s standard for sterilization process monitoring with dependable, high-performance products, an effective, easy-to-follow program, customer service and technical support.
It’s no accident that Load Control is the first level of control on the list. It is the foundation of a successful sterilization process monitoring program. So, what is it? Load Control is the process by which a load is monitored and released based on the result of a biological indicator (BI) in a test pack.

Only a BI can detect the actual killing of microbial spores inside the sterilizer. This is why Load Control remains the most reliable level of testing you can use. Because if all spores die inside the biological indicator, you have assurance that other infectious organisms have also died inside the sterilizer.

Because it detects the killing of microbial spores, a BI yields information more valuable than any other sterilization process monitor. Other types of indicators may be used to help assess sterilizer performance. However, to reliably validate the performance of the load in the routine sterilization process, you still need to use a BI. In fact, only BIs are currently recognized for use to release loads.
In the long run, regular use of a rapid readout BI is more cost effective because it reduces the risk of recall, the release of contaminated loads, and postoperative patient infections.

The sterilization reliability that only a biological indicator can deliver
with implantables. And, when other monitors indicate a possible sterilizer problem, it’s good practice to revalidate the sterilizer with a BI. Given its many applications, you can see why a BI in every load can be the most practical approach to sterilization process monitoring.

Frequent use of a BI is the most reliable way to control loads.

Here’s another way to look at it: If Load Control is done only once daily, you might assume other loads run during the day were as effectively sterilized as the load that was monitored with a BI. This assumption can lead to a false sense of security, and could allow medical devices that weren’t successfully sterilized to be released. In addition, if you get a positive result with a BI, you need to recall all medical devices since your last negative BI. However, if you’re using a BI in every load, you need to recall and reprocess only the one load. It’s also important to remember that BIs yield faster results today than ever before, some as quickly as one hour.

Given its reliability and the quality of the monitoring information received, regular use of a BI leads to better patient outcomes and improves the performance of the sterilization process.
Accepted practices state that a BI should be used in every load of an EO sterilizer and at least once a day in a steam sterilizer. However, to maintain the highest level of effectiveness, a BI in every load of a steam sterilizer is highly recommended. In addition, BIs should always be used in loads with implantables and during installation testing, ongoing quality assurance, after major repairs, after a positive BI result and during product testing.

*With rapid readout technology, every load can be monitored and efficiently quarantined until the BI result is determined. This will do away with recall and credibility issues.*
The inside counts in sterilization process monitoring

First, trust your biological indicator for Load Control, then trust your chemical indicator for Pack Control.
Pack Control

Now that you’re a believer in the value of Load Control using a BI, we can move on to pack control. It’s defined as the use of chemical indicators for internal monitoring of packs, trays, containers and peel pouches. Internal pack monitoring validates that the sterilant has penetrated to the point of placement in the pack and confirms that sufficient exposure conditions have been met. Sounds good, but what does it mean in English?

The basic idea behind Pack Control is this: By placing a multi-parameter or integrating chemical indicator inside every pack, you can detect “local” problems that sometimes occur due to human error or mechanical malfunction. You see, even with a negative BI result, sometimes the sterilant may not penetrate individual packs. This can be caused by a number of things, depending on your method of sterilization. There could be an air pocket in your steam sterilizer or a small leak in the vacuum system, or the pack itself may be wrapped too densely or the load packed too tightly for the sterilant to...
penetrate. And even a short distance apart, chemical indicators can respond differently than biological indicators.

Again, the advantage of Pack Control is that it allows you to single out individual packs that were not exposed to sufficient sterilization conditions. So if your BI for Load Control is negative but your chemical indicator for a specific pack indicates a problem, you know you have to recall and reprocess only the pack.* The trick is to always trust the indicator that indicates a problem and to remember that Pack Control monitoring serves as a companion tool to Load Control, with the results of Load Control taking dominance over Pack Control monitoring. There are two basic types of chemical indicators for internal pack monitoring in steam and EO sterilizers. The most common is the color strip, which is coated with a sensitive chemical that goes through a color change when exposed to the right conditions for sterilization. These are most commonly multi-parameter indicators, meaning they monitor at least two of the critical parameters of the process (i.e., time and temperature).
A higher order of chemical indicators are the integrating indicators, generally referred to as chemical integrators. These chemical monitors are designed to approximate the response of biological indicators to all the critical parameters of the sterilization process. Chemical integrators are moving-front style indicators which use special color chemistry that advances across a window to accept or reject markings. Both types of chemical indicators provide important information about conditions of exposure inside packs—the essence of Pack Control.

*Remember, if the BI results are positive, every pack in the load must be recalled and reprocessed.
Equipment Control

Equipment Control is a way to find out whether or not your sterilizer is doing its job properly. To do this for vacuum-assisted sterilizers, you begin with an air removal test pack such as a Bowie-Dick test.

When using vacuum-assisted cycles, it is critical that you know your steam sterilizer is removing air efficiently before you start your daily sterilization routine. If your sterilizer has a weak or leaking vacuum, air pockets may form inside the sterilizer and prevent proper steam penetration of some packs in the load. This would likely compromise sterility. To detect air pockets in your sterilizer, you should run either a facility-prepared Bowie-Dick towel pack or a commercially available Bowie-Dick type disposable test pack at the beginning of each day. Both use a chemical indicator inside a challenge pack that will not develop properly if air remains trapped.
Equipment Control reveals if the sterilizer is operating to set conditions of time, temperature, pressure, air removal, moisture conditioning and sterilant exposure.

Keeping the mechanics of sterilization process monitoring running smoothly
If the Bowie-Dick test indicates a problem, you must take the sterilizer out of service until the sterilization problem is identified and serviced, or until the unit is replaced. If the Bowie-Dick test shows no problem, you can begin your daily sterilization routine using the other types of Equipment Control: the use of mechanical monitors and chemical integrator test packs. Mechanical monitors allow you to watch the gauges on the sterilizer and record time, temperature and pressure so you can identify an equipment malfunction before it becomes a problem. Incorrect gauge readings, or readings that vary from set conditions, indicate a malfunction and you should consider the load nonsterile. The sterilizer should be taken out of service until you make adjustments or the problem is corrected.

Another means of Equipment Control in the daily sterilization routine is the use of chemical integrator test packs. The test packs utilize chemical integrators contained inside a porous challenge pack. Designed to approximate the response of biological indicator test packs, chemical integrator test packs should be used in every load that does not contain a biological indicator. Test packs with chemical integrators can serve as a monitoring bridge between BI-monitored loads by providing immediate results on sterilizer performance before the load is released.

**Remember to record your results.**
These Equipment Control tests provide information on how the sterilizer is operating to set conditions of time, temperature and pressure as well as its ability to remove air, promote sterilant penetration in packages and condition the load with moisture (EO). Other sources of failure, such as improper packaging and loading, can be caught with the use of Pack Control mentioned earlier. So you’re set. Well, almost set. There are just a couple more things.
Exposure Control monitors may not be multi-parameter or integrating chemical indicators and must not be used as internal Pack Control monitors.
Exposure Control

Since Pack Control for sealed packs is mainly for user departments once the sealed packs have been distributed, there must be another way for sterilizer operators to know whether sealed packs have been exposed to the sterilization process. Enter Exposure Control.

Exposure Control monitoring is a way to identify processed from unprocessed medical devices at a glance. It assures the operator handling the processed items that the pack has been exposed to the sterilization process without the need to open the pack or check Load Control records. Exposure Control involves the use of chemical indicators that are externally visible.

They can be on a tape used to seal packs, on paper strips that can be placed into peel pouches and unwrapped trays, or on load cards. The one most commonly used for Exposure Control is the indicator tape.
Chemical indicators for Exposure Control tell you only whether they were exposed to the sterilization process. The tape, strip and card undergo a color change when they’ve been exposed to the sterilant. The nice thing about tape is its dual purpose. It’s used as an indicator and as a means to secure packages for sterilization. Indicator tapes come in a variety of formats. Some are made for disposable wraps and contain stronger adhesive. Others are made for reusable wraps. Their adhesive is strong enough to hold the wrap, but light enough to leave no adhesive residue on the wrap when it’s cleaned.

Externally visible chemical indicators for Exposure Control should be used with every package. For unwrapped trays or peel pouches, Pack Control monitoring may eliminate the need for exposure indicators since their result is externally visible. As with other chemical indicators, Exposure Control indicators are available for steam and EO.
Though not as reliable, Exposure Control for sterilization operators is like Pack Control for end users.
The final touch to a complete and successful sterilization process monitoring system is Record Keeping. This level of control documents the materials that have been processed and their monitoring control evidence. It’s a way to keep track of the process using record keeping envelopes, forms and labels. If you’ve ever run into a recall situation that forced you to investigate the source of the problem, you know how valuable this can be.

For example, suppose a sealed pack from a load is delivered to a user department. Several days or even weeks later, it is opened and, as indicated by the Pack Control chemical indicator, it wasn’t exposed to sufficient conditions for sterilization. The pack is recalled so it can be reprocessed. Now suppose that several more packs are recalled within a short period of time and a pattern of failure begins to develop. You need to find the origin of the problem. If you’ve been keeping good records, you should be able to trace each pack backward through the levels of monitoring control to the sterilization event itself. This will make it much easier to diagnose the problem. It’s important to note that by using a BI for Load Control in every load, tracing your steps becomes much less complicated. Yet another good reason to get in the habit of using a rapid readout BI in every load and quarantining until the BI results are available.
Each pack should be labeled so it can be traced back through records in the event of a problem.
This is a lot of information to digest. So, to sum up, here are the basics of what you need to do to maintain the most complete and successful sterilization process monitoring program, followed by a chart you can use as a handy reference. We hope this has been helpful.

**THE BASICS**

For the best results, use a rapid readout biological indicator in each load (**Load Control**); a chemical indicator inside each pack (**Pack Control**); a chemical indicator outside each pack, tray, container or peel pouch (**Exposure Control**); a Bowie-Dick test pack each day in each vacuum assisted sterilizer, read and record the mechanical monitors on the sterilizer, use a chemical integrator test pack in each load not monitored with a biological indicator (**Equipment Control**); and record all the monitoring results in a record keeping system (**Record Keeping**).
## Sterilization Process

<table>
<thead>
<tr>
<th>Process Monitoring</th>
<th>How Often?</th>
<th>With What?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Load Control</strong></td>
<td>Every load.</td>
<td>Rapid readout or standard biological indicator.</td>
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<tr>
<td><em>The sterilization reliability that only a biological indicator can deliver.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pack Control</strong></td>
<td>Every pack.</td>
<td>Multi-parameter chemical indicators or chemical integrators.</td>
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<td><em>The inside counts in sterilization process monitoring.</em></td>
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<tr>
<td><strong>Equipment Control</strong></td>
<td>Air removal: Beginning of each day, after major repairs or for installation testing. Mechanical monitoring: Every load. Integrator test pack: Every load that does not have a BI test pack.</td>
<td>Disposable Bowie-Dick test packs, test sheets for AAMI Bowie-Dick test packs and chemical integrator test packs.</td>
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<tr>
<td><em>Keeping the mechanics of sterilization process monitoring running smoothly.</em></td>
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<td></td>
</tr>
<tr>
<td><strong>Exposure Control</strong></td>
<td>Every pack.</td>
<td>Internal indicator rolls, indicator strips or indicator tapes.</td>
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<td><em>Seeing is believing in sterilization process monitoring.</em></td>
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<tr>
<td><strong>Record Keeping</strong></td>
<td>Label each pack so there is a traceable path to monitoring control records.</td>
<td>Load record cards, load labels, record keeping binders and log books.</td>
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<tr>
<td><em>Documenting the evidence in sterilization process monitoring.</em></td>
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3M is a world-wide leader in sterilization assurance products, helping you to ensure safety and product sterility. Combined with our comprehensive product line as well as 3M’s excellence in innovation, experience and service, we stand ready to put our leadership, products and service to work for you.

For more information about 3M’s Sterilization Assurance Program and the full line of monitoring products, to place an order, or for additional copies of this booklet, call 1 800 563-2921 (English), 1 800 361-4488 (Atlantic Canada), or 1 800 361-2650 (French) or call the 3M representative for your area.