Fundamentals of Sterilization Process Monitoring
Your Guide to Sterilization Process Monitoring

Within these pages you’ll find resources to help you 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.

Once you understand the basics, 3M™ Sterile U has many additional educational resources dedicated to improving competency and confidence in the field of sterility assurance.

To learn more about 3M Sterile U, please contact your 3M Sales Representative or contact our 3M Health Care Help Line at 1-800-228-3957.

3M is proud to be your preferred provider of both innovative monitoring products and education solutions.
1 The 5 Steps to Sterile
There are five essential steps in instrument reprocessing: 1) Clean & Disinfect, 2) Prep & Pack, 3) Sterilize, 4) Store, and 5) Issue or Use.

2 3M Sterilization Assurance Program
The 3M Sterilization Assurance Program is a comprehensive and practical approach to sterilization monitoring procedures and methods you can count on to reduce your risk of undetected sterilization process failures.

3 Equipment Control
Equipment Control is a way to find out whether or not your sterilizer is doing its job properly. To monitor dynamic-air-removal (i.e., vacuum-assisted) steam sterilizers, you begin each day with a Bowie-Dick type test to detect air leaks, inadequate air removal, and inadequate steam penetration.

5 Load Control
Load Control, the foundation of a successful sterilization process monitoring program, is the process by which a load is monitored and released based on the result of a biological indicator (BI) in a process challenge device (PCD).

7 Pack Control
Pack Control is the use of chemical indicators for internal monitoring of packs, trays, containers and peel pouches.

9 Exposure Control
Exposure Control monitoring products are a way for sterilizer operators to know at a glance whether packs have been exposed to the sterilization process.

10 Record Keeping
The final step to a complete and successful sterilization process monitoring system is Record Keeping which provides documentation that items have been processed along with evidence of their monitoring results.

11 Answers to the Test Your Knowledge Questions

12 Steam Sterilization Process

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Here are the basics of what you need to do to maintain a comprehensive sterilization process monitoring program.
The 5 Steps to Sterile

There are five essential steps in instrument reprocessing: 1) Clean & Disinfect, 2) Prep & Pack, 3) Sterilize, 4) Store, and 5) Issue or Use.

Monitoring tools verify the outcome of the “Sterilize” step and supply safeguards to the “Issue/Use” step, so patients are not exposed to non-sterile medical devices. The threat of surgical site infections (SSIs) caused by non-sterile devices makes following every step in sterilization process monitoring absolutely critical.

The fact that your instruments have been run through the sterilizer does not guarantee they’re sterile. Many things can adversely affect the sterilization process, including:

- Improper loading or packaging
- Sterilizer malfunction
- Incorrect time or temperature
- Incomplete air removal
- Sterilant failing to reach the center of the pack
- Steam quality issues

1) Clean & Disinfect

Cleaning and disinfecting is critical to the sterilization process. Soil CANNOT be sterilized, so the presence of soil or organic material on instruments reduces the effectiveness of disinfection or sterilization. If your instruments need to be high level disinfected, you must check the concentration of the high level disinfectant in the processor/soaking tray to ensure it is at or above the minimum effective concentration. When timelines are tight and ORs are requesting quick turnarounds, there may be pressure to cut corners in the cleaning process. Failure to thoroughly clean and disinfect items for sterilization, however, can jeopardize the entire process.

2) Prep & Pack

When preparing items for sterilization, instruments should be dried and inspected for cleanliness and functionality. Multipart instruments should be disassembled. Instruments should be held open and unlocked. Whether using sterilization wrappers, paper-plastic pouches or rigid container systems, it’s important to properly place Internal and External Chemical Indicators to effectively monitor sterilant penetration and other exposure conditions. AAMI and AORN recommend labeling each individual pack, so items can be located easily in the event of a recall.

3) Sterilize

Next, instruments are exposed to the actual sterilant (steam, ethylene oxide, etc.). Successful sterilization depends on sterilant contact with all surfaces for the prescribed time. To ensure effective sterilization, the process must be monitored routinely through equipment displays and printouts and also through proper selection and use of Biological and Chemical Indicators.

4) Store

Packages are removed from the sterilizer and quality system documentation is completed. Appropriate storage is required to ensure the integrity of the packaging and the continued sterility of the packages.

5) Issue or Use

Finally, upon request, items are retrieved from storage, checked again to ensure the external Chemical Indicator has reached its endpoint, and then issued for use. Once in the OR, the Internal Chemical Indicators are checked to ensure that the sterilization process was sufficient to penetrate inside of the pack.
3M Sterilization Assurance Program

An undetected sterilization process failure can put patients, staff and the financial health of your facility at risk. Additional costs associated with surgical site 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 you can count on to reduce your risk of undetected sterilization process failures. 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 patient safety and product sterility throughout 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 a comprehensive monitoring portfolio, the 3M™ Sterile U education program, world class technical service support and expert sales support.

The 3M Sterilization Assurance Program consists of five separate, but interrelated steps: Equipment Control, Load Control, Pack 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.
Equipment Control

Equipment Control is a way to find out whether or not your sterilizer is doing its job properly. To monitor dynamic-air-removal (i.e., vacuum-assisted) steam sterilizers, you begin each day with a Bowie-Dick type test to detect air leaks, inadequate air removal, and inadequate steam penetration.

When using dynamic-air-removal (i.e., 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 an inadequate vacuum, air leak or poor steam quality, air pockets may form inside the sterilizer and prevent proper steam penetration of some packs in the load. This would likely compromise sterility.

Test Your Knowledge

1. Should you run a warm-up cycle before you run your Bowie-Dick (BD) cycle?
2. Where do you place your BD type test pack in the sterilizer?
3. Is it OK to run your Bowie-Dick type test with another Bowie-Dick type test or Biological Indicator PCD?
4. If you have a BD failure, what steps should you take?

Answers on page 11
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 process challenge pack that will not develop properly if air remains trapped.

If the Bowie-Dick test shows no problem, you can begin your daily sterilization routine. If the Bowie-Dick test indicates a problem, the sterilizer should be removed from use and your supervisor should be notified.

Equipment Control Monitoring continues throughout the day as you check the physical monitors on your sterilizers. Physical monitors are the gauges on the sterilizer that 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 non-sterile. The sterilizer should be taken out of service until you make adjustments or the problem is corrected.

In summary, Equipment Control tests provide information on how the sterilizer is performing 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 detected with the use of Pack Control.
Load Control

Load Control, the foundation of a successful sterilization process monitoring program, is the process by which a load is monitored and released based on the result of a biological indicator (BI) in a process challenge device (PCD). According to ANSI/AAMI ST79, for routine sterilization efficacy monitoring, a BI PCD should be used preferably every day a steam sterilizer is used and in every load of implantables which should be quarantined until the BI result is negative. This recommended practice refers to all sizes of steam sterilizers:

- Sterilizers larger than 2 cubic feet,
- Table-top sterilizers,
- Immediate-use steam sterilization cycles (I USS).

Only a BI can detect the actual killing of microbial spores inside the sterilizer. This is why Load Control using BI PCDs remains the most reliable level of testing you can use. If all spores die inside the BI, 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.

For sterilizers larger than 2 cubic feet, testing with a BI PCD is done with a full load for each type of cycle utilized (ie. gravity displacement, dynamic-air-removal). Other types of indicators may be used to help assess sterilizer process performance, but a BI PCD in each load provides the highest level of assurance regarding the lethality of the sterilization process.

If a BI PCD is run 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 PCD. 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, then you need to recall all loads processed in that sterilizer back to the last load having a negative BI. In addition, the sterilizer should be taken out of use and the cause of the positive BI should be investigated. If the sterilizer requires a major repair, the sterilizer will need to be requalified before putting it back into use. Reference AAMI ST79 Section 10.8 for more information about Sterilizer Qualification Testing.

In ANSI/AAMI ST79, a BI PCD containing a BI and a Class 5 integrating indicator is recommended practice for releasing loads with implantables. Why? Because if an emergency situation requires the release of an implant before the BI result is known, a Class 5 integrating indicator provides you with more information regarding the sterility of that item than just the sterilizer physical monitor results.

Another Load Control monitoring option is to use a Class 5 integrating integrator in a PCD that is representative of the load to release non-implant loads or loads that do not contain a BI PCD. The use of a Class 5 CI PCD does not replace the use of BI PCDs for release of implant loads, routine sterilizer efficacy testing, sterilizer qualification testing or other product testing because Class 5 integrating indicators do not contain spores and thus do not directly measure the lethality of a sterilization cycle (ANSI/AAMI ST79).

It can, however, serve as a monitoring bridge between those loads monitored with a BI PCD by providing immediate results on sterilizer process performance before the load is released.

Test Your Knowledge

1. What is the AAMI ST79 recommended practice for monitoring implant loads?
2. How frequently should you incubate a positive control?
3. If the BI in your Process Challenge Device (PCD) is positive, which load must be recalled?
4. Describe how you select the appropriate configuration of a BI PCD?

Answers on page 11

In the long run, regular use of a rapid readout BI is more cost effective because it reduces the risk of recall and the release of contaminated loads.
What about monitoring immediate-use steam sterilization (IUSS) cycles? Each type of sterilization mode used and each type of tray configuration used in IUSS sterilization should be tested with a BI PCD. Routine sterilizer efficacy monitoring of IUSS sterilizers is done in an empty load and the BI PCD is placed on the bottom shelf of the sterilizer directly above the drain.

For table-top steam sterilizers that generate their own steam when distilled or deionized water is added, place the BI PCD in the most challenging area for the sterilant to penetrate, as is recommended by the sterilizer manufacturer. Each type of sterilization mode or cycle used (e.g., unwrapped instruments, wrapped instruments) should be tested. The BI PCD should be representative of the same type of package or tray routinely sterilized, and that presents the greatest challenge. For example, a wrapped package would most likely create a greater challenge for air removal and steam penetration than items in a peel pouch.

Therefore, the BI PCD for this example would have a BI placed in the geometric center of a wrapped instrument set. Place an internal chemical indicator next to the BI. Testing is done with a full load.

BI s should also be used for other types of testing, such as product testing and sterilizer qualification testing.

Finally, what about Low Temperature Sterilization? Accepted recommended practices state that a BI PCD should be used in every load in EO sterilizers, and daily but preferably each load in hydrogen peroxide gas plasma, and ozone sterilization processes.

What is Routine Sterilizer Efficacy Testing? (defined in AAMI ST79 Section 10.7)
Establishing a regular pattern of testing the efficacy of the sterilizer if you do not monitor each load with a BI PCD.
Pack Control

Pack Control is the use of chemical indicators for internal monitoring of packs, trays, containers and peel pouches. Internal pack monitoring verifies that the sterilant has penetrated to the point of placement in the pack and confirms that specific exposure conditions have been met. Sounds good, but what does that really mean?

The basic idea behind Pack Control is this: By placing an internal indicator inside every pack, you can detect “local” problems that sometimes occur due to human error, sterilizer malfunction or sterilant quality problems. You see, even with a negative BI result, sometimes the sterilant may not penetrate individual packs. Pack Control failure can be caused by a number of things, depending on the method of sterilization:

- there could be an air pocket in the steam sterilizer or a small leak in the vacuum system;
- not enough sterilant or poor quality;
- the pack itself may be wrapped too densely;
- the load packed too tightly for the sterilant to penetrate.

Test Your Knowledge

The BI in your PCD is negative, but the OR reports that the Chemical Integrator inside of the packs was a reject.

1. What are some possible causes for this pack failure?
2. What action should you take with the pack?
3. What action should you take with the load?

Answers on page 11
The advantage of Pack Control is that it allows you to single out and reprocess individual packs that were not exposed to sufficient sterilization conditions. So if your BI for Load Control is negative but your Chemical Indicator (CI) for a specific pack indicates a problem, the contents of that pack should not be used and should be reprocessed. Use professional judgment about whether to recall other packs processed in that load. If the BI is still incubating, quarantine the rest of the load until the BI results are available. If the load was not monitored with a BI PCD, determine whether to recall that sterilized load based on the sterilizer physical monitor results and the results of CIs elsewhere in the load. Always trust the indicator that indicates a problem and remember that Pack Control monitoring serves as a companion tool to Load Control, with the results of Load Control superceding Pack Control monitoring*. There are different types of chemical indicators for internal pack monitoring in steam sterilizers. These CIs are designed to react to two or more of the critical variables required for steam sterilization to occur: time, temperature and the presence of steam. They are designated by ANSI/AAMI/ISO 11140-1:2005 as Class 4, Class 5 or Class 6 Chemical Indicators. It’s important to note the Classes of Chemical Indicators have no hierarchical significance, meaning a Class 6 CI is not better than a Class 5 CI, etc.

The chart below summarizes the design differences between Chemical Indicators utilized for Pack Control.

*Remember, if the BI results are positive, you need to recall and reprocess all medical devices processed since your last negative BI no matter what the result of pack control monitoring.

<table>
<thead>
<tr>
<th>Class 4: Multi-Variable Indicators</th>
<th>Monitors two or more of the critical variables required for steam sterilization; usually paper strips printed with a chemical indicator ink.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 5: Integrating Indicators</td>
<td>Monitors all three critical variables required for steam sterilization. Their three Stated Values are generated to be equivalent to, or exceed the performance requirements for BIs (per ISO 11138). This means their results provide more information about the effectiveness of the sterilization process than Class 4 or Class 6 chemical indicators.</td>
</tr>
<tr>
<td>Class 6: Emulating Indicators</td>
<td>Reacts to all three critical variables required for steam sterilization for a specific sterilization cycle. A unique Class 6 CI is required for each time and temperature steam sterilization cycle. Unlike the Class 5 Integrating Indicator, the response does not necessarily parallel the time/temperature response of a Biological Indicator.</td>
</tr>
</tbody>
</table>

Class 4, Class 5, and Class 6 Chemical Indicators provide important information about conditions of exposure inside packs – the essence of Pack Control. When selecting a Chemical Indicator for Pack Control, it’s important to understand the differences between indicators so you can make informed decisions about which CI will provide the most accurate information regarding the sterilization conditions achieved inside the pack.
Exposure Control

In most cases, sterilizer operators will not inspect Chemical Indicators used inside sealed packs since they will be opened in the OR or another department. Exposure Control monitoring products are a way for sterilizer operators to know at a glance whether packs have been exposed to the sterilization process. 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 monitors are Class 1 Process Indicators that undergo a color change when they’ve been exposed to the sterilant. They are used to indicate that the unit (i.e., packs, containers) has been directly exposed to the sterilization process and to distinguish between processed and unprocessed items.

Some common types of Class 1 Process Indicator used for Exposure Control are indicator tape and security locks for containerized systems.

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 removed.

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.

An external chemical indicator should be used with every package unless the internal chemical indicator is visible.

Exposure Control Products

As with other chemical indicators, Exposure Control indicators are available for steam, EO, and hydrogen peroxide gas plasma.

- Steam Tape
- Steam Tape for Disposable Wraps
- EO Tape
- Gas Plasma Tape
- Instrument Protector Card

Test Your Knowledge

1. What are common types of exposure control monitoring products?
2. How does the use of exposure control monitors help prevent the use of unsterilized instruments?

Answers on page 11
Record Keeping

The final step to a complete and successful sterilization process monitoring system is Record Keeping which provides documentation that items have been processed along with evidence of their monitoring results. Record keeping envelopes, forms, labels and electronic systems are common documentation tools. If you’ve ever run into a recall situation that required 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. 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 back through the levels of monitoring control to the sterilization event itself making 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.

Test Your Knowledge

1. For each load that is sterilized, what information should be documented in your permanent records?

   Answers on page 11
## Answers to the Test Your Knowledge Questions

### Equipment Control

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Should you run a warm-up cycle before you run your Bowie-Dick (BD) cycle?</td>
<td>Yes, the Bowie-Dick cycle should always be run in a warm sterilizer to avoid false failures.</td>
</tr>
<tr>
<td>(2) Where do you place your BD type test pack in the sterilizer?</td>
<td>On the bottom shelf, over the drain, in an otherwise empty sterilizer.</td>
</tr>
<tr>
<td>(3) Is it OK to run your Bowie-Dick type test with another Bowie-Dick type test or BI PCD?</td>
<td>No, only one BD type test pack should be run in an empty load so residual air left in the chamber can be entrapped inside the single BD type test pack.</td>
</tr>
<tr>
<td>(4) If you have a BD failure, what steps should you take?</td>
<td>If the Bowie-Dick type test indicates a problem, the sterilizer should be removed from use and your supervisor should be notified.</td>
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### Load Control

<table>
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<tr>
<th>Question</th>
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<tbody>
<tr>
<td>(1) What is the AAMI ST79 recommended practice for monitoring implant loads?</td>
<td>Implant loads should be monitored with a BI PCD that also contains a Class 5 Integrating Indicator. The implant should be quarantined until the BI results are negative.</td>
</tr>
<tr>
<td>(2) How frequently should you incubate a positive control?</td>
<td>Every day a test BI is incubated.</td>
</tr>
<tr>
<td>(3) If the BI in your Process Challenge Device (PCD) is positive, which load must be recalled?</td>
<td>All items from that load, and all items from loads processed since the last load with a negative BI result. These items should be considered non-sterile and need to be reprocessed.</td>
</tr>
<tr>
<td>(4) Describe how you select the appropriate configuration of a BI PCD?</td>
<td>The PCD should be representative of the contents of the load and should create the greatest challenge you would find in that load. (i.e. if you are running a 270°F gravity cycle with a rigid container system; the BI PCD should be a blue cap (1491 or 1291) in a rigid container system; if you running a 270°F pre-vac cycle with a mixed load, you should use a 1496V, 1296, 41482V or 41382 PCD).</td>
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### Pack Control

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</tr>
</thead>
<tbody>
<tr>
<td>(1) What are some possible causes for this pack failure?</td>
<td>Pack is too dense, incorrect loading, and/or incorrect sterilization cycle for pack contents could all cause a pack to fail.</td>
</tr>
<tr>
<td>(2) What action should you take with the pack?</td>
<td>The pack should be sent back for reprocessing.</td>
</tr>
<tr>
<td>(3) What action should you take with the load?</td>
<td>In this scenario, because the BI was negative, you could decide to issue the remaining packs from the load. If the BI results were not available when the pack failure was discovered, the load contents should be quarantined until the BI results are known.</td>
</tr>
</tbody>
</table>

### Exposure Control

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) What are common types of exposure control monitoring products?</td>
<td>Indicator tape and security locks for containerized systems.</td>
</tr>
<tr>
<td>(2) How does the use of exposure control monitors help prevent the use of unsterilized instruments?</td>
<td>The purpose of exposure control monitors is to distinguish between unprocessed and processed items, so an unsterilized pack or container is not mistakenly put into use.</td>
</tr>
</tbody>
</table>

### Record Keeping

<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| (1) For each load that is sterilized, what information should be documented in your permanent records? | - Assigned lot number including sterilization date, sterilizer identification and cycle number  
- Specific contents of the load  
- Exposure time and temperature if not provided on the sterilizer print-out  
- Name or initials of operator  
- Results of BI testing and results of Bowie Dick testing  
- Response of CI placed in PCD  
- Any reports of inconclusive or non-responsive CIs found later in the load |
### Steam Sterilization Process

|----------------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Equipment Control - Keeping the mechanics of sterilization process monitoring running smoothly | Beginning of each day, after installation, relocation, malfunctions and major repairs and after sterilization process failures. **Physical monitoring**: Every load | - Disposable Bowie-Dick type test packs (Class 2)  
- Bowie-Dick test sheets in an AAMI towel pack  
- Physical monitors read and recorded for each load | 3M™ Comply™ Bowie-Dick Test Packs  
- 00135LF (with Early Warning sheet)  
- 1233LF |

| Load Control - The sterilization reliability that only a biological indicator can deliver | Routine Testing: Daily, preferably every load  
Sterilizer Qualification Testing: After installation, relocation, malfunctions and major repairs and after sterilization process failures  
Implant Load Release: Each load that contains an implantable device | - PCD containing a rapid readout biological indicator in every load  
- PCD containing a BI and Class 5 integrating indicator in every load containing implants  
- A PCD containing a Class 5 integrating indicator in every load that does not have a BI PCD | **3M**™ Attest™ Super Rapid Readout Biological Indicator System (results in 30–60 minutes)  
- 1491/1492V  
- 1496V/1496VF  
- 41482VF  
**3M**™ Attest™ Rapid Readout Biological Indicators and Test Packs (results in 1–3 hours)  
- 1291/1292  
- 1296 PCD  
- 41382 PCD (for implant load)  
**3M**™ Comply™ (SteriGage™) Chemical Integrator Test Pack  
- 41360 PCD (for loads not monitored with BI PCD) |

| Pack Control - The inside counts in sterilization process monitoring | Every pack | - Class 4 multi-variable indicators, Class 5 integrating integrators, or Class 6 emulating indicators | **3M**™ Comply™ (SteriGage™) Chemical Integrators  
- 1243A/1243B/1243E (ANSI/AAMI/ISO Class 5)  
**3M**™ Comply™ Chemical Indicators  
- 00107  
- 00109/00109A  
- 1250 (ANSI/AAMI/ISO Class 4) |

| Exposure Control - Seeing is believing in sterilization process monitoring | Every pack | - Indicator tapes or other devices to seal packs, load record cards | 3M™ Comply™ Steam Indicator Tapes  
- 1322  
- 1355 |

| Record Keeping - Documenting the evidence in sterilization process monitoring | Label each pack so there is a traceable path to monitoring control records | - Load record cards, load labels, record keeping binders and log books, electronic record keeping systems | Ask your 3M Sales Rep about our full line of log books, envelopes, record charts, and label gun systems |

* 3M Sterilization Assurance Monitoring Products are also available for Ethylene Oxide and Hydrogen Peroxide Gas Plasma sterilization processes. Contact your 3M Sales Rep for a full line catalog.

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**Wrap Up**

This is a lot of information to digest. To sum up, here are the basics of what you need to do to maintain a comprehensive sterilization process monitoring program.

**Equipment Control**
1. Use a Class 2 Bowie-Dick Test Pack each day in each vacuum-assisted steam sterilizer.
2. For all loads, read and record the physical monitors on the sterilizer.

**Load Control**
3. Use a Rapid readout biological indicator in each load; a BI PCD that contains a Class 5 integrating indicator must be used in all implant loads.
4. Use a Class 5 Chemical integrator PCD in each load not monitored with a biological indicator as an additional monitoring tool.

**Pack Control**
5. Use a Class 4, Class 5 or Class 6 Chemical indicator inside each pack.

**Exposure Control**
6. Use a Class 1 Chemical indicator outside each pack, wrapped tray, container or peel pouch, unless the internal CI is visible.

**Record Keeping**
7. Record all the monitoring results in a record keeping system.
3M is a worldwide leader in sterilization assurance products, helping you to ensure patient 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.

3M™ Sterile U Network provides educational services and training resources, provided by 3M and dedicated to improving competency and confidence in the field of sterility assurance.

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 the 3M Health Care Customer Helpline at 1-800-228-3957, or contact your local 3M sales representative.

Outside the United States, contact the local 3M subsidiary.