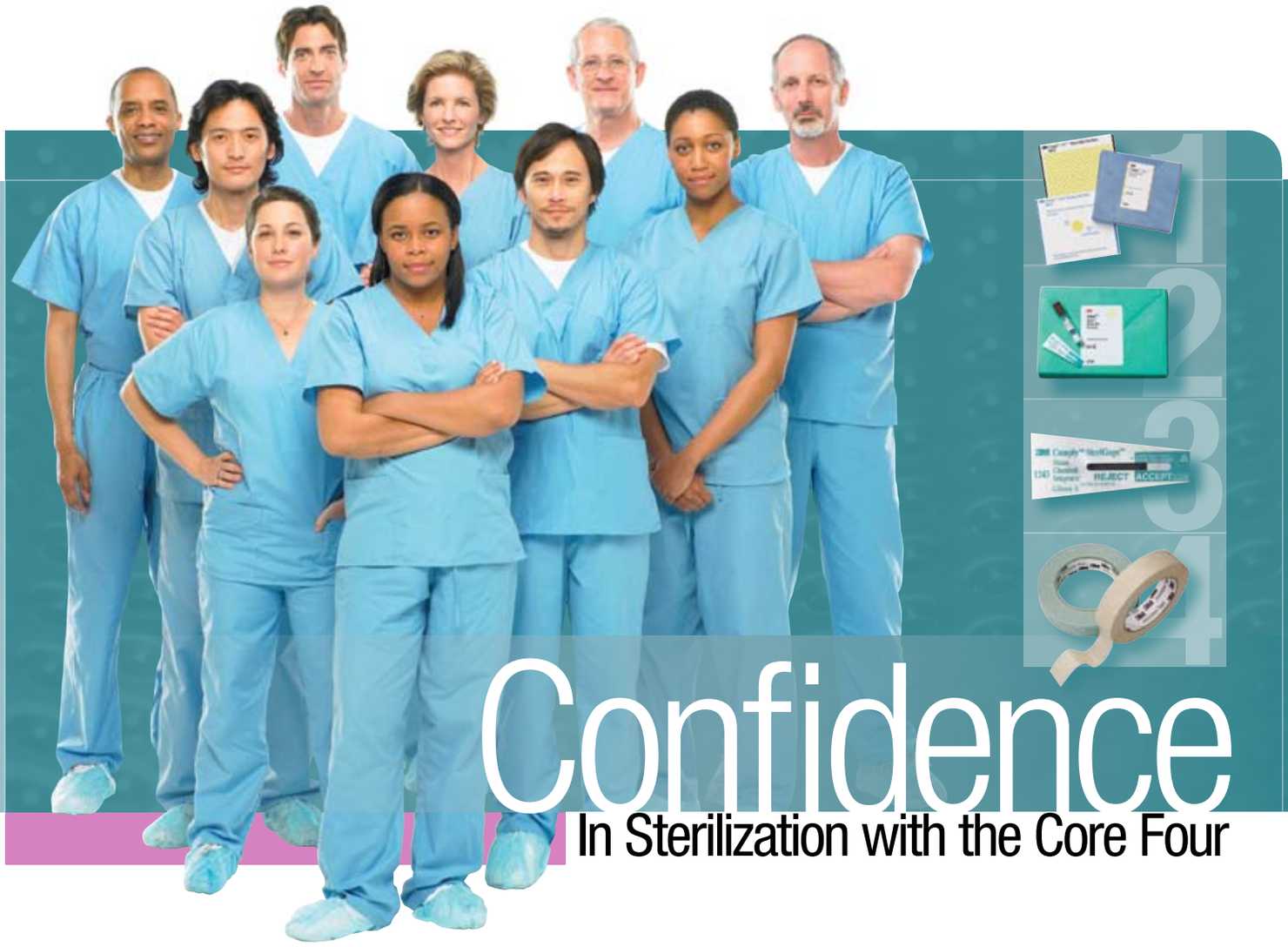
3M™ Sterilization Assurance
Standards Practice



Confidence
In Sterilization with the Core Four

3M

1 Equipment Monitoring

Equipment Monitoring is a way to find out whether or not your sterilizer is doing its job properly. To monitor vacuum-assisted steam sterilizers, you begin each day with a Bowie-Dick type test to detect air leaks, inadequate air removal, inadequate steam penetration and the presence of non-condensable gases, any of which can compromise sterility.

3M™ Comply™ Bowie-Dick Plus Test Pack

- Indicates problems due to air leaks or inadequate vacuum during the air removal test cycle.
- Early Warning Test Sheet provides advance notice of sterilizer problem.
- Chemical indicator ink retains final result so test sheet can be filed for quality assurance records and later compared to current results if a change in sterilizer performance occurs.
- Yellow to brown/black indicator ink color change is easy to interpret.

Putting Standards into Practice

(1) The Bowie-Dick test should always be run in a warm sterilizer to avoid false failures.

(2) Place your BD Process Challenge Device (PCD) on the bottom shelf of the cart, over the drain, in an empty sterilizer.

2 Load Monitoring

Load Monitoring 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). Only a BI can detect the actual killing of microbial spores inside the sterilizer. If all spores die inside the BI, you have assurance that other infectious organisms have also died inside the sterilizer.

3M™ Attest™ Rapid 5 Test Pack

- Includes a 3M™ Attest™ Rapid Readout biological indicator (BI) that provides results in three hours and a 3M™ Comply™ (SteriGage™) moving front Class 5 Integrating Indicator.
- Meets AAMI ST79:2006/A1:2008 steam sterilization guidelines for process challenge device load monitoring requirements of implants.
- Reduces quarantine time by 88% providing BI results in 3 hours compared to 24 hour BI's.
- Enables you to make decisions and take action prior to surgery, reducing the risk and costs associated with recalls and surgical site infections.

Putting Standards into Practice

(1) A positive control should be incubated each day a test BI is incubated in each 3M™ Attest™ Auto-reader.

(2) If a test BI is positive, all items from that load and all items from loads processed since the last load with a negative BI result should be recalled and reprocessed.

(3) Loads containing implants should be quarantined until the BI results are known.

Pack Monitoring

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Pack Monitoring is defined as 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 of the chemical indicator in the pack and confirms that specific exposure conditions have been met.

3M™ Comply™ (SteriGage™) Chemical Integrator

- Conforms to ANSI/AAMI/ISO 11140-1:2005 Class 5 Integrating Indicator performance requirements which ensures the response correlates with a BI at three time/temperature relationship under ideal steam sterilization conditions.
- For use in all 245-280°F steam sterilization cycles which eliminates the potential error of selecting the incorrect Class 6 cycle-specific emulating indicator and reduces your chemical indicator inventory.
- Migrating “moving front style” ink technology provides instant “Accept” or “Reject” results at a glance that do not require color interpretation. A study is available that shows higher reading accuracy than color-change indicators.
- Confirmed by BSI, a leading global independent Product Testing Services Company, to meet the performance requirements of ISO 11140-1:2005.

Putting Standards into Practice

(1) Place an integrator in the geometric center of each pack, peel pouch or unwrapped tray to be steam sterilized. In rigid containers, place an integrator in opposite corners of each level. In multi-level wrapped containers supplied by the manufacturer, place an integrator in the center of each level.

(2) If a pack fails, but 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.

Exposure Monitoring

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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 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.

3M™ Comply™ Steam Indicator Tapes

- Adhesives are designed specifically for disposable or reusable wraps.
  - 3M Comply 1222 Steam Indicator Tape for all wraps.
  - 3M Comply 1255 Steam Indicator Tape for disposable wraps.
- Adhesive seals packs securely. Backing stretches to minimize tape pop-off during sterilization.
- Can be written on or labeled with preprinted labels such as the 3M™ Comply™ Sterilization Load Labels.

Putting Standards into Practice

(1) Use an external chemical indicator on the outside of each package.

(2) If a package allows for visual inspection of an internal indicator, such as those with paper–plastic packaging, an external indicator is not required.

Pocket Panel

Business Card

Standardize To The Core.

3M

Four proven, standards-based answers
for reducing the risk of undetected sterilization process failures.

You understand the value of AAMI and AORN Recommended Practices. And you work hard to stay up to date on them, because you feel responsible for patient safety. But it's not always easy with all that's being demanded of you these days. Training new staff. Educating existing staff. Managing loaner instrumentation. Dealing with recalls. Working to reduce costs in challenging economic times. It's a full plate, and then some.

This is where 3M can help. By standardizing on our Core Four sterilization monitoring products and following Standards and Recommended Practices, you can make sure you're doing the right thing for your facility and its patients.

What's more, through 3M™ Attest™ Sterile U Network, we'll keep you up to date on changes in newly published recommended practices and what they mean to your operation. You can also take your training program to the next level through access to dozens of CE-credited resources and best practices on 3M Attest Sterile U Online. Best of all, you can be sure that if it's 3M Attest Sterile U, the content will always be aligned with the most current Standards and Recommended Practices.

There are no short-cuts to patient safety. But using the 3M Core Four Monitoring Products and the 3M Attest Sterile U educational resources can help you feel more confident of your department's efforts.

What is the purpose of Standards and Recommended Practices in the healthcare setting?

Overall, Standards Organizations strive to promote best practices within your profession. Specifically in the realm of Sterile Processing, these Organizations provide guidelines for the reprocessing of medical devices to be used in the surgical environment to help ensure their safe and effective use. These voluntary guidelines reflect the expertise of a committee comprised of healthcare professionals and in the case of AAMI, also includes representatives from industry and FDA.

As a leader responsible for providing sterilized devices for patient procedures, what Standards and Recommended Practices should I be incorporating into my policies and procedures?

The Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), Centers for Disease Control and Prevention (CDC) and The Joint Commission all have recommended practices and standards that influence the reprocessing of medical devices.

Why is it important to follow Standards and Recommended Practices?

The Joint Commission requires that "hospitals consider clinical practice guidelines when designing or improving processes." (LD.04.04.07)*

Furthermore, as outlined in their National Patient Safety Goals NPSG.07.05.01, "As of January 1, 2010, the hospital implements policies and practices aimed at reducing the risk of surgical site infections that meet regulatory requirements, and are aligned with evidence-based standards (for example, the Center for Disease Control and Prevention [CDC]) and/or professional organization guidelines."*

Following AAMI, AORN and CDC standards will help your facility meet the recommendation of the Joint Commission.

How can I communicate the importance of following Standards and Recommended Practices to the key stakeholders at my facility responsible for patient safety?

In light of increased scrutiny and new reimbursement policies focused on decreasing the alarming number of Healthcare-Associated Infections, referencing Standards and Recommended practices can help you make your case for implementing policies and procedures that improve patient outcomes.

* The Joint Commission. *Hospital Accreditation Standards,* 2009.

In today's healthcare environment, you demand speed, accuracy, credibility and efficiency in all phases of the sterilization process. 3M stands ready to put our leadership, products, services and educational tools to work for you. As a worldwide leader, our comprehensive product line is backed by excellence in every aspect of sterilization assurance.

We're with you. Every step. Every detail. Every day.

To learn more about our Core Four standardization program, or about any 3M Sterilization product or service, call the 3M Health Care Helpline at **1-800-228-3957**, or visit **3M.com/infectionprevention**.

References

1. The Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text).
2. The Association of periOperative Registered Nurses. *Recommended Practices for Sterilization in Perioperative Practice Setting,* 2009.
3. The Association of periOperative Registered Nurses. *Recommended Practices for Selection and Use of Packaging Systems for Sterilization,* 2009.
4. Centers for Disease Control and Prevention. *Guidelines for Disinfection and Sterilization in Healthcare Facilities,* 2008.
5. The Joint Commission. *Hospital Accreditation Standards*, 2009.

3M STERILIZATION ASSURANCE
EVERY STEP. EVERY DETAIL. EVERY DAY.

3M

3M Infection Prevention Division
3M Health Care
3M Center, Building 275-4W-02
St. Paul, MN 55144-1000
U.S.A.
1 800 228-3957
www.3m.com/healthcare

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