



# Something Not Look Right To You?

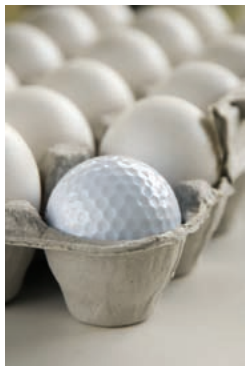
Class 6 Emulating Indicators are not  
for every application.



# 1. Have standards' organizations like AAMI and AORN developed recommended practices for the use of that device and if so, what is the recommended use?

## Perception

A Class 6 Emulating Indicator PCD can be used in place of a BI PCD to release all loads and all items in the load, including implants.



*Should you accept a substitute?*

## Myth or Fact?

**Myth.** Standards and recommended practices from AAMI and AORN are the key documents that healthcare facilities reference to develop appropriate policies and procedures for the reprocessing of medical devices.

AAMI ST79 states “Biological Indicators provide the only direct measure of lethality of the sterilization process. . . Biological Indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization.”<sup>1</sup> (10.5.3.1)

AAMI ST79 recommends weekly preferably daily monitoring with a BI Process Challenge Device (PCD) plus all loads containing implants. A PCD containing a BI and Class 5 Integrating Indicator should be used to monitor all loads containing implants.<sup>1</sup>

The 2008 AORN Recommended Practices for Sterilization follows AAMI's guidelines for weekly preferably daily monitoring with a BI of all cycle types used. Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available. (PNDS: I85, I138) In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 Chemical Integrating Indicator should be run with the load. (PNDS: I70, I98) The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result.<sup>2</sup>

The ANSI/AAMI/ISO 11140-1 (2005) definition of a Class 6 Emulating Indicator, as referenced in the AAMI ST79 (2008) document, does not contain any statement regarding correlation to a BI. A Class 5 Integrating Indicator per these Standards is the only CI with defined requirements for correlation to a BI.

By using a Class 6 CI PCD, emergency release documentation is no longer required if an implant is released before the BI results are known.

**Myth.** AAMI and AORN have NOT developed recommended practice for the use of a Class 6 CIs. According to AAMI ST79, implant loads should be monitored with a BI PCD that also contains a Class 5 Integrating Indicator. Furthermore, “when documented medical exceptions dictate, it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. It is critical that this documentation be fully traceable to the patient.”<sup>1</sup>(10.6.3)



**AAMI ST79:**  
2008 will include recommended practices for the use of Class 6 CIs.

**Myth.** The 2008 update will only include the definition below for Class 6 Emulating Indicators:

Emulating Indicators (Class 6) are cycle verification indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process.<sup>1</sup>

“NOTE—This edition of ANSI/AAMI ST79 does not cover the use and application of Class 6 Emulating Indicators. Refer to the manufacturer's written instructions for use.”<sup>1</sup>

Class 6 CIs are cleared by the FDA for the release of all steam sterilization loads.

**Myth.** FDA is the federal agency responsible for ensuring that medical devices are safe and effective. The FDA's Center for Devices and Radiological Health (CDRH) position has been that decisions about the type of sterilization Indicator(s) used and the frequency of their use are the responsibility of the healthcare facility.

## 2. What are the performance limitations of that device and how might those limitations impact my sterilization monitoring quality control process?

### Perception

Class 6 CIs are the newest technology in sterility assurance monitoring and will replace BIs.



### Myth or Fact?

**Myth.** In 1995 performance requirements were first defined in ISO 11140-1:1995 for Class 6 CIs. They can utilize similar ink technology as Class 4 and some Class 5 CIs that have been on the market for many years.

Class 6 CIs may show a pass in a failure condition where the pack or load fails to reach the exposure condition.

Hospital-Type Gravity Steam Cycle: 1-Minute Exposure at 134°C; 4-Minute Come-up Time	
Indicator Type	# Showing FAIL/ # Tested
Class 5 (SV: 2.2 Min. @ 134°C)	15/15
Class 6 (SV: 3.5 Min. @ 134°C)	0/15
Class 6 (SV: 3.5 Min. @ 134°C)	0/15

Source: 3M Internal Test Results

A Class 6 CI will not show a pass result until it sees the selected exposure time and temperature.

**Fact.** BIs and Class 5 Integrating Indicators that comply with ANSI/AAMI/ISO 11140-1:2005 must respond *correctly* over the full range of temperatures encountered in a steam sterilization cycle which makes their response more accurate than Class 6 CIs. In the same document, Class 6 CIs are only required to respond correctly at one time and temperature (e.g., 270°F @ 4 min).

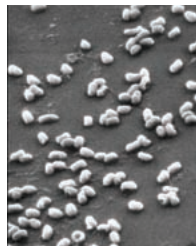
Since Class 6 CIs do not have a Stated Value\* at lower temperatures, they may show a pass in a failure condition where the pack or load fails to reach the exposure temperature. This failure condition can occur when there is: incorrect packaging, incorrect loading, air/steam mixtures, and incorrect cycle for the load contents.

\* Value or values of a critical variable at which the Indicator is designed to reach its endpoint as defined by the manufacturer.<sup>3</sup>

**Myth.** Class 6 CIs will begin to change color during the sterilizer come-up-time and could show a pass in a failure condition where the selected exposure temperature is not achieved. This condition is likely to occur when there is: incorrect packaging, incorrect loading, air/steam mixtures, and incorrect cycle for the load contents. A 3M study tested 15 of each type of Class 5 and Class 6 Indicators in a shortened, hospital-type cycle. All the Class 6 products gave a PASS result which means they failed to detect the shortened exposure time even though their Stated Values at 134°C were greater than that of the Class 5 product. This data shows that the Class 6 products responded during the come-up-time and progressed to their endpoint too soon to detect the steam sterilization process failure that occurred as a result of not remaining at the exposure temperature for an adequate time.

BIs spores begin to die during the sterilizer warm up phase and do not measure as much of the cycle as Class 6 CIs.

*BI spores die too soon?*



**Myth.** Both BI spores begin to die and Chemical Indicator inks begin to change color or migrate during the sterilizer come-up-time (similar to the pre-heat cycle on your oven).

Biological Indicators are designed so the death of the spores mimic and often times exceed the destruction of the most resistant bioburden in the load under ideal steam sterilization conditions. Additionally, Biological Indicators are designed to provide a direct and accurate measure of cycle failure under sub-optimal conditions such as super heated steam or inadequate air removal.

Class 6 CIs measure more of the sterilization cycle than BIs and Class 5 CIs.

*Measure more?*



**Myth.** A class 6 CI will only measure more of the sterilization cycle in an empty cycle in a resistometer\*\*, which has less than 10 seconds of come-up-time. In hospital sterilizers with a full load, Class 6 CIs by design will begin to change faster than Class 5 CIs and BIs.

\*\* Specialized test vessel capable of reproducible cycles and used by manufacturers to characterize the performance of Chemical Indicators.

### 3. What is the appropriate use of that monitoring device should I choose to use it within my sterilization monitoring process?

#### Perception

#### Myth or Fact?

**Class 6 Emulating Indicators are cycle specific.**



**Fact.** Each cycle time, temperature and type must be monitored with a distinct Class 6 CI designed for that cycle. There is a limited number of Class 6 CIs on the market today and chances are you run a cycle time, temperature and type for which a Class 6 CI is not available.

Bottom Line:

If you are running dynamic-air-removal cycles greater than 4 minutes, there is currently not a Class 6 CI commercially available for those extended cycle times.

Additionally, you will need to inventory multiple SKUs and develop a quality control plan to match each Class 6 CI with the appropriate cycle type, time and temperature.

**The appropriate use for Class 6 CIs is for internal pack monitoring.**



**Fact.** Per ISO 11140:2005-1, A Class 6 Emulating Indicator could be used as an Internal Indicator at the pack/tray level in cycles for which it is labeled.

To monitor at the highest level of sterility assurance, 3M recommends the use of one or more Class 5 Integrating Indicators inside each package/container.

## First appearances are not everything.

Today, many claims are being made about the use of Class 6 Emulating Indicators for steam sterilization load and pack control monitoring. However, it's important to remember that before you accept any claims regarding a new monitoring device as fact, you should ask yourself three questions:

1. Have standards' organizations like AAMI and AORN developed recommended practices for the use of that device and if so, what is the recommended use?
2. What are the performance limitations of that device, and how might those limitations impact my sterilization monitoring quality control process?
3. What is the appropriate use of that monitoring device should I choose to use it within my sterilization monitoring process?

In the pages that follow, 3M™ Attest™ Sterile U will address each of these questions so you can gather the facts and make an informed decision.



**Additional fact: Sterile U comes with all 3M™ Attest™ Products.**

3M Attest Products now include Sterile U, a network of educational services and training resources provided by 3M and dedicated to improving competency and confidence in the field of sterility assurance. Encompassing a variety of programs including our on-line education website, FREE CE credited self-study training courses, and traveling seminars, the 3M Attest Sterile U Network offers you a continually-expanding curriculum, tailored for your professional advancement.

Check out current education offerings on our NEW customer exclusive website, 3M Attest Sterile U Online:  
[www.3M.com/AttestSterileUOnline](http://www.3M.com/AttestSterileUOnline).

**References**

- <sup>1</sup> Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities (ANSI/AAMI ST79). Association for the Advancement of Medical Instrumentation, 2008, in progress.
- <sup>2</sup> Recommended Practices for Sterilization in the Perioperative Practice Setting. Association of Perioperative Registered Nurses (AORN), 2008.
- <sup>3</sup> Sterilization of healthcare products-Chemical Indicators-Part 1: General requirements (ISO/ANSI/AAMI 11140-5:2007).



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