

Sterile U Network

T U T O R I A L S

What You Need to Know About Extended Cycles: *Frequently Asked Questions*

Introduction:

Standard steam sterilization exposure times have increased in recent years due to the increase in weight and complexity of instrument trays used in health care facilities.

A concern with currently available sterilization process monitors for use in extended steam sterilization cycles is “Do these monitors provide the necessary ‘challenges’ to meet the medical device manufacturers recommended sterilization requirements?”

This leaves Sterile Processing personnel with some important, but unanswered questions about how to monitor extended steam sterilization cycles today. The following is intended to help you better understand extended cycles, and what you need to know and ask regarding appropriate sterilization process monitoring device choices.

Frequently Asked Questions:

1. Why are instrument manufacturers requiring extended cycles?

There are two basic reasons:

- a) When medical device manufacturers recommend steam sterilization cycle exposure times of 8, 10, 20 minutes, and beyond, that is usually associated with orthopedic or neurological instruments and implants that have lumens and crevices. They are in multiple layer containment devices, all of which create a challenge to air removal and steam penetration.
- b) If the medical device is manufactured in Europe, a required pre-vacuum cycle time of 18 minutes at 134°C is required to inactivate prions associated with “mad cow disease”.

When the medical device manufacturers recommended sterilization parameters are not met there is a risk of inadequate steam penetration and, ultimately, the risk that potentially “unsterile” items may be used on a patient. You should follow their sterilization instructions if the recommended cycle times are longer than the cycles recommended by the sterilizer manufacturer.



2. *What does The Association for the Advancement of Medical Instrumentation, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79:2006 say about “extended cycles”?*

The AAMI ST79 recommended practice provides specific guidance on how to create a challenge pack for typical sterilization cycles. However, there are no general guidelines provided on how to create a challenge pack for monitoring those devices requiring extended cycles. Annex “K” in the back of AAMI ST79 outlines specific sterilization cycles and exposure times for testing the resistance of a 16 towel test pack (PCD). The cycles referenced are considered “typical”. Currently marketed PCDs are designed to match the resistance of a 16 towel test pack.

3. *Can I use my commercially available BIs and PCD products, that are marketed today, for extended cycles?*

Yes. Keep in mind the AAMI Guidelines for constructing a PCD, the 16 towel pack, is validated to typical sterilization cycles (reference annex K in ST79). The biological indicators (BIs) and PCDs designed for 3 or 4 minute steam sterilization cycles may not provide the appropriate challenge when longer cycle times are required. AAMI ST79 states “a PCD for monitoring loads should be equal to or greater in challenge than the most challenging item in the load”. There currently are no guidelines on how to make a PCD for medical devices requiring extended sterilization cycles, and currently there are no disposable PCD products in the marketplace for extended cycles, so your only option is to use the products available today.

4. *How do I know the “extended cycle” met the required parameters?*

It is important to perform “routine efficacy monitoring” and “product testing” according to AAMI ST79. Physical monitors, external and internal chemical indicators (CIs) along with the results of the BI PCD should be evaluated and recorded. The internal CIs should be placed on all layers of complex trays in the corners and next to the biggest heat sink, or in areas determined by the medical device manufacturers to be the greatest challenge.

A newly published manufacturer’s standard entitled *Containment devices for reusable medical device sterilization*, ANSI/AAMI ST77:2006 requires the manufacturer of these containment devices to provide in the product labeling the most challenging area of the containment device for placement of internal CIs and BIs for routine monitoring and product testing. Product testing is to be performed before the medical device is placed into routine use to ensure it can be effectively sterilized (see question 5).



5. How does Product Testing help ensure medical devices requiring extended cycles are being effectively sterilized?

It is important to perform product testing before medical devices are placed into routine use and whenever the contents change. The testing procedure is discussed in AAMI ST79, sections 10.9 and 10.10. Place multiple BIs and CIs in the areas that create the greatest challenge for air removal and steam penetration (see question 4), and run in a standard load according to the medical device manufacturers instructions. Incubate the BIs, read the CIs and record all results including the position of the BIs and CIs in the tray or containment device. The BIs must be negative and the CIs must reach their endpoint result before the medical devices are placed into routine use. This is the only sterilization verification testing that can be done in the health care facility to ensure the medical devices are being effectively sterilized.

6. Does an “extended cycle” have any negative impact on the 3M™ Attest™ Rapid Readout Biological Indicator’s media?

No. 3M has completed a study that shows the 3M Attest Rapid Readout Biological Indicators with the 3 hour enzymatic readout were not affected by exposure of the ampouled media to extended cycle conditions (134°C for 20 minutes and 20 minute dry time). This study demonstrates the ampouled media in the 3M Attest Rapid Readout Biological Indicator functions properly after exposure to extended cycle conditions. *(If you would like a copy of this data, please ask your 3M sales representative for “Effect of Extended Steam Sterilization Cycles on Self Contained Biological Indicators with Enzyme-based Early Readout,” 70-2009-8692-8.)*

Summary:

As you are aware, the subject of sterilization process monitors and extended cycles is somewhat complex. Hopefully this information will help to increase your knowledge by making you aware of current recommended practices and guidelines, as well as appropriate sterilization process monitors that are available for use today.

For more information, call the 3M Help Line: 1-800-228-3957

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